2014 Committee Member Assignments

Legislative Liaison:

Rules Committee:

Compounding Rules Committee:

Prescription Drug Abuse Committee:

Application Review:

ULA Liaison:

PDMP Liaison:

Wholesale Advisory Council:

Negative Formulary Committee:

Tripartite Committee Chair:

Administrative/Budget Liaison:

Pharmacist Ordering Committee:

DEA Liaison:

Weight of the State Liaison:

2013 Board Member Assignments

Legislative Liaison: Mrs. Glass

Rules Committee: Dr. Mesaros (Chair), Dr. Weizer, Mrs. Mullins, Mrs. Glass

Compounding Rules Committee: Dr. Weizer (Chair), Mrs. Glass, Mrs. Mullins, Dr. Mikhael

Prescription Drug Abuse Committee: Mr. Meshad (Chair), Dr. Weizer, Mrs. Mullins, Mrs. Glass

Application Review: Dr. Griffin, Mrs. Glass

ULA Liaison: Mrs. Mullins

PDMP Liaison: Dr. Mesaros

Wholesale Advisory Council: Mr. Garcia

Negative Formulary Committee: TBD

Tripartite Committee Chair: Dr. Griffin

Administrative/Budget Liaison: Dr. Weizer

Pharmacist Ordering Committee: TBD

2014 Association Meetings

FPA

Law and Regulatory Conference
January 25-26, 2014 – San Destin, FL

Clinical Conference
April 5-6, 2014 – Tampa, FL

Law and Clinical Conference
May 17-18, 2014 – Jacksonville, FL

124th FPA Annual Meeting Convention
July 9-13, 2014 – Fort Lauderdale, FL

31st Annual Southeastern Gatherin'
August 3-6, 2014 – Destin, FL

FSHP

House of Delegates
Chair and Executive Director are "Delegates"
August 7-10, 2014 – Orlando, FL

NABP

2014 NABP Annual Meeting
May 17-20, 2014 – Phoenix, AZ

District 3 Meeting
August 2-5, 2014 – Charleston, SC

MPJE State Specific Review
September 4-5, 2014

NAPLEX Item Development Workshop
September 18-19, 2014

FPGEE/PCOA Item Development Workshop
October 16-17, 2014

NAPLEX Standard Setting
November 6-7, 2014

2013 Association Meeting Assignments

FPA

Law and Regulatory Compliance Conference
April 20-21, 2013 – Tampa, FL
Dr. Jeff Mesaros

123rd Annual Meeting and Convention
July 10-14, 2013 – Orlando, FL
Dr. Lee Fallon

30th Annual Southeastern Gathering
August 4-7, 2013 – Destin, FL
Dr. Lee Fallon

Law & Regulatory Compliance Conference
September 7-8, 2013 – Fort Lauderdale, FL
Mr. Albert Garcia

FSHP

House of Delegates, Chair and Executive Director are "Delegates"
August 2, 2013 – Orlando, FL
Dr. Michele Weizer

NABP

MPJE Item Development Workshop
March 21-22, 2013 – Chicago, IL
Mrs. Debra Glass

NABP 109th Annual Meeting
May 18-21, 2013 – St. Louis, MO
Mr. Albert Garcia w/ Dr. Jeff Mesaros as the alternate

The District III Meeting
August 3-5, 2013 – Nashville, TN
Mr. Albert Garcia

Interactive Member Forum – Mr. Albert Garcia

NABP Interactive Executive Officers Forum – Mr. Mark Whitten

MALTAGON

September 29 – October 1, 2013 – Ashville, NC – Mr. Albert Garcia

January 24, 2014

Ronald O. Nickel, R.Ph.
537 Calico Retreat
Mt. Pleasant, SC 29464

RE: MAD-ID Continuing Education

Dear Mr. Nickel:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Tuesday, February 11, 2014. The meeting is being held at the Florida Hotel & Convention Center, 1500 Sand Lake Road, Orlando, FL 32809. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444 ext: 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

MAKING A DIFFERENCE
IN INFECTIOUS DISEASES PHARMACOTHERAPY

MAD-ID • 537 Calico Retreat
Mt. Pleasant, South Carolina 29464
www.mad-id.org

RECEIVED
DEC 18 2013
Florida Board of Pharmacy

December 15, 2013

Department of Health, Board of Pharmacy

4052 Bald Cypress Way , BIN C-04

Tallahassee, Florida 32399-3258

Dear Colleagues:

I am writing this letter and providing the attached information with the earnest and sincere hope that you will consider my request to approve for Consultant Pharmacist credit the MAD ID Making A Difference in Infectious Disease Pharmacotherapy program which occurred in Orlando, Florida on May 9-11, 2013. As I stated in my earlier letter (November 7, 2013), I apologize for the tardiness of submitting the electronic data required for attaining the Consultant category approval. More importantly, I am appealing to you on behalf of about 6 Florida consultant pharmacists who attended the program on the assumption that Consultant credit would be provided. Because of my tardiness, their licenses are in jeopardy, so I am asking for your assistance in this matter.

As I stated in the November letter, I would be willing to attend a Board meeting and personally "plead the case". I stated this in response to the message I received via CE Broker that such a personal appeal would be necessary. No indication was included in the CE Broker message as to when the next Board meeting would occur. I waited several weeks after sending the November letter, hoping for some response and perhaps further directions. I finally called the Board Office, and was able to speak with Ms. Malasha Norton. I inquired if my letter had been received and she indicated she had no knowledge of that letter. I requested to speak with Mr. Whitten (since the letter was addressed to the Board) but was informed that he was no longer with the Board. Ms. Norton informed me that the next Board meeting was scheduled for some time in February and that I should resend all of the original documentation via fax or mail, with a due date of Dec. 20. I have enclosed as much descriptive material as I hope will be helpful to the Board members and may facilitate the issuing of Consultant credit.

Historically, the Board has approved for Consultant credit the same MAD ID program that they have approved for General Pharmacist credit. The 2013 program faithfully followed the format and content of the previous 15 program. I sincerely hope that you can facilitate this matter so that the Florida pharmacists involved will be able to practice and apply the information attained via this program in the care of their fellow Floridians,

Thank you in advance for any assistance you can render in this situation. Please inform me when and where the February meeting of the Board will occur, so I can prepare to attend in person or via conference call.

Ronald O. Nickel, RPh
CE Administrator, MAD ID

MAD-ID - 537 Calico Retreat
Mt. Pleasant, South Carolina 29464
www.mad-id.org

November 7, 2013

Department of Health- Board of Pharmacy

4052 Bald Cypress Way Bin C-04

Tallahassee, Florida 32399-3258

Dear Colleagues:

I am writing this letter in response to your message of 8/22/2013, on CE Broker, pertaining to the MAD ID 2013 program Tracking # 20-403630, titled Making A Difference in Infectious Disease Pharmacotherapy. We had received approval for this program under the "general pharmacy" category but unfortunately submitted the request for "consultant category" credits after the program had been completed. I sincerely regret that I had overlooked sending the e-version of the required forms in a more timely manner. I assure you that the content and format of the 2013 program was very similar to the MAD ID programs your Board has approved for both General and Consultant credits in the past. However, your email message indicated that I appear before the Board, perhaps to better explain the program and answer questions. As a full time faculty of the College of Pharmacy of the Medical University of South Carolina , I was unable to attend a meeting due to a fairly full teaching schedule (I teach three compounding labs weekly). If indeed appearance before the Board would help resolve this approval matter, would it be possible to "attend "via a conference call? I do indeed apologize for submitting the required documents latw, but would like to resolve the issue primarily for the sake of a number of Florida pharmacists who attended with the hopes of receiving the special category of credit.

Thank you in advance for considering this request.

Sincerely,

Ronald O. Nickel, PhD

CE Administrator, MAD ID

FLORIDA BOARD OF PHARMACY CONTINUING EDUCATION QUESTIONNAIRE

Instructions

1. The questionnaire is to be completed and submitted by person(s) or organization(s) wishing to provide continuing education for Florida pharmacists for fulfillment of requirements under Chapter 465.009, Florida Statutes.

2. Please **type or print legibly** all responses and maintain a complete copy of the questionnaire in your files.

3. The amount of space for responses on the questionnaire is not intended to dictate the length of the response. Use additional paper if necessary for an accurate response and identify the question to which responses refer.

4. If you are applying for approval of **HIV/AIDS** programs it **MUST INCLUDE FLORIDA LAW** to be approved.

ORGANIZATION MAD ID _____

CONTACT NAME Ronald O. Nickel

ADDRESS 1145 Windsome Place

CITY Mt. Pleasant, STATE SC ZIP CODE 29464 PHONE 843-881-9799

FAX _____
E-MAIL ADDRESS ronald.nickel@gmal.com

I. ADMINISTRATIVE REQUIREMENTS

NAME OF PROGRAM MAD ID 2013 Making A Difference in Infectous Disease Pharmacy Therapy **DATE** May 9-11,2013
CITY Orlando, **STATE** Florida **ZIP** _____

(a) **Attach a copy of a** sample of the program announcement or promotional piece utilized for the two most recent continuing education programs.

(b) Indicate the number of CE hours and type requested: Live CE 18 Home Study CE _____.

General 18 HIV/AIDS _____ Order/Eval.Lab.Test _____ Consultant Certification _____ Quality Related Event _____

Consultant Recertification 18 Law _____ Medication Error _____ Nuclear _____ Immunization Course _____ Technician CE _____

(c) Please describe the nature of the system used for the maintenance and availability of records of participation in continuing education activities.
An on-line system was used by which the attendee documented each session they attended , and also evaluated the content format,and speaker for each session. Upon completion of the program, the on-line data was used to issue CE credits via CPE Monitor (NABP) and CE Broker.

(d) **ATTACH A COPY OF THE PROGRAM.**

II. EDUCATIONAL CONTENT DEVELOPMENT

1. Name of Program: MAD ID Making A Difference in Infectous Disease Pharmacotherapy
2. List or attach the goals and objectives of your program submitted._____

III. EVALUATION: PLEASE ATTACH A COPY OF THE EVALUATION INSTRUMENT FOR THIS PROGRAM.

1. Describe the methods employed to evaluate the effectiveness of the provider's programming and it's presentation. Please attach a sample of this evaluation that provide feedback of the group's attainment of the learning objectives Participants of the program were directed to use the on-line "survey" to evaluate each MAD ID session they attended. I have attached a sample of the resulting numerical data as well as the free-text

comments they provided. This information not only was used to study and reflect on the 2013 but also is providing insight and information as we plan the 2014 MAD ID program.

IF ALL AREAS ARE NOT COMPLETED THE APPLICATION WILL NOT BE ACCEPTED.

The Completely Automated Continuing Education (CE) Compliance Determination System

CE BROKER

1-877-i-find-CE
(CALL TOLL FREE: 1-877-434-6323)
Monday through Friday, 8:00 am till 5:00 pm EST

Communication Center | Course Completion | Information Updates/Additions | Users | Payment Info

Home > Communication Center > **Course Addition**

USER: RONALD O. NICKEL, Continuing Education Administrator, MAD-ID, INC

Course Profile (* indicates required field)

Learn More

Click here for Approved Educational Provider Course Application Requirements for your approved Boards. For Providers seeking Board approval, the application requirements often include attachments. Since the system will not save unfinished applications, please prepare attachments before beginning the electronic application process.

Course Name: MAD ID 2013 MAKING A DIFFERENCE IN INFECTIOI *

Course Type *

- Anytime (Is not date, time or location specific) — Advanced Selections
  - (Select)
- Live (Interaction with presenter/host) — Advanced Selections
  - Conference (opportunity for interaction with presenter/host)

Optional Comments

Description (Will display for professionals) Up to 4000 characters:

This three day program focussed on Infectious Disease Therapy, with a particular emphasis on Antimicrobial Stewardship. As with the previous 15 "MAD ID" programs, participants benefit from listening to and interacting with

Comments (For Board):

Return to Previous Page | Continue

Please continue. Only finished applications are saved.

Please note that any reference to Board means the Board or the Department where there is no Board.

Florida Department of Health Rule 64B-5.003,F.A.C DH-MQA-CEB-2, May 2006

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The Completely Automated Continuing Education (CE) Compliance Determination System

CE BROKER

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(CALL TOLL FREE: 1-877-434-6323)
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Communication Center | Course Completion | Information Updates/Additions | Users | Payment Info

Home > Communication Center > **Course Application**

USER: RONALD O. NICKEL, Continuing Education Administrator, MAD-ID, INC

Course Credit

Renewal Hours

Course Name: MAD ID 2013 MAKING A DIFFERENCE IN INFECTIOUS DISEASE PHARMACYTHERAPY

Boards for which you are registered — those that appear under Information Updates/Additions, Boards — are displayed. Enter the number of hours for which your course may count toward each profession's renewal and disciplinary continuing education requirements. As an approved educational provider, it is your responsibility to submit hours in accordance with the Laws and Rules of each applicable profession.

For each profession, input the number of renewal hours by subject area, assuming the course would be completed in full by the attendees. The sum of the hours of each profession's subject areas must equal the total number of hours a professional attending your course may count towards their license renewal requirements (exception: concurrent sessions). For example, if you enter 2 hours for Medical Errors and 4 hours for General, the total number of renewal hours for the course would be 6.

Florida Board of Pharmacy

- **Consultant Pharmacist**

In-Depth Analysis of Consultant Pharmacist Practice	18	Minimum 3 hour course. Routes for approval. 64B16-26.302, F.A.C.
General - Order and Evaluation of Laboratory Tests Initial Certification - 3 hours		Routes for approval. 64B16-26.320, F.A.C.
General - Order and Evaluation of Laboratory Tests Recertification - 1 hour		Routes for approval. 64B16-26.320, F.A.C.
Quality Related Event (formerly misfills)		Minimum 8 hour course. Routes for approval. 64B16-26.6012(2), F.A.C.
Laws and Rules of the Board		Minimum 12 hour course. Routes for approval. 64B16-26.6012(1), F.A.C.

- **Nuclear Pharmacist**

In-Depth Treatment of Nuclear Pharmacist Practice		Routes for approval when only Board approved. 64B16-26.304, F.A.C. Effective 5/27/2010, if approved by the ACPE will count for General hours and will not route for approval. 64B16-26.103(3)(c), F.A.C.
Quality Related Event (formerly misfills)		Minimum 8 hour course. Routes for approval. 64B16-26.6012(2), F.A.C.
Laws and Rules of the Board		Minimum 12 hour course. Routes for approval. 64B16-26.6012(1), F.A.C.

- **Pharmacist**

Medication Errors		Minimum 2 hour course. 64B16-26.103(1)(c) F.A.C. -routes for approval
HIV/AIDS		64B16-26.103(1)(a), F.A.C.
General - Order and Evaluation of Laboratory Tests Initial Certification - 3 hours		Routes for approval. 64B16-26.320,F.A.C.
General - Order and Evaluation of Laboratory Tests Recertification - 1 hour		Routes for approval. 64B16-26.320,F.A.C.
General	18	64B16-26.601, F.A.C.
Quality Related Event (formerly misfills)		Minimum 8 hour course. Routes for approval. 64B16-26.6012(2), F.A.C.

Course Inquiry

Learn More

To narrow your search, fill in below or enter the CE Broker Course Tracking #.

To view all courses, click View All Courses

Add a New Course

To export a list of all active courses, click Export Course List

CE Broker Course Tracking # 20- 403630

Course Standing
- Active
- All Other Statuses
  - Not Currently Approved
  - Inactivated by Provider
  - Inactivated by CE Broker

Search by Course Name Expand

Search by Profession/Subject Area Expand

Search by Course Type/Instructor/Provider Course Number Expand

Search

Course List

Course Name	CE Broker Course Tracking #	Publishings	Roster(s)	Course Standing
MAD ID 2013 MAKING A DIFFERENCE IN INFECTIOUS DISEASE PHARMACY THERAPY	20-403630	OTHERS	View	Not Currently Approved

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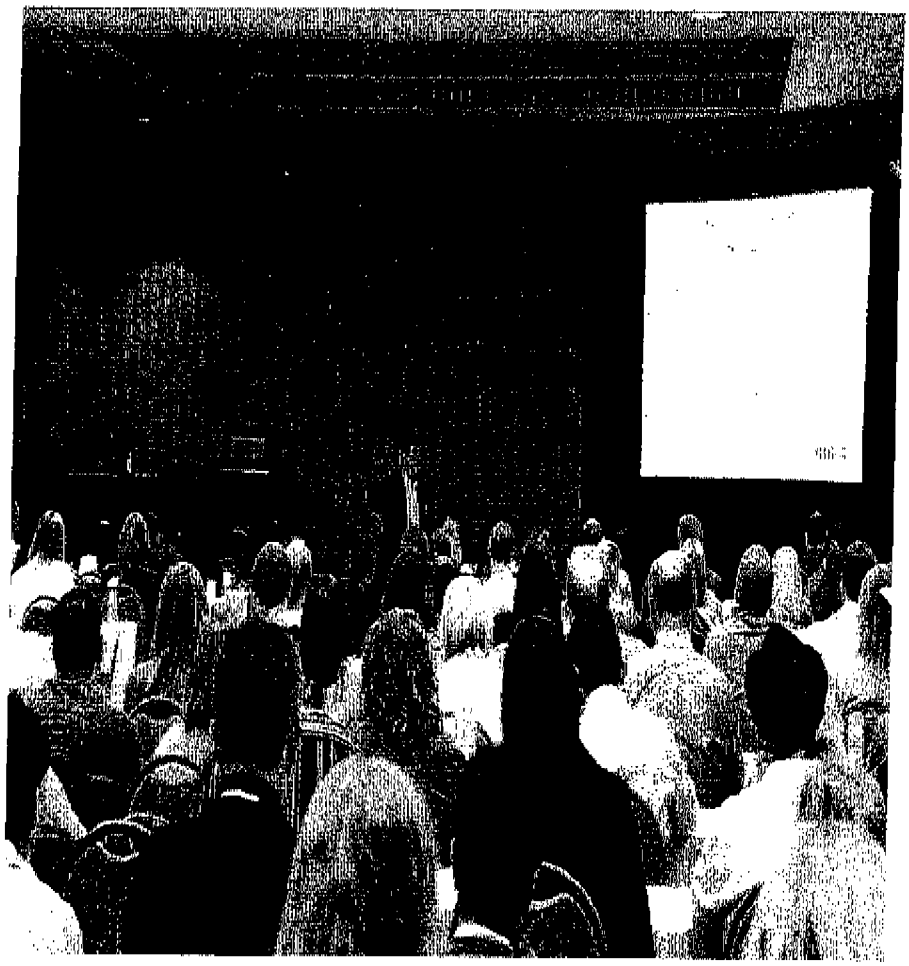
Documents provided

A. The MAD ID programs are "advertised" solely via the MAD ID website. The first attached document essentially includes the information provided on that website pertaining to the 2013 MAD ID program.
B. The second document provides an outline of the three days' content with the Objectives for each session.
C. The third document is an actual summary of the attendee's evaluation of each session of the 2013 MAD ID program.
D. The fourth document records the free-text responses of attendees regarding what they benefitted most from the 2013 program and suggestions for content and format for future MAD ID programs./

MAD-ID
MAKING A DIFFERENCE
IN INFECTIOUS DISEASES PHARMACOTHERAPY

2013 Annual Meeting

2013 Annual Meeting
Agenda
Program Learning Objectives
Hotel, Travel & Shuttle
Registration
Scientific Committee
Program Faculty/Speakers
Abstracts & Posters
Continuing Education Credit
Collaborating Organizations
Satellite Symposia
Sponsoring Organizations
Sponsorship Opportunities
Handouts
Contact Us



The 16th Annual MAD-ID Meeting will be held at the Marriott World Center in Orlando, Florida. May 9 -11, 2013. Pharmacists physicians, and other providers will be given the opportunity to participate in a 3-day educational symposium specifically designed to apply recent research to patient care and antimicrobial stewardship while earning 1.8 CEU (pharmacy).

MAD-ID will provide refunds of registration fees with written notice of cancellation by April 9, 2013 (30 days prior to meeting), less a $40 administration fee. After April 9, 2013, registration fees are non-refundable.

Automatically Reports To CE Broker

MAD-ID is an approved provider and automatically reports to the Board of Pharmacy via CE Broker for Florida pharmacists.

16th Annual MAD-ID Meeting

May 9 – 11, 2013

Program Agenda

NOTE: "AASP" denotes an Advanced Antimicrobial Stewardship Program session (entire program constitutes 18 hours CE [1.8 CEU])

Thursday, May 9, 2013

6:30 am – 8:30 am **Registration**

8:30 am – 10:30 am **Stewardship Classroom #1: (1 hour, repeated): The Art of the Antibiogram (AASP)**

ACPE Program 0485-0000-13-001-L01-P (1.0 Contact Hour)

Speaker: John A. Bosso, Pharm.D.

Stewardship Classroom #2: (1 hour, repeated): Practical PK/PD (AASP)

ACPE Program 0485-0000-13-002-L01-P (1.0 Contact Hour)

Speaker: Jason M. Pogue,Pharm.D.

10:30 am – 11:00 am **Break in Exhibit Hall**

11:00am – 11:15 am **Welcome and Opening Remarks**

11:15 am – 12:15 pm **Keynote: Antimicrobial Stewardship: The CDC's Perspective (AASP)**

ACPE Program 0485-0000-13-003-L01-P (1.0 Contact Hour)

Speaker: Arjun Srinivasan, M.D.

12:15 pm – 1:45 pm **Lunch on ownor REMPEX Satellite Symposium**

2:00 pm – 3:00 pm **What's the Poop on *Clostridium difficile* Infection in 2013?**

ACPE Program 0485-0000-13-004-L01-P (1.0 Contact Hour)

Speaker: Kevin W. Garey, Pharm.D., M.S.

3:00 pm – 4:30 pm **Impact of New Technologies on Antimicrobial Stewardship: Is it ReallyFaster? (AASP)**

ACPE Program 0485-0000-13-005-L01-P (1.5 Contact Hours)

Topic 1: Rapid Diagnostics

Speaker: Kerry L. LaPlante, Pharm.D.

Topic 2: The Microbiologist-Pharmacist Relationship: Married, Separated or Divorced?

Speaker: Preeti Pancholi, Ph.D. D(ABMM)

5:00 pm – 6:30 pm **Scientific Poster Session in Exhibit Hall**

6:30 pm – 8:00 pm **WelcomeReception**

Friday, May 10, 2013

7:00 am – 8:00 am **Continental Breakfast In Exhibit Hall**

8:00 am – 10:00 am **Stewardship Classroom #3: (1 hour, repeated):**

Stewardship MetricsThatJustify Your Job (AASP)

ACPE Program 0485-0000-13-006-L04-P (1.0 Contact Hour)

Speaker: Conan MacDougall, Pharm.D., MAS

Stewardship Classroom #4: (1 hour, repeated):

To be on Formulary or not to be on Formulary, That is the Question (AASP)

ACPE Program 0485-0000-13-007-L04-P (1.0 Contact Hour)

Speaker: Susan L. Davis, Pharm.D.

10:00 am – 10:30 am **Break in Exhibit Hall**

10:30 am – 12:00 pm **Antimicrobial Stewardship in Pediatrics (AASP)**

ACPE Program 0485-0000-13-008-L01-P (1.5 Contact Hours)

Topic 1: Antimicrobial Stewardship in the Pediatric Population: Challenges and Opportunities

Speaker: Jason G. Newland, M.D., MEd

Topic 2: Pediatric PK/PD Applications

Speaker: Holly D. Maples, Pharm.D.

12:00 pm – 1:30 pm **Lunch on own**

1:30 pm – 3:00 pm **Stewardship from the Industry Perspective (AASP)**

ACPE Program 0485-0000-13-009-L04-P (1.5 Contact Hours)

Topic 1: New Antibiotic Discovery and Development: Is it the Singer, Song, or Both?

Speaker: Michael N. Dudley, Pharm.D.

Topic 2: Antimicrobial Stewardship: Measuring the Impact

Speaker: Jack E. Brown, Jr. Pharm.D., MS

3:00 pm – 3:30 pm **Break in Exhibit Hall**

3:30 pm – 5:00 pm **PK/PD in Special Populations (co-sponsored by SIDP)**

ACPE Program 0485-0000-13-010-L01-P (1.5 Contact Hours)

Topic 1: Dosing in Obesity: Finding the "Holy Scale"

Speaker: Manjunath P. Pai, Pharm.D.

Topic 2: Drug Dosing in the Critically Ill

Speaker: Keith A. Rodvold, Pharm.D.

5:00 pm – 6:00 pm **What Did you Miss Because There Was No Funding to Attend the Infectious Diseases Meetings**

ACPE Program 0485-0000-13-011-L04-P (1.0 Contact Hour)

Speaker #1: Kerry L. LaPlante, Pharm.D.

Speaker #2: Marc H. Scheetz, Pharm.D., MSc.

Saturday, May 11, 2013

7:00 am – 8:00 am **Continental Breakfast in Exhibit Hall**

8:00am– 9:30 am **Issues in the Treatment of Respiratory Infections**

ACPE Program 0485-0000-13-012-L01-P (1.5 Contact Hours)

Topic 1: Respiratory Penetration of Antibiotics

Speaker: Keith A. Rodvold, Pharm.D.

Topic 2: Inhaled Antibiotics: Facts, Myths and Questions We Are Afraid to Ask

Speaker: Michael N. Dudley, Pharm.D.

9:30 am – 10:00 am **Updates from the MAD-ID Research Network**

ACPE Program 0485-0000-13-013-L04-P (0.5 Contact Hour)

Speakers: Susan L. Davis, Pharm.D. and Marc H. Scheetz, Pharm.D., MSc.

10:00 am – 10:15 am **Break in Exhibit Hall**

10:15 am – 11:45am **Meet the Professors**

ACPE Program 0485-0000-13-014-L01-P (1.5 Contact Hours)

Panelists: John A. Bosso, Pharm.D.

Debra A. Goff, Pharm.D.

Kerry L. LaPlante, Pharm.D.

Conan MacDougall, Pharm.D., MAS

Jason G. Newland, M.D., MEd

Keith A. Rodvold, Pharm.D.

11:45 am – 1:15 pm **Managing Fungal Infections (AASP)**

ACPE Program 0485-0000-13-015-L01-P (1.5 Contact Hours)

Topic 1: An Antifungal Update: Focus on Echinocandins

Speaker: KennethV. Rolston, M.D.

Topic 2: The Role of Laboratory Testing in Managing Fungal Infections

Speaker: Kevin W. Garey, Pharm.D., M.S.

MAD-ID 2013

PROGRAMMATIC LEARNING OBJECTIVES

As an attendee of MAD-ID 2013, you will be able to earn up to 18 Continuing Education credit hours. At the conclusion of this activity, you should be able to:

1. *List the acceptable rules for constructing antibiograms, analyze susceptibility data and describe pitfalls in use and strategies to avoid them.*
2. *State methods for optimized pharmacodynamics dosing of antimicrobials and demonstrate proficiency with associated dosage regimen design.*
3. *Apply accepted methods for formulary review of new antimicrobial agents.*
4. *List and describe at least six major papers presented at national/ international infectious disease meetings in the last 12 months.*
5. *List similarities and distinguish differences between pediatric and adult pharmacodynamics dosing applications.*
6. *Demonstrate the ability to employ a variety of stewardship metrics that could be used in documenting stewardship initiatives.*
7. *State the broad purposes, distinctions and areas of success of stewardship programs as applied in the pediatric population.*
8. *List basic changes in pharmacokinetics of antimicrobials associated with obesity and how they are accommodated in dosing adjustments.*
9. *List basic changes in pharmacokinetics of antimicrobials associated with critical illness and how they are accommodated in dosing adjustments.*
10. *Describe ways in which the pharmaceutical industry may support and participate in stewardship efforts.*
11. *List and analyze ways the current regulatory environment affects development of new antimicrobials.*
12. *Appraise the relative contributions of rapid diagnostics and the microbiology lab, in general, to stewardship programs.*
13. *Apply data reflecting pulmonary penetration of antibiotics and efficacy of inhaled antibiotics to therapeutic decision making in regard to pulmonary infections.*
14. *State the recent advances in knowledge of pathophysiology of Clostridium difficile infections as well as prevention and treatment.*
15. *Describe proper utilization of laboratory tests in management of fungal infections.*
16. *Identify the proper role of echinocandins in the antifungal armamentarium.*

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Program Faculty /Speakers

John A. Bosso, PharmD, FCCP, FIDSA
Professor
South Carolina College of Pharmacy & Medical University of South Carolina College of Medicine
Charleston, SC

Jack Brown, PharmD,MS
Associate Professor
SUNY Buffalo &
Infectious Disease Pharmacist Specialist
University of Rochester Medical Center
Buffalo, NY

Susan L. Davis, PharmD
Infectious Diseases Pharmacy Specialist
Henry Ford Hospital &
Clinical Associate Professor
Wayne State University
Detroit, MI

Michael N. Dudley, PharmD
Senior Vice President, R & D and Chief Scientific Officer
Rempex Pharmaceuticals
San Diego, CA

Kevin W. Garey, PharmD
Associate Professor & Chair
University of Houston College of Pharmacy
Houston, TX

Debra A. Goff, PharmD
Clinical Associate Professor
Ohio State University
Infectious Disease Specialist
Ohio State University Medical Center
Columbus, OH

Kerry L. LaPlante, PharmD
Associate Professor
University of Rhode Island &
Adjunct Clinical Professor

Alpert Medical School of Brown University
Providence, RI

Conan MacDougall, PharmD
Associate Professor
University of California at San Francisco
San Francisco, CA

Holly D. Maples, PharmD
Associate Professor
UAMS – College of Pharmacy
Little Rock, AR

Jason G. Newland, MD, MEd
Director, Antimicrobial Stewardship Program, Medical Director of Patient Safety and Systems Reliability, Children's Mercy Hospitals & Clinics, Associate Professor of Pediatrics, University of Missouri-Kansas City School of Medicine
Kansas City, MO

Manjunath P. Pai, PharmD
Associate Professor
Albany College of Pharmacy & Health Sciences
Albany, NY

Preeti Pancholi, PhD, D(ABMM)
Director, Clinical Microbiology, Associate Professor, Clinical Pathology
Ohio State University Medical Center, University Hospital East
Columbus, OH

Jason M. Pogue, PharmD
Clinical Pharmacist, Infectious Diseases
Detroit Medical Center
Detroit, MI

Keith A. Rodvold, PharmD
Professor
College of Pharmacy
University of Illinois at Chicago
Chicago, IL

Kenneth V. Rolston, MD
Professor
MD Anderson Cancer Center
Houston, TX

Michael J. Rybak, PharmD, MPH, FCCP, FIDSA
Professor of Pharmacy & Medicine &
Director, Anti-infective Research Laboratory
Wayne State University
Detroit, MI

Marc H. Sheetz, PharmD, MSc
Associate Professor
Midwestern University
Chicago, IL

Arjun Srinivasan, MD, FSHEA
Associate Director for Healthcare Associated Infection Prevention Programs
Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
Atlanta, GA

Accreditation Information

MAD-ID is accredited by the Accreditation Council for Pharmacy Education as the provider of continuing pharmacy education.

MAD-ID is an approved provider and automatically reports earned credit to NAPB through CPE Monitor and via CE Broker for Florida pharmacists.

Annual Meeting Programming represents up to 18 contact hours (1.8 CEU) of continuing pharmacy education.
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:

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The Scientific Committee

John A. Bosso, PharmD, FCCP, FIDSA
Professor and Chair
South Carolina College of Pharmacy – MUSC Campus
Professor of Medicine
Division of Infectious Disease
College of Medicine
Medical University of South Carolina, Charleston, SC
Click to view Dr. Bosso's biography

Dr. Bosso earned his Bachelor of Science in Pharmacy and Doctor of Pharmacy degrees from the State University of New York at Buffalo. He is Professor and Chair, Department of Clinical Pharmacy & Outcomes Sciences, South Carolina College of Pharmacy, MUSC Campus and Professor of Medicine in the Division of Infectious Diseases at the Medical University of South Carolina in Charleston, South Carolina. Dr. Bosso also serves as a Clinical Specialist in Infectious Diseases, and he is board certified in Pharmacotherapy with added qualifications in Infectious Diseases.
His research interests focus on anti-infective pharmacokinetics, pharmacodynamics, and efficacy in both pediatric and adult patients. Dr. Bosso has published articles in *Pharmacotherapy, Antimicrobial Agents and Chemotherapy, The Journal of Infectious Diseases, The Pediatric Infectious Disease Journal, Diagnostic Microbiology and Infectious Disease, Clinical Infectious Diseases*, and *The Journal of Infectious Diseases Pharmacotherapy*. He has written chapters for textbooks that include *Pharmacotherapy: A Pathophysiologic Approach, The Pharmacotherapy Self-Assessment Program*, and *The Textbook of Pediatric Infectious Diseases*. He is a member of the editorial boards of *Antimicrobial Agents and Chemotherapy, Pharmacotherapy*, and *The Journal of Pediatric Pharmacology and Therapeutics*.
Dr. Bosso has been active in a number of professional organizations, and was a founding member and a past-president of the Society of Infectious Diseases Pharmacists, and a past-president of the American College of Clinical Pharmacy.

Debra A. Goff, PharmD, FCCP
Infectious Disease Specialist
Clinical Associate Professor
The Ohio State University Medical Center, Columbus, OH
Click to view Dr. Goff's biography

Dr. Goff is an Infectious Disease Specialist and Director of the Infectious Diseases residency program at The Ohio State University Medical Center (OSUMC). She received her Bachelor of Pharmacy degree, Doctor of Pharmacy degree, and completed her pharmacy residency at the University of Illinois in Chicago. Dr. Goff's research interests include antimicrobial resistance, clinical outcomes research, antifungals, and innovative ways to educate using technology.
She is a member of the OSUMC Antimicrobial Stewardship Program, and is actively involved in developing strategies to control the escalating rate of antimicrobial resistance. The team manages both community-acquired and healthcare-associated infections. She recently developed a medical "app" called STAB-IT (*Staph aureus* bacteremia – is terrible) to help educate clinicians at OSUMC on the management of patients with *Staph aureus* bacteremia. Dr. Goff is the first medical educator to conduct a workshop on "Medical apps for Healthcare Professionals: Using the iPad to Educate", at the Apple® store in Columbus, OH.
She has received numerous research grants and has lectured both nationally and internationally. Dr. Goff has published in several journals, including *Clinical Infectious Diseases, Archives of Internal Medicine, Pharmacotherapy, Current Opinion in Infectious Diseases*, and *Journal of Infection*.
Dr. Goff is an active member of Infectious Diseases Society of America, American College of Clinical Pharmacy, American Society for Microbiology, Society of Infectious Disease Pharmacists, and a board member of the National Foundation for Infectious Diseases. When she is not working, Dr. Goff can be found doing triathlons and photography.

Keith S. Kaye, MD, MPH, FIDSA, FSHEA, FACP
Professor of Medicine
Corporate Medical Director, Hospital Epidemiology and Antimicrobial Stewardship
Detroit Medical Center and Wayne State University, Detroit, MI
Click to view Dr. Kaye's biography

Dr. Kaye received his medical degree from the University of Pennsylvania and completed his internal medicine residency and an infectious diseases fellowship at Beth Israel Deaconess Medical Center in Boston, MA. During his fellowship, Dr. Kaye earned a Masters degree in Public Health from the Harvard School of Public Health. He is board certified in infectious diseases. Dr. Kaye's particular clinical interests and skills are infections in the elderly, intravascular catheter-related infections, epidemiology of and outcomes associated with multidrug resistant bacteria, risk adjustment, prevention, risk factors and outcomes related to surgical site infections and infected prosthetic devices, antimicrobial resistance and infection control issues in community hospitals and tertiary care hospitals, and antimicrobial stewardship.

His principle research areas of interest include hospital-acquired infections, hospital epidemiology, infections in the elderly, antimicrobial resistance, surgical site infection, bloodstream infection, and antibiotic utilization. He is currently studying hospital-acquired infections in the elderly with partial funding for a career development grant from the National Institutes of Health.

Dr. Kaye has authored over 60 peer-reviewed articles and 5 book chapters and has presented numerous abstracts at national conferences.

Jason Newland, MD, MS
Director, Antimicrobial Stewardship Program and
Director, Evidence-based Practice
Children's Mercy Hospital, Kansas City, MO
Click to view Dr. Newland's biography

Dr. Newland grew up in southwest Oklahoma, and obtained his B.S. in Pre-professional studies at the University of Notre Dame in 1996 and medical degree from the University of Oklahoma College of Medicine in 2000. He completed pediatric residency at the University of Nebraska/Creighton Medical Centers in 2003 and fellowship in Pediatric infectious diseases at the Children's Hospital of Philadelphia in 2006, distinguishing himself with teaching awards at both the resident and fellow level.

In August of 2006, he joined the faculty at Children's Mercy Hospitals & Clinics in Kansas City, Missouri where he is the director of the antimicrobial stewardship program and the director of evidence-based practice. An active resident and faculty mentor, he recently completed his master's in education through a joint program offered by the Cincinnati Children's Hospital Medical Center and the University of Cincinnati College of Education, focusing on adult learning, curriculum and teaching methods, and medical education evaluation and research.

His current research spotlights the use of antimicrobials and the impact of an antimicrobial stewardship program at a children's hospital. Additionally, he is interested in the impact of clinical practice guidelines on the care of children. Finally, he has developed mobile apps to further enhance the delivery of guidelines to the practicing clinician.

Joseph A. Paladino, PharmD, FCCP
Director, Outcomes Research
CPL Associates, LLC
Clinical Professor
University at Buffalo School of Pharmacy and Pharmaceutical Sciences, Buffalo, NY
Click to view Dr. Paladino's biography

Dr. Paladino completed a Bachelor of Science degree in biology from Siena College in Albany, New York, earned his pharmacy degree from the Massachusetts College of Boston, and received a Doctor of Pharmacy degree from the Medical University of South Carolina. His research interests include clinical trials of antimicrobial agents, and outcomes analysis, specifically, pharmacoeconomics and pharmacoepidemiology.

He is Consulting Editor of *PharmacoEconomics*, a member of the editorial board of *Surgical Infections*, and a reviewer for many journals, including *Clinical Infectious Diseases, Archives of Internal Medicine, Pharmacotherapy, Journal of Antimicrobial Chemotherapy, Drugs, Antimicrobial Agents and Chemotherapy, Journal of Infectious Diseases,* and the *American Journal of Health-Systems Pharmacy*.
Dr. Paladino has authored more than 100 publications in peer-reviewed journals and several book chapters. His professional memberships include Infectious Diseases Society of America, American Society for Microbiology, Society of Infectious Diseases Pharmacists, American College of Clinical Pharmacy, and International Society for Pharmacoeconomics and Outcomes Research.

Dr. Paladino has lectured in 30 countries, trained eleven post-doctoral fellows, and has served as a sabbatical host for pharmacy and medical practitioners, fellows, and students from Germany, Scotland, and Russia. He has received numerous scholarships and awards, including being named a Fellow of the American College of Clinical Pharmacy, the 1998 Excellence in Research Award of the International Society for Pharmacoeconomics and Outcomes Research, and inclusion in *Who's Who in the World*.

Michael J. Rybak, PharmD, MPH, FCCP
Associate Dean for Research
Professor of Pharmacy and Medicine
Director, Anti-Infective Research Laboratory
Eugene Applebaum College of Pharmacy and Health Sciences, Wayne State University, Detroit, MI
Click to view Dr. Rybak's biography

Dr. Rybak is Associate Dean for Research and Professor of Pharmacy at the Eugene Applebaum College of Pharmacy and Health Sciences (EACPHS). He is also an Adjunct Professor of Medicine in the Division of Infectious Diseases at the School of Medicine at Wayne State University in Detroit, Michigan. Dr. Rybak is Director of the Anti-Infective Research Laboratory at EACPHS, and is affiliated with Detroit Receiving Hospital and University Health Center.

He received his undergraduate degree in Pharmacy from Northeastern University in Boston, Massachusetts, his PharmD from the College of Pharmacy and Health Sciences, and his MPH from the School of Medicine at Wayne State University.

Dr. Rybak's primary research focus is antimicrobial pharmacokinetics and pharmacodynamics (PK/PD) and their relationship to bacterial resistance. He has published several book chapters and numerous articles in scientific journals on topics such as antimicrobial PK/PD and resistance to antimicrobial agents, the importance of bactericidal drugs, and the assessment of patient outcome as it relates to antimicrobial resistance issues. Dr. Rybak is the Scientific Field Editor for the Infectious Diseases section of Pharmacotherapy, and serves as an editorial reviewer for a number of other scientific publications.

He is a member of several professional societies, including the American College of Clinical Pharmacy, the American Society of Health-System Pharmacists, the Society of Infectious Diseases Pharmacists, the American Society for Microbiology, and the Infectious Diseases Society of America.

Jack D. Sobel, MD, FIDSA
Professor of Medicine
Chief, Division of Infectious Diseases
Department of Internal Medicine
Wayne State University School of Medicine
Detroit Medical Center, Detroit, MI

Click to view Dr. Sobel's biography

Dr. Sobel received his medical degree from the University of Witwatersrand in Johannesburg, South Africa. He completed his residency in internal medicine in Johannesburg, and Haifa, Israel, and a fellowship in infectious diseases at the National Institute of Allergy and Infectious Diseases/National Institutes of Health, in Bethesda, Maryland, and the Medical College of Pennsylvania in Philadelphia.

Dr. Sobel considers himself a candidologist rather than a general mycologist. His primary clinical interests relate to invasive candidiasis and candidemia and superficial infections caused by Candida. He has written extensively and performed research for many years in the field of vulvovaginal candidiasis. Dr. Sobel also has an interest in urinary candidiasis and continues to focus his clinical and laboratory research in both these forms of superficial candidiasis.

Making a Difference in Infectious Diseases Pharmacotherapy
16th Annual MAD-ID Meeting
May 9 – 11, 2013

Program Agenda

NOTE: "AASP" denotes an Advanced Antimicrobial Stewardship Program session (entire program constitutes 18 hours CE)

Thursday, May 9, 2013

6:30 am – 8:30 am **Registration**

8:30 am – 10:30 am **The Art of the Antibiogram (AASP)**
ACPE Program 0485-0000-13-001-L01-P (1.0 Contact Hour)

Stewardship Classroom #1: (1 hour, repeated)

Moderator: Debra A. Goff, Pharm.D.

Speaker: John A. Bosso, Pharm.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *State the basic rules/guidelines for construction of an antibiogram*
2. *List limitations in the clinical use and interpretation of antibiograms*
3. *Analyze susceptibility data to produce customized antibiograms*

Practical PK/PD (AASP)
ACPE Program 0485-0000-13-002-L01-P (1.0 Contact Hour)

Stewardship Classroom #2: (1 hour, repeated)

Moderator: Michael J. Rybak, Pharm.D., M.P.H.

Speaker: Jason M. Pogue, Pharm.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *State the advantages and limitations of applying PK/PD principles to patient therapy*
2. *Describe a patient scenario where the use of prolonged beta-lactam infusion is appropriate*
3. *Summarize how the principles used in practice for aminoglycoside and vancomycin PK/PD can be applied to other drug classes*

10:30 am – 11:00 am **Break in Exhibit Hall**

11:00 am – 11:15 am **Welcome and Opening Remarks**

11:15 am – 12:15 pm **Keynote: Antimicrobial Stewardship: The CDC's Perspective**
ACPE Program 0485-0000-13-003-L01-P (1.0 Contact Hour)
(AASP)

Moderator: Michael J. Rybak, Pharm.D., M.P.H.

Speaker: Arjun Srinivasan, M.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Summarize the CDC's view on the impact of antimicrobial resistance on health care*
2. *Review the initiatives that the CDC is involved with to address this issue*
3. *Provide an overview of the CDC's "Get Smart for Healthcare Program"*

12:15 pm – 1:45 pm **Lunch on own or REMPEX Satellite Symposium**

2:00 pm – 3:00 pm **What's the Poop on *Clostridium difficile* Infection in 2013?**
ACPE Program 0485-0000-13-004-L01-P (1.0 Contact Hour)

Moderator: John A. Bosso, Pharm.D.

Speaker: Kevin W. Garey, Pharm.D., M.S.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Discuss the state-of-the-art knowledge on the epidemiology and clinical syndrome of C. difficile infection*
2. *Provide a therapeutic treatment plan for C. difficile infection that minimizes the risk of recurrence*
3. *Describe emerging therapies for the treatment of C. difficile infections*

3:00 pm – 4:30 pm **Impact of New Technologies on Antimicrobial Stewardship: Is it Really Faster? (AASP)**
ACPE Program 0485-0000-13-005-L01-P (1.5 Contact Hours)

Moderator: Debra A. Goff, Pharm.D.

Topic 1: Rapid Diagnostics

Speaker: Kerry L. LaPlante, Pharm.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *State the relationship between rapid diagnostic tests and antimicrobial stewardship*
2. *Review the various rapid diagnostic tests now available to identify bacterial and fungal pathogens*
3. *Give examples from the literature on how these tests have impacted antimicrobial stewardship efforts*

Topic 2: The Microbiologist-Pharmacist Relationship: Married, Separated or Divorced?

Speaker: TBD

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Describe the role of the clinical microbiologist as part of the antimicrobial stewardship team*
2. *Explain the laboratory tests regularly performed by the microbiology laboratory*
3. *Review the importance of appropriate interpretation of susceptibility testing, selective reporting and the use of antibiograms*
4. *Provide examples of partnering with clinical microbiology to assist in antimicrobial stewardship efforts*

5:00 pm – 6:30 pm **Scientific Poster Session in Exhibit Hall**

6:30 pm – 8:00 pm **Welcome Reception**

Friday, May 10, 2013

7:00 am – 8:00 am **Continental Breakfast in Exhibit Hall**

8:00 am – 10:00 am **Stewardship Metrics That Justify Your Job (AASP)**
ACPE Program 0485-0000-13-006-L04-P (1.0 Contact Hour)

Stewardship Classroom #3: (1 hour, repeated)

Moderator: Debra A. Goff, Pharm.D.

Speaker: Conan MacDougall, Pharm.D., MAS

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Identify three levels of antimicrobial use to measure utilization*
2. *Given a dataset of antimicrobial use, calculate defined daily doses and days of therapy per thousand patient-days*
3. *Identify two strategies for putting antimicrobial utilization data in context for interpretation*

To be on Formulary or not to be on Formulary,
That is the Question (AASP)
ACPE Program 0485-0000-13-007-L04-P (1.0 Contact Hour)

Stewardship Classroom #4: (1 hour, repeated)

Moderator: John A. Bosso, Pharm.D.

Speaker: Susan L. Davis, Pharm.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Relate health-system formulary process to the goals of antimicrobial stewardship*
2. *Analyze antimicrobial drug characteristics and institutional priorities to develop appropriate drug use policies and /or restrictions*
3. *Create a plan for educating clinicians about formulary guidelines and polices*

10:00 am – 10:30 am **Break in Exhibit Hall**

10:30 am – 12:00 pm **Antimicrobial Stewardship in Pediatrics**
ACPE Program 0485-0000-13-008-L01-P (1.5 Contact Hours)
(AASP)

Moderator: Michael J. Rybak, Pharm.D., M.P.H.

Topic 1: Antimicrobial Stewardship in the Pediatric Population: Challenges and Opportunities

Speaker: Jason G. Newland, M.D., MEd

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Describe the impact guidelines have on antimicrobial use both in the hospital and the ambulatory setting*
2. *List the features required of a good clinical guideline*
3. *List the methods and challenges of implementing a guideline*

Topic: 2 Pediatric PK/PD Applications

Speaker: Holly D. Maples, Pharm.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *List basic PK/PD differences in the pediatric patient that would necessitate different dosing*
2. *State existing practices for PK/PD dosing in children that have been validated and described in the literature*

3. *Propose PD dosing practices that have been established in adult patients that could be adapted for pediatric use*

12:00 pm – 1:30 pm **Lunch on own**

1:30 pm – 3:00 pm **Stewardship from the Industry Perspective**
ACPE Program 0485-0000-13-009-L04-P (1.5 Contact Hours)
(AASP)

Moderator: John A. Bosso, Pharm.D.

Topic 1: New Antibiotic Discovery and Development: Is it the Singer, Song, or Both?

Speaker: Michael N. Dudley, Pharm.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Outline the steps in antibiotics drug discovery and development and identify "critical path" activities*
2. *Describe the problems with new target drug discovery programs and development of resistance, and recent examples of failures*
3. *Contrast the obstacles for the discovery of new agents directed to Gram-negative vs. Gram-positive bacteria*
4. *Discuss recent regulatory changes and incentives to stimulate antibiotic development*

Topic 2: Antimicrobial Stewardship: Measuring the Impact

Speaker: Peggy S. McKinnon, Pharm.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Describe endpoints that may be measured to understand the impact of stewardship programs and understand utility and limitations of various approaches*
2. *Explain the confounding and bias that may be evident in evaluating the relationship between antibiotic treatment and outcomes*
3. *Describe potential methods that may assist clinicians in appropriately evaluating outcomes due to various treatments or intervention*

3:00 pm – 3:30 pm **Break in Exhibit Hall**

3:30 pm – 5:00 pm **PK/PD in Special Populations**
ACPE Program 0485-0000-13-010-L01-P (1.5 Contact Hours)

Moderator: Michael J. Rybak, Pharm.D., M.P.H.

Topic 1: Dosing in Obesity: Finding the "Holy Scale"

Speaker: Amit P. Pai, Pharm.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Describe the effects of body size descriptors on the estimate of kidney function for a given obese adult patient case*
2. *Interpret the effects of body size on antimicrobial exposure based on a review of the extant population pharmacokinetic model(s)*
3. *Recommend the potential antimicrobial dose modification that may be necessary in an obese adult patient case*

Topic 2: Drug Dosing in the Critically Ill

Speaker: Keith A. Rodvold, Pharm.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *List those physiological changes in critically ill patients which could affect drug disposition*
2. *Describe and compare pharmacokinetic alterations that are known to occur with critical illness and provide examples of antimicrobial agents affected*
3. *Describe at least two antimicrobial agents with well-known pharmacokinetic alterations in the face of critical illness and propose appropriate dosing alterations.*

5:00 pm – 6:00 pm **What Did you Miss Because There Was No Funding to Attend the Infectious Diseases Meetings**
ACPE Program 0485-0000-13-011-L04-P (1.0 Contact Hour)

Moderator: Debra A. Goff, Pharm.D.

Speaker #1: Kerry L. LaPlante, Pharm.D.

Speaker #2: Marc H. Scheetz, Pharm.D., MSc.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *List and describe some of the major issues and controversial topics regarding drug efficacy, toxicity and resistance presented at the recent ID meetings*
2. *Provide an overview of some of the most important therapeutic advancements including new compounds under development presented at the recent ID meetings*
3. *Describe the most recent trends in emerging antimicrobial resistance*

Saturday, May 11, 2013

7:00 am – 8:00 am **Continental Breakfast in Exhibit Hall**

8:00 am – 9:30 am **Issues in the Treatment of Respiratory Infections**
ACPE Program 0485-0000-13-012-L01-P (1.5 Contact Hours)

Moderator John A. Bosso, Pharm.D.

Topic 1: Respiratory Penetration of Antibiotics

Speaker: Keith A. Rodvold, Pharm.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *List and contrast the common methodologies that have been used for measuring concentrations of antibiotics in the lung*
2. *Describe and compare the physiochemical and host-related factors that may influence penetration of antibiotics at the site of lung infections*
3. *Discuss and rank antibiotics that are particularly appropriate for treatment of respiratory tract infections*

Topic 2: Inhaled Antibiotics: Facts, Myths and Questions We Are Afraid to Ask

Speaker: Michael N. Dudley, Pharm.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Identify the advantages of inhaled antibiotic administration*
2. *Describe the importance of formulation and particle size on deposition of antibiotics in the lung*
3. *Describe the results of recent clinical trials of aerosol antibiotics in cystic fibrosis and ventilator-associated pneumonia*

9:30 am – 10:00 am **Updates from the MAD-ID Research Network**
ACPE Program 0485-0000-13-013-L04-P (1.0 Contact Hour)

Moderator: Debra A. Goff, Pharm.D.

Speaker #1: Susan L. Davis, Pharm.D.

Speaker #2: Marc H. Scheetz, Pharm.D., MSc.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *State the objectives and goals of the MAD-ID Research Network*
2. *Describe the results from the MAD-ID Research Network's recent hospital survey*
3. *List the various ways in which MAD-ID members and participants can gain access and contribute to the MAD-ID Research Network research presentations and publications*

10:00 am – 11:30am **Meet the Professors**
ACPE Program 0485-0000-13-014-L01-P (1.5 Contact Hours)

Moderator: Michael J. Rybak, Pharm.D., M.P.H.

Panelists: TBA

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *List the acceptable rules for constructing antibiograms, analyze susceptibility data and describe pitfalls in use and strategies to avoid them*
2. *State methods for optimized pharmacodynamics dosing of antimicrobials and demonstrate proficiency with associated dosage regimen design*
3. *Apply accepted methods for formulary review of new antimicrobial agents*
4. *List and describe at least six major papers presented at national/ international infectious disease meetings in the last 12 months*
5. *List similarities and distinguish differences between pediatric and adult pharmacodynamics dosing applications*
6. *Demonstrate the ability to employ a variety of stewardship metrics that could be used in documenting stewardship initiatives*
7. *State the broad purposes, distinctions and areas of success of stewardship programs as applied in the pediatric population*
8. *List basic changes in pharmacokinetics of antimicrobials associated with obesity and how they are accommodated in dosing adjustments*
9. *List basic changes in pharmacokinetics of antimicrobials associated with critical illness and how they are accommodated in dosing adjustments*
10. *Describe ways in which the pharmaceutical industry may support and participate in stewardship efforts*
11. *List and analyze ways the current regulatory environment affects development of new antimicrobials*
12. *Appraise the relative contributions of rapid diagnostics and the microbiology lab, in general, to stewardship programs*
13. *Apply data reflecting pulmonary penetration of antibiotics and efficacy of inhaled antibiotics to therapeutic decision making in regard to pulmonary infections*
14. *State the recent advances in knowledge of pathophysiology of Clostridium difficile infections as well as prevention and treatment*
15. *Describe proper utilization of laboratory tests in management of fungal infections*
16. *Identify the proper role of echinocandins in the antifungal armamentarium*

11:30 am – 1:00 pm **Managing Fungal Infections**
ACPE Program 0485-0000-13-015-L01-P (1.5 Contact Hours)
(AASP)

Moderator: John A. Bosso, Pharm.D.

Topic 1: An Antifungal Update: Focus on Echinocandins

Speaker: Kenneth V. Rolston, M.D.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Describe the contemporary proper place in therapy of the major antifungal classes*
2. *State and defend those situations in which an echinocandin would be considered the antifungal of choice*
3. *Compare the relative advantages and disadvantages of the commercially available echinocandins*

Topic 2: The Role of Laboratory Testing in Managing Fungal Infections

Speaker: Kevin W. Garey, Pharm.D., M.S.

Learning Objectives:
Upon completion of this session, the participant will be able to:

1. *Review the evidence on appropriate timing of antifungals in patients with systemic candidiasis*
2. *Describe the current protocols and diagnostic tests for the rapid identification of patients with systemic candidiasis*
3. *Forecast the role for future diagnostic tests in the rapid diagnosis of systemic candidiasis*

1:00 pm **Meeting Adjourns**

Were the following overall meeting learning objectives met?

Total Respondents:	256
Total Skipped:	0

	Yes	No	N/A	Response Total
List the acceptable rules for constructing antibiograms.	98.4% 252	1.2% 3	0.4% 1	256
State methods for optimized pharmacodynamics dosing of	99.2% 254	0.4% 1	0.4% 1	256
Apply accepted methods for formulary review of new	98.0% 251	1.6% 4	0.4% 1	256
List and describe at least six major papers	97.7% 250	2.0% 5	0.4% 1	256
List similarities and distinguish differences between	99.2% 254	0.0% 0	0.8% 2	256
Demonstrate the ability to employ a variety of stewardship	98.0% 251	1.6% 4	0.4% 1	256
State the broad purposes, distinctions and areas of	98.0% 251	0.8% 2	1.2% 3	256
List basic changes in pharmacokinetics of	98.0% 251	2.0% 5	0.0% 0	256
List basic changes in pharmacokinetics of	98.4% 252	1.6% 4	0.0% 0	256
Describe ways in which the pharmaceutical industry may	96.5% 247	3.5% 9	0.0% 0	256
List and analyze ways the current regulatory	98.4% 252	1.6% 4	0.0% 0	256
Appraise the relative contributions of rapid	100.0% 256	0.0% 0	0.0% 0	256
Apply data reflecting pulmonary penetration of	98.4% 252	0.8% 2	0.8% 2	256
State the recent advances in knowledge of pathophysiolog	99.2% 254	0.8% 2	0.0% 0	256

Describe proper utilization of laboratory tests in management	98.4% 252	0.8% 2	0.8% 2	256
Identify the proper role of echinocandins in the antifungal	98.0% 251	1.2% 3	0.8% 2	256
Totals:	**4,030**	**50**	**16**	

The Art of the Antibiogram AASP

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	72.3% 185	19.5% 50	1.2% 3	0.0% 0	0.0% 0
Relevant to practice	73.4% 188	17.6% 45	1.6% 4	0.4% 1	0.0% 0
Objective/non-biased	77.0% 197	14.8% 38	0.8% 2	0.0% 0	0.4% 1
Will benefit my practice	68.8% 176	18.8% 48	5.1% 13	0.4% 1	0.0% 0
Handouts aided learning	63.7% 163	24.2% 62	5.1% 13	0.0% 0	0.0% 0
Well-organized	68.4% 175	20.3% 52	4.3% 11	0.0% 0	0.0% 0
Effective speaker	70.7% 181	19.1% 49	3.1% 8	0.0% 0	0.0% 0
Totals:	**1,265**	**344**	**54**	**2**	**1**

Practical PK/PD AASP

ACPE Pro Form 0485-0000-13-002-L04-P

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	73.8% 189	17.6% 45	0.4% 1	0.8% 2	0.0% 0
Relevant to practice	76.6% 196	12.9% 33	2.7% 7	0.4% 1	0.0% 0
Objective/non-biased	77.7% 199	13.3% 34	1.2% 3	0.0% 0	0.4% 1
Will benefit my practice	72.3% 185	16.0% 41	3.5% 9	0.8% 2	0.0% 0
Handouts aided learning	70.3% 180	16.4% 42	4.3% 11	1.2% 3	0.4% 1
Well-organized	71.5% 183	16.8% 43	2.3% 6	2.0% 5	0.0% 0
Effective speaker	73.4% 188	16.8% 43	1.2% 3	1.2% 3	0.0% 0
Totals:	**1,320**	**281**	**40**	**16**	**2**

Keynote: Antimicrobial Stewardship: The CDC's Perspective AASP

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	83.6% 214	11.3% 29	0.4% 1	0.0% 0	0.0% 0
Relevant to practice	78.9% 202	12.9% 33	3.5% 9	0.0% 0	0.0% 0
Objective/non-biased	82.0% 210	12.1% 31	0.8% 2	0.0% 0	0.4% 1
Will benefit my practice	73.8% 189	16.4% 42	4.3% 11	0.8% 2	0.0% 0
Handouts aided learning	76.2% 195	16.8% 43	2.3% 6	0.0% 0	0.0% 0
Well-organized	82.8% 212	11.7% 30	0.8% 2	0.0% 0	0.0% 0
Effective speaker	85.5% 219	8.6% 22	1.2% 3	0.0% 0	0.0% 0
Totals:	**1,441**	**230**	**34**	**2**	**1**

What's the Poop on Clostridium difficile Infection in 2013?
ACPE Program 0485-0000-13-004-L01-P (1.0 Contact Hour)

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	81.6% 209	14.1% 36	0.0% 0	0.0% 0	0.0% 0
Relevant to practice	82.0% 210	11.3% 29	2.3% 6	0.0% 0	0.0% 0
Objective/non-biased	77.7% 199	16.0% 41	0.4% 1	0.8% 2	0.8% 2
Will benefit my practice	78.5% 201	13.3% 34	3.9% 10	0.0% 0	0.0% 0
Handouts aided learning	78.9% 202	14.5% 37	2.3% 6	0.0% 0	0.0% 0
Well-organized	80.5% 206	13.7% 35	1.6% 4	0.0% 0	0.0% 0
Effective speaker	80.1% 205	12.9% 33	2.3% 6	0.4% 1	0.0% 0
Totals:	**1,432**	**245**	**33**	**3**	**2**

Impact of New Technologies on Antimicrobial Stewardship:
Is it Really Faster? AASP

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	75.8% 194	17.6% 45	1.2% 3	0.0% 0	0.0% 0
Relevant to practice	68.0% 174	23.8% 61	2.0% 5	0.4% 1	0.4% 1
Objective/non-biased	75.4% 193	16.4% 42	2.3% 6	0.0% 0	0.4% 1
Will benefit my practice	63.3% 162	25.8% 66	4.3% 11	0.8% 2	0.4% 1
Handouts aided learning	69.1% 177	21.9% 56	3.5% 9	0.0% 0	0.0% 0
Well-organized	67.2% 172	23.4% 60	3.5% 9	0.4% 1	0.0% 0
Effective speaker	68.4% 175	20.3% 52	4.7% 12	0.8% 2	0.4% 1
Totals:	**1,247**	**382**	**55**	**6**	**4**

StewardshipMetrics That Justify Your Job AASP

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	72.7% 186	19.1% 49	1.6% 4	0.0% 0	0.4% 1
Relevant to practice	70.3% 180	20.3% 52	2.7% 7	0.4% 1	0.0% 0
Objective/non-biased	78.1% 200	14.1% 36	1.2% 3	0.0% 0	0.4% 1
Will benefit my practice	67.6% 173	17.6% 45	8.2% 21	0.4% 1	0.0% 0
Handouts aided learning	67.2% 172	21.1% 54	4.7% 12	0.4% 1	0.4% 1
Well-organized	69.1% 177	20.3% 52	2.7% 7	1.2% 3	0.4% 1
Effective speaker	70.3% 180	19.5% 50	2.7% 7	1.2% 3	0.0% 0
Totals:	**1,268**	**338**	**61**	**9**	**4**

To be on Formulary or not to be on Formulary,
That is the Question AASP

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	71.1% 182	19.1% 49	2.3% 6	0.8% 2	0.0% 0
Relevant to practice	70.7% 181	18.0% 46	3.9% 10	0.8% 2	0.0% 0
Objective/non-biased	75.4% 193	15.6% 40	1.6% 4	0.0% 0	0.8% 2
Will benefit my practice	65.2% 167	20.7% 53	5.5% 14	2.0% 5	0.0% 0
Handouts aided learning	66.8% 171	20.3% 52	3.9% 10	2.3% 6	0.0% 0
Well-organized	71.1% 182	16.8% 43	3.5% 9	1.2% 3	0.8% 2
Effective speaker	70.7% 181	18.0% 46	2.3% 6	1.6% 4	0.8% 2
Totals:	**1,257**	**329**	**59**	**22**	**6**

Antimicrobial Stewardship in Pediatrics AASP

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	72.7% 186	16.0% 41	0.0% 0	0.0% 0	0.0% 0
Relevant to practice	58.6% 150	20.3% 52	7.0% 18	2.7% 7	0.0% 0
Objective/non-biased	72.3% 185	15.6% 40	0.4% 1	0.0% 0	0.4% 1
Will benefit my practice	54.7% 140	21.5% 55	9.0% 23	3.5% 9	0.0% 0
Handouts aided learning	68.0% 174	18.8% 48	2.0% 5	0.0% 0	0.0% 0
Well-organized	70.7% 181	17.2% 44	0.8% 2	0.0% 0	0.0% 0
Effective speaker	69.9% 179	16.8% 43	2.0% 5	0.0% 0	0.0% 0
Totals:	**1,195**	**323**	**54**	**16**	**1**

Stewardship from the Industry Perspective AASP

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	66.8% 171	21.9% 56	4.3% 11	1.2% 3	0.4% 1
Relevant to practice	57.0% 146	25.4% 65	10.2% 26	0.8% 2	1.2% 3
Objective/non-biased	62.9% 161	24.2% 62	4.3% 11	0.8% 2	2.3% 6
Will benefit my practice	52.7% 135	25.4% 65	13.3% 34	1.2% 3	2.0% 5
Handouts aided learning	56.6% 145	25.4% 65	9.8% 25	2.0% 5	0.8% 2
Well-organized	60.2% 154	25.4% 65	5.9% 15	2.0% 5	1.2% 3
Effective speaker	58.6% 150	27.0% 69	6.6% 17	0.8% 2	1.6% 4
Totals:	**1,062**	**447**	**139**	**22**	**24**

PK/PD in Special Populations

Total Respondents:	256
TotalSkipped:	0

	5	4	3	2	1
Met objectives	73.4% 188	19.1% 49	2.3% 6	0.4% 1	0.0% 0
Relevant to practice	79.3% 203	13.7% 35	2.3% 6	0.0% 0	0.0% 0
Objective/non-biased	80.5% 206	13.7% 35	0.8% 2	0.0% 0	0.4% 1
Will benefit my practice	74.2% 190	16.4% 42	3.9% 10	0.8% 2	0.0% 0
Handouts aided learning	70.3% 180	20.7% 53	3.9% 10	0.4% 1	0.0% 0
Well-organized	73.0% 187	18.0% 46	4.3% 11	0.0% 0	0.0% 0
Effective speaker	70.7% 181	21.1% 54	3.5% 9	0.0% 0	0.0% 0
Totals:	**1,335**	**314**	**54**	**4**	**1**

What Did You Miss Because There Was No Funding to Attend the Infectious Disease Meetings?

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	66.4% 170	19.5% 50	0.4% 1	0.8% 2	0.4% 1
Relevant to practice	61.7% 158	19.9% 51	4.7% 12	0.8% 2	0.4% 1
Objective/non-biased	66.0% 169	18.4% 47	2.0% 5	0.4% 1	0.8% 2
Will benefit my practice	58.2% 149	20.7% 53	7.4% 19	0.8% 2	0.4% 1
Handouts aided learning	59.8% 153	21.5% 55	5.1% 13	0.8% 2	0.4% 1
Well-organized	61.3% 157	19.9% 51	5.1% 13	0.8% 2	0.4% 1
Effective speaker	63.3% 162	18.4% 47	4.3% 11	0.8% 2	0.8% 2
Totals:	**1,118**	**354**	**74**	**13**	**9**

Issues in the Treatment of Respiratory Infections

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	67.2% 172	16.4% 42	1.6% 4	0.4% 1	0.0% 0
Relevant to practice	65.6% 168	16.0% 41	3.5% 9	0.4% 1	0.0% 0
Objective/non-biased	68.4% 175	14.1% 36	2.0% 5	0.8% 2	0.4% 1
Will benefit my practice	62.9% 161	17.6% 45	5.1% 13	0.0% 0	0.0% 0
Handouts aided learning	63.7% 163	18.0% 46	3.9% 10	0.0% 0	0.0% 0
Well-organized	66.0% 169	16.8% 43	2.3% 6	0.4% 1	0.0% 0
Effective speaker	64.8% 166	16.4% 42	4.3% 11	0.0% 0	0.0% 0
Totals:	**1,174**	**295**	**58**	**5**	**1**

Updates from the MAD-ID Research Network

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	62.9% 161	15.6% 40	2.0% 5	0.0% 0	0.0% 0
Relevant to practice	56.6% 145	17.2% 44	6.3% 16	0.4% 1	0.0% 0
Objective/non-biased	61.7% 158	14.8% 38	3.1% 8	0.4% 1	0.4% 1
Will benefit my practice	55.9% 143	18.4% 47	5.1% 13	1.2% 3	0.0% 0
Handouts aided learning	55.5% 142	18.0% 46	6.3% 16	0.4% 1	0.4% 1
Well-organized	60.9% 156	16.0% 41	3.1% 8	0.4% 1	0.0% 0
Effective speaker	59.8% 153	18.0% 46	2.0% 5	0.8% 2	0.0% 0
Totals:	**1,058**	**302**	**71**	**9**	**2**

Meet the Professors

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	59.0% 151	13.3% 34	1.6% 4	0.0% 0	0.0% 0
Relevant to practice	55.9% 143	15.2% 39	2.7% 7	0.0% 0	0.0% 0
Objective/non-biased	60.2% 154	12.1% 31	1.2% 3	0.0% 0	0.4% 1
Will benefit my practice	55.9% 143	13.7% 35	4.3% 11	0.0% 0	0.0% 0
Handouts aided learning	50.0% 128	11.3% 29	8.2% 21	0.8% 2	3.1% 8
Well-organized	54.7% 140	16.0% 41	3.1% 8	0.0% 0	0.0% 0
Effective speaker	57.8% 148	14.5% 37	1.6% 4	0.0% 0	0.0% 0
Totals:	**1,007**	**246**	**58**	**2**	**9**

Managing Fungal Infections

Total Respondents:	256
Total Skipped:	0

	5	4	3	2	1
Met objectives	62.5% 160	15.2% 39	0.4% 1	0.0% 0	0.4% 1
Relevant to practice	59.4% 152	16.0% 41	2.3% 6	0.4% 1	0.4% 1
Objective/non-biased	63.7% 163	12.9% 33	0.8% 2	0.0% 0	1.2% 3
Will benefit my practice	59.4% 152	15.2% 39	3.1% 8	0.4% 1	0.4% 1
Handouts aided learning	59.8% 153	15.6% 40	2.3% 6	0.4% 1	0.4% 1
Well-organized	63.7% 163	12.5% 32	2.0% 5	0.0% 0	0.4% 1
Effective speaker	61.7% 158	14.1% 36	2.3% 6	0.0% 0	0.4% 1
Totals:	**1,101**	**260**	**34**	**3**	**9**

Needs Assessment Result of 2013 Annual MAD ID meeting

Need for more research-based presentations in addition to antimicrobial stewardship

Not currently - firsrt time and very much enjoyed/appreciated all content and speakers!

This was a very beneficial program but I would recommend a more variety and spread amongst the speakers.

Classroom sessions were very hands on and helpful.

It would have been good have wi-fi through MAD-ID in conference rooms since we were expected to have our laptops.

Might consider two tracks at each meeting: one track for new ID practitioners and ASP's, and a second, more advanced track for established practioners and programs.

"PLEASE PLEASE PLEASE choose a site with free wifi. After spending >$1500 to attend this conference, I found it ridiculous I had to spend additional money to pay for use of wifi... Even McDonald's has free wifi. Very few people had downloaded info prior to meeting with expectation that we could do so while at the meeting.

Other than lack of internet - i really enjoyed this conference & found it contained very useful information. I especially liked the updates from ICAAC, IDSA week."

This was my first program and I enjoyed the speakers very much. I was a little surprised at how few sponsors there were but I guess that reflects how few companies are manufacturing abx presently.

"PLEASE move off of Mother's Day weekend. This will likely prevent me from attending in the future due to logistical challenges.

Maybe if someone from the FDA came and described the approval process?

How AS can become more involved with core measures and other initiatives by JC and CMS to help justify the program

More practical applications and help with difficult patients or talks on how to approach physicians, residents, pharmacists with AS strategies and education.

More time in workshops. They were done so quickly it was hard to grasp the concepts.

The questions on the tests for the Advanced certification did not always follow the presentation. Some of the questions were not answerable from the info given. It was difficult to follow the presentation for trying to answer the questions.

would like to see more interactive presentation but the groups need to be broken into groups of 5 to 10 participates so cases can be worked through and have more complete professor interaction

Despite the long days, I appreciated that the wealth of information was presented in 3 days rather than stretched out further.

The session by Dr. Brown was incredibly biased and provided zero benefit to clinicians.

"This meeting was excellent. I got alot of great ideas, learned alot, and am excited about doing more with my AMS program.

It seemed there were alot of questions / discussion about resistance and susceptibility questions / challenges especially with all the new literature on this topic. I think an excellent session for next year would be a mechanisms of resistance and susceptibility type lecture / workshop on identifying and managing different phenyotypic resistance patterns.

I also think that the research network could be a great opportunity to study some quesitons like adverse drug reactions and certain outcomes? Some things that are harder to evaluate with smaller AMS programs, just a thought. Another great research network question might be AMS process related. I say that because per the IDSA website they are working on a guideline about conducting stewardship programs, and while probably many of the meeting's speakers may be involved, it might be a good way to get input about what most people are doing currently. That may not be feasible within the timeframe of that guideline development though.

In order to facilitate more people attending from around the country it might be nice if the location was more centralized, but that is my own biased opinion as someone coming from the west coast.

"The CE programs themselves were excellent in content, topics, and the speakers -- extremely beneficial meeting to have attended. A lot of the programs had great hands on content as well to facilitate learning. Q&A periods were also pivotal in the experience.

Next year consider not printing the CE slides book (only publish PDFs on website); if individuals still want it then include a checkbox option during registration."

"Give the option for soft or hard copies. I prefer the info downloaded on a USB

Allow more Q&A at the end of every dAy. Meet the professors was very beneficial , I would like more of that.

Start a LIst SErvers to learn what others are doing for ABX stewardship, and answer clinical Abx related queations.

"Include a workshop for vancomycin dosing.

The workshops were great - include more."

In the workshops have the whole group go through the exercises that way we all work through the different examples

I think the workshops, in particular, were very helpful. Doing is always preferable to listening, and I think all workshop speakers provided effective, insightful guidance on important practices within stewardship. Including more workshops at future meetings may be of benefit.

There needs to be at least a 5 minute break between each session. Sometimes we went 3 hours without a break. Not good for our health. Also, satellite symposia are well attended so why not have more of those and a longer mid afternoon break? I could learn more if the sessions weren't all crammed into one block.

The programming was very helpful, appropriate, and presented well.

I woud consider having the MAD-ID research network, update from other ID meetings, and meet the professors session at the very end of the meeting, since those sessions are more optional it may allow people to take earlier flights home."

This years program was a nice balance between lecture material and hands on skills.

Grouping of the topics; put microbiology as the first lecture as the antibiotics and antibiogram build from that

Handouts as a 3 slide per page made some slides unreadable

liked the audience participation with the voting. I remember one meeting we had pre questions prior to the presentation that we voted on as well. This is always a great meeting. Liked the other ID meeting updates/pearls.

All classroom activities need desk with which to work.

"Great meeting! As a new practitioner/trainee I thought that the interactive workshops were incredibly helpful as I will be starting a new stewardship program in the coming months! As far as future meetings go, it may be helpful to have some workshops/sessions targeted toward beginners and some targeted toward more advanced stewardship applications.

Enjoyed CDC speaker plus antibiogram, c.diff and pediatric review. Did not enjoy the meeting rooms that did not allow for tables.

The conference was very well planned and as far as I can tell went very smoothly. The one comment I would make is that it may have been beneficial to have at least a 5-10 minute break between all sessions to give people a chance to stretch their legs.

the pk/pd sessions and the alterations of pk in special populations were the most beneficial. The keynote speaker was also very good. The pediatric lectures were least relevant to my personal practice.

I think an every other year HIV talk would be helpful

"Many of the speakers had to rush & spoke very quickly. Trim the topics or allow more time.

Loved the hands on approach. Would love to have more hands on experience as I do not have PGY2 experience in ID

"1. The workshops were particularly interesting and practical. Pharmacists would benefit from this style of presentation for basic understanding of stewardship measures.

2. Expansion on combination therapy strategies for bacterial infections."

Really appreciated the handouts. If these are to be done away with to save cost, would recommend making sure that site has good/free WiFi throughout conference area.

"1. In some of the evaluations above, there is only one evaluation for both speakers. In one or two cases, one speaker was clearly better than the other, but the questionnaire does not allow separate ratings.

2. Keep encouraging everybody, even very small hospitals like mine. I believe in the concept - it's just hard to get the resources and support from administration needed to create a quality ASP."

A metrics handbook for dummies with detailed definitions, suggested spreadsheets, calculations would be helpful.

Overall, excellent conference. Strongly enjoyed the workshop-style morning programs - they were both interesting and useful. The Meet the Professors should be the last session of the conference - those truly interested will stay until the end regardless. Potential future programs: 1. Stewardship strategies for difficult situations (ex: de-escalation for fever of unknown origin, febrile neutropenia, negative cultures, etc.) 2. Geographic variability of stewardship practices (maybe have a roundtable session divided by region) 3. Medication usage evaluation strategies 4. Management of anti-infective drug shortages

"Some of the presentations (e.g. drug dosing in obesity) were more theoretical than practical. I would like to see more presentations that require audience participation through discussion of institutional practices (small groups), patient cases, etc...

The practical applicability of the topics was extremely beneficial to me because I am able to see how I will be able to use them in the future.

particularly enjoyed the workshops

Please include information that relates to infections in the immunocompromised host. Also there were not any presentations about antivial agents.

"The hands-on workshops were fun and a great way to enhance learning.

Provision of useful references by the speakers would be helpful. Contact info (eg. email addresses) for the speakers would be a great asset."

The crowd seemed like they were looking for more straight-forward answers. Maybe more case based scenarios would be a good addition.

II really enjoyed the stewardship workshops in the morning and interacting with so many different people. This meeting as a whole had such great speakers with excellent presentations that were well researched and organized. It was extremely helpful to me and made me excited and motivated to implement some new ideas into my antimicrobial stewardship program (ex. a start on antiretroviral stewardship would be exciting to me.. and also very helpful as we are starting to see more and more HIV patients at my institiution).

Include antiretroviral stewardship

I am amazed that one can come year after year and new material is presented. I always feel like I am learning something new.

"Second time attending. I really like the melding of the 'bench' academic experts with the everyday practitioners like me - pulling the science together with the practice.

The workshops are helpful - perhaps it would help to allow a little more time for Q & A with these. I missed a few concepts while trying to do the 'hands-on' work.

Providing electronic versions of the lecture handouts were very helpful.

could there be different topics which take place at the same time? This would allow staff to maximize their areas of focus. For example, Pediatrics discussion from 0800-0900 and Geriatrics topic from 0800-0900. I understand this would require more speakers and meeting facilities

more about resistance mechanisms for antibiotics

This was a great meeting. Incorporating both ASP workshops and metrics, as well as, ID review is very worthwile.

"devote a day to abx controversies so that attendees get latest perspective from experts on practical issues we are dealing with

remember that most of your audience does not work in a large teaching hospital, we are in community hospitals with limited resources"

Keep the classroom programs, they were helpful.

Susan Davis' presentation was disappointing. She did not allot sufficient time to discuss the group activities. The information discussed regarding restriction of abx was basic and incomplete.

"The slides in some of the handouts were so small that they were more confusing than useful.

The quality of the speakers was phenomenal, especially Keith Rodvold, Kerry LaPlante, and Kevin Garey.

Workshops were helpful. Finding a universal metric to report for stewardship programs would be very helpful.

All workshops need tables. Friday workshop sessions were difficult logisticall to do calculation, write justifications, etc.

I would appreciate a program on implementing stewardship at smaller hospitals where budgets are tighter and manpower is less.

"I found the Stewardship Classroom sessions to be particularly helpful to me. There was discussion and hands on learning.

I also really got a lot of useful information from the Meet the Professors session."

Antibiogram for outpatient or our community will be useful to the physicians in our clinic. Networking is very helpful and the studies obtained from this could impact future therapies as we now know it. I hope to be a part of this in the near future.

"1- The 'hands-on' workshops were great learning sessions. However, sometimes they went rather fast. Having practice problems to complete after the workshop is over would be helpful.

2 - More workshops!

3 - Updates on guidelines on the most common disease states, including drug selection, duration of therapy, monitoring, etc."

"There was much in terms of studies and concepts but need to focus on applicability to practice. I think the importance is what is done in practice and the ability to learn from the examples from other institutions or practice sites.

Poster session exploded this year. Great job!"

"Please create list serve for discussions with colleagues in MAD ID.

Appreciated working groups for Antibiogram - would like more on that.

Really liked the workshops but would like the answers and discussion to be projected better and more explaination during the walk through

"the PK PD talk was too advnaced and too fast for a beginner to follow. group work in many sessions was not really 'group work' it was more like tlak to person to your left or right if they are interested--perhaps faciliators to lead each group and assist would work better.

maybe you can have session options for advance and basic --depending on where you are with ASP and different learning objections;

Programs were well organized with a variety of knowledgeable speakers. Will certainly attend again.

More information on dosing in obesity and abx in patients with COPD

Try not to schedule a Cdiff talk right after lunch.

Please look for workshop classrooms that have tables for feasibly of performing assigned tasks ... otherwise a wealth of knowledge provided in an effective environment overall! As always, I look forward to attending the program and watching it expand!

"The hands-on workshops were specifically beneficial. Quantifying utilization metrics was a helpful exercise and I would be interested in a similar workshop dedicated at clinical outcome metrics.

I also enjoyed working through a pharmacoeconomic analysis when considering addition of a new antimicrobial to the formulary.

I'm always interested in reviewing more of the ID literature regarding orthopedic infections as well as indications within OB/GYN."

Updates on guidelines and the reasoning behind the changes would be interesting.

Jack Brown's presentation was one of the worst I have attended. Information for stewardship course was somewhat basic for an advanced course.

The workshops were difficult due to the size of the groups and the orientation of the room. I did not find them to be optimal for learning new concepts. It would have been much more beneficial to have all the cases/scenarious discussed by the professors. The workshop concept is great but asking people to work in groups impromptu, in a short amount of time to cover a relatively large amount of material did not work well. The diversity of the groups did not help the situation. You had ID fellows mixed with community practitions.

I would have added more themes about the practical job strategies implementing an Stewardship Program, what are the barriers encountered and how did you surpasssed them. In general I was expecting more examples of initiatives on how to start, implement a program in detail. For example our team in Bayamon Puerto Rico developed a program that includes initiatives for descalation,renal adjustments,TDM and we are implementing them with a multidisciplinary round evaluating the patient clinic. First of all we defined descalation etc. Thats really what i wanted to hear.And be more specific about how to measure the succes of the program based on your initiative.

#2: Program content. The changes you've made in program content over the past few years is terrific. It is a nice mix of advanced information and basic tools we all need to work with daily. The growth of the poster program has been good to see with some fine projects being shared. Thanks for all of your hard work in bringing this meeting to us each year. It is by far the best and most useful CE!!"

Keep up the excellent work. This was my first MAD-ID conference and it was fantastic. The amount of information dispensed during this conference was incredible and applicable to my daily practice.

I loved having the meetings in the same room; I also loved not having to choose between presentations (and having the opportunity to attend all talks). I loved having such a large number of engaging/mentally stimulating workshops and also having the opportunity to hear lectures from such KOLs in the field. I liked the booklet of slides to work through. Lastly, I found the review questions for the presentation to be a helpful reinforcement of what I just learned. At the end of the meeting there was an interactive clicker polling session and there was one question about posting the posters online. When I answered the question, I thought this option was in addition to the current poster session. I wonder if any other members thought this option was to post posters online (AND have session) vs. eliminate session and only post online.... as a large majority of members selected this answer..

Give practice strategies about antimicrobial stewardship or let people share their experience.

Please open the MADID research network to questions

I thought the program was great!! I gathered a wealth of knowledge to share with our antimicrobial stewardship team. I look forward to attending again next year.

some discussion on duration of therapy and descalation initiatives. I feel many patients are started on empiric treatment, covering for potential healthcare associated infections ,when there symptoms dont justify the combinations. I think many get started on triple therapy when there really is not a need ..it then takes 3-4days to begin the deescalation period. This dangerous in the resistance era we are in.

The workshops were very practical and helpful.

Please make sure that there are tables in all the conference rooms. One of the mornings we didn't have tables and I found it very difficult to juggle all my notes and the book we were given. Encourage speakers to put all slides in handouts and actually go in order. There were a couple of sessions where I felt lost for most of the time because they would jump around or not have the slides in the handouts.

Review of IDSA guidelines from previous year.

Enjoyed the hands-on PK problems. More cases!

The workshops should have just used scree shots. The rooms were long and narrow and you could not see the computer screen so it was impossible to follow along plus time consuming for the speaker to enter the data in the computer

The workshop on metrics to follow for the impact of antimicrobial stewardship was especially useful. I am trying to get administration to look at parameter other than purchasing data from the pharmacy dept.

some more basic concepts for the beginners (maybe have beginner and advanced sessions so that everyone can be accommodated)

I was a little disappointed in the presentations at this year's meeting. I would read the titles of the lectures and expect to get an overview on how effectively treat a specific infection in practice. Instead,

many presentations highlighted topics for which the speaker could not provide a clear-cut answer and sometimes there were no good hints as to the general direction they would take when treating these infections. I got the feeling from many of the audience questions that I was not the only one who wanted more specific guidance. I think more cases with tricky scenarios and the treatment chosen would have been beneficial. I felt far too much time was spent on laboratory test methods. I think that many pharmacists who are not yet ID experts (but trying to get there) would benefit from some more basic talks on antibiotics as used to treat infectious diseases. I think it would be VERY beneficial to add extra time to the conference every couple of years and do a crash course in antibiotic selection and the basics for starting up an ID program from scratch for the beginner ID pharmacist. I know that you offer an online stewardship class, but I feel that even this lacks some of the benefit pharmacists could gain from attending classes in this area.

A few more lectures focused on treatment or prevention of infectious diseases, please.

presentations centered around practical application of stewardship or key studies/ data to support recommendations.

allow for a couple of platform presentations by the abstract presenters; some of that data is really interesting. Allow for some dedicated time for networking, perhaps centered around the research network.

Liked the mix of work shops and lectures

"I think it might be interesting to have more pediatrics sessions. Also, I really liked the workshops. It might be nice to have some of the basic poerful tools of microsoft Excel taught (ie pivot tables, filter, if formulas, eliminate duplicates etc); this could be done as a workshop calculating DOTs and LOTs from raw MAR data in a matter of 45 minutes.

I think it's also very helpful to have more sessions on MDROs, as we're all beginning to see them as commonplace."

Would have liked more meetings on Stewardship itself and the process of making it successful.

I am hoping that in the future with the increasing data collected by the research network, small community hospitals, such at the one where I practice, will have a place to 'go' for answers regarding dosing and use of ABX.

I really appreciated the PK/PD portion of the meeting and the new uses for old drugs discussion.

I liked how some of the sessions were more liked workshops.

"Program was excellent. My second year in a row and thought it was a little better than last year. Would love to see more vendors there. Think I might have liked the Caribe Royale a bit better last year, but Marriott was fine too.

Many of the speakers were rushing to get through their info. in the allotted time. The handouts particularly toward the latter part of the conference did not follow with the speakers.

"need a kinetics101 or refresher for some of us.

microbiology refresher would be good.

Continue to recruit wonderful speakers such as the C-diff speaker from Tx. He was wonderful. Also maybe have a session focussing a little more on the smaller rural hospitals as our bugs don't always match the big institutions' bugs.

"Suggestions for future programs would be the following:

1. Include more specific examples of different stewardship programs and how they were implemented.

2. Include real-life examples of types of antibiotic reports that are used to identify patients in hospitals that do not have surveillance software.

3. How to de-escalate therapy in patients with negative cultures (i.e. pneumonia, SSTIs)"

"Really enjoyed practical workshops

The accesibility of leaders in the field was remarkable

For the workshops, I liked having worksheets that could be filled out.

A case conference style workshop with audience feedback and live debate over the issues in the case.

Focus on the new health care environment

-Liked the idea of the practical sessions. Maybe new ones like 'designing an antibiotic PK protocol', etc.

Only use workshop rooms with tables for feasibility of preforming assigned task ... otherwise a wealth of knowledge provided in an effective environment overall! As always, I look forward to attending the program and watching it expand year after year.

Consider covering more basic topics in antibiotic stewardship, particularly in selection of antibiotics for pneumonia and UTIs. A lot of the conference was focused on the big, bad bugs. However, a big part of ABX stewardship is every day handing of negative cultures, asymptomatic bacteriuria etc.

I would like to see less on how to develop a stewardship program and more on the treatment/ideas surrounding the development of resistant organisms. I felt that quite a bit of the information was more theoretical, like I was in college again. I would like to see more sharing of ideas/proposal of how different institutions are battling certain issues and the latest treatment guidelines available. More

user-friendly handouts that may be brought back to our institutions for use, i.e. treatment guideline table for c. diff treatment.

Would love to have more courses similar to the fungal course that were clinical review based.

Have more classroom sessions

Do an activity in which people can share their antimicrobial stewardship programs and experiences.

As an HIV specialist, would like to see more HIV incorporated, albeit a very different world of ID.

Workshops were very beneficial however would have liked more time for discussion with presenter -- a bit difficult to work out a plan to present with such large groups but thought they were helpful nonetheless

The anti-fungal presentation as well as the Clostridium difficile infection one was fantastic. More presentations that are similar in format to those would be beneficial to all clinical practicing clinical pharmacists.

I would like to thank you for the opportunity to present my research poster at the conference, as well as the generous travel awards. I hope I was able to share new ideas with other health care providers in order to improve patient care.

More practical examples regarding setting up antimicrobial stewardship programs in various size institutions

I have attended four prior MAD-ID annual meetings, and I thought this was one of the best yet. I particularly appreciated more advanced stewardship sessions and the basic science posters. Kudos to the meeting planners and the faculty. I will definitely be back again next year.

The PK/PD programs were exciting and outstanding, and kept the program fresh. Nonetheless, the majority of the conference remains at a 'beginner's' level. I would love an advanced track, or for this conference to merge with the SIDP conference to allow for more flexibility in programming.

"Would like to have tables in classrooms for all 'working' sessions like the one on calculating TDDs, etc. We had to hold our books in our laps."

Tips and tools for the everyday practitioner would be helpful.

Would like to learn more from experts in optimizing antimicrobial therapy for treatment of infections caused by multidrug resistant organisms

Susan Davis' Formulary lecture was by far the worse lecture. She really did not demonstrate an unbiased lecture. She constantly commented on 'Henry Ford' practice as well as 'her residents and fellow'. It's demeaning to refer to people as possessions as if she 'owned' these post-grads.

Additionally she did not complete the discussion points with the hands on activity. Formulary management is definitely a topic that we can all relate to warranting a thorough discussion. Unfortunately in my opinion, this lecture did not meet its objectives."

more workshops for new practionears

I would love to see more practical workshops available!

Consider stewardship talks from the point of the more disadvantaged hospitals. Not all hospitals are willing to supply the best technologies however still expect to show significant results with the supplies at hand.

Voting or sharing one's opinion via texting is unfortunately not possible to everyone. Perhaps ask for show of hands for these people

Some lectures on advanced and innovative ASP practices and ideas would be beneficial to those who already have a good grasp on the fundamentals

It seems like same 3 people run the conference & all the speakers are close friends/colleagues. Maybe it is just a small community

Would like to see other infectious disease inclusion, such as vaccines and immunizations

Rules Report

BOARD OF PHARMACY

January 2014

Rule Number	Rule Title	Rule Development Published	Notice Published	Adopted	Effective	Comments
Fla. Admin. Code R. 64B16-26.206	Application for Pharmacist Licensure by Endorsement (Foreign Pharmacy Graduates)	10/1/2012	5/24/2013 Tolled 7/31/13			To be withdrawn
Fla. Admin. Code R. 64B16-27.700	Definition of Compounding	12/20/2013				
Fla. Admin. Code R. 64B16-27.797	Standards of Practice for Compounding Sterile Preparations	12/20/2013				
Fla. Admin. Code R. 64B16-28.140	Recod Maintenance Systems for Community, Special-Limited Community, Special Closed Systems, Special-Parenteral, and Nuclear Permits	1/6/2014				
Fla. Admin. Code R. 64B16-28.301	Destruction of Controlled Substances - Institutional Pharmacies	10/21/2013	11/7/2013			JAPC Ltr 11/15/13, response 12/09/13
Fla. Admin. Code R. 64B16-28.450	Centralized Presciption Filling, Delivering and Returning	9/6/2013	9/24/2013 NOC 12/12/13			JAPC Ltr. Rec'd 10/04/13, Resp. 12/9/13
Fla. Admin. Code R. 64B16-28.608	Automated Filling Systems within a Pharmacy	1/6/2014				
Fla. Admin. Code R. 64B16-28.810	Special Pharmacy - Limited Community Permit	10/18/2013	11/6/2013			JAPC Ltr 11/14/13, Response 11/20/13
Fla. Admin. Code R. 64B16-28.840	Special Non-Resident (mail-service)	1/3/2013	Development expired			Pending SERC reqired forms and language.

BOARD OF PHARMACY

Rule Number	Rule Title	Rule Development Published	Notice Published	Adopted	Effective	Comments
Fla. Admin. Code R. 64B16-28.901	Nuclear Pharmacy-General Requirements	9/6/2013	9/24/2013	12/11/2013	12/31/2013	JAPC Ltr Rec'd 10/04/13
Fla. Admin. Code R. 64B16-30.001	Disciplinary Guidelines, Range of Penalties, Aggravating and Mitigating Circumstances	9/6/2013	9/24/2013 NOC 12/11/13			JAPC Ltr Rec'd 10/04/13, 10/31/13, 12/02/13 Response 11/12/13, 11/13/13, 12/09/13

January 24, 2014

BTV Pharmacy
4310 NW 7th Avenue
Miami, FL 33127

RE: Request for Declaratory Statement

Dear BTV Pharmacy:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Tuesday, February 11, 2014. The meeting is being held at the Florida Hotel & Convention Center, 1500 Sand Lake Road, Orlando, FL 32809. The meeting will begin at 1:00 p.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444 ext: 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

PLEASE DISREGARD THE PREVIOUS LETTER YOU RECEIVED THAT STATED THE MEETING STARTED AT 9:00A.M.

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JAN 0 6 2014

BTV Pharmacy
4310 NW 7th Avenue
Miami, FL 33127
Pharmacy License No: 26147
Phone: 305.751.7882
Fax: 305.751.7884

Department of Health Agency Clerks Office
4052 Bald Cypress Way
Bin # A02
Tallahassee, FL 32399-1703
RE: Petition for Declaratory Statement from Florida State Board of Pharmacy

December 20, 2013

Dear Sir(s):

BTV Pharmacy is requesting a declaratory statement from the Florida State Board of Pharmacy pursuant to section 120.56 of Florida Statutes regarding a recent decision from a Pharmacy Benefit Manager (PBM) to recover monies for claims they are citing were incorrectly dispensed. OptumRx, the auditing PBM, cited that the pharmacy incorrectly dispensed medications for patients that were transferred to the pharmacy due to the actual "original amount dispensed" not specifically stated on the prescription. It was our pharmacy's contention that the amount was implied from the number of refills remaining and the last amount dispensed, which is included on the transfer order. The organization is standing by their decision because they are literally interpreting Florida Statute 465.026 (1) (d). It is the pharmacy's position that the inference can be made about the original amount dispensed. In fact, the pharmacy further feels the PBM is "interfering with their professional judgment according to Florida Statute 465.026 (1) (e).

We, therefore, ask for the Florida State Board of Pharmacy to make a declaratory statement on behalf of the interpretation or intent of the statute. Our pharmacy is facing s $22,890.20 recovery from a single audit, representing only 13 claims from this organization. The impact could be much more significant, should this PBM or others choose to recover monies on any and all transfer prescriptions this pharmacy has received.

The goal of our pharmacy is to dispense all medications safely and accurately according to state and federal law; however, we feel the lack of flexibility in these circumstances presents an unjust recovery for medications that OptumRx patients needed, have received, and were dispensed in good faith.

We eagerly await your statement in this matter. Should you need any additional information or assistance, we may be contacted using the above information. We appreciate the Florida State Board of Pharmacy's assistance with this matter.

Respectfully,

Basel Asali, RPh
Owner, BTV Pharmacy

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE DEC 18 2013

BTV Pharmacy
4310 NW 7th Ave.
Miami, FL 33127

Pharmacy license no: 26147
Phone: 305-751-7882
Fax: 305-751-7884

Department of Health's Agency Clerk's Office
4052 Bald Cypress Way, Bin #A02
Tallahassee, FL 32399-1703
RE: Petition for Declaratory Statement before the State Board of Pharmacy

December 11, 2013

To whom it may concern,

This letter is being written for a "Petition for Declaratory Statement before the State Board of Pharmacy". My name is Basel Asali and I am the owner of BTV Pharmacy (NCPDP# 5710377) and I am requesting a declaratory statement regarding Florida Statute 465.026 (d).

My pharmacy recently underwent an audit from OptumRx and was cited a recovery of $22,890.20 referencing this statute for invalid prescription transfer orders on 13 claims. Specifically they are stating the transfer does not contain the "original amount dispensed" even though this can be inferred or calculated with the information provided on the transfer orders. I am including these orders with the PHI removed for your review and consideration when making the determination. If this determination is upheld this recovery will substantially affect my pharmacy's ability to do business due to the large amount of money involved on these targeted extremely high dollar claims. Also, I would like to point out that if this can be done without a declaratory statement we are fine with a document from the state board acknowledging they reviewed the prescriptions and determined they are valid under Florida State Law since they are using that statute as cause for recovering the money.

It is our pharmacy's goal to dispense all medication accurately and according to state/federal law, however we feel the lack of flexibility in this case by OptumRx is recovering an unjust amount for claims dispensed in good faith. I appreciate the Board of Pharmacy's assistance in this matter and look forward to working with you as needed. I can be reached at the pharmacy using the contact information listed above.

Respectfully,

Basel Asali
Owner, BTV Pharmacy

(3)

05) 324-5604

07/12/2013 11:02:05 AM

VH Pharmacy

1000 SW 1st
Miami, FL 33130
(305) 324-8777 Fax:(305) 324-5604
DEA: AV6332441

PRESCRIPTION TRANSFER DETAIL

):

ARMACY:	BTV PHARMACY
DRESS:	4310 NW 7 AVE
TY, ST ZIP:	MIAMI, FL 33127
ONE:	(305) 751-7882
X:	(305) 751-7884
PHARMACIST:	BEATRICE
A:	FP3605409

FROM:

PHARMACY:	VH PHARMACY
ADDRESS:	1000 SW 1ST
CITY, ST ZIP:	MIAMI, FL 33130
PHONE:	(305) 324-8777
FROM PHARMACIST:	EDDY
DEA:	A
TRANSFER DATE:	07/12/2013

ATIENT INFORMATION:

ATIENT NAME:	[redacted]
DDRESS:	[redacted]
TY, ST ZIP:	[redacted]
HONE:	[redacted]
ATE OF BIRTH:	[redacted]

RX INFORMATION:

RX NUMBER:	6398049
DATE WRITTEN:	06/07/2013
FIRST FILL DATE:	06/19/2013
LAST FILL DATE:	06/19/2013
DRUG NDC:	59148-0009-13
DRUG NAME:	ABILIFY 15MG
WRITTEN QTY:	60
ORIG REFILLS AUTH:	5
LAST DISP QTY:	60
QTY REMAINING:	300.000
FILLS REMAINING:	5.000
REFILL EXP DATE:	06/06/2014
SIG:	TAKE 1 TABLET TWICE DAILY
NOTES:	AV6332441

OCTOR INFORMATION:

OCTOR NAME:	MENDOZA, LILIANA
DDRESS	100 NE 38TH ST
ITY, ST ZIP:	MIAMI, FL 33137
HONE:	(305) 576-1599
OCTOR DEA:	BM9204443
OCTOR NPI:	1750585139

THIS REPORT CONTAINS PATIENT INFORMATION WHICH IS LEGALLY PROTECTED UNDER HIPAA LEGISLATION.
IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, DO NOT DISTRIBUTE THE INFORMATION ANY FURTHER.

59148-0009-13 04 REFILLS PRICE 1372.63

TAKE 1 TABLET TWICE DAILY

ADJ:	1372.63
COPAY:	.00
TOTAL:	1372.63
ORIG: 5	

MENDOZA,LIAN
100 NE 38 ST
MIAMI, FL 33137

BM9204443
305-576-1599
AARP
ORG DT- 06/07/13

Auth# 131822251933094999 (6)

Who	RxNumb	..Date..	Code	Customer.....	Status
AA	06009288	07/01/13	[redacted]		Rejected (D)

CD	Description.....
75	Prior Authorization Required
75	Prior Authorization Required
569	Provide Beneficiary with CMS Notice of Appeal Rights

Policy#:0048269371 Group#:PDPIND Birth Date:12/07/1956

Enter ? for Help

ins ~~Phone~~ # 18778896510

PHONED	PROMISED	DELIVER	WILL CALL
A. M. / P. M.			

TXFR
Skyemed Phar
866-778-8255
347093

For [redacted]

Address

℞ Victrelis 200mg
336
4c (800mg) tid, 7-9hrs apart w/food.

OR/ST
6/10/13
RPh Sonia
WS

REFILL 10 TIMES

Adam Peuton M.D. _____ M.D.

SUBSTITUTION PERMITTED DISPENSE AS WRITTEN

NPI 1558565578

DATE 6/12/13 DEA No. (305) 689-1800 ADDRESS WA

McK-2

6009288-00
07/02/13

[redacted]

Attn:
Ms. Tyann

STW PHARMACY
P (305) 751-7882
F (305) 751-7884
4310 NW 7TH AVE, MIAMI, FL 33127
P 305 751 7882
F 305 751 7884

Thanks
Anne

00085-0314-02 00 REFILLS 330 CAP MERCK PRICE 5674.58

TAKE 4 CAPSULES (800MG) 3 TIMES A DAY 7-9 HOURS APART WITH FOOD

ADJ: 5674.58
COPAY: .00
TOTAL: 5674.58
ORIG: S

PEYTON, ADAM
1321 NW 14 ST
MIAMI, FL

305-689-1800
AARP
ORG DT- 06/10/13

(8)

VH Pharmacy

1000 SW 1st
Miami, FL 33130
(305) 324-8777 Fax:(305) 324-5604
DEA: AV6332441

PRESCRIPTION TRANSFER DETAIL

Rph Eddie

TO:

PHARMACY:	BTV PHARMACY
ADDRESS:	4310 NW 7 AVE
CITY, ST ZIP:	MIAMI, FL 33127
PHONE:	(305) 751-7882
FAX:	(305) 751-7884
TO PHARMACIST:	SHIREEN
DEA:	FP3605409

FROM:

PHARMACY:	VH PHARMACY
ADDRESS:	1000 SW 1ST
CITY, ST ZIP:	MIAMI, FL 33130
PHONE:	(305) 324-8777
FROM PHARMACIST:	EDDY
DEA:	AV6332441
TRANSFER DATE:	04/05/2013

PATIENT INFORMATION:

PATIENT NAME:	[redacted]
ADDRESS:	[redacted]
CITY, ST ZIP:	[redacted]
PHONE:	[redacted]
DATE OF BIRTH:	[redacted]

RX INFORMATION:

RX NUMBER:	6373411
DATE WRITTEN:	01/03/2013
FIRST FILL DATE:	01/03/2013
LAST FILL DATE:	03/20/2013
DRUG NDC:	61958-0701-01
DRUG NAME:	TRUVADA
WRITTEN QTY:	30
ORIG REFILLS AUTH:	6
LAST DISP QTY:	30
QTY REMAINING:	90.000
FILLS REMAINING:	3.000
REFILL EXP DATE:	01/02/2014
SIG:	TAKE (1) TABLET DAILY.
NOTES:	

DOCTOR INFORMATION:

DOCTOR NAME:	BOLIVAR, HECTOR
ADDRESS	1611 NW 12 AVE
CITY, ST ZIP:	MIAMI, FL 33136
PHONE:	(305) 585-1111
DOCTOR DEA:	1234567
DOCTOR NPI:	1558398206

THIS REPORT CONTAINS PATIENT INFORMATION WHICH IS LEGALLY PROTECTED UNDER HIPAA LEGISLATION.
IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, DO NOT DISTRIBUTE THE INFORMATION ANY FURTHER.
IMMEDIATELY NOTIFY US AND DESTROY THE ORIGINAL MESSAGE.

[redacted] SA

6007712-
04/12/13
SA ALA

(9)

305-634-7635 30 TAB GILEA
TRUVADA 200 MG-300 MG TAB PRICE 1254.65
61958-0701-01 02 REFILLS ADJ: 1254.65
TAKE 1 TABLET ONCE DAILY COPAY: .00
TOTAL: 1254.65
ORIG: 5

BOLIVAR,HECT 305-585-1111
1611 NW 12 AVE AARP
MIAMI, FL 33136 ORG DT- 01/03/13

(11)

NDC 0007 4433 9102

PHONED	PROMISED	DELIVER	WILL CALL
A. M. P. M.			

3/1/2013

For [redacted]

Address [redacted]

R/ovs

[redacted] 5/12

Humira Pen 40 mg

(2)

Brand Pharmacy

1-888-244-2340

Rph - Andrew

Inject 40 mg s/c every other week

REFILL 1+6 TIMES

Carlos Sesin M.D.

SUBSTITUTION PERMITTED

DISPENSE AS WRITTEN M.D.

305-531-6766

DEA No.

DATE

ADDRESS

WA

McK-2 NDI 1659304707

SMITH, MARTHA

6006754-00

RX 133989.

(12)

[redacted]

[redacted]

[redacted]

03/01/13
AR ALA

[redacted]

HUMIRA 40 MG/0.8 ML PEN 2 PEN ABBVI
00074-4339-02 06 REFILLS PRICE 2245.28

INJECT 40MG SUBCUTANEOUSLY EVERY OTHER WEEK AS DIRECTED

ADJ:	2241.78
COPAY:	3.50
TOTAL:	2245.28
ORIG: 5	

SESIN,CARLOS
4300 ALTON RD
MIAMI BEACH, FL 33140

305-674-2121
AARP
ORG BY- 11/05/12

(15)

RPh FA Tech MMD — Prescription Edit/Label — Wed Feb 6, 2013

Patient R[redacted], A[redacted]
FLD384-00
Doctor POWELL, ALEXIS

Phone ([redacted]) 67
DOB [redacted]
Phone [redacted]

Rx # 63045
Rf # 2
DEA BP-5225708

Drug PREZISTA 600 MG TABLET
NDC 59676-0562-01 BRAND PS 60.00
P

Qty 60 Dispensed 60 QtyLeft 240
Onhand -2820 LstQty 60 On 01/17/13
Unit Dose? N Refills 6 Remaining 4

Directions
TAKE 1 TABLET TWICE DAY

Day's Supply 30
10 Day's Left in This Fill

Plan(s)	Pay		
B08	1117.48P	$ 1117.48*	Last CASH
REWARDS		$ 1117.48*	Price CASH
		$	Disc
		$	Tax
Orig Rx 11/27/12		$ 1117.48	Total
Rx Date 01/17/13		$ 999.54	Cost(999.54)
Written 11/27/12		$ 117.94	Margin
Expires 11/27/13		$ 0.00	Patient Pays

SIGNED & PICKED UP

Rx Memo TRANSFERRED OUT Wed Feb 6, 201>>
Status Transferred Delivery Rx Pickup
Labels 1 Label 4457c Prt 1

ORIG 1 WRITTEN DAW 0

F1AddRx F2Clear F4Label F5RxHistF6RfHistF7DetailF8OptionF9 Help 10 Edit

6006236-00

[illegible] 03 REFILLS PRICE 1120.14

TAKE 1 TABLET TWICE DAILY

ADJ:	1120.14
COPAY:	.00
TOTAL:	1120.14

POWELL, ALEX
1611 NW 12 AVE
MIAMI, FL

AP2448620
305-243-1615
AARP
ORG DT- 11/27/12

(A)

(17)

RPh FA Tech MMD Prescription Edit/Label Login: FA /MMD

Patient [redacted], [redacted]
FLD384=00
Doctor POWELL, ALEXIS

Phone [redacted]
DOB [redacted] (52)
Phone ([redacted]

Rx # 63044
Rf # 2
DEA BP-5225708

Drug INTELENCE 100 MG TABLET
NDC 59676-0570-01 BRAND PS 120.00
P

Qty 60 Dispensed 60 QtyLeft 240
Onhand -3780 LstQty 60 On 01/17/13
Unit Dose? N Refills 6 Remaining 4

Directions
TAKE 1 TABLET TWICE A DAY

Day's Supply 30
0 Day's Left in This Fill

Plan(s)	Pay			
B08	445.05P	$	445.05*	Last CASH
REWARDS		$	445.05*	Price CASH
		$		Disc
		$		Tax
Orig Rx 11/27/12		$	445.05	Total
Rx Date 01/17/13		$	397.57	Cost(397.57)
Written 11/27/12		$	47.48	Margin
Expires 11/27/13		$	0.00	Patient Pays

SIGNED & PICKED UP

ORIG 1 WRITTEN DAW 0

Rx Memo TRANSFERRED OUT Wed Feb 6, 201>>
Status Transferred Delivery Rx Pickup
Labels 0 Label 4457c Prt 1

F1AddRx F2 Undo F4 Done F5RxHistF6RfHistF7DetailF8OptionF9 Help 10 Edit

This transfer was not in question, but we sent it because it's the only page that had the transfer pharmacy information.

Tech Pharmaceuticals
1900 W 68 St
Hialeah, FL 33014
305-556-9221
BT-9628706

Maria Diaz

ROUNDTREE, AUDREY

Michelle

(19)

[redacted]

6004210-00
10/18/12
DG AIA

FOR [redacted]

ADDRESS [redacted] DATE 09/28/12

Rx

1382791 Rejoctay 300 #60 (1+1)
1 BID
8/19/12
9/25/12
Dr. Xavier Valera
305-940-0522

1378888 Depo-Provera Shot (1+1)
inject muscle
8/27/12
9/24/12
Dr. Janina Eldridge
AF 9351377
305-944-2902

Walgreens
305-891-1262
Liliana
12:00

REFILL _____ TIMES DR. _____

DEA NO _____ ADDRESS

REORDER # 19115 (AME-1) - SAMUELS PRODUCTS, Inc. - 1-800-543-7155 - FAX - 1-513-891-4520

DR.

20

[redacted]

REYATAZ 300 MG CAPSULE 60 CAP BMSPR
00003-3622-12 01 REFILLS PRICE 2094.77
TAKE 1 CAPSULE TWICE DAILY

ADJ: 2094.77
COPAY: .00
TOTAL: 2094.77

VARELA,XAVIE
721 SE 17TH STREET CSWY
FORT LAUDERDALE, FL

305-940-0522
AARP
ORG DT- 08/19/1?

OR [redacted]

ADDRESS [redacted] DATE 09/28/12

℞

32791 Rejatay 300 #60 (1+1)
BID
8/19/12
9/05/12
Dr. Xavier Valera
305-940-0522

788888 Depo-Provera 50mg (1+1)
inject muscle
8/27/12
9/24/12
Dr. Janina Eldridge
AF 9331377
305-944-2702

Walgreens
305-891-1262
Liliana
12:00

REFILL _____ TIMES DR. _____

DEA NO _____ ADDRESS _____

REORDER # 1911G (AME-1) · SAMUELS PRODUCTS, Inc. · 1-800-643-7156 · FAX · 1-513-801-4650

DR

6004781-00
11/27/12
RA RSA

[redacted]

21

[illegible] 150 M 1 ML GREEN
59762-4537-01 01 REFILLS PRICE 44.64
INJECT INTRAMUSCULARLY AS DIRECTED

ADJ:	44.64
COPAY:	.00
TOTAL:	44.64

ELDRIDGE,JAN
16601 NE 19TH AVE
NMB, FL 33162

305-944-2902
AARP
ORG DT- 08/27/12

22

BTV Pharmacy #5710377
Section I Audit Findings
nal Findings

Member Last	Member First	RX	Written Date	Filled Date	RF	NDC desc	Qty	DS	MD First	MD Last	Approved Amount Paid	Preliminary Findings Reclaim Amount	Preliminary Findings	Final Findings Reclaim Amount	Final Findings
[redacted]		6009733	7/24/2013	07/24/2013	00	PROCRIT INJ 40000/ML	4	28	ADAM	PEYTON	$3,170.50	$0.00		$0.00	
[redacted]		6009504	6/7/2013	07/12/2013	00	ABILIFY TAB 15MG	60	30	LIANA	MENDOZA	$1,372.63	$1,372.63	Full recoupment. Invalid prescription. Transfer prescription record does not contain the original amount dispensed as required per Florida Statute 465.026 (d). See last page for full statute.	$1,372.63	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6009390	7/8/2013	07/08/2013	00	MEPRON SUS	210	21	PIERRE	BLEMUR	$1,191.19	$0.00		$0.00	
[redacted]		6009288	6/10/2013	07/02/2013	00	VICTRELIS CAP 200MG	336	28	ADAM	PEYTON	$5,674.58	$5,674.58	Full recoupment. Invalid prescription. Transfer prescription record does not contain the original amount dispensed as required per Florida Statute 465.026 (d). See last page for full statute.	$5,674.58	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6009034	6/12/2013	06/14/2013	00	TRIZIVIR TAB	60	30			$1,650.62	$0.00		$0.00	
[redacted]		6008937	6/10/2013	06/10/2013	00	ISENTRESS TAB 400MG	60	30	MICHAEL	HIN	$1,101.72	$0.00		$0.00	
[redacted]		6008917	5/13/2013	06/10/2013	00	TRUVADA TAB 200-300	30	30	LUIS	ESPINOZA	$1,252.01	$0.00		$0.00	
[redacted]		6008468	5/14/2013	05/14/2013	00	STRIBILD TAB	30	30	NICOLA	KEMMERER	$2,401.56	$0.00		$0.00	
[redacted]		6008118	10/31/2012	04/29/2013	00	RENVELA TAB 800MG	540	36	JORGE	DIEGO	$1,477.21	$0.00		$0.00	
[redacted]		6008010	4/25/2013	04/25/2013	00	PREZISTA TAB 600MG	60	30	RAYMOND	FAHLER	$1,118.83	$0.00		$0.00	
[redacted]		6007929	4/22/2013	04/22/2013	00	COMPLERA TAB	30	30	JONATHAN	FOX	$1,985.56	$0.00		$0.00	
[redacted]		6007789	2/6/2013	04/16/2013	00	ATRIPLA TAB	30	30	NICOLA	KEMMERER	$1,925.81	$0.00		$0.00	
[redacted]		6007712	1/3/2013	04/12/2013	00	TRUVADA TAB 200-300	30	30	HECTOR	BOLIVAR	$1,254.65	$1,254.65	Full recoupment. Invalid prescription. Transfer prescription record does not contain the original amount dispensed as required per Florida Statute 465.026 (d). See last page for full statute.	$1,254.65	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6007712	1/3/2813	05/06/2013	01	TRUVADA TAB 200-300	30	30	HECTOR	BOLIVAR	$1,254.65	$1,254.65	Full recoupment. Invalid prescription. Transfer prescription record does not contain the original amount dispensed as required per Florida Statute 465.026 (d). See last page for full statute.	$1,254.65	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6007712	1/3/2013	05/29/2013	02	TRUVADA TAB 200-300	30	30	HECTOR	BOLIVAR	$1,254.65	$1,254.65	Full recoupment. Invalid prescription. Transfer prescription record does not contain the original amount dispensed as required per Florida Statute 465.026 (d). See last page for full statute.	$1,254.65	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6007700	1/23/2013	04/12/2013	00	ABILIFY TAB 30MG	60	30	CARLOS	VACA	$1,830.87	$0.00		$0.00	
[redacted]		6007536	3/27/2013	04/05/2013	00	SENSIPAR TAB 90MG	30	30	JUAN	CUELLAR	$1,365.11	$0.00		$0.00	
[redacted]		6006826	3/7/2013	03/07/2013	00	RENVELA TAB 800MG	900	60	ALFREDO	SANCHEZ-FORTIS	$2,457.84	$0.00		$0.00	
[redacted]		6006754	11/5/2012	03/01/2013	00	HUMIRA PEN KIT 40MG/0.8	2	28	CARLOS	SESIN	$2,241.78	$2,241.78	Full recoupment. Invalid prescription. Transfer prescription record does not contain the date of original dispensing, original amount dispensed, or the prescription number as required per Florida Statute 465.026 (d). See last page for full statute.	$2,241.78	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6006754	11/5/2012	04/18/2013	02	HUMIRA PEN KIT 40MG/0.8	2	28	CARLOS	SESIN	$2,245.28	$2,245.28	Full recoupment. Invalid prescription. Transfer prescription record does not contain the date of original dispensing, original amount dispensed, or the prescription number as required per Florida Statute 465.026 (d). See last page for full statute.	$2,245.28	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6006514	2/21/2013	02/21/2013	00	HUMIRA PEN KIT 40MG/0.8	2	28	PAUL	SWEENEY	$2,238.68	$0.00		$0.00	
[redacted]		6006408	2/15/2013	02/15/2013	00	TRUVADA TAB 200-300	30	30	NICOLA	KEMMERER	$1,248.05	$0.00		$0.00	
[redacted]		6006392	2/13/2013	02/15/2013	00	SENSIPAR TAB 90MG	30	30	ALFREDO	SANCHEZ-FORTIS	$1,361.61	$0.00		$0.00	
[redacted]		6006236	12/27/2012	02/11/2013	00	PREZISTA TAB 600MG	60	30	RICHARD	POWELL	$1,120.14	$1,120.14	Full Recoupment. Invalid prescription. Transfer prescription record does not contain the name of the pharmacy at which the prescription was on file as required per Florida Statute 465.026 (d). See last page for full statute. Additionally, pharmacy submitted wrong prescriber. Prescription written by Alexis Powell, pharmacy submitted Richard Powell.	$1,120.14	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6006236	12/27/2012	03/06/2013	01	PREZISTA TAB 600MG	60	30	RICHARD	POWELL	$1,118.83	$1,118.83	Full Recoupment. Invalid prescription. Transfer prescription record does not contain the name of the pharmacy at which the prescription was on file as required per Florida Statute 465.026 (d). See last page for full statute. Additionally, pharmacy submitted wrong prescriber. Prescription written by Alexis Powell, pharmacy submitted Richard Powell.	$1,118.83	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6006236	11/27/2012	03/29/2013	02	PREZISTA TAB 600MG	60	30	RICHARD	POWELL	$1,118.83	$1,118.83	Full Recoupment. Invalid prescription. Transfer prescription record does not contain the name of the pharmacy at which the prescription was on file as required per Florida Statute 465.026 (d). See last page for full statute. Additionally, pharmacy submitted wrong prescriber. Prescription written by Alexis Powell, pharmacy submitted Richard Powell.	$1,118.83	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6005945	1/22/2013	01/24/2013	00	ABILIFY TAB 15MG	60	30	ALEJANDRO	ROTTER	$1,289.91	$0.00		$0.00	

11/26/13 AA

Member Last	Member First	RX	Written Date	Filled Date	RF	NDC desc		Qty	DS	MD First	MD Last	Approved Amount Paid	Preliminary Findings Reclaim Amount	Preliminary Findings	Final Findings Reclaim Amount	Final Findings
[redacted]		6005658	1/10/2013	01/10/2013	00	ATRIPLA	TAB	30	30	DEBORAH	HOLMES	$1,921.47	$0.00		$0.00	
[redacted]		6004841	11/29/2012	11/30/2012	00	TRUVADA	TAB 200-300	30	30	MARIA	ALE-CASTRO	$1,204.53	$0.00		$0.00	
[redacted]		6004210	8/19/2012	10/18/2012	00	REYATAZ	CAP 300MG	60	30	XAVIER	VARELA	$2,094.77	$2,094.77	Full recoupment. Invalid prescription. Transfer prescription record does not contain the original amount dispensed as required per Florida Statute 465.026 (d). See last page for full statute.	$2,094.77	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6004210	8/19/2012	11/13/2012	01	REYATAZ	CAP 300MG	60	30	XAVIER	VARELA	$2,094.77	$2,094.77	Full recoupment. Invalid prescription. Transfer prescription record does not contain the original amount dispensed as required per Florida Statute 465.026 (d). See last page for full statute.	$2,094.77	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
[redacted]		6004781	8/27/2012	11/27/2012	00	MEDROXYPRAC INJ 150MG/ML		1	90	JANINA	ELDRIDGE	$44.64	$44.64	Full recoupment. Invalid prescription. Transfer prescription record does not contain the original amount dispensed as required per Florida Statute 465.026 (d). Additionally, Prescription does not conform to all regulatory requirements. Missing quantity as required per Florida statute 456.42. See last page for full statute.	$44.64	Appeal letter/documents received; however, insufficient to amend findings. Therefore, findings still stand.
												$55,083.28	$22,890.20		$22,890.20	

Florida Statute 456.42 Written prescriptions for medicinal drugs.— (1) A written prescription for a medicinal drug issued by a health care practitioner licensed by law to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be dated; and must be signed by the prescribing practitioner on the day when issued. However, a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must be dated and signed by the prescribing practitioner only on the day issued, which signature may be in an electronic format as defined in s. 668.003(4).

(2) A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats, must be dated with the abbreviated month written out on the face of the prescription, and must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department or electronically prescribed as that term is used in s. 408.0611. As a condition of being an approved vendor, a prescription pad vendor must submit a monthly report to the department which, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may, by rule, require the reporting of additional information.

Florida Statute 465.026 Filling of certain prescriptions.— Nothing contained in this chapter shall be construed to prohibit a pharmacist licensed in this state from filling or refilling a valid prescription which is on file in a pharmacy located in this state or in another state and has been transferred from one pharmacy to another by any means, including any electronic means, under the following conditions:

(1) Prior to dispensing any transferred prescription, the dispensing pharmacist must, either verbally or by any electronic means, do all of the following:

(a) Advise the patient that the prescription on file at the other pharmacy must be canceled before it may be filled or refilled.

(b) Determine that the prescription is valid and on file at the other pharmacy and that the prescription may be filled or refilled, as requested, in accordance with the prescriber's intent expressed on the prescription.

(c) Notify the pharmacist or pharmacy where the prescription is on file that the prescription must be canceled.

(d) Record in writing, or by any electronic means, the prescription order, the name of the pharmacy at which the prescription was on file, the prescription number, the name of the drug and the original amount dispensed, the date of original dispensing, and the number of remaining authorized refills.

(e) Obtain the consent of the prescriber to the refilling of the prescription when the prescription, in the dispensing pharmacist's professional judgment, so requires. Any interference with the professional judgment of the dispensing pharmacist by any pharmacist or pharmacy permittee, or its agents or employees, shall be grounds for discipline.

January 24, 2014

Vicki McConnell, PharmD
556 Florida Central Parkway, Suite 1044
Longwood, FL 32750

RE: Request for Declaratory Statement

Dear Ms. McConnell:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Tuesday, February 11, 2014. The meeting is being held at the Florida Hotel & Convention Center, 1500 Sand Lake Road, Orlando, FL 32809. The meeting will begin at 1:00 p.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444 ext: 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

PLEASE DISREGARD THE PREVIOUS LETTER YOU RECEIVED THAT STATED THE MEETING STARTED AT 9:00A.M.

FLORIDA HOSPITAL
Home Infusion LLP

October 17, 2013

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE NOV 0 8 2013

Florida Board of Pharmacy
4052 Bald Cypress Way
Tallahassee, Fl 32399

Request for Declaratory Statement

Esteemed Board Members,

We would like the Board of Pharmacy to make a declaratory statement in regards to ARNP's prescribing and whose name should appear on the prescription label. If an ARNP writes a prescription is it mislabeling if the name of the physician, under whose auspices the ARNP practices, appears on the label as the prescriber?

We are aware that under the Nurse Practice Act 464.0012(3) an ARNP can monitor and alter drug therapies and may initiate appropriate therapies for "certain" conditions and perform additional functions as may be determined by rule in accordance with section 464.003(2) of the Florida statues. Our concerns are twofold. First, since pharmacies are not routinely provided with a copy of the ARNP protocol how can we assure that their signature is for "certain" conditions within their scope of practice? The second concern may be outside the scope/consideration of the board but has the potential to impact pharmacies on a regular basis and ultimately affect our ability to practice: insurance companies may not recognize and therefore may not reimburse for prescriptions that carry the ARNPs name/signature.

The Board of Pharmacy regulations state that the prescriber's name should appear on the prescription. We did not find a definition of prescriber only a practitioner as defined in 893.02(20)...a physician licensed pursuant to Chapter 458, a dentist licensed pursuant to Chapter 466, a veterinarian licensed pursuant to Chapter 474, an osteopathic physician licensed pursuant to Chapter 459, a naturopath licensed pursuant to Chapter 462, or a podiatric physician licensed pursuant to Chapter 461. Although 893.02 applies to controlled substances, we do not see RN or ARNP defined in this section.

Thank you for your clarification of this matter.

Sincerely,

Vicki McConnell

RECEIVED
OCT 2 5 2013
Florida Board of Pharmacy

Vicki McConnell, Pharm.D.

Director of Pharmacy

Florida Hospital Home Infusion, LLP

556 Florida Central Parkway, Suite 1044 ◦ Longwood, FL 32750 ◦ 407.865.5489 ◦ 800.446.2564 ◦ Fax 407.865.5479 ◦ 855.446.2564

January 24, 2014

Mark Schneider
1100 Central Park Drive, Suite 500
Sanford, FL 32771

RE: Request for Variance of Waivers

Dear Mr. Schneider:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Tuesday, February 11, 2014. The meeting is being held at the Florida Hotel & Convention Center, 1500 Sand Lake Road, Orlando, FL 32809. The meeting will begin at 1:00 p.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard.

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If you have any questions regarding this information, please contact me at 850-245-4444 ext: 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

PLEASE DISREGARD THE PREVIOUS LETTER YOU RECEIVED THAT STATED THE MEETING STARTED AT 9:00A.M.

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE DEC 17 2013

TeamCare
PHARMACY SERVICES

12/2/2013

Florida Department of Health
Florida Board of Pharmacy
Mark Whitten
Executive Director
4052 Bald Cypress Way
Bin #C04
Tallahassee, Florida 32399-3254

Variance request for: 64B16-28.820 Sterile Products and Special Parenteral/Enteral Compounding

Mr. Whitten,

TeamCare Infusion Orlando, Inc. (PH20960), TeamCare Infusion, Inc. (PH15891) herby requests a variance(s) or waiver(s) to rule 64B16-28.820(1)(a) as to "limited in scope of pharmacy practice to render sterile products and parenteral/enteral compounding functions".

64B16-28.820
(1) Sterile Products and Parenteral/Enteral Compounding.
(a) A sterile products and parenteral/enteral compounding pharmacy is a type of special pharmacy as provided by Section 465.0196, F.S., which is limited in scope of pharmacy practice to render sterile products and parenteral/enteral compounding functions. This pharmacy practice facilitates the utilization of certain institutional therapeutic measures by patients in the home environment or by patients in an institutional environment where such pharmacy service is unavailable. Pharmacy services, sterile products and parenteral/enteral products provided by a special sterile products and parenteral/enteral compounding pharmacy pursuant to prescription as defined by Section 465.003(13), F.S., shall be limited to the compounding and/or dispensing of:
1. Sterile preparations for parenteral therapy, parenteral nutrition, and/or
2. Sterile preparations for jejunostomy feeding and sterile irrigation solutions, and/or
3. Sterile preparations of cytotoxic or antineo-plastic agents, and/or
4. Sterile products (i.e., injectables, eye drops, etc.).

I am requesting that the two pharmacies listed above, be allowed to compound Non-Sterile medicines. The Florida Board of Pharmacy has no type of permit that allows both, Sterile and Non-Sterile compounding without multiple permits. TeamCare's pharmacies are not in the retail business and have no desire to be in the retail business. For the past 15 years, TeamCare has contracted with numerous HMO's in Florida to provide the services as outlined in 64B16-28.820. We are truly a Stand alone P&E pharmacy. Our hours of operation are very felxable so that we can meet the needs of all our patients. While our pharmacits are on site at our pharmacies for multiple hours, they are not on a posted schedule, they are available upon the needs of our patients. We are available 24 hours 365 days and every holiday is covered. Our business model is much like a hospital pharmacy, with the exception that we provide care to the patients in their home settings. For these reasons we do not want to seek a community pharmacy permit, but we would like to be able to provide non-sterile medicines to our contracted HMO patients.

We are experts at compounding and wish to also compound non-sterile medicines. I have been advised that this rule restricts us from doing so.

I propose that the following will take place in the event that our request is approved;

1) We will not co-mingle non-sterile and sterile procedures.
2) We will prepare non-sterile compounds in a separate clean area away from our sterile cleanroom.
3) We intend to construct a separate clean room with a certification of ISO 8 or better and have the compounding environment exhausted to the outside air, not back into the common air of the pharmacy. When non-sterile powder medicines are compounded, they can become air-born and ingested by the pharmacy staff and/or general public. This environment for non-sterile compounding will eliminate the air-born particles from the medicines to reach the pharmacy staff or the general public outside of this room.

Currently as the board is aware, there are no such requirements for non-sterile compounding. In fact there are no requirements at all for non-sterile compounding (as to the compounding itself). So while these non-sterile compounds are prepared in close proximity to the general public, unfiltered outside air, no specific clean work surfaces, etc… We propose a better way to provide a much safer product to the general public.

In addition to the above we will also:

1) Obey all prescription requirements and only dispense "patient specific" medicines for individual patients.
2) Not bulk compound or deliver non ordered medicines to anyone including physicians.
3) Apply all dispensing laws and rules for sterile-compounded medicines (where applicable).

These self-imposed policies would provide a safer and better quality of dispensed non-sterile medicines to the people in Florida. The proposed non-sterile compounding environment will also make the pharmacy a safer work place.

If there is anything else I can provide you with or if you would like to speak with me, please contact my office.

Sincerely,

Mark Schneider
President

TeamCare Pharmacy Services, Inc. 1100 Central Park Drive, Suite 500 407-328-8787 407-330-4746 fax

January 24, 2014

Sylvan D. Wong
United Care Pharmacy, LLC
13339 SW 42nd Street
Miami, FL 33175

RE: Request for Reduction of Hours

Dear Mr. Wong:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Tuesday, February 11, 2014. The meeting is being held at the Florida Hotel & Convention Center, 1500 Sand Lake Road, Orlando, FL 32809. The meeting will begin at 1:00 p.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444 ext: 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

PLEASE DISREGARD THE PREVIOUS LETTER YOU RECEIVED THAT STATED THE MEETING STARTED AT 9:00A.M.

UNITED CARE PHARMACY, LLC
13339 SW 42nd ST
MIAMI, FL, 33175
Ph: 305-485-1021
Fax: 305-485-1022
License: PH 26508
Email: unitecarepharmacy@gmail.com

November 13, 2013

Florida Board of Pharmacy
Fax: 850-413-6982
To whom it may concern,

The following letter is to petition that the Board of Pharmacy would allow us to operate the prescription department 20 hours per week. At this moment, our pharmacy has only two Medicare Part-D contract and we do not have the DEA number yet. If approved, our new hours of operation will be Monday and Wednesday from 9:00 am to 4:00 pm, and Friday from 10:00 AM to 4:00 PM, closed Tuesday, Thursday, Saturday and Sunday. We will upgrade our Policy and Procedure manual and provide our patients with an emergency number to contact the pharmacist after hours.

Sincerely,

Sylvan D Wong, Pharmacy Manager
PS 21512

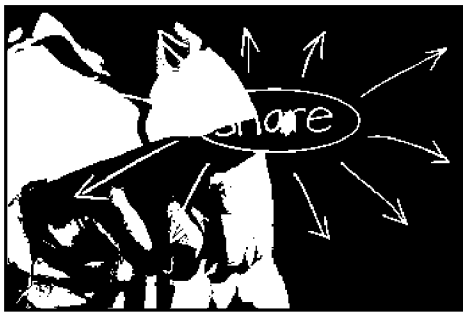
NABP Verified Pharmacy Program™

Providing a vital resource for the boards of pharmacy for use when making licensure and registration determinations.

In the wake of the New England Compounding Center (NECC) tragedy, member state boards of pharmacy spoke out very clearly about the need to build regulatory uniformity among the states and enhance the services offered by the National Association of Boards of Pharmacy® (NABP®). Due to the strength and leadership of its member boards, NABP had a strong foundation to rapidly build and deploy services to assist member boards in their charge to protect the public health. Building from a wide range of existing services – including license verification; the Electronic Licensure Transfer Program® ; NABP Clearinghouse, which includes disciplinary information; accreditation; and inspection services – NABP developed the Verified Pharmacy Program™ (VPP™) to assist member boards in enhancing the licensure processes they already have in place.

What Is VPP?

VPP, or the Verified Pharmacy Program, is an inspection service and information sharing network the boards of pharmacy may use to share critical inspection and licensing data with their fellow boards. Similar to the Electronic Licensure Transfer Program for pharmacists, VPP also facilitates what could be described as the nonresident pharmacy licensure transfer process.



What Is VPP Meant to Accomplish?

VPP creates e-Profiles for each pharmacy and links these facility e-Profiles to key personnel e-Profiles, including those of the pharmacist-in-charge (PIC) in the state of domicile as well as any nonresident PICs.

The program is meant to enhance what the state boards of pharmacy are already doing in terms of determining qualifications for pharmacy licensure and ensure that the boards have complete and accurate information for making licensure decisions on nonresident pharmacies.

What Does Recognizing and/or Requiring VPP Mean for the Boards?

The boards can recognize VPP and/or require that nonresident pharmacies apply through VPP when seeking to obtain or renew licensure. If an e-Profile for the applicant does not already exist, one will be created and applicable alerts pertaining to that facility's disciplinary and inspection history will automatically be pushed to the board of pharmacy. Additionally, participating boards will have access to the e-Profiles and will have the capability to search for facilities by a variety of categories. The boards also have the ability to attach their own inspection reports and other documentation to the e-Profiles.

Recognizing and/or requiring VPP does not necessarily mean that the board is requiring that an inspection be conducted by NABP. When a VPP application from a pharmacy is received, NABP reviews and verifies the data submitted by the pharmacy. This includes any recent inspection reports, if available. Should an applicant submit a "qualified" inspection report and/or already have a qualified inspection report attached to the pharmacy e-Profile through the Inspection Clearinghouse, that pharmacy will not require a new inspection and all qualifying information will be pushed directly to the state board of pharmacy where the pharmacy is seeking licensure. In addition, the information will be provided to any other states where the pharmacy holds a license in order to provide supplemental data for the states to utilize when making licensing decisions.

If the applicant is found to not have a "qualified" inspection, an inspection will be scheduled through NABP. All VPP inspections are conducted by licensed pharmacists.

NABP provides all data directly to the applicable state boards of pharmacy and does not render any judgment on an applicant, as this authority is left to the state boards.

What Is a "Qualified" Inspection and What Inspection Forms Are Available?

A qualified inspection is one that has been conducted within the past 18-24 months, if the facility provides routine retail pharmacy services, or within the past 12 months if it provides compounding services, and includes the appropriate modules of inspection standards depending on the services provided.

The simple presence of an inspection by the state of domicile does not necessarily mean the nonresident facility meets nonresident states' requirements. Further, if a facility has been performing sterile compounding, it is possible that it may not have been subjected to a thorough compliance inspection by a properly trained inspector in many years, if ever.

NABP recently convened a task force to compile licensure standards that are consistent across the states with the purpose of structuring a uniform inspection form. Drawing from the expertise provided during the task force meeting, this form is under development and will assist in further defining a qualified inspection. The form will continue to evolve to meet the states' needs. In addition, NABP has worked to develop uniform compounding inspection forms using elements of several different states' inspection forms that inspect to United States Pharmacopeia Chapter <795> and Chapter <797> as a minimum standard for compounding. These will also evolve to further meet the needs identified by the member boards of pharmacy.

NABP is also exploring the possibility of forming specialized working groups to develop inspection form modules based on the varying types of pharmacy services.

The uniform, qualified inspections can also be coupled with self-reported facility information in order to identify sterile compounding facilities.

What Are the Fees for VPP?

If recognizing and/or requiring VPP, and the board has the ability to pass the costs of an inspection along to the applicant/licensee, the board can direct nonresident pharmacies to NABP to begin the application process.

VPP applicants pay fees dependent on the type of pharmacy:

- Routine Retail: $1,995
- Nonsterile Compounding or Large Mail Order: $2,500
- Sterile Compounding or Institutional: $3,000

If an applicant already has a resident state inspection deemed qualified through NABP processes, the applicant is refunded all but a $500 processing fee. Pharmacies seeking licensure in multiple states will likely experience savings in inspection fees by avoiding costs associated with multiple state inspections.

For those states that must bear the costs of the inspections, NABP still recommends that states send their applicants through the VPP process and subsidize the inspection fee for the applicants. The Association may be able to work with the board on a discounted inspection fee.

The fees were developed based on estimates of NABP's costs of performing inspections and other processing functions and are not intended to generate excess revenue. Any excess revenue will be used to support member boards of pharmacy through programs and services including, but not limited to, additional compliance training, the development of uniform inspection forms, and the development of other technology and tools to perform inspections.

For more information or to apply for VPP, visit *www.nabp.net/programs/licensure/verified-pharmacy-program*.

Or contact VPP staff via phone at 847/391-4406 or via e-mail at vpp@nabp.net.

National Association of Boards of Pharmacy
1600 Feehanville Drive, Mount Prospect, IL 60056
(P) 847/391-4406 • (F) 847/391-4502 • *www.nabp.net*

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New License Report for 2201 : Pharmacist
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Processed: 1/22/2014 11:27:35PM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51318	11/01/2013	Cales, Scott Gary	05/08/1973	Florida A & M University		10103 Clet Harvey Rd	Glen Saint Mary, FL 32040
PS	51319	11/01/2013	Mcgrath, Bobbi Jo	03/21/1968	University Of Kansas Main Campus		209 Arizona Ave.	Holton, KS 66436
PS	51320	11/04/2013	Ho, Chien Thanh	06/21/1981	Harding Univeristy		15355 Sw 21 St Place	Miramar, FL 33027
PS	51321	11/04/2013	Martinez, Miteisy	12/22/1978	University Of Florida		2477 Ocean View Blvd Apt #104	Ocoee, FL 34761
PS	51322	11/05/2013	Chittle, Dennis James	11/26/1950	University Of Michigan Ann Arbor		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51323	11/05/2013	Faglie, Lance Copeland	05/05/1986	University Of Georgia		467 Pooler Pkwy	Pooler, GA 31322
PS	51324	11/05/2013	Galantis, Stelios Lambros	03/27/1986	University Of North Carolina Chapel Hill		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51325	11/05/2013	Hammons, Bradley Stevenson	12/06/1979	University Of Mississippi Main Campus		600 Ironwood Lane	Raleigh, MS 39153
PS	51326	11/06/2013	Gowler, Aimee Joy	11/12/1984	University Of Arizona		1600 Sw Archer Road	Gainesville, FL 32610
PS	51327	11/06/2013	Salama, Ramy	04/07/1984	Long Island University Brooklyn Campus		2220 S Us Hwy 1	Fort Pierce, FL 34950
PS	51328	11/06/2013	Holt, Gretchen Marie	11/13/1969	Albany College Of Pharmacy		529 Central Ave	Dunkirk, NY 14048
PS	51329	11/06/2013	Ilkevitch, Alina	07/21/1988	Midwestern State University		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51330	11/06/2013	Johnson, Brian Andrew	10/26/1987	University Of Kansas Main Campus		2228 Pinecrest Circle	Salina, KS 67401
PS	51331	11/06/2013	Kebede, Mekebebe Girmachew	02/08/1982	South University		4240 Youngstown Cir	Stone Mountain, GA 30083
PS	51332	11/06/2013	Manfredi, Lorraine Ann	07/22/1952	University Of Rhode Island		47 Village Plaza Way	North Scituate, RI 02857
PS	51333	11/06/2013	Sanger, Matthew Karl	12/14/1967	Creighton University		105 Western Ave	Waupaca, WI 54981
PS	51334	11/06/2013	Vuurens, Rodney Kim	12/05/1954	Ferris State University		640 S Expressway 77 Ste 1	Raymondville, TX 78580
PS	51335	11/07/2013	O'Mara, Keliana Leilani	08/08/1982	University Of North Carolina Chapel Hill		11001 David Stone Dr.	Chapel Hill, NC 27517
PS	51336	11/07/2013	Hernandez Arnaldy, Christie Marie	09/30/1984	University Of Puerto Rico Medical Scienc		383 Ave F.D. Roosevelt	San Juan, PR 00918
PS	51337	11/07/2013	Kocher, Keith Noel	03/04/1962	Ferris State University		1215 E. Michigan	Lansing, MI 48912
PS	51338	11/07/2013	Francois, Jean Dominique	06/20/1979	Florida A & M University		1940 Sw 129Th Terrace	Miramar, FL 33027

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51339	11/07/2013	Alhamzawi, Khaled	10/20/1977	Foreign Schools		6204 Benjamin Road	Tampa, FL 33634
PS	51340	11/08/2013	Mankaryous, Nancy	11/10/1985	Albany College Of Pharmacy		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51341	11/08/2013	Patel, Archita Niranjan	02/25/1985	University Of Maryland School Of Pharmacy		23 Pierside Dr Apt 426	Baltimore, MD 21230
PS	51342	11/08/2013	Tran, Long Thuan	03/02/1988	University Of Florida		825 Saint Michel Drive	Rockledge, FL 32955
PS	51343	11/08/2013	Diaz-Latorre, Edgardo L	03/18/1985	University Of Puerto Rico Medical Scienc		1111 Vine Street	Kissimmee, FL 34743
PS	51344	11/12/2013	Nguyen, Ryan Tan	12/29/1988	University Of Florida		5280 S. John Young Pkwy	Orlando, FL 32839
PS	51345	11/12/2013	Syed, Ayesha	09/25/1986	Nova Southeastern University		4106 Sw 190 Ave	Miramar, FL 33029
PS	51346	11/12/2013	Bastien, Roudelyne	12/12/1987	Florida A & M University		6201 Sw 8Th St	North Lauderdale, FL 33068
PS	51347	11/12/2013	Kuppusamy, Annadurai	05/14/1967	Foreign Schools		115 115 Nw Santa Fe Blvd	High Springs, FL 32643
PS	51348	11/12/2013	Bahorik, John Scott	02/28/1958	University Of Cincinnati Main Campus		1980 Freedom Parkway	Washington, IL 61571
PS	51349	11/12/2013	Belcourt, Todd Henry Jr	11/15/1988	Massachusetts College Of Phar & Allied H		44 Strawberry Lane	Southington, CT 06489
PS	51350	11/12/2013	Espada Torres, Anabel	07/20/1978	Nova Southeastern University		5409 Conch Shell Pl	Apollo Beach, FL 33572
PS	51351	11/12/2013	Harter, Arlen Trevor	11/16/1981	University Of Florida		1505 26Th Ave East	Bradenton, FL 34208
PS	51352	11/12/2013	Rich, David Jason	05/06/1975	University Of Georgia		153 Highwoods Parkway	Newnan, GA 30265
PS	51353	11/12/2013	Abinanti, Joseph Thomas	03/05/1951	Saint John'S University New York		82-68 164 Street	Jamaica, NY 11432
PS	51354	11/12/2013	Biedenharn, Todd Christopher	06/15/1969	University Of Cincinnati Main Campus		9843 Windisch Road	West Chester, OH 45069
PS	51355	11/12/2013	Howell, Trishwanda Kristina	07/22/1989	Florida A & M University		6516 Landover Rd	Landover, MD 20785
PS	51356	11/12/2013	Faltaoos, John Kamel Habeb	08/04/1980	Foreign Schools		36515 U S Hwy 19 N	Palm Harbor, FL 34684
PS	51357	11/13/2013	Kohli, Ashok	12/14/1949	Texas Southern University		11264 Beach Blvd	Jacksonville, FL 32246
PS	51358	11/13/2013	Wallace, Marquita Terrieka	06/17/1983	Florida A & M University		5108 Norwood Avenue	Jacksonville, FL 32208
PS	51359	11/13/2013	Joachin, Sabine	10/22/1981	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		220 Cape Harbour Loop Unit 102	Bradenton, FL 34212
PS	51360	11/13/2013	Youwakim, Ledia Morcos Salama	08/17/1988	Foreign Schools		3200 Lake Washington Rd	Melbourne, FL 32934

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PS	51361	11/14/2013	Rouhani, Ali	09/04/1982	University Of Florida		1201 County Rd #581	Wesley Chapel, FL 33543
PS	51362	11/14/2013	Donlow, Latricia Yvonne	02/12/1987	Florida A & M University		6606 Camden Bay Drive Apt 207	Tampa, FL 33635
PS	51363	11/14/2013	Abraham, Blessy Mary	04/18/1988	Albany College Of Pharmacy		1568 Abbot Avenue	Merrick, NY 11566
PS	51364	11/14/2013	Bennett, Alexandria Nicole	02/01/1985	Wayne State University		15715 Edgewood	Livonia, MI 48154
PS	51365	11/14/2013	Garcia Vazquez, Maria Magdalena	12/25/1968	Long Island University Central Office		2325 Flat Bush Ave	Brooklyn, NY 11234
PS	51366	11/14/2013	Nunez Roman, Yesenia	12/05/1979	University Of Puerto Rico Medical Scienc		4203 Calle Marginal	Fajardo, PR 00738
PS	51367	11/14/2013	Tripathi, Shalini	09/19/1979	Nova Southeastern University		9072 Nw 6Th Ct	Plantation, FL 33324
PS	51368	11/14/2013	Umar, Asmau A	09/15/1987	Florida A & M University		2011 26Th St. S.	Saint Petersburg, FL 33712
PS	51369	11/14/2013	Castor, Veronese	03/14/1983	Florida A & M University		12200 Ne 6Th Avenue Apt #108	Miami, FL 33161
PS	51370	11/15/2013	Trieu, Hoc Quang	09/06/1978	Florida A & M University		5667 Grand Canyon Drive	Orlando, FL 32810
PS	51371	11/15/2013	Mikhail, Diana	12/06/1983	Long Island University Brooklyn Campus		2200 Gulf To Bay Blvd	Clearwater, FL 33765
PS	51372	11/15/2013	Hahn, Kimberly Ann	09/05/1973	University Of North Carolina Chapel Hill		1810 Stillmeadow Drive	Valrico, FL 33596
PS	51373	11/15/2013	Soni, Vipul Jagdishchandra	01/15/1965	Butler University		3019 Interstate Drive	San Antonio, TX 78219
PS	51374	11/15/2013	Barrett, Jill Williamson	07/13/1970	University Of Mississippi Main Campus		7390 Bain Drive	Milton, FL 32583
PS	51375	11/15/2013	Cunliffe, Thomas Edward	05/03/1984	Nova Southeastern University		6203 Palmview Ct.	Tampa, FL 33625
PS	51376	11/18/2013	Delgado Robles, Rafael Ruben	03/06/1983	University Of Puerto Rico Medical Scienc		2505 Carr 841 Df 003921	Guaynabo, PR 00969
PS	51377	11/19/2013	Thomas, Haleena Michelle	11/17/1974	Ferris State University		401 S. Ballenger Hwy	Flint, MI 48532
PS	51378	11/19/2013	Ogden, Lauren Elizabeth	09/17/1980	Mercer University		4020 N Lecanto Hwy	Beverly Hills, FL 34465
PS	51379	11/19/2013	Ulysse, Shasly	04/18/1989	Florida A & M University		4107 Shelter Bay Drive	Kissimmee, FL 34746
PS	51380	11/19/2013	Beasley, Ronald Anthony	11/02/1989	Florida A & M University		3737 Ocita Dr	Orlando, FL 32837
PS	51381	11/19/2013	Baker, Nichole Renee	01/25/1977	Roseman University		2389 E Windemill Lane	Las Vegas, NV 89123

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51382	11/19/2013	Awad, Marina Youssef	02/20/1989	Florida A & M University		5233 Leeds Rd	Fort Myers, FL 33907
PS	51383	11/19/2013	Zaky, Myriam Magdy	07/17/1986	Foreign Schools		255 Sunrise Ave	Palm Beach, FL 33480
PS	51384	11/20/2013	Sivkov, Alexander	08/14/1981	Long Island University Brooklyn Campus		150 Corbin Place #2 P	Brooklyn, NY 11235
PS	51385	11/20/2013	Jarek, Ashley Nicole	08/07/1987	University Of Florida		1037 Nw 50Th Terrace	Gainesville, FL 32605
PS	51386	11/21/2013	Rhoades, Jenna Alison	11/09/1985	University Of Florida		830 Ohio Ave	Lynn Haven, FL 32444
PS	51387	11/22/2013	Ransbottom, Heath Matthew	02/05/1988	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		7718 Lake Vista Court Apt 201	Bradenton, FL 34202
PS	51388	11/22/2013	O'Neel, Cory Dean	06/14/1976	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		530 Truman Ave	Key West, FL 33040
PS	51389	11/25/2013	Salibi, Julie M	05/02/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		2344 Immokalee Rd.	Naples, FL 34110
PS	51390	11/25/2013	Bronk, Erika N	04/07/1976	Albany College Of Pharmacy		1315 East Beecher Hill Rd	Owego, NY 13827
PS	51391	11/25/2013	Cohen, Kenneth R	09/17/1953	Idaho State University		271-11 76Th Avenue	New Hyde Park, NY 11040
PS	51392	11/25/2013	Le, Phuoc Huy	04/21/1984	Regis University		5512 Sedgefield Street	Orlando, FL 32808
PS	51393	11/25/2013	Friesleben, Melinda Kristine	05/23/1978	Creighton University		1665 Aurora Ct Rm 2221	Aurora, CO 80045
PS	51394	11/25/2013	Galician, Korey Matthew	09/06/1984	University Of Florida		1702 Vestal Drive	Coral Springs, FL 33071
PS	51395	11/25/2013	Giles, Breanna Grayson	03/12/1982	South Carolina College Of Pharmacy		8422 Navarre Pkwy	Navarre, FL 32566
PS	51396	11/25/2013	Hegazy, Ahmed Mohammed	02/10/1988	University Of Toledo		4811 Claremont St #2	Midland, MI 48642
PS	51397	11/25/2013	Murphy, Hanna V	07/07/1972	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		11320 Walden Loop	Parrish, FL 34219
PS	51398	11/25/2013	Simmons, Leah Whitt	06/07/1989	University Of Mississippi Main Campus		146 S. Thomas St Suite A	Tupelo, MS 38801
PS	51399	11/26/2013	Mckinnon, Ta'Shae Durrell	01/13/1987	Florida A & M University		4468 Cool Emerald Drive	Tallahassee, FL 32303
PS	51400	12/02/2013	Nguyen, Huy	07/23/1981	Touro College Of Pharmacy		3333 Broadway Apt E22A	New York, NY 10031

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51401	12/02/2013	Kheireddine, Sunny Rockhill	08/03/1984	Wingate University School Of Pharmacy		4327 Waterbury Drive	Charlotte, NC 28209
PS	51402	12/02/2013	Graumenz, Mitchell Lee	07/02/1986	St Louis College Of Pharmacy		212 Millwell Drive	Maryland Heights, MO 63122
PS	51403	12/02/2013	Koebel, Cimeon Israel	04/04/1985	Mercer University		3228 Wrightsboro Road	Augusta, GA 30909
PS	51404	12/02/2013	Vanmali Patel, Radha Satish	07/03/1985	Philadelphia College Of Pharmacy And Sci		600 South 43Rd Street	Philadelphia, PA 19104
PS	51405	12/02/2013	Plitnick, Robert J	02/28/1967	Albany College Of Pharmacy		12 Jupiter Lane	Albany, NY 12205
PS	51406	12/02/2013	Lange, Raquel Maria	08/16/1979	University Of Florida		3712 E Esther Street	Orlando, FL 32812
PS	51407	12/02/2013	Persaud, Robert Anthony	03/21/1988	University Of Florida		2235 Margarita Court	Kissimmee, FL 34741
PS	51408	12/02/2013	Paup, Jeffrey Eugene	06/12/1987	University Of Maryland School Of Pharmacy		8905 Belair Rd	Nottingham, MD 21236
PS	51409	12/02/2013	Neason, Deanna Trudy	03/21/1962	Howard University		800 James Bowie Drive	New Boston, TX 75570
PS	51410	12/02/2013	Mcbride, Aric William	07/18/1969	Midwestern State University		1306 Lucas Ave #1004	Saint Louis, MO 63103
PS	51411	12/02/2013	Kovacs, James Allen	08/12/1949	Rutgers The State University Central Off		5001 Collins Ave Apt 15-D	Miami Beach, FL 33140
PS	51412	12/02/2013	Auerbach, Douglas Andrew	03/24/1972	Ohio State University Main Campus		3402 Lenox Village Drive #242	Fairlawn, OH 44333
PS	51413	12/02/2013	Barriger, Robert Guy	04/24/1954	University Of Kentucky		3545 W 86Th Street	Indianapolis, IN 46268
PS	51414	12/02/2013	Belhomme, Roath' Naudell	03/16/1985	Nova Southeastern University		9148 S W 21St Ct Apt F	Boca Raton, FL 33428
PS	51415	12/02/2013	Lee, Bernard Ryan	08/24/1980	Rutgers The State University Central Off		1055 79Th St South	Saint Petersburg, FL 33707
PS	51416	12/02/2013	Patton, Jana L	04/06/1980	South University		1027 South Main St	Moultrie, GA 31768
PS	51417	12/02/2013	Zeidan, Mohamad Mohamad Ghaleb	11/05/1984	Lebanon American University		4106 W Lake Mary Blvd Suite 130	Lake Mary, FL 32746
PS	51418	12/03/2013	Nakhla, Balsam Saiden	01/10/1953	Foreign Schools		10 Cypress Drive	Albany, NY 12211
PS	51419	12/04/2013	Bollaert, Sara Elizabeth	08/31/1989	Creighton University		12017 Villanova Dr Apt 102	Orlando, FL 32837
PS	51420	12/05/2013	Becker, Richard Paul Jr	02/04/1965	Philadelphia College Of Pharmacy And Sci		2800 E Sunrise Blvd Unit 17E	Fort Lauderdale, FL 33304
PS	51421	12/05/2013	Evoghlian, Mojgan Farzaneh	09/12/1965	Temple University		1701 Welsh Rd Ste 4	Philadelphia, PA 19115
PS	51422	12/05/2013	Nguyen, Hong An	06/01/1984	South University		3518 Woodland Dr	Belden, MS 38826

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PS	51423	12/05/2013	Bobo, Herbert Otis Jr	10/11/1949	Auburn University Main Campus		2032 Pine Island Circle	Miramar Beach, FL 32550
PS	51424	12/06/2013	James, Edwin	09/10/1986	Touro College Of Pharmacy		16961 Alico Mission Way	Fort Myers, FL 33908
PS	51425	12/06/2013	Nguyen, Ngoctuyen Than	08/16/1972	Creighton University		10765 Kenworthy	El Paso, TX 79934
PS	51426	12/06/2013	Raquipo, Jennifer Ann	07/30/1988	University Of Florida		807 Silver Springs Blvd	Ocala, FL 34470
PS	51427	12/06/2013	Manduca, Arlyn	08/25/1986	Nova Southeastern University		15022 Sw 69Th St.	Miami, FL 33193
PS	51428	12/10/2013	Dance, Richard Nathaniel	06/26/1988	University Of Florida		1111 Amsterdam Avenue	New York, NY 10025
PS	51429	12/10/2013	Johnston, Carol Rhee	11/25/1976	St Louis College Of Pharmacy		4738 Glen Heather Dr	Frisco, TX 75034
PS	51430	12/10/2013	Paramo, Sara Vanessa	05/15/1980	Philadelphia College Of Pharmacy And Sci		2301 S Broad Street	Philadelphia, PA 19148
PS	51431	12/10/2013	Czech, Carrie Lynn	03/31/1974	Ferris State University		128 E Brandon Blvd	Brandon, FL 33511
PS	51432	12/10/2013	Sheikh, Mohammed Hasib	10/16/1983	Jefferson School Of Pharmacys		205 Nw 128 Ave	Miami, FL 33182
PS	51433	12/12/2013	Henry, Velma Ellen	04/20/1982	University Of Kentucky		1607 Saint James Court	Tallahassee, FL 32308
PS	51434	12/12/2013	Blaire, Michael Richard	08/15/1958	St Johns College Main Campus		7631 E Indian School Rd	Scottsdale, AZ 85251
PS	51435	12/12/2013	Camacho, Felipe	08/13/1981	University Of Florida		9150 Kings Crossing	Fort Myers, FL 33912
PS	51436	12/12/2013	Norwood-Williams, Carlette Elaine	03/20/1965	Texas Southern University		1350 South Hickory Street	Melbourne, FL 32901
PS	51437	12/12/2013	Kandinov, Raisa	08/19/1980	St Johns College Main Campus		560 Ridgeland Terrace	Englewood, NJ 07631
PS	51438	12/13/2013	Simon, Tony Cherukara	01/26/1985	Xavier University		2124 38Th Street	Kenner, LA 70065
PS	51439	12/17/2013	Awobusuyi, Olufeyikemi Aanuoluwapo	03/26/1985	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		407 W Vine Street	Kissimmee, FL 34741
PS	51440	12/17/2013	Quirk, Fatmeh	06/12/1981	Foreign Schools		5416 Town N Country Blvd.	Tampa, FL 33615
PS	51441	12/17/2013	Carden, Robert Scott	04/11/1974	University Of Tennessee-Knoxville		367 Whispering Lake Dr	Santa Rosa Beach, FL 32459
PS	51442	12/17/2013	Smith, James Nicholas	06/07/1983	Mercer University		1035 Red Bud Rd	Calhoun, GA 30701
PS	51443	12/17/2013	Ganesh, Omjoy Kumar	04/22/1976	University Of Florida		1329 Nw 16 Street Suite 2170	Gainesville, FL 32608

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PS	51444	12/18/2013	Sales, Maria Lovella Brucal	09/25/1974	Foreign Schools		4090 S Tamiami Trail	Venice, FL 34293
PS	51445	12/19/2013	Brodersen, Sherry Littlepage	12/27/1971	Texas Tech University Health Sciences Center Of Pharmacy		15710 Ibisridge Dr	Lithia, FL 33547
PS	51446	12/19/2013	Hudson, Lauren Cole	01/29/1983	South University		3016 W. Gandy Blvd.	Tampa, FL 33611
PS	51447	12/19/2013	Saed, Areeman	11/26/1982	Long Island University Brooklyn Campus		9745 Touchton Rd Unit 3323	Jacksonville, FL 32246
PS	51448	12/19/2013	Rook, Alan Olsen	10/09/1962	University Of Florida		3739 25Th Avenue North	Saint Petersburg, FL 33713
PS	51449	12/19/2013	Weatherington, Erika Denise	01/30/1987	Florida A & M University		6916 Blowing R K Ln	Jacksonville, FL 32222
PS	51450	12/20/2013	Crass, Melanie Brooke	12/18/1987	East Tennessee State University		1011 Bloomingdale Ave	Valrico, FL 33596
PS	51451	12/30/2013	Waggoner, Tori Darlene	02/20/1976	Drake University		1003 Hwy 65 N	Carrollton, MO 64633
PS	51452	12/30/2013	Abdanan, Hamid Reza	05/19/1956	University Of Arkansas For Medical Scien;University Of Missouri-Kansas City		6020 W. Parker Rd	Plano, TX 75093
PS	51453	12/30/2013	Cordova, Michael J	04/26/1973	University Of Colorado Health Sciences C		7472 S Tucson Way	Centennial, CO 80112
PS	51454	12/30/2013	Duncan, Jamie Shirlene	10/09/1983	Florida A & M University		9126 Sabalridge Grove Pl Apt 203	Tampa, FL 33610
PS	51455	12/30/2013	Hughes, Shenika Gertrude	03/27/1988	Florida A And M University		2001 Spirit Lake Rd	Winter Haven, FL 33880
PS	51456	12/30/2013	Kertman, Robert John	05/26/1949	Philadelphia College Of Pharmacy And Sci		235 Bells Lake Rd	Turnersville, NJ 08012
PS	51457	12/30/2013	Konds, Fady Helal	03/04/1984	Long Island University Central Office		60-55 Myltle Ave	Ridgewood, NY 11385
PS	51458	12/30/2013	Mcdaniel, Steven Dale	07/17/1953	University Of Oklahoma		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51459	12/30/2013	Pan, Stephen Gene-Lloyd	05/20/1980	Duquesne University		1328 Orchid Ave	Winter Park, FL 32789
PS	51460	12/30/2013	Roberts, Jonathan	08/02/1983	Massachusetts College Of Phar & Allied H		1835 Florida Club Cir Apt 3204	Naples, FL 34112
PS	51461	12/30/2013	Sanders, Steven Winston	11/30/1953	University Of Colorado Health Sciences C;Purdue University Main Campus		1795 Whitecap Cir	North Fort Myers, FL 33903

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51462	12/30/2013	Smith, Jessica Huffstetler	03/21/1986	Mercer University		6175 Hickory Flat Hwy	Canton, GA 30115
PS	51463	12/31/2013	Velez-Hoy, Sonia Luz	10/21/1965	University Of Florida		1901 W Screnen St	Quitman, GA 31643
PS	51464	12/31/2013	Morcos, Caroline Nagy Elias	11/12/1982	Foreign Schools		2208 Us Hwy 19 N	Holiday, FL 34691

Total Records: **147**

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COMPAS DataMart Reporting System
Exam Eligibility Report For Board of 2201 : Pharmacist
Eligible Between 11/ 1/2013 - 12/31/2013

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Profession	File Nbr	Licensee Name	Eligible Date	Exam Modifiers
2201	44065	Varieur, Melissa Ann	11/01/2013	
2201	44127	Tran, Suong Que	11/01/2013	
2201	44187	Deras, Ricardo Antonio	11/01/2013	
2201	43578	Matlock, Jessica Anne	11/04/2013	
2201	43992	Akpabio, Ini Paul	11/04/2013	
2201	44190	Shatz, Michael David	11/04/2013	
2201	44229	Bhuiyan, Akm Alauddin	11/04/2013	
2201	34961	Velez Rosado, Alexandra	11/06/2013	
2201	42543	Blankinchip-Rodriguez, Cheryl Lynn	11/06/2013	
2201	44216	Minkovich, Irina	11/12/2013	
2201	44208	Mcgowens, Sarita Iris	11/13/2013	
2201	44227	Ringel, Moshe Z	11/13/2013	
2201	44246	Schutter, Susan Marie	11/13/2013	
2201	44248	Gust, Michael Alan	11/13/2013	
2201	44223	Campbell, Laurie Ann	11/15/2013	
2201	44251	Treadway, Sarah Angel	11/15/2013	
2201	33454	De Jesus Torres, Irian	11/19/2013	
2201	42808	Nihalani, Parag Doulat	11/20/2013	
2201	44239	Blyumin, Gabriella Eileen	11/20/2013	
2201	44257	Jenkins, Precious Miceala	11/20/2013	
2201	44068	Van Deventer, Laura Jane	11/21/2013	
2201	41157	Hoang, Peni Vu	11/22/2013	
2201	44076	Irizarry-Hernandez, Wilmiris	11/22/2013	
2201	44264	Brittain, Jeffery Bryan	11/26/2013	
2201	42702	Ionan, Elena	12/02/2013	
2201	44253	Zayas-Aiken, Carmen Yazmin	12/03/2013	
2201	44232	Murdasanu, Juliana	12/04/2013	
2201	44274	Olszewski, Vicki Reagan	12/04/2013	
2201	42748	Tenis, Vedia	12/05/2013	
2201	44238	Bohunicky, Brian Anthony	12/05/2013	
2201	44249	Hernandez, Marlen	12/05/2013	
2201	44270	Burt, Ashley Peavy	12/05/2013	
2201	27205	Thomas, Jeeva	12/06/2013	
2201	42951	Klar, Terence F	12/06/2013	
2201	44102	Coers, Pat Handley	12/06/2013	
2201	44225	Rathod, Deepa Ganpat	12/06/2013	
2201	44272	Kajee, Fatima	12/06/2013	
2201	42875	Patel, Poumil	12/10/2013	
2201	44119	Lee, Jonathan Christopher	12/10/2013	
2201	44153	Walters, Marta	12/10/2013	
2201	44261	Kincaid, Michele Rae	12/10/2013	
2201	44224	Onuorah, Afoma Marystella	12/11/2013	
2201	44231	Lassiter, Eric Blake	12/11/2013	
2201	44247	Olia, Sarah Shabbir	12/12/2013	
2201	44259	Henderson, James E	12/12/2013	

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Exam Eligibility Report For Board of 2201 : Pharmacist
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Profession	File Nbr	Licensee Name	Eligible Date	Exam Modifiers
2201	44281	Rudyshyn, Natalie Mayor	12/12/2013	
2201	42866	Igbinoba Okojie, Osarhieme	12/13/2013	
2201	43276	Phipps, Lemuel Bryan	12/13/2013	
2201	44143	Yanni, Niveen	12/16/2013	
2201	44252	Ivezic, Sandra	12/16/2013	
2201	44269	Ebrahem, Christeen Farid	12/16/2013	
2201	44288	Dedania, Amita Pravin	12/16/2013	
2201	24784	Khanum, Shahida	12/17/2013	
2201	44040	Singh, Sandeep Kumar	12/17/2013	
2201	44211	Halim, Sherif Nabil	12/19/2013	
2201	44254	Cotto, Marlene	12/19/2013	
2201	44265	Taylor, Anya Chimere	12/19/2013	
2201	44289	Patel, Livia Tan May	12/19/2013	
2201	44292	Tirado, Carmen Laura	12/19/2013	
2201	44233	Matiak, Amy Lynn	12/20/2013	
2201	44266	O'Donnell, Karen Lynn	12/20/2013	
2201	44297	Alameddine, Sarah	12/20/2013	
2201	44299	Jacob, Zachariah	12/20/2013	
2201	42734	Nashed, Nadine Adel	12/30/2013	
2201	44235	Leber, Michael Anthony	12/30/2013	
2201	44258	Li, Christine Chu	12/30/2013	
2201	44304	Attri, Lakshay	12/30/2013	
2201	44306	Correa, Stefan	12/30/2013	
2201	40784	Jimenez Rosario, Jacqueline	12/31/2013	
2201	44085	Gupta, Deepak	12/31/2013	
2201	44256	Yoon, Sooyoung	12/31/2013	
2201	44271	Ortiz, Jelitza Amaez	12/31/2013	
2201	44286	Kenneh, Vafin M	12/31/2013	
2201	44309	Awadallah, Sandra Magdy Boshra	12/31/2013	
2201	44310	Dao, Khanh Manh Trung	12/31/2013	
2201	44311	Lakhchaura, Vipin Harish	12/31/2013	
2201	44312	Ulizza, Emily Michelle	12/31/2013	

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32065	11/04/2013	Palma, Stephanie M	06/25/1992			15882 Sw 63 Terr	Miami, FL 33193
PSI	32066	11/04/2013	Telci, Adem M	08/06/1990			4460 Hodges Blvd #1824	Jacksonville, FL 32224
PSI	32067	11/04/2013	Sedky, Christine Ayman Kamal	09/26/1989			5916 Nw 54Th Circle	Coral Springs, FL 33067
PSI	32068	11/04/2013	Shvetz, Julia	08/15/1980			11875 Sw 16Th St	Pembroke Pines, FL 33025
PSI	32069	11/04/2013	Stacey, Mcclellan Lucille	01/10/1992			650 Dekalb St Unit 1209	Auburn, AL 36830
PSI	32070	11/04/2013	Dipnarine, Christopher				8433 Southside Blvd Apt 1401	Jacksonville, FL 32256
PSI	32071	11/04/2013	Coy, Larry Samuel	03/23/1990			6034 Du-Clay Rd	Jacksonville, FL 32244
PSI	32072	11/04/2013	Church, Michael Joel	12/05/1989			8737 Bardmoor Place	Seminole, FL 33777
PSI	32073	11/04/2013	Brown, Nathan Richard	11/26/1991			308 Aries Drive	Orange Park, FL 32073
PSI	32074	11/04/2013	Hochstetler, Alexis Elizabeth	04/28/1991			601 Simmons Ave	Sarasota, FL 34232
PSI	32075	11/05/2013	Ghaly, Erin Magdy Moris	12/25/1986			1715 Sarong Place	Winter Park, FL 32792
PSI	32076	11/05/2013	Kaldas, Michael S	06/15/1979			2700 N Atlantic Ave Unit #416	Daytona Beach, FL 32118
PSI	32077	11/05/2013	Assaf, Claudia	07/30/1982			8777 Collins Ave Apt #601	Surfside, FL 33154
PSI	32078	11/06/2013	Kapadia, Payal M	11/18/1990			9468 Sliverthorn Rd	Largo, FL 33777
PSI	32079	11/06/2013	Lynch, Brian David	05/11/1991			6751 Nw 21 Terrace	Fort Lauderdale, FL 33309
PSI	32080	11/06/2013	Jones, Mark Anthony	10/25/1988			21428 Montclare Blvd	Strongsville, OH 44149
PSI	32081	11/06/2013	Nevil, Janna Marie	10/15/1992			106 Sonata Circle	Pooler, GA 31322
PSI	32082	11/06/2013	Owusu Korkor, Ebunoluwa Oluvomi	09/04/1991			1415 South Martin Luther King Blvd	Tallahassee, FL 32307
PSI	32083	11/06/2013	Johnson, Deontae Jabora	01/28/1990			1415 S Mlk Jr Blvd	Tallahassee, FL 32307
PSI	32084	11/06/2013	Jordan, Melony Denise	05/01/1993			1415 S. Martin Luther King Jr. Blvd	Tallahassee, FL 32307
PSI	32085	11/06/2013	Steinberg, Adam Lee	10/21/1981			400 N W 87 Ln Apt 204	Plantation, FL 33324
PSI	32086	11/06/2013	Rose, Tiffany M	01/09/1991			8787 Southside Blvd #1418	Jacksonville, FL 32256
PSI	32087	11/06/2013	Acheson, Gerald Philip	03/28/1962			223-233 North St.	Calais, ME 04619
PSI	32088	11/08/2013	Butler, Jaria Nicole	09/03/1985			528 Riverwood Dr	Crestview, FL 32536

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32089	11/08/2013	Grant, Jerome	08/24/1989			1000 Patriot Ln Apt 232B	Crestview, FL 32539
PSI	32090	11/08/2013	Hanley, Rhonda Kay	01/04/1968			2051 Hamill Road	Hixson, TN 37343
PSI	32091	11/13/2013	Mathews, Megan Nicole	04/14/1991			1878 E. 9 Mile Rd Apt #902	Pensacola, FL 32514
PSI	32092	11/13/2013	Keeney, Jennifer Rae	06/17/1984			53 Exchange Street	Richmond Hill, GA 31324
PSI	32093	11/13/2013	Khairalla, Ahmad Saad Mouhamed	05/27/1987			62-29 84 St	Queens, NY 11379
PSI	32094	11/13/2013	Pavlov, Stephanie Tucker	05/06/1988			1042 Sanford Avenue Apt 1 Sw	Saint Louis, MO 63139
PSI	32095	11/13/2013	Poling, Kelsey Alexandra	07/11/1991			1516 S. Greenleaf Court	Winter Springs, FL 32708
PSI	32096	11/13/2013	Le, Tuyet Minh Ngoc	01/03/1993			708 Sw 4Th Avenue	Gainesville, FL 32601
PSI	32097	11/13/2013	Piedra, Katrina Michelle	02/24/1991			227 Sw 8Th St.	Miami, FL 33130
PSI	32098	11/13/2013	Kelly, Jonathan Ross	04/22/1992			3500 Sw 19Th Ave. Apt. 123	Gainesville, FL 32607
PSI	32099	11/13/2013	Daniel George, Stephen	03/22/1984			5432 Moon Valley Dr.	Lakeland, FL 33812
PSI	32100	11/13/2013	Andonov, Metodija	01/30/1988			500 Grafton Street	Worcester, MA 01604
PSI	32101	11/13/2013	Adams, Magen Nicole	08/17/1993			5055 North 9Th Avenue	Pensacola, FL 32504
PSI	32102	11/13/2013	Abdelnour, Tawfeles Nessem	07/23/1986			457 Cypress Street	Altamonte Springs, FL 32714
PSI	32103	11/13/2013	Cornelius, Jennifer Marie	06/27/1990			1875 Fireside Dr.	Cincinnati, OH 45255
PSI	32104	11/15/2013	Shatz, Katelyn Elizabeth	10/19/1990			2814 Kipps Colony Dr	Gulfport, FL 33707
PSI	32105	11/15/2013	Robinson, Corey Douglas	06/15/1989			950 Backstage Lane	Orlando, FL 32836
PSI	32106	11/15/2013	Sinclair Reid, Corretta Cecelia	01/16/1969			201 Nw 78 Terrace Apt 201	Pembroke Pines, FL 33024
PSI	32107	11/18/2013	Williams, Kristen Patrice	01/24/1992			2566 W Tennessee St Apt 8322-C	Tallahassee, FL 32304
PSI	32108	11/18/2013	Shahid, Talya Alysia	02/02/1987			1415 S. Martin Luther King Jr Blvd	Tallahassee, FL 32307
PSI	32109	11/20/2013	Acampado, Kayla Leigh Angot	04/08/1993			15862 Nw 10Th St	Pembroke Pines, FL 33028
PSI	32110	11/20/2013	Gonzalez, Mary-Ann	07/05/1992			3021 S.W. 92 Ct	Miami, FL 33165
PSI	32111	11/20/2013	Delgado, Claudia	01/03/1988			2555 East 4Th Ave Apto 7	Hialeah, FL 33013

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32112	11/20/2013	Choi, Young H	09/04/1989			2880 Sw 75Th Way #2208	Davie, FL 33314
PSI	32113	11/20/2013	Gomez, Julian A	11/09/1990			2600 S. University Dr #220	Davie, FL 33328
PSI	32114	11/20/2013	Christie, Diana	01/11/1988			3301 College Ave	Fort Lauderdale, FL 33314
PSI	32115	11/20/2013	Derose, Jenny Lee	12/19/1989			6380 Nw 38Th Terrace	Virginia Gardens, FL 33166
PSI	32116	11/20/2013	Ali, Md Hasan	01/07/1982			25580 Sw 137 Ave Apt #203	Homestead, FL 33032
PSI	32117	11/20/2013	Al-Ghamdi, Ahlam Ali	05/19/1985			9082 Cleary Blvd	Fort Lauderdale, FL 33324
PSI	32118	11/20/2013	Diaz, Ana Gabriela	02/02/1991			1520 Sw 16 St	Miami, FL 33145
PSI	32119	11/20/2013	Bartholomew, Brent James	03/14/1989			2881 Sw 73Rd Way Apt 2109	Davie, FL 33314
PSI	32120	11/20/2013	Custovic, Zejna	12/13/1986			1401 Se 15Th St Apt 217	Fort Lauderdale, FL 33316
PSI	32121	11/20/2013	Heuett, Carl Isaac	02/21/1975			2937 Utopia Dr	Miramar, FL 33023
PSI	32122	11/20/2013	Hernandez, Diana	03/06/1989			2640 South University Drive	Davie, FL 33328
PSI	32123	11/20/2013	Falcon Nieves, Dianexy	09/08/1984			449 Avenida Noel Estroda	Isabela, PR 00662
PSI	32124	11/20/2013	Harrison, Tiffany Adair	08/28/1990			571 Nw 72Nd Terrace	Plantation, FL 33317
PSI	32125	11/20/2013	Brown, Elisa Ann	09/22/1990			12301 Blue Jay Rd	Newark, OH 43056
PSI	32126	11/20/2013	Aoun, Nader M	02/28/1986			4491 Woodglen Apt B	Kent, OH 44240
PSI	32127	11/20/2013	Dahham, Elias George	07/13/1975			2477 Aquarius Rd	Orange Park, FL 32073
PSI	32128	11/20/2013	Haraka, Mohab				16201 S R 50 E Suite 301	Clermont, FL 34711
PSI	32129	11/25/2013	Rodriguez Yera, Pavel	04/10/1975			Box 290636	Davie, FL 33329
PSI	32130	11/25/2013	Siddiqui, Sanna	09/04/1985			12411 Nw 15Th Pl #307	Sunrise, FL 33323
PSI	32131	11/25/2013	Sandoval, Walter Jorge	03/25/1988			9039 Nw 40Th Place	Sunrise, FL 33351
PSI	32132	11/25/2013	Zekery-Saad, Sara Atef	11/13/1993			40A Leon Street	Boston, MA 02115
PSI	32133	11/25/2013	Middlebrook, Giovanna	01/26/1990			10420 N. Mckinley Drive Apt 8313	Tampa, FL 33612

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32134	11/27/2013	Nguyen, My-Oanh Thi	01/20/1990			401 Sw 178 Way	Pembroke Pines, FL 33029
PSI	32135	11/27/2013	Nguyen, Phuc Minh	09/19/1988			6101 Palm Trace Landings Dr Apt 103	Davie, FL 33314
PSI	32136	11/27/2013	Phyu, Jessica	08/27/1992			5532 Albin Drive	Greenacres, FL 33463
PSI	32137	11/27/2013	Makar, Peter Helmy Aziz	08/03/1992			2431 Sw 82Nd Ave I-303	Davie, FL 33324
PSI	32138	11/27/2013	Jimmy, Jiny Elizabeth	10/27/1991			3625 College Avenue Rolling Hills	Fort Lauderdale, TX 33314
PSI	32139	11/27/2013	Nichols, Brandi Dawn	06/06/1992			2791 Sw 71St Terrace Apt 901	Davie, FL 33314
PSI	32140	11/27/2013	Ortega, Monica Fernanda	05/14/1991			7431 N Federal Hwy	Boca Raton, FL 33487
PSI	32141	11/27/2013	Marrero, Alejandro	02/03/1989			1116 Nw 136Th Ave	Miami, FL 33182
PSI	32142	11/27/2013	Lall, Bhagmatie	12/02/1988			2 South Federal Hwy	Deerfield Beach, FL 33441
PSI	32143	11/27/2013	Pasco, Yuslin Martha	10/04/1986			5910 Nw 5Th St	Miami, FL 33126
PSI	32144	11/27/2013	Morejon, Maylin	10/02/1986			421 Redding Rd Apt #69	Lexington, KY 40517
PSI	32145	11/27/2013	Kissee Bynum, Anthony Girard	08/12/1986			261 Business Park Blvd Apt 228	Columbia, SC 29203
PSI	32146	11/27/2013	Kozman, Samir A A Angelo	01/19/1979			545 S. Forte Lauderdale Beach Blvd	Fort Lauderdale, FL 33316
PSI	32147	11/27/2013	Kasten, Kory Thomas	07/09/1989			17047 Mock Rd	Berlin Center, OH 44401
PSI	32148	11/27/2013	Cvetkovski, Zhaklina Votslav	08/30/1982			2355 Ne 26Th St	Fort Lauderdale, FL 33308
PSI	32149	11/27/2013	Abdelrehim, Amany Bekhit	12/07/1976			8826 B Grand Palms Cir	Kissimmee, FL 34741
PSI	32150	11/27/2013	Hemmert, Ryan David	08/25/1989			205 E Palmer Ave	Bellefontaine, OH 43311
PSI	32151	11/27/2013	Dickey, Jason Shane	03/14/1988			249 Parkway Street	Winchester, VA 22601
PSI	32152	11/27/2013	Gasmen, Melissa Rochelle	07/16/1985			8042 Horse Ferry Road	Orlando, FL 32835
PSI	32153	11/27/2013	Gerges, Haidy Safwat Fawzy	07/15/1982			1704 Destiny Blvd Apt #101	Kissimmee, FL 34741
PSI	32154	11/27/2013	Leyva, Natalia	01/04/1983			9020 Old Cutler Rd	Miami, FL 33156
PSI	32155	11/27/2013	Le, Jennifer Vu	06/17/1987			314 Ennis Lane	Jupiter, FL 33458
PSI	32156	11/27/2013	Molchanov, Vera	08/04/1982			1409 Barlow Court	Palm Beach Gardens, FL 33410

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32157	12/02/2013	Osterfeld, Lindsey Ann	05/05/1991			2337 Sw Archer Road Apt 1086	Gainesville, FL 32608
PSI	32158	12/02/2013	Penha, Janell C	07/26/1984			1705 Sw 99 Terrace	Miramar, FL 33025
PSI	32159	12/02/2013	Robinson, Tonisha Simone	03/02/1980			13280 N W 18Th Street	Pembroke Pines, FL 33028
PSI	32160	12/05/2013	Lim, Chel Ho	02/19/1978			2751 Sw 71St Terrace Apt 807	Davie, FL 33314
PSI	32161	12/05/2013	Nguyen, Thuy Duong Nang	02/24/1989			2810 Sw 87 Ave Apt #914	Davie, FL 33328
PSI	32162	12/05/2013	Parmar, Viralsinh R	09/30/1988			2640 South University Dr Apt 216	Davie, FL 33328
PSI	32163	12/05/2013	Flores, Sergio Antonio	10/02/1989			14212 S W 30Th Street	Miami, FL 33175
PSI	32164	12/05/2013	Huneycutt, Emily Danielle	02/23/1991			411 Musgrove Street Apt 202	Clinton, SC 29325
PSI	32165	12/05/2013	Erouk, Islam Farid Nagah Elsayed	12/12/1979			10623 Gibsonton Drive	Riverview, FL 33569
PSI	32166	12/05/2013	Homer, Antonie William	08/22/1989			1200 N W 31St Way	Fort Lauderdale, FL 33311
PSI	32167	12/05/2013	Ryan, Amanda Leigh	07/13/1991			97 Promenade Lane	Williamsville, NY 14221
PSI	32168	12/05/2013	Prewitt, Travis Seth	02/13/1987	University Of Kentucky		3101 Richmond Road	Lexington, KY 40509
PSI	32169	12/05/2013	Jernigan, Johnathan Patrick	12/18/1992			2310 S. Hwy 77	Lynn Haven, FL 32444
PSI	32170	12/05/2013	Patel, Urvi D	03/11/1992			1225 Center Drive	Gainesville, FL 32610
PSI	32171	12/05/2013	Pai, Preetika Niranjan	12/30/1989			1225 Center Drive	Gainesville, FL 32610
PSI	32172	12/05/2013	Kerr, Amanda Jo	03/09/1990			4602 18Th Ave. N	Velva, ND 58790
PSI	32173	12/06/2013	Bibawi, Gergis Magdi Nassif	05/07/1980			566 Onderdonk Ave	Ridgewood, NY 11385
PSI	32174	12/06/2013	Tokatlian, Sose Rita	10/07/1984			706 Gardens Drive #102	Pompano Beach, FL 33069
PSI	32175	12/06/2013	Ramirez, Melissa A	10/24/1983			92 Sw 3Rd Street Apt 2708	Miami, FL 33130
PSI	32176	12/09/2013	Thrall, Jennifer Lynn	09/20/1980			7050 Fairway Bend Ln #265	Sarasota, FL 34243
PSI	32177	12/09/2013	Rayford, Antonio Demtrius	06/25/1988			850 Capital Walk Drive Apt 7102	Tallahassee, FL 32303
PSI	32178	12/10/2013	Kim, Jiyeon	06/07/1992			2515 Sw 35Th Place #105	Gainesville, FL 32608

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32179	12/10/2013	Kim, Jisun	06/07/1992			2515 Sw 35Th Place Apt 105	Gainesville, FL 32608
PSI	32180	12/10/2013	Mohamed, Maison Abdalla	08/16/1981	Other	University Of Medical Sciences And Technology, Khartum, Sudan	2055 Bradley St Apt 206	Maplewood, MN 55117
PSI	32181	12/10/2013	Black, Danielle Candice	07/28/1981			136 Shady Lane	Crestview, FL 32536
PSI	32182	12/10/2013	Johnson, Jasmine Alexandria	11/14/1989			800 Spring Creek Blvd Apt #5201	Crestview, FL 32536
PSI	32183	12/10/2013	Alexis, Mark Phil	04/13/1987			2421 Jackson Bluff Rd. Unit 334A	Tallahassee, FL 32304
PSI	32184	12/12/2013	Hafling, Jennifer Marie	12/10/1988	University Of Georgia		1020 High Tide Court	Loganville, GA 30052
PSI	32185	12/12/2013	Fulks, Katie Anne	07/09/1991	Mercer University		3001 Mercer University Dr Apt 227B	Atlanta, GA 30341
PSI	32186	12/12/2013	Graham, Julie Marie	01/01/1988			130 South Main Street	Elmira, NY 14904
PSI	32187	12/12/2013	Espinosa Valero, Yusimi	04/01/1975	Foreign Schools	Universidad Central Martha Abreu De Las Villas.	12650 Sw 88Th St	Miami, FL 33186
PSI	32188	12/12/2013	Coole, Ashley Marina	01/18/1989			28031 Annabelle Lane	Daphne, AL 36526
PSI	32189	12/12/2013	Cueto Garcia, Andys	12/11/1988			520 Nw 114Th Ave Apt 204	Miami, FL 33172
PSI	32190	12/12/2013	Elia, Vincent E	07/05/1990			4736 Gladiator Circle	Greenacres, FL 33463
PSI	32191	12/12/2013	Garcia, Alberlui	09/29/1984			640 Flagami Blvd	Miami, FL 33144
PSI	32192	12/12/2013	Gross, Sofia M	09/29/1984			9830 Sw 59 Street	Cooper City, FL 33328
PSI	32193	12/12/2013	Stahler, Robert Ewing	04/22/1990			304 Ashbrook Dr.	Bellefontaine, OH 43311
PSI	32194	12/13/2013	Khan, Sadia Humayra	01/07/1991			3455 Sw Archer Rd.	Gainesville, FL 32608
PSI	32195	12/13/2013	Lee, Eric Joseph	04/19/1985			2230 Windsor Lakes Circle	Sanford, FL 32773
PSI	32196	12/13/2013	Pham, Jason Q	10/17/1982			6450 Us Hwy 1	Rockledge, FL 32955
PSI	32197	12/16/2013	Sheppard, De'Andre Kahri	01/28/1993			1415 S. Mlk Jr. Blvd	Tallahassee, FL 32307
PSI	32198	12/16/2013	Siciliano, Nicole Lynn	04/07/1988			3862 Hunters Isle Dr	Orlando, FL 32837
PSI	32199	12/16/2013	Sterling, Justin Evan	01/25/1991			616 Edwin St	Hollywood, FL 33020
PSI	32200	12/16/2013	Tien, David Huu	02/19/1990			2600 S. University Dr Unit 220	Davie, FL 33328
PSI	32201	12/16/2013	St John, Aolani Kaimi	02/28/1985	Massachusetts College Of Phar & Allied H		509 Eastern Ave	Lynn, MA 01907

COMPAS DataMart Reporting System
New License Report for 2202 : Pharmacist Intern
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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32202	12/16/2013	Pita, Arlene	05/28/1977	Foreign Schools	University Marta Abreu Las Villas	17441 Sw 29 Ct	Miramar, FL 33029
PSI	32203	12/17/2013	Ahmed, Selma Salahaldeen Dfalla	01/01/1981			4503 Tree House Ln Apt 8A	Tamarac, FL 33319
PSI	32204	12/17/2013	Jiang, Ting	12/22/1989			9298 Sw 167Th Ter	Miami, FL 33157
PSI	32205	12/18/2013	Shenegelegne, Cherinet Ambaye	04/29/1959			Tampa General Hospital	Tampa, FL 33606
PSI	32206	12/19/2013	Motley, Dean Alan	02/12/1991			5501 W Sample Rd	Coconut Creek, FL 33073
PSI	32207	12/19/2013	Pena Gutierrez, Irene	06/16/1984			825 S W 6Th St	Florida City, FL 33034
PSI	32208	12/19/2013	Roehm, Daniella Cecilia	03/18/1988			3603 Data Dr. Apt. #301	Tampa, FL 33613
PSI	32209	12/19/2013	Van Den Berg, Phyllis	07/25/1962			18271 Coral Isles Drive	Boca Raton, FL 33498
PSI	32210	12/20/2013	Bizzak, John Anton Jr	09/23/1989	Dyouville College		63 Hedley Place	Buffalo, NY 14208
PSI	32211	12/20/2013	Gorgy, Eman Milad Abadeer	10/31/1956	Other	Assiut University Of Pharmacy	172 C Springwood Circle	Longwood, FL 32750
PSI	32212	12/20/2013	Alrawi, Mahmood Saieb	01/15/1991			3113 Chapelgate Way Apt B	West Lafayette, IN 47906
PSI	32213	12/20/2013	Horlacher, Randall Jeffrey	06/17/1987			1575 Niagara Falls Blvd	Amherst, NY 14228
PSI	32214	12/23/2013	Candia, Rodolfo Rene	08/03/1977	Other	Universidad Evangelica Boliviana	4701 Haines Rd N	St Petersburg, FL 33714

Total Records: **150**

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New License Report for 2208 : Registered Pharmacy Technician
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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51073	11/01/2013	Legoute, Ricky	12/26/1994		Technical Education Center Of Osceola	1048 Kenmore St Nw	Palm Bay, FL 32907
RPT	51074	11/01/2013	Matos, Katerin	01/11/1992			2511 Swann Ave Suite 102	Tampa, FL 33609
RPT	51075	11/01/2013	Santos, Omar	08/17/1982	Other	U.S Army Amedd C/S	2700 Sandmine Rd 112 Capri Dr	Davenport, FL 33897
RPT	51076	11/04/2013	Orozco, Wil	09/05/1989	Prime Pharmacy Services, L.L.C.		5621 24Th St West	Bradenton, FL 34207
RPT	51077	11/04/2013	Milton, Waellzly Hannah	12/12/1989			7030 Jog Road	Lake Worth, FL 33467
RPT	51078	11/04/2013	Zeigler, Andrew Thomas	04/07/1994	Publix Super Market, Inc.		4086 Seadragon Bluff	Spring Hill, FL 34609
RPT	51079	11/04/2013	Bissessar, Joanne Amrit	10/02/1990	Winn Dixie		704 Veronica Circle	Ocoee, FL 34761
RPT	51080	11/04/2013	Smith, Katrina Michelle	09/09/1979	Wal-Mart		900 Parksouth Court Suite 100	Orlando, FL 32837
RPT	51081	11/04/2013	Helms, George Michael	09/11/1987	Other	Everest University	1721 Cedarwood Drive	Melbourne, FL 32935
RPT	51082	11/04/2013	Hernandez, Bianca Paloma	10/10/1993	Publix Super Market, Inc.		10418 Falcon Parc Blvd. Apt.205	Orlando, FL 32832
RPT	51083	11/04/2013	Hicks, Julie Ann	08/04/1977	Cvs Caremark		2690 Drew St Apt 401	Clearwater, FL 33759
RPT	51084	11/04/2013	Bencon, Devenn John	10/27/1994	Publix Super Market, Inc.		112 Lago Vista Blvd.	Casselberry, FL 32707
RPT	51085	11/04/2013	Sparkman, Rene	03/25/1991	Cvs Caremark		2271 50Th Circle East	Palmetto, FL 34221
RPT	51086	11/04/2013	Grim, Kaytlyn Michele	06/03/1992	Cvs Caremark		4280 Southside Boulevard	Jacksonville, FL 32216
RPT	51087	11/04/2013	Mendez, Andres Hugo	04/22/1993			3580 N Federal Hwy	Lighthouse Point, FL 33064
RPT	51088	11/04/2013	Maman, Erika Miriam	01/26/1995			1109 East Hallandale Bch Blvd	Hallandale, FL 33009
RPT	51089	11/04/2013	Garlinghouse, Diane Ellie Marie	12/08/1993	Cvs Caremark		141St 15137 Ne 141St St	Fort Mccoy, FL 32134
RPT	51090	11/04/2013	Petrik, Landon Lee	01/18/1992			13733 N Us Hwy 441	Lady Lake, FL 32159
RPT	51091	11/04/2013	Baxter, Zachary	10/29/1990	Walgreens		1707 Pickens Circle	Baker, FL 32531
RPT	51092	11/04/2013	Reyes Hernanadez, Melayne	08/02/1987	Other	Pass Assured	220 Henthorne Drive Apt C-7	Palm Springs, FL 33461
RPT	51093	11/04/2013	Collazo, Gianna Christine	10/24/1992	Publix Super Market, Inc.		3626 101D Jefferson Commons Dr	Tampa, FL 33613

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51094	11/04/2013	Dummer, Frederick John V	07/23/1992	Other	2419	1020 Peachtree Dr	Lake Placid, FL 33852
RPT	51095	11/04/2013	Harney, Kaylee Marie	04/22/1989	Wal-Mart		11012 North Williams Street	Dunnellon, FL 34432
RPT	51096	11/04/2013	Atkinson, Sharon Avonelle	01/22/1970	Wal-Mart		1450 Johns Lake Road	Clermont, FL 34711
RPT	51097	11/04/2013	Domago, Ellen Elizabeth	08/12/1952	Target Pharmacy		1771 Dunlawton Ave	Port Orange, FL 32119
RPT	51098	11/04/2013	Del Rio, Christopher	09/02/1989	Wal-Mart		2906 Crestwood Terrace	Margate, FL 33063
RPT	51099	11/05/2013	Arias, Lea Elizabeth	06/30/1987	Publix Super Market, Inc.		7806 Aniseed Court	Jacksonville, FL 32244
RPT	51100	11/05/2013	Ear, Jaclyn Marie	07/05/1994	Cvs Caremark		1439 S. Ladera Terr	Inverness, FL 34452
RPT	51101	11/05/2013	Donahue, Brittany Ann	03/28/1990	Other	University Of Florida - College Of Pharmacy	2528 Lancien Ct	Orlando, FL 32826
RPT	51102	11/05/2013	Chapman, Chelsea Julia	01/28/1993	Walgreens		3805 S Nova	Port Orange, FL 32129
RPT	51103	11/05/2013	Batista, Brenda	11/01/1990	Cvs Caremark		6226 Sw 165 Pl	Miami, FL 33193
RPT	51104	11/05/2013	Dallas, Cherita Lavina	07/07/1987	Wal-Mart		6767 103Rd Street	Jacksonville, FL 32210
RPT	51105	11/05/2013	Hardy, Demeka Angela	03/29/1988	Other	Everest University Jacksonville	2209 W 44Th St	Jacksonville, FL 32209
RPT	51106	11/05/2013	Dort, Joel	10/05/1978			1448 Barton Rd Apt 1	Lake Worth, FL 33460
RPT	51107	11/05/2013	Anderson, Jessica Marie	12/20/1990			17708 46Th Ct N	Loxahatchee, FL 33470
RPT	51108	11/05/2013	Greene, Candace	10/31/1990	Winn Dixie		2678 Corby Dr Apt 1312	Orange City, FL 32763
RPT	51109	11/05/2013	Brown, Kaniya D	10/01/1990	Other	Ultimate Medical Academy	4410 Porpoise Drive	Tampa, FL 33617
RPT	51110	11/05/2013	Rice, Keno Shaquill	08/31/1992		Anthem College-Orlando	3050 Brown Ave	Mt Dora, FL 32703
RPT	51111	11/05/2013	Davis, Karla S	07/28/1993	Other	Ultimate Medical Academy	3804 W. Crawford Street	Tampa, FL 33614
RPT	51112	11/05/2013	Cabrera, Alda N	04/29/1989	Other	Ultimate Medical Academy	3726 W. Idlewild Circle #119	Tampa, FL 33614
RPT	51113	11/05/2013	Coleman, Destiny J	07/23/1988	Walmart And Sam'S Club Pharmacies		8090 Atlantic Blvd Apt C-508	Jacksonville, FL 32211
RPT	51114	11/05/2013	Saunders, Jonetia Montrice	07/13/1992	Pinellas County Job Corps Center		500 500 22Nd Street South	St.Petersburg, FL 33712
RPT	51115	11/05/2013	Orrego Toro, Alberto	10/08/1986	Other	Everest Institute	15540 Sw 80Th St Apt#102	Miami, FL 33193
RPT	51116	11/05/2013	Suleman, Suhaylah Zulfikar	12/04/1990	Cvs Caremark		3905 Wekiva Springs Road	Longwood, FL 32779
RPT	51117	11/05/2013	Cambria, Amber	07/29/1989	Other	Fortis Institute	2311 Wilson St	Hollywood, FL 33020

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51118	11/05/2013	Castro, Feige Dennise	10/17/1991			21568 Windham Run	Estero, FL 33928
RPT	51119	11/05/2013	Tooker, Lisa Gail	10/18/1961	Other	Passassureds Pharmacy Technician Training Course	240 Se Laduke Court	Lake City, FL 32024
RPT	51120	11/06/2013	Garcia-Rodriguez, Yoanna	03/29/1989	Other	Professional Training Center	8843 Nw 117Th St	Hialeah Gardens, FL 33018
RPT	51121	11/06/2013	Cookson, Amanda	07/19/1988	Pinellas County Job Corps Center		500 22Nd St S	St.Petersburg, FL 33712
RPT	51122	11/06/2013	Zambrano, Maria J	03/20/1993	Other	Mci Institute Of Technology	1862 Abbey Rd Apt 813	West Palm Beach, FL 33415
RPT	51123	11/06/2013	Workman, Rachel Erin	10/14/1991	Other	University Of Florida College Of Pharmacy	N/A	Ocala, FL 34471
RPT	51124	11/06/2013	Breaux, Gozel Jean-Anne	01/01/1985	Other	Everest University	5990 Nw 16Th Pl Apt 202	Sunrise, FL 33313
RPT	51125	11/06/2013	Batres, Adilene	07/08/1993	Other	Everest University-Lakeland	200 Gladys Fewox Rd	Mulberry, FL 33860
RPT	51126	11/06/2013	Allen, Jennifer	11/30/1989	Cvs Caremark		388 Periwinkle Road	Venice, FL 34293
RPT	51127	11/06/2013	Goldy, Aaron Christopher	02/03/1979	Cvs Caremark		1139 Herbert St	Port Orange, FL 32129
RPT	51128	11/06/2013	Asbury, Sarah Elizabeth	10/31/1993	Other	Everest University-Lakeland	137 Carolyn Dr	Lakeland, FL 33803
RPT	51129	11/06/2013	Cohen, Diana Arway	09/06/1953			101 S. Old Coachman Rd #214	Clearwater, FL 33765
RPT	51130	11/06/2013	Stetson, Wendy Marie	06/23/1987	Cvs Caremark		7001 Estero Blvd	Fort Myers Beach, FL 33931
RPT	51131	11/06/2013	Reid-Smith, Racine N	11/30/1989	Jacksonville Job Corps Center		631 Spice Trader Way Apt#A	Orlando, FL 32819
RPT	51132	11/06/2013	Iglesias, Jacqueline	12/31/1985		National School Of Technology	1725 N W 79Th Ave	Doral, FL 33125
RPT	51133	11/06/2013	Gedeon, Rick	06/15/1989			7932 Nw 5Th Ave	Miami, FL 33150
RPT	51134	11/06/2013	Burns, Ambur Marie	07/31/1982	Cvs Caremark		175 Sr 312	St Augustine, FL 32080
RPT	51135	11/06/2013	Davidson, Amanda Gail	10/27/1987			610 Eglin Pkwy Ne	Fort Walton Beach, FL 32547
RPT	51136	11/06/2013	Hamilton, Sandra Elizabeth	01/10/1971	Walgreens		#3250 18300 Nw 37Th Avenue Miami Garden	Miami, FL 33056
RPT	51137	11/06/2013	Fuentes, Tania	05/23/1982	Other	Everest Institute	4054 W. 8 Lane	Hialeah, FL 33012
RPT	51138	11/06/2013	Barber, Nytacia	01/09/1987	Other	Everest Institute	210 Nw 9Th Street Apt. 4	Miami, FL 33136
RPT	51139	11/06/2013	Fenelon, Judith	02/08/1994	Other	Heritage Institute	3032 Calvin Blvd.	Fort Myers, FL 33901

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51140	11/06/2013	Cunningham, Kaylon Leora	07/09/1991			897 Saxon Blvd	Orange City, FL 32763
RPT	51141	11/07/2013	Tuller, Jeffrey Peter	11/11/1955	Other	Scf Via Mrxl And Kushan Education	771 Planters Manor Way	Bradenton, FL 34212
RPT	51142	11/07/2013	Landa, Dianelys	11/14/1975	Other	Mci Institute Of Technology	11676 Pipit Ct	Wellington, FL 33414
RPT	51143	11/07/2013	Wagner, Brittany Lynn	04/16/1991	Other	Florida Institute Of Technology	Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
RPT	51144	11/07/2013	Waite, Daniel Graham	03/21/1990	Other	University Of Florida - College Of Pharmacy	75Th 2303 Sw 75Th St	Jonesville, FL 32669
RPT	51145	11/07/2013	Szasz, Matthew Drake	07/08/1990	Publix Super Market, Inc.		16560 N Nebraska Ave	Lutz, FL 33549
RPT	51146	11/07/2013	Snider, Christopher Alan	05/02/1964	Wal-Mart		232 Hidden Bay Drive #301	Osprey, FL 34229
RPT	51147	11/07/2013	Ballew, Aimee Leah	10/21/1984	Target Corporation		3103 Captiva Bluff Rd N	Jacksonville, FL 32226
RPT	51148	11/07/2013	Almestica, Brittney Ann	09/01/1991	Other	University Of Florida-College Of Pharmacy	3137 Conrad Court	Kissimmee, FL 34744
RPT	51149	11/07/2013	Cook, Ariel Rhiannon	08/02/1983			8703 Fort Jefferson Blvd	Orlando, FL 32822
RPT	51150	11/07/2013	Weiss, Lauren Nicole	05/09/1986	Other	University Of Florida College Of Pharmacy	7630 Red Mill Circle	New Port Richey, FL 34653
RPT	51151	11/07/2013	Burgess, Kayla Andrena	10/21/1992	Other	Everest Institute	9900 Sw 165 Terr	Miami, FL 33157
RPT	51152	11/07/2013	Cisneros, Yadira	05/01/1981	Ep Medical Equipment, Inc		10710 Nw 7 St #10	Miami, FL 33172
RPT	51153	11/07/2013	Griffith, Lisa Carol	02/10/1964	Other	Everest University	5965 Strawflower Lane	Fleming Island, FL 32003
RPT	51154	11/07/2013	Viola, Patricia Ann	06/01/1986	A-1 Pharmacy		12080 S Jog Rd	Pipers Glenn, FL 33437
RPT	51155	11/07/2013	Ridings, Salena	10/16/1989	Other	Ultimate Medical Academy	4135 Land O Lakes	Land O Lakes, FL 34639
RPT	51156	11/08/2013	Charles, Julia Lewis	10/12/1971			780 Ne 199 St Apt #107E	Miami, FL 33179
RPT	51157	11/08/2013	Dunlop, Deven A	02/05/1993			9251 University Pkwy	Pensacola, FL 32514
RPT	51158	11/08/2013	Helton, Darian Keith	07/08/1977			2001 W. Granada Blvd	Ormond Beach, FL 32174
RPT	51159	11/08/2013	Atreidis, Jennifer Ruth	05/22/1971			3202 Se Federal Hwy	Stuart, FL 34997
RPT	51160	11/08/2013	Mcpherson, Deneese Nicole	04/14/1981			222 Cheshire Court	Kissimmee, FL 34758
RPT	51161	11/08/2013	Robles, Hector Luis	11/26/1991			911 Hoffner Ave	Orlando, FL 32809
RPT	51162	11/08/2013	Beach, Emily Gayle	04/09/1992	Publix Super Market, Inc.		383 Springhaven Loop	Spring Hill, FL 34608
RPT	51163	11/08/2013	Charles, Samantha	03/14/1986	Other	Everest Institute	17855 Nw 18 Avenue	Miami Gardens, FL 33056
RPT	51164	11/08/2013	Alvarez, Agnelys	08/02/1983	Other	Everest Institute	16145 Nw 20 Avenue	Miami, FL 33054

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51165	11/08/2013	Harrell, Quentin	03/14/1989	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51166	11/08/2013	Washington, Skye P	05/07/1983	Other	Ultimate Medical Academy	606 Polynesian Ct.	Kissimmee, FL 34758
RPT	51167	11/08/2013	Butler, Gina	03/12/1991	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51168	11/08/2013	Irizarry, Olga Luz	11/11/1982	Other	Everest University Jacksonville	2113 Willesdon Dr E	Jacksonville, FL 32246
RPT	51169	11/08/2013	Jordan, Jerrica Dominique	05/30/1994	Other	Everest University Jacksonville	3203 Fair Fax St.	Jacksonville, FL 32209
RPT	51170	11/08/2013	Pierre-Louis, James	02/13/1986	Walgreens		411 Chapel Dr Apt 119	Tallahassee, FL 32304
RPT	51171	11/08/2013	Lacy, Tammy Sue	11/04/1964	Publix Super Market, Inc.		4000 4000 N. Goldenrod Rd 4000 N. Goldenrod Rd	Winter Park, FL 32792
RPT	51172	11/08/2013	Ngamsiri, Nath	07/20/1987	Other	Everest Institute	9410 Caribbean Blvd	Cutler Bay, FL 33189
RPT	51173	11/08/2013	Mikell, Michele Caitlyn	12/09/1992	Other	Lee County High Tech Center North	2120 Nw 2Nd Pl	Cape Coral, FL 33993
RPT	51174	11/08/2013	Nava, Gabrielle	12/31/1987	Complete Pharmacy And Medical Solutions		5829 Nw 158Th Street	Miami Lakes, FL 33014
RPT	51175	11/08/2013	Pacheco, Nair Cecilia	07/22/1956	Other	Everest University	201 Harbor City Pky, Apto G 340	Melbourne, FL 32937
RPT	51176	11/08/2013	Person, Arnold	06/20/1994	Other	Everest Institute	117 Miami Gardens Road	West Park, FL 33023
RPT	51177	11/08/2013	Perez, Maritza V	09/14/1962	Miami Sunset Adult Education Center;Miami Sunset Adult Education Center		1510 Sw 149 Ave	Miami, FL 33194
RPT	51178	11/08/2013	Thomas Brown, Stacey Annmarie	07/24/1975	Walgreens		7372 Beacon Hill Apartment #2 Apt #2	Orlando, FL 32818
RPT	51179	11/08/2013	Oriundo, Janira	12/18/1993	Cvs Caremark		3212 Curry Ford Rd	Orlando, FL 32806
RPT	51180	11/08/2013	Jenkins, Mikeya Raynisha	11/12/1989	Other	Everest University	5481 Timberleaf Blvd Apt 1204	Orlando, FL 32811
RPT	51181	11/08/2013	Laffin, Patrick James	08/23/1994	Publix Super Market, Inc.		8231 Princeton Square Blvd Apt 1416	Jacksonville, FL 32256
RPT	51182	11/08/2013	Mcmillon, Dana Louis	01/10/1967	Other	Ultimate Medical Academy	915 7Th Street North	Safety Harbor, FL 34695
RPT	51183	11/08/2013	Lang, Melanie	11/14/1959	Walmart And Sam'S Club Pharmacies		4763 West Irlo Bronson Memorial Hwy	Kissimmee, FL 34746
RPT	51184	11/08/2013	Flores, Jannieleen A	01/24/1992			2760 Daveston Ave	Saint Augustine, FL 32084
RPT	51185	11/12/2013	Salas, Gabriela Andrea	02/24/1995	Other	Miami Lakes Educational Center	199Th 19930 Nw 53Rd Ct Lot 275	Miami, FL 33055
RPT	51186	11/12/2013	Witt, Erikka Summer	01/13/1992		Express Training Services	3483 Jabro Drive	Pace, FL 32571
RPT	51187	11/12/2013	Perez, Ileana	04/13/1972	Other	Everest Institute	1699 W. 68 Street	Hialeah, FL 33014

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51188	11/12/2013	Lovato, Tommie Brent	03/23/1992	Walgreens		3514 Nw 7Th Place	Gainesville, FL 32607
RPT	51189	11/12/2013	Johnson, Abigail Joy	09/10/1986	Cvs Caremark		4292 N Atlantic Ave	Cocoa Beach, FL 32931
RPT	51190	11/12/2013	Lainez, Kiara D	03/25/1989	Cvs Caremark		150 Se 3Rd Ave	Miami, FL 33131
RPT	51191	11/12/2013	Lee, Jessica Tayler	03/02/1994	Publix Super Market, Inc.		19100 S Tamiami Trail	Fort Myers, FL 33908
RPT	51192	11/12/2013	Mesa, Sthefany	09/25/1993	Cvs Caremark		2900 Boggy Creek Rd.	Kissimmee, FL 34744
RPT	51193	11/12/2013	Mallory, Sara Lee	07/26/1983			13136 Carrollwood Creek Drive	Tampa, FL 33624
RPT	51194	11/12/2013	Mckinley, Natalia Nicole	04/23/1993	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51195	11/12/2013	Mtpleasant, Kristi Ann	12/26/1977	Cvs Caremark		4504 26Th St Sw	Lehigh Acres, FL 33973
RPT	51196	11/12/2013	Kow, Jenny	08/22/1992	Cvs Caremark		7300 Curry Ford Rd	Orlando, FL 32822
RPT	51197	11/12/2013	Piedra, Ryan	05/22/1989	Other	Everest Institute	101 E. 59 Street	Hialeah, FL 33013
RPT	51198	11/12/2013	Mcguigan, Marguerite Marie	02/19/1959	Walgreens		3120 Kathleen Rd	Lakeland, FL 33810
RPT	51199	11/12/2013	Moore, Romie	09/28/1993	Other	Ultimate Medical Academy	711 E. Lotus Avenue	Tampa, FL 33612
RPT	51200	11/12/2013	Orta, Maria Eugenia	12/17/1986	Other	University Of Florida - College Of Pharmacy	201 7753 Nw 201 Terr	Hialeah, FL 33015
RPT	51201	11/12/2013	Perkins, Deidra D	10/28/1993	Other	Everest University Jacksonville	1646 West 45Th St. Apt. M 172	Jacksonville, FL 32208
RPT	51202	11/12/2013	Michael, Ophelia	11/05/1971	Cvs Caremark		646 Sw Blvd N	St.Pete, FL 33703
RPT	51203	11/12/2013	Patel, Deep	09/08/1990	Cvs Caremark		12112 Knights Krossing Circle 202	Orlando, FL 32817
RPT	51204	11/12/2013	Pine, Caitlin Elizabeth	06/20/1991	Publix Super Market, Inc.		2420 Santa Barbara Blvd	Cape Coral, FL 33914
RPT	51205	11/12/2013	Peace, William Jonathan	04/27/1982	Other	University Of Florida - College Of Pharmacy	161 Sw Stonegate Terr.	Lake City, FL 32024
RPT	51206	11/12/2013	Lewis, Darron	11/12/1991	Walmart And Sam'S Club Pharmacies		9870 Bayleaf Ct	Parkland, FL 33076
RPT	51207	11/12/2013	Merritt, Dinitria Shenee	11/10/1992	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51208	11/12/2013	Chester-Romsey, Courtney Marie	10/06/1988		Coastal Carolina Comm Coll	1880 Pristine Trail	Orange City, FL 32763
RPT	51209	11/12/2013	Walkins, Sherica Erica	03/31/1984	Other	Barry University	920 S.W 15Th Terrace Apt A	Fort Lauderdale, FL 33312
RPT	51210	11/12/2013	John, Adedeji Ademola	10/27/1991	Walgreens		145 Oak Grove Ct	Winter Park, FL 32789
RPT	51211	11/12/2013	Olisma, Kerven	06/27/1986	Other	Fortis Institute	10735 Eureka Street	Boca Raton, FL 33428

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RPT	51212	11/12/2013	Masson, Brandon Christopher	09/02/1995	Cvs Caremark		11375 W Atlantic Blvd	Coral Springs, FL 33071
RPT	51213	11/12/2013	Jacobs-Moore, Harvey Nellson	02/18/1958	Walgreens		23469 Chimes Avenue	Port Charlotte, FL 33980
RPT	51214	11/12/2013	Kurtzner, Theresa Mary	11/12/1971	Publix Super Market, Inc.		500 East Lake Raod	Palm Harbor, FL 34685
RPT	51215	11/12/2013	Lorenzi, Jacob William	03/15/1991	Walgreens		279 279 Hernando Rd.	Winterhaven, FL 33884
RPT	51216	11/12/2013	Manneru, Vasanthi	03/29/1974	Other	Rite Aid Certified Technician	467 Cabernet Pl	Saint Augustine, FL 32084
RPT	51217	11/12/2013	Medina, Luz	07/10/1958	Other	Mci Institute Of Technology	885 Sumter Road Est	West Palm Beach, FL 33415
RPT	51218	11/12/2013	Zietlow-Hossain, Kristine	03/21/1968	Other	Sanford Brown Institute Tampa	9015 Avenue Club Dr. Apt # 101	Tampa, FL 33637
RPT	51219	11/12/2013	Rowe, Lindsey Nicole	11/15/1990	Wal-Mart		23101 Dover Dr.	Land O Lakes, FL 34639
RPT	51220	11/12/2013	Jones, Vonessa Lea Mae	01/18/1993	Other	Fortis Institute	2820 Sw 3Rd Street	Fort Lauderdale, FL 33312
RPT	51221	11/12/2013	Linn, Kathleen Theresa	11/18/1985	Cvs Caremark		5990 South Pointe Boulevard	Fort Myers, FL 33919
RPT	51222	11/12/2013	Montes Lopez, Jessica	02/10/1994	Other	Southeastern College	6620 Patricia Dr	West Palm Beach, FL 33413
RPT	51223	11/12/2013	Johnson, Michelle Trenise	09/22/1990			12911 Wood St	Miami, FL 33167
RPT	51224	11/12/2013	Olivo, Wanda I	05/02/1960	Wal-Mart		2020 Andromeda Ln	Weston, FL 33327
RPT	51225	11/12/2013	Magavero, Sarah Marie	02/03/1994	Publix Super Market, Inc.		11400 Ridge Rd	New Port Richey, FL 34654
RPT	51226	11/12/2013	Safford, Jerridean	10/27/1955	Other	Everest University	1080 Sheeler Oaks	Apopka, FL 32703
RPT	51227	11/12/2013	Inigo, Dianny	11/19/1991	Walgreens		13 2651 Nw 13 St Apt # 34	Miami, FL 33125
RPT	51228	11/12/2013	Moore, Katrina Marie	01/15/1980	Walgreens		1103 Us Hwy 331 S	Defuniak Springs, FL 32435
RPT	51229	11/12/2013	Harrell, Kaitlyn Breanne	06/02/1993	Cvs Caremark		894 Enterprise Ct E Apt B	Jacksonville, FL 32227
RPT	51230	11/13/2013	Vaiyanet, Carissa Kaitlyn	02/27/1989	Other	Tampa Family Pharmacy	2919 W Swann Ave Ste 101	Tampa, FL 33609
RPT	51231	11/13/2013	Wallace, Nicole Jo	10/13/1989	Walgreens		9640 Sr 72	Sarasota, FL 34241
RPT	51232	11/13/2013	Holgate, Julia Lileen	10/27/1960	Other	Fortis Institute	1700 Nw 58Th Terr Apt 2N	Sunrise, FL 33313

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RPT	51233	11/13/2013	Ramphal, Trisha	10/09/1989	Cvs Caremark		28Th 10217 N. 28Th Street	Tampa, FL 33612
RPT	51234	11/13/2013	Kerrutt, Sandra Rohini	06/01/1990	Cvs Caremark		6217 Silver Star Rd	Orlando, FL 32808
RPT	51235	11/13/2013	Orton, Eric Glenn	01/24/1969			722 Pinellas Bayway S. Apt #104	Tierra Verde, FL 33715
RPT	51236	11/13/2013	Turner, Lee Robert	02/02/1975	Other	Sanford-Brown Tampa	3838 Langdrum Drive	Wesley Chapel, FL 33543
RPT	51237	11/13/2013	Peterson, Shakara D	12/26/1990	Other	Medical Instuite Of Palm Beach	4583 Cherry Road	West Palm Beach, FL 33417
RPT	51238	11/13/2013	Patel, Sanjiv	02/12/1964	Tmrx Ventures, L.L.C.		16744 Cagan Crossing Blvd Ste 207 A	Clermont, FL 34714
RPT	51239	11/13/2013	Mcphee, Jalisa Marie	11/22/1991	Cvs Caremark		2400 15Th Ave S Apt 55	St Petersburg, FL 33712
RPT	51240	11/13/2013	Maynard, Patricia Ann	04/20/1969			12633 Shannon Dale Dr.	Fort Myers, FL 33913
RPT	51241	11/13/2013	Farshid, Joshua	03/15/1983	Other	Southeastern College	9240 Nw 14Th St	Pembroke Pines, FL 33024
RPT	51242	11/13/2013	Nunez Ortega, Tania T	11/27/1973	Other	Professional Training Centers	5975 Sw 137Th Ave Apt 401	Miami, FL 33183
RPT	51243	11/13/2013	Perez Blanco, Maria Elena	10/11/1954	My Family Pharmacy & Discount, Llc		180 Sw 104 Ct	Miami, FL 33174
RPT	51244	11/14/2013	Zepeda, Christopher Abraham	08/13/1992	Familycare Discount Pharmacy		5720 22Nd St W	Bradenton, FL 34207
RPT	51245	11/14/2013	Taylan, Samantha Nicole	09/03/1990	Cvs Caremark		312 Northlake Blvd	North Palm Beach, FL 33408
RPT	51246	11/14/2013	Wells, Sarah	04/09/1988	Other	Everest University Lakeland	702 Winfree Ave Apt. 3	Lakeland, FL 33803
RPT	51247	11/14/2013	Neri, Romeo M	05/19/1965	Other	Everest University Brandon Campus	9915 E. Ellicott St Lot T	Tampa, FL 33610
RPT	51248	11/14/2013	Ramirez, Debbie	08/22/1989	Cvs Caremark		8640 Taft Street	Pembroke Pines, FL 33024
RPT	51249	11/14/2013	Thomas, Julia L	05/08/1987	Walgreens		5324 Mahogany Blvd	Bunnell, FL 32110
RPT	51250	11/14/2013	Tejada, Elizabeth Michelle	02/22/1992	Cvs Caremark		5659 5659 Telipa Drive	Orlando, FL 32839
RPT	51251	11/14/2013	Almodovar Rivera, Nikole	10/07/1994	Other	Professional And Technical High School	2638 Judge Loop	Kissimmee, FL 34743
RPT	51252	11/14/2013	Bulay, Esin	01/03/1958	Walgreens		1090 Nw 20 Ave	Delray Beach, FL 33445
RPT	51253	11/14/2013	Taylor, Ashlae N	10/02/1989	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51254	11/14/2013	Perdomo-Snyder, Anita Lee	05/28/1970	Walgreens		8337 South Park Circle	Orlando, FL 32819

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RPT	51255	11/14/2013	Dimanche, Edna	07/03/1993	Other	Mci Institute Of Technology	133 Sw 9Th Avenue	Boynton, FL 33435
RPT	51256	11/14/2013	Van, Ngon Vincent	05/22/1991	Cvs Caremark		7996 Conroy Windermere Road	Orlando, FL 32835
RPT	51257	11/14/2013	Williams, Vanessa L	10/12/1991	Other	Medical Instuite Of Palm Beach	5027 Northern Lights Drive	Greenacres, FL 33463
RPT	51258	11/15/2013	King, Finnell L	08/28/1973	Other	Everest University	122 Windtree Lane	Winter Garden, FL 34787
RPT	51259	11/15/2013	Zaronias, Anthony C	01/16/1983	Walgreens		2598 Bayshore Dr	Dunedin, FL 34698
RPT	51260	11/15/2013	Brightful, Tiffany Rei	06/23/1981	Other	Southeastern College	2254 21St Avenue South	Saint Petersburg, FL 33712
RPT	51261	11/15/2013	Hovatter, Justin Scott	04/02/1992	Other	Southeastern College	406 Feathertree Dr.	Clearwater, FL 33765
RPT	51262	11/15/2013	Tancreti, Michael Paul	10/01/1993	Cvs Caremark		5851 Cachette De Riviera Court 5851 Cachette De Riviera Court	New Port Richey, FL 34655
RPT	51263	11/15/2013	Forrester, Whitfield Whittingham	09/20/1958			2711 Sw 120Th Terrace	Miramar, FL 33025
RPT	51264	11/15/2013	Barnwell, Precious Martha	02/19/1994			17400 N W 48Th Ave	Miami Gardens, FL 33055
RPT	51265	11/15/2013	Walker, Isabella Routlidge	10/26/1965	Hillsborough Community College Continuing Education		6910 Rock Springs Way	Tampa, FL 33625
RPT	51266	11/15/2013	Rodriguez, Lidia	09/01/1967		Florida Education Institute	60 East 3Rd St No. 1208	Hialeah, FL 33010
RPT	51267	11/15/2013	Guillaume, Guytchina	06/01/1993	Other	Fortis Institute	3821 Nw 21St Street Apt 310	Laudredale Lakes, FL 33311
RPT	51268	11/15/2013	Rodriguez, Zady	11/22/1981		Professional Training Centers	11400 W Flagler St Suite #109	Miami, FL 33174
RPT	51269	11/15/2013	Shepherd, Julie Ann	11/28/1975	Wal-Mart		9600 Parksouth Ct #120	Orlando, FL 32738
RPT	51270	11/15/2013	Desamour, Erline	09/03/1993	Other	Everest University	1040 Ne 24Th Ave #8	Pompano Beach, FL 33062
RPT	51271	11/15/2013	Colon, Pedro Manuel	08/04/1966	Other	Fortis Institute	2429 Ne 7Th Ave	Wilton Manors, FL 33305
RPT	51272	11/15/2013	Glazier, Arthur Quinton Mr	04/01/1992	Cvs Caremark		2205 89Th Ave	Vero Beach, FL 32966
RPT	51273	11/15/2013	Alvarez, Emily Deann	01/06/1992	Cvs Caremark		1948 Gardenia Crt	Riviera Beach, FL 33404
RPT	51274	11/15/2013	Epps, Stacey	08/22/1984	Other	Heritage Institute	149 Se 8Th Street	Cape Coral, FL 33990
RPT	51275	11/15/2013	Allen, Jade Janae	02/22/1994	Other	Everest University Jacksonville	1782 West 13Th St	Jacksonville, FL 32209
RPT	51276	11/15/2013	Buckheit, Roberta Louise	07/02/1961			92100 Overseas Highway	Tavernier, FL 33070

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RPT	51277	11/15/2013	Davis, Kayla Jane	05/24/1988	Walgreens		37701 March Ln	Zephryhills, FL 33541
RPT	51278	11/15/2013	Rabbani, Avi	06/13/1990		Barry Univ	1109 E. Hallandale Bch Blvd	Hallandale, FL 33009
RPT	51279	11/18/2013	Castor, Orlando	10/11/1992	Other	Westside Tech	Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
RPT	51280	11/18/2013	Wiles, Christopher	05/04/1989	Other	Sanford Brown Institute Tampa	1799 Blair Castle Circle 1799	Ruskin, FL 33570
RPT	51281	11/18/2013	Pavia Lara, Ariel	06/28/1971			1255 W 25Th Plane	Hialeah, FL 33010
RPT	51282	11/18/2013	Suhwiel, Margarita Maria	10/09/1977	Other	University Of Florida-College Of Pharmacy	2843 Thaxton Dr. #38	Palm Harbor, FL 34684
RPT	51283	11/18/2013	Lawrence, Leesha Laine	10/21/1981	Other	Atlantic Technical Center	4420 Nw 107Th Avenue	Coral Springs, FL 33065
RPT	51284	11/18/2013	Rodriguez, Lynnette Mercedes	11/19/1984	Other	Everest Institute	14810 Sw 77 Th St	Miami, FL 33193
RPT	51285	11/18/2013	Miller, Kathy D	12/18/1967	North Florida Pharmacy, Inc.		110 Sw Woodberry Court	Lake City, FL 32024
RPT	51286	11/18/2013	Sarraga, Nechma L	01/05/1969	Walgreens		4529 Cove Dr. Apt.107	Orlando, FL 32812
RPT	51287	11/18/2013	Tift, Temperance Andriana	07/14/1990	Concorde Career Institute		2348 Cody Street	Hollywood, FL 33020
RPT	51288	11/18/2013	Worrell, Fabian Ray	09/27/1988	Wal-Mart		11720 State Road 574	Seffner, FL 33584
RPT	51289	11/18/2013	Passley, Cristina Alicia	03/05/1988	Other	Fortis Institute	3222 Nw 84Th Avenue Apt. 206	Sunrise, FL 33351
RPT	51290	11/18/2013	Rodriguez, Disheama Ivette	01/16/1982	Cvs Caremark		2187 Howland Blvd	Deltona, FL 32738
RPT	51291	11/18/2013	Watkins, Tavaris Breyon	07/20/1993	Walgreens		5108 Norwood Avenue	Jacksonville, FL 32208
RPT	51292	11/18/2013	Urrego-Utrera, Michael Arturo	01/09/1992	Other	Fortis College	1660 Ne 191Th Street Apt # 200	Miami, FL 33179
RPT	51293	11/18/2013	Veigel, Angie Maria	12/04/1977	Other	Everest University Brandon Florida	822 Greenbelt Cir	Brandon, FL 33510
RPT	51294	11/19/2013	Perederina, Dekabrina	08/19/1973	Other	Pinellas Technical Education Centers	2117 Lakewood Club Dr S Apt L	Saint Petersburg, FL 33712
RPT	51295	11/19/2013	Parady, Corey Allen	09/05/1990	Other	Heritage Institute	1016 Asther Street	Lehigh Acres, FL 33974
RPT	51296	11/19/2013	Frazier, James Earl	08/05/1966	Other	First Coast Technical College	524 Juniper Spring Court	St. Augustine, FL 32092
RPT	51297	11/19/2013	Abramson, Janice	05/26/1949			2351 Sw Chestnut Ln	Port Saint Lucie, FL 34953

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RPT	51298	11/19/2013	Garcia, Janet A	05/30/1971	Other	Medical Instuite Of Palm Beach	2424 Avenida Madrid Estate	West Palm Beach, FL 33415
RPT	51299	11/19/2013	Galyon, Margaret Rita	04/28/1971	Publix Super Market, Inc.		1616 Cape Coral Pkwy West	Cape Coral, FL 33914
RPT	51300	11/19/2013	Dallmann, Teresa J	04/30/1959	Other	Everest University	3671 Double Branch Lane	Orange Park, FL 32073
RPT	51301	11/19/2013	Honaker, Jennifer Irene	10/20/1987	Cvs Caremark		8075 Canterbury St	Spring Hill, FL 34606
RPT	51302	11/19/2013	Bridgelal, Nadia Caroline	12/20/1994	Publix Super Market, Inc.		15502 Stoneybrook West Parkway	Winter Garden, FL 34787
RPT	51303	11/19/2013	Hernandez, Nebi	05/15/1975	Other	University Of Florida	3659 Atrium Dr. 3659 Atrium Dr.	Orlando, FL 32822
RPT	51304	11/19/2013	Harricharan, Ashley Geeta	07/07/1993	Publix Super Market, Inc.		2491 Prairie View Drive	Winter Garden, FL 34787
RPT	51305	11/19/2013	Pimenta Filho, Paulo Saraiva	05/15/1993	Smart Pharmacy		3792 Barbizon Cir S	Jacksonvile, FL 32247
RPT	51306	11/19/2013	Confrey, Ronald Hubert John	06/06/1966			8603 Florida Mining Blvd	Tampa, FL 33634
RPT	51307	11/19/2013	Evans, Teandra Lashay	01/31/1989	Other	Heritage Institute	2511 2511 64Th Street West	Lehigh Acres, FL 33971
RPT	51308	11/19/2013	Adams, Dana Marie	10/31/1984	Cvs Caremark		10925 Sr 54	New Port Richey, FL 34655
RPT	51309	11/19/2013	Dotson, Tywonia Marceia	01/05/1989	Other	Everest University	5620 Collins Rd Apt 821	Jacksonville, FL 32244
RPT	51310	11/19/2013	Dorcine, Wesney	08/13/1992	Other	Everest University	211 Ne 51St St	Oakland Park, FL 33334
RPT	51311	11/19/2013	Hicks, Brittany Cornelia	05/31/1995	Winn Dixie		906 S Main Street	Labelle, FL 33935
RPT	51312	11/20/2013	Romero, Lidio Guillermo	10/22/1981	Elsa Pharmacy Inc		25 St 555 E 25 St	Hialeah, FL 33013
RPT	51313	11/20/2013	Sykes, Justin	10/14/1992	Pinellas County Job Corps Center		609 West Ball St Apt #6	Plant City, FL 33563
RPT	51314	11/20/2013	Gonzalez Suarez, Yanetsi	10/27/1975	Other	Everest Institute	8794 Sw 12 St Apt#105	Miami, FL 33174
RPT	51315	11/20/2013	Neal, Audrey Sanders	07/29/1964	Other	Everest University	6734 Lorain St	Orlando, FL 32810
RPT	51316	11/20/2013	Randall, Chelsea Walker	05/18/1991	Other	Heritage Institute	1182 Betmar Blvd	North Fort Myers, FL 33903
RPT	51317	11/20/2013	Polynice, Magalie	12/23/1990	Other	Everest University	2673 Staley Ct.	Orlando, FL 32818
RPT	51318	11/20/2013	Nguyen, Mai Thanh Quyen	06/16/1985	Cvs Caremark		5388 Downington Drive	Jacksonville, FL 32257
RPT	51319	11/20/2013	Jusufovic, Ferid	03/17/1995	Cvs Caremark		8280 43Rd Way	Pinellas Park, FL 33781

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RPT	51320	11/20/2013	Leavens, Rebecca Lynn	12/29/1967	Cvs Caremark		99 Magnolia Drive	Auburndale, FL 33823
RPT	51321	11/20/2013	Kulsum, Saleha	03/08/1981	Other	Everest University,Brandon Campus	12425 Fairlawn Dr	Riverview, FL 33579
RPT	51322	11/20/2013	Zorrilla, Joel Javier	11/08/1991	Other	Miami Lakes Educational Center	197 19723 Nw 49Th Place	Miami Gardens, FL 33055
RPT	51323	11/20/2013	Riddell, Stacey Renee	01/22/1986	Other	Everest University	2317 South Dolphin Ave	Middleburg, FL 32068
RPT	51324	11/20/2013	Sutton, Tabitha Nicole	03/21/1985	Other	Sanford-Brown Institute Jacksonville	999 Sw 6Th Ave Lot 9	Lake Butler, FL 32054
RPT	51325	11/20/2013	Reinertson, Corey Renee	01/30/1991	Other	Sanford Brown Institute-Jacksonville	844 Warner Road	Green Cove Springs, FL 32043
RPT	51326	11/20/2013	Takla, Randa				4401 Sheridan Street	Hollywood, FL 33021
RPT	51327	11/21/2013	Swederski, Jeffrey William	03/16/1985	Walgreens		2007 Linsey St	Tampa, FL 33605
RPT	51328	11/21/2013	Williams, Cierria L	03/27/1989	Concorde Career Institute		5270 North Orange Blossom Trail Apt 302	Orlando, FL 32810
RPT	51329	11/21/2013	Wood, Jennifer Amber	07/29/1981	Concorde Career Institute		15024 Cape Lane	Orlando, FL 32831
RPT	51330	11/21/2013	Strohminger, Elizabeth Ann	12/08/1992		First Coast Technical College	600 Plantation Island Drive	Saint Augustine, FL 32080
RPT	51331	11/21/2013	Liu, Tsz Fei	10/21/1986			202 Yamato Road	Boca Raton, FL 33431
RPT	51332	11/21/2013	Irizarry, Jasmine Ivette	06/30/1986			9600 Parksouth Ct.	Orlando, FL 32837
RPT	51333	11/21/2013	Lester, Tiara Arnese	05/25/1988			6815 Biscayne Blvd Suite 103-356	Miami, FL 33038
RPT	51334	11/21/2013	Jean-Baptiste, Cassandra	01/16/1989			11142 Lakewood Pointe Dr Apt 201	Seffner, FL 33584
RPT	51335	11/21/2013	Nguyen, Tho Jeffrey	10/23/1991			15174 N W Us Highway 441	Alachua, FL 32615
RPT	51336	11/21/2013	Suarez, Jandro	05/26/1987	Concorde Career Institute		3538 Pendleton Way	Land O Lakes, FL 34639
RPT	51337	11/21/2013	Pingley, Victoria Mary	05/24/1979			886 W State Rd 436	Altamonte Springs, FL 32714
RPT	51338	11/21/2013	Cepeda Ramos, Gonzalo	03/01/1989	Publix Super Market, Inc.		6530 6530 Swissco Drive Apt 1127	Orlando, FL 32822
RPT	51339	11/21/2013	Porto, Lauren	06/27/1991	Walgreens		1820 Oak Trail W Apt 113	Clearwater, FL 33764

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RPT	51340	11/21/2013	Rodriguez Hernandez, Yaimi	09/23/1984	Other	Everest Institute	3211 Nw 6Street	Miami, FL 33125
RPT	51341	11/22/2013	Murray, Dorothea	05/01/1991	New Era Pharmaceuticals, Llc		5801 N Federal Hwy	Boca Raton, FL 33487
RPT	51342	11/22/2013	Lavine, Jasmine Eva	04/14/1993	Cvs Caremark		5400 4Th Street North	Saint Petersburg, FL 33703
RPT	51343	11/22/2013	Burke, Charles Edward	08/12/1992	Walgreens		2235 Parr Dr	The Villages, FL 32162
RPT	51344	11/25/2013	Turenne, Brinel	04/05/1981	Other	Everest University	20 Nw 19Th Street	Pompano Beach, FL 33060
RPT	51345	11/25/2013	Knox, Veronica Yvonne	08/17/1989	Other	Atlantic Technical Center	1400 Ne 56Th St Apt 111	Fort Lauderdale, FL 33334
RPT	51346	11/25/2013	Moise, Christina	10/17/1985	Other	Mci Institute Of Technology	711 Olive Tree Circle	Greenacres, FL 33413
RPT	51347	11/25/2013	Lakatos, Daniel Patrick	07/14/1993	Wells Pharmacy Network		8228 Se 126Th Place	Belleview, FL 34420
RPT	51348	11/25/2013	Thomas, Saji	04/25/1969	Other	University Of Florida College Of Pharmacy	2828 Lafayette Trace Drive Lafayette Trace Drive	Saint Cloud, FL 34772
RPT	51349	11/25/2013	Perdomo, Lori	08/24/1976	Cvs Caremark		5010 South Florida Ave	Lakeland, FL 33811
RPT	51350	11/25/2013	Kelly, Jason Alan	11/10/1985	Cvs Caremark		6373 Nw 180Th Street	Starke, FL 32091
RPT	51351	11/25/2013	Prophete, Youvens	10/31/1987	Other	Everest University	18 Laurel Oaks Drive #204	Winter Springs, FL 32708
RPT	51352	11/25/2013	Sanchez Marrero, Luis Manuel	07/16/1967	Other	2419	4 Se 21St Ave	Cape Coral, FL 33990
RPT	51353	11/25/2013	Lowe, Valentina-Joy Ellen-Margret				21324 St Andrews Blvd	Boca Raton, FL 33433
RPT	51354	11/25/2013	Jones, Valencia Shauntel	03/01/1991	Cvs Caremark		2927 Oakcove Ln	Jacksonville, FL 32277
RPT	51355	11/25/2013	Montero, Paola Anali	07/21/1983			6720 Nw 6Th Ct.	Margate, FL 33063
RPT	51356	11/25/2013	Morton, Nellie Jean	10/06/1989	Other	Sanford-Brown Institute Tampa	10406 Richardson St.	Gibsonton, FL 33534
RPT	51357	11/25/2013	Johnson, Erica Lynn	02/22/1992	Publix Super Market, Inc.		212 Hazeltine Drive	Debary, FL 32713
RPT	51358	11/25/2013	Kinne, Natasha	05/11/1993	Cvs Caremark		760 Ne 181St St	North Miami Beach, FL 33162
RPT	51359	11/25/2013	Varone, Harrison	12/27/1992	Cvs Caremark		4401 W Gandy Blvd	Tampa, FL 33611
RPT	51360	11/25/2013	Rodriguez, Theresa Negron	08/04/1968	Walmart And Sam'S Club Pharmacies		11 Pine Trace Way	Ocala, FL 34472

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51361	11/25/2013	Tedder, Sherri Lynn	12/17/1965	Wal-Mart		1575 Ne 161St Pl	Citra, FL 32113
RPT	51362	11/25/2013	Evans Mclean, Kindra Alysse	01/17/1977	Cvs Caremark		420 North Main Street	Bushnell, FL 33513
RPT	51363	11/25/2013	Killeen, Lisa Jane	07/08/1972	Cvs Caremark		13998 Walsingham Road	Largo, FL 33774
RPT	51364	11/25/2013	Palushaj, Anxhela	04/22/1991	Walgreens		1728 El Trinidad Dr E	Clearwater, FL 33759
RPT	51365	11/25/2013	Labelle, Heather Kathleen	10/27/1965	Other	University Of Florida-College Of Pharmacy	2966 Grande Oaks Way	Fleming Island, FL 32003
RPT	51366	11/25/2013	Pezanetti, Anthony Ryan	05/07/1981	Other	Everest University	2429 Jungle Street	Lakeland, FL 33801
RPT	51367	11/25/2013	Neal, Shakeriay Latavia	03/14/1986	Other	Everest University	6734 Lorain St	Orlando, FL 32810
RPT	51368	11/25/2013	O'Neal, Stacey Ava L	07/18/1970			Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
RPT	51369	11/25/2013	Aponte, Gustavo Andres	11/08/1985	Publix Super Market, Inc.		6601 Woods Island Circle #4-201	Port St Lucie, FL 34953
RPT	51370	11/25/2013	Lawrence, Summer Dawn	09/08/1988	Other	First Coast Technicial College	3511 Begonia Street	St. Augustine, FL 32084
RPT	51371	11/25/2013	Poulos, Jennifer Flynn	04/28/1993	Other	University Of Florida - College Of Pharmacy	3901 Sw 20Th Ave #708	Gainesville, FL 32607
RPT	51372	11/25/2013	Payne, Kristen Paige	11/20/1993	Publix Super Market, Inc.		13170 Atlantic Blvd Ste 29	Jacksonville, FL 32266
RPT	51373	11/25/2013	Beeche, Shelby Lynn	06/04/1992	Walmart And Sam'S Club Pharmacies		20620 Us Hwy 129	O'Brien, FL 32071
RPT	51374	11/25/2013	Burney, Patricia Sue	01/16/1953	Cvs Caremark		1000 E Tarpon Av	Tarpon Springs, FL 34689
RPT	51375	11/25/2013	Vazquez De Llado, Yamila	07/17/1966	Other	University Of Florida College Of Pharmacy	2253 W 74Th Place	Hialeah, FL 33016
RPT	51376	11/25/2013	Green, Samantha Lynn	09/11/1991	Other	University Of Florida - College Of Pharmacy	2583 Barbara Lane	Hilliard, FL 32046
RPT	51377	11/25/2013	Hughes, Jana D	09/13/1983	Other	Ultimate Medical Academy	17830 County Road 6 East	Jasper, FL 32052
RPT	51378	11/25/2013	Carter, Casey Deanne	01/08/1990	Cvs Caremark		1005 South Ohio Avenue	Live Oak, FL 32064
RPT	51379	11/25/2013	Hines, Brianna Nichole	12/31/1994	Publix Super Market, Inc.		2603 Nw 13Th Street #177	Gainesville, FL 32609
RPT	51380	11/25/2013	El-Salhy, Brandi	02/13/1992	Cvs Caremark		3904 Nw 13Th St	Gainesville, FL 32609
RPT	51381	11/25/2013	Bouchard, April Susan	04/10/1975	Walgreens		1650 Dunlawton Ave	Port Orange, FL 32127

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51382	11/25/2013	Guevara, Cassandra Dawn	07/21/1991	Cvs Caremark		660 East Business Highway 98	Panama City, FL 32401
RPT	51383	11/25/2013	Leon, Yunetsy	10/16/1990	Other	Professional Training Centers	2441 Nw 13Th St. Apt 62	Miami, FL 33125
RPT	51384	11/25/2013	Kassis, Briana Lynn	06/30/1995	Cvs Caremark		10556 Oakhaven Drive	Pinellas Park, FL 33782
RPT	51385	11/25/2013	Lopez Abreus, Yesiney	12/26/1987	Other	Professional Training Centers	12430 Sw 187Th St.	Miami, FL 33177
RPT	51386	11/25/2013	Gonzalez, Melissa	08/02/1984	Cvs Caremark		8820 Brennan Cir. Apt. # 308	Tampa, FL 33615
RPT	51387	11/25/2013	Dix, Kayla Nicole	08/12/1988	Cvs Caremark		8717 8717 Orange Oaks Circle	Temple Terrace, FL 33637
RPT	51388	11/25/2013	Fernung, Nicole	05/16/1991	Cvs Caremark		8518 Queen Brooks Court	Temple Terrace, FL 33637
RPT	51389	11/25/2013	Thomas, Sandra Lee	10/27/1980	Walgreens		12895 Linden Drive	Spring Hill, FL 34609
RPT	51390	11/25/2013	Coughlan, Holly	07/03/1980	Cvs Caremark		2502 W. Hillsborough Ave.	Tampa, FL 33614
RPT	51391	11/25/2013	Morgan, Kimberly Amber	08/09/1988	Other	Everest University Jacksonville	302 Dora Lloyd Rd	Folkston, GA 31537
RPT	51392	11/25/2013	Longworth, Samantha Lynn	03/24/1989	Other	Everest University	2040 Wells Road Apt 15F	Orange Park, FL 32073
RPT	51393	11/25/2013	Deleon, Mary Louise	09/18/1975			5228 Montserrat Dr.	Lakeland, FL 33812
RPT	51394	11/26/2013	Franasiak, Karly Joy	08/12/1992	Walgreens		1350 N Wickham Rd	Melbourne, FL 32935
RPT	51395	11/26/2013	Homer, Sylvia Denise	05/03/1990			2004 Tidewater Ct.	Tampa, FL 33619
RPT	51396	11/26/2013	Celento, Steffany Anne	10/24/1986			7730 W. Commercial Blvd	Lauderhill, FL 33321
RPT	51397	11/26/2013	Buchanan, Elizabeth Anne	11/11/1989			15880 Summerlin Rd	Fort Myers, FL 33908
RPT	51398	11/26/2013	Quinones, Ryan	06/23/1993	Other	2419 - University Of Florida - College Of Pharmacy	9008 9008 Harding Avenue	Surfside, FL 33154
RPT	51399	11/26/2013	Rivera, Swannette Marie	02/22/1993	Other	Everest University	903 Maplewood St	Tavares, FL 32778
RPT	51400	11/26/2013	Gonzalez, Andrea	05/22/1990			8507 Wayland Ct	Tampa, FL 33634
RPT	51401	11/26/2013	Fischoff, Eileen	07/10/1964			4297 Oldfield Crossing Dr.	Jacksonville, FL 32223
RPT	51402	11/26/2013	Restrepo, Ana Maria	03/30/1967		Drug Depot	4308 Grouper Ln	New Port Richey, FL 34653
RPT	51403	11/26/2013	Youngblood, Jeremiah Tecumseh	07/29/1990	Other	University Of Florida - College Of Pharmacy	27527 Tierra Del Sol Ln.	Bonita Springs, FL 34135

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RPT	51404	11/26/2013	Dahl, Natasha M	08/22/1984			410 Scorpio Lane	Orange Park, FL 32073
RPT	51405	11/26/2013	Hall, Jeremy Dominique	06/01/1987			3040 Aloma Ave F3	Winter Park, FL 32792
RPT	51406	11/26/2013	Del Toro, Claudia	09/25/1992			763 N W 132 Ct	Miami, FL 33182
RPT	51407	11/26/2013	Blanc, Victoria Elizabeth	09/20/1992			463737 State Rd 200	Yulee, FL 32097
RPT	51408	11/26/2013	Brito, Javier	04/12/1989			4307 N. Armenia Ave	Tampa, FL 33607
RPT	51409	11/26/2013	Husman, Farouk Allie	01/04/1968			12625 Nw 23 St	Pembroke Pines, FL 33028
RPT	51410	11/26/2013	Hockey, Sarah Elizabeth	06/26/1987			2460 East Bay Dr.	Largo, FL 33771
RPT	51411	11/26/2013	Turner, Zachary Alexander	03/11/1995	Publix Super Market, Inc.		1631 Del Prado Blvd Ste 500	Cape Coral, FL 33914
RPT	51412	11/26/2013	Gonzalez, Juan Antonio	08/15/1987			15005 Sw 88 St	Miami, FL 33196
RPT	51413	11/26/2013	Parsa, Leyla	10/12/1980	Other	Cni College	501 Se 2Nd St.	Fort Lauderdale, FL 33301
RPT	51414	11/27/2013	Boehm, Amber Leigh	06/16/1995	Cvs Caremark		6025 Mobile Hwy	Pensacola, FL 32526
RPT	51415	11/27/2013	Hodges, Stephanie Marie	03/16/1992	North Florida Pharmacy, Inc.		347 Sw Main Blvd Suite 102	Lake City, FL 32025
RPT	51416	11/27/2013	Correa, Jorge M	11/02/1991			7912 N W 164 Terrace	Miami Lakes, FL 33016
RPT	51417	11/27/2013	Garces, Ruth Nuemi	06/01/1986	Cvs Caremark		7575 Osceola Polk Line Road	Davenport, FL 33896
RPT	51418	11/27/2013	Argueta Berlioz, Alexandra	01/06/1993			998 Sw 8Th Pl	Florida City, FL 33034
RPT	51419	12/02/2013	Thomas, Joeann K	01/02/1992	Other	Rasmussen College	25350 U.S Hwy 19 N Apt 104	Clearwater, FL 33763
RPT	51420	12/02/2013	Zabala, Blanca Rosa	03/01/1963	Other	Fortis College	9460 Fountainbleau Blvd #226	Miami, FL 33172
RPT	51421	12/02/2013	Sowards, Jodi Lang	09/11/1969	Smart Pharmacy		1650 San Pablo Road South Suite 17	Jacksonville, FL 32224
RPT	51422	12/02/2013	Rigby, Victoria K	12/20/1989	Cvs Caremark		7330 Curry Ford Rd	Orlando, FL 32822
RPT	51423	12/02/2013	Tucker, Leah Anne	10/17/1975	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51424	12/02/2013	Singh, Sangeen R	09/15/1993	Walgreens		8337 South Park Cr	Orlando, FL 32819
RPT	51425	12/02/2013	Warsono, Nfn	12/14/1972	Other	Atlantic Technical Center	300 E Oakland Park Blv #134	Wilton Manors, FL 33334
RPT	51426	12/02/2013	Tharpe, Kristen Marie	01/31/1994	Publix Super Market, Inc.		2845 County Rd 210 W	Saint Johns, FL 32259

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51427	12/02/2013	Vogel, Sherri Lynn	12/30/1969	Other	Everest University Brandon Campus	1107 Emerald Hill Way	Valrico, FL 33594
RPT	51428	12/02/2013	Robinson, Tykeiah Irene	04/07/1993	Publix Super Market, Inc.		1500 Beville Rd Ste 300	Daytona Beach, FL 32114
RPT	51429	12/02/2013	Moroz, Liubov	01/19/1965			915 N E 8 St #206	Hallandale Beach, FL 33009
RPT	51430	12/02/2013	Linyushina, Eleonora Alekseyevna	08/31/1988			1109 E. Hallandale Beach Blvd	Hallandale Beach, FL 33009
RPT	51431	12/02/2013	Joseph, Claudel	02/14/1972	Other	Everest Institute	12825 Nw 13 Avenue	Miami, FL 33167
RPT	51432	12/02/2013	Myat, Nyein Su	07/02/1990	Other	Everest University	1361 S Federak Hwy Apt 102	Boca Raton, FL 33432
RPT	51433	12/02/2013	Pitaluga, Gina	09/28/1991	Other	Everest Institute	1819 Nw 5Th Street	Miami, FL 33125
RPT	51434	12/03/2013	Nodal, Osvaldo	03/03/1987	Other	Everest Institute	2450 W. 67 Place Apt. 12	Hialeah, FL 33016
RPT	51435	12/03/2013	Jones, Tyler Steven	09/30/1994	Cvs Caremark		3520 Island Club Dr Apt 6	North Port, FL 34288
RPT	51436	12/03/2013	Khouzam, Peter	07/16/1989			4401 Sheridan Street	Hollywood, FL 33021
RPT	51437	12/03/2013	Ussery, Lori Kay	04/14/1972	Publix Super Market, Inc.		11145 Windhaven Dr S	Jacksonville, FL 32225
RPT	51438	12/03/2013	Rivera, Eliza Jeanette	08/12/1991	Publix Super Market, Inc.		2985 2985 Westview Court	Kissimmee, FL 34746
RPT	51439	12/03/2013	Rodriguez, Maria Luisa	08/06/1990	Other	Ultimate Medical Academy	701 57 Th Street Apt B	West Palm Beach, FL 33407
RPT	51440	12/03/2013	Steele, Jeffery Leonard	09/20/1987	Cvs Caremark		5001 Grande Drive #122	Pensacola, FL 32504
RPT	51441	12/03/2013	Bacallao Sosa, Kenia	01/04/1971		Florida Education Institute	3160 Palm Ave #2	Hialeah, FL 33012
RPT	51442	12/03/2013	Schroeder, Matthew Michael	07/17/1991	Cvs Caremark		4141 North Beach Road	Englewood, FL 34223
RPT	51443	12/03/2013	Stuker, Allison Nicole	09/20/1984	Hometown Supermarkets, Llc		512 Sw 117Th St.	Gainesville, FL 32607
RPT	51444	12/03/2013	Tarris, Chasity Yvette	08/20/1994	Other	Atlantic Technical Center	8429 Forest Hills Dr Apt 202	Coral Springs, FL 33065
RPT	51445	12/03/2013	Stiltner-Sulzener, Angel Rose	09/08/1984	Walgreens		5478 Rogers Ave	Port Orange, FL 32127
RPT	51446	12/03/2013	Benjamin, Kimisha Natalia	03/20/1991	Other	Sanford-Brown Institue Jacksonville	10960 Beach Blvd Lot 347	Jacksonville, FL 32246
RPT	51447	12/03/2013	Desrosiers, Mary Beth	07/06/1959	Cvs Caremark		6217 Silver Star Rd.	Orlando, FL 32808
RPT	51448	12/03/2013	Brookins, Sabrina Starr	02/01/1987	Other	Sanford-Brown Institute-Jacksonville	433 Broward Street	Jacksonville, FL 32204

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51449	12/03/2013	Gates, Allison J	08/14/1992	Cvs Caremark		715 W Dr Martin Luther King Jr	Seffner, FL 33584
RPT	51450	12/03/2013	Blackburn, Theresa Maria	09/13/1980	Publix Super Market, Inc.		2871 Clayton Crossing Way Suite 1001	Oviedo, FL 32765
RPT	51451	12/03/2013	Boynton, Juliet G	10/19/1983	Other	Everest University	1809 De Barry Ave. Apt. B7	Orange Park, FL 32073
RPT	51452	12/03/2013	Johnson, Shamell N	02/19/1985	Other	Everest University Jacksonville	3456 Turkey Oaks Dr W	Jacksonville, FL 32257
RPT	51453	12/03/2013	Heppern, Verniqua Vernette	11/26/1990			101 E New Hampshire Ave #18B	Deland, FL 32724
RPT	51454	12/03/2013	Klishin, Clint Hinson	04/06/1994	Other	University Of Florida College Of Pharmacy	10365 10365 Se County Rd 763	Arcadia, FL 34266
RPT	51455	12/03/2013	Brown, Alysha J	07/28/1992	Cvs Caremark		1912 Capeside Circle	Wellington, FL 33414
RPT	51456	12/03/2013	Daley, Leon Dwight	05/05/1994	Walgreens		3299 N. Woodland Blvd	Deland, FL 32720
RPT	51457	12/03/2013	Bonisteel, Pamela M	07/21/1951	Walgreens		3851 4Th Street N	Saint Petersburg, FL 33703
RPT	51458	12/03/2013	Grant, Audrey Rose	09/24/1991	Wal-Mart		5800 N Highway 98	Lakeland, FL 33809
RPT	51459	12/04/2013	Chillura, Amanda Rose	10/28/1989			2535 State Road 60 East	Valrico, FL 33594
RPT	51460	12/04/2013	Burgos, Zulmarie	09/21/1986	Other	Pharmacy Technician Certification Board	1251 Se 27Th St Unit 206	Homestead, FL 33035
RPT	51461	12/04/2013	Adams, Crystal Darlene	10/13/1993	Other	Everest University	1317 Paradise Ln	Winter Park, FL 32792
RPT	51462	12/04/2013	Sikes, Justin Ellis	01/06/1988	Pointe Med Pharmacy		1996 Kingsley Ave	Orange Park, FL 32073
RPT	51463	12/04/2013	Aybar, Cynthia	02/23/1978	Other	Everest University	863 Bella Vida Blvd	Orlando, FL 32828
RPT	51464	12/04/2013	Banks, Bianca Ty'Brittane	10/02/1989			1985 Erving Circle Apt 8305	Ocoee, FL 34761
RPT	51465	12/04/2013	Calvo, Ileana	11/03/1964	Vivi Pharmacy, Llc		2467 W 70Th St	Hialeah, FL 33016
RPT	51466	12/04/2013	Diatlova, Tatiana	06/24/1974	Other	Everest Institute	12380 Sw 123Rd Pass	Miami, FL 33186
RPT	51467	12/04/2013	Adderley, Danesha Jeanette	05/20/1994	Other	Everest University Brandon Campus	3030 Moss Hill Street	Zephyrhills, FL 33542
RPT	51468	12/04/2013	Drummond, Delaine	04/12/1993	Other	Everest Institute	5831 Washington St. Apt. 43	Hollywood, FL 33023
RPT	51469	12/04/2013	Turner, Carol La'Trece	05/10/1986	Other	Everest University Bandon	5038 Temple Heights Rd	Tampa, FL 33617
RPT	51470	12/04/2013	Davila, Sharoll	07/15/1992	Other	Everest Institute	1176 W. 37 Terrace	Hialeah, FL 33012
RPT	51471	12/04/2013	Mcguire, Kristina Marie	09/26/1992			410 E Jolly Road	Lansing, MI 48910

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RPT	51472	12/04/2013	Chinea, Frances Daimary	08/14/1993	Other	Kmart Pharmacy	1002 E Highway 50	Clermont, FL 34711
RPT	51473	12/04/2013	Wright, Candyce Megan	04/29/1985	Cvs Caremark		772 Pondella Rd Apt 267	North Fort Myers, FL 33903
RPT	51474	12/04/2013	Pettit, Rosetta	03/18/1967			1930 State Road 44	New Smyrna Beach, FL 32168
RPT	51475	12/04/2013	Hatem, Mary Rose	03/19/1973	Other	Barry University	10525 Sw 200 St	Miami, FL 33157
RPT	51476	12/04/2013	Espinoza, Natalie Bianca	03/03/1995	Publix Super Market, Inc.		798 W 31 St	Hialeah, FL 33012
RPT	51477	12/04/2013	Chadwick, Joy M	11/16/1961	Publix Super Market, Inc.		2850 W. Rainbow Circl	Sarasota, FL 34231
RPT	51478	12/04/2013	Leon Chaviano, Jorge Luis	09/01/1984	Las Villas Pharmacy Discount And Medical Supplies		449 West 46 Pl	Hialeah, FL 33012
RPT	51479	12/04/2013	Bennett, Joy M	12/23/1966	Other	University Of Florida - College Of Pharmacy	351 Mohawk Trail	Winter Springs, FL 32708
RPT	51480	12/04/2013	Clark, Theresa Anne	08/29/1964	Target Pharmacy		10500 Ulmerton Road East	Largo, FL 34641
RPT	51481	12/04/2013	Dudley, Shanice Nicole	11/09/1988	Other	Everest	8090 Atlantic Blvd.E117	Jacksonville, FL 32211
RPT	51482	12/04/2013	Foster, Natalie Latrice	11/07/1984	Other	Everest University Jacksonville	2134 Burgoyne Dr	Jacksonville, FL 32208
RPT	51483	12/04/2013	Damio, Michelle Elizabeth	11/20/1983	Publix Super Market, Inc.		5998 Mobile Hwy	Pensacola, FL 32526
RPT	51484	12/04/2013	Conner, Kathleen L	01/04/1959	Cvs Caremark		1889 N Us Hwy 1	Fort Pierce, FL 34946
RPT	51485	12/04/2013	Gebrehewet, Azmera H	02/01/1967	Other	Everest University	531 Lake Tivoli Blvd Apt E	Kissimmee, FL 34741
RPT	51486	12/04/2013	Eager, Kiana M	11/25/1992	Other	Fortis College Mobile Alabama	4460 Hodges Blvd. Apt 1224	Jacksonville, FL 32224
RPT	51487	12/04/2013	Elize, David	11/15/1958			6221 N.W. 14 Ct	Sunrise, FL 33313
RPT	51488	12/04/2013	Wilson, Tanyetta Patrice	06/08/1973	Other	Southeastern College	2139 57Th Ave. So Apt.501	St.Pete, FL 33712
RPT	51489	12/04/2013	Warr, Stephanie Marie	05/28/1992	Walgreens		32854 Crooked Oaks Lane	Leesburg, FL 34748
RPT	51490	12/04/2013	Valdes, Melissa Marie	08/17/1993	Other	Passassured, Llc	13911 Sw 42 Street Suite 203	Miami, FL 33175
RPT	51491	12/04/2013	Saintil, Island	10/13/1984		Atlantic Technical Center	416 Sw 1St Court Apt 2	Pompano Beach, FL 33060

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RPT	51492	12/04/2013	Edwards, Kandace	05/02/1982			Box 100174	Fort Lauderdale, FL 33310
RPT	51493	12/05/2013	Rodriguez, Viviana	10/15/1988	Complete Pharmacy And Medical Solutions		11750 Sw 18Th St Apt 511	Miami, FL 33175
RPT	51494	12/05/2013	Brown, Leigh Ann	05/05/1986	Washington-Holmes Technical Center		1242 Main Street	Chipley, FL 32428
RPT	51495	12/05/2013	Salas, Osmery	06/08/1993		Miami Dade College	633 E 23 St	Hialeah, FL 33013
RPT	51496	12/05/2013	Lemme-Sampson, Audrey Lyn	07/12/1971	Publix Super Market, Inc.		3122 Mahan Drive	Tallahassee, FL 32308
RPT	51497	12/05/2013	Saylor, Jeannell	03/16/1992	Caremart Inc		813 W. Bearss Ave	Tampa, FL 33313
RPT	51498	12/05/2013	Klocke, Susan Christine	01/10/1964			10255 Sw 86Th Circle	Ocala, FL 34481
RPT	51499	12/05/2013	Mackey, Charity B	09/25/1982			406 11Th Street N W	Largo, FL 33770
RPT	51500	12/05/2013	Foschini, Teresa Charlene	12/29/1992			4001 Nw 118 Terrace	Sunrise, FL 33323
RPT	51501	12/05/2013	Mccarthy, Kathryn Lee	09/20/1985			5710 Hoover Blvd	Tampa, FL 33634
RPT	51502	12/05/2013	Gaviria Restrepo, Laura	06/26/1991	Krs Global Biotechnology Inc		9679 Sunny Isles Circle	Boca Raton, FL 33428
RPT	51503	12/05/2013	Wallace, Linda Joyce	03/15/1950	Cvs Caremark		3743 Star Leaf Rd W	Jacksonville, FL 32210
RPT	51504	12/05/2013	Vadakkel, Grashma Chackochan	10/25/1992	Cvs Caremark		3710 North Ocean Blvd	Fort Lauderdale, FL 33308
RPT	51505	12/05/2013	Hellmann, Kelsey Suzanne	08/04/1992			450 Sr13 N	Saint Johns, FL 32259
RPT	51506	12/05/2013	Curtis, Norma Jean	03/02/1941			3015 Sw Pine Island Rd	Cape Coral, FL 33991
RPT	51507	12/05/2013	Samuel, Shaina Olesia	09/13/1979	Other;Other	Everest Institute;Everest Institute	5130 Nw 8 Ave #1	Miami, FL 33127
RPT	51508	12/05/2013	Ramirez Encinas, Daniela Monserrat	02/08/1990	Cvs Caremark		2502 W. Hillsborough Ave.	Tampa, FL 33614
RPT	51509	12/05/2013	Smith, Lashantis Denae	11/19/1987	Other	Everest University - North Orlando Campus	2494 2494 Ravenall Ave	Orlando, FL 32811
RPT	51510	12/05/2013	Santana, Luis Y	02/23/1975	1492 Pharma Group Corp.		6355 Sw 8 St Apt#1108	Miami, FL 33144
RPT	51511	12/05/2013	Beaubrun, Pascal	10/29/1987	Other	The Manhattan Institute	4535 Lucerne Lakes Blvd W #105	Lake Worth, FL 33467
RPT	51512	12/05/2013	Bengochea-Collazo, Mary Angelie	07/17/1981			1148 Saint Tropez Ct	Kissimmee, FL 34759
RPT	51513	12/06/2013	Bonhomme, Alleyne Phillippe	09/18/1984	Cvs Caremark		513 Wisteria Road	Daytona Beach, FL 32118

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RPT	51514	12/06/2013	Demetriou, Georgina	04/14/1988	Other	Southeastern College	14541 Bayhills Dr	Largo, FL 33774
RPT	51515	12/06/2013	Baxter, Keitrah Tiana	12/23/1987	Other	Fortis College	11023 Sw 167Th St	Miami, FL 33157
RPT	51516	12/06/2013	Dixon, Rosemary	11/29/1959	Other	Everest University Brandon Campus	2912 N. 26Th Street	Tampa, FL 33605
RPT	51517	12/06/2013	Darling, Jonathan Alexander	03/05/1994	Walgreens		315 West Platt Street	Tampa, FL 33606
RPT	51518	12/06/2013	Randle, Shanise T	11/30/1988		Fortis College	3958 W. D Judge Dr #133	Orlando, FL 32808
RPT	51519	12/06/2013	Blum, Debra Jane	09/06/1957	Other	Sanford Brown Institute Pittsburgh Pa	644 City View Ave	Avalon, PA 15202
RPT	51520	12/06/2013	Cowart, Shalaina J	03/01/1986	Other	Fortis College	223 11830 Sw 223 St	Miami, FL 33170
RPT	51521	12/06/2013	Clark, Ashley	11/14/1991	Other	Fortis College	268 St 12080 Sw 268 St Unit 28	Homestead, FL 33032
RPT	51522	12/06/2013	Whitley, Brittany Michelle	01/06/1991	Walgreens		1515 N. Flager	West Palm Beach, FL 33401
RPT	51523	12/06/2013	Barnett, Hunter Christine	06/01/1992	Other	Allied Business Schools	8 Short Vine St	Crawfordville, FL 32327
RPT	51524	12/06/2013	Thomas, Andrew Michael	09/07/1986	Wal-Mart		2765 10Th Ave N.	Palm Springs, FL 33461
RPT	51525	12/06/2013	Sibrun, Wisner	03/06/1986		Florida Keys Comm College	6500 Malony Ave Lot 28	Key West, FL 33040
RPT	51526	12/06/2013	Forchion, Shanelle Moneat	01/13/1987	Other	Heritage Institute	1913 Art Museum Dr #46	Jacksonville, FL 32207
RPT	51527	12/06/2013	Battle, Dawn Marie	01/01/1979	Other	Everest University	473 Wynfield Circle	Fleming Island, FL 32003
RPT	51528	12/06/2013	Graham, Mario Ii	10/21/1992	Publix Super Market, Inc.		8601 Nw 186 Ave	Miami, FL 33015
RPT	51529	12/06/2013	Fatimah, Kahkashan	05/30/1991	Cvs Caremark		114 Sw 19Th Terrace	Cape Coral, FL 33991
RPT	51530	12/06/2013	Croffut, Kristen Lyn	11/07/1991	Other	University Of Florida College Of Pharmacy	3051 Commerce Ave	Spring Hill, FL 34609
RPT	51531	12/06/2013	Shelton, Racquel Lashay	01/05/1987	Other	Indian River State College	4123 37Th Drive	Vero Beach, FL 32967
RPT	51532	12/06/2013	Elshaer, Mohammed	10/26/1989	Cvs Caremark		1929 Bruce B. Downs Boulevard	Wesley Chapel, FL 33543
RPT	51533	12/06/2013	Cabrera, Alexa	09/15/1991	Cvs Caremark		4221 W Spruce St Unit 2127	Tampa, FL 33607
RPT	51534	12/06/2013	Brand, Timothy R	09/09/1964	Other	Southeastern College	17905 Crawley Road	Odessa, FL 33556
RPT	51535	12/06/2013	Perkins, Jonathan Charles	02/03/1985		Express Training Centers	3500 Windmeadows Blvd	Gainesville, FL 32608
RPT	51536	12/06/2013	Declark, Linda K	05/05/1963	Wal-Mart		1334 Lech Ave Nw	Palm Bay, FL 32907

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51537	12/06/2013	Smith, Rachel Nanette	02/18/1978	Assuredrx, Llc		540 Nw 4Th Avenue Apt 2407	Fort Lauderdale, FL 33311
RPT	51538	12/06/2013	Bridges, Amanda Lynn	08/27/1988	Walgreens		2420 E. Colonial Drive	Orlando, FL 32803
RPT	51539	12/06/2013	Cardona, Maria Elena	11/02/1986	Publix Super Market, Inc.		31060 Avenue D	Big Pine, FL 33043
RPT	51540	12/06/2013	Amos, Sarah Page	05/16/1979	Other	University Of Florida - College Of Pharmacy	14022 Evening Sky Place	Orlando, FL 32828
RPT	51541	12/06/2013	Cabrera, Donessa	10/15/1981	Cvs Caremark		1205 West Vine Street	Kissimmee, FL 34741
RPT	51542	12/06/2013	Salcedo, Doel Alexis	05/28/1960	Other	University Of Florida - College Of Pharmacy	8101 Moritz Court	Orlando, FL 32825
RPT	51543	12/06/2013	Batista, Jovanie Toy	08/23/1994	Walgreens		2425 2425 U.S. 92	Lakeland, FL 33801
RPT	51544	12/06/2013	Strong, Claudia Elaine	12/22/1952			1517 Alabama Ave	Saint Cloud, FL 34769
RPT	51545	12/06/2013	Sellers, Tenise	01/12/1989	Wal-Mart		27 Aiken Street Unit B	Norwalk, CT 06851
RPT	51546	12/06/2013	Sessions, Jason Earl	09/19/1973	Other	North Seattle Community College	1904 East Scott St	Pensacola, FL 32503
RPT	51547	12/06/2013	Smith, Jamerica Shante	03/10/1987	Other	Lively Technical Center	1120 Poplar Rd	Chattahoochee, FL 32324
RPT	51548	12/09/2013	Bostick, Tiffany	09/11/1985	Cvs Caremark		7589 Garibaldi Cr	Naples, FL 34114
RPT	51549	12/09/2013	Cammock, Samara Allison	09/11/1990	Cvs Caremark		8331 Bernwood Cove Loop #1402	Fort Myers, FL 33966
RPT	51550	12/09/2013	Sikkema, Daniel J	08/28/1982	Other	Ultimate Medical Academy	1805 N Bay Road	Mount Dora, FL 32757
RPT	51551	12/09/2013	Hassan, Bibi Aneeza	06/29/1991	Cvs Caremark		5730 Lakeside Drive Apt 405	Margate, FL 33063
RPT	51552	12/09/2013	Allaire, Cory Scott	05/25/1990	Walmart And Sam'S Club Pharmacies		1375 Poinciana Rd	Venice, FL 34293
RPT	51553	12/09/2013	Demyanovich, Ashley Arlene	10/09/1992	Other	2419 University Of Florida-College Of Pharmacy	11150 4Th Street N Apt 3904	Saint Petersburg, FL 33716
RPT	51554	12/09/2013	Galindo, Vilma Karina	01/09/1994	Cvs Caremark		845 4Th Street North	Saint Petersburg, FL 33701
RPT	51555	12/09/2013	Barksdale, Chelsea Sheree	03/29/1993	Cvs Caremark		1311 35Th St N	Saint Petersburg, FL 33713
RPT	51556	12/09/2013	Mitchell, Joi Courtnee	12/12/1990			866 Park Lake Cr.	Maitland, FL 32751
RPT	51557	12/09/2013	Ruiz, Nichole	06/29/1993	Other	Fortis College	13520 Sw 64Th Ln	Miami, FL 33183
RPT	51558	12/09/2013	Garcia, Yennifer	04/09/1992	Other		100 Tower Pon Cir Apt #428	Lake Wales, FL 33859

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RPT	51559	12/09/2013	Wilkinson, Amanda Sue	02/11/1989	Target Corporation;Walgreens		1408 28Th St Nw	Winter Haven, FL 33881
RPT	51560	12/09/2013	Smith, Dominique Clinique	01/09/1985	Other	Everest University	4853 Judy Ann Ct.	Orlando, FL 32808
RPT	51561	12/09/2013	Suthar, Mit	03/20/1989	Publix Super Market, Inc.		2771 Monument Rd	Jacksonville, FL 32225
RPT	51562	12/09/2013	Nova, Luban Nasreen	09/27/1994			916 S Main St	Belle Glade, FL 33430
RPT	51563	12/09/2013	Meierdierck, Michael John	08/23/1968			2633 Forest Ridge Drive	Fernandina Beach, FL 32034
RPT	51564	12/09/2013	Joslyn, Brooke Kristen	06/08/1994			450 State Road 13 #109	Saint Johns, FL 32259
RPT	51565	12/09/2013	Lovince, Judith	04/29/1995			3580 N. Federal Highway	Lighthouse Point, FL 33064
RPT	51566	12/09/2013	Rosier, Najee Katia	09/10/1987	Walgreens		1920 W Blue Heron Blvd	Riviera Beach, FL 33404
RPT	51567	12/09/2013	Van Valkenburg, Teresa Ann	08/02/1969	Other	Everest Univ.;Everest University	2120 Bridle Path	Melbourne, FL 32935
RPT	51568	12/09/2013	Ruiz, Oliver	09/28/1990	Cvs Caremark		280 East 56 Street	Hialeah, FL 33013
RPT	51569	12/09/2013	Medina, Mario	03/27/1960	Med-Source Pharmacy Services Corporation		11800 Sw 18 Street Apt 504	Miami, FL 33175
RPT	51570	12/09/2013	Dunbar-Karavakis, Aimee	08/06/1973	Cvs Caremark		5300 S John Young Parkway	Orlando, FL 32839
RPT	51571	12/09/2013	Padua, David Anthony	08/15/1989	Cvs Caremark		701 Sw 62Nd Blvd Apt Y176C	Gainesville, FL 32607
RPT	51572	12/09/2013	Louis-Charles, Kenneth	08/03/1976	Other	Everest University	Penn C 1134 Penn Ct Nw	Palm Bay, FL 32907
RPT	51573	12/09/2013	Pimentel, Mark Alexis	11/24/1971	Cvs Caremark		920 E Hathaway Avenue Apartment 3	Bronson, FL 32621
RPT	51574	12/09/2013	Murphy, Meghan Nicole	04/23/1992	Winn Dixie		14600 Palm Beach Blvd	Ft Myers, FL 33905
RPT	51575	12/09/2013	Lisojo, Vanessa Andrea	02/01/1995	Other	Winter Park Tech-Avalon Campus	14343 Lake Underhill Rd	Orlando, FL 32828
RPT	51576	12/09/2013	Lugo, Karen P	10/27/1992	Other	Ultimate Medical Academy	207 Waverly Way	Clearwater, FL 33756
RPT	51577	12/09/2013	Nasworthy, Rebecca Ann	12/10/1968	Walgreens		115 N Lawrence Blvd	Keystone Heights, FL 32656
RPT	51578	12/09/2013	Krause, Paula A	07/11/1969	Other	Ultimate Medical Academy	712 New Jersey Street	Clearwater, FL 33756
RPT	51579	12/09/2013	Moreno, Lori Lambert	07/06/1973	Other	Collins Career Center	10810 Winged Foot Terrace	Bradenton, FL 34202
RPT	51580	12/09/2013	Prajapati, Ravish	10/06/1986	Cvs Caremark		175 Sr 312, St Augustine, Fl ?	Saint Augustine, FL 32080

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51581	12/10/2013	Karoub, Lauren A	06/13/1987	Target Pharmacy		4271 Tamiami Trl S	Venice, FL 34293
RPT	51582	12/10/2013	Oscar, Richard	08/22/1991	Other	Mcfatter Technical School	6309 Sw 7Th Street	Margate, FL 33068
RPT	51583	12/10/2013	Mccoy, William Murray	05/02/1987			15043 S Dixie Hwy	Palmetto Bay, FL 33176
RPT	51584	12/10/2013	Large, Gabrielle Marie	07/19/1994	Target Corporation		1004 Monticello Blvd N	St. Petersburg, FL 33703
RPT	51585	12/10/2013	Pequeno, Thomas John	03/13/1984	Target Pharmacy		2926 28 Ave. N.	St. Petersburg, FL 33703
RPT	51586	12/10/2013	Lamoute, Samonia Lashae	03/09/1991	Total Care Medical, Inc		365 Hinson Circle	Havana, FL 32333
RPT	51587	12/10/2013	Allen, Chelsea Dene	02/15/1991			1606 Shonnora Dr	Gotha, FL 34734
RPT	51588	12/10/2013	Hall, Jazz'Men Peacolia	11/23/1992			937 Grand St	Orlando, FL 32805
RPT	51589	12/10/2013	Dukes, Latitia Rochelle	06/09/1993			1200 S.W. 3Rd St Apt #1	Homestead, FL 33030
RPT	51590	12/10/2013	Storch, Allina Marie	01/06/1994	Other	Sanford-Brown Institute Jacksonville	393 Blairmore Blvd East	Orange Park, FL 32073
RPT	51591	12/10/2013	O'Neill, Emily Taylor	06/29/1991	Publix Super Market, Inc.		630 Atlantic Blvd	Neptune Beach, FL 32266
RPT	51592	12/10/2013	Juresic, Sanny	02/24/1993	Cvs Caremark		5323 Summit Lake Dr.	Jacksonville, FL 32258
RPT	51593	12/10/2013	Jones, Megumi	04/02/1980	Other	Everest University	1594 Green Moss Lane	Orange Park, FL 32065
RPT	51594	12/10/2013	Menegia, Yanet	08/18/1983	Cvs Caremark		8200 Nw 10Th St Unit 13	Miami, FL 33126
RPT	51595	12/10/2013	Woof, Ashley Nicole	07/20/1992	Other	Everest University	112 Kennedy Ave	Interlachen, FL 32148
RPT	51596	12/10/2013	Pederson, Velislava Vasileva	06/29/1973	Target Corporation		3200 3200 N Federal Hwy	Fort Laudedale, FL 33306
RPT	51597	12/10/2013	Pyle, Abbra Christine	03/30/1991	Other	University Of Florida-College Of Pharmacy	2832 Myra Street	Jacksonville, FL 32205
RPT	51598	12/10/2013	Nguyen, Ashley	08/21/1991	Walgreens		125 East Main Street	Apopka, FL 32703
RPT	51599	12/10/2013	Parra, Adriana	05/22/1988	Cvs Caremark		6424 Wilshire Dr	Tampa, FL 33615
RPT	51600	12/10/2013	Torres, Tracy Mcclain	08/28/1971	Other	Midlands Technical College	6204 Benjamim Rd	Tampa, FL 33634
RPT	51601	12/10/2013	Kurland, Jennifer Ann	09/06/1976	Other	University Of Florida - College Of Pharmacy	915 South Us Highway 1	Vero Beach, FL 32962
RPT	51602	12/10/2013	Lounsbury, Alina Elaine	02/08/1988	Walgreens		378 Cordova Ave	Deleon Springs, FL 32724
RPT	51603	12/10/2013	Padgett, Trenton Payne	10/07/1993			3959 Hwy 273	Graceville, FL 32440
RPT	51604	12/10/2013	Mena, Irina	12/18/1979	Other	Heritage Institute	2140Sw 4Th Court	Cape Coral, FL 33991

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RPT	51605	12/10/2013	Ham, Erica	04/19/1992	Other	Heritage Institute	27571 Riverbank Drive	Bonita Springs, FL 34134
RPT	51606	12/10/2013	Cueves, Luz Thalia	01/07/1993	Other	Heritage Institute	418 Se 21St Street	Cape Coral, FL 33990
RPT	51607	12/10/2013	Key, Dameyca Kionis	11/29/1990	Other	Everest University	2584 Troubador St.	Orlando, FL 32839
RPT	51608	12/10/2013	Killenbec, Nichole Lila	11/06/1981	Other	Everest University	1136 Castlewood Terrace Apt 202	Casselberry, FL 32707
RPT	51609	12/10/2013	Palacios, Kristine	02/15/1989	Other	Heritage Institute	551 S Davis St	Labelle, FL 33935
RPT	51610	12/10/2013	Levin, Lisa M	08/28/1963	Other	Ultimate Medical Academy	6916 N. Glen Avenue	Tampa, FL 33614
RPT	51611	12/10/2013	Mitchnick, Hope Sharon	09/20/1958	Walgreens		3063 Northlake Blvd	Palm Beach Gardens, FL 33403
RPT	51612	12/10/2013	Watts, Maria Lyn	10/15/1975	Cvs Caremark		1596 Highway A1A	Satellite Beach, FL 32937
RPT	51613	12/10/2013	Mallard, Kaci Lynn	12/08/1994	Cvs Caremark		7614 Leafy Forest Way	Jacksonville, FL 32277
RPT	51614	12/10/2013	Peterson, Shaundra Leann	10/31/1985	Other	Everest University	1861 Nw 46Th Ave Apt 312E	Lauderhill, FL 33313
RPT	51615	12/10/2013	Ceballos, Angel Eduardo	08/17/1993	Walgreens		3063 Mandolin Drive	Kissimmee, FL 34744
RPT	51616	12/10/2013	Brown, Barbara Annette	06/21/1967			1700 S. Federal Highway	Fort Lauderdale, FL 3316
RPT	51617	12/10/2013	Clausen, Cole Calvin	12/08/1994	Target Corporation		4450 Park Street	Saint Petersburg, FL 33709
RPT	51618	12/10/2013	Francis, Maurice Bornwell	12/16/1972	Other	Barry University/Ace Institute For Training & Professional Dev.	168 4958 168Th Ave	Miramar, FL 33027
RPT	51619	12/10/2013	Daniel, Crystal Gayle	10/17/1983			76253 Longleaf Loop	Yulee, FL 32097
RPT	51620	12/10/2013	Bracetti, Emmanuel Alexander	01/11/1994	Other	Westside Tech	6171 Arundel Dr.	Orlando, FL 32808
RPT	51621	12/10/2013	Burke, Ladell	06/18/1972			9998 Front Beach Rd	Panama City Beach, FL 32407
RPT	51622	12/10/2013	Guerrero, Claudia	12/17/1986	Other	University Of Florida	14601 Sw 16 St	Miami, FL 33175
RPT	51623	12/10/2013	Davis, Regina L	10/24/1973	Cvs Caremark		2020 N. 7Th. Ave.	Pensacola, FL 32503
RPT	51624	12/10/2013	Derkovitz, Rachel Lynn	06/18/1988	Cvs Caremark		3506 N Lecanto Hwy	Beverly Hills, FL 34465
RPT	51625	12/10/2013	Hennen, Jodi Ann	11/30/1993	Cvs Caremark		13700 Sutton Park Dr N Apt 825	Jacksonville, FL 32224
RPT	51626	12/10/2013	Crenshaw, Bryant Christopher	04/27/1992	Publix Super Market, Inc.		264 Wilson Green Blvd	Tallahassee, FL 32305
RPT	51627	12/11/2013	Desai, Falgunibahen D	10/17/1969	Walgreens		4340 Southflorida Avenue	Lakeland, FL 33813

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RPT	51628	12/11/2013	Bigelow, Derrik Nels	07/11/1988	Cvs Caremark		13Th 1621 Sw 13Th Street	Gainesville, FL 32608
RPT	51629	12/11/2013	Fielder, Charles L	09/11/1964	Other	Ultimate Medical Academy	2319 Magnolia Avenue	Seffner, FL 33584
RPT	51630	12/11/2013	Anjos, Milene Andreia	11/10/1990			1149 Baycove Ln	Lutz, FL 33549
RPT	51631	12/11/2013	Price, Molly Jane	08/17/1994	Walgreens		2705 Highway 44 West	Inverness, FL 34453
RPT	51632	12/11/2013	Monsanto, Lois	01/21/1991	Cvs Caremark		2252 Sandridge Circle	Eustis, FL 32726
RPT	51633	12/11/2013	Curran, Jennifer Faith	10/14/1983	Adventist Health System		582 Monroe Rd	Sanford, FL 32771
RPT	51634	12/11/2013	Almeida, Claudia	03/18/1992	Walgreens		21358 Sw 112 Ave Apt 101	Miami, FL 33189
RPT	51635	12/11/2013	Everett, Tanisha La'Shay	05/09/1988	Other	Everest University	843 Old Still Rd	Woodbine, GA 31569
RPT	51636	12/11/2013	Caraballo, Michelle	04/24/1993	Other	Everest Institute	12103 Sw 213Th Terr	Miami, FL 33177
RPT	51637	12/11/2013	Baker, Amanda Maie	01/17/1994			4210 Sr 64 East	Bradenton, FL 34208
RPT	51638	12/11/2013	Cawthra, Marina Catherine	03/04/1992	Tequesta Drugs Inc		6080 Eagles Nest Drive	Jupiter, FL 33458
RPT	51639	12/11/2013	Christian, Tiffany Ann	05/27/1994	Other	Everest University	9799 Se 308Th Terrace Rd.	Altoona, FL 32702
RPT	51640	12/11/2013	Boles, Devontae Antonio	07/12/1993	Other	Mcfatter Technical Center	1800 S University Drive	Miramar, FL 33025
RPT	51641	12/11/2013	Hewlett, Sally Wynn	12/08/1962	Publix Super Market, Inc.		19034 Bruce B Downs Blvd.	Tampa, FL 33647
RPT	51642	12/11/2013	Toten, Janet Grace	04/07/1959	Ominicare, Inc.		11102 Summer Drive	Tampa, FL 33624
RPT	51643	12/11/2013	Mohammed, Leah	03/23/1988	Cvs Caremark		4550 Lyons Road	Pompano, FL 33066
RPT	51644	12/11/2013	Ibrahimovic, Merima	10/26/1979			7999 9Th St. N.	Saint Petersburg, FL 33702
RPT	51645	12/11/2013	Martinez, Anthony Michael	06/11/1990	Cvs Caremark		808 N. Franklin St. Unit 1414	Tampa, FL 33602
RPT	51646	12/11/2013	Jacques-Michel, Anne	09/05/1979	Other	Everest Institute	129 Nw 117 Street	Miami, FL 33168
RPT	51647	12/11/2013	Du Toit, Nicole Margaret	06/15/1989	Walgreens		10899 Baymeadows Rd	Jacksonville, FL 32256
RPT	51648	12/11/2013	Pendray, Amanda Brianne	07/13/1992	Cvs Caremark		1390 Green Valler Cir Apt 1104	Naples, FL 34104
RPT	51649	12/11/2013	Rodriguez, Judith	01/22/1974	Publix Super Market, Inc.		106 Ponce De Leon Blvd	Miami, FL 33135
RPT	51650	12/11/2013	Lopez, Lisa Marie	08/01/1984	Other	University Of Florida - College Of Pharmacy	136 Teakwood Dr	Kissimmee, FL 34743

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RPT	51651	12/11/2013	Wendland, Julie Ann	02/05/1964	Other	Milwaukee Area Technical College	10400 75 Th St.	Kenosha, WI 53142
RPT	51652	12/11/2013	Rehman, Nida	07/12/1991	Cvs Caremark		9940 Yamato Road	Boca Raton, FL 33498
RPT	51653	12/12/2013	Aycock, Daniel Lee	01/05/1993	Other	University Of West Florida	742 Overbrook Drive	Fort Walton Beach, FL 32547
RPT	51654	12/12/2013	Ambroise, Joanne Natalie	04/25/1991	Cvs Caremark		1690 South Federal Hwy	Delray Beach, FL 33483
RPT	51655	12/12/2013	Flamenco-Mendoza, Fernanda C	07/21/1989	Walgreens		501 E Sheridan Street	Dania, FL 33004
RPT	51656	12/12/2013	Call, Starr Angel	12/28/1988	Other	Heritage Institute	9765 9765 Cobbletone Creek Dr.	Boynton Beach, FL 33472
RPT	51657	12/12/2013	Vernio, Izabelle	06/12/1983	Other	Everest University	4100 Eastridge Circle	Deerfield Beach, FL 33064
RPT	51658	12/12/2013	Coleman, Davida Areal	11/18/1993	Jacksonville Job Corps Center		2678 St Johns Bluff Road	Jacksonville, FL 32246
RPT	51659	12/12/2013	Hurst, Alyssa Alexandra	12/18/1990	Other	Aventura Hospital	13620 North Miami Ave.	Miami, FL 33168
RPT	51660	12/12/2013	Greco, Nicole Olivia	03/25/1994	Other	Mk Education	6047 Abigail Ave	North Port, FL 34287
RPT	51661	12/12/2013	Bozarth, Connie Sue	01/01/1962			670 Marsh Landing Parkway	Jacksonville Beach, FL 32250
RPT	51662	12/12/2013	Seaton, Craig Duvaughn	07/08/1988	Cvs Caremark		65 Cvs Pharmacy East Main Street	Apopka, FL 32703
RPT	51663	12/12/2013	Follese, Adriana	06/11/1975			4600 Summerlin Rd	Fort Myers, FL 33919
RPT	51664	12/12/2013	Correa, Michelle Dolores	02/05/1993	Cvs Caremark		7705 Sw 127 Ct	Miami, FL 33183
RPT	51665	12/12/2013	Hester, Joshua Blake	01/29/1992	Other	Whitney M. Young Job Corps	1818 Bruman Terrace	Melbourne, FL 32935
RPT	51666	12/12/2013	Hernandez, Brenda	03/20/1995	Cvs Caremark		220 10Th St S.E	Naples, FL 34117
RPT	51667	12/12/2013	Russell, Marie Dorothy	03/07/1981	Cvs Caremark		11496 Sw 51 Circle	Ocala, FL 34476
RPT	51668	12/12/2013	Gray, Nikia D	12/16/1974	Other	Everest University Jacksonville	3820 Losco Rd. Apt.124	Jacksonville, FL 32257
RPT	51669	12/12/2013	Comas, Laura	12/31/1955			12811 Glades Rd	Boca Raton, FL 33498
RPT	51670	12/12/2013	Huff, Brett Joseph	03/15/1994	Wal-Mart		3993 Tyrone Blvd Suite 700	St. Petersburg, FL 33709
RPT	51671	12/12/2013	Serrano, Jorge	03/14/1952	Other	Everest University	2803 Arlington Street	Orlando, FL 32805
RPT	51672	12/12/2013	Garma Diaz, Mayelin	07/13/1977	Other	Professional Training Centers	2560 Sw 122 Ct.	Miami, FL 33175

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RPT	51673	12/12/2013	Farooq, Muhammad Umar	04/14/1984	Walmart And Sam'S Club Pharmacies		8557 Crooked Tree Dr	Jacksonville, FL 32256
RPT	51674	12/12/2013	Ruffin, Antonio	01/07/1987	Other	Southeastern College	4714 North Habana Ave Apt 604	Tampa, FL 33614
RPT	51675	12/12/2013	Knese, Jessica Dawn	05/10/1982	Winn Dixie		10393- Se Highway 441-27	Belleview, FL 34420
RPT	51676	12/12/2013	Petit-Frere, Edith Agatha	07/21/1975	Other	Everest University	2908 Ne 8Th Terrace Apt 203	Wilton Manors, FL 33334
RPT	51677	12/12/2013	Calvo, Karina	01/05/1974			4148 Sw 13 Street	Miami, FL 33134
RPT	51678	12/12/2013	Cerrat, Joanne	09/07/1942	Other	Heritage Institute	114 Lapasada Circle W.	Ponte Vedra Beach, FL 32082
RPT	51679	12/12/2013	Besaly, Sarah	04/26/1993	Publix Super Market, Inc.		455 Alt 19 #185	Palm Harbor, FL 34683
RPT	51680	12/12/2013	Odaiyar, Keisha S	05/26/1992			18950 Sw 54Th Pl	Southwest Ranches, FL 33332
RPT	51681	12/12/2013	Hall, Carl A Jr	01/03/1991	Cvs Caremark		3035 Apalachee Parkway, Talla	Tallahassee, FL 32301
RPT	51682	12/13/2013	Crawford, Kumiko Koyanagi	03/02/1963			1190 Washington Circle Unit J	Homestead, FL 33034
RPT	51683	12/13/2013	Dandridge, Leigh Houseman	06/19/1979	Other	Ed2Go/Unf	287 287 Huntington Shortcut Rd.	Crescent City, FL 32112
RPT	51684	12/13/2013	Mcdaniel, Marissa Lynn	08/21/1989	Other	Everest University	3372 Penny Lane	Middleburg, FL 32068
RPT	51685	12/13/2013	Miller, Jackie Lynn	01/02/1990			311 Memorial Blvd	Lakeland, FL 33801
RPT	51686	12/13/2013	Mendez, Marisela	07/29/1990			929 April Hills Blvd	Lady Lake, FL 32159
RPT	51687	12/13/2013	Kostman, Jessica Kay	05/12/1990			400 Colony Blvd	The Villages, FL 32162
RPT	51688	12/13/2013	Jones, Arthur Lee	08/01/1975	Other	Fortis Institute	2841 S Oakland Forest Dr Apt.203	Oakland Park, FL 33309
RPT	51689	12/13/2013	Kolmetz, Megan Arielle	07/09/1990	Cvs Caremark		2855 Holly Road	Ponce De Leon, FL 32455
RPT	51690	12/13/2013	Muri, Barbara Jean	12/19/1959	Other	University Of Florida College Of Pharmacy	772 July Circle	N Ft Myers, FL 33903
RPT	51691	12/13/2013	Patten, Brent Wayne	09/19/1994	Cvs Caremark		1300 Apalachee Parkway	Tallahassee, FL 32301
RPT	51692	12/13/2013	Thrne, Illonis P	11/08/1991		Lively Tech Center	2074 Midyette Rd #1111	Tallahassee, FL 32301
RPT	51693	12/13/2013	Martin, Austin Chandler	10/18/1992	Shands Jacksonville Medical Center		1760 River Hills Drive	Fleming Island, FL 32003
RPT	51694	12/13/2013	Baxter, Alexandra Nicole	04/29/1993	Cvs Caremark		128 Hibiscus Dr	Fort Myers Beach, FL 33931

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51695	12/13/2013	Antunes, Dena Marie	07/11/1966	Cvs Caremark		215 Jacaranda Blvd.	Venice, FL 34292
RPT	51696	12/13/2013	Tirado, Katrinah Ivette	10/17/1991	Cvs Caremark		617 Via Tunis Dr	Punta Gorda, FL 33950
RPT	51697	12/13/2013	Castillo, Toby Lisa	10/10/1961	Cvs Caremark		4723 Nw 36Th Avenue	Cape Coral, FL 33993
RPT	51698	12/13/2013	Solmo, Alexandra Michel	10/07/1995	Publix Super Market, Inc.		1700 Morning Sun Lane	Naples, FL 34119
RPT	51699	12/16/2013	Smith, Cody Barrett	03/09/1994	Other	Everest University	6313 Buster Drive	Tampa, FL 33619
RPT	51700	12/16/2013	Trevino, Michelle	12/03/1993	Hawa Pharmacy		646 S Dillard St	Winter Garden, FL 34747
RPT	51701	12/16/2013	Quinones, Maryshelly	07/14/1987	Other	University Of Florida - College Of Pharmacy	3425 Sw 2Nd Ave Apt # 150	Gainesville, FL 32607
RPT	51702	12/16/2013	Ragan, Teala Cauley	01/26/1976	Weeks'S Pharmacy, Llc		132 State Hwy 20 East	Freeport, FL 32439
RPT	51703	12/16/2013	Vanderhoof, Michelle Lee	05/15/1995	Publix Super Market, Inc.		11948 Blaze Lane	New Port Richey, FL 34654
RPT	51704	12/16/2013	Shazer, Ashley	11/12/1982	Other	Ultimate Medical Academy	3111 E. 9Th Avenue	Tampa, FL 33605
RPT	51705	12/16/2013	Similien, Thelma	06/29/1988	Other	Barry University	1281 Nw 117 St	Miami, FL 33167
RPT	51706	12/16/2013	Lenza, Monica Amanda	02/20/1967			9682 Fountaibleau Blv #405	Miami, FL 33172
RPT	51707	12/16/2013	Jimenez Hiedra, Raydel Eraldo	03/11/1970			8260 Sw 32Nd Terrace	Miami, FL 33155
RPT	51708	12/16/2013	Munoz Diaz, Sonia	05/14/1969			163 Nw 59Th Ave	Miami, FL 33126
RPT	51709	12/16/2013	Capote Piedra, Elen	12/26/1979	Other	Everest Institute	15101 Sw 306Th St	Homestead, FL 33033
RPT	51710	12/16/2013	Maldonado, Jose Franciso	08/09/1974	Other	Everest University	446 West Oakridge Road Apt #110	Orlando, FL 32809
RPT	51711	12/16/2013	Martinez, Evan Noel	12/19/1989	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51712	12/16/2013	Sedano, Shelby Jeau	01/19/1996	Other	Atlantic Technical Center	24 Ct 9200 Nw 24 Ct	Sunrise, FL 33322
RPT	51713	12/16/2013	Dibella, Alexis Monteleone	10/28/1990	Cvs Caremark		611 S Howard Ave	Tampa, FL 33606
RPT	51714	12/17/2013	Hidalgo, Vivianna Alejandra	11/04/1991	Wal-Mart		4649 72Nd Ct E	Bradenton, FL 34203
RPT	51715	12/17/2013	Anferova, Inga	10/15/1975	Other	Uf College Of Pharmacy	1652 Mary Beth Dr 1652 Mary Beth Drive	Middleburg, FL 32068
RPT	51716	12/17/2013	Ritchie, Melissa Lynn	08/31/1979	Other	Southeastern College	3757 Park Lane Villas Road	Lake Park, FL 33403
RPT	51717	12/17/2013	Do, Korena Makayla	08/12/1993	Other	Sanford-Brown Institute Jacksonville	12116 Blackfoot Trail	Jacksonville, FL 32223
RPT	51718	12/17/2013	Turner, Antonio Maurice	08/09/1959	Other	Everest University	405 Prescott St.	Eustis, FL 32726

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RPT	51719	12/17/2013	Bakhtiar, Roza	04/18/1972	Other	Cerritos Collage	112 Oak Grove Cir	Lake Mary, FL 32746
RPT	51720	12/17/2013	Willis, Paul A	02/01/1995	Other	Barry University Ace Institute	4376 Sw Lagrange St	Port St. Lucie, FL 34953
RPT	51721	12/17/2013	Walters, Andrea K	08/24/1980	Other	Everest Tampa	9611 Montague St	Tampa, FL 33626
RPT	51722	12/17/2013	Sutliff, Ryan Griffe	09/18/1990	Kash N' Karry Food Stores, Inc		3527 39Th Lane South Apt F	Saint Petersburg, FL 33711
RPT	51723	12/17/2013	Hinson, Kayla Lashay	12/26/1988	Other	Mci Institute Of Technology	1630 West 13Th Street	Riviera Beach, FL 33404
RPT	51724	12/17/2013	Alford, Krista Paige	07/05/1993	Cvs Caremark		7112 West Highway 98	Panama City Beach, FL 32407
RPT	51725	12/17/2013	Boady, Patricia-Ann Olivia	09/03/1990	Cvs Caremark		665 Se Karrigan Terr	Port Saint Lucie, FL 34983
RPT	51726	12/17/2013	Abdul-Salaam, Hameed Ismail	03/15/1985	Cvs Caremark		5905 Us Highway 301 South	Riverview, FL 33569
RPT	51727	12/17/2013	Nichols, Jeana Marie	08/27/1987	Other	Fortis Institute	90 Isle Of Venice Dr #7	Fort Lauderdale, FL 33301
RPT	51728	12/17/2013	Poirier, Stacie Lee	02/19/1990			9801 Lake Chrise Lane	Port Richey, FL 34668
RPT	51729	12/17/2013	Ball, Justin Martel	09/23/1990	Publix Super Market, Inc.		5473 Nw Saint James Dr	Port Saint Lucie, FL 34983
RPT	51730	12/17/2013	Amador, Amanda Carol	10/22/1988	Other	Heritage Institute	790 Platt Rd	Naples, FL 34120
RPT	51731	12/17/2013	Espino, Elena Hilaria	11/04/1993	Other	Heritage Institute	1463 Heiman Ave	Fort Myers, FL 33905
RPT	51732	12/17/2013	Higgs, Jade	09/06/1991	Other	Heritage Institute	1376 Marshgrass Ct	Jacksonville, FL 32218
RPT	51733	12/17/2013	Wissert, Katherine Jeanne	10/01/1990	Cvs Caremark		3601 W North A St	Tampa, FL 33609
RPT	51734	12/17/2013	Desimone, Jessica Leigh	06/02/1991	Walgreens		96Th 8636 96Th Ave	Vero Beach, FL 32976
RPT	51735	12/17/2013	Moreno, Patricienn Kaponson	05/03/1955	Other	University Of West Florida	433 Elcino Drive	Pensacola, FL 32526
RPT	51736	12/17/2013	Jefferies, Demi Adina	03/28/1990	Target Pharmacy		6010 Drexel Lane 1115	Fort Myers, FL 33919
RPT	51737	12/17/2013	Franco, Esmeralda	02/25/1991	Other	Pharm Con	213 N 6Th Street	Immokalee, FL 34142
RPT	51738	12/17/2013	Irizarry, Orlando	01/22/1993	Walgreens		11283 N Williams St	Dunnelon, FL 34432
RPT	51739	12/17/2013	St Fleur, Richenel	09/16/1982	Other	Medvance Institute	421 Nw 42Nd Court Apt 204	Pompano Beach, FL 33064
RPT	51740	12/17/2013	Wainman, Lyndsay Rae	11/15/1991	Cvs Caremark		1940 Nw 2Nd Ave	Gainesville, FL 32603
RPT	51741	12/17/2013	Marquez-Arroyo, Rebecca Lannae	04/30/1991	Other	Heritage Institute	13300 Atalantic Blvd #1519	Jacksonville, FL 32225

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RPT	51742	12/17/2013	Butterfield, Dawn Marie	08/29/1980	Other	United States Air Force	5935 Pinto Lane	Orlando, FL 32822
RPT	51743	12/17/2013	Amaya, Ritva Hannella	04/10/1968			205 Sw Starfish Ave.	Port Saint Lucie, FL 34984
RPT	51744	12/17/2013	Gomes, Jared Marlon	12/29/1989			7621 Southern Brook Bend #304	Tampa, FL 33635
RPT	51745	12/17/2013	Donato, Milagros Angelica	12/05/1995			12 Northfleet Lane	Kissimmee, FL 34758
RPT	51746	12/17/2013	Alberson, Kimberly Milstead	05/27/1975			1865 Wells Rd Apt 0-226	Orange Park, FL 32073
RPT	51747	12/17/2013	Hairsine, Priscilla	09/11/1970	Cvs Caremark		223 Ancona St	Fort Myers, FL 33913
RPT	51748	12/18/2013	Lafargue Perez, Ailenis	03/17/1987	Other	Professional Training Centers	8002 Sw 149Th Avenue Apt B-302	Miami, FL 33193
RPT	51749	12/18/2013	Jones, Leronda	01/03/1980	Other	Sanford Brown Institute Tampa	4307 Deleuil Ave	Tampa, FL 33610
RPT	51750	12/18/2013	Taylor, Debra Jean	04/16/1985	Walgreens		4860 Donald Ross Rd	Palm Beach Gardens, FL 33418
RPT	51751	12/18/2013	Bienaime, Nerlande Charles	08/17/1969	Other	Everest University	3327 Gondolier Way	Lake Worth, FL 33462
RPT	51752	12/18/2013	Calvi Rodriguez, Dainelis	10/15/1983	Other	Professional Training Centers	4631 Sw 132Nd Avenue	Miami, FL 33175
RPT	51753	12/18/2013	Rego, Amanda Mrs	09/05/1981	Cvs Caremark		15134 Verona Ave Apt. A	Clearwater, FL 33760
RPT	51754	12/18/2013	Tennison, Kendall Emanuel	10/02/1989	Cvs Caremark		14355 West Newberry Road	Jonesville, FL 32669
RPT	51755	12/18/2013	Sheffield, Kimberly Ann	08/14/1981	Other	Pharmacy Technicians University	355 W Pearl St	Bartow, FL 33830
RPT	51756	12/18/2013	Rodriguez Rodriguez, Anamarys	09/15/1971		Florida Education Instutue	3840 Sw 102 Ave #D205	Miami, FL 33165
RPT	51757	12/18/2013	Rencurrell Aguilar, Luzday	05/29/1982		Florida Education Institute	9500 Sw 36Th Street	Miami, FL 33165
RPT	51758	12/18/2013	Sainristil, Marie Dominique	10/28/1981	Other	Everest University	3930 Crystal Lake Dr Apt 212	Pompano Beach, FL 33064
RPT	51759	12/18/2013	Rose, Amber Nicole	04/02/1991		Rasmussen College - New Prot Richey	4158 Mariner Blvd	Spring Hill, FL 34609
RPT	51760	12/19/2013	Kreisler, Howard Samuel	02/02/1992			686 Glades Rd	Boca Raton, FL 33431
RPT	51761	12/19/2013	Patel, Krupaliben R	06/06/1989	Wal-Mart		6500 Lake Gray Blvd, Apt # 409	Jacksonville, FL 32244

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51762	12/19/2013	Manuel, Michael Hamilton	04/16/1993	Other	Everest University	3425 Nw 44Th St	Fort Lauderdale, FL 33309
RPT	51763	12/19/2013	Mena, Daniela	11/21/1992	Other	Heritage Institute	760 14Th St Ne	Naples, FL 34120
RPT	51764	12/19/2013	Pickett, Melanie Ann	01/07/1990	Other	Heritage Institute	10353 Lewana Dr	Jacksonville, FL 32257
RPT	51765	12/19/2013	Patel, Preya Jayesh	05/10/1995	Cvs Caremark		554 E Nine Mile Rd	Pensacola, FL 32514
RPT	51766	12/19/2013	Karg, Amy Marie	02/25/1981	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51767	12/19/2013	Massey, Aimee	10/17/1973	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51768	12/19/2013	Jopling, Amanda Lee	01/25/1988	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51769	12/19/2013	Martin, Bethany	01/13/1990	Cvs Caremark		1813 Oak Pond Street	Ruskin, FL 33570
RPT	51770	12/19/2013	Hill, Lauren J Ms	11/26/1971	Other	Ultimate Medical Academy	19086 Se Southgate Dr	Tequesta, FL 33469
RPT	51771	12/19/2013	Lyke, Ashley Kay	07/17/1989			260 U.S. 1	Tequesta, FL 33469
RPT	51772	12/19/2013	Faust, Eric D	09/18/1966	Cvs Caremark		810 Se 20Th Ct	Cape Coral, FL 33990
RPT	51773	12/19/2013	Matthew, Tiffany Angelica	10/06/1989	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51774	12/19/2013	Smith, Amber Jael	06/06/1986	Concorde Career Institute	Cci -Tampa	5704 Bratton Dr	Tampa, FL 33617
RPT	51775	12/19/2013	Anderson, Shimara Sharee	11/01/1980	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51776	12/19/2013	Medina, Heidi Marie	01/04/1991	Walgreens		8337 Southpark Cir	Orlando, FL 32819
RPT	51777	12/19/2013	Pineda, Moises David	09/26/1987			9380 Sw 56Th Street	Miami, FL 33165
RPT	51778	12/19/2013	Morales Garcia, Carlos Enrique	10/16/1986			2131 Nw Sooth River Dr	Miami, FL 33125
RPT	51779	12/19/2013	Celestine, Eva	12/09/1977	Cvs Caremark		7442 39Th Place North	Saint Petersburg, FL 33709
RPT	51780	12/19/2013	Alexandre, James	03/24/1986	Other	Fortis Institute	3556 Nw 34Th St	Lauderdale Lakes, FL 33309
RPT	51781	12/19/2013	Verdejo-Cruz, Eileen	11/10/1965			725 Creekwater Terrace 211	Lake Mary, FL 32746
RPT	51782	12/19/2013	Damidaux, Dominique Christina	05/09/1985	Cvs Caremark		11234 Nw 46Th Drive	Coral Springs, FL 33076
RPT	51783	12/19/2013	Bacon, Amanda Linn	09/10/1993	Cvs Caremark		12015 Little Rd	Hudson, FL 34667
RPT	51784	12/19/2013	Aaron, Chanel Anamarie	10/23/1990	Other	Everest University	6231 Nw 14Th Ct	Sunrise, FL 33313
RPT	51785	12/19/2013	Benjamin, Rebecca Kathleen	06/20/1971	Cvs Caremark		11500 Ridge Road	New Port Richey, FL 34654
RPT	51786	12/19/2013	Ciceron, Marie	12/24/1974	Other	Everest Institute	14425 Ne 6 Avenue Apt. #202	Miami, FL 33161

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RPT	51787	12/20/2013	Zaldivar Poey, Idalmis M	05/19/1966		Florida Education Institute	3545 N W 6Th Street	Miami, FL 33125
RPT	51788	12/20/2013	Cole, Chandler Paige	08/02/1993	Other	Lutgert College Of Business And My Career Skill	7009 Interbay Blvd Apt 523	Tampa, FL 33616
RPT	51789	12/20/2013	Aupont, Liliane Dorothy	11/13/1990			120 W Grant Street	Orlando, FL 32806
RPT	51790	12/20/2013	D'Haiti, Daphne	01/05/1989	Other	Manhattan Institute	3566 Wind River Run	Clermont, FL 34711
RPT	51791	12/20/2013	Deans, Deborah Ann	08/10/1971	Other	Everest University	2577 Nw 49Th Ave #102	Lauderdale Lakes, FL 33313
RPT	51792	12/20/2013	Fairbanks, Briana Lyn	07/03/1993			1075 Oakleaf Plantation Pkwy	Orange Park, FL 32065
RPT	51793	12/20/2013	Hernandez, Noemi	07/15/1962			216 Nw 56Th Ave	Miami, FL 33126
RPT	51794	12/20/2013	Canora, Anna Marie	02/09/1968			6270 W. Sample Rd	Coral Springs, FL 33067
RPT	51795	12/20/2013	Bracey, Audrey Conchitta	02/07/1989			5500 Sw Archer Rd Apt I203	Gainesville, FL 32608
RPT	51796	12/20/2013	Wilson, Sineade Raven	03/12/1991	Cvs Caremark		14895 N E 9Th Court	Miami, FL 33161
RPT	51797	12/20/2013	Bychkovska, Liliana	05/07/1993			6017 San Salvador Rd.	North Port, FL 34291
RPT	51798	12/20/2013	Echevaria, Damy	07/23/1976	Other	Everest Institute	671 E. 11 Place	Hialeah, FL 33010
RPT	51799	12/23/2013	Storey, Jeffrey Daniel	11/02/1962	Other	Ultimate Medical Academy	18196 Ga. Hwy 3	Thomasville, GA 31792
RPT	51800	12/23/2013	Pennyfeather, Amy Sylvia	03/09/1990	Other	Everest University	980 Maumee St.	Orlando, FL 32828
RPT	51801	12/23/2013	Macdonald, Elizabeth Jean	09/22/1992	Other	Heritage	1008 Sw 21 Lane	Cape Coral, FL 33991
RPT	51802	12/23/2013	Oyler, Michelle Diane	07/10/1969	Other	University Of Florida-College Of Pharmacy	3639 3639 Worth Circle	The Villages, FL 32162
RPT	51803	12/23/2013	Knight, Sandra Lee	01/11/1967			1604 Rock Prairie Box 10000	College Station, TX 77845
RPT	51804	12/23/2013	Le, Quan Dinh	05/22/1987			115 E Sr 434	Longwood, FL 32750
RPT	51805	12/23/2013	Klinger, Alexander Brenton	06/14/1994	Walgreens		55Th 8391 55Th Way N	Pinellas Park, FL 33781
RPT	51806	12/23/2013	Pinero, Bryan	12/14/1991	Wal-Mart		7706 Nottingham Sky Dr	Apollo Beach, FL 33572
RPT	51807	12/23/2013	Viera, Jean B	12/04/1976	Vivi Pharmacy, Llc		7361 West 29Th Way	Hialeah, FL 33018
RPT	51808	12/23/2013	Welch, Kathryn Kristyne	12/06/1994	Walgreens		140 Capital Circle Sw	Tallahassee, FL 32304
RPT	51809	12/23/2013	Mccray, Deshawn L	05/10/1991	Cvs Caremark		943 Ashton Cove Ter	Jacksonville, FL 32218

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RPT	51810	12/23/2013	Saincimuste, Ketlie	11/15/1982	Other	Steps Corp	7891 Johnson Street Apt 202	Pembroke Pines, FL 33024
RPT	51811	12/26/2013	Paulo, Arnold Jr	08/04/1991	Cvs Caremark		4780 North Kings Highway	Fort Pierce, FL 34951
RPT	51812	12/26/2013	Monroe, Amber Michelle	06/22/1995	Other	University Of Florida - College Of Pharmacy	13672 233Rd Rd	Live Oak, FL 32060
RPT	51813	12/26/2013	Jackson, Veronica	02/05/1969	Aguilas International Medical Institute		11110 11110 Causeway Blvd	Brandon, FL 33511
RPT	51814	12/26/2013	Pompa, Yilliam	10/02/1986	Aguilas International Medical Institute		7702 Rivergate Dr Apt 801	Tampa, FL 33619
RPT	51815	12/26/2013	Kangethe, Susan Muthoni	12/26/1991	Cvs Caremark		1325 Verona Street	Daytona Beach, FL 32114
RPT	51816	12/26/2013	Patel, Roshni B	02/01/1995	Cvs Caremark		37317 Highridge Dr.	Dade City, FL 33525
RPT	51817	12/26/2013	Nappo, Marialidia	12/04/1991	Cvs Caremark		6196 Lynn Lake Drive South Apt: B	St.Petersburg, FL 33712
RPT	51818	12/26/2013	Lantigua, Tamel Markel	07/17/1986	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51819	12/26/2013	Rood, Cara	01/11/1988	Cvs Caremark		7325 State Road 54	New Port Richey, FL 34653
RPT	51820	12/26/2013	Stetzel, Heylin Raquel	06/04/1980		Florida Education Institute	185 Nw 13 Ave #1332	Miami, FL 33125
RPT	51821	12/26/2013	Rossano, Katie Lynn	01/12/1995	Cvs Caremark		6579 Kings Rd	Keystone Heights, FL 32656
RPT	51822	12/26/2013	Paccione, Linda A	06/08/1965	Other	Southeasern College	2249 Sw Cree Road	Port Saint Lucie, FL 34953
RPT	51823	12/26/2013	Woods, Nicholas Timothy	10/17/1986	Cvs Caremark		209 South Temple Ave	Starke, FL 32091
RPT	51824	12/26/2013	Tojar, Joseph Daniel	12/10/1991	Publix Super Market, Inc.		12231 East Colonial Dr	Orlando, FL 32826
RPT	51825	12/26/2013	Welch, Laura Kristen	06/21/1985			6314 N 9Th Avenue	Pensacola, FL 32504
RPT	51826	12/26/2013	Rudolph, Diane Carol	10/18/1963	Publix Super Market, Inc.		2040 58Th Avenue	Vero Beach, FL 32966
RPT	51827	12/26/2013	Moorer, Destany De'Ondra	09/12/1989			1000 N 6Th Avenue	Pensacola, FL 32501
RPT	51828	12/26/2013	Anderson, Jean Marie	10/17/1972	Other	Postgraduate Healthcare Education,Llc	Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
RPT	51829	12/26/2013	Rossi, Brittany Leanne	07/19/1989	Other	Florida Institute Of Technology	5 Atlantic Drive	Palm Coast, FL 32137
RPT	51830	12/26/2013	Sise, Omar Jamal	02/09/1991	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51831	12/26/2013	Valencia, Jonathan	10/24/1985	Walgreens		8337 South Park Circle	Orlando, FL 32819

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RPT	51832	12/26/2013	Rodriguez, Magela De Lamercede	09/24/1980	Winn Dixie		11252 Nw 6 St	Miami, FL 33172
RPT	51833	12/26/2013	Vasquez, Tatiana Alexandria	01/18/1994	Publix Super Market, Inc.		84 Tuscan Way	Saint Augustine, FL 32092
RPT	51834	12/26/2013	Rutkowski-Starr, Kathy Elizabeth	05/15/1969	Walgreens		5094 Ne122Nd Blvd	Oxford, FL 34484
RPT	51835	12/26/2013	Turner, Nashaiya Shacoyia	12/20/1993	Jacksonville Job Corps Center		5020 72Nd St. E.	Bradenton, FL 34203
RPT	51836	12/26/2013	Trace, Lisa Ann	06/14/1994	Other	Orange County Public Schools, Winter Park Tech	309 Breckenridge Circle Se	Palm Bay, FL 32909
RPT	51837	12/26/2013	Sloan, Stacey Marie	08/09/1980	Cvs Caremark		11527 Ashton Field Ave	Riverview, FL 33579
RPT	51838	12/27/2013	Vecchio, Florencia Dafne	05/11/1992	Cvs Caremark		3406 3406 3Rd Ave West	Bradenton, FL 34205
RPT	51839	12/27/2013	Sheffield, Nicole Elyse	06/02/1988	Walmart And Sam'S Club Pharmacies		9890 Hutchinson Park Drive	Jacksonville, FL 32225
RPT	51840	12/27/2013	Riviere, Mireille	09/05/1968	Other	Southeastern College	2500 Springdale Blvd Apt# G-303	Palm Spring, FL 33461
RPT	51841	12/27/2013	Roman, Caleb	04/11/1986	Cvs Caremark		5606 Post Oak Blvd	Wesley Chapel, FL 33543
RPT	51842	12/27/2013	Patel, Roshni Kaushik	11/12/1993	Cvs Caremark		2806 Barret Ave	Plant City, FL 33566
RPT	51843	12/27/2013	Rivery, Sivels	07/30/1973	Cvs Caremark		1013 1013 Nw 129 Pl 1013 Nw 129 Pl	Miami, FL 33182
RPT	51844	12/27/2013	Walthall, Annie Elizabeth	09/05/1990	Walmart And Sam'S Club Pharmacies		1226 Highway 331 South	Defuniak Springs, FL 32433
RPT	51845	12/27/2013	Rossman, Erin Nicole	03/15/1990	Publix Super Market, Inc.		4550 Gateway Blvd.	Wesley Chapel, FL 33544
RPT	51846	12/27/2013	Telfair, Iris Louise	05/13/1992	Other	Everest University Jacksonville	2285 West 16Th Street	Jacksonville, FL 32209
RPT	51847	12/27/2013	Slater, Heather Anne	08/03/1988	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51848	12/27/2013	Timmons, Jevon Terryll	06/20/1992	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51849	12/27/2013	Wilson, Michelle N C	01/27/1995	Other	Miami Lakes Educational Center	Florida A M University Cropper Hall 112-70177	Tallahassee, FL 32307
RPT	51850	12/27/2013	Rodriguez Diaz, Jorge L	03/26/1980	Cvs Caremark		7825 Ne Bayshore Ct Apto 105	Miami, FL 33138
RPT	51851	12/27/2013	Vallejo, Diana	02/28/1978	Other	Everest Institute	19721 Nw 48 Avenue	Miami Gardens, FL 33055
RPT	51852	12/27/2013	Negron, Debrann	12/07/1971	Walgreens		805 Havendale Blvd	Winter Haven, FL 33881
RPT	51853	12/30/2013	Veigas, Nathalee	08/28/1989	Other	Everest Institute	460 E. 23 Street Apt. 111	Hialeah, FL 33013

COMPAS DataMart Reporting System
New License Report for 2208 : Registered Pharmacy Technician
11/ 1/2013 - 12/31/2013

Sort Order: Original License Date

Processed: 1/22/2014 11:41:37PM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51854	12/30/2013	Sheposh, Doreen Marie	08/14/1953		Henry Ford Comm College	1395 6Th Street N W	Winter Haven, FL 33881
RPT	51855	12/30/2013	Watson, Holly Nicole	12/26/1986		The Precription Place	1337 Us Hwy 90 West	Defuniak Springs, FL 32433
RPT	51856	12/31/2013	Sheats, Dakota Jc	11/20/1992	Walmart And Sam'S Club Pharmacies		17000 Tamiami Trail	North Port, FL 34287
RPT	51857	12/31/2013	Bras, Glennisha Jema	07/27/1992	Other	Jacksonville Job Corps	2148 Crosshair Circle	Orlando, FL 32837
RPT	51858	12/31/2013	Grantham, Traci Ann	03/15/1964	Cvs Caremark		575 West Indiantown Rd	Jupiter, FL 33458
RPT	51859	12/31/2013	Cleaveland, Richard Jeffery	01/05/1965	Other	Ultimate Medical Academy	3033 South Buckley Point	Inverness, FL 34450
RPT	51860	12/31/2013	Taylor, Kyndall Chekia	06/15/1988		Virginia College - Pensacola	700 W Truman Ave Apt A11	Pensacola, FL 32505
RPT	51861	12/31/2013	Akuoko-Sarpong, Awo	10/10/1977		Northern Virginia Comm. Coll.	15821 Canoe Creek Dr	Jacksonville, FL 32218
RPT	51862	12/31/2013	Gordon, Ashley Marie	11/13/1984		Concorde Career Institue - Tampa	5116 Springwood Dr.	Tampa, FL 33624

Total Records: **790**

Division of
Medical Quality Assurance

MQA

Processed: 1/22/2014 11:46:38PM

COMPAS DataMart Reporting System
New License Report for 2203 : Consultant Pharmacist
11/ 1/2013 - 12/31/2013

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PU	7354	11/15/2013	Ramsaroop, Marisa Ann				16414 Sw 1St Street	Pembroke Pines, FL 33027
PU	7355	11/15/2013	Brown, Dorothy Cassandra				2235 Nw 142 Way	Pembroke Pines, FL 33028
PU	7356	11/18/2013	Beverly, Amanda Louise				23230 Stelling Ave	Port Charlotte, FL 33980
PU	7357	11/19/2013	Raczka, Richard Joseph				1004 Sw 4Th Place	Cape Coral, FL 33991
PU	7358	11/19/2013	Parker, William Cecil				11505 Blue Crane Street	Riverview, FL 33569
PU	7359	11/19/2013	Lam, Brandee Cecelia				841 Ne 98 Street	Miami Shores, FL 33138
PU	7360	11/19/2013	Byers, Courtney L				5011 Wiles Rd #206	Coconut Creek, FL 33073
PU	7361	11/25/2013	Sweet, Ragan Michelle				3244 Addison Lane	Tallahassee, FL 32317
PU	7362	12/02/2013	Hough, Mary C	03/18/1974			101 Mill Hollow Drive	Crawfordville, FL 32327
PU	7363	12/09/2013	Hickman, Lauren				121 Breakers Dr Apt 134	Myrtle Beach, SC 29579
PU	7364	12/10/2013	Puri, Chris Brune	08/31/1957			59 Cathedral Avenue	Florham Park, NJ 07932
PU	7365	12/12/2013	Gilzene, Tenille D'Andrea				3760 Inverrary Dr #2E	Lauderhill, FL 33319
PU	7366	12/18/2013	Wood, Suzette Clair				3971 Wild Lime Lane	Coral Springs, FL 33065
PU	7367	12/30/2013	Estrada, Juan Eduardo				6279 West 15 Court	Hialeah, FL 33012
PU	7368	12/30/2013	Dimarco, Salvatore Steven				16744 Sw 10Th St	Pembroke Pines, FL 33027
PU	7369	12/30/2013	Butt, Jimmy Chie-Young	03/17/1986			5000 West Oakland Park Blvd	Ft Lauderdale, FL 33313

Total Records: **16**

Division of
Medical Quality Assurance

MQA

Processed: 1/22/2014 11:49:29PM

COMPAS DataMart Reporting System
New License Report for 2204 : Nuclear Pharmacist
11/ 1/2013 - 12/31/2013

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location

Total Records:

Division of
Medical Quality Assurance

MQA

Processed: 1/22/2014 11:50:15PM

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
11/ 1/2013 - 12/31/2013

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27189	11/01/2013	Healthy Living Detox Llc				250 Thelma Avenue	Jupiter, FL 33458
PH	27190	11/01/2013	Memorial Health Care System-Talent Acqui				2261 N. University Drive Suite #102	Pembroke Pines, FL 33024
PH	27191	11/01/2013	Palm Garden Of Ocala, Llc				3400 Sw 27Th Ave	Ocala, FL 34474
PH	27192	11/01/2013	Proact Pharmacy Services, Inc				1226 Us Hwy 11	Gouverneur, NY 13642
PH	27193	11/01/2013	Destrehan Drugs Inc.				3001 Ormond Blvd Ste A	Destrehan, LA 70047
PH	27194	11/04/2013	Summerton Drugs Compounding And Dispensa				115 B Main Street	Summerton, SC 29148
PH	27195	11/05/2013	Oshun Pharmacy Discount Inc				1554 W 68Th St	Hialeah, FL 33014
PH	27196	11/05/2013	Afm Pharmacy Inc				5757 S W 8 Street #117	Miami, FL 33144
PH	27197	11/05/2013	J & S Pharmacy And Discount, Inc				4920 East 4Th Avenue	Hialeah, FL 33013
PH	27198	11/06/2013	Florida Hospital Home Infusion, Llp				11461 U.S. Hwy 301 Suite 105	Thonotosassa, FL 33592
PH	27199	11/06/2013	Pharmacy Care Center				7413 Maimi Lakes Drive	Miami Lakes, FL 33014
PH	27200	11/06/2013	Poinciana Medical Center, Inc.				325 Cypress Parkway	Kissimmee, FL 34758
PH	27201	11/06/2013	North Beaches Pharmacy, Inc				1510 Penman Rd	Jacksonville Beach, FL 32250
PH	27202	11/06/2013	South Broward Hospital District				3700 Johnson Street	Hollywood, FL 33021
PH	27203	11/06/2013	Main Avenue Pharmacy				1094 A Main Ave	Clifton, NJ 07011
PH	27204	11/06/2013	Homechoice Partners, Inc				426 W. 2Nd Avenue	Albany, GA 31701
PH	27205	11/06/2013	Clarksville Pharmacy I Llc				801 N 2Nd St	Clarksville, TN 37040
PH	27206	11/06/2013	North Brevard County Hospital District				951 North Washington Ave	Titusville, FL 32796
PH	27207	11/06/2013	Fountain Park Pharmacy Inc				1901 Manhattan Blvd Building F, Suite 104	Harvey, LA 70058
PH	27208	11/06/2013	Hope Hospice & Community Services				9470 Health Park Circle	Fort Myers, FL 33908

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
11/ 1/2013 - 12/31/2013

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27209	11/07/2013	Fort Myers Kidney Center, Llc				14181 S. Tamiami Trail	Fort Myers, FL 33912
PH	27210	11/07/2013	As Pharmacy L.L.C.				11719 Bee Caves Road Suite 201	Bee Cave, TX 78738
PH	27211	11/08/2013	Ag Naples Senior Housing I Opco, Llc				4750 Aston Gardens Way	Naples, FL 34109
PH	27212	11/08/2013	Palm Garden Of West Palm Beach, Llc				300 Executive Center Drive	West Palm Beach, FL 33401
PH	27213	11/08/2013	Global Medical Equip & Supplies				922 20Th St	Haleyville, AL 35565
PH	27214	11/12/2013	Genoa Healthcare Of Florida, Llc				5664 Sw 60Th Avenue Suite 2A	Ocala, FL 34474
PH	27215	11/12/2013	Ridgeland Allied Pharmacy Inc				804 West Bloomingdale Ave	Brandon, FL 33511
PH	27216	11/12/2013	West Florida- Mht, Llc				2901 W Swann Avenue	Tampa, FL 33609
PH	27217	11/12/2013	West Florida- Mht, Llc				2901 W Swann Avenue	Tampa, FL 33609
PH	27218	11/12/2013	Palm Garden Of Port St. Lucie, Llc				1751 Hillmoor Drive Se	Port Saint Lucie, FL 34952
PH	27219	11/12/2013	Palm Garden Of Vero Beach, Llc				1755 37Th Street	Vero Beach, FL 32960
PH	27220	11/13/2013	Beacom Pharmacy, Inc.				752 West Flagler St	Miami, FL 33130
PH	27221	11/13/2013	Beacom Pharmacy Inc.				752 West Flagler St	Miami, FL 33130
PH	27222	11/13/2013	Lili Pharmacy And Discount Llc				4869 Nw 36Th St	Miami Springs, FL 33166
PH	27223	11/13/2013	Leal Pharmacy Llc				632 Washington Ave	Homestead, FL 33030
PH	27224	11/13/2013	South Broward Hospital District				1150 North 35Th Avenue Suite 270	Hollywood, FL 33021
PH	27225	11/13/2013	Gulf Medical Services Inc				6776 Caroline St	Milton, FL 32570
PH	27226	11/13/2013	South Broward Hospital District				20801 Biscayne Blvd Suite 200	Aventura, FL 33180
PH	27227	11/13/2013	South Broward Hospital District				603 North Flamingo Road Suite 157	Pembroke Pines, FL 33028
PH	27228	11/13/2013	South Broward Hospital District				801 North Flamingo Road	Pembroke Pines, FL 33028
PH	27229	11/13/2013	Peak Rx, Llc				801 S Perry St Suite 100	Castle Rock, CO 80104

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
11/ 1/2013 - 12/31/2013

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27230	11/13/2013	Florida Hospital Home Infusion, Llp				556 Florida Central Parkway Suite 1044	Longwood, FL 32750
PH	27231	11/13/2013	Emilior Pharmaceutical Compounding, Inc				2510 Westchester Ave Ste 207	Bronx, NY 10461
PH	27232	11/13/2013	Ck / Kc Inc.				436 East Main Street	Middletown, PA 17057
PH	27233	11/13/2013	Manhattan Beach Pharmacy Inc				1224 Ave U	Brooklyn, NY 11229
PH	27234	11/15/2013	Florida Health Sciences Center				10718 Countryway Blvd	Tampa, FL 33626
PH	27235	11/15/2013	Abbaspour Inc.				7320 E. 82Nd Street	Indianapolis, IN 46256
PH	27236	11/18/2013	Blue Moon Pharmacy & Discount Corp				7884 Nw 52 St	Doral, FL 33166
PH	27237	11/18/2013	Center For Alcohol And Drug Studies, Inc				3151 Prince Drive	Lake Worth, FL 33461
PH	27238	11/18/2013	Bioscrip Infusion Services, Llc				5912 Breckenridge Parkway Suite E	Tampa, FL 33610
PH	27239	11/18/2013	Arriva Medical, Llc				500 Eagles Landing Drive Suite B	Lakeland, FL 33810
PH	27240	11/19/2013	Opharma Group Llc				4733 W. Atlantic Ave Suite 2	Delray Beach, FL 33445
PH	27241	11/19/2013	Opharma Group Llc				4733 W. Atlantic Ave Suite 2	Delray Beach, FL 33445
PH	27242	11/19/2013	Palm Garden Of Jacksonville, Llc				5725 Spring Park Road	Jacksonville, FL 32216
PH	27243	11/19/2013	Lillian Pharmacy, Inc				12831 Sixth Street	Lillian, AL 36549
PH	27244	11/19/2013	Hospice Of North East Florida, Inc				4266 Sunbeam Road	Jacksonville, FL 32257
PH	27245	11/21/2013	University Of Miami				3850 Hollywood Blvd Suite 1B	Hollywood, FL 33021
PH	27246	11/21/2013	Publix Super Markets, Inc				7524 Dr Phillips Blvd	Orlando, FL 32819
PH	27247	11/21/2013	R & A Gupta Llc				25444 Sr 46 Suite 3	Sorrento, FL 32776
PH	27248	11/21/2013	Surgery Center Of North Miami, Llc				585 N W 161 Street	Miami, FL 33169
PH	27249	11/21/2013	Coral Springs Police Dept Humane Unit				4130 Hw 121 Ave	Coral Springs, FL 33065
PH	27250	11/22/2013	Meds Direct Rx Of Ny, Llc				882 3Rd Ave 10Th Floor, Suite 1000	Brooklyn, NY 11232

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
11/ 1/2013 - 12/31/2013

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27251	11/26/2013	Remed Pharmacy				10163 S Us Hwy 1	Port Saint Lucie, FL 34952-5610
PH	27252	11/26/2013	First Choice Pharmacy Inc				5743 Sw 8 St	Miami, FL 33144
PH	27253	11/26/2013	Compound Md Inc.				10948 N 56Th Street Suite 202	Temple Terrace, FL 33617
PH	27254	11/26/2013	Sarju Group Llc				305 Clyde Morris Blvd Suite #200	Ormond Beach, FL 32174
PH	27255	11/26/2013	C & M Healthpro Llc				1530-B West Vine Street	Kissimmee, FL 34741
PH	27256	11/27/2013	Vista Specialty Pharmacy				235 W Hwy 50	Clermont, FL 34711
PH	27257	11/27/2013	Quality Rx Pharma Inc				1778 W Flagler St	Miami, FL 33135
PH	27258	11/27/2013	Romat Ventures, Inc.				166 Marion Oaks Blvd. Unit 9	Ocala, FL 34473
PH	27259	12/02/2013	Diabetes Management & Supplies				10 Commerce Ct	New Orleans, LA 70123
PH	27260	12/03/2013	Streamline Llc				14965 Old St. Augustine Rd Unit # 108	Jacksonville, FL 32258
PH	27261	12/03/2013	Carepoint Healthcare Llc				911 B N Plum Grove Rd	Schaumburg, IL 60173
PH	27262	12/03/2013	Sky Pharmacy And Discount Corp				2414 Sheridan St	Hollywood, FL 33020
PH	27263	12/04/2013	White Drug Co. Of Jamestown Inc				706 38Th Street Nw Unit Def	Fargo, ND 58102
PH	27264	12/04/2013	Accredo Health Group, Inc.				2825 W. Perimeter Rd Ste 112	Indianapolis, IN 46241
PH	27265	12/04/2013	Noble Health Services, Inc.				6040 Tarbell Road	Syracuse, NY 13206
PH	27266	12/04/2013	Burmans Pharmacy Inc				3400 Edgmont Avenue	Brookhaven, PA 19015
PH	27267	12/04/2013	N R M Holdings Ltd.				600 W. Manchester Ave	Los Angeles, CA 90044
PH	27268	12/04/2013	Henry Ford Pharmacy Advantage Southfield				735 John R Road	Troy, MI 48083
PH	27269	12/05/2013	St Petersburg General Hospital				6500 38Th Avenue North	Clearwater, FL 33767
PH	27270	12/05/2013	Madame Rx, Llc				829 Spruce Street Suite 100	Philadelphia, PA 19107

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
11/ 1/2013 - 12/31/2013

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27271	12/05/2013	Medscript Pharmacy				14401 John Humphrey Dr	Orland Park, IL 60462
PH	27272	12/05/2013	Livingston Infusion Care, Inc				603 Montrose Avenue	South Plainfield, NJ 07080
PH	27273	12/06/2013	Wal-Mart Stores East, Lp				2677 Roosevelt Blvd	Largo, FL 33760
PH	27274	12/06/2013	Wal-Mart Stores East, Lp				2171 Gulf To Bay Blvd	Clearwater, FL 33765
PH	27275	12/06/2013	Valued Choice Pharmacy Llc				5537 Sheldon Road Suite Y	Tampa, FL 33615
PH	27276	12/06/2013	Ginger Pharmacy				739 South Orange Blossom Trail 441	Apopka, FL 32703
PH	27277	12/10/2013	Univv Inc				2814 Lee Blvd Unit 1	Lehigh Acres, FL 33971
PH	27278	12/10/2013	Manatee Pharmacy Services, Inc				3549 1St Street	Bradenton, FL 34208
PH	27279	12/11/2013	Compounding Pharmacies Of La, Inc				128 Curran Lane	Lafayette, LA 70506
PH	27280	12/11/2013	Leehar Distributors Inc				701 Emerson Rd Ste 332	Saint Louis, MO 63141
PH	27281	12/11/2013	Ppm, Llc				3300 Nw 56Th Suite 101	Oklahoma City, OK 73112
PH	27282	12/11/2013	Allcare Pc				112 S Oxley Dr	Lyons, GA 30436
PH	27283	12/11/2013	700 Pharmacy Llc				700 East Townshipline Road Suite Ll1	Havertown, PA 19083
PH	27284	12/11/2013	Premier Pharmacy Labs, Inc				8265 Commercial Way	Weeki Wachee, FL 34613
PH	27285	12/11/2013	Oncomed Oncology Pharmacy Of Phildelphia				1553 Chester Pike Suite 206	Crum Lynne, PA 19022
PH	27286	12/11/2013	Healthsouth Rehabilitation Hospital Of L				901 Clearwater Largo Rd North	Largo, FL 33770
PH	27287	12/12/2013	Senior Care Pharmacy Of Florida Llc				4175 S. Pipkin Road Suite 208	Lakeland, FL 33811
PH	27288	12/12/2013	Paramount Pharmacy Llc				7200 S 180Th St Ste 140	Tukwila, WA 98188
PH	27289	12/12/2013	Lourdes Dialysis, Llc				7560 Red Bug Lake Rd Ste 1048	Oviedo, FL 32765

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
11/ 1/2013 - 12/31/2013

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27290	12/12/2013	Pharmetrics Speciality Group Of Tampa				11880 28Th Street N. Suite 100-C	Saint Petersburg, FL 33716
PH	27291	12/12/2013	Wal-Mart Stores East, Lp				1499 South Dixie Hwy	Homestead, FL 33033
PH	27292	12/12/2013	Vista Medical Group, Llc				15511 N Florida Ave Suite C-2	Tampa, FL 33613
PH	27293	12/12/2013	Julius Holdings, Llc				13244 Telecom Dr.	Tampa, FL 33637
PH	27294	12/13/2013	Oneway Pharmacy, Inc				823 N.W. 119Th Street	North Miami, FL 33168
PH	27295	12/13/2013	Apothecary Of Harleysville, Llc				345 Main St Suite 7	Harleysville, PA 19438
PH	27296	12/13/2013	Rph Partners, Llc				6388 Folsom Dr.	Beaumont, TX 77706
PH	27297	12/16/2013	Healthsouth Rehabilitation Hospital Of S				6400 Edgelake Drive	Sarasota, FL 34230
PH	27298	12/16/2013	Health South Sunrise Rehabilitation Hosp				4399 Nob Hill Rd	Sunrise, FL 33351
PH	27299	12/16/2013	Insight Pharmaceutical Solutions Llc				700 East Township Line Road Suite LI2A	Havertown, PA 19083
PH	27300	12/16/2013	Shriners Hospitals For Children				12502 U S F Pine Drive	Tampa, FL 33612
PH	27301	12/16/2013	Pharmacy Express & Discount, Corp				6350 Sw 40 St	Miami, FL 33155
PH	27302	12/16/2013	Antares Pharmacy Discount Inc				6741 Coral Way Suite 52-53	Miami, FL 33155
PH	27303	12/16/2013	Legacy Drugstore Corp				4700 Nw 7 St #1	Miami, FL 33126
PH	27304	12/18/2013	Express Scripts Pharmacy, Inc				5701 E. Hillsborough Avenue Suite 1300	Tampa, FL 33610
PH	27305	12/18/2013	Express Scripts Pharmacy, Inc				8800 Hidden River Parkway	Tampa, FL 33637
PH	27306	12/18/2013	Liberty For All Pharmacy, Inc				8444 W. Oakland Park Blvd	Sunrise, FL 33351
PH	27307	12/18/2013	Bay County Health System, Llc				801 E6Th St Suite 604	Panama City, FL 32401
PH	27308	12/19/2013	Rx Care Specialty Pharmacy, Llc				2812 W. Mlk Blvd	Tampa, FL 33607

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
11/ 1/2013 - 12/31/2013

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27309	12/19/2013	Rose Nursing & Pharmacy Services				10008 Pines Blvd	Pembroke Pines, FL 33024
PH	27310	12/19/2013	Bay County Health System, Llc				2421 Thomas Drive	Panama City Beach, FL 32408
PH	27311	12/19/2013	Sterile Compounding Pharmacy, Llc				7381 114Th Ave Suite 405 A	Largo, FL 33773
PH	27312	12/19/2013	A & K Medical Supply, Inc				1450 Emerson Avenue Suite 110	Maclean, VA 22101
PH	27313	12/19/2013	Pharmex Llc.				393 Center Pointe Circle Suite 1481 & 1483	Altamonte Springs, FL 32701
PH	27314	12/19/2013	J And S Rx Pharmacy Inc.				1252 E Hillsborough Ave	Tampa, FL 33604
PH	27315	12/19/2013	Maheem Enterprise Llc				5055 Babcock Street Suite #3	Palm Bay, FL 32905
PH	27316	12/19/2013	Adventist Health System/Sunbelt, Inc.				894 East Altamonte Dr 3Rd Floor	Altamonte Springs, FL 32701
PH	27317	12/19/2013	Bay County Health System, Llc				2420 Jenks Ave	Panama City, FL 32405
PH	27318	12/19/2013	Ekg Pharmacy Llc				7305 N W 36 Street	Miami, FL 33166
PH	27319	12/19/2013	Gardens Drugs, Inc				2100 45Th St #B1	West Palm Beach, FL 33407
PH	27320	12/20/2013	Gmh Tequesta Holdings Llc				701 Old Dixie Hwy	Tequesta, FL 33469
PH	27321	12/20/2013	Ricky'S Pharmacy Corp				2324 Sw 67 Ave	Miami, FL 33155
PH	27322	12/23/2013	Pccc Of Volusia Llc				1055 N Dixie Freeway	New Smyrna Beach, FL 32168
PH	27323	12/23/2013	Arlington Dialysis Center, Llc				7645 Merrill Rd Suite 204	Jacksonville, FL 32277
PH	27324	12/23/2013	Interamerican Services Corporation				6801 Nw 77 Ave Suite 106	Miami, FL 33166
PH	27325	12/23/2013	Fleming Island Pharmacy Llc				2349 Village Square Parkway Unit # 106	Fleming Island, FL 32003
PH	27326	12/23/2013	Advance Pharmacy Service				4726 N. Habana Ave Suite 101	Tampa, FL 33614
PH	27327	12/23/2013	Blue Rx Pharmacy				251 Park Blvd	Miami, FL 33126
PH	27328	12/23/2013	West Florida-Pph, Llc				1501 Pasadena Avenue South	Saint Petersburg, FL 33707

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
11/ 1/2013 - 12/31/2013

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27329	12/26/2013	St Pete Compounding Pharmacy Llc				3434 13Th Ave	Saint Petersburg, FL 33713
PH	27330	12/26/2013	Express Pharmacy Since 2013, Llc				1218 Winter Garden Vineland Rd #112	Winter Garden, FL 34787
PH	27331	12/26/2013	Tcs Labs L.L.C				4000 Park Street N.	Saint Petersburg, FL 33709
PH	27332	12/27/2013	Wal-Mart Stores East, Lp				3155 S. Federal Hwy	Delray Beach, FL 33483
PH	27333	12/27/2013	Boca Raton Pharmacy, Inc				4802 Nw 2 Avenue	Boca Raton, FL 33431
PH	27334	12/27/2013	Avenix Pharmaceuticals				3200 N Federal H'Way Ste 223	Boca Raton, FL 33431
PH	27335	12/27/2013	Galen Of Florida Inc.				6500 38Th Avenue North	Saint Petersburg, FL 33710
PH	27336	12/27/2013	Pharmacy Corporation Of America				7970 Bay Berry Road Ste 4	Jacksonville, FL 32256
PH	27337	12/27/2013	Option Care Enterprises, Inc.				11341 Lindbergh Blvd	Fort Myers, FL 33913
PH	27338	12/27/2013	Germaine Pharmacy & Compounding Inc				2511 Swan Ave Ste 102	Tampa, FL 33609
PH	27339	12/27/2013	United Pharmacy, Llc				3951 North Haverhill Road Suite 120-121	West Palm Beach, FL 33417
PH	27340	12/27/2013	Pharmerica Drug Systems, Llc				2200 Tall Pines Drive Ste 118	Largo, FL 33771
PH	27341	12/27/2013	Pharmerica Drug Systems, Llc				775 Bell Road	Sarasota, FL 34240
PH	27342	12/27/2013	Pharmacy Corporation Of America				337 Northlake Blvd	Altamonte Springs, FL 32701
PH	27343	12/30/2013	Kidney Kare Of Jacksonville, Inc.				4168 Southpoint Parkway Suite 103	Jacksonville, FL 32216
PH	27344	12/30/2013	Comfort Iv Therapy, Llc				1800 Northgate Blvd Ste A7	Sarasota, FL 34234
PH	27345	12/30/2013	University Of South Florida Board Of Tru				13330 Usf Laurel Drive Suite 6116	Tampa, FL 33612
PH	27346	12/31/2013	Briovarx Of Indiana, Llc				1050 Patrol Road	Jeffersonville, IN 47130

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New License Report for 2205 : Pharmacy
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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location

Total Records: **158**

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2205	AAP PHARMACY				20515		12/02/2013	3PTR	APPL IN PROC	171 WESTWARD DRIVE MIAMI SPRINGS, FL 33166		Miami-Dade
2205	ACARIAHEALTH PHARMACY, INC	ACARIAHEALTH PHARMACY, INC	PH	26727	19690	03/05/2013	12/11/2013	3PTR	CLEAR	6923 LEE VISTA BLVD SUITE 300 ORLANDO, FL 32822	407-903-1308	Orange
2205	ADVANCE PHARMACY SERVICE		PH	27326	20498	12/23/2013	11/26/2013	2PTR	CLEAR	14457 CORONADO DR SPRING HILL, FL 34609		Hernando
2205	ADVENTIST HEALTH SYSTEM SUNBELT HEALTHCA	EXPEDIEN RX PHARMACY			20542		12/06/2013	3PTR	APPL IN PROC	582 MONROE RD STE 1412 B SANFORD, FL 32771		Seminole
2205	ADVENTIST HEALTH SYSTEM/SUNBELT, INC	FLORIDA HOSPITAL CENTRAL DISTRIBUTION CE			20486		11/22/2013	3PTR	APPL IN PROC	601 EAST ROLLINS STREET ORLANDO, FL 32803		Orange
2205	ADVENTIST HEALTH SYSTEM/SUNBELT, INC.	FLORIDA HOSPITAL KISSIMMEE AMBULATORY IN			20471		11/18/2013	3PTR	APPL IN PROC	2450 N. ORANGE BLOSSOM TRAIL KISSIMMEE, FL 34744		Osceola
2205	ADVENTIST HEALTH SYSTEM/SUNBELT, INC.	FLORIDA HOSPITAL ALTAMONTE AMBULATORY IN	PH	27316	20472	12/19/2013	11/18/2013	3PTR	CLEAR	601 ROLLINS ST ORLANDO, FL 32803		Orange
2205	ANTARES PHARMACY DISCOUNT INC	ANTARES PHARMACY DISCOUNT INC	PH	27302	20514	12/16/2013	12/02/2013	3PTR	CLEAR	6741 CORAL WAY SUITE 52-53 MIAMI, FL 33155		Miami-Dade
2205	ARRIVA MEDICAL, LLC	RX CARE CLUB	PH	27239	20442	11/18/2013	11/08/2013	3PTR	CLEAR	4252 NW 120TH AVENUE CORAL SPRINGS, FL 33065		Broward
2205	ARTWOOD PROJECTS II, LLC	EMA'S PHARMACY			20605		12/30/2013	3PTR	APPL IN PROC	1075 NE 84 ST MIAMI, FL 33138		Miami-Dade
2205	AVENIX PHARMACEUTICALS	AVENIX PHARMACEUTICALS	PH	27334	20543	12/27/2013	12/10/2013	2PTR	CLEAR	3200 N FEDERAL H'WAY STE 223 BOCA RATON, FL 33431		Palm Beach
2205	AZUL PHARMACY CORP	AZUL PHARMACY CORP			20571		12/06/2013	2PTR	APPL IN PROC	11338 SW 184 Street MIAMI, FL 33157		Miami-Dade
2205	BAPTIST HOSPITAL	PHARMACY DEPARTMENT			20468		11/15/2013	3PTR	APPL IN PROC	1000 W. MORENO STREET PENSACOLA, FL 32501		Escambia
2205	BAYCARE HOME CARE, INC.	BAYCARE HOME CARE			20608		12/31/2013	2PTR	APPL IN PROC	8452 118TH AVENUE NORTH LARGO, FL 33773		Pinellas
2205	BLUE RX PHARMACY	BLUE RX PHARMACY	PH	27327	20526	12/23/2013	12/03/2013	3PTR	CLEAR	251 PARK BLVD MIAMI, FL 33126		Miami-Dade
2205	BOCA RATON PHARMACY INC	SPECIALTY CARE PHARMACY			20592		12/26/2013	3PTR	APPL IN PROC	4802 NW 2 AVENUE BOCA RATON, FL 33431		Palm Beach
2205	BOCA RATON PHARMACY, INC	SPECIALTY CARE PHARMACY	PH	27333	20487	12/27/2013	11/22/2013	3PTR	CLEAR	4802 NW 2 AVENUE BOCA RATON, FL 33431		Palm Beach
2205	BOCA RATON REGIONAL HOSPITAL, INC	CENTER FOR HEMATOLOGY ONCOLOGY	PH	8177	1232	11/10/1982	12/11/2013	3PTR	CLEAR	800 MEADOWS RD BOCA RATON, FL 33486	(561) 955-4060	Palm Beach
2205	BOCA RATON REGIONAL HOSPITAL, INC		PH	30	5		12/11/2013	3PTR	CLEAR	800 MEADOWS RD BOCA RATON, FL 33486-2304		Palm Beach
2205	C & M HEALTHPRO LLC	ALL-SCRIPTS PHARMACY	PH	27255	20450	11/26/2013	11/12/2013	2PTR	CLEAR	8902 GREY HAWK PT. ORLANDO, FL 32836		Orange
2205	EKG PHARMACY LLC	EKG PHARMACY LLC	PH	27318	20523	12/19/2013	12/03/2013	3PTR	CLEAR	7305 NW 36 STREET MIAMI, FL 33166		Miami-Dade
2205	EMERGENCY PHARMACY, INC.	EMERGENCY PHARMACY, INC.			20600		12/30/2013	3PTR	APPL IN PROC	4742 WEST FLAGLER ST CORAL GABLES, FL 33134		Miami-Dade
2205	EPIC CARE PHARMACY LLC	EPIC CARE PHARMACY LLC			20443		11/08/2013	2PTR	APPL IN PROC	1002 N W 139TH TERRACE PEMBROKE PINES, FL 33028		Broward

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2205	FIRST CHOICE PHARMACY INC	FIRST CHOICE PHARMACY INC	PH	27252	20415	11/26/2013	11/04/2013	2PTR	CLEAR	5743 SW 8 ST MIAMI, FL 33144		Miami-Dade
2205	FLAGLER HOSPITAL INC	FLAGLER HOSPITAL PHARMACY			20574		12/20/2013	3PTR	APPL IN PROC	400 HEALTH PARK BLVD SAINT AUGUSTINE BEAC, FL 32086		St.Johns
2205	FLEMING ISLAND PHARMACY LLC	FLEMING ISLAND PHARMACY LLC	PH	27325	20424	12/23/2013	11/05/2013	3PTR	CLEAR	2349 VILLAGE SQUARE PARKWAY UNIT # 106 FLEMING ISLAND, FL 32003		Clay
2205	FLORIDA HEALTH CARE PLAN, INC.	FLORIDA HEALTH CARE PLANS			20422		11/05/2013	3PTR	APPL IN PROC	4932 W STATE ROAD 46 UNIT 1000 SANFORD, FL 32771		Seminole
2205	FLORIDA HOSPITAL HOME INFUSION, LLP	FLORIDA HOSPITAL HOME INFUSION, TAMPA DI	PH	27198	20385	11/06/2013	11/06/2013	2PTR	CLEAR	11461 U.S. HWY 301 SUITE 105 THONOTOSASSA, FL 33592		Hillsborough
2205	FLORIDA HOSPITAL WATERMAN, INC.	FLORIDA HOSPITAL WATERMAN	PH	27360	20551	01/08/2014	12/13/2013	3PTR	CLEAR	1000 WATERMAN WAY TAVARES, FL 32778		Lake
2205	GALEN OF FLORIDA INC.	ST. PETERSBURG HOME INFUSION DEPT	PH	27335	20545	12/27/2013	12/12/2013	2PTR	CLEAR	6500 38TH AVENUE NORTH SAINT PETERSBURG, FL 33710		Pinellas
2205	GALEN OF FLORIDA, INC.	COLUMBIA ST. PETERSBURG MEDICAL CENTER	PH	8139	1206	12/09/1982	12/05/2013	2PTR	CLEAR	6500 38TH AVE N ST PETERSBURG, FL 33710-1629	(727) 341-4831	Pinellas
2205	GARDENS DRUGS, INC	GARDENS DRUGS	PH	27319	20521	12/19/2013	12/03/2013	3PTR	ERROR	2100 45TH ST #B 1 WEST PALM BEACH, FL 33407		Palm Beach
2205	GEORGE PHARMACY, INC.	GEORGE PHARMACY			20425		11/05/2013	3PTR	APPL IN PROC	2566 S. ATLANTIC AVE DAYTONA BEACH SHORES, FL 32118		
2205	GERMAINE PHARMACY & COMPOUNDING INC	GERMAINE PHARMACY & COMPOUNDING INC	PH	27338	20467	12/27/2013	11/15/2013	3PTR	CLEAR	2511 SWAN AVE STE 102 TAMPA, FL 33609		Hillsborough
2205	GINGER PHARMACY	GINGER PHARMACY	PH	27276	20417	12/06/2013	11/04/2013	3PTR	CLEAR	1541 CRAWFORD DRIVE APOPKA, FL 32703		Orange
2205	GREEN HOPE PHARMACY INC	GREEN HOPE PHARMACY INC			20595		12/30/2013	3PTR	APPL IN PROC	5309 SW 8TH STREET MIAMI, FL 33134		Miami-Dade
2205	GUARDIAN PHARMACY OF TAMPA, LLC				20593		12/30/2013	3PTR	APPL IN PROC	9402 INTERNATIONAL COURT N SAINT PETERSBURG, FL 33716		Pinellas
2205	GULF MEDICAL SERVICES INC	GULF MEDICAL SERVICES INC	PH	27225	20430	11/13/2013	11/07/2013	3PTR	CLEAR	6776 CAROLINE ST MILTON, FL 32570		Santa Rosa
2205	HCA HEALTH SERVICES OF FLORIDA, INC	REGIONAL MEDICAL CENTER BAYONET POINT			20569		12/17/2013	3PTR	APPL IN PROC	14000 FIVAY ROAD HUDSON, FL 34667		Pasco
2205	HCA HEALTH SERVICES OF FLORIDA, INC.	OAK HILL HOSPITAL			20604		12/30/2013	3PTR	APPL IN PROC	11375 CORTEZ BLVD BROOKSVILLE, FL 34613		Hernando
2205	HEALTH PROMOTE PHARMACY	HUMAN & ANIMAL PHARMACY	PH	27352	20553	01/03/2014	12/13/2013	2PTR	CLEAR	12701 SOUTH JOHN YOUNG PARKWAY #120 ORLANDO, FL 32837		Orange
2205	HEALTH SOUTH SUNRISE REHABILITATION HOSP	HEALTH SOUTH SUNRISE REHABILITATION HOSP	PH	27298	20518	12/16/2013	12/02/2013	3PTR	CLEAR	4399 NOB HILL RD SUNRISE, FL 33351		Broward
2205	HEALTHCARE PHARMACY LLC	HEALTHCARE PHARMACY	PH	27362	20603	01/09/2014	12/30/2013	3PTR	CLEAR	1933 N PINELLAS AVE TARPON SPRINGS, FL 34689		Pinellas
2205	HEALTHSOUTH REHABILITATION HOSPITAL OF L	HEALTHSOUTH REHABILITATION HOSPITAL OF L	PH	27286	20478	12/11/2013	11/21/2013	2PTR	CLEAR	901 CLEARWATER LARGO RD NORTH LARGO, FL 33770		Pinellas
2205	HOSPICE OF NORTH EAST FLORIDA, INC	COMMUNITY HOSPICE PHARMACY	PH	27244	20421	11/19/2013	11/05/2013	3PTR	CLEAR	4266 SUNBEAM ROAD JACKSONVILLE, FL 32257		Duval

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2205	IFB PHARMACY, LLC	IFB PHARMACY, LLC			20438		11/08/2013	3PTR	APPL IN PROC	6517 TAFT STREET SUITE 101 HOLLYWOOD, FL 33024		Broward
2205	INFUSION SYSTEMS OF SWFL	MYERLEE PHARMACY			20613		12/31/2013	3PTR	APPL IN PROC	1826 BAY SCOUT DRIVE FORT MYERS, FL 33907		Lee
2205	J-M WARD ENTERPRISES, LLC	JOHN'S PHARMACY			20538		12/06/2013	3PTR	APPL IN PROC	9048 BONITA BEACH RD SE BONITA SPRINGS, FL 34135		Lee
2205	JAC NAPLES L.L.C.	GULF SHORE APOTHECARY			20512		12/02/2013	3PTR	WITHDREW	1400 GULFSHORE BLVD N. #100 NAPLES, FL 34102		Collier
2205	JELMA CORPORATION	HAPPY PHARMACY	PH	10142	1980	12/14/1987	12/05/2013	3PTR	CLEAR	13379 SW 42ND STREET MIAMI, FL 33175-3204		Miami-Dade
2205	LAKE SHORE HMA, LLC	SHANDS LAKE SHORE REGIONAL MEDICAL CENTE			20582		12/23/2013	3PTR	APPL IN PROC	368 NE FRANKLIN ST LAKE CITY, FL 32055		Columbia
2205	LATIN QUARTERS DRUG STORE INC.	LATIN QUARTERS DRUG STORE INC.			20511		12/02/2013	3PTR	APPL IN PROC	425 SW 22ND AVE SUITE #E1 MIAMI, FL 33135		Miami-Dade
2205	LEE MEMORIAL HEALTH SYSTEM	HEALTHPARK MEDICAL CENTER			20559		12/17/2013	3PTR	APPL IN PROC	9981 S. HEALTHPARK DRIVE FORT MYERS, FL 33908		Lee
2205	LEGACY DRUGSTORE CORP	LEGACY DRUGSTORE CORP	PH	27303	20488	12/16/2013	11/22/2013	3PTR	CLEAR	4700 NW 7 ST #1 MIAMI, FL 33126		Miami-Dade
2205	LIBERTY FOR ALL PHARMACY, INC	LIBERTY FOR ALL PHARMACY, INC	PH	27306	20504	12/18/2013	11/27/2013	3PTR	CLEAR	8444 W OAKLAND PARK BLVD SUNRISE, FL 33351		Broward
2205	LIFE LINE HOME CARE SERVICES, INC.	LIFE LINE HOME CARE SERVICES	PH	27387	20566	01/15/2014	12/17/2013	3PTR	CLEAR	3740 ST. JOHNS BLUFF RD SUITE 1 JACKSONVILLE, FL 32224		Duval
2205	LOWLITE INVESTMENTS, INC	OLYMPIA PHARMACY			20466		11/15/2013	3PTR	APPL IN PROC	6700 CONROY RD STE 140 ORLANDO, FL 32835		Orange
2205	MARLINS PHARMACY & DISCOUNT INC.	MARLINS PHARMACY & DISCOUNT			20554		12/13/2013	3PTR	APPL IN PROC	439-441 NW 12 AVE MIAMI, FL 33128		Miami-Dade
2205	MARTIN MEMORIAL MEDICAL CENTER INC.	TRADITION MEDICAL CENTER	PH	27107	20205	09/30/2013	11/05/2013	3PTR	CLEAR	PO BOX 9010 STUART, FL 34994		Martin
2205	MARTINEZ DRUG STORE INC		PH	13023	3748	08/19/1994	11/01/2013	3PTR	CLEAR	874 E 41 STREET HIALEAH, FL 33013	(305) 693-0441	Miami-Dade
2205	MAZ PHARMACY DISCOUNT CORP	MAZ PHARMACY DISCOUNT CORP			20610		12/31/2013	3PTR	APPL IN PROC	3825 W. 16TH AVE SUITE #6 HIALEAH, FL 33012		Miami-Dade
2205	MEDOZ PHARMACY OF POLK INC.	MEDOZ PHARMACY OF POLK			20586		12/26/2013	3PTR	APPL IN PROC	4581 BARRISTER DRIVE CLERMONT, FL 34711		Lake
2205	MEDOZ PHARMACY OF POLK INC.	MEDOZ PHARMACY OF POLK			20589		12/26/2013	3PTR	APPL IN PROC	4581 BARRISTER DRIVE CLERMONT, FL 34711		Lake
2205	MEMORIAL HOSPITAL WEST	MEMORIAL HOSPITAL WEST			20591		12/30/2013	3PTR	APPL IN PROC	703 NORTH FLAMINGO ROAD PEMBROKE PINES, FL 33029		Broward
2205	MOUNT SINAI CENTER OF FLORIDA, INC.	MOUNT SINAI CENTER OF FLORIDA, INC.	PH	27374	20558	01/16/2014	12/16/2013	3PTR	CLEAR	4300 ALTON ROAD MIAMI BEACH, FL 33140		Miami-Dade
2205	ONE INFUSION PHARMACY, LLC	ONE INFUSION PHARMACY			20506		11/27/2013	3PTR	APPL IN PROC	3850 BIRD ROAD SUITE 303 MIAMI, FL 33146		Miami-Dade
2205	ONE INFUSION PHARMACY, LLC	ONE INFUSION PHARMACY			20520		12/03/2013	3PTR	APPL IN PROC	3850 BIRD ROAD SUITE 303 MIAMI, FL 33146		Miami-Dade

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2205	OPHARMA GROUP LLC	ONCOLOGY PHARMACY GROUP	PH	27240	20381	11/19/2013	11/13/2013	3PTR	CLEAR	4733 W. ATLANTIC AVE SUITE 2 DELRAY BEACH, FL 33445		Palm Beach
2205	OPTION CARE ENTERPRISES, INC	WALGREENS INFUSION SERVICES			20490		11/22/2013	3PTR	APPL IN PROC	PO BOX 377 DEERFIELD, IL 60015		Unknown
2205	OPTION CARE ENTERPRISES, INC.	WALGREENS INFUSION SERVICES	PH	27337	20500	12/27/2013	11/27/2013	3PTR	CLEAR	P O BOX 377 DEERFIELD, IL 60015		Unknown
2205	PALM BEACH COUNTY HEALTH CARE DISTRICT	HEALTH CARE DISTRICT PHARMACY	PH	21939	14279	04/17/2006	12/04/2013	3PTR	CLEAR	1250 SOUTHWINDS DRIVE LANTANA, FL 33462	561 655 8100	Palm Beach
2205	PEARL SHAH LLC	ST. PETERSBURG PHARMACY			20461		11/15/2013	3PTR	APPL IN PROC	6399 38TH AVE NORTH SUITE A-5 SAINT PETERSBURG, FL 33710		Pinellas
2205	PHARMERICA DRUG SYSTEMS, LLC	PHARMERICA			20590		12/26/2013	3PTR	APPL IN PROC	3690 NW 53 ST STE 104 FORT LAUDERDALE, FL 33309		Broward
2205	PHARMETRICS SPECIALITY GROUP OF TAMPA	PHARMETRICS SPECIALITY RX OF TAMPA	PH	27290	20423	12/12/2013	11/05/2013	3PTR	CLEAR	11880 28TH STREET N. SUITE 100-C SAINT PETERSBURG, FL 33716		Pinellas
2205	PHARMEX LLC.	PHARMEX	PH	27313	20410	12/19/2013	11/01/2013	3PTR	CLEAR	393 CENTER POINTE CIRCLE SUITE 1481 & 1483 ALTAMONTE SPRINGS, FL 32701		Seminole
2205	PHARMSCRIPT OF FLORIDA LLC	PHARMSCRIPT OF FLORIDA SOUTH	PH	27387	20429	01/22/2014	11/07/2013	3PTR	CLEAR	81 GLENDALE AVE EDISON, NJ 08817		Unknown
2205	PREMIER PHARMACY LABS, INC	PREMIER PHARMACY LABS, INC	PH	27284	20436	12/11/2013	11/08/2013	3PTR	CLEAR	PO BOX 6510 SPRING HILL, FL 34611		Hernando
2205	PUBLIX SUPER MARKETS, INC.	PUBLIX PHARMACY #0822	PH	27390	20455	01/23/2014	11/12/2013	3PTR	CLEAR	P O BOX 32018 LAKELAND, FL 33802		Polk
2205	PVRX PHARMACY CORP	PVRX PHARMACY CORP	PH	27380	20513	01/21/2014	12/02/2013	3PTR	CLEAR	10327 NW 27 AVE MIAMI, FL 33147		Miami-Dade
2205	RICKY'S PHARMACY CORP	RICKY'S PHARMACY	PH	27321	20525	12/20/2013	12/03/2013	3PTR	CLEAR	2324 SW 67 AVE MIAMI, FL 33155		Miami-Dade
2205	SARJU GROUP LLC	COMMUNITY PHARMACY OF ORMOND BEACH	PH	27254	20445	11/26/2013	11/08/2013	3PTR	CLEAR	305 CLYDE MORRIS BLVD SUITE #200 ORMOND BEACH, FL 32174		Volusia
2205	SENIOR CARE PHARMACY OF FLORIDA LLC	SENIOR CARE PHARMACY OF FLORIDA	PH	27287	20428	12/12/2013	11/05/2013	3PTR	CLEAR	4175 S. PIPKIN ROAD SUITE 208 LAKELAND, FL 33811		Polk
2205	SHAFA PHARMACY	SHAFA PHARMACY	PH	27389	20583	01/22/2014	12/23/2013	2PTR	CLEAR	6447 LAKE WORTH RD LAKE WORTH, FL 33463		Palm Beach
2205	SHRINERS HOSPITALS FOR CHILDREN	SHRINERS HOSPITALS FOR CHILDREN	PH	27300	20530	12/16/2013	12/04/2013	3PTR	CLEAR	12502 U S F PINE DRIVE TAMPA, FL 33612		Hillsborough
2205	SILVER LAKE PHARMACY, LLC	SILVER LAKE PHARMACY	PH	27348	20494	01/03/2014	11/26/2013	3PTR	CLEAR	2705 COTTON CT. EUSTIS, FL 32726		Lake
2205	SIMPLE SCRIPTS INC	SIMPLE SCRIPTS INC			20453		11/12/2013	3PTR	APPL IN PROC	528- 528 HIALEAH DR HIALEAH, FL 33010		Miami-Dade
2205	SKY PHARMACY AND DISCOUNT CORP	SKY PHARMACY AND DISCOUNT CORP	PH	27262	20469	12/03/2013	11/15/2013	3PTR	CLEAR	2414 SHERIDAN ST HOLLYWOOD, FL 33020		Broward
2205	SOUTHERN BAPTIST HOSPITAL OF FLORIDA, IN	BAPTIST MEDICAL CENTER			20570		12/18/2013	3PTR	APPL IN PROC	800 PRUDENTIAL DR JACKSONVILLE, FL 32207		Duval
2205	SPRINGS DRUG STORE INC.	SPRINGS DRUG STORE INC.			20484		11/21/2013	3PTR	APPL IN PROC	261 WESTWARD DR SUITE 108 MIAMI SPRINGS, FL 33166		Miami-Dade
2205	ST JOSEPH'S HOSPITAL, INC	ST. JOSEPH'S HOSPITAL-NORTH	PH	24185	16867	07/27/2009	12/05/2013	3PTR	CLEAR	4211 VAN DYKE ROAD PHARMACY DEPARTMENT LUTZ, FL 33558	(813) 443-7401	Hillsborough

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2205	ST PETERSBURG GENERAL HOSPITAL	GALEN OF FLORIDA/COLUMBIA ST. PETERSBURG	PH	27269	20465	12/05/2013	11/15/2013	2PTR	CLEAR	6500 38TH AVENUE NORTH CLEARWATER, FL 33767		Pinellas
2205	SUNCOAST COMMUNITY HEALTH CENTERS INC.	PALM RIVER COMMUNITY HEALTH CENTER			20452		11/12/2013	3PTR	APPL IN PROC	PO BOX 1349 RUSKIN, FL 33575		Hillsborough
2205	SUNNY PHARMACY & DISCOUNT INC	SUNNY PHARMACY & DISCOUNT INC	PH	27379	20457	01/21/2014	11/12/2013	3PTR	CLEAR	2140 NW 36 STREET MIAMI, FL 33142		Miami-Dade
2205	SYNERGY PHARMACY SERVICES, INC	SYNERGY PHARMACY SERVICES, INC			20482		11/21/2013	2PTR	APPL IN PROC	31201 US HWY 19 N STE 2 PALM HARBOR, FL 34684		Pinellas
2205	TCS LABS L.L.C	COMPOUNDING SHOP	PH	27331	20579	12/26/2013	12/17/2013	3PTR	CLOSED	4000 PARK STREET N. SAINT PETERSBURG, FL 33709	727-381-9799	Pinellas
2205	TRIM NUTRITION PHARMACY LLC	NUTREX PHARMACY	PH	24695	17464	06/17/2010	12/11/2013	3PTR	CLEAR	22079 US HWY 19 NORTH CLEARWATER, FL 33765	(727) 286-6231	Pinellas
2205	UNITED PHARMACY, LLC	UNITED PHARMACY, LLC	PH	27339	20451	12/27/2013	11/12/2013	3PTR	CLEAR	3951 NORTH HAVERHILL ROAD SUITE 120 & 121 WEST PALM BEACH, FL 33417		Palm Beach
2205	UNIVERSITY OF SOUTH FLORIDA BOARD OF TRU	UNIVERSITY OF SOUTH FLORIDA BOARD OF TRU	PH	27345	20435	12/30/2013	11/07/2013	2PTR	CLEAR	13330 USF LAUREL DRIVE SUITE 6116 TAMPA, FL 33612		Hillsborough
2205	VALLEJOS PHARMACY, CORP	VALLEJOS PHARMACY, CORP			20578		12/23/2013	3PTR	APPL IN PROC	4750 NW 7 ST MIAMI, FL 33126		Miami-Dade
2205	VILLAGES TRICOUNTY MEDICAL CENTER, INC.	VILLAGES REGIONAL HOSPITAL			20449		11/12/2013	3PTR	APPL IN PROC	1451 El Camino Real THE VILLAGES, FL 32159		Lake
2205	VINTAGE PHARMACY, LLC	VINTAGE PHARMACY			20474		11/06/2013	3PTR	APPL IN PROC	PO BOX 67 LADY LAKE, FL 32158		Lake
2205	VISTA MEDICAL GROUP, LLC	MEDICASCRIPTS PHARMACY	PH	27292	20475	12/12/2013	11/18/2013	3PTR	CLEAR	156 GRAND VILLA DRIVE LUTZ, FL 33548		Hillsborough
2205	WAL-MART STORES EAST, LP	WALMART PHARMACY #10-3183	PH	27291	20432	12/12/2013	11/07/2013	3PTR	CLEAR	702 SW 8TH ST BENTONVILLE, AR 72716-0230		Unknown
2205	WAL-MART STORES EAST, LP	WALMART PHARMACY #10-6400	PH	27358	20433	01/07/2014	11/07/2013	3PTR	CLEAR	702 SW 8TH ST BENTONVILLE, AR 72716-0230		Unknown
2205	WAL-MART STORES EAST, LP	WALMART PHARMACY #10-2406	PH	27332	20476	12/27/2013	11/19/2013	3PTR	CLEAR	702 SW 8TH ST. BENTONVILLE, AR 72716		Unknown
2205	WAL-MART STORES EAST, LP	WALMART PHARMACY #10-4141			20615		12/31/2013	3PTR	APPL IN PROC	702 SW 8TH ST. BENTONVILLE, AR 72716		Unknown
2205	WAL-MART STORES EAST, LP	WALMART PHARMACY #10-3161			20616		12/31/2013	3PTR	APPL IN PROC	702 SW 8TH ST. BENTONVILLE, AR 72716		Unknown
2205	WALGREEN CO.	WALGREENS #15495	PH	27349	20505	01/03/2014	11/27/2013	3PTR	CLEAR	PO BOX 901 DEERFIELD, IL 60015		Unknown
2205	WALGREEN CO.	WALGREENS #15178			20541		12/06/2013	3PTR	APPL IN PROC	P O BOX 901 DEERFIELD, IL 60015		Unknown

Total: 109

Division of
Medical Quality Assurance

MQA

COMPAS DataMart Reporting System
New License Report for 2209 : Pharmacy Technician Training Program
11/ 1/2013 - 12/31/2013

Sort Order: Original License Date

Processed: 1/22/2014 11:56:31PM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RTTP	440	11/01/2013	Leon Medical Centers				11501 S W 40Th St	Miami, FL 33165
RTTP	441	11/01/2013	Maria Angelica Pharmacy & Discount Inc				11355 West Flagler Street	Miami, FL 33174
RTTP	442	11/01/2013	Ocala Pharmacy Llc				8602 Sw Hwy 200 Ste # A& B	Ocala, FL 34481
RTTP	443	11/01/2013	Med Care Choice Pharmacy				3570 Consumer Street Suite 8	West Palm Beach, FL 33404
RTTP	444	11/05/2013	Rx One Pharmacy				717 West Lancaster Rd	Orlando, FL 32809
RTTP	445	11/05/2013	Xinim Corporation / Holly Hill Pharmacy				1702 Ridgewood Ave Suite C	Holly Hill, FL 32117
RTTP	446	11/05/2013	School Board Of Polk County				700 Edgewood Drive North	Fort Meade, FL 33841
RTTP	447	11/08/2013	Asa College				3909 Ne 163Rd St	North Miami Beach, FL 33160
RTTP	448	11/12/2013	Tata Pharmacy Discount, Llc				3810 Sw 8Th Street	Coral Gables, FL 33134
RTTP	449	11/13/2013	My Community Pharmacy				2615 State Rd 7 Ste B530	Wellington, FL 33414
RTTP	450	11/13/2013	Wise'S Drug Store Inc				708 Sw 4 Ave	Gainesville, FL 32601
RTTP	451	11/13/2013	Cardinal Health, Inc.				1929 N W 40 Court	Pompano Beach, FL 33064
RTTP	452	11/14/2013	Scott'S Pharmacy, Llc				6505 Hwy 29 North	Molino, FL 32577
RTTP	453	11/15/2013	East Coast Pharmacy Llc				695 N Washington Ave Ste 101	Titusville, FL 32796
RTTP	454	11/18/2013	Sunshine Pharmacy Services, Llc				120 Carter Blvd #6	Polk City, FL 33868
RTTP	455	11/18/2013	Sullivan And Cogliano Training Centers,				7740 North Kendall Drive	Miami, FL 33156
RTTP	456	11/19/2013	Bushnell Pharmacy				417 N West Street	Bushnell, FL 33513
RTTP	457	12/03/2013	Colonial Drugs Of Orlando Llc.				155 E. New England Avenue	Winter Park, FL 32789
RTTP	458	12/04/2013	Radiance Enterprises Inc				1153 Main St Ste 102	Dunedin, FL 34698
RTTP	459	12/04/2013	Trinity Pharmacy Ii Inc.				1474 S Belcher Rd	Clearwater, FL 33764
RTTP	460	12/06/2013	Ensley Pharmacy, Inc				8814 C. Palafox St	Pensacola, FL 32514
RTTP	461	12/06/2013	Adel Consulting Inc.				3606 Madaca Lane	Tampa, FL 33618

COMPAS DataMart Reporting System
New License Report for 2209 : Pharmacy Technician Training Program
11/ 1/2013 - 12/31/2013

Sort Order: Original License Date

Processed: 1/22/2014 11:56:31PM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RTTP	462	12/09/2013	Jalvarez Pharmacy, Inc				483 Nw 42 Avenue	Miami, FL 33126
RTTP	463	12/10/2013	Life Worth Living Foundation				6488 Currin Dr	Orlando, FL 32835
RTTP	464	12/11/2013	Med-Care Medical Center				9766 Sw 24Th Street S-9	Miami, FL 33165
RTTP	465	12/11/2013	Peter Botros Pharmacy, Inc				1431 Orange Camp Rd Suite #102	Deland, FL 32724
RTTP	466	12/12/2013	Ready Scripts, Inc				9783 Sw 72Nd St	Miami, FL 33173
RTTP	467	12/12/2013	Chancellor Institute, Inc.				5648 West Atlantic Blvd.	Margate, FL 33063
RTTP	468	12/13/2013	Pharmacy Plus, Inc.				7645 Merrill Rd Ste #210	Jacksonville, FL 32277
RTTP	469	12/17/2013	Vital Rx, Inc				1000 E Atlantic Blvd Ste 110	Pompano Beach, FL 33060
RTTP	470	12/17/2013	Rph Solutions Inc				14306 7Th Street	Dade City, FL 33523
RTTP	471	12/17/2013	Chemists N Druggists, Inc.				3599 W. Woolbright Road	Boynton Beach, FL 33436
RTTP	472	12/18/2013	Psj Pharmacy Llc				6801-1 Us Hwy 1 North	Cocoa, FL 32927
RTTP	473	12/18/2013	Friends Pharmacy, Llc				1813 E. Fowler Avenue	Tampa, FL 33612
RTTP	474	12/19/2013	Physician Choice Pharmacy				4529 N Pine Island Rd	Sunrise, FL 33351
RTTP	475	12/26/2013	J'S Pharmacy Llc				6416 Ridge Rd	Port Richey, FL 34668

Total Records: **36**

Provider Name	Provider #	Course Name	Course #	Status	Approved Date
FLORIDA PHARMACY ASSOCIATION	50-754	REDUCING MEDICATION ERRORS THROUGH IMPLEMENTING A CONTINUOUS QUALITY IMPROVEMENT PROGRAM	20-419004	APPROVED	11/17/2013
UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY	S0-2419	SELF-STUDY ACTIVITY FOR PHARMACISTS IN LONG-TERM CARE	20-418206	APPROVED	10/18/2013
DADE COUNTY PHARMACY ASSN C/O ACEVES	S0-2488	18TH ANNUAL SOUTH FLORIDA RESIDENCY SEMINAR: ON THE ROAD TO PROVIDING PRIMARY CARE SERVICES.RCE.SAT	20-418313	APPROVED	12/S/2013
AMERICAN SOCIETY OF CONSULTANT PHARMACISTS	50-3997	2013 ASCP ANNUAL MEETING & EXHIBITION	20-414015	APPROVED	11/17/2013
DADE COUNTY PHARMACY ASSN C/O ACEVES	50-2488	18TH ANNUAL SOUTH FLORIDA RESIDENCY SEMINAR ON THE ROAD TO PROVIDING PRIMARY CARE SERVICES - RCE SUN	20-418314	APPROVED	12/5/2013
FREECE.COM	S0-3S1S	THE GRAYING OF HIV	20-418236	APPROVED	11/17/2013
FLORIDA SOCIETY OF HEALTH SYSTEM PHARMACISTS	S0-3036	NORTHEAST SOCIETY FALL MEETING: PHARMACY PRACTICE UPDATES 2013	20-411293	APPROVED	10/1/2013
FLORIDA PHARMACY ASSOCIATION	50-754	REGULATORY AND LAW CONFERENCE	20-418496	APPROVED	11/17/2013
FLORIDA A&M UNIVERSITY COLLEGE OF PHARMACY AND PHARMACEUTICAL SCIENCES	50-3072	AN INITIAL CERTIFICATION SEMINAR FOR CONSULTANT PHARMACISTS AND CONSULTANT RECERTIFICATION	20-423790	APPROVED	12/11/2013

Provider Name	Provider #	Course Name	Course #	Status	Approved Date
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Individual Name	Title of Course	Hours Offered
Uyen Francis	Ulcerative Colitis: The What, When, and Why of Treatment	1.5 hours of General
Uyen Francis	Clinical Practice Skills in a Changing World	13 hours of General

MEETING MINUTES
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
FULL BOARD MEETING

December 3-4, 2013
Hilton Hotel University of Florida
1714 SW 34th Street
Gainesville, FL 32607
(352) 371-3600

Board Members:
Albert Garcia, BPharm, MHL, Chair, Miami
Jeffery J. Mesaros, PharmD, Vice-Chair, Orlando
Leo J. "Lee" Fallon, BPharm, PhD, The Villages
Debra B. Glass, BPharm, Tallahassee
Gavin Meshad, Consumer Member, Sarasota
Mark Mikhael, PharmD, Orlando
Jeenu Philip, BPharm, Jacksonville
Lorena Risch, Consumer Member, Bradenton
Michele Weizer, PharmD, Boca Raton

Board Staff:
Tammy Collins, Acting Executive Director
Christy Robinson, Program Operations Administrator
Jay Cumbie, Regulatory Specialist II

Board Counsel:
David Flynn, Assistant Attorney General
Lynette Norr, Assistant Attorney General

Department of Health Staff:
Yolonda Green, Assistant General Counsel
Matthew Witters, Assistant General Counsel
Christopher Jurich, Assistant General Counsel

Tuesday, December 3, 2013 – 1:00 p.m.

1:00 p.m. Call to Order by Albert Garcia, BPharm, MHL, Chair

All Board members were present with the exception of Gavin Meshad.

Mr. Garcia welcomed newly appointed Board member Jeenu Philip to the Florida Board of Pharmacy.

Mr. Garcia informed everyone in attendance of Mark Whitten's recent promotion to "Chief of Investigative Services" and thanked him for all of his hard work and dedication to the Board of Pharmacy during his tenure as Executive Director.

TAB 1 REPORTS

A. Chair's Report – Albert Garcia, BPharm, MHL, Chair

1. Update on Executive Director Position

Mr. Garcia informed the Board that Tammy Collins will be serving as Acting Executive Director during the search for a new permanent Executive Director.

Mr. Garcia also gave a brief overview of the process the Department will go through in selecting a new Executive Director.

Mr. Garcia introduced a request from the University of Florida pharmacy on campus to modify their hours for a week during the holidays.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to approve the request. Motion carried.

B. Acting Executive Director's Report – Tammy Collins

Ms. Collins informed the Board that the full Rules Committee report will be heard on December 4, 2013 as to give the Board members a chance to review the discussions from the earlier meeting.

Ms. Collins also stated that the committee reports will be heard on the second day of the full Board meeting moving forward.

Dr. Mesaros informed the Board of a question that arose at the Rules Committee regarding Nurse practitioners. Dr. Mesaros then asked Dr. Mikhael to present the question and to have Mr. Flynn's response included on the record.

Dr. Mikhael asked if advanced registered nurse practitioners are allowed to order prescriptions under the attending physicians name and if that would be considered mislabeling?

Mr. Flynn stated that a pharmacist can dispense any prescription that is written by a healthcare provider which is authorized by state or federal law to write said prescription. Mr. Flynn stated any verification issue that a pharmacist comes across can be verified using the same process as any other prescription such as calling the physician if the pharmacist wishes to do so.

George Malone approached the Board to request further clarification on the legality concerning "labeling" of a prescription between an ANRP and a Doctor.

Brian Kahan approached the Board to suggest a revision of the rule that describes the definition of a prescription to state that an ARNP has prescriptive authority to create a valid prescription.

Bob Parrado approached the Board to suggest the Board attempt to change the insurance requirement for the pharmacy to use the MPI of the ARNP as opposed to the physicians DEA number.

1. Compounding Rules Committee – Michele Weizer, PharmD

Dr. Weizer provided a report from the December 2, 2013 Compounding Rules Committee and stated that the committee is ready to give two recommendations to the Board. Dr. Weizer highlighted the two different exceptions that were discussed at the committee meeting including facility design and the cleaning of a workspace.

Dr. Weizer introduced Federal Legislation titled "HR 3204 Drug Quality and Security Act" that had recently been signed into law by the President and requested that the Board open up the office-use compounding rule to look at quantity issues as well as find any conflicts that may be present due to the new Federal legislation.

Mr. Flynn gave a high level summary of "HR 3204Drug Quality and Security Act" and gave a brief description of how this legislation could potentially affect the practice and profession of pharmacy in Florida.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to open up House Bill 3204 to look at limited quantities and to look at the Board's rule with implications from the FDA. Motion carried.

2. Update on Sterile Compounding Permits

Ms. Collins provided an update on the sterile compounding permits. Ms. Collins stated that 28 applications had been submitted with 12 currently under review in the Board office and 16 having already been issued. Ms. Collins stated that all Pharmacies that currently engage in sterile compounding have until March 21, 2014 to obtain this permit free of charge.

3. Healthy Weight Liaison

Ms. Collins informed the Board of the Surgeon General's request for a volunteer to serve as a "Healthy Weight Liaison" from each Board.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to nominate Albert Garcia to be the "Healthy Weight Liaison". Motion carried.

C. Attorney General's Report – Lynette Norr, Assistant Attorney General

1. Request for Declaratory Statement – David Benoit

Mr. Flynn gave a brief overview of the petition for a declaratory statement that was submitted by a Mr. Benoit. Mr. Flynn stated that an exemption provision for "isolated transactions" in Chapter 465 that already answers the question effectively and recommended that the Board deny the petition for declaratory statement.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to deny the petition for a declaratory statement. Motion carried.

D. Chief Investigative Services Report – Mark Whitten

Mark Whitten thanked the Board for their support over his time working for the Board. Mr. Whitten also mentioned that the majority of the 28 sterile compounding permits that have been issued have been from institutional pharmacies.

Mr. Whitten stated that pharmacy opened the fiscal year with 4,987 inspections needing to be done with 1,867 having already been completed at a completion rate of 37.44%. Mr. Whitten also stated that dispensing practitioners started this fiscal year with 8,049 and have completed 2,830 at a completion percentage of 35.16%. Mr. Whitten stated that out of the 649 sterile compounding facilities, 361 have been inspected with 6 of the facilities being closed.

Dr. Mesaros thanked Mark Whitten for all his hard work and dedication during his tenure as the Executive Director of the Board of Pharmacy.

TAB 2 BUSINESS – Albert Garcia, BPharm, MHL, Chair

A. Ratification of Issued Licenses/Certificates & Staffing Ratios

1. Pharmacist (Licensure) (Client 2201) – 198
2. Pharmacist (Exam Eligibility) (Client 2201) – 104
3. Pharmacist Interns (Client 2202) – 932
4. Registered Pharmacy Technicians (Client 2208) – 880
5. Consultant Pharmacist (Client 2203) – 37
6. Nuclear Pharmacist (Client 2204) – 0
7. Pharmacies/Facilities (Client 2205) – 136
8. Registered Pharmacy Technician Ratios (2:1 or 3:1)- 78
9. Pharmacy Technician Training Program (Client 2209) - 28

10. CE Providers – 10
11. CE Courses – 24
12. CE Individual Requests (Approved) – 3
13. CE Individual Requests (Denied) - 0

Motion: by Dr. Fallon, seconded by Dr. Weizer, to ratify licenses, certificates, & staffing ratios. Motion carried.

B. Review and Approval of Minutes

1. October 8-9, 2013 Meeting Minutes

Motion: by Mrs. Glass, seconded by Dr. Fallon, to approve the October 8-9, 2013 meeting minutes. Motion carried.

C. Election of Officers

1. Chair

Motion: by Dr. Weizer, seconded by Dr. Fallon, to nominate Dr. Jeff Mesaros for Chair. Motion carried.

2. Vice-Chair

Motion: by Dr. Mikhael, seconded by Dr. Mesaros, to nominate Mrs. Debra Glass for Vice-Chair.

Motion: by Dr. Mesaros, seconded by Mrs. Risch, to nominate Dr. Michele Weizer for Vice-Chair.

The Board conducted a vote and Dr. Michele Weizer was elected Vice-Chair by a vote of 5 – 3. Motion carried.

D. Presentations

1. GetMyRx, Inc

Edwin Bayo, Esquire and the CEO of GetMyRx, Inc. gave a brief presentation regarding their mobile device app designed for ordering prescriptions.

Public Comments: Albert Garcia opened up the floor to public comments.

Dr. Mesaros requested the Board consider changing the date of the February 4-5, 2014 Board of Pharmacy meeting to February 11-12, 2014.

Dr. Mesaros brought up the issue of employees that are labeled cashier and only function as a cashier being counted against the technician ratio.

Dr. Salem approached the Board to speak about the issue and stated that employees that are working non-drug functions should not be counted against the technician ratio.

The Board referenced a discussion had at the June 4-5, 2013 Board of Pharmacy meeting in Miami, FL and reiterated that electronic prescriptions for controlled substances are recognized and authorized by Florida law as long as they are compliant with CFR. The Board also reiterated the fact that a fax copy of an electronically generated prescription, though not electronically submitted, is not authorized by Florida law. The Board went on to elaborate on that point stating that a prescription has to be created, submitted, and received electronically in order to be considered a valid electronic prescription.

Motion: by Dr. Fallon, seconded Dr. Weizer to **ADJOURN** the meeting at 3:01pm. Motion carried.

Wednesday, October 9, 2013 – 9:00 a.m.

9:00 a.m. Call To Order by Albert Garcia, BPharm, MHL, Chair

All members were present with the exception of Gavin Meshad.

Mr. Garcia introduced the newest Board member Jeenu Philip to the audience and had Mr. Philip give a brief introduction and his history in the profession of pharmacy.

Mr. Garcia informed the audience that the Rules Committee report, originally scheduled for December 3, 2013, is going to be presented today.

Mr. Mesaros gave a brief overview of the proceedings of the Rules Committee and asked Ms. Norr to present the rules and rule changes that are ready for a Board vote.

Ms. Norr presented the changes to 64B16-30.001 and requested a vote from the Board.

Motion: by Dr. Mesaros, seconded by Dr. Weizer, to accept the changes to 64B16-30.001. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Ms. Norr then presented the changes to Rule 64B16-28.450 and requested a vote from the Board.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, to accept the changes to Rule 64B16-28.450. Motion carried.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Ms. Norr presented the comments presented by JAPC (Joint Administrative Procedures Committee) regarding Rule 64B16-28.301 and explained that the Rules committee suggested that the JAPC comments were addressed by Rule 64B16-28.140.

Motion: by Dr. Mesaros, seconded by Dr. Weizer, that the comments presented by JAPC are covered by Rule 64B16-28.140. Motion carried.

Ms. Norr presented the changes to Rule 64B16-28.100 and requested a vote from the Board.

Motion: by Dr. Mesaros, seconded by Dr. Weizer, to accept the changes to Rule 64B16-28.100. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Ms. Norr presented Rule 64B16-26.608 and requested a vote from the Board.

Dr. Weizer suggested editing the language to include the words "of record" when referring to consultant pharmacists.

Mr. Garcia suggested editing the language by replacing the word "licensed" with "registered" when referring to pharmacy technicians.

Motion: by Dr. Mikhael, seconded by Dr. Weizer, to accept Rule 64B16-26.608 with edits suggested by Dr. Weizer and Mr. Garcia. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Fallon, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Ms. Norr presented Rule 64B16-28.303 to the Board and requested a vote from the Board.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to accept the Rule as presented. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

At the request of Mr. Garcia, Ms. Norr gave a brief overview of JAPC (Joint Administrative Procedures Committee) and its functions for the benefit of the students in the audience.

Ms. Norr presented the changes to Rule 64B16-28.140 and requested a vote from the Board.

Motion: by Mr. Philip, seconded by Dr. Fallon, to accept the changes to Rule 64B16-28.140. Motion carried.

Motion: by Dr. Fallon, seconded by Dr. Mikhael, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Fallon, seconded by Mrs. Glass, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

TAB 3 Prosecuting Attorney Report – Yolonda Green, Assistant General Counsel

1. Prosecuting Services Report

Ms. Yolonda Green presented the Prosecuting Services Unit.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to allow PSU to continue prosecuting cases one year or older. Motion carried.

Ms. Green informed the Board that the Prosecution Services Unit has assembled a Pharmacy team within the Unit that will deal exclusively with Pharmacy cases. The team will be led by Matthew Witters and will also include Christopher Jurich, Ana Gargollo-McDonald, and a fourth team member to be determined later.

TAB 4 DISCIPLINARY CASES – Yolonda Green, Assistant General Counsel

A. SETTLEMENT AGREEMENT– APPEARANCE REQUIRED CASES

A-1 Millenium Pharmacy, Inc., PH 25300. Miami, FL.
Case No. 2013-02802 - PCP: Weizer/Meshad

Respondent violated:
Count One: Section 465.023(1)(c), F.S. (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-27.420(4)(a), F.A.C., by failing to insure a registered pharmacy technician was properly identified.
Count Two: Section 465.023(1)(c), F.S. (2012), through a violation of Rule 64B16-28.102(5)(a), F.A.C., by failing to have a copy of a current Facts and Comparisons.
Count Three: Section 465.023(1)(c), F.S. (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.110, F.A.C., by failing to remove from the prescription department all pharmaceuticals which bear upon the container an expiration date which has been reached.
Count Four: Section 465.023(1)(c), F.S. (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.118(4), F.A.C., because copy of inventory for purchased medication was missing lot numbers.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay costs limited to $2,000.00. Respondent shall pay a fine of $1,000.00. Respondent must correct all deficiencies.

Respondent was not present.

This case was pulled by the Prosecution Services Unit.

A-2 Senior Living Properties, PH 22106 – Maitland, FL.
Case No. 2013-06756 – PCP: Mesaros/Glass

Respondent violated:
Count One: Section 456.072(1)(dd), F.S. (2010 and 2012), by violating Section 456.073, F.S., by providing regulated services as a class I institutional pharmacy without an active status permit.

Terms of Settlement Agreement: Respondent shall by present. Respondent shall pay a fine of $1,000.00. Respondent shall pay costs of $1,285.74.

The Regional Director of Operations for Senior Living Properties was present and sworn in by the court reporter. The respondent was not represented by counsel.

Motion: by Dr. Fallon, seconded by Dr. Weizer, to accept the Settlement Agreement. Motion carried.

A-3 Dino Aljoni, PS 38099 – St. Augustine, FL
Case No. 2012-08758 – PCP: Fallon/Meshad

Respondent violated:
Count One: Section 465.016(1)(e), F.S. (2011), by violating 893.04(1)(b), F.S. (2011).

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay an administrative fine in the amount of $5,000.00 payable within 90 days. Respondent shall pay costs limited to $2,833.91 within 90 days. Respondent shall be placed on probation for a period of 1 year with standard terms.

The respondent was present and sworn in by the court reporter. The respondent was not represented by counsel.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, to reject the Settlement Agreement. Motion carried.

Motion: by Dr. Weizer, seconded by Mr. Garcia, for the same Settlement Agreement with the addition of a 12 hour laws and rules CE. Motion failed due to a 3 in favor to 4 in opposition vote.

Motion: by Mr. Philip, seconded by Dr. Mikhael, for the original Settlement Agreement with the addition of the 12 hour laws and rules CE but without the 1 year probationary period. Motion carried with Mr. Garcia, Mrs. Glass, and Dr. Weizer in opposition.

A-4 Shiang-Tyng Lee, PS 39134 – Jacksonville, FL
Case No. 2011-19742 – PCP: Glass/Mesaros

Respondent violated
Count One: Section 465.016(1)(h), F.S. (2012), by having been disciplined by a regulatory agency in another state for any offense that would constitute a violation of this chapter.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay administrative fine in the amount of $2,000.00 payable within 30 days. Respondent shall pay costs of $1,627.50. Respondent shall be placed on probation for 1 year. Respondent shall complete a 12 hour laws and rules CE to be completed within 1 year.

Respondent was present and sworn in by the court reporter. Respondent was represented by Robert P. Esgro.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to allow Mr. Esgro to serve as counsel as a Qualified Representative. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to reject the Settlement Agreement. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Fallon, for the same Settlement Agreement with the addition of the condition that the respondent not be permitted to work as a PDM during the probationary period. Motion carried.

A-5 Scott Edward Kierenia, PS 47160 – Winter Garden, FL
Case No. 2013-06313 – PCP: Weizer/Meshad

Count One: Respondent violated Section 465.016(1)(g), F.S. (2012), by furnishing upon prescription an ingredient or article different in any manner from the ingredient or article prescribed.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay a fine in the amount of $1,000.00 within 30 days. Respondent shall pay costs of $1,248.98 within 90 days. Respondent shall complete 8 hour med errors course.

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, to accept the Settlement Agreement. Motion carried.

A-6 Sinkiwe Chiwara, PS 36603 – Lauderdale Lakes, FL
Case No. 2013-04483 – PCP: Weizer/Meshad

Count One: Respondent violated Section 465.016(1)(r), F.S. (2012), by violating Section 465.022(11)(a), F.S. (2012), by failing to ensure the Permittee's compliance with Rule 64B16-28.102(4), F.A.C., which requires that the prescription department of each pharmacy be provided with adequate sanitation to insure the prescription department is operating under clean, sanitary, uncrowded, and health conditions.
Count Two: Respondent violated Section 465.016(1)(r), F.S. (2012), by violating 465.022(11)(a), F.S. (2012), by failing to ensure the Permittee's compliance with Rule 64B16-28.110, F.A.C., which requires expired medications be removed from the shelves.
Count Three: Respondent violated Section 465.016(1)(r), F.S. (2012), by violating Section 465.022(11)(a), F.S. (2012), by violating Section 893.07(1)(b), F.S. (2012), by failing to maintain a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by him or her.
Count Four: Respondent violated 465.016(1)(e), F.S. (2012), by violating Section 499.005(2), F.S. (2012), by the adulteration or misbranding of any drug, device, or cosmetic.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay administrative fine in the amount of $2,500.00 payable within 30 days. Respondent must pay costs not to exceed $1,016.70. Respondent shall be placed on probation for the period of one year. Respondent must completed a 12 hour laws and rules CE within one year.

Respondent was present and sworn in by the court reporter. Respondent was represented by Brian Kahan, Esquire.

Motion: by Mr. Garcia, seconded by Mrs. Glass, to reject the Settlement Agreement. Motion carried.

Motion: by Mr. Garcia, seconded by Mrs. Glass, for the same Settlement Agreement with the condition that she can only act as a PDM at the pharmacy holding permit PH23858. Motion carried.

Motion: by Dr. Mesaros, seconded by Mrs. Glass, to extend payment deadline to one year. Motion carried.

A-7 El Vignoble, LLC, PH 23858. Lauderdale Lakes, FL
Case No. 2013-04482 – PCP Weizer/Meshad

Count One: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-102(4), F.A.C., which requires that the prescription department of each pharmacy be provided with adequate sanitation to insure the prescription department is operating under clean, sanitary, uncrowded, and healthy conditions.
Count Two: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.110, F.A.C., which requires expired medications be removed from the shelves.
Count Three: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Section 893.07(1)(b), F.S. (2012), which requires dispensers of controlled substances to maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by him or her.
Count Four: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Section 499.005(2), F.S. (2012), by the adulteration or misbranding of any drug, device, or cosmetic.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay a fine of $2,500.00 within 30 days. Respondent shall pay costs not over $1,087.03. Respondent shall be placed on probation for a period of one year with terms to include: semi-annual inspections, development of a corrective action plan, and a mandate to appear in front of the Board within the last 3 months of probationary period.

Sinikiwe Chiwara was present on behalf of El Vignoble, LLC and sworn in by the court reporter. Respondent was represented by Brian Kahan, Esquire.

Motion: by Dr. Mikhael, seconded by Mr. Philip, to accept the Settlement Agreement with the oral amendment to extend payment deadline to one year. Motion carried.

A-8 Melissa Terpos, RPT 39879 – Stuart, FL
Case No. 2013-11591 – PCP Glass/Mesaros

Count One: Respondent violated Section 465.016(1)(e), F.S. (2012), by violating Section 893.13(6)(a), F.S. (2012), by being "in actual possession of a controlled substance" without having a valid prescription for the controlled substance.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay a fine of $2500.00. Respondent shall pay costs through the date of entry of the final order. Respondent shall be placed on a probationary period of one year to run concurrent with any PRN contract. Respondent shall receive an evaluation from PRN within 60 days and comply with any requirements presented by PRN.

Respondent was present and sworn in by the court reporter. The respondent was not represented by counsel.

Motion: Dr. Fallon, seconded by Dr. Weizer, to reject the Settlement Agreement. Motion carried.

A-9 HVVP Rx, LLC, PH 25109 – Seminole, FL
Case No. 2013-06250 – PCP Fallon/Glass

Count One: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.820(3)(a), F.A.C.

Count Two: Respondent violated Section 465.023(1)(c). F.S. (2012), by violating Rule 64B16-28.830(5).
Count Three: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-27.797(7)(b), F.A.C.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay a fine of $2,500.00. Respondent shall pay costs of $3, 254.88. Respondent shall surrender Special Parenteral/Enteral modifier. Respondent shall be placed on a probationary period of one year.

Respondent (Pharmacy Manager) was present and sworn in by the court reporter. Respondent was represented by Daniel G. Musca, Esquire.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to accept the Settlement Agreement. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Mesaros, to impose costs. Motion carried.

A-10 Uchenna Chineye Ezenwa, PS 42502 – Pembroke Pines, FL
Case No. 2013-03004 – PCP Fallon/Glass

Count One: Respondent violated Section 465.016(1)(t)(1), F.S. (2012), by committing an error or omission during the performance of a specific function of prescription drug processing.

Terms of Settlement Agreement: Respondent shall be present. Respondent must pay a fine of $1,000.00. Respondent must pay costs of $1,022.43. Respondent must complete an 8 hour continuing education course in the prevention of medication errors.

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Dr. Mikhael, seconded by Mrs. Risch, to accept the Settlement Agreement. Motion carried.

A-11 Palm Springs General Hospital, PH 2235. Hialeah, FL
Case No. 2013-04842 – PCP Mesaros/Risch

Count One: Section 456.072(1)(k), F.S. (2012) by violating Rule 64B16-27.797(1)(a), F.A.C. which requires an anteroom area to be maintained within ISO Class 8 level of particulate contamination.
Count Two: Section 456.072(1)(k), F.S. (2012) by violating Rule 64B16-27.797(1)(f), F.A.C. which requires the buffer area to be maintained within ISO Class 7 level of particulate contamination and not contain a sink or drain.
Count Three: Section 456.072(1)(k), F.S. (2012) by violating Rule 64B16-27.797(1)(k), F.A.C. which requires that the pharmacy compounding parenteral and sterile preparation shall have appropriate environmental control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay a fine of $2,000.00. Respondent shall pay costs of $1,821.10.

Dr. Alphonso was present on behalf of the respondent and was sworn in by the court reporter. The Respondent was represented by Miles A. McGrane III, Esquire.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to accept the Settlement Agreement. Motion carried.

A-12 Infupharma, PH 23566 – Hollywood, FL
Case No. 2011-11350 – PCP Fallon/Glass

Count One: Respondent violated Section 456.072(1)(k), F.S. (2010, 2011), by violating Section 499.005(22), by operating as a prescription drug repackager without first obtaining the proper permit to do so.
Count Two: Respondent violated Section 456.072(1)(o), F.S. (2010, 2011), by practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay a fine of $10,000.00. Respondent shall costs limited to $6,139.10. Respondent shall surrender Special Parenteral and Enteral Modifier to the Board of Pharmacy. Respondent must complete an 8 hour laws and rules CE course to be completed within one year of the filing of the final order. Respondent shall be placed on probation for a period of 2 years with semi-annual inspections to be conducted at respondent's cost.

Mark Ezzo was present on behalf of Infupharma and was sworn in by the court reporter. The respondent was represented by Edwin Bayo, Esquire.

Motion: by Dr. Weizer, seconded by Mr. Philip, to accept the Settlement Agreement. Motion carried.

A-13 Gino Alberto Bolanos, PS 23866 – Miami, FL
Case No. 2013-00502 – PCP Glass/Mesaros

Count One: Respondent violated Section 456.072(1)(k), F.S. (2012), by violating Section 465.022(11)(a), F.S. (2012), by failing to ensure the permittee's compliance with Section 499.005(28), F.S. (2012), by failing to acquire a pedigree paper.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay a fine of $500.00. Respondent shall pay costs limited to $1,010.77. Respondent shall complete a 12 hour laws and rules CE.

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to accept the Settlement Agreement. Motion carried.

B. DETERMINATION OF WAIVER

DOW-1 Nohelia Pena, RPT 30775 – Kissimmee, FL
Case No. 2013-06080 – PCP Weizer/Meshad

Count One: Respondent violated Section 456.072(1)(aa), F.S. (2012), which subjects a licensee to discipline for testing positive for any drug, as defined in Section 112.0455, on any confirmed pre-employment or employer-ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using the drug.

The respondent was present and sworn in by the court reporter. The respondent was not represented by counsel.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to find that respondent was properly served and has waived the right to a formal hearing. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Mesaros, to accept the investigative report into evidence for the purposes of imposing a penalty and that you adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Motion: by Dr. Mesaros, seconded by Mrs. Glass, to vacate previous motions. Motion carried.

Motion: by Dr. Mikhael, seconded by Dr. Fallon, to find that respondent was properly served and has waived the right to a formal hearing. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Fallon, to accept the investigative report into evidence for the purposes of imposing a penalty and that you adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Dr. Mesaros, seconded by Mrs. Glass, to vacate motion that she waived her right and to continue as an informal hearing. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: License to remain suspended until respondent has undergone a PRN evaluation. Respondent must receive PRN evaluation within 60 days and sign any required contract within 90 days of request. Board reserves jurisdiction to impose probation at reasonable terms not to exceed respondent's PRN contract. Respondent must pay a fine of $500.00 to be paid within 90 days of reinstatement. Respondent must pay costs in an amount to follow.

Motion: by Dr. Mikhael, seconded by Dr. Fallon, to accept the recommendations of the Department. Motion carried.

Motion: by Dr. Fallon, seconded by Dr. Weizer, to asses costs in the amount of $984.55 within 90 days of reinstatement. Motion carried.

DOW-2 Ryan Daniel Rodriguez, RPT 5867 – Jacksonville, FL
Case No. 2013-00926 – PCP Fallon/Glass

Count One: Respondent violated Section 456.072(1)(q), F.S. (2012), by violating a lawful order of the department or the Board.

The case was pulled by the Department.

DOW-3 Ihab S. Barsoum, PS 30945 – Tampa, FL.
Case No. 2011-17660 – PCP Glass/Mullins

Count One: Respondent violated Section 456.072(1)(c), F.S. (2012), by being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

Count Two: Respondent violated Section 456.072(1)(x), F.S. (2012), by failing to report to the Board in writing within thirty days after the licensee has been conceited of found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction.

Respondent was not present nor represented by counsel.

Motion: by Dr. Mikhael, seconded by Dr. Weizer, to find that respondent was properly served and has waived the right to a formal hearing. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Dr. Mikhael, seconded by Dr. Weizer, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: Revocation

Motion: by Dr. Weizer, seconded by D. Mikhael, to accept the recommendations of the Department. Motion carried.

The Department withdrew its motion for costs.

DOW-4 Katy Elizabeth Wallis, PS 48435 – Sarasota, FL
Case No. 2013-07966 – PCP Mesaros/Glass

Count One: Respondent violated Section 465.016(1)(e), F.S. (2011), when she possessed hydrocodone, which she did not obtain lawfully or pursuant to a valid prescription or order, in violation of Title 21, United States Code, section 843.
Count Two: Respondent violated Section 456.072(1)(c), F.S. (2011), when she pled guilty to unlawful possession of a controlled substance.

The respondent was not present nor represented by counsel.

Motion: by Dr. Mikhael, seconded by Dr. Fallon, to find that respondent was properly served and has waived the right to a formal hearing. Motion carried.

Motion: by Dr. Mikhael, seconded by Dr. Weizer, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Dr. Fallon, seconded by Dr. Weizer, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: License shall remain suspended until respondent has undergone a PRN evaluation within 60 days and sign any contract offered within 90 days of PRN's request. Respondent shall pay a fine of $1,000.00 within 90 days of reinstatement.

Motion: by Dr. Fallon, seconded by Mr. Garcia, to accept the recommendations or the Department. Motion: failed with all Board members in opposition.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to have respondent remain suspended indefinitely until PRN will advocate on respondent's behalf that they are able to practice with reasonable skill and safety with terms and fines to be determined later. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to asses costs of $2,101.45 to be paid within 90 days of reinstatement. Motion carried.

C. VOLUNTARY RELINQUISHMENTS

VR's voted on at one time: VR's 1,2,3,4, and 5 were voted on as a group.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to accept the above-listed Voluntary Relinquishments. Motion carried.

VR-1 Samantha Margarita Solis, RPT 41014 – Lake Mary, FL.
Case No. 2013-12552 – PCP (None)

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See motion above.

VR-2 Robert S. Wesley, RPT 47994 – New Port Richey, FL
Case No. 2013-08298 – PCP Waived

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See motion above.

VR-3 Alexis Michelle Stall, PSI 29247
Case No. 2013-11854 – PCP Waived

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See motion above.

VR-4 SDU, Inc., PH 13238 – Boca Raton, FL
Case No. 2013-06926 – PCP Waived

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See motion above.

VR-5 NTC Urgent Care Centers, LLC, PH 21462 – Clermont, FL
Case No. 2013-07117 – PCP Waived

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See motion above.

VR-6 Las Mercedes Drug Store, Inc., PH 25947 – Miami, FL
Case No. 2013-01125 – PCP Risch/Mesaros

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to accept the Voluntary Relinquishment. Motion carried.

VR-7 Roy Cole Sr., RPT 19986 – Tarpon Springs, FL
Case No. 2013-08984 – PCP Weizer/ Meshad

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Motion: by Dr. Mesaros, seconded by Mrs. Glass, to accept the Voluntary Relinquishment. Motion carried.

VR-8 Main Street Family Pharmacy, LLC, PH 24815 – Newbern, TN
Case No. 2013-07092 – PCP Glass/Mesaros

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to accept the Voluntary Relinquishment. Motion carried.

VR-9 Avalon Park Pharmacy, PH 24071 – Orlando, FL
Case No. 2012-13103 – Weizer/Meshad

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Martin Dix, Esquire was present on behalf of the Respondent.

This case was pulled by the Department.

D. BOARD ACTION BY HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

I-1 James M. Maister, PS 34202 – Wesley Chapel, FL.
Case No. 2010-19143 – PCP Meshad/Weizer

This case was granted a continuance and will be heard at the February Board of Pharmacy meeting.

I-2 Dino Jose Antonioni, PS 38504. Miramar, FL
Case No. 2012-14458. PCP – Griffin/Mesaros

Mr. Garcia recused himself from this case.

Respondent was not present nor represented by counsel.

Count One: Respondent violated Section 456.072(1)(c), F.S. (2012) by being convicted of found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice pharmacy.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to proceed as an informal hearing. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to accept the investigative report into evidence for the purposes of imposing a penalty and to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Departments Recommendation: Revocation

Motion: by Dr. Fallon, seconded by Mrs. Glass, to accept the recommendations of the Department. Motion carried.

The Department withdrew motion for costs.

I-3 Lamonte George Hambrick, RPT 8527 – Tampa, FL
Case No. 2013-01501 – PCP Weizer/Meshad

Count One: Respondent violated Section 465.023(1)(x), F.S. (2012), by failing to report to the Board, or the department if there is no board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction, constitutes grounds for discipline.

Respondent was not present nor represented by counsel.

Mr. Flynn informed the Board of the respondent's request to either have his case be continued until his appeals process is completed or have his case heard telephonically due to his current incarceration.

Motion: Dr. Mesaros, seconded by Mrs. Glass, to provide a statement to the respondent that he has the ability to submit a written argument for the Board regarding his circumstances or send representation. The statement shall also deny the respondent's request for a telephonic hearing and inform the respondent that voluntary relinquishment is still an option. Motion carried.

I-4 Eric Jansen Gaines II, RPT 45259 – Crawfordville, FL
Case No. 2012-16863 – PCP Mesaros/Risch

Count One: Respondent has violated Section 465.016(1)(e), F.S. (2012), by violating Chapter 893, F.S. (2012)
Count Two: Respondent violated Section 456.072(1)(c), F.S. (2012), by being convicted of or entering a plea of nolo contendere to a crime in any jurisdiction which relates to the practice of, or the ability to practice, Respondent's profession.

Respondent was present and sworn in by the court reporter. Respondent was represented by Martin Dix, Esquire.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Respondent requested a continuance until the next Board of Pharmacy meeting.

Dr. Brown (Professional Resource Network) stated that his initial evaluation concluded that the respondent is not safe to practice.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to deny the respondent's request for a continuance. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Departments Recommendation: Revocation

Motion: by Dr. Fallon, seconded by Dr. Weizer, to accept the recommendations of the Department. Motion carried.

The Department withdrew motion for costs.

I-5 Matthew Louis Earney, PS 45018 – Naples, FL
Case No. 2013-05487. PCP – Mesaros/Glass

Count One: Respondent violated Section 456.072(1)(k), F.S. (2012), by violating Section 465.022(11)(a), F.S. (2012), by failing to ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

This case was pulled by the Department.

I-6 Misir Drugs, LLC, PH 25701 – Naples, FL
Case No. 2013-05486. PCP – Mesaros/Glass

Count One: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.108(3)(e), F.A.C., which requires the label on the immediate container of a repackaged product or a multiple unit prepackaged drug product shall include the expiration date of the enclosed medication.
Count Two: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.108(3)(f), F.A.C., which requires the label on the immediate container of a repackaged product or a multiple unit prepackaged drug product shall include the lot number of the medication enclosed within.
Count Three: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Section 456.42(2), F.S. (2012), by filling and dispensing prescriptions for controlled substances on non-Department approved counterfeit-proof prescription pads.
Count Four: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Section 893.07(2), F.S. (2012), by failing to properly complete DEA Form 222.
Count Five: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.140(4) F.A.C., by failing to properly maintain compounding records.

This case was pulled by the Department.

I-7 Afshin Sadeghi, PS 41434 – Bakersfield, CA
Case No. 2012-04658 – PCP Garcia/Risch

Respondent was not present nor represented by counsel.

Count One: Respondent violated Section 465.016(1)(g), F.S. (2008), by furnishing upon prescription an ingredient or article different in any manner from the ingredient or article prescribed.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Departments Recommendation: Respondent shall pay a fine of $1,000.00. Respondent shall complete a medication error CE within 6 months of final order.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to accept the recommendations of the Department with the amendment that the medication errors CE be completed within 1 year of the final order. Motion carried.

Motion: by Mrs. Glass seconded by Dr. Weizer, to asses costs of $1,258.32. Motion carried.

I-8 Bonnie Christina Smith, RPT 3325 - Port Saint Lucie, FL
Case No. 2013-02273 – PCP Weizer/Meshad

Count One: Respondent violated 456.072(1)(c), F.S. (2012), by being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Dr. Martha Brown (Professional Resource Network) was present and advocated on the respondent's behalf.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Dr. Martha Brown (Professional Resource Network) spoke on behalf of the respondent and stated that she has been compliant with her existing PRN contract. Dr. Brown also stated that PRN does not believe she is ready to return to practice yet.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Departments Recommendation: Revocation

Motion: by Dr. Mikhael, seconded by Dr. Fallon, for stayed suspension until PRN decides the respondent is able to return to practice with reasonable skill and safety. At which time, the respondent shall be placed on probation for a period of time to run coterminous with completion of the PRN contract and at which time the Board reserves jurisdiction to add future conditions. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to asses costs of $753.57 payable within 90 days of reinstatement. Motion carried.

TAB 5 APPLICATIONS REQUIRING BOARD REVIEW – Debra Glass, BPharm

A. Examination Applicants

1. Sandeep Singh, File: 44040 – Tampa, FL

Applicant was present and sworn in by the court reporter. Applicant was not represented by counsel.

Motion: by Dr. Mesaros, seconded by Dr. Weizer, to allow the applicant to sit for the exam. Prior to the license being issued, the applicant must receive a PRN evaluation and comply with all conditions required by PRN. If a contract with PRN is not required, license will issue. Motion carried.

2. Marta Walters, File: 44153 – San Juan, PR

Applicant was not present nor represented by counsel.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to accept the application. Motion carried.

B. Endorsement Applicants

1. Darren James Palmer, File: 42962 – Ft. Lauderdale, FL

Applicant was present and sworn in by the court reporter. Applicant was not represented by counsel.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to grant licensure on the condition that prior to the license being issued, the applicant must receive a PRN evaluation and comply with all conditions required by PRN. If a contract with PRN is not required, license will issue. Motion carried.

2. Jonathan Lee, File: 44119 – Grantham, NH

Applicant was present and sworn in by the court reporter. Applicant was not represented by counsel.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to accept the application. Motion carried.

C. Pharmacy Intern Applications.

1. Curtis Michael Drees, File: 19170 – Fort Loramie, OH

Applicant was not present nor represented by counsel.

Motion: by Mrs. Glass, seconded by Mr. Philip, to deny the application. Motion carried.

D. Registered Pharmacy Technician Applications.

1. Andrew Michael Maniscalco, File: 52809 – Gainesville, FL

Applicant was not present nor represented by counsel.

Motion: by Dr. Mesaros, seconded by Dr. Weizer, to require an appearance at one of the next two Board meetings. Motion carried.

2. Jermaine Raymond, File: 51288 – St. Petersburg, FL

Respondent was not present nor represented by counsel.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to reject the application. Motion carried.

E. Non-Resident Pharmacy Permit Applications.

1. PPM, LLC, File: 20164 – Oklahoma City, OK

Ryan Orton (Pharmacy Owner for PPM, LLC) was present and sworn in by the court reporter. Applicant was not represented by counsel.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to accept the application. Motion carried.

2. Town & Country Compounding and Consultation Services, LLC.

John Herr (Owner) was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Mr. Philip, seconded by Dr. Mikhael, to reject the application. Motion carried.

3. Allcare PC, File: 20159 – Lyons, GA

Robert Driggers (Prescription Department Manager) and Eric Medlock (Technician) were present and sworn in by court reporter. Respondent was not represented by counsel.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to accept the application. Motion carried.

TAB 6 **LICENSURE ISSUES**

A. Request for Termination of Probation

1. Zhaoqi Zhu, File: 22754 – Miami, FL.

Petitioner was present and sworn in by the court reporter. Petitioner was not represented by counsel.

Motion: by Dr. Mesaros, seconded by Dr. Fallon, to accept the request for termination of probation. Motion carried.

2. Anthony M. Pecoraro, File: 21937 – Boca Raton, FL

Petitioner was present and sworn in by the court reporter. Petitioner was not represented by counsel.

Dr. Martha Brown (PRN) advocated for the petitioner.

Motion: by Dr. Mikhael, seconded by Mrs. Risch, to accept the request for termination of probation. Motion carried.

3. Jean Jones, File: 11521 – Gainesville, FL

Petitioner was present and sworn in by the court reporter. Petitioner was represented by Edwin Bayo, Esquire. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to accept the request for termination of probation. Motion carried.

B. Petition for Reinstatement

1. John Scott Clopton, File: 11949 – Silverhill, AL

Petitioner was present and sworn in by the court reporter. Petitioner was not represented by counsel.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to reinstate the license as well as reinstate the petitioner's ability to practice in the state of Florida. Motion carried.

C. Petition to Relinquish License and to Request an Extension of Payment.

1. G.M.G. Pharmacy and Discount, Inc., File: 18980 – Hialeah, FL.

Respondent was not present nor represented by counsel.

No action was taken.

2. John White, File: 475 – Ft. Myers, FL

Petitioner was present and sworn in by the court reporter. Petitioner was not represented by counsel.

Motion: by Dr. Fallon, seconded by Mrs. Risch, to vacate the costs of $880.80. Motion carried with Mr. Garcia in opposition.

D. Motion for Modification of Final Order

1. AnazaoHealth Corporation – Tampa, FL

Petitioner was present and sworn in by court reporter. Petitioner was represented by Edwin Bayo, Esquire.

Motion: by Dr. Fallon, seconded by Dr. Weizer, to accept the past four successful inspections as meeting the requirements of the Final Order. Motion carried.

TAB 7 INFORMAL LICENSURE HEARINGS

A. Request to Appeal Notice of Intent to Deny

1. EntirelyPets Pharmacy, LLC, File: 19899 – Union City, CA

Rashmi Shingari (Owner) was present and sworn in by the court reporter. Applicant was represented by Noah Jussim, Esquire.

Motion: by Dr. Weizer, seconded Dr. Mikhael, to proceed as an informal hearing. Motion carried.

Motion: by Dr. Mikhael, seconded by Dr. Fallon, to uphold the initial denial of the application. Motion failed due to a tie vote.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to allow the applicant to withdraw their application. Motion carried.

EntirelyPets accepted the Board's offer to withdraw their application.

Motion: by Dr. Mesaros, seconded by Mrs. Glass, to vacate previous order of intent to deny application. Motion carried.

B. Request to Voluntary Relinquish License

1. Andrew Brandt, RPT 50740 – Clermont, FL.

This case was pulled to let the Board office accept the Voluntary Relinquishment.

END OF CASES. ----

The Board members discussed and determined that the February 4-5, 2013 Board of Pharmacy meeting will be moved to February 11-12, 2013 with a location to be confirmed later.

Motion: by Dr. Weizer, seconded Mrs. Glass to delegate the authority to approve holiday modification of hours to the Board chair. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass to delegate signature authority for PCP memorandums to the Executive Director. Motion carried.

Mr. Garcia asked Ms. Norr to present the rule changes discussed at the December 3, 2013 Rules Committee for a vote.

Motion: by Dr. Mesaros, seconded by Mrs. Glass, to remove the sentence in the mitigating and aggravating factors subsection of Rule 64B16-30.001 that JAPC stated is in conflict with Statute 456.079. Motion carried.

Motion: by Dr. Mesaros, seconded by Mr. Philip, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Mesaros, seconded by Mrs. Glass, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Mrs. Glass and Dr. Weizer requested that the Chair appoint another member to the Compounding Rules Committee.

Dr. Mesaros appointed Dr. Mark Mikhael to the Compounding Rules Committee.

The Board acknowledged Mr. Garcia for his great work over the past year serving as the Chairman to the Board of Pharmacy.

Mr. Garcia opened the floor to public comments.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to **ADJOURN** the meeting 6:13pm. Motion carried.

Florida
HEALTH

Rick Scott
Governor

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201216088

JOHN T READING,
RESPONDENT.

NOTICE

TO: JOHN T READING
3407 RIVER GARDEN CIRCLE
PENSACOLA, FL 32514-8113

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

HEALTH

Mission:
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Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

PERSONAL AND CONFIDENTIAL

January 14, 2014

PRESTON E MCDONALD
5740 WESTMONT ROAD
MILTON, FL 32583

Re: DOH v. John T Reading
Case # 201216088

Dear Preston E Mcdonald:

I am writing to you concerning the Department of Health's review of certain health care provided by the above named health care practitioner. That review included a full investigation and the filing of an Administrative Complaint. That review is nearing a conclusion and Board of Pharmacy is scheduled to take final disciplinary action in the matter on Wednesday, February 12, 2014.

This is one of several matters that will be part of the public meeting. You are welcome to attend this public meeting, but you are not required to attend, and this is not a request that you attend the meeting. Cases shown on the agenda may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled to begin at 9 a.m.; therefore, if you choose to attend it is imperative that you arrive promptly at 9 a.m. and be prepared to remain until the case is heard as cases may be heard in a different order than they appear on the agenda.

Florida law provides that the person who made the complaint to the Department ("complainant") is entitled to provide oral or written communication to the Board concerning the alleged violation or the appropriate penalty. Likewise, the patient/legal representative in the case who was not the "complainant" may request that the Board allow them the same opportunity to provide such written or oral communication. The Board has granted such requests. If you have any questions concerning this matter, please contact the Department's Prosecution Services Unit prior to the meeting at (850)245-4640. Please reference the above case number when calling.

All final disciplinary actions of the Board are reflected in written orders which are available on the Department's website at: www.flhealthsource.com. Please allow 30-60 days after the board meeting for the posting of these orders.

Sincerely,

for Tammy Collins

Executive Director
Board of Pharmacy

Florida Department of Health
Division of Medical Quality Assurance
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3260
PHONE: (850) 245-4444 • FAX : (850) 245-4791

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Ana Gargollo-McDonald, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. John T Reading, R. Ph.
DOH Case Number 2012-16088
DATE: November 6, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	John T Reading
Subject's Address of Record:	3407 River Garden Circle Pensacola, FL 32514-8113
Enforcement Address:	3407 River Garden Circle Pensacola, FL 32514-8113
Subject's License No:	10065 **Rank:** PS
Licensure File No:	2099
Initial Licensure Date:	Fifty (50) Year Pharmacist
Board Certification:	No
Required to Appear:	Yes
Current IPN/PRN Contract:	No
Allegation(s):	456.072(1)(k), FS (2012) 465.016(1)(r), FS (2012) 465.022(11)(a), FS
Prior Discipline:	4075, 02/09/1993
Probable Cause Panel:	September 5, 2013; Mesaros & Glass
Subject's Attorney:	Pro Se
Complainant/Address:	Preston E McDonald 5740 Westmont Road Milton, FL 32583
Materials Submitted:	Memorandum to the Board Settlement Agreement Exhibit A - Administrative Complaint Election of Rights Board Notification Letter

Cost Summary Report
Probable Cause Memorandum
Final Investigative Report with Exhibits

DISCIPLINARY GUIDELINES:

456.072(1)(k), FS (2012): From $1,500 fine to $2,500 fine and one year probation.

465.016(1)(r), FS (2012): From $1,500 fine to $5,000 and one year suspension for non-scheduled legend drugs, or from $5,000 fine and one year probation to revocation for scheduled legend drugs.

PRELIMINARY CASE REMARKS: SECTION 120.57(2) HEARING (INFORMAL)

This is the hearing in the matter of taking disciplinary action against the licensee and case number referenced above. **THE ABOVE LISTED PCP MEMBERS ARE EXCUSED FROM PARTICIPATION PURSUANT TO SECTION 456.073(6), F.S.**

TERMS OF SETTLEMENT:

1. Appearance
2. Administrative Fine in the amount of $2,000.00 payable within 90 days
3. Costs not to exceed $2,063.00 payable within 90 days

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-16088**

JOHN T. READING, R.PH.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, John T. Reading, Sr., R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 10065. Respondent's mailing address of record is 3407 River Garden Circle, Pensacola, Florida 32514.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

3. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

4. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

5. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

6. **Fine**- The Board of Pharmacy shall impose an administrative fine of **TWO THOUSAND DOLLARS** ($2,000.00). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

7. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND AND SIXTY-THREE DOLLARS** ($2,063.00). Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

8. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

9. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute

a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

10. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

11. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice

the Board or any of its members from further participation, consideration, or resolution of these proceedings.

12. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

13. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

14. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

15. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 28th day of SEPTEMBER, 2013.

JOHN T. READING, R.PH.
CASE NO. 2012-16088

STATE OF FLORIDA

COUNTY OF ESCAMBIA

Before me personally appeared JOHN T. READING, Sr.RPh, R.Ph., whose identity is known to me or by FLDL (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 28th day of SEPTEMBER, 2013.

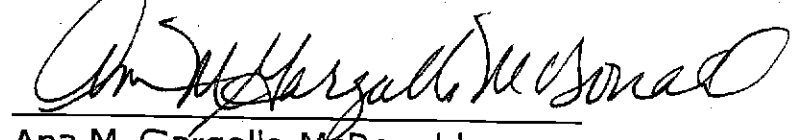
Notary Public
My Commission number:
My Commission Expires:

BENJAMIN V. FENN
Commission # EE 855488
Expires March 31, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

PRACTITIONER REGULATION
LEGAL
2013 OCT -1 AM 9:23

APPROVED this 25th day of October, 2013.

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health



Ana M. Gargollo-McDonald
Assistant General Counsel

Counsel for Petitioner
Ana M. Gargollo-McDonald
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No. 0085907
Telephone: (850) 245-4444 Ext. 8133
Facsimile: (850) 245-4683
ana_gargollo-mcdonald@doh.state.fl.us

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-16088**

JOHN T. READING, SR., RPh,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, John T. Reading, Sr., RPh, and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the State of Florida, having been issued license number PS 10065.

EXHIBIT
A

3. Respondent's address of record is 3407 River Garden Circle, Pensacola, Florida 32514.

4. At all times material to this complaint, Respondent was the prescription department manager (PDM) of Cantonment Pharmacy (the Permittee), located at 433 Highway 29 South, Cantonment, Florida 32533.

5. Section 465.022(11)(a), Florida Statutes, provides that the prescription department manager must ensure the permittee's compliance with all rules adopted under Chapter 465, Chapter 499, or Chapter 893, Florida Statutes, as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

6. Section 465.015(2), Florida Statutes (2012), to sell or dispense drugs as defined in Section 465.003(8), Florida Statutes, without first being furnished with a prescription.

7. As the PDM, Respondent was responsible for ensuring the Permittee complied with Sections 465.015(2), Florida Statutes (2012).

8. On or about February 4, 2013, the Department of Health Investigator went to Cantonment Pharmacy, and obtained six (6) azithromycin 250 mg tablets, a prescription only medication, without a valid prescription.

9. Azithromycin is an antibiotic that fights bacteria and is a prescription drug.

10. Section 456.072(1)(k), Florida Statutes (2012), provides that violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto, constitutes grounds for disciplinary action by the Board of Pharmacy.

11. Section 465.022(11)(a), Florida Statutes (2012), provides that the prescription department manager must ensure the permittee's compliance with all rules adopted under Chapter 465, Chapter 499, or Chapter 893, Florida Statutes, as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

12. Section 465.015(2)(c), Florida Statutes (2012), it is unlawful for any person to sell or dispense drugs as defined in Section 465.003(8), Florida Statutes, without first being furnished with a prescription.

13. As set forth above in paragraph 8, on or about February 4, 2013, Respondent failed to ensure the Permittee's compliance with Section 465.015(2)(c), Florida Statutes.

14. Based on the foregoing, Respondent has violated Section 456.072(1)(k), and Section 465.016(1)(r), Florida Statutes (2012), by

violating Section 465.022(11)(a), Florida Statutes, by failing to ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 5th **day of** September, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Ana M. Gargollo-McDonald
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No. 0085907
Telephone: (850) 245-4444 Ext. 8133
Facsimile: (850) 245-4683
ana_gargollo-mcdonald@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Angel Sanders
DATE: SEP 05 2013

/AGM

PCP: 9/5/13
PCP Members: Meros & Glass

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

November 6, 2013

John Reading
3407 River Garden Circle
Pensacola, FL 32514-8113

Re: DOH vs. John T. Reading, R.Ph.
DOH Case Number: 2012-16088

Dear Mr. Reading:

I am in receipt of the settlement agreement executed by you on September 28, 2013, concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next regularly scheduled meeting of the Florida Board of Pharmacy. Please be advised your case will be set at the convenience of the Department and/or the Board and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Ana Gargollo-McDonald
Assistant General Counsel

AM/ab

Search | Complaint/Case Number: 201216088 | MAIN | HELP

Complaint Cost Summary

Complaint Number: 201216088

Subject's Name: READING, JOHN T

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.60	$32.94
Investigation:	11.70	$743.57
Legal:	4.70	$497.26
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	17.00	$1,273.77
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,273.77

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **John T. Reading, Sr., R.Ph. (AMM)**
Case Number: 2012-16088

MEMBERS: **~~Cynthia Griffin~~ Glass, PharmD and Jeffrey Mesaros**

DATE OF PCP: **September 5, 2013** **AGENDA ITEM: A-16**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 456.072(1)(k), and Section 465.016(1)(r), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes;

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)

____ Upon **reconsideration**, dismiss

____ **other**

Chair, Probable Cause Panel
Board of Pharmacy

9/5/13
Date

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area I, Pensacola	Date of Case: 4/8/13	Case Number: PS 2012-16088

Subject:	Source:
JOHN T. READING SR, RPH 3407 River Garden Circle Pensacola, FL 32514 (850) 477-2499	**PRESTON MCDONALD, RPH** 5740 Westmont Road Milton, FL 32583 (850) 983-0916

Prefix:	License #:	Profession:	Board:	Report Date:
PS	10065	PHARMACIST	PHARMACY	7/8/13

Period of Investigation: 4/17/13-7/8/13	Type of Report: FINAL

Alleged Violation: **FS 456.072(1)(k)** Failing to perform any statutory or legal obligation placed upon a licensee. **(n)** Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party. **(dd)** Violating any provision of this chapter **FS 465.015(2)** It is unlawful for any person: **(c)** To sell or dispense drugs without first being furnished with a prescription. **FS 465.016(1)(i)** Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. **(r)** Violating any provision of this chapter ... **and FS 465.023(1)** The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline **(c)** Violated any of the requirements of this chapter

Synopsis: This investigation is predicated upon receipt of a complaint (Case Summary and Attachments) **(EXHIBIT 1)** submitted by MCDONALD in regard to READING. MCDONALD, a former pharmacist at Cantonment Pharmacy, alleged staff there are dispensing prescription medications without a prescription including antibiotics, erectile dysfunction oral tablets (Viagra), albuterol inhalers, and possibly non-controlled medications. Allegedly customers come to the pharmacy on a daily basis to purchase Penicillin, Amoxicillin, Flagyl, Diflucan, and cough syrup with codeine without a prescription from a physician. READING is allegedly dispensing these medications without a prescription. On 2/4/13, a Pensacola investigator went to the pharmacy and purchased a "Z-Pak" (six Azithromycin 250mg tablets, prescription only medication) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/ Tripolidine Hydrochloride 2.5mg) tablets. On 03/28/13, another Pensacola ISU staff member went to the pharmacy and purchased Chloraseptic with Lidocaine added (which requires a prescription) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/ Tripolidine Hydrochloride 2.5mg) tablets. The pharmacist was not identified on 2/4/13 or 3/28/13.

READING was notified of the investigation by letter dated 4/17/13 **(EXHIBIT 2)** and was provided a copy of the Case Summary and originating documents from Exhibit 1.

A check of DOH computer licensure records revealed READING is currently licensed as a PHARMACIST. READING earned his Bachelor of Science in Pharmacy from Sanford University in Birmingham, AL (year not indicated) per the resume included with his response **(EXHIBIT 8)**.

No patients were identified; therefore, patient notification was not required.

READING SR. is not known to be represented by an attorney in this matter

On 5/7/13 by US mail, Investigator LANIER received READING statement dated 5/4/13 **(EXHIBIT 8)**. READING denied the allegations.

Related Case: RPT 2012-16092, RPT 2012-16089, PH 2012-16087, PS 2012-16091, PS 2012-16090, PS 2013-06754

Investigator/Date:	Approved By/Date:
7/8/13 Received Investigative Services Ben Lanier, BI-35, Investigator	for 7/8/13 Cathy Martin, Investigator Supervisor

Distribution: HQ/ISU

JUL 09 2013

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Tallahassee FL

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INVESTIGATIVE DETAILS

On 2/4/13, Investigator LANIER drove to Cantonment Pharmacy. Upon entering the pharmacy, "EMILY" the cashier asked how she could help. Investigator LANIER stated he had a sinus infection and EMILY told Investigator LANIER to go to the pharmacy consultation window. Investigator LANIER walked to the consultation window and a man, without a name tag, presumably the pharmacist, with short brown hair and a goatee asked how he could help. Investigator LANIER told him that he had a sinus infection and a swollen throat. Investigator LANIER told him that a friend of his had the same thing recently and a Z-pak seemed to help. The pharmacist asked if Investigator LANIER wanted a Z-pak and Investigator LANIER told him yes. The pharmacist asked if Investigator LANIER was taking any kind of Antihistamine and Investigator LANIER told him no. The pharmacist told Investigator LANIER to also purchase an Antihistamine to clear up his sinuses. Investigator LANIER told him that funds were limited and the man said it would be roughly $31.00 in total. There was no counseling offered on how to take either the Z-pak or Antihistamine. EMILY assisted Investigator LANIER check out and asked for Investigator LANIER's driver's license. EMILY wrote down Investigator LANIER's name, address, and driver's license number in a book. Then Investigator LANIER signed the log and left the pharmacy. While in the pharmacy Investigator LANIER did not see a sign offering the sale of Viagra. A "Z-pak" (six Azithromycin 250mg tablets, prescription only medication) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets were provided by the pharmacist.

On 3/28/13, Investigator Supervisor CATHY MARTIN presented to Cantonment Pharmacy with complaints of lingering cough and sore throat. The cashier immediately instructed Investigator Supervisor MARTIN to go the pharmacy window. A man with short brown hair and a goatee, presumably the pharmacist but with no name tag, asked what symptoms were present. The symptoms were repeated to the pharmacist, and he instructed Investigator Supervisor MARTIN to select a bottle of Chloraseptic. He stated, with a wink, that he would add an ingredient to relieve the symptoms. He asked if Investigator Supervisor MARTIN was taking any decongestants, and Investigator Supervisor MARTIN responded no. He asked no other questions. A selection of the orange flavored Chloraseptic was made and Investigator MARTIN returned to the pharmacy window. The pharmacist stated that the orange flavor was not very good and to go back and get the red bottle. Investigator MARTIN did so. The pharmacist took the bottle, and a few minutes later he passed a white paper bag with contents to the cashier. The pharmacist stated that he added Lidocaine to the Chloraseptic. The cashier instructed Investigator MARTIN to approach the counter and provide a driver license. Investigator Supervisor MARTIN did so, and the cashier copied information from the driver license to a worn green ledger. The cashier then instructed Investigator Supervisor MARTIN to enter address information in the log and sign where indicated. Investigator MARTIN did so. During this process, Investigator MARTIN asked what the purpose of the log was, and the cashier stated it was for the Sudafed pills being provided. Investigator MARTIN also asked for the pharmacist's name, and the cashier provided a first name of "Gene." She informed the total was $11.10, and Investigator Supervisor MARTIN provided the cashier a $50 bill. Change of $38.90 was provided, and Investigator Supervisor MARTIN thanked the cashier and the pharmacist and left. The cost of the Chloraseptic was $5.12, and a blue bottle with 24 small white pills was also provided for a cost of $5.98. No prescriptions were presented to the pharmacy, and no instructions for taking the medications were provided. Chloraseptic with Lidocaine added (which requires a prescription) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets were provided by the pharmacist. The pharmacist was not identified on 2/4/13 or 3/28/13.

Thirteen pictures of these medications and receipts from both purchases are provided on CD and included as **EXHIBIT 6**.

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

EXHIBIT 1 is information forwarded by the Consumer Services Unit (CSU) with the complaint. This information consists of a Case Summary, corrected Case Summary, complaint form by MCDONALD, and the following:

- Complaint narrative by MCDONALD noting he was previously employed at Winn-Dixie pharmacy located nearby Cantonment Pharmacy. While at work on many occasions, he would have customers ask if he could sell them antibiotics. It was explained to them that a prescription was required, and their response was always that they could obtain them from Cantonment Pharmacy. MCDONALD did not believe the customers for the most part, contributing it to Cantonment Pharmacy selling something to the customers and telling them it worked almost as good as antibiotics. Through diverging circumstances, MCDONALD became employed at Cantonment Pharmacy as a pharmacist. The very first day at work not long after they opened, a customer came up and asked him for antibiotics. MCDONALD told the customer that they had to have a prescription for antibiotics. Throughout the day about six different customers asked him for antibiotics and without fail, every day to this date, he had customers telling him they had purchased antibiotics in the past from one registered pharmacy technician (RPT1) or sometimes another registered pharmacy technician (RPT2) was mentioned, and that they would like to purchase some more. MCDONALD refused and always told the customers that a prescription was required. Antibiotics mentioned to MCDONALD that customers had purchased in the past included Penicillin, Amoxicillin, Z-Pak, Keflex, Flagyl, and Diflucan. As corroborating evidence of this practice of selling antibiotics without a prescription to customers, there are large bottles of Penicillin, Amoxicillin, and SMZ-TMP on a counter near the counseling window, which is outside of the area of stock of all other medications, and separate from its normal location (for filling prescriptions).

  MCDONALD also had several male customers ask to purchase Viagra tablets, stating that they had bought them in the past from RPT1 or sometimes RPT2 and wanted some more. MCDONALD refused and always told the customers a prescription was required. MCDONALD stated there are handwritten signs above/below the Viagra tablets on the prescription stock area of "$24" which indicated that customers are charged $24.00 for each Viagra tablet (sold without a prescription). MCDONALD also had a customer come to the counseling window and ask him for an Albuterol inhaler. After MCDONALD explained that a prescription was needed, the customer stated that he had purchased them before from RPT1 and RPT2, and he became irate that MCDONALD would not sell him an Albuterol inhaler.

  Finally, MCDONALD alleged there is a well-known practice in the community that Cantonment Pharmacy sells a "cough syrup" that is mixed at the pharmacy which contains codeine. This is a C-V medication that can be legally sold without a prescription, but it can only be sold by a pharmacist. MCDONALD had several customers tell him they wanted that special "cough syrup" they got from RPT1 or RPT2 in the past. MCDONALD witnessed it being sold to customers by a clerk without consultation of the pharmacist on duty. MCDONALD stated it was a common practice for RPT1 to give medical advice to customers and otherwise infer to customers that he was a licensed pharmacist, and to also sell them prescription medications without a prescription. This was also the case for RPT2, although to a lesser extent.

  MCDONALD listed the licensed employees of the pharmacy who were allegedly guilty of dispensing medications without a prescription. These employees allowed RPT1 to portray himself as a licensed practitioner prescriber or pharmacist. This technician was allowed to perform duties only allowed by

law to be performed by a licensed practitioner prescriber or pharmacist such as 1) diagnosing patients and prescribing prescription medications by virtue of selling the prescription medications to customers without a valid prescription, 2) giving medical advice to customers without consultation of a licensed pharmacist, 3) holding himself as a pharmacist, 4) acting/speaking as a pharmacist over the telephone to other pharmacists in the transfer of prescriptions, without identifying himself as a pharmacy technician, 5) individually selling C-V medications (i.e., cough syrup with codeine) to customers without involvement, consultation, and approval of a pharmacist. MCDONALD noted that the primary principal or violator was RPT1, who had for many years acted as a pharmacist and performed pharmacist-only duties. The owner of the pharmacy is listed as the pharmacist-in-charge, who has a legal responsibility in developing and enforcing policies and procedures for the pharmacy. It is extremely difficult to believe that the owner, although absent from the day to day operations of the pharmacy, is not aware of the violations occurring on a daily basis. The two most recent pharmacists employed by the pharmacy are also participants in these violations by virtue of allowing them to occur while on duty and failing to report them. MCDONALD did not know if those two pharmacists were guilty of selling medications that require a prescription without one, or just knowingly allowed such. MCDONALD stated the pharmacy technicians were not identifying themselves when answering or speaking on the phone and did not regularly wear name tags/badges that readily identify themselves as pharmacy technicians. MCDONALD stated the pharmacy is also in violation by not having an easily accessible sink near the prescription counter.

EXHIBIT 3 is a copy of a letter dated 4/17/13 to MCDONALD informing him of the status of the case.

EXHIBIT 4 is a copy of a letter dated 5/16/13 to READING providing a corrected Case Summary. The original Case Summary made two references to Hydrocodone which should have read Hydrochloride.

EXHIBIT 5 is copies of three previous inspection forms dated 9/22/09, 10/18/10, and 1/23/12 for inspections conducted at Cantonment Pharmacy printed by Investigator LANIER on 4/18/13. The three previous inspections indicate passing results; however, the inspection form dated 9/22/09 indicated there were some improperly labeled medications found.

EXHIBIT 6 is a copy of thirteen pictures placed on CD by Investigator LANIER. The pictures are of prescription medications purchased from Cantonment Pharmacy by Pensacola ISU staff on 2/4/13 and 3/28/13, and the respective receipts, dispensed without providing a prescription. The medications consist of a "Z-pak" (six Azithromycin 250mg tablets, prescription only medication), 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets, Chloraseptic with Lidocaine added (which requires a prescription), and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets.

EXHIBIT 7 is a copy of the formula for the "Cantonment Wine" provided by BENJAMIN FENN, RPH, on 4/26/13 to Investigator LANIER at the Pensacola ISU office.

INTERVIEW OF PRESTON MCDONALD, RPH (PS 33121)–SOURCE:
Address of Record:
5740 Westmont Road
Milton, FL 32583
(850) 983-0916

On 11/26/12, Investigator LANIER interviewed MCDONALD by telephone. MCDONALD stated he quit working at the pharmacy close to a month prior. MCDONALD stated the pharmacy did not keep a record of the medications that customers were buying. MCDONALD stated the cough syrup did not contain full strength codeine and it did not require a prescription, but a pharmacist had to be involved. MCDONALD state Registered Pharmacy Technicians were also providing the cough syrup to customers. MCDONALD stated he could not specifically remember any patient names.

INTERVIEW OF BENJAMIN FENN, RPH (PS 13028)–WITNESS:
Address of Record:
6212 Kristen Dr.
Pensacola, FL 32504
(850) 476-7132

Employment: Cantonment Pharmacy
433 Highway 29 South
Cantonment, FL 32533
(850) 968-2489

FENN stated he worked full time at Cantonment Pharmacy on Mondays, Tuesdays, Thursdays, and Fridays. FENN stated he talked the owner into hiring MCDONALD because he was retiring and FENN was only going to be the on call/relief pharmacist. FENN stated that he was now completely retired; however, if anyone from Cantonment Pharmacy called and asked for him to work a shift that he would. FENN stated Cantonment Pharmacy was the only community pharmacy in Cantonment for about 30 years. FENN stated he was "guilty of all of it." FENN stated he did provide customers with prescription medications without a prescription. FENN stated he helped a lot of sweet black people who would come in mainly with toothaches and ask him for Penicillin. FENN stated he would sell them about a dozen Penicillin tablets to help them. FENN stated he wanted to help people who did not have insurance or who did not have a lot of money. FENN stated he never diagnosed people. FENN would also sell Diflucan to women who were experiencing vaginal problems. FENN stated that during his time there, READING did this for a lot of customers. FENN stated Cantonment Pharmacy was a family pharmacy that helped out the community. FENN stated this behavior had to stop because the times have changed. FENN stated the pharmacy did keep a price right below the Viagra which noted that each pill was $28.00. FENN stated that was also done for the Cialis and Levitra. FENN stated the pharmacy was not making any money off the Viagra because they sold it at cost. FENN stated he also sold Amoxicillin without a prescription. FENN stated he had seen every employee that worked there do it as well, even the pharmacy techs. FENN stated he had seen PH2, READING, RPT1, and RPT2, all do it. FENN stated RPT2 was READING's grandson. FENN stated there was a new pharmacist PH3 that was working there. FENN stated he could not recall PH3's last name, but that he had it written down and he would call Investigator LANIER with the last name. FENN stated Investigator LANIER would not believe how many marriages he thought he saved by selling the Viagra. FENN stated Viagra could be purchased online anyway

and provided Investigator LANIER with a number of (800) 530-6596 to verify it. FENN stated he also thought he had wiped out Syphilis with the antibiotics he sold. FENN stated customers would also come in and ask for extra tablets of what they were already taking and staff, mainly RPT1, would check to see if they had already been previously prescribed the medication before providing it to them. FENN stated he felt taken advantage of by the customers as well because he would help someone out one time and they would keep coming back after that. FENN stated he did not want to make people mad. FENN stated they also sell "Cantonment Wine" (cough syrup). FENN stated every staff member sold the Cantonment Wine, even the cashiers. FENN stated RPT1 and his nieces would premix a large container of the cough syrup. The container was approximately 480cc. FENN stated the cashiers would sell it to their church friends etc. FENN stated it was legal for them to sell it without a prescription. FENN stated he had the formula for the cough syrup written down and he provided a copy to Investigator LANIER **(EXHIBIT 7)**. FENN stated that basically the cough syrup contained Codeine, Guaifenesin, and Benadryl. FENN stated they did keep a log of who the cough syrup was sold to because it contained Codeine. FENN stated the pharmacy techs also sold it and he had to take the blame for that as well because they did it under his watch. FENN stated the cough syrup has been sold there for 30 years. FENN stated RPT1 told him not to worry about it because there was not enough Codeine in it to do anything. RPT1 told FENN someone could drink the whole bottle and not feel any affects. FENN stated he did not trust anyone anymore with Codeine. FENN stated RPT1 was also a federal attorney, but FENN did not believe he was licensed as such anymore. FENN stated RPT1. told him that he was going to get them all out of trouble and that he planned to represent all of them. FENN stated he thought RPT1 wanted to protect him, but he did not feel comfortable with that. FENN stated he wanted to confess his sins and get this off of his mind. FENN stated he was just trying to help people but that it had to come to an end because the times had changed. FENN stated he had spent his whole life trying to help people and that he did not regret it. FENN stated he was now retired and glad, but he still did not want to have to go to Tallahassee and lose his license. FENN stated he never received any complaints from patients or customers or other pharmacists until now. FENN stated this activity could have resulted in adverse problems and that he understood that. FENN stated someone could have been allergic to the medication that was dispensed to them. FENN stated he believed MCDONALD filed this complaint because READING offered to sell MCDONALD the pharmacy for two million dollars, but they withdrew the offer because MCDONALD wanted to turn their pharmacy into a compounding pharmacy. FENN stated he did not want to lose his license but that he would be fine with it if it was necessary because he was guilty. FENN stated he refused to sell to some customers because he was not familiar with them, but he thought some customers were dear friends of READING because the customers would call READING and then READING would call FENN at the pharmacy and tell him to sell to them, so he did. FENN asked to pray with Investigator LANIER for forgiveness of his sins. FENN stated he never dispensed the morning-after pill because he did not want to kill babies. FENN stated the pharmacy had recently gotten in trouble with the DEA. FENN stated the pharmacy was filling prescriptions for a doctor had her patients sign a contract noting they would only get their prescriptions filled at Cantonment Pharmacy. FENN stated another doctor was writing for a lot of tablets on most all of his prescriptions. FENN stated when the DEA came in, they told READING Sr. they were selling way too much Oxycontin and READING gave up their DEA license without any argument. FENN stated he was just trying to keep READING alive these days and really thinks he needs to sell the pharmacy. FENN thanked Investigator LANIER for his time and asked that prayers be said for him.

On the same date, FENN telephoned Investigator LANIER and provided PH3's last name.

On 5/6/13, Investigator LANIER attempted to telephone FENN; however, he was not available and there was no voicemail option. On 5/7/13, FENN telephoned Investigator LANIER and stated he had seen that he missed the

call. Investigator LANIER explained to FENN that a statement was received with his name on it that seemed to provide a conflicting response as to what was discussed on 4/26/13. FENN stated he never saw or read the statement, but allowed RPT1 to write it for him. Investigator LANIER informed FENN that the statement had his name at the bottom of it, as if it was written by him. FENN stated he did not want to tell RPT1 that he had already talked with Investigator LANIER about this matter. FENN stated that what he had previously told Investigator LANIER at the ISU office was the truth. FENN stated Cantonment Pharmacy was a family pharmacy and every employee had sold prescription medications without a prescription. FENN stated RPT2 was spoiled and that READING still called him "sugar boy." FENN stated he was not sure where RPT2 had received his education but READING trained him. FENN stated Cantonment Pharmacy was the only place RPT2 could get a job. FENN stated PH2, RPT2, RPT1 and READING had all sold prescription medications without a prescription. FENN opined that PH3 had done the same; however, he never worked with or witnessed him do it because PH3 started after FENN retired. FENN stated this happened with various medications but no controlled substances. FENN stated Viagra, Z-paks, and other antibiotics were sold without prescriptions. FENN stated he had even sold things in the past to Sheriff's deputies, etc, but times were changing. FENN stated he went along with everything at the pharmacy but should not have. FENN stated the pharmacy kept hiring older people because the young pharmacists did not want to do business the way they did. FENN stated the pharmacy was run by incompetents and that FENN had tried to hold everything together. FENN stated that apparently he "could not get out of their fast enough before he was caught." FENN stated he knew this was going to happen someday. FENN stated the only thing wrong in MCDONALD's complaint was that FENN had always seen the tech's wear name tags.

INTERVIEW OF SUSAN HALFEN, RPH (PS 32697)–WITNESS:

Employment: Winn-Dixie
1550 Hwy 29 North
Cantonment, FL 32533
(850) 968-3318

On 5/10/13 and 5/14/13, Investigator LANIER attempted to telephone HALFEN; however, she was not available and voicemail messages were left requesting a return call.

On 5/15/13, HALFEN returned the call and left a voicemail message for Investigator LANIER stating she was working all day on this date, but that she should be available for Investigator LANIER to call. On the same date, Investigator LANIER returned the call. HALFEN stated she had been a pharmacist at Winn-Dixie for about six years and that their location was very close to Cantonment Pharmacy. HALFEN stated that since she started working at Winn-Dixie pharmacy, one to two customers come in every month or so to try and get prescription medications without a prescription. HALFEN stated these customers were mainly seeking antibiotics and told her that they had gotten them in the past without a prescription from Cantonment Pharmacy. HALFEN stated she also knew Cantonment Pharmacy provided a cough syrup. HALFEN stated she knew pharmacists were allowed to sell the cough syrup. HALFEN stated that was all she really knew about Cantonment Pharmacy's operation.

INTERVIEW/STATEMENT OF JOHN T. READING, SR., RPH–SUBJECT:

Address of Record:
3407 River Garden Circle
Pensacola, FL 32514
(850) 477-2499

Employment: Cantonment Pharmacy
433 Highway 29 South
Cantonment, FL 32533
(850) 968-2489

On 5/7/13 by US mail, Investigator LANIER received READING's statement dated 5/4/13. READING earned his Bachelor of Science in Pharmacy from Sanford University in Birmingham, AL (year not indicated) per the resume included with his response **(EXHIBIT 8)**.

READING denied the allegations and stated MCDONALD was a serial liar. READING stated the nature of the complaint was inappropriate prescribing. READING asked that his resume be read and to note the details of the last few years of medical issues and the fact that he had not been the pharmacist on duty for more than a few hours or more for about a dozen times in the last five or more years. READING denied prescribing anything that was not permitted under Florida law.

READING stated he would be happy to face MCDONALD in person in an interview setting now that he knew what a liar he is, and also an anti-Semitic slug. READING questioned his employees and he apparently never left the prescription department except for bathroom breaks and possibly a sandwich break. That means that anything that he had accused his employees of doing, was done either at his direction, in his presence, or with his approval.

READING stated that he had spent a couple of hours in the pharmacy with MCDONALD showing him around, explaining very specifically that everyone is trained that the pharmacist is the boss at all times, no matter how his staff might customarily do their job. MCDONALD has a good motivation to try to cause trouble for his business. He had worked, until terminated, at Winn-Dixie near them for a few years. MCDONALD knew they had a good business. When MCDONALD was terminated (from Winn-Dixie), he inquired if READING would sell him the business. At READING's age, it did come to mind once in a while and he told him that he would sell it for $2 million dollars, but he would be crazy to buy any pharmacy without putting in some time at the pharmacy. MCDONALD was invited to come to work for them and look things over, for his period of evaluation that he recommended. This was certainly not something READING would have done if the pharmacy was operated in any degree along the lines that he has alleged, BELATEDLY.

READING stated he emphasized BELATEDLY, because after accepting his offer to come and work with his staff and meet their patients, they arranged for a banker to meet with READING's C.P.A to go over their books. MCDONALD came back with an offer to purchase (after having worked at the pharmacy and after having the books examined at his expense) that was about one-forth of what READING had asked initially. READING expected a significantly lower counter offer but nothing as ridiculous as MCDONALD came back with. MCDONALD has said that he would be satisfied if READING's license was revoked and he was fined. READING stated there was nothing in the record to justify such a vindictive attitude or request that would make sense to a normal person, especially considering his age and acuity. This is just a belly-full of bile that MCDONALD has as a result as a frustrated purchaser and an anti-Semite.

READING also provided the following:

- Emergency Declaration by Governor RICK SCOTT
- Memo to employees regarding theft and behavior
- Store Policy Manual Procedures Rule Book

- Memo noting the filling of out of town prescriptions was restricted
- Letter dated 7/18/12 noting an employee had tendered their resignation and MCDONALD would be the pharmacist's replacement.
- Newspaper editorial on READING

On 5/14/13, Investigator LANIER interviewed READING by telephone. READING stated he did write the response that was provided and he was wondering if Investigator LANIER had received it. READING stated he could not honestly say what took place in the pharmacy on a daily basis because he had only visited the pharmacy a handful of times in the last couple years. READING stated he was a 53 year pharmacist and that he still received a paycheck because he was the owner, but that he had been in and out of the Mayo clinic for a couple of years.

CONFIDENTIAL AND EXEMPT MATERIALS

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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April 17, 2013

CONFIDENTIAL

Preston E. McDonald, RPH
5740 Westmont Road
Milton, FL 32583

Reference Number: PS 2012-16088
Subject: John T. Reading, RPH

Dear Mr. McDonald:

Please be advised that the Investigative Services Unit is conducting an investigation on John T. Reading, RPH, and I am the investigator assigned to your case.

Florida law requires that all information in a complaint remain confidential until 10 days after probable cause is found. Patient names and records are never released to the public.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please call me at (850) 475-5470. In addition, if you have any concerns or suggestions about our complaint process, please fill-out our *Customer Concerns or Suggestions* form at www.floridashealth.com/mqa/survey.html.

Sincerely,

Ben Lanier
Investigator

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

File # 498

Insp # 86062

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT CANTONMENT PHARMACY INC		PERMIT NUMBER 2748	DATE OF INSPECTION 9/22/2009
DOING BUSINESS AS		DEA NUMBER AC5573767	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 433 HIGHWAY 29 S		TELEPHONE # 850-968-2489 EXT.	JOHN T READING
CITY CANTONMENT	COUNTY 27	STATE/ZIP 32533-1401	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 10065

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	6pm	6pm	6pm	6pm	6pm	3pm	

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Benjamin Fenn PS 13028
2. Johnny Reading PTech
3. Karen Bonanno PTech

	SATISFACTORY	N/A	YES	NO
1 Current pharmacy permit displayed. [465.015(1)(a),F.S.]			X	
2 Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]			X	
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4 Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]			X	
5 Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]			X	
6 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			X	
7 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]			X	
8 Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]			X	
9 Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.			X	
10 Generic drug sign displayed. [465.025(7),F.S.]			X	
11 Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]			X	
12 Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*		X		
13 Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]			X	
14 Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]			X	
15 Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]			X	
16 Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			X	
17 Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]			X	
18 Prescription department clean and safe. [64B16-28.105,F.A.C.]			X	
19 Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]			X	
20 Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]			X	
21 Medication properly labeled [64B16-27.101,F.A.C.]				X
22 All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]			X	
23 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]			X	
24 Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]			X	
25 "Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]			X	
26 All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]			X	
27 Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]			X	
28 Complete pharmacy prescription records. [64B16-28.140,F.A.C.]			X	
29 Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]			X	
30 Controlled substance records readily retrievable. [893.07,F.S.]			X	
31 Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]			X	
32 Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]			X	
33 Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			X	
34 Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]			X	
35 All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			X	
36 Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]			X	
37 Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			X	
38 Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]			X	
39 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]			X	
40 DEA 222 order forms properly completed. [893.07(2),F.S.]			X	
41 Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*			X	
42 Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]			X	
43 Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]			X	
44 Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *			X	
45 Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *		X		
46 Compounding records properly maintained [64B16-28.140(4),F.A.C.] *		X		
47 Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *		X		

** Questions with (*) may be answered n/a (not applicable).*

Remarks: Missy Shores PTech. #3 DEA expires 8-31-2011. #5 NA. #7 Tech ratio letter 6-22-1994. #21 Two bottles of OTC drug in pharmacy stock without expiration date. #23 Last CQI meeting 9-15-2009. #39 CS inventory 5-1-2009. #44 Logbook. Rx drug purchases from Smith Drug, AmerisourceBergen, Masters, & Top Rx.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Benjamin Fenn, RPh

Institutional Representative

09-22-2009
Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

Exhibit 5

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

File # 498

Insp # 94915

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT CANTONMENT PHARMACY INC		PERMIT NUMBER 2748	DATE OF INSPECTION 10/18/2010
DOING BUSINESS AS		DEA NUMBER AC5573767	PRESCRIPTION DEPARTMENT MANAGER JOHN T READING
STREET ADDRESS 433 HIGHWAY 29 S		TELEPHONE # 850-968-2489 EXT.	
CITY CANTONMENT	COUNTY 27	STATE/ZIP 32533-1401	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 10065

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	6pm	6pm	6pm	6pm	6pm	3pm	

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Benjamin Fenn PS 13028
2. Wilton Glover PS 7751
3. Melissa Shores RPT 21008

	SATISFACTORY	N/A	YES	NO
1 Current pharmacy permit displayed. [465.015(1)(a),F.S.]			X	
2 Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]			X	
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4 Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]			X	
5 Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]			X	
6 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			X	
7 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]			X	
8 Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]			X	
9 Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.			X	
10 Generic drug sign displayed. [465.025(7),F.S.]			X	
11 Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]			X	
12 Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*		X		
13 Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]			X	
14 Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]			X	
15 Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]			X	
16 Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			X	
17 Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]			X	
18 Prescription department clean and safe. [64B16-28.105,F.A.C.]			X	
19 Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]			X	
20 Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]			X	
21 Medication properly labeled [64B16-27.101,F.A.C.]			X	
22 All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]			X	
23 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]			X	
24 Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]			X	
25 "Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]			X	
26 All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]			X	
27 Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]			X	
28 Complete pharmacy prescription records. [64B16-28.140,F.A.C.]			X	
29 Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]			X	
30 Controlled substance records readily retrievable. [893.07,F.S.]			X	
31 Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]			X	
32 Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]			X	
33 Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			X	
34 Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]			X	
35 All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			X	
36 Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]			X	
37 Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			X	
38 Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]			X	
39 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]			X	
40 DEA 222 order forms properly completed. [893.07(2),F.S.]			X	
41 Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*			X	
42 Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]			X	
43 Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]			X	
44 Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *			X	
45 Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *		X		
46 Compounding records properly maintained [64B16-28.140(4),F.A.C.] *		X		
47 Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *		X		

** Questions with (*) may be answered n/a (not applicable).*

Remarks: Leslie Johnson RPT 21005; John Reading, Jr. RPT 21007. #3 DEA expires 8-31-2011. #5 NA. #7 Tech ratio letter 6-22-1994. #23 Last CQI meeting #39 CS inventory #43 Book - OK. #44 Logbook. Rx drug purchases from Smith Drug-Valdosta and AmerisourceBergen-Orlando.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Benjamin Fenn, RPh

Institutional Representative

10-18-2010
Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 498

Insp # 103821

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
CANTONMENT PHARMACY INC	2748	1/23/2012
DOING BUSINESS AS	DEA NUMBER Ac5573767	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 433 HIGHWAY 29 S	TELEPHONE # 850-968-2489 EXT.	JOHN T READING
CITY CANTONMENT / COUNTY 27	STATE/ZIP 32533-1401	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 10065

PRESCRIPTION DEPARTMENT HOURS	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	6pm	6pm	6pm	6pm	6pm	3pm	

REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
1. Joseph Gibson PS 26203	
2. Benjamin Fenn PS 13028	
3. Melissa Shores RPT 21008	

	SATISFACTORY	N/A	YES	NO
1 Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2 Pharmacy technicians properly identified and supervised. [64B16-27.410, F.A.C.]			X	
3 Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4 Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			X	
5 A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6 Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7 Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			X	
8 Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9 Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10 Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11 CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			X	
12 Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]		X		
13 Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
14 Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15 All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16 Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
17 Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]			X	
19 DEA 222 order forms properly completed. [893.07, F.S.]			X	
20 Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
21 Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]			X	
22 Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			X	
23 Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]			X	
24 Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]		X		
25 Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]		X		
26 Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]			X	
27 Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]		X		
28 Compounding records properly maintained. [64B16-27.700, F.A.C.]*		X		
29 Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]		X		
30 Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			X	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: Adam Bass RPT 21001; John Reading RPT 21007; Karin Bonano RPT 21006; Leslie Johnson RPT 21005. DEA expires 8-31-2014. #2 Tech ratio letter 6-22-1994. #11 Last CQI meeting 9-1-2011. #12 Future requirement. #18 CS inventory 5-1-2011. #22 Logbook. #23 One incident - Escambia CSO. #24 None since 7-1-2011.
CII prescription file survey (60Rxs): Local Practitioner - 97%; Local Patient - 100%; Pain Therapy - 78%; Non-pain Therapy - 22%.
No batch compounding. No compounding for practitioner office stock.
Rx drug suppliers: Smith Drug-Valdosta; AmericansourceBergen-Orlando.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Joseph Gibson, RPh

Institutional Representative

01-23-2012
Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

DOH CASE # PS 2012-16088

JOHN T. READING SR, RPH

CD containing 13 pictures of medications

Exhibit 6

CONFIDENTIAL

34-46

Manufactured by:
Wockhardt Limited,
Mumbai, INDIA.

*Each film-coated tablet contains azithromycin anhydrous equivalent to 250 mg of azithromycin.

Usual Dosage: See accompanying prescribing information.

This blister card package is not child-resistant.

RECOMMENDED [illegible]AGE: Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].

Your healthcare provider has been provided with full prescribing information for azithromycin.

Affix pharmacy label here.

Distributed by:
Wockhardt USA LLC.
20 Waterview Blvd.
Parsippany, NJ 07054
USA.

LOT LM1068E
EXP APR 2015

Rev.131010

MH/DRUGS/101

3Z 6 4 67 9 9 6 10 4 9

211282

NDC 64679-961-04

Azithromycin 250 mg*
Tablets

A full course of antibiotic therapy in just 5 doses

Rx only

WOCKHARDT

1 Card x Six 250 mg* Tablets

To remove, push tablets through from other side.

*Each film-coated tablet contains azithromycin anhydrous equivalent to 250 mg of azithromycin.

Usual Dosage: See accompanying prescribing information.

This blister card package is not child-resistant.

RECOMMENDED STORAGE: Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].

Your healthcare provider has been provided with full prescribing information for azithromycin.

Manufactured by:
Wockhardt Limited.
Mumbai, INDIA

Distributed by:
Wockhardt USA LLC.
20 Waterview Blvd.
Parsippany, NJ 07054
USA.

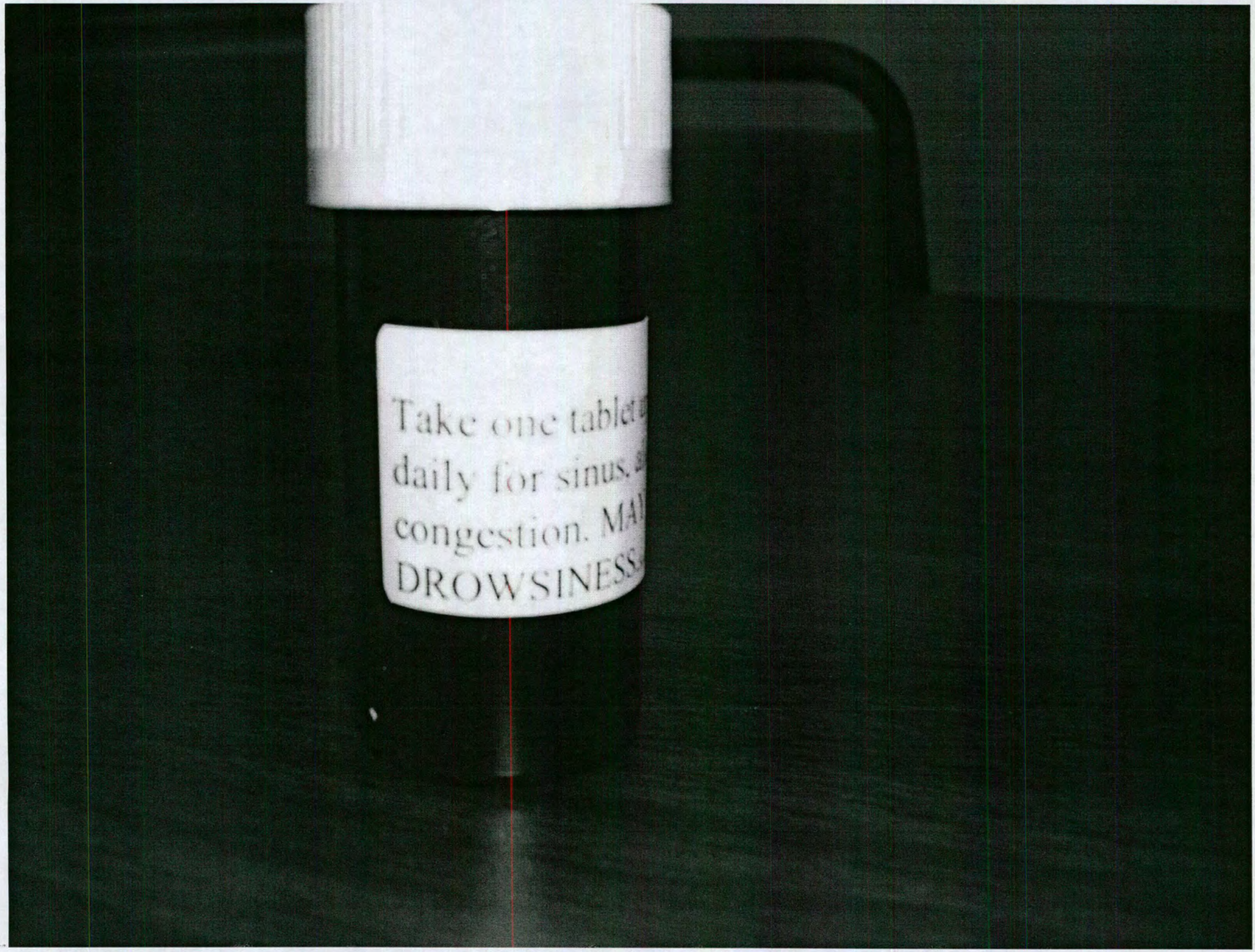
Rev.131010

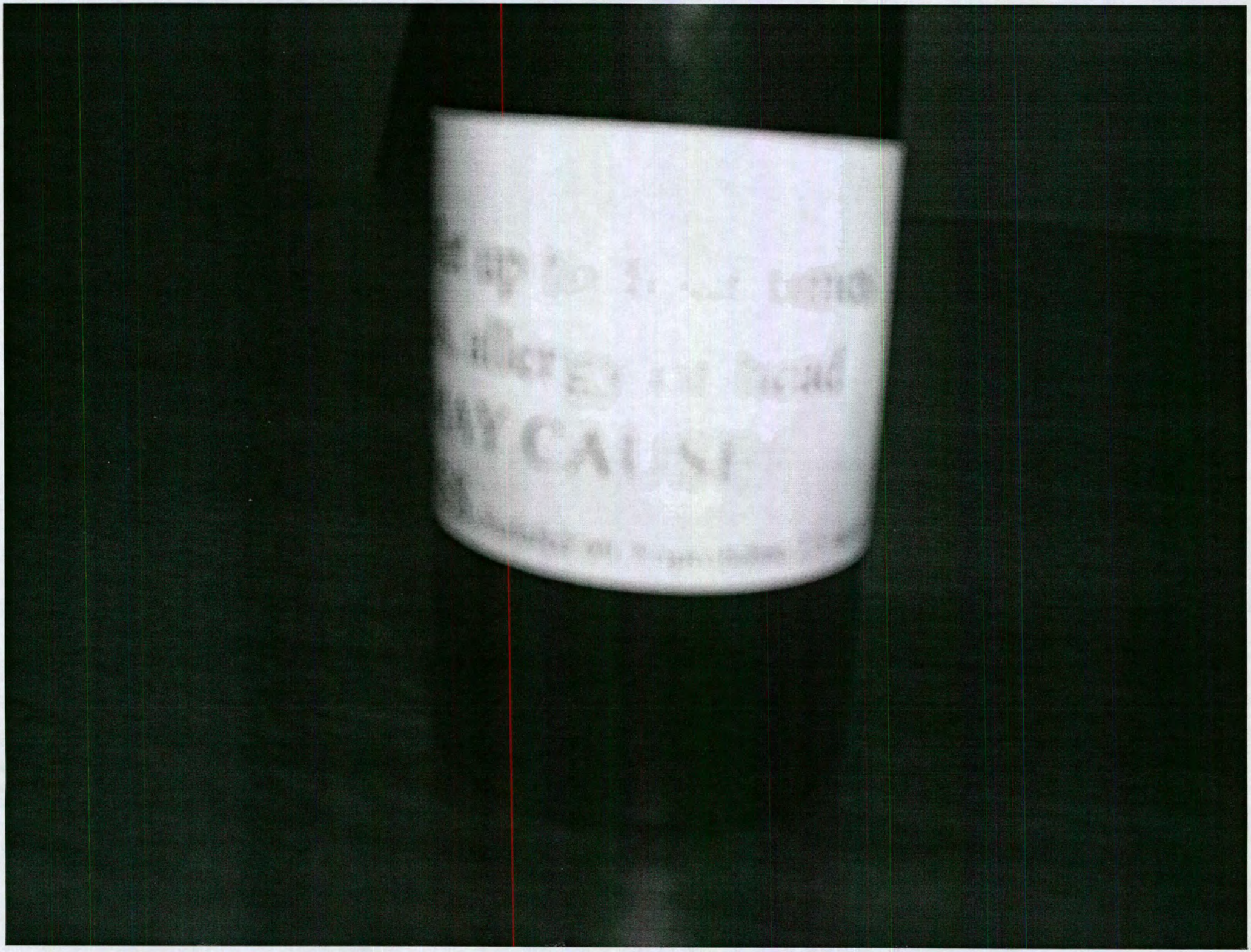
LOT 1H1095
EXP APR 2015

211282

MH/DRUGS/101

Affix pharmacy label here.


Take one tablet
daily for sinus,
congestion. MA
DROWSINESS



CANTONMENT PHARMACY
433 HIGHWAY 29 SOUTH
CANTONMENT,FL 32533
850-968-2489

Description	Qty	Total
NON-TAXABLE	1	24.98
NON-TAXABLE	1	5.98

(F) = ELIGIBLE FLEXIBLE SPENDING ACCOUNT ITEM (FSA)

Discounts	0.00
SubTotal	30.96
Tax	0.00
Total	30.96
CASH	**40.00**

Change Due $9.04
Items 2

Receipt # 95235
Register #
DateTime: 2/4/2013 5:38:21PM

THANK YOU SO MUCH AND COME BACK AND SEE US!!!!!

NDC 64679-961-04

Azithromycin
Tablets

250 mg*

A full course of antibiotic therapy in just 5 doses

Rx only

WOCKHARDT

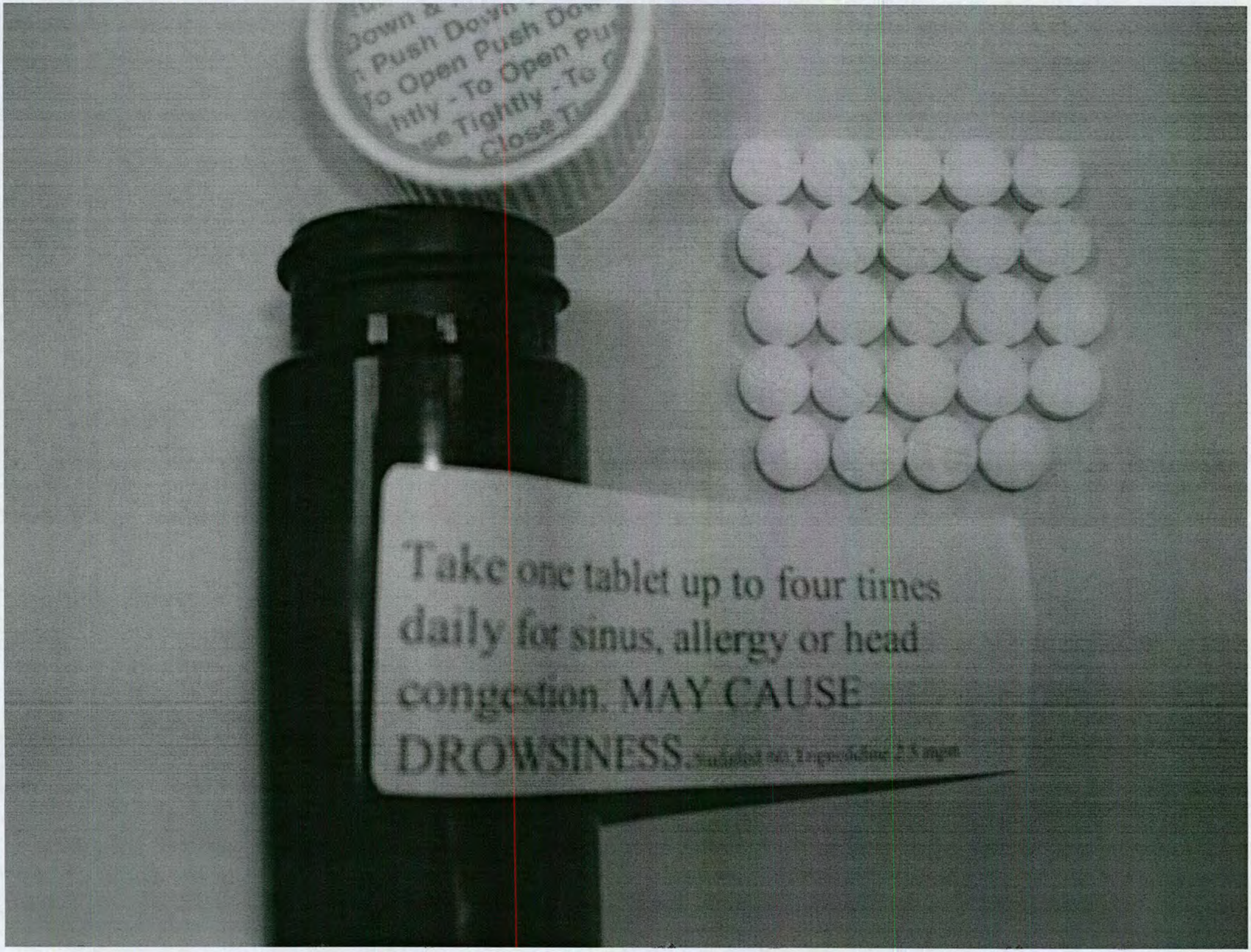
1 Card x Six 250 mg* Tablets

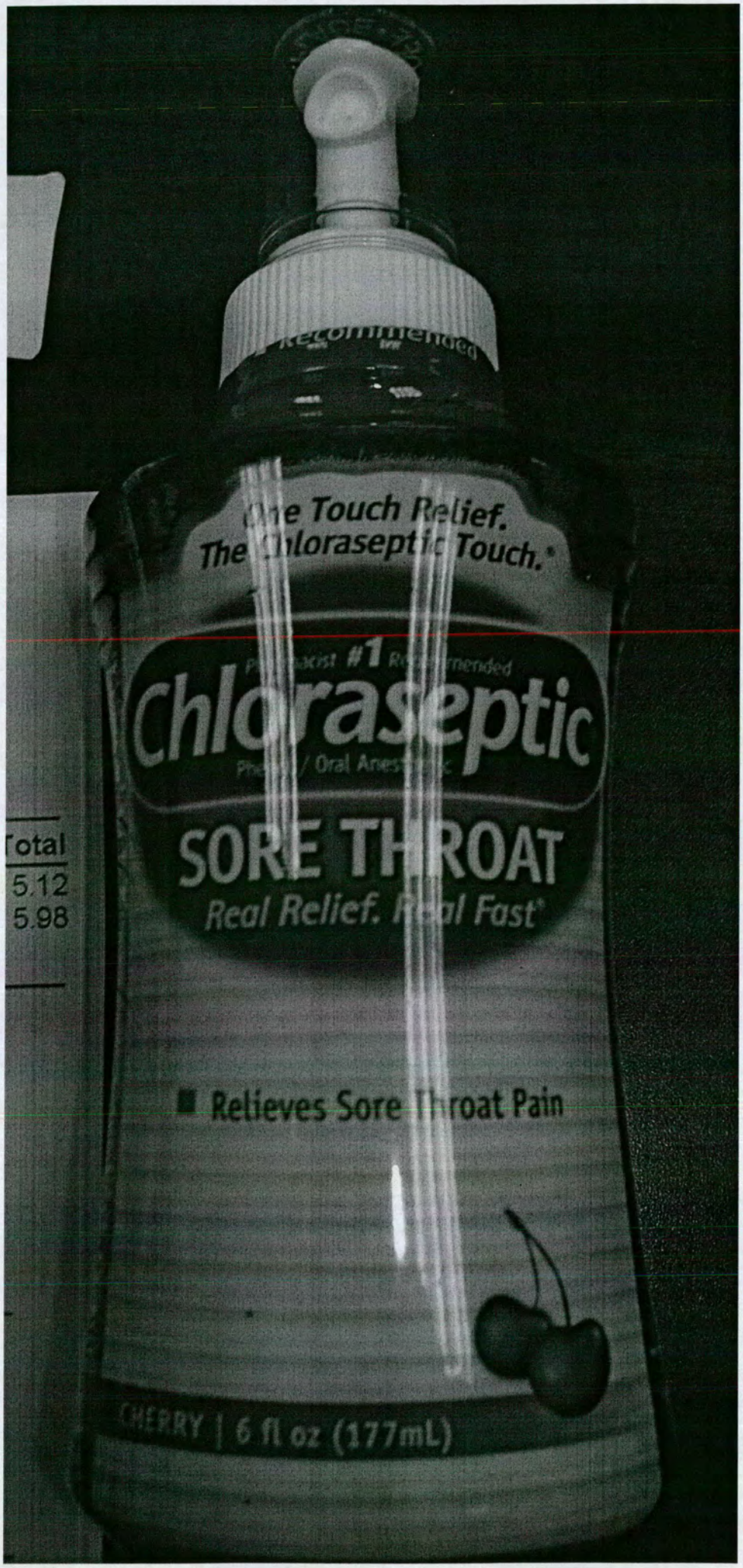
GOOD NEIGHBOR PHARMACY®

Get to know your neighbor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

ABC# 786 614


Take one tablet up to four times
daily for sinus, allergy or head
congestion. MAY CAUSE
DROWSINESS.


Touch Relief.
Chloraseptic
SORE THROAT
Real Relief.
Relieves Sore
CHERRY | 6 fl oz (177mL)

PRESCRIPTIONS

SAVE FOR TAX OR INSURANCE RECORDS

DATE _____

FOR _____

ADDRESS _____

DOCTOR _____

Rx No. _____ $ _____

Rx No. _____ $ _____

Rx No. _____ $ _____

Rx No. _____ $ _____

PHARM. _____ TAX $ _____

Thank You TOTAL $ _____

HealthWise PHARMACY

Take one tablet up to four times daily for sinus, allergy or head congestion. MAY CAUSE DROWSINESS. Sudafed 60, Triprolidine 2.5 mgm

CANTONMENT PHARMACY
433 HIGHWAY 29 SOUTH
CANTONMENT, FL 32533
850-968-2489

Description	Qty	Total
CHLORSEPTC SF	1	5.12
NON-TAXABLE	1	5.98

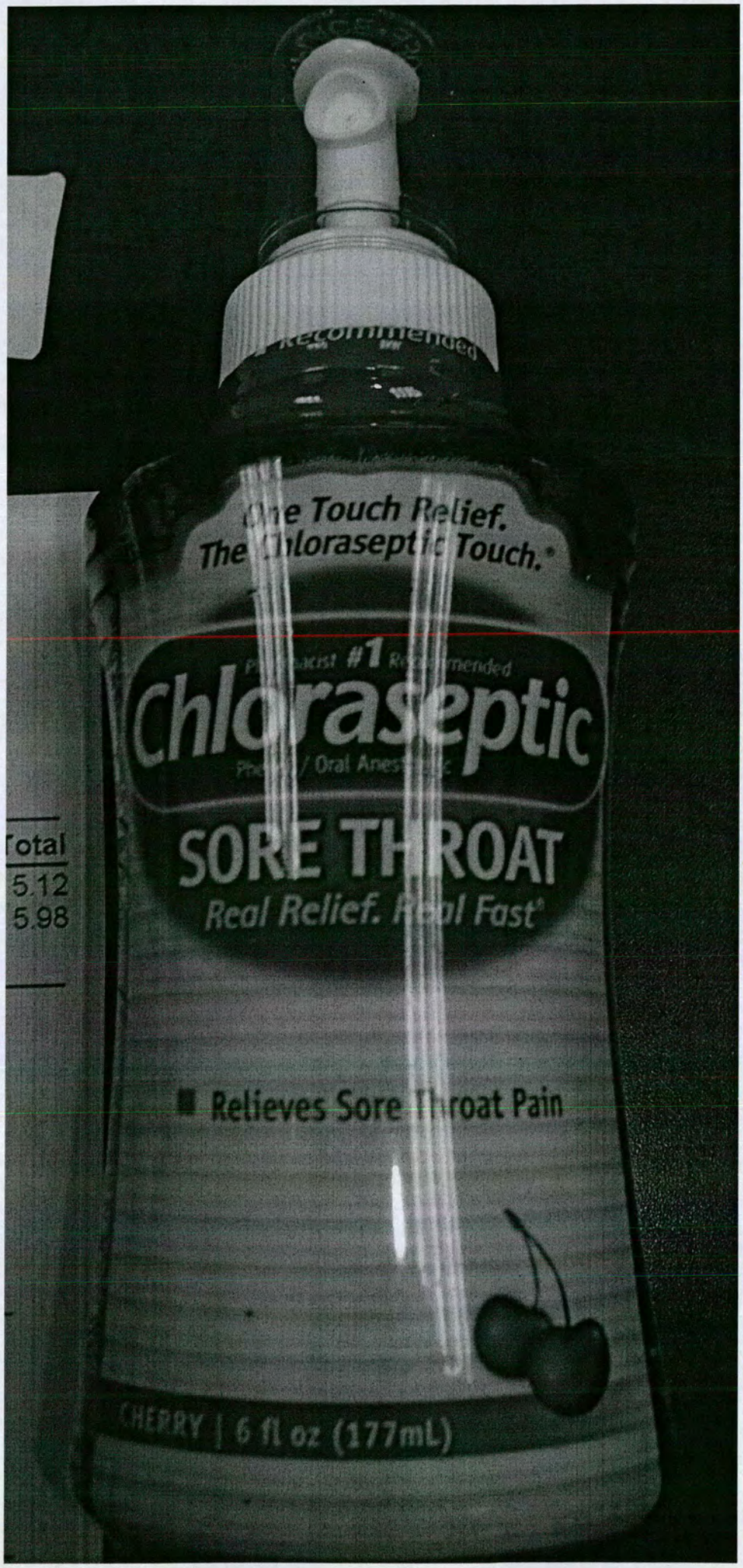
(F) = ELIGIBLE FLEXIBLE SPENDING ACCOUNT ITEM (FSA)

Discounts	0.00
SubTotal	11.10
Tax	0.00
Total	11.10
CASH	50.00

Change Due $38.90
Items 2

Receipt # 98983
Register #
DateTime: 3/27/2013 5:40:59PM

THANK YOU SO MUCH AND COME BACK AND SEE US!!!!!


Touch Relief.
Chloraseptic
SORE THROAT
Real Relief.
Relieves Sore
CHERRY | 6 fl oz (177mL)
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5.12
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CONFIDENTIAL AND EXEMPT MATERIALS

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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HEALTH

Rick Scott
Governor

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307014

ENRIQUE MOISES PALLARES,
RESPONDENT.

NOTICE

TO: ENRIQUE MOISES PALLARES
2496 MONTEREY COURT
WESTON, FL 33327

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307014

ENRIQUE MOISES PALLARES,
RESPONDENT.

NOTICE

AND: KEVIN JAKAB
1936 SAN MARCO BOULEVARD
JACKSONVILLE, FL 32207

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PERSONAL AND CONFIDENTIAL

January 14, 2014

DALIAH P. WEST
2401 FLAMINGO DRIVE
MIRAMAR, FL 33023

Re: DOH v. Enrique Moises Pallares
Case # 201307014

Dear Daliah P. West:

I am writing to you concerning the Department of Health's review of certain health care provided by the above named health care practitioner. That review included a full investigation and the filing of an Administrative Complaint. That review is nearing a conclusion and Board of Pharmacy is scheduled to take final disciplinary action in the matter on Wednesday, February 12, 2014.

This is one of several matters that will be part of the public meeting. You are welcome to attend this public meeting, but you are not required to attend, and this is not a request that you attend the meeting. Cases shown on the agenda may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled to begin at 9 a.m.; therefore, if you choose to attend it is imperative that you arrive promptly at 9 a.m. and be prepared to remain until the case is heard as cases may be heard in a different order than they appear on the agenda.

Florida law provides that the person who made the complaint to the Department ("complainant") is entitled to provide oral or written communication to the Board concerning the alleged violation or the appropriate penalty. Likewise, the patient/legal representative in the case who was not the "complainant" may request that the Board allow them the same opportunity to provide such written or oral communication. The Board has granted such requests. If you have any questions concerning this matter, please contact the Department's Prosecution Services Unit prior to the meeting at (850)245-4640. Please reference the above case number when calling.

All final disciplinary actions of the Board are reflected in written orders which are available on the Department's website at: www.flhealthsource.com. Please allow 30-60 days after the board meeting for the posting of these orders.

Sincerely,

for Tammy Collins
Executive Director
Board of Pharmacy

Florida Department of Health
Division of Medical Quality Assurance
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3260
PHONE: (850) 245-4444 • FAX : (850) 245-4791

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

HEALTH

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MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Christopher A. Jurich, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Enrique Moises Pallares, R.Ph.
DOH Case Number 2013-07014
DATE: November 5, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Enrique Moises Pallares, R.Ph.
Subject's Address of Record:	2496 Monterey Court Weston, FL 33327
Enforcement Address:	2496 Monterey Court Weston, FL 33327
Subject's License No:	24103 **Rank:** PS
Licensure File No:	13195
Initial Licensure Date:	8/10/1988
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No
Allegation:	Section 465.016(1)(g), F.S. (2012)
Prior Discipline:	None
Probable Cause Panel:	October 24, 2013 Leo Fallon & Debra Glass
Subject's Attorney:	Kevin Jakab 1936 San Marco Boulevard Jacksonville, FL 32207

Complainant: D.P.W.

Materials Submitted:

Memorandum to the Board
Settlement Agreement
    Exhibit A – Administrative Complaint
Board Notification Letter
Election of Rights
Cost Summary
Defense Attorney Document dated 10-31-13
PCP Memorandum
456 Materials
    456 Request
    Signed Confidentiality Form
Final Investigative Report
    Exhibits 1 thru 9

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-07014**

ENRIQUE MOISES PALLARES, R.Ph.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Enrique Moises Pallares, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 24103. Respondent's mailing address of record is 2496 Monterey Court, Weston, Florida 33327.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that she is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **TWO HUNDRED FIFTY DOLLARS ($250.00)**. The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within **30 days** from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. Costs- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND FIVE HUNDRED SIXTY-SIX DOLLARS AND TWENTY-FOUR CENTS ($2,566.24).** Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **90 days** from the date the Final Order is filed with the Department Clerk.

4. **CE Course-** Respondent shall successfully complete a Continuing Education Course on the subject of **PREVENTION OF MEDICAL ERRORS** consisting of **EIGHT (8) HOURS** of credit, which has been approved by the Florida Board of Pharmacy, within **one (1) year** of the filing of a Final Order accepting and incorporating this Settlement Agreement. These continuing education hours shall be in addition to the

hours required for license renewal. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

6. **Future Conduct**- Respondent shall not violate Chapters 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

7. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

8. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

9. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

10. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

11. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

12. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

13. **Current Addresses**- Respondent shall keep current her mailing address and her practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 31 day of October, 2013.

Enrique Moises Pallares, R.Ph.
Case No. 2013-07014

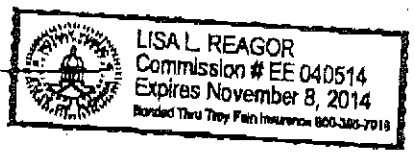
STATE OF Florida

COUNTY OF Duval

Before me personally appeared Enrique Pallares R.Ph., whose identity is known to me or by _____ (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 31st day of October, 2013.

Lisa Reagor
Notary Public
My Commission Expires:



APPROVED this 5th day of November, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Christopher A. Jurich
Christopher A. Jurich
Assistant General Counsel

Counsel for Petitioner
Christopher A. Jurich
Florida Bar No. 0099014
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 245-4444 ext. 8174
Fax: (850) 245-4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-07014**

ENRIQUE MOISES PALLARES, R.Ph.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Enrique Moises Pallares, R.Ph., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license PS 24103.

EXHIBIT A

3. Respondent's address of record is 2496 Monterey Court, Weston, Florida 33327.

4. At all times material to this Administrative Complaint, Respondent was employed as the prescription department manager of Costco Pharmacy, d/b/a Costco Pharmacy Store #182, located in North Miami Beach, Florida.

5. At all times material to this Administrative Complaint, T.W. was a then seven (7) year-old customer and patient of Costco Pharmacy.

6. On or about February 21, 2013, D.W., T.W.'s mother, presented to Costco Pharmacy with a prescription for T.W. for "Diastat 12.5 mg".

7. Diastat, also known as Diastat AcuDial or Diastat Pediatric, is a brand name of diazepam that is administered rectally to treat seizures. According to Section 893.03(4), Florida Statutes, diazepam is a Schedule IV controlled substance that has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States. Abuse of diazepam may lead to limited physical or psychological dependence relative to the substances in Schedule III.

8. On or about February 25, 2013, Respondent filled T.W.'s prescription and dispensed a syringe with a 20 milligram (mg) dose of diazepam to T.W.

9. The syringe dispensed by Respondent in paragraph eight (8) is a diazepam rectal gel delivery system. The syringe has four dose options, 12.5mg, 15mg, 17.5mg, and 20mg, and the dose is selected by "dialing" the syringe until the prescribed dose is displayed in the window on the syringe. After the prescribed dose is selected, the dose must be "locked" by the pharmacist before the syringe is dispensed to the patient.

10. The syringe dispensed to T.W. by Respondent in paragraph eight (8) was not dialed to the prescribed 12.5mg dose and locked by Respondent before it was dispensed.

11. Section 465.016(1)(g), Florida Statutes (2012), provides that using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in Section 465.019(6), Florida Statues, or Section 465.025, Florida Statutes, constitutes grounds for disciplinary action.

12. As set forth above, Respondent furnished a syringe with a 20mg dose of diazepam to patient T.W. when T.W. presented a prescription for Diastat 12.5mg.

13. Based on the foregoing, Respondent has violated Section 465.016(1)(g), Florida Statutes (2012), by using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 24th **day of** October**, 2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Christopher A. Jurich

CHRISTOPHER A. JURICH
Assistant General Counsel
Fla. Bar No. 0099014
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: christopher_jurich@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE OCT 24 2013

/CAJ

PCP: October 24, 2013
PCP Members: Leo Fallon, Debra Glass

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

Mission:
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Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

November 14, 2013

VIA US MAIL

Kevin Jakab, Esquire
1936 San Marco Boulevard
Jacksonville, Florida 32207

Re: DOH v. Enrique Moises Pallares, R.Ph.
DOH Case Number: 2013-07014

Dear Mr. Jakab:

I am in receipt of the settlement agreement executed by your client on October 31, 2013 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for February 5, 2014 at the Doubletree by Hilton, 60 South Ivanhoe Boulevard, Orlando, Florida 32804. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Christopher A. Jurich

Christopher A. Jurich
Assistant General Counsel

CAJ/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

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Complaint Cost Summary

Complaint Number: 201307014

Subject's Name: PALLARES, ENRIQUE MOISES

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.70	$38.43
Investigation:	15.90	$1,017.30
Legal:	5.30	$563.69
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	21.90	$1,619.42
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,619.42

October 31, 2013

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED AND FACSIMILE

Christopher A. Jurich, Asst. General Counsel
Florida Department of Health
Office of the General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265

RE: *Florida Department of Health v. Enrique Moises Pallares, R.Ph.*
Case No.: 2013-17014

Dear Mr. Jurich:

We are in receipt of your October 25, 2013 correspondence that contained the Administrative Complaint (Case No.: 2013-07014), in the above-captioned case. After due consideration of the allegations contained in said Complaint and in light of the settlement offer to completely resolve this matter, our client, Enrique Pallares, R.Ph., hereby accepts your settlement offer related to this matter. Please find enclosed the following:

1. Mr. Pallares' signed and notarized Election of Rights; and
2. A signed and notarized copy of the Settlement Agreement.

Please copy our office on any further correspondence related to this case and forward the meeting date, time, and location of the Board meeting regarding the settlement agreement. We also request that the Board approve this settlement agreement without the need for Mr. Pallares to be present (personally), if possible.

Thank you for your time and attention to this matter. If you have any questions or comments, please feel free to contact our office at any time.

Sincerely,

KEVIN E. JAKAB, ESQ.

KEJ:llr
Enclosures

cc: Enrique Moises Pallares, R.Ph. (w/encls.)

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: **Department of Health, Prosecution Services Unit**

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Enrique Moises Pallares, R.Ph.**
Case No. 2013-07014

MEMBERS: Leo Fallon & Debra Glass

DATE OF PCP: **October 24, 2013** **AGENDA ITEM: A-5**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1)(g), F.S. (2012)

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**
a)
b)
c)

___ Upon **reconsideration**, dismiss

___ **other** _____

Amy Collins for Debra Glass 16 Jan 2014
Chair, Probable Cause Panel Date
Board of Pharmacy

JAKAB
L A W

RECEIVED

JUL 2 5 2013

DOH/MIAMI
INVESTIGATIVE SERVICES

July 22, 2013

VIA EMAIL & U.S. MAIL

Jeneice Mayers, Investigation Specialist II
Investigative Services Unit
Medical Quality Assurance
Florida Department of Health
8350 N.W. 52nd Terrace, Suite 400
Doral, FL 33166-7709

RE: Investigation of Enrique Moises Pallares
DOH Case No.: PS 2013-07014

Dear Ms. Mayers:

It was a pleasure speaking to you regarding the above-captioned case on Friday, July 19, 2013. We understand that your investigation of Mr. Pallares is expected to be completed this week. Thank you for updating us regarding the status of the investigation.

Attached to this correspondence you will find the Affidavit of Enrique Moises Pallares. Please review this Affidavit prior to sending the file to the Probable Cause Panel. We also request a copy of DOH's investigation file.

Thank you for your time and attention to this matter. If you have any questions or comments, please feel free to contact our office at any time.

Sincerely,

KEVIN E. JAKAB, ESQ.

KEJ:llr
Enclosure

cc: Enrique Moises Pallares

Acknowledgement of and
Agreement to Maintain Patient Confidentiality

I, Enrique Pallares, am the Subject of an investigation by the Department of Health. As the Subject of such an investigation, I am entitled to inspect or receive a copy of the investigative report, including any expert witness report or patient records connected with the investigation pursuant to Section 456.073(10), Florida Statutes, if I agree in writing to maintain the confidentiality of any information received under this provision, until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to Section 456.057, Florida Statutes.

I understand the cost associated with duplicating x-rays and I want ( ) do not want ( ) to receive a copy of any x-rays that are contained within the investigative file.

SIGNED this 20th day of August, 2013.

Enrique Moises Pallares, R.Ph.
2013-07014

SIGNED this 20th day of August, 2013 on behalf of Enrique Moises Pallares, R.Ph.

Kevin Jakab, Esquire

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Miami XI	Date of Case: 05/02/2013	Case Number: PS 2013-07014

Subject:	Source:
ENRIQUE MOISES PALLARES 2496 Monterey Court Weston, FL 33327 (954) 384-4975 (H)	DW (PATIENT)

Prefix:	License #:	Profession:	Board:	Report Date:
2201	24103	Pharmacist	Pharmacy	08/02/13

Period of Investigation: 05/20/13 – 08/02/13	Type of Report: FINAL

Alleged Violation of SS. 456.072(1)(k) (dd) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken: Failing to perform any statutory or legal obligation placed upon...; Violating any provision of this...; 465.016(1)(e)(g)(i)(r) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2): Violating chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug...; Using in the compounding of a prescription...; Compounding, dispensing, or distributing a legend drug...; Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto. F.A.C.; Rule 64B16-27.101 No pharmacist or pharmacy employee or proprietor shall knowingly purchase, sell, possess or distribute drugs...; F.A.C.; Rule 64B16-27.101(1)(c) A pharmacist or pharmacy intern must: Interpret and identify prescription contents.

Synopsis: This investigation is predicated upon receipt of a complaint (Case Summary and Initiating Documents Exhibit #1), submitted by DW (mother of minor patient/child TVW). DW alleges that ENRIQUE MOISES PALLARES dispensed an undialed suppository of Valium 20mg for her daughter (TVW 7 y/o/female) on 02/23/13 at COSTCO PHARMACY (PH 18472); a Community Pharmacy, d/b/a COSTCO PHARMACY Store #182, located at 14585 Biscayne Blvd, North Miami Beach, FL 33181. The prescription was written for Diastat 12.5mg. DW also alleges that PALLARES dispensed raw materials to her daughter patient TVW.
PALLARES was notified of the investigation by letter, dated 05/10/13 (Exhibit #2) and was provided a copy of the Case Summary and Attachments from (Exhibit #1).

A search of the DOH licensure database reveals that ENRIQUE MOISES PALLAES is currently licensed as a Pharmacist.

No patient(s) notification is required for this case, because DW (parent of minor patient/child TVW) is the source. Upon interview via telephonically on 06/13/13, DW requested periodic updates on the case.

ENRIQUE MOISES PALLARES is represented by Attorney KEVIN E JAKAB, located at 1936 San Marco Boulevard, Jacksonville, FL 32207; (904) 683-2290 (Exhibit #8). JAKAB has requested a copy of the entire investigative file immediately upon completion of the investigation, pursuant to Florida Statute F.S. 456.073 (10).

On 07/03/13, Attorney KEVIN E JAKAB submitted a written response (via US Mail) on behalf of Prescription Department Manager (PDM), ENRIQUE MOISES PALLARES neither admitted nor denying the allegations (Exhibit #8).

Related Case(s): NONE

Investigator/Date: August 2, 2013	Approved By/Date: August 2, 2013
Jeneice Mayers, Investigation Specialist	Caridad Rodriguez, Investigator Supervisor

Received
Investigative Services
AUG 05 2013

13 AUG -5 PM 3:17
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Distribution: HQ/ISU

DOH/MQA
Tallahassee HQ

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* 1. Case Summary and Attachments 6-15
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***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10) (a), FLORIDA STATUTES**

INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit 3: Copy of Status 30 Letter dated 05/10/13, that was sent to DW, mother of minor patient/child TVW.

Exhibit 4: Contains the Florida Department of State Division of Corporations, listing CT CORPORATION SYSTEM as the registered agent of COSTCO PHARMACY (PH 18472), d/b/a COSTCO PHARMACY Store #182
Status: Active

Exhibit 5: Documentation that were obtained from ENRIQUE MOISES PALLARES, Costco pharmacy (PH 18472), d/b/a COSTCO PHARMACY Store #182 PDM on 06/21/13 by this investigator, which contains the following:

- Printouts of TVW prescription (pp. 22-23)
- TVW prescription Status Trail/Notes (pg. 24)
- TVW Prescription Profile from 06/18/07 – 02/23/13 (pp. 25-26)
- Costco Pharmacy Register for the numbers of prescriptions filled on the day of the alleged misfill 02/23/13 (pp. 27-30)
- Costco Sales Summary for 02/23/13 (pp. 31-33)
- Costco Usage Report for 02/23/13 (pp. 34-36)
- Employee Performance Log (pp. 37-39)
- CQI for the month of June (pg. 40)

Exhibit 6: Contains copies of COSTCO PHARMACY (PH 18472), d/b/a COSTCO PHARMACY Store #182 Inspection Reports for the following dates:

- 09/22/08 – (Satisfactory) Routine Inspection
- 09/03/09 – (Satisfactory) Routine Inspection
- 03/17/11 – (Satisfactory) Routine Inspection
- 06/21/13 – (Satisfactory) Routine re-Inspection

Exhibit 7: Documentation that were obtained from DW, mother of minor patient/child TVW, which contains the following:

- Photograph & label of the medication that is in question Diazepam (pp. 46-51)
- Receipt & patient counseling information for 02/23/13 (pp. 52-53)
- Prescription receipt from Publix pharmacy that was filled on 04/10/13 (pg. 54)

Exhibit 8: Letter of Representation dated 06/28/13 and written response dated 07/22/13 from Attorney KEVIN E JAKAB, on behalf his client Prescription Department Manager (PDM), ENRIQUE MOISES PALLARES, letter of representation also requested a 20 day extension which was received on 07/03/13 (via US Mail) and written response received on 07/25/13 at the Miami Investigative Service Unit Office.

INTERVIEW OF DW, PATIENT TVW'S MOTHER – (Source)

On 08/01/13, this Investigator interviewed DW, mother of minor patient/child TVW in the Miami Investigative Service Unit Office. DW reiterated her complaint that are noted within the Healthcare Practitioner Complaint Form that she submitted to DOH/Consumer Servicer Unit (Exhibit #1) and stated to this Investigator that DR TATYANA DUBROVSKY wrote a prescription for Diastat 12.5mg for her daughter and her daughter was given Valium 20mg which was a misfilled prescription (see photos Exhibit #7 PP. 46-51). This investigator also asked DW was counseling provided or offered at the time of dispensing and she stated "no". DW also stated to this investigator that she nor her family will no longer fill prescriptions at COSTCO PHARMACY (PH 18472), d/b/a COSTCO PHARMACY Store #182. DW further stated to this Investigator that her daughter TVW didn't ingest any of the misfiled prescription.

INVESTIGATOR NOTES:

DW (mother of minor patient/child TVW) has the medication in her possession and stated to this investigator that she is willing to produce the medication if the case goes for a hearing.

INTERVIEW OF TATYANA DUBROVSKY, MD – (WITNESS)

Employment Address:
JOE DIMAGGIO CHILDREN'S HOSPITAL PEDIATRIC NEUROLOGY DEPARTMENT
1150 N. 35th Avenue
Suite 520
Hollywood, FL 33021
(954) 265-2423 (W)

On 05/10/13, this Investigator and Investigator Specialist II GABRIEL CRUZ presented to JOE DIMAGGIO CHILDREN'S HOSPITAL PEDIATRIC NEUROLOGY DEPARTMENT, located at 1150 N. 35th Avenue, Suite 520, Hollywood, FL 33021 and conducted an interview with TATYANA DUBROVSKY, MD. In summary, DUBROVSKY stated to this Investigator that patient/child TVW has been her patient since 02/2013 and has been treated for seizure problems. DUBROVSKY also pulled patient/child TVW's chart and verified the medication that was prescribe on 02/21/13 was Diastat 12.5mg.

STATEMENT OF ENRIQUE MOISES PALLARES, PDM (PS 24103) – (SUBJECT/EXHIBIT #8)
Employment Address:
JAKAB LAW
1936 San Marco Boulevard
Jacksonville, FL 32207
(904) 683-2290 (W)

On 07/03/13, this Investigator received a Letter of Representation dated 06/28/13 and written response on 07/25/13 dated 07/22/13 from Attorney KEVIN E JAKAB, on behalf his client Prescription Department Manager (PDM), ENRIQUE MOISES PALLARES (Exhibit #8). In summary, JAKAB stated the following: "You will find Affidavit of ENRIQUE MOISED PALLARES please review this Affidavit prior to sending the file to the Probable Cause Panel" (Exhibit #8 pp. 59-60). JAKAB also requested a copy of DOH's investigation file.

INVESTIGATOR NOTES:
On 06/21/13, this Investigator and Medical Quality Assurance Investigator DAVID WARSHOFSKY presented to the address of Costco pharmacy (PH 18472), d/b/a COSTCO PHARMACY Store #182. WARSHOFSKY conducted a Routine re-inspection (Exhibit #6 pg. 45) and patient/child TVW's prescriptions profiles (Exhibit #5 pp. 25-26) were retrieved during the routine satisfactory re-inspection.

The Confidential Index is Exhibit 9.

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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FLORIDA DEPARTMENT OF STATE
DIVISION OF CORPORATIONS

Detail by Entity Name

Foreign Profit Corporation

COSTCO WHOLESALE CORPORATION

Cross Reference Name

CWC CORPORATION

Filing Information

Document Number	P14754
FEI/EIN Number	911223280
Date Filed	06/08/1987
State	WA
Status	ACTIVE
Last Event	CORPORATE MERGER
Event Date Filed	04/28/1995
Event Effective Date	NONE

Principal Address

999 LAKE DRIVE
ISSAQUAH, WA 98027

Changed: 01/08/2004

Mailing Address

P.O. BOX 35005
ATTN: LICENSING DEPT.
SEATTLE, WA 98124

Changed: 01/04/2011

Registered Agent Name & Address

CT CORPORATION SYSTEM
1200 S. PINE ISLAND ROAD
PLANTATION, FL 33324

Name Changed: 03/05/1992

Address Changed: 03/05/1992

Officer/Director Detail

Name & Address

Title VPAS

EXHIBIT 4

CONFIDENTIAL

OLIN, RICHARD J
999 LAKE DR
ISSAQUAH, WA 98027

Title PD, CEO

JELINEK, WALTER C
999 LAKE DR
ISSAQUAH, WA 98027

Title SVPS

BENOLIEL, JOEL
999 LAKE DR
ISSAQUAH, WA 98027

Title EVC

GALANTI, RICHARD ACFO
999 LAKE DRIVE
ISSAQUAH, WA 98027

Title SVP

PETTERSON, DAVID S
999 LAKE DRIVE
ISSAAQUAH, WA 98027

Title Assistant Secretary

Tsuboi, Gail E
999 LAKE DRIVE
ISSAQUAH, WA 98027

Title VP/Treasurer

Kaplan, Harold E
999 LAKE DRIVE
ISSAQUAH, WA 98027

Title VP/Assistant Secretary

Callans, Patrick J
999 LAKE DRIVE
ISSAQUAH, WA 98027

Title VP/Assistant Secretary

Minola, John M
999 LAKE DRIVE
ISSAQUAH, WA 98027

Title VP/Assistant Secretary

Sullivan, John C
999 LAKE DRIVE
ISSAQUAH, WA 98027

Title Assistant Secretary

McCulla, Margaret C
45940 Horseshoe Drive, Suite 150
Sterling, VA 20166

Annual Reports

Report Year	Filed Date
2011	01/04/2011
2012	01/06/2012
2013	01/24/2013

Document Images

01/24/2013 -- ANNUAL REPORT	View image in PDF format
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01/31/2000 -- REINSTATEMENT	View image in PDF format
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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

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ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 10603

Insp # 76717

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT COSTCO WHOLESALE CORPORATION		PERMIT NUMBER 18472	DATE OF INSPECTION 9/26/2008
DOING BUSINESS AS COSTCO PHARMACY #182		DEA NUMBER bc7689637	PRESCRIPTION DEPARTMENT MANAGER ENRIQUE M PALLARES
STREET ADDRESS 14585 BISCAYNE BOULEVARD		TELEPHONE # (407) 681-2125 EXT.	
CITY NORTH MIAMI BEACH	COUNTY 23	STATE/ZIP 33181	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 24103

PRESCRIPTION DEPARTMENT HOURS	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open							
Close							

REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
1.	
2.	
3.	

	SATISFACTORY	N/A	YES	NO
1 Current pharmacy permit displayed. [465.015(1)(a),F.S.]			X	
2 Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]			X	
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4 Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]			X	
5 Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]			X	
6 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			X	
7 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]			X	
8 Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]			X	
9 Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.			X	
10 Generic drug sign displayed. [465.025(7),F.S.]			X	
11 Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]			X	
12 Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*			X	
13 Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]			X	
14 Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]			X	
15 Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]			X	
16 Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			X	
17 Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]			X	
18 Prescription department clean and safe. [64B16-28.105,F.A.C.]			X	
19 Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]			X	
20 Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]			X	
21 Medication properly labeled [64B16-27.101,F.A.C.]			X	
22 All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]			X	
23 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]			X	
24 Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]			X	
25 "Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]			X	

	SATISFACTORY	N/A	YES	NO
26 All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]			X	
27 Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]			X	
28 Complete pharmacy prescription records. [64B16-28.140,F.A.C.]			X	
29 Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]			X	
30 Controlled substance records readily retrievable. [893.07,F.S.]			X	
31 Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]			X	
32 Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]			X	
33 Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			X	
34 Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]			X	
35 All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			X	
36 Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]			X	
37 Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			X	
38 Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]			X	
39 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]			X	
40 DEA 222 order forms properly completed. [893.07(2),F.S.]			X	
41 Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*			X	
42 Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]			X	
43 Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]			X	
44 Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *			X	
45 Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *			X	
46 Compounding records properly maintained [64B16-28.140(4),F.A.C.] *			X	
47 Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *			X	

Questions with (*) may be answered n/a (not applicable).

Remarks:

CONFIDENTIAL

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

EXHIBIT 6

PRINT NAME OF RECIPIENT enrique pallares

Institutional Representative

09-26-2008

Date

Investigator/Sr. Pharmacist Signature

ID mi168

INV 359 Revised 01/07 Replaces 12/02

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

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ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 10603

Insp # 86200

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT COSTCO WHOLESALE CORPORATION		PERMIT NUMBER 18472	DATE OF INSPECTION 9/3/2009
DOING BUSINESS AS COSTCO PHARMACY #182		DEA NUMBER BC7689637	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 14585 BISCAYNE BOULEVARD		TELEPHONE # (407) 681-2125 EXT.	ENRIQUE M PALLARES
CITY NORTH MIAMI BEACH	COUNTY 23	STATE/ZIP 33181	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 24103

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	10AM	10AM	10AM	10AM	10AM	930PM	CLOSED
Close	7PM	7PM	7PM	7PM	7PM	6PM	CLOSED

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. ENRIQUE M/ PALLARES/PS24103
2. SHARI VASSEL/TECHNICIAN
3.

	SATISFACTORY	N/A	YES	NO
1 Current pharmacy permit displayed. [465.015(1)(a),F.S.]			X	
2 Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]			X	
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4 Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]			X	
5 Items properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]			X	
6 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			X	
7 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]			X	
8 Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]			X	
9 Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.			X	
10 Generic drug sign displayed. [465.025(7),F.S.]			X	
11 Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]			X	
12 Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*		X		
13 Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]			X	
14 Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]			X	
15 Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]			X	
16 Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			X	
17 Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]			X	
18 Prescription department clean and safe. [64B16-28.105,F.A.C.]			X	
19 Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]			X	
20 Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]			X	
21 Medication properly labeled [64B16-27.101,F.A.C.]			X	
22 All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]			X	
23 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]			X	
24 Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]			X	
25 "Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]			X	

	SATISFACTORY	N/A	YES	NO
26 All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]			X	
27 Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]			X	
28 Complete pharmacy prescription records. [64B16-28.140,F.A.C.]			X	
29 Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]			X	
30 Controlled substance records readily retrievable. [893.07,F.S.]			X	
31 Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]			X	
32 Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]			X	
33 Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			X	
34 Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]			X	
35 All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			X	
36 Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]			X	
37 Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			X	
38 Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]			X	
39 Controlled substance inventory taken on a biennial basis and available for Inspection. [893.07(1)(a),F.S.]			X	
40 DEA 222 order forms properly completed. [893.07(2),F.S.]			X	
41 Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*			X	
42 Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]			X	
43 Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]			X	
44 Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *			X	
45 Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *		X		
46 Compounding records properly maintained [64B16-28.140(4),F.A.C.] *		X		
47 Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *		X		

** Questions with (*) may be answered n/a (not applicable).*

Remarks: #5 N/A #23 LAST CQI DATE:8/10/09
#42 LAST BIENNIAL CS INVENTORY DATE: 4/30/09

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT ENRIQUE M/ PALLARES/PS24103

ID mi192

Institutional Representative

09-03-2009
Date

Investigator/Sr. Pharmacist Signature

INV 359 Revised 01/07 Replaces 12/02

: 00042

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

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ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 10603

Insp # 94563

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT COSTCO WHOLESALE CORPORATION		PERMIT NUMBER 18472		DATE OF INSPECTION 3/17/2011
DOING BUSINESS AS COSTCO PHARMACY #182		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 14585 BISCAYNE BOULEVARD		TELEPHONE # (407) 681-2125	EXT.	ENRIQUE M PALLARES
CITY NORTH MIAMI BEACH	COUNTY 23	STATE/ZIP 33181		PRESCRIPTION DEPARTMENT MANAGER LICENSE # 24103

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1.	
Open								2.	
Close								3.	

	SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]		X	
2	Pharmacy technicians properly identified and supervised. [64B16-27.410, F.A.C.]		X	
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]		X	
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]*		X	
5	Written and verbal offer to counsel patients. [64B16-27.820(1), F.A.C.]		X	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]		X	
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]		X	
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]		X	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]		X	
10	CQI Policy and Procedures and quarterly meetings. [64B16-27.300, F.A.C.] [766.101, F.S.]		X	
11	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]		X	
12	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]		X	
13	Controlled substance records readily retrievable. [893.07 (4) (B), F.S.]		X	
14	All controlled substance prescriptions contain information required. [893.04, F.S.]		X	
15	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]		X	
16	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1) (a), F.S.]		X	
17	DEA 222 order forms properly completed. [893.07, F.S.]		X	
18	Controlled substance Rx information in computer system is retrievable. [21CFR 1306.22] [893.07, F.S] [64B16-28.140, F.A.C.]*		X	
19	Controlled substance records maintained for 2 years. [21CFR 1304.04] [21CFR 1306.22] [893.07(4)(b), F.S.]		X	
20	Certified daily log OR printout maintained as required by section. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]		X	
21	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.] *		X	
22	Compounding records properly maintained. [64B16-27.797, F.A.C.]*		X	
23	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]*		X	
24	Pedigree records retrievable. [64F-12.012(3)(a)2., (d)]		X	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: Please refer to manual attachment due to tablet issues.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT N/A

Institutional Representative

03-17-2011
Date

Investigator/Sr. Pharmacist Signature

ID mi187

INV 359 Revised 10/10, 10/09; 5/06, 12/02, 12/00

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
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FLORIDA DEPARTMENT OF HEALTH

COMMUNITY PHARMACY

FILE#_____

INSPECTION#_____

ROUTINE ☑ CHANGE LOC ☐ NEW ☐ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

INSPECTION AUTHORITY – CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT	PERMIT NUMBER	EXPIRATION DATE	DATE OF INSPECTION
COSTCO Wholesale Pharmacy	18472		3/16/2011

DOING BUSINESS AS	TELEPHONE NUMBER	EXTENSION

STREET ADDRESS	CITY	COUNTY	STATE	ZIP
14585 Biscayne Blvd	Miami	Dade	Fl	33181

DEA NUMBER	EXPIRATION DATE
BC7689637	

PRESCRIPTION DEPARTMENT MANAGER NAME	PDM NOTIFICATION DATE	LICENSE NUMBER	
Enrique M. Pallares		PS24103	
VENDOR WHOLESALER PHARMACY	VENDOR LICENSE NUMBER		

REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE NUMBER	
1		
2		
3		

	SATISFACTORY	NA	YES	NO
1. Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			✓	
2. Pharmacy technicians properly identified and supervised. approval date. [64B16-27.410. F.A.C.]			✓	
3. Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			✓	
4. Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035F.A.C.] [64B16-27.400(6), F.A.C.]*			✓	
5. Written and verbal offer to counsel patients. [64B16-27.820(1). F.A.C.]			✓	
6. Prescription department has convenient sink/running water. [64B16-28.102(1). F.A.C.]			✓	
7. Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			✓	
8. Proper equipment and references as required. [64B16-28.102, F.A.C.]			✓	
9. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			✓	
10. CQI Policy and Procedures and quarterly meetings. [64B16-27.300, F.A.C. [766.101, F.S.] 2/21/2010.			✓	
11. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1) (c) 6, F.S.] [64B16-28.140(3) (b). F.A.C.]			✓	
12. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			✓	
13. Controlled substance records readily retrievable. [893.07 (4)(B), F.S.]			✓	
14. All controlled substance prescriptions contain information required. [893.04(1) (c), F.S.]			✓	
15. Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1) (g), F.S.] [64B16-28.114, F.A.C.]			✓	
16. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1) (a). F.S.] 3/10/11			✓	
17. DEA 222 order forms properly completed. [893.07(2), F.S.]			✓	
18. Controlled substance Rx information in computer system is retrievable. [21CFR 1306.22] [893.07, F.S] [64B16-28.140, F.A.C.]*			✓	
19. Controlled substance records maintained for 2 years. [21CFR 1304.04][21CFR 1306.22] [893.07(4) (b), F.S.]			✓	
20. Certified daily log OR printout maintained as required by section. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b). F.A.C.]			✓	
21. Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.] *			✓	
22. Compounding records properly maintained. [64B16-27.700, F.A.C.] [64B16-28.140(4), F.A.C.]*		✓		
23. Unit dose records properly maintained. [465.016(1) (l), F.S.][64B16-28.118, F.A.C.] *		✓		
** Questions with (*) may be answered n/a (not applicable)*				

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: Pharmacy is within compliance at this time very safe and clean. Educated PDM on behalf the inspection prior to signing. Pharmacy buys from Mckesson

I have read and have had this inspection report and the laws and regulations concerned explained, and the information given is true and correct to the best of my knowledge.

Signature of Pharmacist — Date: 3/16/2011 — Investigator/Sr. Pharmacist Signature/ID Number: NJ187.

Enrique Pallares
Print Name

INV 359 Revised 06/09 05/07; 5/06, Replaces 12/02, 12/00

: 00044

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

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File # 16715

Insp # 7

ROUTINE [1] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT: Costco wholesale	PERMIT NUMBER: Ph. 18472	DATE OF INSPECTION: 6-21-13
DOING BUSINESS AS:	DEA NUMBER: BE 7689637	PRESCRIPTION DEPARTMENT MANAGER: Enrique Pallares
STREET ADDRESS: 14585 Biscayne Blvd.	TELEPHONE #: 305-956-3874 EXT.	
CITY: N. Miami Bch COUNTY: MD	STATE/ZIP: Fl 33181	PRESCRIPTION DEPARTMENT MANAGER LICENSE #: PS 24103

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	10:00					9:30	X
Close	8:00					6:00	

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Elari Vassel, RPT 18872
2. Enrique Pallares
3.

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			✓	
2	Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]			✓	
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			✓	
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			✓	
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			✓	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			✓	
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			✓	
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			✓	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			✓	
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			✓	
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.] - June 2013			✓	
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]			✓	
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			✓	
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			✓	
15	All controlled substance prescriptions contain information required. [893.04, F.S.]			✓	
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].		✓		
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			✓	
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] → May 31, 2013			✓	
19	DEA 222 order forms properly completed. [893.07, F.S.]			✓	
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			✓	
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]			✓	
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			✓	
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]		✓		
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]			✓	
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]			✓	
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]		✓		
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]	✓			
28	Compounding records properly maintained. [64B16-28.140(4), F.A.C.]*	✓			
29	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]	✓			
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			✓	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: wholesaler McKesson, ABC wholesaler.
#10 no expired meds
#11 last CQI - June 2013
#18 last control inventory May 31, 2013.
#22 reviewed last 10 Day End reports.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT: Enrique Pallares

Institutional Representative

6-21-13
Date

Investigator/Sr. Pharmacist Signature

ID MI 200

Save

INV 359 Revised 5/12, 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

: 00045

CONFIDENTIAL AND EXEMPT MATERIALS

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201302905

MICHAEL W HALFEN,
RESPONDENT.

NOTICE

TO: MICHAEL W HALFEN
748 BOULDER CREEK DR
PENSACOLA, FL 32514

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Mary Miller, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Michael W. Halfen, R.Ph.
DOH Case Number 2013-02905
DATE: December 5, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Michael W. Halfen, R.Ph.
Subject's Address of Record:	748 Boulder Creek Drive Pensacola, FL 32514
Enforcement Address:	748 Boulder Creek Drive Pensacola, FL 32514
Subject's License No:	32618 **Rank:** PS
Licensure File No:	21628
Initial Licensure Date:	7/25/1997
Board Certification:	None
Required to Appear:	Yes
Current IPN/PRN Contract:	No
Allegation(s):	Section 465.016(1)(r), F.S. (2012), by violating Section 465.022(11)(a), F.S. (2012)
Prior Discipline:	None
Probable Cause Panel:	June 27, 2013 Fallon Glass
Subject's Attorney:	Pro Se
Complainant/Address:	Department of Health/Investigative Services Unit-Tallahassee

Materials Submitted:

Memorandum to the Board
Settlement Agreement
Exhibit A – Administrative Complaint
Board Notification Letter
Election of Rights
Cost Summary
PCP Memo
Final Investigative Report with Exhibits 1 - 5

Disciplinary Guidelines:

None

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

On 2/11/13, Respondent was the PDM of Gulf Medical Services, Inc. and responsible for ensuring the pharmacy complied with the rules regulating pharmacy. On 2/11/13, the Department conducted a routine inspection of Respondent's facility and the Department's inspector noted the pharmacy's sterilized high-risk preparations did not pass a sterility test or were not properly stored as required by board rule. The Department's inspector also noted that the pharmacy's high-risk compounding personnel had not completed a media-filled test with a high-risk test kit on a semi-annual basis, as required by board rule.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-02905**

MICHAEL W. HALFEN, R.Ph.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Michael W. Halfen, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 32618. Respondent's mailing address of record is 748 Boulder Creek Drive, Pensacola, Florida 32514.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **ONE THOUSAND DOLLARS and NO CENTS ($1,000.00)**. The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320,**

Tallahassee, Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND FOUR HUNDRED TWENTY SIX DOLLARS AND THIRTY-SEVEN CENTS ($1,426.37).** Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

4. **CE Course**- Respondent shall successfully complete a Continuing Education Course on the subject of **Laws and Rules of Pharmacy** consisting of **a minimum of 8 hours** of credit, which has approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. These continuing education hours shall be in addition to the

hours required for license renewal. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

5. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses**- Respondent shall keep current its mailing address and its practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 23 day of October, 2013

Michael W. Halfen

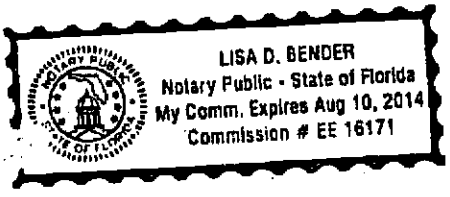
Michael W. Halfen, R.Ph.
CASE NO. 2013-02905

STATE OF FLORIDA

COUNTY OF Santa Rosa

Before me personally appeared Michael Halfen whose identity is known to me or by Personally Known (type of identification), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 23rd day of October, 2013.



Notary Public
My Commission Expires: 8/10/14

APPROVED this 29th day of October, 2013.

John H. Armstrong, MD, FACS
Surgeon General & Secretary
Florida Department of Health

Mary Miller
Assistant General Counsel
Florida Department of Health
Florida Bar Number 0780420
4052 Bald Cypress Way
Tallahassee, Florida 32399-3265
Telephone: 850-245-4444, ext. 8104
Fax: 850-245-4683
E-Mail: mary.miller2@flhealth.gov

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-02905**

MICHAEL W. HALFEN, R.Ph.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Michael W. Halfen, R.Ph., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 32618.

EXHIBIT
A

3. Respondent's address of record is 748 Boulder Creek Drive, Pensacola, Florida 32514.

4. At all times material to this complaint, Respondent was the prescription department manager (PDM) of Gulf Medical Services, Inc. (the Permittee), which is a permitted community pharmacy within the state of Florida having permit number 16983.

5. Section 465.022(11)(a), Florida Statutes (2012), states "[t]he prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs."

6. As the PDM, Respondent was responsible for ensuring the Permittee complied with the following Rules:

a. Rule 64B16-27.797(1)(i)(4), Florida Administrative Code, which provides the standard of practice for storing High-Risk Level compounded sterile preparations (CSPs), cannot exceed specified time periods enumerated in the Rule;

b. Personnel authorized to compound high-risk compounded sterile preparations (CSPs), had not

completed a media-filled test with high-risk test kit on a semi-annual basis.

7. On or about February 11, 2013, a Department inspector conducted a routine inspection of the Permittee at its business address of 6776 Caroline Street, Milton, Florida 32570.

8. On or about February 11, 2013, the Department inspector noted the following deficiencies:

a. Sterilized high-risk preparations did not pass a sterility test or preparations were not properly stored as required by Rule 64B16-27.797(1)(i)(4), Florida Administrative Code; and/or

b. Personnel authorized to compound high-risk compounded sterile preparations (CSPs), had not completed a media-filled test with high-risk test kit on a semi-annual basis.

9. Section 465.016(1)(r), Florida Statutes (2012), provides that violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto, constitutes grounds for denial of a license or disciplinary action.

10. Section 465.022(11)(a), Florida Statutes (2012), provides that the prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

11. Respondent failed to ensure the Permitee's compliance with the rules regulating pharmacy in one or more of the following ways:

a. By failing to ensure the permittee complied with Rule 64B16-27.797(1)(i)(4), Florida Administrative Code, as set forth in paragraph 8 above; and/or

b. By failing to ensure the permittee complied with Rule 64B16-27.797(1)(i)7, Florida Administrative Code, as set forth above in paragraph eight above.

12. Based on the foregoing, Respondent violated Section 465.016(1)(r), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes (2012), by failing to ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 27th day of June, 2013.

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and Secretary of Health

Mary S. M

Mary S. Miller
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No. 0780420
(850) 245-4444, ext. 8104, telephone
(850) 245-4683 fax
Mary_Miller2@doh.state.fl.us E-Mail

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUN 27 2013

PCP: June 27, 2013
PCP Members: Fallon + Glass

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

December 5, 2013

Michael W. Halfen
748 Boulder Creek Drive
Pensacola FL 32514

Re: DOH vs. Michael W. Halfen, R.Ph.
DOH Case Number: 2013-02905

Dear Mr. Halfen:

I am in receipt of the settlement agreement executed by you on October 23, 2013 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next regularly scheduled meeting of the Florida Board of Pharmacy. You will receive official notification from the Board of the date and time your case is set for hearing approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Mary S. Miller
Assistant General Counsel

MSM/cmn

CONFIDENTIAL AND EXEMPT MATERIALS

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Complaint Cost Summary

Complaint Number: 201302905

Subject's Name: HALFEN, MICHAEL W

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.60	$32.94
Investigation:	4.50	$223.27
Legal:	2.40	$255.24
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	7.50	$511.45
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$511.45

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Michael Halfen, R.Ph. (MSM)**
Case Number: 2013-02905

MEMBERS: **Lee Fallon and Debra Glass**

DATE OF PCP: **June 27, 2013** **AGENDA ITEM: A-3**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1)(r), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Stattues (2012);

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**
a)
b)
c)

___ Upon **reconsideration**, dismiss

___ **other** _____

Leo J. Fallon 6/27/2013

Chair, Probable Cause Panel Date
Board of Pharmacy

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area I Pensacola	Date of Case: 2/15/13	Case Number: **PS 2013-02905**

Subject:	Source:
MICHAEL W. HALFEN, RPh, Pharm. D. 748 Boulder Creek Dr. Pensacola, FL 32514 (850) 994-0430	**DOH/ISU TALLAHASSEE** **JOHN TAYLOR, SENIOR PHARMACIST** 4030 Esplanade Way Tallahassee, FL 33901 (850) 519-1181

Prefix:	License #:	Profession:	Board:	Report Date:
PS	32618	PHARMACIST	PHARMACY	4/18/13

Period of Investigation: 2/27/13 – 4/18/13	Type of Report: FINAL

Alleged Violation: **FS 456.072(1)(dd)** Violating any provision of this chapter... **465.016(1)(r)** Violating any provision of this chapter... **FAC 64B16-27.797 (CSPs) (1)(i)** 4. For properly stored sterilized high-risk preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and exposed for not more than 24 hours at controlled room temperature, and for not more than 3 days at a cold temperature (2-8 degrees Celsius) and for not more than 45 days in solid frozen state at -20 degrees celsius or colder.

Synopsis: This investigation is predicated upon receipt of a complaint, and Class II Institutional Pharmacy, Standards of Practice for Compounding Sterile Preparations (CSPs) inspection forms and Case Summary **(EXHIBIT 1)** submitted by Senior Pharmacist JOHN TAYLOR in regard to HALFEN reporting HALFEN is the PDM for Gulf Medical Pharmacy. Senior Pharmacist TAYLOR conducted a routine inspection of Gulf Medical Services Inc, d.b.a. Gulf Medical Pharmacy, a Community Pharmacy located at 6776 Caroline Street, Milton, FL 32570, on 2/11/2013. Findings of inspection alleged violation for failure to provide evidence of sterility for dispensed high risk preparation for which an extended beyond use date (20 days with storage at room temperature) was assigned. Findings further alleged failure to provide evidence that compounders of high risk preparations have successfully completed a high risk media test within the last six months.

HALFEN was notified of the investigation by letter dated 2/27/13 and was provided a copy of the case summary and the originating documentation from EXHIBIT 1 **(EXHIBIT 2)**.

A check of Department computer records revealed HALFEN is currently licensed as a consultant pharmacist (PU4936) and as a pharmacist. HALFEN received his BS in Marketing & Business Administration at Nicholls State University and his Doctor of Pharmacy at Xavier University of Louisiana (years not provided). HALFEN provided a copy of his CV which is attached as **EXHIBIT 5**.

There was no patient involved in this case; therefore, notification was not required.

HALFEN is not know to be represented by attorney in this matter.

On 3/13/13, Investigator RICHARD received HALFEN's response statement and attachments via hand service at ISU Pensacola **(EXHIBIT 5)**. HALFEN admitted the allegations and immediately took steps to correct the allegations.

RECEIVED LEGAL 13 APR 22 PM 3:10

Related Case: PH 2013-02904

Investigator/Date:	Approved By/Date:
S. Richard 4-18-13 Lloyd E. Richard, BI-27, Investigator	Cathy Martin 4/18/13 Cathy Martin, Investigator Supervisor

Received Investigative Service APR 22

Distribution: HQ/ISU/PSU

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IV. EXHIBITS
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2. Copy of notification letter mailed to HALFEN dated 2/27/13 with enclosures 13-19
3. Pharmacy inspection forms completed on 3/20/12, 1/10/11 and 12/22/09 20-25
4. CQI meeting for 1st Quarter 2013 26-27
5. HALFEN's response (not dated) received on 3/13/13 with attachments 28-42

*** RECORDS CONTAINS INFORMATION WHICH IDENTIFY PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10) (a), FLORIDA STATUTES.**

INVESTIGATIVE DETAILS

Complaint was found during routine inspections by Senior Pharmacist TAYLOR for Community Pharmacy and Standards of Practice for Compounding Sterile Preparations (CSPs) at Gulf Medical Pharmacy on 2/11/13. Items 1 and 2 were not complied with on the CSPs inspection form.

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

EXHIBIT 1 is information forwarded by the Consumer Services Unit (CSU) to ISU. This information consists of a Case Summary and the following:

- DOH/MQA complaint form completed by the Senior Pharmacist Inspector TAYLOR who provided:
- Community Pharmacy inspection form completed on 2/11/13; no deficiencies.
- Standards of Practice for Compounding Sterile Preparations (CSPs) inspection form completed on 2/11/13; items 1 and 2 were found deficient; item 1 - example found of high risk compounded product dispensed with a five day beyond use date with no evidence of sterility testing of product prior to dispensing; item 2 – compounding staff has not completed high risk media fill testing.
- IV Worksheet on Rx #02001856 for Hydromorphone HCL power 2500 mg / 500 ml dated 2/8/13 compounded with sodium CHL 0.9%
- Medication label for Rx #02001856 for Hydromorphone HCL 2500 mg / 500 ml; no refills, discard after 2/28/13.

EXHIBIT 3 was printed by Investigator RICHARD from COMPAS. Exhibit included:

- Community Pharmacy inspection form completed on 3/20/12; no deficiencies.
- Standards of Practice for CSPs inspection form completed on 3/20/12; no deficiencies.
- Community Pharmacy inspection form completed on 1/10/11; no deficiencies.
- Sterile Products and Special-Parenteral Enteral Compounding Pharmacy form completed on 1/10/11; no deficiencies.
- Community Pharmacy inspection form completed on 12/22/09; no deficiencies.
- Sterile Products and Special-Parenteral Enteral Compounding Pharmacy form completed on 12/22/09; no deficiencies.

All the above inspections passed.

EXHIBIT 4 was provided to Investigator RICHARD by HALFEN on 4/17/13. Exhibit included 1st Quarter CQI meeting notes. No issue with CSPs.

STATEMENT/INTERVIEW OF MICHAEL W. HALFEN, RPH, PHARM. D. - SUBJECT:

Address of record:
748 Boulder Creek Dr.
Pensacola, FL 32514
Residence telephone: (850) 994-0430; (850) 206-9736 (C)
Address of Employment:
GULF MEDICAL SERVICES, INC
6776 Caroline Street
Milton, FL 32570
Employment telephone: (850) 983-3705

On 3/5/13, HALFEN left a voice message to return his call. On 3/5/13, Investigator RICHARD contacted HALFEN at (850) 983-3705. HALFEN stated he would come to ISU Pensacola on 3/7/13.

On 3/7/13, HALFEN presented to the ISU Pensacola office. Investigator RICHARD interviewed HALFEN in person. HALFEN stated he took action to correct the issues on 2/11/13, the same day of the pharmacy inspection. He has a reminder on his Outlook calendar for dates of test. In regard to the violation of personal aseptic technique testing with high risk media; he thought he was using the only test available. When he called his supplier for a test kit the supplier had to call around to find the new USP format. He ordered the test kit the same day and started testing upon receipt.

The high risk preparations are compounded PCA infusions that are dispensed to hospice patients and are usually infused over a period of 7 to 10 days unless the patient expires. He is contact with the Covenant Hospice and made staff aware of labeling discard date, stability and sterility issues. He will provide a written response (**EXHIBIT 5**).

On 3/13/13, Investigator RICHARD received HALFEN's response statement and attachments via hand service at ISU Pensacola (**EXHIBIT 5**).
This letter is in response to the allegations of the pharmacy inspection of 2/11/13. He has 16 years of pharmacy practice during which he has not been cited for any violation. With regard to the violation of personal aseptic technique testing with high risk media, he has over the past 3 years been testing the compounding technicians semi-annually with what was to his knowledge the only PATT (Personal Aseptic Technique Test) available on the market. After being notified by the pharmacy inspector on this second inspection with the new USP formatted form (previous inspection 3/20/12) that this was not satisfactory, he contacted his two infusion suppliers, who also had to call their suppliers to find a valid high risk media fill kit which he immediately ordered and has implemented with the compounding technicians (see attachment completion dates).

The allegation of failure to provide evidence of sterility for a dispensed high risk preparation with an extended beyond use date brought forth an issue that could not be adequately answered by the inspector. These high risk preparations are compounded PCA infusions that are dispensed to hospice patients and are usually infused over a period of 7 to 10 days unless the patient expires sooner. Thus labeling these infusion bags with a 3 day or less expiration would not be accurate since this time period only applies to the storage prior to administration per USP 797, and the rule (64B16-27.797(1)(i)4. The issue therefore is the rule and the rule's use of USP 797 addresses concerns about sterility prior to administration and NOT stability of the preparation after administration has begun. The beyond use or discard after date that was assigned to the infusion was based on independent lab testing of stability and sterility of the previous sampling as part of their QA program (see attached lab reports). To become compliant with the rule, he had to immediately change his labeling of these products to reflect a "Start Infusion By" date that is within the Rule and USP 797 guidelines (see attached example). However this still does not address the labeling of stability on these preparations.

HALFEN asked if there should there be additional labeling with a "Discard after" date to address this issue since clinically they would not want the infusion running on a patient - for example – for a month thereby exceeding an established stability and very possibly a sterility window? Since his care for the patient does not end when the administration begins, he feels this issue warrants some additional ruling or direction.

He does not feel the previous QA program was sub-par. In light of this inspection he has substantially increased their testing of their compounding personnel, compounding environment, and their products to further insure the safety of their patients (see attached testing schedule). He takes the safety of their patients seriously and he is dedicated to remaining compliant with the rules of his profession.

Attachments to response statement:

1. HALFEN's Curriculum Vitae – HALFEN received his BS in Marketing & Business Administration at Nicholls State University and his Doctor of Pharmacy at Xavier University of Louisiana (years not provided).

2. Investigator RICHARD signed receipt of documents from HALFEN on 3/13/13.
3. Testing Schedule 2013 for personnel with dates.
4. Pharmacy Label for Morphine indicating start infusion by date (example).
5. Certificate of Analysis on Morphine Sulfate 1 mg/ml, lot #2001289; date tested 4/23/12.
6. Certificate of Analysis on Morphine Sulfate 1 mg/ml, lot #2001289; date tested 3/26/12.
7. Certificate of Analysis on Hydromorphone 1 mg/ml, lot #081106H1, received on 8/17/06.
8. Microbiology Report on Hydromorphone 1 mg/ml, lot #081106H1 test results, received on 8/17/06.
9. Certificate of Analysis on Morphine Sulfate 10 mg/ml, lot #081106M10, date tested 8/28/06.
10. Microbiology Report on Morphine Sulfate 10 mg/ml for lot #081106M10, results date tested 9/5/06.
11. Certificate of Analysis on Baclofen 2 mg/ml, lot #071210MH; tested 9/13/10.
12. Microbiology Report on Baclofen 2 mg/ml, lot #071210MH; tested 8/11/10.
13. Blank Testing Schedule (new management form for CSPs testing requirements).
14. HALFEN's business card.

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 10801

Insp # 105809

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT GULF MEDICAL SERVICES, INC		PERMIT NUMBER 18700	DATE OF INSPECTION 3/20/2012
DOING BUSINESS AS GULF MEDICAL PHARMACY		DEA NUMBER BG7912771	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 6776 Caroline Street		TELEPHONE # 850-983-3705 EXT.	MICHAEL W HALFEN
CITY MILTON	COUNTY 67	STATE/ZIP 32570	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 32618

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1. Donna Pittman PS 8932	
Open	8am	8am	8am	8am	8am	closed	closed	2. George Anderson PS 12203	
Close	4:30pm	4:30pm	4:30pm	4:30pm	4:30pm			3. Tiffany Denham RPT 29518	

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2	Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]			X	
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			X	
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			X	
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			X	
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]		X		
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15	All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]			X	
19	DEA 222 order forms properly completed. [893.07, F.S.]			X	
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]			X	
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			X	
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]		X		
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	X			
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]			X	
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]		X		
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]	X			
28	Compounding records properly maintained. [64B16-27.700, F.A.C.]*			X	
29	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]			X	
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			X	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: Melissa McGuffey RPT 18664; Joy Patterson RPT 37779; Sharon Fort RPT 27620, Rita Jones - Tech Trainee; Yvonne Lee - Tech Trainee. DEA expires 9-30-2014. #2 Tech ratio letter 11-10-2005. #11 Last CQI meeting 2-3-2012. #12 Future Requirement. #18 CS inventory 1-30-2012. #22 Printout. #23 None since 7-1-2011. #24 None since 7-1-2011.
No outpatient CII prescriptions.
Batch compounding. No compounding for practitioner office stock.
Rx drug suppliers: McKesson-Lakeland, Anda-Weston; Medisca (23:1911).

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Michael Halfen, RPh

M Halfen

Institutional Representative

03-20-2012

Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

EXHIBIT # 3

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

Standards of Practice for Compounding Sterile Preparations (CSPs)

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 10801

Insp # 105809

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT GULF MEDICAL SERVICES, INC		PERMIT NUMBER 18700	DATE OF INSPECTION 3/20/2012
DOING BUSINESS AS GULF MEDICAL PHARMACY		DEA NUMBER BG7912771	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 6776 Caroline Street		TELEPHONE # 850-983-3705 EXT.	MICHAEL W HALFEN
CITY MILTON	COUNTY 67	STATE/ZIP 32570	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 32618

		SATISFACTORY	N/A	YES	NO
1	Types of sterile compounding prepared (or expected to prepare) per [64B16-27.797, F.A.C.]. Undersigned pharmacist attests:				
	a) High-Risk Level CSPs (If yes, must complete items 5 & 6 - may not answer N/A)			X	
	b) Immediate Use CSPs (If yes, must complete items 7 & 8 - may not answer N/A)				X
	c) Low-Risk Level CSPs (If yes, must complete items 9 & 10 - may not answer N/A)			X	
	d) Medium-Risk CSPs			X	
	e) Antineoplastic Drugs (Cytotoxins) (If yes, must complete items 18, 19, 20 & 22 - may not answer N/A)				X
2	All sterile compounds prepared in barrier isolator? If yes, may answer NA to 3b, 3c, 3d, 4, & 21. [64B16-27.797(5)(e), F.A.C.]	X			
3	Compounding environment appropriate for Risk Level (certification by independent qualified organization).				
	a) Barrier Isolator?	X			
	b) Anteroom/Ante area?			X	
	c) Buffer Area (Clean Room)?			X	
	d) Laminar Air Flow Hood(s)?			X	
4	Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.]			X	
5	Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified in rule. [64B16-27.797(1)(l), F.A.C.]			X	
6	Personnel authorized to compound high-risk-level CSPs completed a media-filled test within the past 6 months (semiannually). [64B16-27.797(1)(i),F.A.C.]			X	
7	Preparation time does not exceed 1 hour when preparing immediate use CSPs. [64B16-27.797(1)(j), F.A.C.]	X			
8	Preparation is properly labeled if preparer does not administer or witness administration when preparing immediate-use CSPs. [64B16-27.797(1) (j), F.A.C.]	X			
9	Storage recommendations in rules are not exceeded when preparing low-risk CSPs. [64B16-27.797(1)(n), F.A.C.]			X	
10	Personnel authorized to compound low-risk level CSPs completed a media-filled test within the past 12 months. [64B16-27.797(1)(n), F.A.C.]			X	
11	P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16.27-797(4), F.A.C.]			X	
12	P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.]			X	
13	P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.]			X	
14	P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.]			X	
15	Appropriate disposal containers. [64B16-27.797(5), F.A.C.]			X	
16	Appropriate temperature and transport devices. [64B16-27.797(5), F.A.C.]			X	
17	Adequate supplies (gloves, mask, etc.) to preserve a suitable environment for aseptic preparation. [64B16-27.797(5), F.A.C.]			X	
18	Spill kits for antineoplastic agent spills if required. [64B16-27.797(5), F.A.C.]	X			
19	Current reference material (hard-copy or on-line). [64B16-27.797(5); and 64B16-27.797(1)(2), F.A.C.]			X	
20	All preparations are compounded in a vertical flow, Class II or biological safety cabinet. [64B16-27.797(6), F.A.C.]	X			
21	Protective apparel requirements are met. [64B16-27.797(6), F.A.C.]			X	
22	Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.]	X			
23	Documented on-going quality assurance. [64B16-27.797(7), F.A.C.]			X	
24	Quality assurance audits at regular planned intervals. [64B16-27.797(7), F.A.C]			X	
25	Compounding personnel skilled and trained based on observation. [64B16-27.797(7), F.A.C]			X	

Remarks: #3 ENV Services Testing & Certification, 4758 Research Drive, San Antonio, TX 78240. (February 15, 2012.)

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Michael Halfen, RPh

M Halfen — Institutional Representative

03-20-2012 — Date

Jon A Taylor — Investigator/Sr. Pharmacist Signature

ID ci20

INV 797 Revised 12/11 Created 8/11

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 10801

Insp # 96803

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT GULF MEDICAL SERVICES, INC		PERMIT NUMBER 18700	DATE OF INSPECTION 1/10/2011
DOING BUSINESS AS GULF MEDICAL PHARMACY		DEA NUMBER BG7912771	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 6776 Caroline Street		TELEPHONE # 850-893-3705 / EXT.	MICHAEL W HALFEN
CITY MILTON	COUNTY 67	STATE/ZIP 32570	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 32618

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8:30am	8:30am	8:30am	8:30am	8:30am	closed	closed
Close	4:30pm	4:30pm	4:30pm	4:30pm	4:30pm		

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Donna Pittman PS 8932
2. Elloitt Roberts PS 8262
3. George Anderson PS 12203

		SATISFACTORY	N/A	YES	NO
1	Current pharmacy permit displayed. [465.015(1)(a),F.S.]			X	
2	Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]			X	
3	Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4	Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]			X	
5	Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]			X	
6	Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			X	
7	Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]			X	
8	Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]			X	
9	Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.			X	
10	Generic drug sign displayed. [465.025(7),F.S.]			X	
11	Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]			X	
12	Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*		X		
13	Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]			X	
14	Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]			X	
15	Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]			X	
16	Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			X	
17	Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]			X	
18	Prescription department clean and safe. [64B16-28.105,F.A.C.]			X	
19	Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]			X	
20	Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]			X	
21	Medication properly labeled [64B16-27.101,F.A.C.]			X	
22	All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]			X	
23	CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]			X	
24	Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]			X	
25	"Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]			X	
26	All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]			X	
27	Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]			X	
28	Complete pharmacy prescription records. [64B16-28.140,F.A.C.]			X	
29	Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]			X	
30	Controlled substance records readily retrievable. [893.07,F.S.]			X	
31	Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]			X	
32	Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]			X	
33	Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			X	
34	Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]			X	
35	All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			X	
36	Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]			X	
37	Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			X	
38	Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]			X	
39	Controlled substance inventory taken on a biennial basis and available for Inspection. [893.07(1)(a),F.S.]			X	
40	DEA 222 order forms properly completed. [893.07(2),F.S.]			X	
41	Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*			X	
42	Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]			X	
43	Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]			X	
44	Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *			X	
45	Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *		X		
46	Compounding records properly maintained [64B16-28.140(4),F.A.C.] *			X	
47	Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *			X	

** Questions with (*) may be answered n/a (not applicable).*

Remarks: Sarah Steele PS 38813. Tiffany Denham RPT29518; Edward Ilano RPT26662; Derek Luke RPT 27889. #3 DEA expires 9-30-2011. #5 NA. #7 Tech ratio letter 11-10-2005. #23 Last CQI meeting 10-14-2010. #39 CS inventory 1-14-2010. #43 NA. #44 Printout. Rx drug purchases McKesson-Lakeland and Medisca.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Michael Halfen, RPh

Michael Halfen — Institutional Representative

01-10-2011 — Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

STERILE PRODUCTS AND SPECIAL-PARENTERAL ENTERAL COMPOUNDING PHARMACY

File # 10801

Insp # 96803

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT GULF MEDICAL SERVICES, INC	PERMIT NUMBER 18700	DATE OF INSPECTION 1/10/2011
DOING BUSINESS AS GULF MEDICAL PHARMACY	DEA NUMBER BG7912771	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 6776 Caroline Street	TELEPHONE # 850-893-3705 EXT.	MICHAEL W HALFEN
CITY MILTON / COUNTY SANTA ROSA	STATE/ZIP 32570	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 32618

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8:30am	8:30am	8:30am	8:30am	8:30am	closed	closed
Close	4:30pm	4:30pm	4:30pm	4:30pm	4:30pm		

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. see community inspection form
2.
3.

	SATISFACTORY	N/A	YES	NO
1 Current sterile products and special parenteral/enteralcompounding pharmacy permit displayed. [64B16-28.82, F.A.C.]			X	
2 Board of Pharmacy notified in writing of current Rx department manager. [64B16-28.820(3)(a), F.A.C.]			X	
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4 Pharmacist license/renewal certificate displayed. [64B16-27.100(1),F.A.C.]			X	
5 Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400,F.A.C.]			X	
6 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410,F.A.C.] [64B16-27.420,F.A.C.]			X	
7 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.][64B16-27.400,F.A.C.]			X	
8 Prescription area set apart for sterile prescriptions from general work/storage area/adequately air-conditioned or under positive pressure. [64B16-28.820(5)(b)1,F.A.C.]			X	
9 Working sink convenient to the clean room. [64B16-28.820(5)(c)3,F.A.C.]			X	
10 Refrigeration/freezer/sink/appropriate waste containers for used needles/ syringes. [64B16-28.820(5)(c)2,4(a),F.A.C.]			X	
11 Gloves/masks/gowns/various standard sizes of needles/syringes/ disinfectant cleaning agent/clean towels. [64B16-28.820(5)(d)1-4,F.A.C.]			X	
12 Bacterial hand-washing materials/vacuum containers and various transfer sets, "spill kits" for cytotoxic agent spills. [64B16-28.820(5)(c)5-F.A.C.]			X	
13 Appropriate waste containers for all cytotoxic waste including apparel used in prescriptions. [64B16-28.820(5)(c)4b,F.A.C.]			X	
14 Certified horizontal or vertical laminar airflow hood(s). [64B16-28.820(3)(e),F.A.C.]			X	
15 Certified vertical laminar airflow hood used for cytotoxins. [64B16-28.820(3)(e),F.A.C.]*	X			
16 Board approved policy and procedure manual available for inspection. [64B1628.820(3)(d,F.A.C.]			X	
17 Separate manual/equipment/handing procedures and protection for personnel if cytotoxic agents are dispensed. (64B16-28.820(3)(e). F.A.C			X	
18 "Practice Guidelines for Personnel Dealing With Cytotoxic Drugs". (64B16-28.820(5)(e)7. F.A.C.			X	
19 Current chapter of Florida Statutes: 465 and 499 and 893, and Board Rules [64B16-28.820(5)(e)1-4,F.A.C.]			X	
20 CurrentUnited StatesPharmacopoela & National Formulary or Remington Pharmaceutical Sciences or U.S. Dispensatory along with the latest supplementals or an equivalent thereof sufficient in scope to meet the professional practice need of the pharmacy AND a current authoritative therapeutic reference. [64B16-28.820(5)(e)5,F.A.			X	
21 Current edition of the Handbook of Injectable Drugs by American Society of Healthsystem Pharmacists.[64B16-28.820(5)(e)6,F.A.C.]			X	
22 Pharmaceutical stock examined at least every four months and deteriorated or outdated items removed. [64B16-28.11,F.A.C]			X	
23 Medication properly labeled. [64B16-27.101,F.A.C.]			X	
24 "Discard After" date provided on prescription label. [64B1628.402(1)(h),F.A.C.]			X	
25 Written offer to counsel. [64B16-27.820,F.A.C.]			X	
26 Special handling/packing/labeling/delivery of prescriptions with telephone accessibility to pharmacist at all hours. [64B16-28.820(3)(b),F.A.C.]			X	
27 Licensed pharmacist certifies accuracy of final preparation and documents in a manner that responsibility can be traced to the pharmacist. [64B16-27.400(2)(c)(d),F.A.C.]			X	
28 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S] [64B16-27.300.F.A.C.] *			X	
29 Prescriber's name/address/DEA # on all controlled substance prescription. [F.S. 893.04(1)(c)2,F.A.C.]			X	
30 Initials of pharmacist filling controlled substance prescriptions on prescription. [893.04(1)(c)6,F.S.]			X	
31 Controlled substance inventory taken on biennial basis and available for inspection. [893.07(1)(a),F.S.]			X	
32 DEA 222 order forms properly completed. [893.07,F.S.]			X	
33 Certified daily log OR printout maintained as required by section. (64B16-28.140(3)(c) or (e),F.A.C.] *			X	
34 Dispensing done pursuant to prescriptions with patient profiles maintained. (64B16-28.820(3)(c), F.A.C.			X	
35 Results of quality assurance program available for inspection. (64B16-28.820(3)(D), F.A.C			X	

*Questions with *may be answered n/a (not applicable).

Remarks: See community inspection form for details. #12, #13, #15, #17, & #18 - No cytotoxins prepared. Hoods certified 12-29-2010.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Michael Halfen, RPh

Michael Halfen — Institutional Representative

01-10-2011 — Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 364 Revised 01/07 Replaces 12/02

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 10801

Insp # 88189

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT GULF MEDICAL SERVICES, INC		PERMIT NUMBER 18700	DATE OF INSPECTION 12/22/2009
DOING BUSINESS AS GULF MEDICAL VITAL CARE;GULF MEDICAL PHA		DEA NUMBER BG7912771	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 6776 Caroline Street		TELEPHONE # 850-983-6705 EXT.	MICHAEL W HALFEN
CITY MILTON	COUNTY 67	STATE/ZIP 32570	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 32618

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8:30am	8:30am	8:30am	8:30am	8:30am	closed	closed
Close	4:30pm	4:30pm	4:30pm	4:30pm	4:30pm		

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Amanda McClure PTech
2. Kelly Ward PTech
3. Derek Luke PTech

	SATISFACTORY	N/A	YES	NO
1 Current pharmacy permit displayed. [465.015(1)(a),F.S.]			X	
2 Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]			X	
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4 Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]			X	
5 Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]			X	
6 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			X	
7 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]			X	
8 Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]			X	
9 Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.			X	
10 Generic drug sign displayed. [465.025(7),F.S.]			X	
11 Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]			X	
12 Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*	X			
13 Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]			X	
14 Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]			X	
15 Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]			X	
16 Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			X	
17 Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]			X	
18 Prescription department clean and safe. [64B16-28.105,F.A.C.]			X	
19 Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]			X	
20 Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]			X	
21 Medication properly labeled [64B16-27.101,F.A.C.]			X	
22 All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]			X	
23 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]			X	
24 Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]			X	
25 "Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]			X	

	SATISFACTORY	N/A	YES	NO
26 All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]			X	
27 Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]			X	
28 Complete pharmacy prescription records. [64B16-28.140,F.A.C.]			X	
29 Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]			X	
30 Controlled substance records readily retrievable. [893.07,F.S.]			X	
31 Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]			X	
32 Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]			X	
33 Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			X	
34 Date controlled substance Rx was filled on Rx [893.04(1)(c)6,F.S.]			X	
35 All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			X	
36 Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]			X	
37 Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			X	
38 Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]			X	
39 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]			X	
40 DEA 222 order forms properly completed. [893.07(2),F.S.]			X	
41 Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*			X	
42 Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]			X	
43 Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]			X	
44 Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *			X	
45 Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *	X			
46 Compounding records properly maintained [64B16-28.140(4),F.A.C.] *			X	
47 Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *			X	

** Questions with (*) may be answered n/a (not applicable).*

Remarks: #3 DEA expires 9-30-2011. #5 NA. #7 Tech ratio letter 11-10-2005. #23 Last CQI 10-9-2009. #39 CS inventory 1-20-2009. #43 NA. #44 Printout. Rx drug purchases from McKesson-Lakeland and Medisca.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Michael Halfen, RPh

Michael Halfen — Institutional Representative

12-22-2009 — Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

STERILE PRODUCTS AND SPECIAL-PARENTERAL ENTERAL COMPOUNDING PHARMACY

File # 10801

Insp # 88189

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
GULF MEDICAL SERVICES, INC	18700	12/22/2009
DOING BUSINESS AS: GULF MEDICAL VITAL CARE;GULF MEDICAL PHA	DEA NUMBER: BG7912771	PRESCRIPTION DEPARTMENT MANAGER: MICHAEL W HALFEN
STREET ADDRESS: 6776 Caroline Street	TELEPHONE #: 850-983-6705 EXT.	
CITY: MILTON / COUNTY: SANTA ROSA	STATE/ZIP: 32570	PRESCRIPTION DEPARTMENT MANAGER LICENSE #: 32618

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8:30am	8:30am	8:30am	8:30am	8:30am	oncall	oncall
Close	4:30pm	4:30pm	4:30pm	4:30pm	4:30pm		

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Amanda McClure PTech
2. Kelly Ward PTech
3. Derek Luke PTech

	SATISFACTORY	N/A	YES	NO
1 Current sterile products and special parenteral/enteralcompounding pharmacy permit displayed. [64B16-28.82, F.A.C.]			X	
2 Board of Pharmacy notified in writing of current Rx department manager. [64B16-28.820(3)(a), F.A.C.]			X	
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4 Pharmacist license/renewal certificate displayed. [64B16-27.100(1),F.A.C.]			X	
5 Intems properly registered and supervised. [465.013,F.S.] [64B16-26.400,F.A.C.]			X	
6 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410,F.A.C.] [64B16-27.420,F.A.C.]			X	
7 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.][64B16-27.400,F.A.C.]			X	
8 Prescription area set apart for sterile prescriptions from general work/storage area/adequately air-conditioned or under positive pressure. [64B16-28.820(5)(b)1,F.A.C.]			X	
9 Working sink convenient to the clean room. [64B16-28.820(5)(c)3,F.A.C.]			X	
10 Refrigeration/freezer/sink/appropriate waste containers for used needles/ syringes. [64B16-28.820(5)(c)2,4(a),F.A.C.]			X	
11 Gloves/masks/gowns/various standard sizes of needles/syringes/ disinfectant cleaning agent/clean towels. [64B16-28.820(5)(d)1-4,F.A.C.]			X	
12 Bacterial hand-washing materials/vacuum containers and various transfer sets, "spill kits" for cytotoxic agent spills. [64B16-28.820(5)(c)5-F.A.C.]			X	
13 Appropriate waste containers for all cytotoxic waste including apparel used in prescriptions. [64B16-28.820(5)(c)4b,F.A.C.]			X	
14 Certified horizontal or vertical laminar airflow hood(s). [64B16-28.820(3)(e),F.A.C.]			X	
15 Certified vertical laminar airflow hood used for cytotoxins. [64B16-28.820(3)(e),F.A.C.]*		X		
16 Board approved policy and procedure manual available for inspection. [64B1628.820(3)(d,F.A.C.]			X	
17 Separate manual/equipment/handing procedures and protection for personnel if cytotoxic agents are dispensed. {64B16-28.820(3)(e), F.A.C			X	
18 "Practice Guidelines for Personnel Dealing With Cytotoxic Drugs". (64B16-28.820(5)(e)7, F.A.C.			X	
19 Current chapter of Florida Statutes: 465 and 499 and 893, and Board Rules [64B16-28.820(5)(e)1-4,F.A.C.]			X	
20 CurrentUnited StatesPharmacopoeia & National Formulary or Remington Pharmaceutical Sciences or U.S. Dispensatory along with the latest supplementals or an equivalent thereof sufficient in scope to meet the professional practice need of the pharmacy AND a current authoritative therapeutic reference. [64B16-28.820(5)(e)5,F.A.			X	
21 Current edition of the Handbook of Injectable Drugs by American Society of Healthsystem Pharmacists.[64B16-28.820(5)(e)6,F.A.C.]			X	
22 Pharmaceutical stock examined at least every four months and deteriorated or outdated items removed. [64B16-28.11,F.A.C]			X	
23 Medication properly labeled. [64B16-27.101,F.A.C.]			X	
24 "Discard After" date provided on prescription label. [64B1628.402(1)(h),F.A.C.]			X	
25 Written offer to counsel. [64B16-27.820,F.A.C.]			X	
26 Special handling/packing/labeling/delivery of prescriptions with telephone accessibility to pharmacist at all hours. [64B16-28.820(3)(b),F.A.C.]			X	
27 Licensed pharmacist certifies accuracy of final preparation and documents in a manner that responsibility can be traced to the pharmacist. [64B16-27.400(2)(c)(d),F.A.C.]			X	
28 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S] [64B16-27.300,F.A.C.]*			X	
29 Prescriber's name/address/DEA # on all controlled substance prescription. [F.S. 893.04(1)(c)2,F.A.C.]			X	
30 Initials of pharmacist filling controlled substance prescriptions on prescription. [893.04(1)(c)6,F.S.]			X	
31 Controlled substance inventory taken on biennial basis and available for inspection. [893.07(1)(a),F.S.]			X	
32 DEA 222 order forms properly completed. [893.07,F.S.]			X	
33 Certified daily log OR printout maintained as required by section. {64B16-28.140(3)(c) or (e),F.A.C.]*			X	
34 Dispensing done pursuant to prescriptions with patient profiles maintained. {64B16-28.820(3)(c), F.A.C.			X	
35 Results of quality assurance program available for inspection. {64B16-28.820(3)(D), F.A.C			X	

*Questions with *may be answered n/a (not applicable).

Remarks: See community inspection form for details. #12, #13, #15, & #18 NA - No cytotoxins prepared. #14 Hoods certified 10-29-2009.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Michael Halfen, RPh

Michael Halfen — Institutional Representative

12-22-2009 — Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 364 Revised 01/07 Replaces 12/02

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201305745

WILLIAM CLERO,
RESPONDENT.

NOTICE

TO: WILLIAM CLERO
6267 SW 8 STREET
MIAMI, FL 33144

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201305745

WILLIAM CLERO,
RESPONDENT.

NOTICE

TO: JUAN P. BROCHE
75 VALENCIA STREET, SUITE 800
FRANK QUINTERO, JR., P.A.
CORAL GABLES, FL 331324

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 –

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Mary Miller, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. William Clero, RPT
DOH Case Number 2013-05745
DATE: December 11, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	William Clero
Subject's Address of Record:	6267 SW 8 Street Miami, FL 33144
Enforcement Address:	6267 SW 8 Street Miami, FL 33144
Subject's License No:	11309 **Rank:** RPT
Licensure File No:	16256
Initial Licensure Date:	11/20/2009
Board Certification:	No
Required to Appear:	Yes
Current IPN/PRN Contract:	No
Allegation(s):	456.072(1)(a), FS (2009)
Prior Discipline:	None
Probable Cause Panel:	July 30, 2013; Weizer & Meshad
Subject's Attorney:	Juan P. Broche 75 Valencia Street, Suite 800 Coral Gables, FL 331324
Complainant/Address:	Department Of Health/Consumer Services Unit
Materials Submitted:	Memorandum to the Board Settlement Agreement Administrative Complaint Notification Letter Cost Summary Report Final Investigative Report with Exhibits

DISCIPLINARY GUIDELINES:

Section 456.072(1)(k), Florida Statutes (2009) by violating Section 456.072(1)(a), Florida Statutes (2009):

From $1,500 fine and one (1) year probation to revocation.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

This is a one count administrative complaint alleging Respondent made misleading, deceptive, or fraudulent representations in or related to the practice of pharmacy by entering pleas of nolo contendere to 1 count of Grand Theft, a 2nd degree felony and 1 count of Organized Scheme to Defraud, a 1st degree felony on 10/3/06. On 11/9/09, Respondent submitted an initial application to be licensed as an RPT to the Board of Pharmacy and denied he entered any pleas or was convicted of any crimes more serious than minor traffic violations on his application.

Terms of Settlement Agreement:

- Appearance
- Fine of $2,000.00
- Reimbursement of Costs not to exceed $2,273.38
- Probation for 2 years

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-05745**

WILLIAN CLERO, R.P.T.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, **WILLIAN CLERO, R.P.T.,** was a registered pharmacy technician in the state of Florida, having been issued license number **RPT 11309**.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **TWO THOUSAND DOLLARS AND NO CENTS ($2,000.00)**. The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within one year from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND DOLLARS TWO HUNDRED SEVENTY THREE DOLLARS AND TWENTY-THREE CENTS ($2,273.28).** Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 180 days from the date the Final Order is filed with the Department Clerk.

4. **Probation**- Respondent's license as a Registered Pharmacy Technician shall be placed on probation for two years. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. If Respondent works for a placement agency, Respondent shall provide to the Department's Compliance Officer the name, address and telephone number of the agency. If Respondent works as a relief Registered Pharmacy Technician, Respondent may not work at or for more than two pharmacies during the probationary period, unless Respondent

obtains prior approval from the Board. Respondent's report shall list the pharmacies, including addresses and dates that Respondent worked at each pharmacy, and the name of the supervising or primary pharmacist. These reports shall be submitted to the Compliance Officer every three (3) months in a manner as directed by the Compliance Officer.

b. Respondent shall submit documentation evidencing that his employer, or if employed as a relief Registered Pharmacy Technician, his supervising pharmacist(s) and the relief agency, have been provided with a copy of the Final Order describing these probationary terms within ten (10) days of the entry of the Final Order or upon initiation of employment.

c. Respondent shall ensure that his employer or, if employed as a relief Registered Pharmacy Technician, the supervising pharmacist at each pharmacy at which Respondent works, submits written reports to the Compliance Officer for the Board of Pharmacy. These reports shall contain: the name, current address, license number, and telephone number of each pharmacy intern, pharmacy technician, relief pharmacist, and prescription department manager working with the Respondent in the prescription department; a brief description of Respondent's duties and responsibilities; and Respondent's work schedule. These reports shall be submitted by the

employer to the Compliance Officer every three (3) months in a manner directed by the Department Compliance Officer.

d. During the period of Respondent's probation, the Department shall conduct semi-annual audits of five (5) randomly selected controlled substances at the Respondent's place of employment at Respondent's cost.

e. Respondent shall make a mandatory appearance before the Board of Pharmacy during his last three (3) months of probation. The Board retains the right to extend Respondent's term of probation or to impose additional restrictions, conditions or limitations on Respondent's license.

5. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 6 day of November, 2013.

Willian Clero, R.P.T.

STATE OF Florida

COUNTY OF Miami Date

Before me personally appeared Willian Clero, R.P.T., whose identity is known to me or by _____ (type of identification), and who, under oath, acknowledges that his signature appears above.

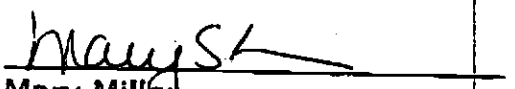
Sworn to and subscribed before me this 6 day of November, 2013.

DULCE M. GARCIA
MY COMMISSION # EE 122220
EXPIRES: August 18, 2015
Bonded Thru Notary Public Underwriters

Notary Public
My Commission Expires:

APPROVED this 7th day of November, 2013.

John H. Armstrong, MD, FACS
Surgeon General & Secretary
Florida Department of Health



Mary Miller
Assistant General Counsel
Florida Department of Health
Florida Bar Number 0780420
4052 Bald Cypress Way
Tallahassee, Florida 32399-3265
Telephone: 850-245-4444, ext. 8104
Fax: 850-245-4683
E-Mail: mary_miller2@doh.state.fl.us

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-05745**

WILLIAN CLERO, R.P.T.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Willian Clero, R.P.T., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a registered pharmacy technician (R.P.T.) within the state of Florida, having been issued license number RPT 33144.

EXHIBIT
A

3. Respondent's address of record is 6267 Southwest 8th Street, Miami, Florida 33144.

4. On or about February 7, 2005, in Miami-Dade County, Miami-Dade police officers arrested Respondent on five counts of Grand Theft, a third degree felony, in violation of Section 812.014, Florida Statutes (2003 – 2004); and five counts of Uttering a Forged Instrument, a felony in violation of Section 831.02, Florida Statutes (2003 – 2004).

5. On or about October 3, 2006, in the Circuit Court of the Eleventh Judicial Circuit, in and for Miami-Dade County, Florida, in case no. F05-004126, Respondent entered pleas of nolo contendere to one count of Grand Theft, a second degree felony, in violation of Section 812.014(2), Florida Statutes (2003 – 2004); and one count of Organized Scheme to Defraud, a first degree felony, in violation of Section 817.034(4), Florida Statutes (2003 – 2004).

6. On or about November 9, 2009, Respondent submitted an initial application to be licensed as an R.P.T. to the Board of Pharmacy.

7. On or about November 9, 2009, respondent denied he entered any pleas or was convicted of any crimes more serious than minor traffic violations on his initial application for licensure as an R.P.T. to the Board.

8. On or about November 20, 2009, the Board approved Respondent's initial application for licensure as an R.P.T.

9. Section 456.072(1)(a), Florida Statutes (2009), provides that making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession constitutes grounds for discipline.

10. Respondent made misleading, deceptive, or fraudulent representations in or related to the practice of the Respondent's profession by submitting an initial application to the Board of Pharmacy to practice as an R.P.T. and representing he had not entered any pleas or been convicted of any crimes more serious than minor traffic violations.

11. Based on the foregoing, Respondent violated Section 456.072(1)(a), Florida Statutes (2009), by making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of

fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 30th **day of** July, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

MARY S. MILLER
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Fla. Bar No. 0780420
(850) 245-4444 phone, ext. 8104
(850) 245-4683 fax
E-mail: Mary_Miller2@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUL 30 2013

PCP: July 30, 2013
PCP Members: Weizer & Meshad

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

Search	Complaint/Case Number: 201305745	MAIN	HELP

Complaint Cost Summary

Complaint Number: 201305745

Subject's Name: CLERO, WILLIAM

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	2.70	$148.23
Investigation:	6.80	$421.44
Legal:	7.80	$829.13
Compliance:	0.05	$1.67
	**********	**********
Sub Total:	17.35	$1,400.47
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,400.47

December 12, 2013

Juan P. Broche, Esquire
75 Valencia St #800
Coral Gables, FL 33124

Re: DOH vs. William Clero, R.P.T.
DOH Case Number: 2013-05745

Dear Mr. Broche:

I am in receipt of the settlement agreement executed by your client on November 6, 2013, concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next regularly scheduled meeting of the Florida Board of Pharmacy. Please be advised your case will be set at the convenience of the Department and/or the Board and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Mary S. Miller
Assistant General Counsel

MM/ab

cc: William Clero, RPT

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

FLORIDA DEPARTMENT OF HEALTH

Additional Information Required
Work Experience Form

Division of Medical Quality Assurance
MQA

Name: Mr. WILLIAN CLERO
Profession: 2208
Transaction Code: 1020
File Number: 16256

If your employer is submitting proof of your 1500 hours of work experience directly to the Board of Pharmacy you do not need to submit this form. Please verify with your employer before submitting.

PHARMACY TECHNICIAN REGISTRATION WORK EXPERIENCE FORM

1. Biographical Information			
Applicant Name: WILLIAM CLERO	National Certification Number (if applicable): 11309	Phone Number: 786-389-4441	
Street Address: 6267 SW 8 St	City: MIAMI	State: FL	Zip: 33144

I HEREBY APPLY FOR WORK EXPERIENCE AS OUTLINED BELOW UNDER THE SUPERVISION OF:

2. Pharmacy Information			
Pharmacist's Name: MERCADO ONEIDA M. SANCHEZ		License Number: PS 22956	
Pharmacy Name: MORON DRUG & DISCOUNT		Permit Number: PH 21315	
Street Address: 6267 SW 8 St	City: MIAMI	State: FL	Zip: 33144
Phone Number: 305-262-0225	3. Dates of Experience From: 2/3/05 To: PRESENT		
4. Average number of hours worked per week: 40	5. Total hours of work experience: 11,560		

Applicant's Signature _____ Date 7/8/10

This report is a correct statement of fact. The above information was taken from the records of the above named pharmacy and is available for inspection by the Board of Pharmacy.

Supervising Pharmacist's Signature _____ Date 7/8/10

Please mail this form to:

Florida Board of Pharmacy
4052 Bald Cypress Way, Bin # C-04
Tallahassee, Florida 32399-3254

Board of
JUL 12 2010
Pharmacy

Current Date: 7/7/10

FLORIDA DEPARTMENT OF HEALTH

Additional Information Required
Work Experience Form

Division of Medical Quality Assurance
MQA

Board of
AUG 1 6 2010
Pharmacy

Name: Mr. WILLIAN CLERO
Profession: 2208
Transaction Code: 1020
File Number: 16256

Board of
AUG 1 6 2010
Pharmacy

If your employer is submitting proof of your 1500 hours of work experience directly to the Board of Pharmacy you do not need to submit this form. Please verify with your employer before submitting.

PHARMACY TECHNICIAN REGISTRATION WORK EXPERIENCE FORM

1. Biographical Information			
Applicant Name WILLIAN CLERO	National Certification Number (if applicable)	Phone Number 786-389-4441	
Street Address 6267 SW 8 St	City MIAMI	State FL	Zip 33144

I HEREBY APPLY FOR WORK EXPERIENCE AS OUTLINED BELOW UNDER THE SUPERVISION OF:

2. Pharmacy Information			
Pharmacist's Name M. ONEIDA SANCHEZ		License Number PS 22956	
Pharmacy Name MORON DRUG & DISCOUNT		Permit Number PH 21315	
Street Address 6267 SW 8 St	City MIAMI	State FL	Zip 33144
Phone Number 305-262-0225	3. Dates of Experience From: 2/13/05 To: 8/10/10		
4. Average number of hours worked per week 40	5. Total hours of work experience 11,360		

Applicant's Signature _____ Date 8/10/10

This report is a correct statement of fact. The above information was taken from the records of the above named pharmacy and is available for inspection by the Board of Pharmacy.

Supervising Pharmacist's Signature _____ Date 8/10/10

Please mail this form to:

Florida Board of Pharmacy
4052 Bald Cypress Way, Bin # C-04
Tallahassee, Florida 32399-3254

Current Date: 8/5/10

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **William Clero, R.P.T. (MSM)**
Case Number: 2013-05745

MEMBERS: **Michele Weizer, PharmD and Gavin Meshad**

DATE OF PCP: ~~**May 30, 2013**~~ July 30, 2013 **AGENDA ITEM: A-1**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 456.072(1)(a), Florida Statutes (2009);

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **other** _____

Michele Weizer PharmD, BCPS July 30/2013
Chair, Probable Cause Panel Date
Board of Pharmacy

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Miami XI	Date of Case: 08/30/2012	Case Number: RPT 2013-05745

Subject: **MR. WILLIAM CLERO** 6267 SW 8th Street Miami, FL 33144 (305) 262-0225 (H)	Source: **DOH/INVESTIGATIVE SERVICES/MIAMI**

Prefix:	License #:	Profession:	Board:	Report Date:
2208	11309	Registered Pharmacy Technician	Pharmacy	05/20/13

Period of Investigation: 05/17/13 – 05/20/13	Type of Report: Supplemental - 1

Alleged Violation: SEE FINAL REPORT

Synopsis: This Supplemental Report is predicated upon receipt of Supplemental request from CASSANDRA NICHOLOSON Assistant for General Counselor, MARY MILLER, ESQ from the Department of Health Prosecution Services Unit requesting the following information: To obtain a copy of WILLIAM CLERO's arrest and booking records.

On 05/20/13, this Investigator successfully obtained arrest and booking records from the Miami-Dade Clerk of Courts as well as from the Miami Dade Police Department.

Exhibit(s):
S1 – Arrest Records (pp. 2-4)
S2 – Booking Records (pp. 5-127)

Related Case(s): 2011-18457, 2011-18460, & 2012-12853

Investigator/Date: May 20, 2013 Gabriel Cruz, Investigation Specialist II	Approved By/Date: May 20, 2013 Caridad Rodriguez, Investigation Supervisor

Distribution: HQ/ISU

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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FLORIDA DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: CONSUMER SERVICES	Date of Complaint: 4/9/13	Case Number: 201305745

Subject: **WILLIAM CLERO** 6267 SW 8 St Miami, FL 33144 (305) 262-0225	Source: **DEPARTMENT OF HEALTH** Consumer Services

Prefix:	License # :	Profession:	Board:	Report Date:
RPT	11309	Registered Pharmacy Technician	Pharmacy	5/8/13

Period of Investigation: 5/2/13-5/8/13	Type of Report: FINAL

Alleged Violation: § 456.072(1)(c)(dd); 465.016(1)(f)(r); Violate statute; Having been convicted or found guilty in a court of this state or other jurisdiction, of a crime which directly relates to the ability to practice of pharmacy

Synopsis: This investigation is predicated on the receipt of information from the DEPARTMENT OF HEALTH alleging on 10/3/06 CLERO was convicted of Grand theft [812.014(2)(B)] and Organized Fraud [817.034(4)(A)1] in Miami-Dade County, Florida. Adjudication of Guilt Withheld. Court Documents attached. (EXHIBIT #1)

CLERO was notified of this complaint by letter, dated 5/2/13. The notification was sent to the address of record Forwarded with this letter were copies of the UCF and the initiating documents. (EXHIBIT #2)

DOH licensure information was obtained on 5/8/13. It reflected CLERO's license is in a Clear/Active Status.

No patient(s) was/were identified, thus patient notification was not required.

CLERO does not appear to be represented at this time.

CLERO has not responded as of the date of this report, if he does it will be forwarded to file.

Related Case:

Investigator/Date: Leo Paulson (HA107) 5/8/13	Approved By/Date: Shane Walters, OMC Manager MAY 09 2013

Distribution: Prosecution Services Unit/Consumer Services Unit

RECEIVED-LEGAL 13 MAY 13 AM 7:58

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II. INVESTIGATIVE DETAILS

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2) SUBJECT's Notification Letter 85

INVESTIGATIVE DETAILS

SUMMARY OF RECORDS

There were no authorizations, medical records, or Verification of Completeness of Record forms at issue in this matter.

Exhibit #1 contains the following:

Court documents from Miami-Dade County showing on 10/3/06 CLERO was convicted of Grand theft [812.014(2)(B)] and Organized Fraud [817.034(4)(A)1] in Miami-Dade County, Florida. Adjudication of Guilt Withheld.

INTERVIEW/STATEMENT OF DEPARTMENT OF HEALTH -Source

On 4/9/13 investigator PAULSON received information from the Department of Health alleging on 10/3/06 CLERO was convicted of Grand theft [812.014(2)(B)] and Organized Fraud [817.034(4)(A)1] in Miami-Dade County, Florida. Adjudication of Guilt Withheld.

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Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

May 2, 2013

CONFIDENTIAL
Mr. Willian Clero, R.Ph.T.
6267 South West 8 Street
Miami, FL 33144

Complaint #: 201305745

Dear Mr. Clero:

The Consumer Services Unit has received the enclosed complaint against you. We reviewed the complaint or report and determined that the Florida Pharmacy Act may have been violated. Therefore, we have opened an investigation into this matter. Please submit a written response to this complaint within 20 days of receipt of this letter.

You may make a written request for a copy of the investigative file. This complaint and all investigative information will remain confidential until 10 days after the probable cause panel has determined that a violation has occurred or you give up the right to confidentiality.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please call the Consumer Services Unit at (850) 245-4339. In addition, if you have any concerns or suggestions about our complaint process, please fill out our *Customer Concerns or Suggestions* form at www.floridashealth.com/mqa/survey.html.

Sincerely,

Leo W. Paulson
Government Analyst I

lp/kd
Enclosure

CONFIDENTIAL

DOH-Form300

Florida Department of Health
Division of Medical Quality Assurance- Bureau of Enforcement
4052 Bald Cypress Way, Bin C-75 • Tallahassee, FL 32399-3275
PHONE: (850) 245-4339 • FAX: (850) 488-0796

REPORT
EXHIBIT# 2
PAGE# 85

HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201309121

MAGDI MIKHAIL BISHARA,
RESPONDENT.

NOTICE

TO: MAGDI MIKHAIL BISHARA
2227 KENT PLACE
CLEARWATER, FL 33764

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201309121

MAGDI MIKHAIL BISHARA,
RESPONDENT.

NOTICE

TO: RICHARD SEBEK
501 EAST KENNEDY BLVD SUITE 1500
TAMPA, FL 33602

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201309121

MAGDI MIKHAIL BISHARA,
RESPONDENT.

NOTICE

TO: CATHLEEN E O'DOWD
101 EAST KENNEDY BLVD
SUITE 2800 BANK OF AMERICA PLAZA
BANK OF AMERICA PLAZA
TAMPA, FL 33602

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Shaffer Claridge, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Magdi Mikhail Bishara, R.Ph
DOH Case Number 2013-09121
DATE: December 10, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject: Magdi Mikhail Bishara, R.Ph
Subject's Address of Record: 2227 Kent Place
Clearwater, FL 33764
727-524-6827 Telephone

Enforcement Address: 2227 Kent Place
Clearwater, FL 33764

Subject's License No: 47410 **Rank:** PS

Licensure File No: 39254

Initial Licensure Date: 4/6/2011

Board Certification: None

Required to Appear: Yes

Current IPN/PRN Contract: No

Allegation(s):
COUNT I: Section 465.016(1)(m), Florida Statutes (2012-2013)
COUNT II: Section 465.016(1)(i), Florida Statutes (2012-2013)
COUNT III: Section 465.016(1)(r), Florida Statutes (2012-2013) by violating Section 456.072(1)(b), Florida Statutes (2012-2013)

Prior Discipline: None

Probable Cause Panel: September 23, 2013
Jeffrey J. Mesaros, PharmD and Lorena Risch

Subject's Attorney:

Cathleen E. O'Dowd, Esquire
101 East Kennedy Blvd, Suite 2800
Bank Of America Plaza
Tampa, FL 33602
813-229-7600 Telephone

Complainant/Address:

Department Of Health/Consumer Services Unit

Materials Submitted:

Memorandum to the Board
Settlement Agreement
Administrative Complaint
Supplemental Investigative Report dated 7/8/13 with Exhibits S4 1 - 3
Supplemental Investigative Report dated 7/2/13 with Exhibits S3 – 1-3
Supplemental Investigative Report dated 7/2/13 with Exhibits S2-1
Supplemental Investigative Report dated 6/24/13 with Exhibits S1-1
Final Investigative Report dated 6/14/13 with Exhibits 1 - 9
Additional Information from Investigations
Mental and Physical Evaluation
CV of Evaluator
CV of Respondent
Election of Rights Form
Memorandum of Finding Probable Cause
Order OF Emergency Restriction Of License
Cost Summary Report

DISCIPLINARY GUIDELINES:

Section 465.016(1)(m), Florida Statutes (2012-2013): $250 fine, indefinite suspension with PRN review and board appearance

Section 465.016(1)(i), Florida Statutes (2012-2013): $2250 fine and complete approved CE course in the prevention of medication errors of no less than eight (8) hours

Section 465.016(1)(r), Florida Statutes (2012-2013), by violating Section 456.072(1)(b), Florida Statutes (2012-2013): $1,500 fine and one (1) year probation

PRELIMINARY CASE REMARKS:

The Department filed an Administrative Complaint against Respondent on September 25, 2013. On October 3, 2013, Respondent accepted service of the Administrative Complaint, along with an Explanation of rights, an Election of Rights, and a Settlement Agreement. On or about October 23, 2013, Respondent returned his executed Election of Rights to the

Department. On or about November 22, 2013, Respondent executed the Settlement Agreement and returned it to the Department. The Department's prosecutor has executed the Settlement Agreement and submitted it for consideration by the Board of Pharmacy.

SETTLEMENT AGREEMENT TERMS:

- $1,000 fine
- Costs to be capped at $3,554.40
- Laws and Rules Course
- Evaluation by Department/PRN approved evaluator and compliance with all recommendations
- One year probation

CONSIDERATIONS SUPPORTING THE SETTLEMENT AGREEMENT:

1. Respondent has no history of discipline during his licensure term.
2. No patients were harmed by Respondent's actions as they involved dispensing medications to himself.
3. Respondent has been unable to practice pharmacy since the issuance of a restriction order on September 5, 2013.
4. Respondent has contacted PRN to begin the process of participation with the program.

SC/bp

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-09121**

MAGDI MIKHAIL BISHARA, R.Ph.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Magdi Mikhail Bishara was a pharmacist in the state of Florida, having been issued license number PS 47410. Respondent's mailing address of record is 2227 Kent Place, Clearwater, Florida 33764.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **one thousand dollars** ($1,000.00). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-**

6320, within **ninety (90) days** from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter. The Department and Respondent agree that the amount of Department costs to be paid in this case shall be capped at **$3,554.40**. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **ninety (90) days** from the date the Final Order is filed with the Department Clerk.

4. **CONTINUING EDUCATION-** Respondent shall successfully complete a Continuing Education Course on the subject of **LAWS AND RULES** consisting of 12 hours of credit, which has approved by the Florida Board of Pharmacy, within **ONE (1) YEAR** of the filing of a Final Order accepting and incorporating this Settlement Agreement. These continuing education hours shall be in addition to the hours required for license renewal. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the

continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

5. **Evaluation**- Respondent shall contact the Professional Resource Network (PRN) shall undergo an evaluation by a Department/PRN approved evaluator and follow all requirements and recommendations.

6. **Probation**- Respondent's Florida pharmacist license shall be placed on probation for one year for a period concurrent with his PRN contract if any. During the period of probation Respondent must follow all PRN recommendations and requirements, if any. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. If Respondent works for a placement agency, Respondent shall provide to the Department's Compliance Officer the name, address and telephone number of the agency. If Respondent works as a relief pharmacist, Respondent may not work at or for more than two pharmacies during the probationary period, unless Respondent obtains prior approval from the Board. Respondent's report shall list the pharmacies, including addresses and dates that Respondent worked at each pharmacy, and the name of the supervising or primary pharmacist. These reports shall be

submitted to the Compliance Officer every three (3) months in a manner as directed by the Compliance Officer.

b. Respondent shall submit documentation evidencing that her employer, or if employed as a relief pharmacist, her supervising pharmacist(s) and the relief agency, have been provided with a copy of the Final Order describing these probationary terms within ten (10) days of the entry of the Final Order or upon initiation of employment.

c. Respondent shall ensure that her employer or, if employed as a relief pharmacist, the supervising pharmacist at each pharmacy at which Respondent works, submits written reports to the Compliance Officer for the Board of Pharmacy. These reports shall contain: the name, current address, license number, and telephone number of each pharmacy intern, pharmacy technician, relief pharmacist, and prescription department manager working with the Respondent in the prescription department; a brief description of Respondent's duties and responsibilities; and Respondent's work schedule. These reports shall be submitted by the employer to the Compliance Officer every three (3) months in a manner directed by the Department Compliance Officer.

d. During the period of Respondent's probation, the Department shall conduct semi-annual audits of five (5) randomly selected controlled substances at the Respondent's place of employment at Respondent's cost.

e. Respondent shall make a mandatory appearance before the Board of Pharmacy during her last three (3) months of probation. The Board retains the right to extend Respondent's term of probation or to impose additional restrictions, conditions or limitations on Respondent's license.

7. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

8. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

9. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the

Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

10. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

11. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional

proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

12. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

13. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

14. **Current Addresses**- Respondent shall keep current its mailing address and its practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 22 day of November, 2013

MAGDI MIKHAIL BISHARA, R. PH.
CASE NO. 2013-09121

STATE OF Florida

COUNTY OF Hillsborough

Before me personally appeared Magdi Mikhail Bishara, R. Ph. whose identity is known to me or by MAGDI MIKHAIL BISHARA (type of identification), and who under oath, acknowledges that his signature appears above.

Sworn to and subscribed by Respondent before me this 22nd day of NOVEMBER, 2013.

Notary Public
My Commission Expires: JANUARY 9th 2015.

AURELIE WESTE
Notary Public, State of Florida
Commission# EE 53982
My comm. expires January 09, 2015

APPROVED this 10th day of December, 2013.

John H. Armstrong, MD, FACS, FCCP
State Surgeon General & Secretary
of Health, State of Florida

FL Bar #0021640

J. Friedberg, for
R. Shaffer Claridge
Assistant General Counsel

Counsel for Petitioner
R. Shaffer Claridge
Florida Bar No. 0095549
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: 850.245.4444
Fax: 850.245.4662

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

CASE NUMBER 2013-09121

MAGDI MIKHAIL BISHARA, R.PH.,

Respondent.

_____/

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health ("Department"), by and through undersigned counsel, files this Administrative Complaint against the Respondent, MAGDI MIKHAIL BISHARA, R.PH. ("Respondent"), and states:

FINDINGS OF FACT

1. The Department of Health ("Department") is the state agency charged with regulating the practice of pharmacy pursuant to Chapters 20, 456, and 465, Florida Statutes (2012-2013).

2. At all times material to this Order, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 47410, and was employed by the Walgreens Pharmacy ("Walgreens") doing business at 1801 Gulf to Bay Boulevard, Clearwater, Florida 33765.

3. On or about May 7, 2013, a co-worker observed Respondent at the

filling station at Walgreens filling a prescription for phendimetrazine 35mg. While speaking with Respondent, the co-worker discovered that Respondent was filling his own prescription. Respondent deleted the prescription and gave the medication to the co-worker.

4. Phendimetrazine is a stimulant drug commonly used as an appetite suppressant. According to Section 893.03(3), Florida Statutes (2012-2013), phendimetrazine is a Schedule III controlled substance that has a potential for abuse less than the substances in Schedules I and II and has a currently accepted medical use in treatment in the United States. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

5. On or about May 8, 2013, Respondent was questioned by the Walgreens Loss Prevention Officer and officers from the Clearwater Police Department. Respondent admitted to forging the prescription for phendimetrazine. Respondent also admitted that he previously forged a prescription for 180 dosage units of phendimetrazine 35mg, which he filled on April 1, 2013.

6. Respondent further admitted to forging and filling three prescriptions for 12 dosage units each of hydrocodone, which he filled on June

13, 2012; July 15, 2012; and August 22, 2012.

7. Hydrocodone is commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012-2013), hydrocodone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of hydrocodone may lead to severe psychological or physical dependence.

8. On or about July 25, 2013, a Department-approved evaluator, examined Respondent. Dr. Bishara admitted using the diverted phendimetrazine and hydrocodone. Dr. Bishara explained that he would fill orders for the diverted medications as if a physician had called the order into the pharmacy. The evaluator diagnosed Respondent with phendimetrazine and opioid abuse, and concluded that Respondent is not currently able to safely practice pharmacy.

COUNT ONE

9. Petitioner realleges and incorporates by reference paragraphs one (1) through eight (8) as if fully set forth herein.

10. Section 465.016(1)(m), Florida Statutes (2012-2013), subjects a pharmacist to discipline for "[b]eing unable to practice pharmacy with

reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition."

11. The Department's evaluator determined that Respondent is unable to practice pharmacy with reasonable skill and safety by reason of use of drugs or narcotics.

12. Based on the foregoing, Respondent violated Section 465.016(1)(m) by being unable to practice pharmacy with reasonable skill and safety by reason of use of drugs or narcotics.

COUNT TWO

13. Petitioner realleges and incorporates by reference paragraphs one (1) through eight (8) as if fully set forth herein.

14. Section 465.016(1)(i), Florida Statutes (2012-2013), subjects a pharmacist to discipline for "[c]ompounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy."

15. Respondent dispensed controlled substances other than in the course of the professional practice of pharmacy by dispensing to himself dosage units of phendimetrazine and hydrocodone.

16. Based on the foregoing, Respondent violated Section 465.016(1)(i), Florida Statutes (2012-2013), by dispensing controlled substances to himself for reasons outside of the course of the professional practice of pharmacy.

COUNT THREE

17. Petitioner realleges and incorporates by reference paragraphs one (1) through eight (8) as if fully set forth herein.

18. Section 465.016(1)(r), Florida Statutes (2012-2013), subjects a pharmacist to discipline for "[v]iolating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto."

19. Section 456.072(1)(b), Florida Statutes (2012-2013), subjects a pharmacist to discipline for "[m]aking misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession."

20. Respondent made misleading or fraudulent representations in the course of his practice of pharmacy when he obtained medication by acting as if a doctor had called in an order prescribing the medication.

21. Based on the foregoing, Respondent violated Section 465.016(1)(r), Florida Statutes (2012-2013), by violating Section 456.072(1)(b), Florida Statutes (2012-2013), by making misleading or fraudulent representations in the practice of pharmacy.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board of Pharmacy deems appropriate.

SIGNED this 23rd day of September, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE SEP 25 2013

R. Shaffer Claridge, Esq.
Florida Bar No. 0095549
Assistant General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(P) 850-245-4444, extension 8166
(F) 850-245-4662
(E)shaffer_claridge@doh.state.fl.us

PCP Date: September 23, 2013.
PCP Members: Dr. Mesaros & Ms. Risch.

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: St Petersburg	Date of Case: 06/10/2013	Case Number: 2013-09121

Subject: **MAGDI MIKHAIL BISHARA, R. Ph** 2227 Kent Place Clearwater, Florida 33764 Tel: (727) 524-6827	Source: Self Report

Prefix: PS	License # 47410	Profession: Pharmacist	Board: Pharmacy	Report Date: 09/09/2013

Period of Investigation: 09/05/2013 – 09/09/2013	Type of Report: Supplement 4

Alleged Violation: Possible violation of ss. 456.072(1)(k)(z) dd) and 465.016(1)(d)(2)(m)(r) F.S. Impaired from alcohol/drugs/other; Violate Statute/Rule of Board; Failure to perform legal obligation.

Synopsis:

This supplemental report is predicated upon receipt of request from PSU to hand serve **BISHARA** (Exh. S4-1) the attached ERO. (Exh. S4-2).

Service was made via email and U.S. postal service to Attorney RICHARD SEBEK of Banker, Lopez, Gassler, P.A., 501 East Kennedy Blvd., Suite 1500, Tampa, Florida 33602 on behalf of **BISHARA.**

An Affidavit of Service and email confirmation from Attorney SEBEK is Exh S4-3.

PSU was notified via email on 9/9/13.

RECEIVED-LEGAL
13 SEP 12 AM 9:16

Related Case(s): none

Investigator/Date: Marlene Toledo Marlene Toledo, MQAI (PI-47) 9/9/13	Approved By/Date: Karen Hanzal 9.9.13 Karen Hanzal, Investigations Supervisor (PI-28)

Distribution: HQ/ISU

Received
Investigative Services
SEP 11 2013
DOH/MQA
Tallahassee HQ

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

FLORIDA HEALTH

Vision: To be the Healthiest State in the Nation

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

PSU REQUEST FORM

FROM: Tamia Christopher For Shaffer Claridge, Esquire	TO: Karen Hanzal, Invest. Supervisor ISU: St. Petersburg
Date: 9/5/13	TO: CSU
Phone #: 850/245/4444 Ext. 8200	CC: Toledo

Case Number: 2013-09121
Subject: Magdi Mikhail Bishara, R.Ph
Requested Completion Date: A.S.A.P.
Board: Pharmacy
HL Code: HLL101A
Status: 90

RECEIVED-LEGAL
13 SEP 12 AM 9:16

(PSU) TYPE OF REQUEST: (describe details below)

- [x] Process Service* (**Activity Code 160**)
- [ ] Additional Information Requested (**Activity Code 145**)
- [ ] Deficiency in Investigative Work (**Activity Code 150**)

Details: **For Hand Service of ERO**
Last Known Address: 2227 Kent Place, Clearwater, Florida 33764
Last Known Name & Phone Number: Magdi Mikhail Bishara, (727) 524-5827
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES [ ] No [x]; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES [ ]** No [ ] NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

- [x] Process Service Completed (Activity Code 161)
- [ ] Process Service NOT Completed (Activity Code 162)
- [ ] Additional Info Sent to Legal (Activity Code 156)
- [ ] Supp. Investigation Request Cancelled (Activity Code 157)

Email to:	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami	Pensacola
	Consumer Services	ULA									

Florida Department of Health
Division of Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-
PHONE: 850-245-4444 • FAX 850-245-4662

al Order No. DOH-13-1793-ERO-MQA
FILED DATE SEP 0 5 2013
Department of Health
By: Angel Sanders
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: The Emergency Restriction of the License of
Magdi Mikhail Bishara, R.Ph.
License Number PS 47410
Case Number 2013-09121

ORDER OF EMERGENCY RESTRICTION OF LICENSE

John H. Armstrong, MD, FACS, State Surgeon General and Secretary of Health, ORDERS the Emergency Restriction of the License of Magdi Mikhail Bishara, R. Ph. ("Mr. Bishara"), to practice as a pharmacist in the State of Florida. Mr. Bishara holds license number PS 47410. His address of record is 2227 Kent Place, Clearwater, Florida 33764. The following Findings of Fact and Conclusions of Law support the emergency restriction of Mr. Bishara's license to practice as a pharmacist in the State of Florida.

FINDINGS OF FACT

1. The Department of Health ("Department") is the state agency charged with regulating the practice of pharmacy pursuant to Chapters 20, 456, and 465, Florida Statutes (2012-2013). Section 456.073(8), Florida Statutes (2012-2013), empowers the State Surgeon General to summarily restrict Mr. Bishara's license to practice as a pharmacist in the State of Florida in accordance with Section 120.60(6), Florida Statutes (2012-2013).

2. At all times material to this Order, Mr. Bishara was a licensed

pharmacist within the state of Florida, having been issued license number PS 47410, and was employed by the Walgreens Pharmacy ("Walgreens") doing business at 1801 Gulf to Bay Boulevard, Clearwater, Florida 33765.

3. On or about May 7, 2013, a co-worker observed Mr. Bishara at the filling station at Walgreens filling a prescription for phendimetrazine 35mg. While speaking with Mr. Bishara, the co-worker discovered that Mr. Bishara was filling his own prescription in violation of Walgreens' policy. Mr. Bishara deleted the prescription and gave the medication to the co-worker. Upon further inspection, the co-worker noticed that the prescription was for 180 dosage units, while the bottle which Mr. Bishara filled contained 200 dosage units.

4. Phendimetrazine is a stimulant drug commonly used as an appetite suppressant. According to Section 893.03(3), Florida Statutes (2012-2013), phendimetrazine is a Schedule III controlled substance that has a potential for abuse less than the substances in Schedules I and II and has a currently accepted medical use in treatment in the United States. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

5. On or about May 8, 2013, Mr. Bishara was questioned by the Walgreens Loss Prevention Officer and officers from the Clearwater Police

Department. Mr. Bishara admitted to forging the prescription for phendimetrazine. Mr. Bishara also admitted that he previously forged a prescription for 180 dosage units of phendimetrazine 35mg, which he filled on April 1, 2013.

6. Mr. Bishara further admitted to forging and filling three prescriptions for 12 dosage units each of hydrocodone, which he filled on June 13, 2012; July 15, 2012; and August 22, 2012.

7. Hydrocodone is commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012-2013), hydrocodone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of hydrocodone may lead to severe psychological or physical dependence.

8. On or about July 25, 2013, Dr. D.B., M.D., a Department-approved evaluator, examined Mr. Bishara. Dr. Bishara admitted using the diverted phendimetrazine and hydrocodone. Dr. Bishara explained that he would fill orders for the diverted medications as if a physician had called the order into the pharmacy.

9. Dr. D.B. diagnosed Mr. Bishara with phendimetrazine and opioid

abuse, and concluded that Mr. Bishara is not currently able to safely practice pharmacy. Dr. D.B. recommended that Mr. Bishara complete a twelve-week outpatient program and sign a monitoring contract.

10. Pharmacists work with highly addictive and potentially dangerous controlled substances. Pharmacists must possess good judgment in the execution of their duties.

11. Mr. Bishara's dependence on phendimetrazine and hydrocodone and diversion thereof indicate that he does not possess the requisite judgment necessary to safely practice pharmacy.

12. A less restrictive sanction would not sufficiently protect the public from the threat that Mr. Bishara poses. Mr. Bishara has demonstrated a willingness to abuse his position as a pharmacist to illegally obtain controlled substances. Mr. Bishara will continue to pose a danger so long as he has access to controlled substances. Nothing short of the immediate restriction of Mr. Bishara's license to practice pharmacy, according to the terms of this order, will sufficiently protect the public.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General concludes as follows:

1. The State Surgeon General has jurisdiction over this matter pursuant to Sections 20.43 and 456.073(8), Florida Statutes (2012-2013), and Chapter 465, Florida Statutes (2012-2013).

2. Section 465.016(1)(m), Florida Statutes (2012-2013), subjects a pharmacist to discipline, including restriction, for "[b]eing unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition."

3. Mr. Bishara violated Section 465.016(1)(m), Florida Statutes (2012-2013), by being unable to practice pharmacy by reason of use of drugs or narcotics.

4. Section 465.016(1)(i), Florida Statutes (2012-2013), subjects a pharmacist to discipline, including restriction, for "[c]ompounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy."

5. Mr. Bishara violated Section 465.016(1)(i), Florida Statutes (2012-2013), by dispensing controlled substances to himself for reasons outside of the course of the professional practice of pharmacy.

6. Section 465.016(1)(r), Florida Statutes (2012-2013), subjects a pharmacist to discipline, including restriction, for "[v]iolating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto."

7. Section 456.072(1)(b), Florida Statutes (2012-2013), subjects a pharmacist to discipline, including restriction, for "[m]aking misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession."

8. Mr. Bishara violated Section 465.016(1)(r), Florida Statutes (2012-2013), by violating Section 456.072(1)(b), Florida Statutes (2012-2013), by obtaining medication by acting as if a doctor had called in an order prescribing it.

9. Section 120.60(6), Florida Statutes (2012-2013), authorizes the Department to restrict a pharmacist's license if the Department finds that the pharmacist presents an immediate, serious danger to the public health, safety, or welfare.

10. Mr. Bishara's continued practice as a pharmacist constitutes an immediate serious danger to the health, safety, and welfare of the public and this summary procedure is fair under the circumstances to adequately protect the public.

WHEREFORE, in accordance with Section 120.60(6), Florida Statutes (2012-2013), it is **ORDERED THAT**:

1. The license of Magdi Mikhail Bishara, R.Ph., license number PS 47410, is hereby immediately restricted to prohibit him from practicing pharmacy until such time as PRN recommends to the Department that Mr. Bishara is safe to practice pharmacy.

2. A proceeding seeking formal discipline of the license of Magdi Mikhail Bishara to practice as a pharmacist will be promptly instituted and acted upon in compliance with Sections 120.569 and 120.60(6), Florida Statutes (2012-2013).

DONE and ORDERED this 4th day of September, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

PREPARED BY:
R. Shaffer Claridge, Esq.
Florida Bar No. 0095549
Assistant General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(P) 850-245-4444, extension 8166
(F) 850-245-4662
(E) shaffer_claridge@doh.state.fl.us

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Sections 120.60(6), and 120.68, Florida Statutes, this Order is judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Proceedings are commenced by filing a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, with the District Court of Appeal, accompanied by a filing fee prescribed by law, and a copy of the Petition with the Agency Clerk of the Department within 30 days of the date this Order is filed.

Toledo, Marlene

From: Richard Sebek [RSebek@BANKERLOPEZ.COM]
Sent: Friday, September 06, 2013 3:33 PM
To: Toledo, Marlene
Subject: RE: ESO

Marlene:
I have it. Thanks.
Have an enjoyable weekend.
Sincerely,

Rick Sebek
Richard M. Sebek, Esquire
Banker Lopez Gassler P.A.
501 East Kennedy Blvd.
Ste. 1500
Tampa, Florida 33602
(813) 222-1121 (direct)
(813) 222-3066 (fax)
rsebek@bankerlopez.com

From: Marlene_Toledo@doh.state.fl.us [mailto:Marlene_Toledo@doh.state.fl.us]
Sent: Friday, September 06, 2013 12:48 PM
To: Richard Sebek
Subject: ESO

Richard,

Please find the attached ESO for your client...Magdi Bishara.

Can you please send me a quick email verifying you received this? I will also be sending you the hard copy.

Marlene Toledo
Medical Quality Assurance Investigator
DOH - MQA/ISU/St. Petersburg
525 Mirror Lake Drive North #310A
St. Petersburg, FL 33701
Phone: 727-552-2700- Fax: 727-552-1157
Customer Satisfaction Survey

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, and community efforts. Vision: To be the ***Healthiest State*** *in the Nation.*

Please note: *Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.*

Please consider the environment before printing this email.

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

DEPARTMENT OF HEALTH
Petitioner

vs

Case No. 2013-09121

MAGDI MIKHAIL BISHARA, R.Ph.
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:
1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on 09/06/13, Affiant made a diligent effort to locate Respondent, to serve _____ Administrative Complaint and related papers; ____ Order compelling examination(s); Subpoena(s); _____Final order; _____Notice to cease and desist; ___X___ ESO/ERO and related papers.

3) Check applicable answer below:

_____X Affiant made personal service on Respondent's attorney on 09/06/2013.
_____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers
Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

Marlene Toledo
Marlene Toledo
Affiant

State Of Florida
County Of Pinellas

Before me, personally appeared Marlene Toledo whose identity is known to me and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 9th day of September 2013.

Patrick L. Coleman
Notary Public-State of Florida

_____
My Commission Expires

PATRICK L. Coleman
Type or Print Name

PATRICK L. COLEMAN
Commission # EE 877919
Expires March 19, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

INV FORM 321

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area VI Tampa	Date of Case: 06/10/13	Case Number: 201309121

Subject: **MAGDI MIKHAIR BISHARA, R. PH** 2227 Kent Place Clearwater, Florida 33764 Telephone (727) 524-6827	Source: **SELF - REPORT**

Prefix:	License #:	Profession:	Board:	Report Date:
PS	47410	Pharmacist	Pharmacy	07/08/13

Period of Investigation: 07/03/13 to 07/08/13	Type of Report: Supplemental – 4

Alleged Violation: See Final Report

Synopsis: This supplemental report is predicated on a PSU Request Form (Exhibit #: S4 – 1) from SHAFFER CLARIDGE, Attorney in PSU, requesting hand-service of an Order Compelling Examination.

On 07-03-13, Investigator GREGORY RAMER met with RICHARD M. SEBEK, Attorney for MAGDI BISHARA, R. Ph., to hand-serve the Order Compelling Examination. SEBEK was served the Order at his office located at 501 E. Kennedy Blvd, Ste. 1500, Tampa, FL. SEBEK hand-wrote a confirmation of receipt of the Order on behalf of his client, MAGDI BISHARA (Exhibit #: S4 – 2).

An Affidavit of Service is attached as Exhibit #: S4 – 3.

RECEIVED-LEGAL
13 JUL -9 PM 3:01

Exhibits

S4 – 1: PSU request form (page 2)

S4 – 2: Hand-written confirmation of service from Attorney SEBEK (page 3)

S4 – 3: Affidavit of Service (page 4)

Related Case(s): None

Investigator/Date: 07-08-13 Gregory Ramer TI – 147 Investigation Specialist II	Approved By/Date: 07-08-13 Babette S. Agett, TI – 115 Investigation Supervisor

Received
Investigative Services
JUL 09 2013

Distribution: HQ/ISU

DOH/MQA
Tallahassee, FL

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

FROM: Denise Shannon for Shaffer Claridge, Esq.	TO: ISU Karen Hanzal
Date: July 3, 2013	TO: CSU
Phone #: (850) 245-4444 X 8148	CC: Marlene Toledo

Case Number: 2013-09121
Subject: **Magdi Mikhair Bishara, R. Ph**
Requested Completion Date: ASAP

Board: **Pharmacy**
HL Code:HLL**101a**
Status: **67**

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Please Hand Serve Order Compelling to Subject's attorney, Ricard Sebek. Please contact me by July 20, 2013 if you are unable to serve the subject. Thank you very much.

*The following additional information is needed for each service request:

Last Known Address **Banker Lopez Gassler P.A., 501 East Kennedy Blvd., Ste. 1500, Tampa, FL 33602**
Last Known Name & Phone Number: **Richard M. Sebek, Esq., (813) 222-1121**
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☐; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☐** No ☒ NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☒ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

RECEIVED 13 JUL -9 PM 3:01 LEGAL

Email to:
Pensacola Tallahassee Alachua Jacksonville St. Pete Tampa Orlando Ft. Myers West Palm Ft. Lauderdale Miami
Consumer Services ULA

INV FORM 376, Revised 1/12, 10/11, 6/10, 06/09, 4/09, 11/08 Created 4/05

54-1

2

RECEIPT

I, Richard M. Sebek, Esquire, hereby confirm receipt of the ORDER COMPELLING AN EXAMINATION from the Department of Health dated June 27, 2013 this date.

Richard M. Sebek, Esq
Counsel for Masd. Bushara Rph
Case No. 2013-09121

Dated: July 3, 2013

EXHIBIT#
S9-2

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

AFFIDAVIT OF SERVICE

DEPARTMENT OF HEALTH
Petitioner
vs

Case NO. 2013-09121

RICHARD M. SEBEK, ESQ.
Respondent

COMES NOW, the affiant, who first being duly swom, deposes and states:
1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on July 03, 2013, Affiant personally served order compelling examination.

3) Check applicable answer below:

___X___Affiant made personal service of order compelling examination, on Wednesday, July 03, 2013, to Richard M. Sebek, Esq. attorney for, Magdi Mikhair Bishara, R. Ph., at 501 East Kennedy Blvd, Ste. 1500, Tampa, FL 33602.
_____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers
Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

_____
Affiant

State Of Florida
County Of Hillsborough

Before me, personally appeared Gregory Ramer whose identity is known to me by personal knowledge and who, acknowledges that his/her signature appears above.

Swom to or affirmed by Affiant before me this 08th day of July 2013.

Patricia Allen
Notary Public-State of Florida

_____
My Commission Expires

Patricia Allen
Type or Print Name

PATRICIA ALLEN
Commission # FF 000935
Expires March 20, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

INV FORM 321

PAGE S4-3

4

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: St Petersburg	Date of Case: 06/10/2013	Case Number: 2013-09121

Subject: **MAGDI MIKHAIL BISHARA, R. Ph** 2227 Kent Place Clearwater, Florida 33764 Tel: (727) 524-6827	Source: Self Report

Prefix: PS	License # 47410	Profession: Pharmacist	Board: Pharmacy	Report Date: 07/02/2013

Period of Investigation: 07/02/2013	Type of Report: Supplement 3

Alleged Violation: Possible violation of ss. 456.072(1)(k)(z) dd) and 465.016(1)(d)(2)(m)(r) F.S. Impaired from alcohol/drugs/other; Violate Statute/Rule of Board; Failure to perform legal obligation.

Synopsis:

This supplemental report is predicated upon receipt of request from PSU to hand serve **BISHARA** (Exh. S3-1) the attached Order Compelling Examination. (Exh. S3-2).

Service was made via email and U.S. postal service to Attorney RICHARD SEBEK of Banker, Lopez, Gassler, P.A., 501 East Kennedy Blvd., Suite 1500, Tampa, Florida 33602 on behalf of **BISHARA.**

An Affidavit of Service and email confirmation from Attorney SEBEK is Exh S3-3.

RECEIVED-LEGAL
13 JUL -9 AM 8:00

Related Case(s): none

Investigator/Date: Marlene Toledo Marlene Toledo, MQAI (PI-47) 07/02/13	Approved By/Date: Matto Kaspel 7/2/13 for Karen Hanzal, Investigations Supervisor (PI-28)

Distribution: HQ/ISU

Received
Investigative Services
JUL 08 2013
DOH/MQA
Tallahassee, FL

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

FROM: Denise Shannon for Shaffer Claridge, Esq.	TO: ISU Karen Hanzal
Date: July 1, 2013	TO: CSU
Phone #: (850) 245-4444 X 8148	CC: Marlene Toledo FI-47

Case Number: 2013-09121 Board: **Pharmacy**
Subject: **Magdi Mikhair Bishara, R. Ph** HL Code:HLL**101a** Status: **67**
Requested Completion Date: ASAP

(PSU) TYPE OF REQUEST: (describe details below)

RECEIVED-LEGAL
13 JUL -9 AM 8:00

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Please Hand Serve Order Compelling. Please contact me by July 18, 2013 if you are unable to serve the subject. Thank you very much.

*The following additional information is needed for each service request:

Last Known Address **2227 Kent Place, Clearwater, FL 33764** Last Known Name & Phone Number: **Magdi Mikhair Bishara, R. Ph, (727) 524-6827.**
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☐; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☐** No ☒ NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☒ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Email to:

Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

INV FORM 376, Revised 1/12. 10/11, 6/10, 06/09, 4/09, 11/08 Created 4/05

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: The Order Compelling Examination of
Magdi Mikhail Bishara, R.Ph.
License Number PS 47410
Case Number 2013-09121

ORDER COMPELLING AN EXAMINATION

The Department of Health ("Department") is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes (2012); Chapter 456, Florida Statutes (2012); and Chapter 465, Florida Statutes (2012).

For probable cause shown and pursuant to the authority vested in the Department by Chapter 465, Florida Statutes (2012), you are hereby ordered to report and submit to a mental and physical examination to be conducted by the following named physician at the date, time and place indicated.

MENTAL AND PHYSICAL EXAMINATION

DEBRA M. BARNETTE, M.D.
14437 UNIVERSITY COVE PLACE
TAMPA, FLORIDA 33613
(813) 972-7946
TUESDAY, JULY 23, 2013 @ 1:30 P.M.

The above-directed mental and physical examination is for the purpose of obtaining examination reports and expert opinion and testimony concerning your ability to practice pharmacy with reasonable skill and safety pursuant to

Sections 456.072(1)(z) and 465.016(1)(m), Florida Statutes (2012), and for introduction into evidence at any administrative hearing to be conducted on any administrative complaint filed against you which may allege a violation of Section 456.072(1)(z) and/or 465.016(1)(m), Florida Statutes (2012). This Order is predicated upon the following Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

1. At all times material to this Order, Magdi Mikhail Bishara (Mr. Bishara), was a licensed pharmacist within the state of Florida, having been issued license number PS 47410.

2. At all times material to this Order, Mr. Bishara was employed by the Walgreens Pharmacy ("Walgreens"), maintaining an address of record at 1801 Gulf to Bay Boulevard, Clearwater, Florida 33765.

3. On or about May 7, 2013, a co-worker observed Mr. Bishara at the filling station filling a prescription for phendimetrazine 35mg. While speaking with Mr. Bishara, the co-worker discovered that Mr. Bishara was filling his own prescription in violation of Walgreens' policy. Mr. Bishara deleted the prescription and gave the medication to the co-worker. Upon further inspection, the co-worker noticed that the prescription was for 180 dosage units; the bottle which Mr. Bishara had filled contained 200 dosage units.

4. Phendimetrazine is a stimulant drug commonly used as an appetite suppressant. According to Section 893.03(3), Florida Statutes (2012), phendimetrazine is a Schedule III controlled substance that has a potential for abuse less than the substances in Schedules I and II and has a currently accepted medical use in treatment in the United States. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

5. On or about May 8, 2013, Mr. Bishara was questioned by the Walgreens Loss Prevention Officer and officers from the Clearwater Police Department. Mr. Bishara admitted to forging the prescription for the phendimetrazine. Mr. Bishara also admitted that he had previously forged a prescription for 180 dosage units of phendimetrazine 35mg, which he had filled on April 1, 2013.

6. Mr. Bishara also admitted to forging and filling three prescriptions for 12 dosage units of hydrocodone, which he filled on June 13, 2012; July 15, 2012; and August 22, 2012.

7. Hydrocodone is commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012), hydrocodone is a Schedule II controlled substance that has a high potential for abuse and has a currently

accepted but severely restricted medical use in treatment in the United States. Abuse of hydrocodone may lead to severe psychological or physical dependence.

8. Because Mr. Bishara admitted to forging prescriptions to obtain phendimetrazine and hydrocodone for personal use, a thorough and complete mental and physical examination is necessary to protect the public and to determine whether Mr. Bishara is capable of practicing pharmacy with reasonable skill and safety.

CONCLUSIONS OF LAW

1. The Department of Health, by and through the State Surgeon General, has jurisdiction over this matter pursuant to Chapters 456 and 465, Florida Statutes (2012).

2. Section 456.072(1)(z), Florida Statutes (2012), states, in pertinent part, "the department shall have, upon a finding of the State Surgeon General or the State Surgeon General's designee that probable cause exists to believe that the licensee is unable to practice because of the reasons stated in this paragraph, the authority to issue an order to compel a licensee to submit to a mental or physical examination by physicians designated by the department."

3. Mr. Bishara's diversion of phendimetrazine and hydrocodone gives cause to believe that Mr. Bishara is impaired. Therefore, the State Surgeon General, through his undersigned designee, concludes that probable cause exists to believe Mr. Bishara is unable to practice pharmacy with reasonable skill and safety, pursuant to Sections 456.072(1)(z) and 465.016(1)(m), Florida Statutes (2012). A thorough and complete mental and physical examination of Mr. Bishara is necessary to protect the public and ensure that he is able to practice pharmacy with reasonable skill and safety.

4. In accordance with the authority vested in the Department of Health under Chapters 456 and 465, Florida Statutes, the State Surgeon General, through his undersigned designee, concludes that 456.072(1)(z), Florida Statutes (2012), should be enforced.

DONE and ORDERED by the Department of Health on this 27th day of June, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

J. Martin Stubblefield
Deputy Secretary for Administration

COUNSEL FOR DEPARTMENT:
R. Shaffer Claridge, Esq.
Florida Bar No. 0095549
Assistant General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(P) 850-245-4444, extension 8166
(F) 850-245-4662
(E) shaffer_claridge@doh.state.fl.us

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

DEPARTMENT OF HEALTH
Petitioner

vs

Case No. 2013-09121

MAGDI MIKHAIR, R. Ph
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:
1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on July 2, 2013, Affiant made a diligent effort to locate Respondent, to serve _ Administrative Complaint and related papers; X____ Order compelling examination(s); Subpoena(s); _____Final order; _____Notice to cease and desist; _____ ESO/ERO and related papers.

3) Check applicable answer below:

X_____Affiant made personal service on Respondent's attorney, at attorney's office, on July 2, 2013.
_____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers
Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

Marlene Toledo
Marlene Toledo
Affiant

State Of Florida
County Of Pinellas

Before me, personally appeared Marlene Toledo whose identity is known to me and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 2nd day of July 2013.

Notary Public-State of Florida

My Commission Expires

Yolanda Loera
Type or Print Name

YOLANDA LOERA
Commission # DD 933601
Expires October 18, 2013
Bonded Thru Troy Fain Insurance 800-385-7019

INV FORM 321

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: St Petersburg	Date of Case: 06/10/2013	Case Number: 2013-09121

Subject: **MAGDI MIKHAIL BISHARA, R. Ph** 2227 Kent Place Clearwater, Florida 33764 Tel: (727) 524-6827	Source: Self Report

Prefix: PS	License # 47410	Profession: Pharmacist	Board: Pharmacy	Report Date: 07/02/2013

Period of Investigation: 07/02/2013	Type of Report: Supplement 2

Alleged Violation: Possible violation of ss. 456.072(1)(k)(z) dd) and 465.016(1)(d)(2)(m)(r) F.S. Impaired from alcohol/drugs/other; Violate Statute/Rule of Board; Failure to perform legal obligation.

Synopsis:

This supplemental report is predicated upon receipt of an email from Attorney RICHARD SEBEK, P.A. on behalf of **BISHARA** which includes a written response and **BISHARA** 's CV. (S2-1)

RECEIVED-LEGAL
13 JUL -5 AM 8:58

Related Case(s): none

Investigator/Date: Marlene Toledo 7/2/13 Marlene Toledo, MQAI (PI-47)	Approved By/Date: for Matthew Kanzel PI-33 7/2/13 Karen Hanzal, Investigations Supervisor (PI-21)

Distribution: HQ/ISU

Received
Investigative Services
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Tallahassee HQ

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: St Petersburg	Date of Case: 06/10/2013	Case Number: 2013-09121

Subject: **MAGDI MIKHAIL BISHARA, R. Ph** 2227 Kent Place Clearwater, Florida 33764 Tel: (727) 524-6827	Source: Self Report

Prefix: PS	License # 47410	Profession: Pharmacist	Board: Pharmacy	Report Date: 06/24/2013

Period of Investigation: 06/24/2013	Type of Report: Supplement 1

Alleged Violation: Possible violation of ss. 456.072(1)(k)(z) dd) and 465.016(1)(d)(2)(m)(r) F.S. Impaired from alcohol/drugs/other; Violate Statute/Rule of Board; Failure to perform legal obligation.

Synopsis:

This supplemental report is predicated upon receipt of photocopies of prescriptions that **BISHARA** wrote to himself from Walgreen's Pharmacy. Walgreen's Pharmacy included a Certification of Records. (S1-1)

RECEIVED-LEGAL
13 JUN 27 AM 7:36

Related Case(s): none

Investigator/Date: Marlene Toledo Marlene Toledo, MQAI (PI-47) 6/24/13	Approved By/Date: Karen Hanzal 6-24-13 Karen Hanzal, Investigations Supervisor (PI-21)

Distribution: HQ/ISU

Received
Investigative Services
JUN 26 2013
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Tallahassee HQ

CONFIDENTIAL AND EXEMPT MATERIALS

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

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STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: St Petersburg	Date of Case: 06/10/2013	Case Number: 2013-09121

Subject: **MAGDI MIKHAIL BISHARA, R. Ph** 2227 Kent Place Clearwater, Florida 33764 Tel: (727) 524-6827	Source: Self Report

Prefix: PS	License # 47410	Profession: Pharmacist	Board: Pharmacy	Report Date: 06/14/2013

Period of Investigation: 06/11/2013 – 06/14/2013	Type of Report: Final

Alleged Violation: Possible violation of ss. 456.072(1)(k)(z) dd) and 465.016(1)(d)(2)(m)(r) F.S. Impaired from alcohol/drugs/other; Violate Statute/Rule of Board; Failure to perform legal obligation.

Synopsis:
This investigation is predicated upon a self report received from subject (Exh 1) stating he was arrested for drug charges. The subject states that he recently turned himself in for unlawfully obtaining diet pills and hydrocodone in Pinellas County. The subject states that he is currently in the process of trying to get into a diversion program.

A notification letter, copy of the Case Summary and Voluntary Relinquishment, dated 6/11/2013, were sent via U.S. Postal Service to **BISHARA.** This investigator also hand served **BISHARA's** mother on behalf of **BISHARA** on 6/12/13. (Exh 2)

A check of DOH computer records revealed **BISHARA** is currently Clear/Active as a Pharmacist. His license was originally issued on 4/6/11 and is set to expire on 9/30/13.

Patient notification was not necessary due to the allegations.

BISHARA is represented by RICHARD SEBEK, Esquire, Banker, Lopez, Gassler, P.A. 501 East Kennedy Blvd, Ste 1500, Tampa, FL 33602, Tel (813) 221-1121. (Exh 7)

Attorney SEBEK stated that he will be sending in a response and **BISHARA's** CV in the near future.

Related Case(s): none

Investigator/Date: Marlene Toledo 6/14/13 Marlene Toledo, MQAI (PI-47)	Approved By/Date: Karen Hanzal 6·14·13 Karen Hanzal, Investigations Supervisor (PI-21)

Distribution: HQ/ISU

13 JUN 19 AM 8:09
RECEIVED-LEGAL

Received
Investigative Services
JUN 18 2013
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Tallahassee HQ

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JANELLE SAYLOR, RPT – Witness 5

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4. Pinellas County Case Progress Docket 15-16
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9. Pharmacy records 45-50

***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES**

****These records are sealed pursuant to Section 456.057(10)(a), Florida Statutes and copies of same are not maintained in the St Petersburg Investigative Services office**

*****This exhibit contains confidential records concerning reports of abuse, neglect or exploitation of the vulnerable adult, including reports made to the central abuse hotline, and is sealed pursuant to section 415.107(1), Florida Statutes**

INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit 3 is Pinellas County Sheriff's Office Subject Charge Report. Date of arrest 5/30/13 charged with:

1) Obtaining controlled substance through fraud (hydrocodone) F.S. 893.13(7)(a)(9)/F
2) Obtaining controlled substance through fraud (phendimetrazine) F.S. 893.13(7)(a)(9)/F

Exhibit 4 is the Pinellas County Court Case Progress Docket.

Exhibit 5 is the Clearwater Police Department report # CW13-66781, which states **BISHARA** admitted filling the following prescriptions for himself:

- RX806402 and RX2145646 for 35mg Phendimetazine, 180 pills, on 4/1/13 and 5/17/13.
- RX1563629, RX1658292 and RX2113237 of Hydrocodone-Acet, 12 pills each, on 6/13/12, 7/15/12 and 8/22/12.
- All prescriptions were filled at Walgreen's Pharmacy where he was employed.

Exhibit 6 is the PRN response stating **BISHARA** is not known to PRN.

Exhibit 7 is a letter of representation from RICHARD SEBEK, Esquire, Banker, Lopez, Gassler, P.A. 501 East Kennedy Blvd, Ste 1500, Tampa, **FL** 33602, Tel (813) 221-1121.

Exhibit 8 is a sworn statement from Dr. NADER SAID stating he did not authorize, call-in or sign the prescriptions RX 806403 and RX 2145646 for 180 pills of Phendimetrazine.

Exhibit 9 is the pharmacy records which includes the following:

- Break down of prescriptions **BISHARA** filled, showing 5 fraudulent prescriptions.
- Walgreens call in prescription for Phendimetrazine 35mg #180, dated 4/1/13
- Walgreens call in prescription for Phendimetrazine 35mg #180, dated 5/7/13
- Original prescription written and verified by Dr. LAZARO for Vicodin ES #12, dated 4/23/12, 2 refills
- 2 call in refills for hydrocodone/acetaminophen, #12

INTERVIEWS/STATEMENTS

INTERVEW OF JOHN FELLENBAUM –Witness

Employment:

Detective
Pinellas County Sheriff's Office

10750 Ulmerton Rd
Largo, FL 33778
Tel: (727) 582-2840

This investigator interviewed FELLENBAUM at which time he made the following statements

- **BISHARA** stated that he used to have a prescription for Phendimetazine from Dr. SAID, but it has since expired.
- Dr. SAID's office is far away and **BISHARA** did not have time to go out there for an appointment so he wrote the prescriptions to himself.
- **BISHARA** filled 3 prescriptions for Hydrocodone-Acet using Dr. LAZARO's name, as a call in refill.
- **BISHARA** was cooperative and admitted he made a mistake.
- FELLENBAUM advised **BISHARA** that he would be contacting DOH and recommended that he not work anyplace as a Pharmacist until the criminal case is over.

INTERVEW OF NADER SAID, M.D. – Witness (lic # ME 78087)

Employment:

Florida Pain Medical Management
8115 State Road 54
New Port Richey, FL 34655
Tel: (727) 376-6199

This investigator interviewed SAID via telephone on 6/13/13 at which time he made the following statements:

- SAID did not prescribe Phendimetrazine or any other medications to **BISHARA** on 4/1/13, 5/7/13 or any time before or after that date.
- SAID again verified that he did not call, write or have anyone else call in medications for **BISHARA.**
- SAID stated he does not call in controlled substances to pharmacies.

**********Sworn statement is Exhibit 8**********

INTERVEW OF EDUARDO LAZARO, M.D. – Witness (lic # DN 14605)

Employment:

3165 McMullen Booth Rd
Bldg A Ste. 2
Clearwater, FL 33761
Tel: (727) 796-2183

This investigator interviewed LAZARO via telephone on 6/14/13 at which time he made the following statements:

- LAZARO wrote the original prescription on 4/23/12 for Vicodin ES, with 2 refills, 12 pills each prescription.
- LAZARO stated the refills would cover dates 4/29/12 and 5/30/12.
- LAZARO did not write or call in prescriptions for any dates after that time.

INTERVEW OF JANELLE SAYLOR, RPT –Witness (lic # RPT 39542)

Employment:

Walgreens Pharmacy
1801 Gulf to Bay Blvd.
Clearwater, FL 33756
Tel: (937) 790-0870

This investigator interviewed SAYLOR via telephone on 6/14/13 at which time she made the following statements;

- SAYLOR went to a meeting and when she came back **BISHARA** was there working.
- **BISHARA** is a floater pharmacist and she has seen him before working there.
- **BISHARA** was filling a prescription and SAYLOR didn't think anything about it until he turned the bag around and she saw his name on it.
- SAYLOR asked **BISHARA** if the prescription was for him and he told her it was.
- SAYLOR told him that he couldn't fill his own prescriptions and **BISHARA** said "really?".
- SAYLOR asked why he would want to fill his own prescription anyway and give anyone a reason to question it.
- SAYLOR told **BISHARA** to delete it, re-enter it and she would fill it.
- When Saylor emptied the bottle to re-fill the prescription she noticed the prescription for Phendimetrazine was for 180 and he had 200 pills in the bottle.
- The next day when they contacted the physician office to verify the prescription, since it was a call in, they stated they had no one by the name of the person that supposedly called it in working there.
- The staff verified with the doctor and he stated he did not have anyone call in the prescription for **BISHARA.**
- SAYLOR said **BISHARA** did not appear to be impaired.

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June 11, 2013

CONFIDENTIAL TO:
Magdi Mikhail Bishara
2227 Kent Place
Clearwater, Florida 33764

Case # 2013-09121

Dear Mr. Bishara:

We are currently investigating the enclosed document received by the Department of Health. This investigation was initiated after it was determined that you may have violated the Nursing Practice Act.

Within **twenty (20) days** of receiving this letter, you may:
- submit a **written response** to the address below; **or**
- call our office to schedule an **interview**.

Please provide a copy of your **curriculum vitae** and identify your **specialty** even if you choose not to submit a response. Include the above-referenced case number in any correspondence that you send.

Florida law requires that this case and all investigative information remain confidential until 10 days after the Probable Cause Panel has determined that a violation occurred or you give up the right to confidentiality. Therefore, the contents of the investigation cannot be disclosed to you or the general public.

You may make a written request for a copy of the investigative file and it will be sent to you when the investigation is complete. You may submit an additional written response to the information in the investigative file within 20 days of receipt. Your response (if one is provided), along with the information in the file, will be considered by the panel when determining whether a formal administrative complaint should be filed in this matter.

You are not required to answer any questions or give any statement, and you have the right to be represented by an attorney. It is not possible to estimate how long it will take to complete this investigation because the circumstances of each investigation differ.

The mission of the Department of Health is to promote, protect and improve the health of all people in Florida. If you have any questions please call us at 727 552-1145. In addition, if you have any concerns or suggestions about our complaint process, please fill-out our *Customer Concerns or Suggestions* form at www.floridashealth.com/mqa/survey.html.

Sincerely,

Marlene Toledo
Medical Quality Assurance Investigator

Enclosure

Exh 2

: 00009

CASE SUMMARY

CONFIDENTIAL

Case No: 201309121
Please use this number in all correspondence with the Department concerning this matter.

RESPONDENT INFORMATION

License No: 47410 Profession: 2201 Pharmacist
Name: Magdi Mikhail Bishara
Address: 2227 KENT PLACE
Clearwater, FL 33764
Home Phone: 727-524-6827

SOURCE OF INFORMATION

Name: Department Of Health/Consumer Services Unit
Address:
Home Phone:

REPORTED INFORMATION

Receive Date: 06/10/2013 Source Code: 68 Form Code: 1
Responsible Party: ha115 Status Code: 10 Priority: 1
Classification Code: Incident Date: 05/31/2013

Patient Name:

Possible Code(s): 33, 15, 18

Summary:
Possible Violation SS. 456.072(1)(k)(z)(dd) and 465.016(1)(d)(2)(m)(r), F.S.
Impaired from alcohol / drugs / other; Violate Statute / Rule of Board; Failure to perform legal obligation

Self-report received from the Subject stating she was arrested for drug charges. The Subject states that she recently turned herself in of Unlawfully Obtaining Diet Pills and Hydrocodone in Pinellas County. The Subject states that she is currently in the process of trying to get into a diversion program.
Antoinette Carter 06/10/13

6 '09121 115

RECEIVED
JUN 10 2013
BY:

Magdi Bishara
2227 Kent Place
Clearwater, FL 33764
June 5, 2013

Florida Department of Health, Board of Pharmacy
4052 Bald Cypress Way Bin C-75
Tallahassee, FL 32399

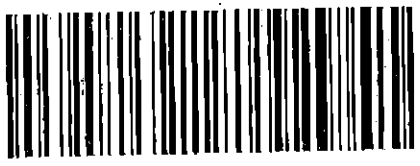
To whom it may Concern:

I Magdi Bishara am writing this letter to inform that I recently turned myself in for arrest for unlawfully obtaining diet pills and hydrocodone. I am a licensed pharmacist in the state of Florida (Licensed #PS47410), and currently in the process of applying to be accepted into a diversion program in the state of Florida.

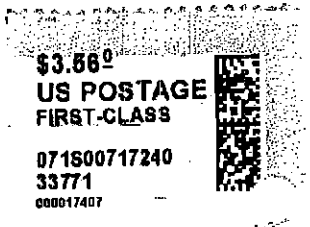
Sincerely,

6/5/2013
Magdi M. Bishara

Magdi Bishara
2227 Kent Place
Clearwater, FL 33764



7012 0470 0001 3850 1386



Florida Department of Health, Board of Pharmacy
4052 Bald Cypress Way Bin C-75
Tallahassee FL, 32399

32399701752

00012

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KEN BURKE, CPA

CLERK OF THE CIRCUIT COURT AND COMPTROLLER
PINELLAS COUNTY, FLORIDA

Adult - Case Progress Docket - Fct K

Return to Previous Page Records Main Menu

Pinellas Case			Uniform Case	Entitlement	Date Filed
CRC1309471CFANO			522013CF009471XXXXNO	STATE VS BISHARA,M	05/31/2013
Type	Ant	Cal	Final Disposition	Comp	Division
					I

Name	COC
BISHARA,MAGDI	DEFENDANT A

Select Dockets per Page: 100

Submit

Select Page: 1

8 docket entries displayed of 8 New Search

Current Sort is: -Original Sort-

Reset Original Sort	Docket Date	Docket Entry	Defendant
1	06/03/2013	WAIVER OF APPEARANCE: AT PRE-TRIAL HEARING	A
2	06/03/2013	DEMAND FOR DISCOVERY	A
3	06/03/2013	WRITTEN PLEA NOT GUILTY-ATTORNEY	A
4	06/03/2013	DEMAND/REQUEST FOR COPY OF INFORMATION	A
5	06/03/2013	WAIVER OF APPEARANCE: AT ARRAIGNMENT	A
6	06/03/2013	NOTICE OF APPEARANCE: DONALD J KILFIN	A
7	05/31/2013	COMPLAINT - OBT/ATT/OBT/CONTROLL SUBST/FRAUD-PHENDIMETRAZINE	A
8	05/31/2013	SURETY BOND POSTED	A

New Search

Select Page: 1

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ant - Appearance Date
COC - Connection Code (Connection to Case
DOC - Date Docket Created

Exh 4

KEN BURKE, CPA

CLERK OF THE CIRCUIT COURT AND COMPTROLLER
PINELLAS COUNTY, FLORIDA

Adult - Case Progress Docket - Fct K

Return to Previous Page Records Main Menu

Pinellas Case			Uniform Case	Entitlement	Date Filed
CRC1309470CFANO			522013CF009470XXXXNO	STATE VS BISHARA,M	05/31/2013
Type	Apl	Cat	Final Disposition	Comp	Division
					I

Name	COC
BISHARA,MAGDI	DEFENDANT A

Select Dockets per Page: 100

Submit

Select Page: 1

8 docket entries displayed of 8 New Search

Current Sort is: *-Original Sort-*

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5	06/03/2013	WAIVER OF APPEARANCE: AT ARRAIGNMENT	A
6	06/03/2013	NOTICE OF APPEARANCE: DONALD J KILFIN	A
7	05/31/2013	COMPLAINT - OBT/ATT/OBT/CONTROLL SUBSTANCE BY FRAUD-HYDRO	A
8	05/31/2013	SURETY BOND POSTED	A

New Search

Select Page: 1

Return to Top of Page: Top of Page

COC - Appearance Date
COC - Connection Code - Connection to Case
Final Date - Case Closed

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Toledo, Marlene

From: Richard Sebek [RSebek@BANKERLOPEZ.COM]
Sent: Thursday, June 13, 2013 2:26 PM
To: Toledo, Marlene
Cc: 'Magdi Bishara'
Subject: DOH Investigation of Magdi Bishara RPh Case No. 2013-09121

Ms. Toledo:

Please accept this as my notice to you that I have been retained by Dr. Bishara to represent him in this matter. Please address all future correspondence to me. My contact information is below.

Sincerely,

Rick Sebek
Richard M. Sebek, Esquire
Banker Lopez Gassler P.A.
501 East Kennedy Blvd.
Ste. 1500
Tampa, Florida 33602
(813) 222-1121 (direct)
(813) 222-3066 (fax)
rsebek@bankerlopez.com

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MEMORANDUM OF FINDING OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy
RE: **DOH v. Magdi Mikhail Bishara, R. Ph.**
DOH Case Number 2013-09121

MEMBERS: Jeffrey J. Mesaros, PharmD and Lorena M. Risch

DATE OF PCP: **September 23, 2013** **AGENDA ITEM: A-1**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative report, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1)(m), FS (2012-2013)
Section 465.016(1)(i), FS (2012-2013)
Section 465.016(1)(r), FS (2012-2013) by violating
Section 456.072(1)(b), FS (2012-2013)

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **Other** _____

9/23/13

Chair, Probable Cause Panel
Board of Pharmacy

Date

Final Order No. DOH-13-1793-ERO-MQA
FILED DATE SEP 0 5 2013
Department of Health
By: Angel Sanders
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: The Emergency Restriction of the License of
Magdi Mikhail Bishara, R.Ph.
License Number PS 47410
Case Number 2013-09121

ORDER OF EMERGENCY RESTRICTION OF LICENSE

John H. Armstrong, MD, FACS, State Surgeon General and Secretary of Health, ORDERS the Emergency Restriction of the License of Magdi Mikhail Bishara, R. Ph. ("Mr. Bishara"), to practice as a pharmacist in the State of Florida. Mr. Bishara holds license number PS 47410. His address of record is 2227 Kent Place, Clearwater, Florida 33764. The following Findings of Fact and Conclusions of Law support the emergency restriction of Mr. Bishara's license to practice as a pharmacist in the State of Florida.

FINDINGS OF FACT

1. The Department of Health ("Department") is the state agency charged with regulating the practice of pharmacy pursuant to Chapters 20, 456, and 465, Florida Statutes (2012-2013). Section 456.073(8), Florida Statutes (2012-2013), empowers the State Surgeon General to summarily restrict Mr. Bishara's license to practice as a pharmacist in the State of Florida in accordance with Section 120.60(6), Florida Statutes (2012-2013).

2. At all times material to this Order, Mr. Bishara was a licensed

pharmacist within the state of Florida, having been issued license number PS 47410, and was employed by the Walgreens Pharmacy ("Walgreens") doing business at 1801 Gulf to Bay Boulevard, Clearwater, Florida 33765.

3. On or about May 7, 2013, a co-worker observed Mr. Bishara at the filling station at Walgreens filling a prescription for phendimetrazine 35mg. While speaking with Mr. Bishara, the co-worker discovered that Mr. Bishara was filling his own prescription in violation of Walgreens' policy. Mr. Bishara deleted the prescription and gave the medication to the co-worker. Upon further inspection, the co-worker noticed that the prescription was for 180 dosage units, while the bottle which Mr. Bishara filled contained 200 dosage units.

4. Phendimetrazine is a stimulant drug commonly used as an appetite suppressant. According to Section 893.03(3), Florida Statutes (2012-2013), phendimetrazine is a Schedule III controlled substance that has a potential for abuse less than the substances in Schedules I and II and has a currently accepted medical use in treatment in the United States. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

5. On or about May 8, 2013, Mr. Bishara was questioned by the Walgreens Loss Prevention Officer and officers from the Clearwater Police

Department. Mr. Bishara admitted to forging the prescription for phendimetrazine. Mr. Bishara also admitted that he previously forged a prescription for 180 dosage units of phendimetrazine 35mg, which he filled on April 1, 2013.

6. Mr. Bishara further admitted to forging and filling three prescriptions for 12 dosage units each of hydrocodone, which he filled on June 13, 2012; July 15, 2012; and August 22, 2012.

7. Hydrocodone is commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012-2013), hydrocodone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of hydrocodone may lead to severe psychological or physical dependence.

8. On or about July 25, 2013, Dr. D.B., M.D., a Department-approved evaluator, examined Mr. Bishara. Dr. Bishara admitted using the diverted phendimetrazine and hydrocodone. Dr. Bishara explained that he would fill orders for the diverted medications as if a physician had called the order into the pharmacy.

9. Dr. D.B. diagnosed Mr. Bishara with phendimetrazine and opioid

abuse, and concluded that Mr. Bishara is not currently able to safely practice pharmacy. Dr. D.B. recommended that Mr. Bishara complete a twelve-week outpatient program and sign a monitoring contract.

10. Pharmacists work with highly addictive and potentially dangerous controlled substances. Pharmacists must possess good judgment in the execution of their duties.

11. Mr. Bishara's dependence on phendimetrazine and hydrocodone and diversion thereof indicate that he does not possess the requisite judgment necessary to safely practice pharmacy.

12. A less restrictive sanction would not sufficiently protect the public from the threat that Mr. Bishara poses. Mr. Bishara has demonstrated a willingness to abuse his position as a pharmacist to illegally obtain controlled substances. Mr. Bishara will continue to pose a danger so long as he has access to controlled substances. Nothing short of the immediate restriction of Mr. Bishara's license to practice pharmacy, according to the terms of this order, will sufficiently protect the public.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General concludes as follows:

1. The State Surgeon General has jurisdiction over this matter pursuant to Sections 20.43 and 456.073(8), Florida Statutes (2012-2013), and Chapter 465, Florida Statutes (2012-2013).

2. Section 465.016(1)(m), Florida Statutes (2012-2013), subjects a pharmacist to discipline, including restriction, for "[b]eing unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition."

3. Mr. Bishara violated Section 465.016(1)(m), Florida Statutes (2012-2013), by being unable to practice pharmacy by reason of use of drugs or narcotics.

4. Section 465.016(1)(i), Florida Statutes (2012-2013), subjects a pharmacist to discipline, including restriction, for "[c]ompounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy."

5. Mr. Bishara violated Section 465.016(1)(i), Florida Statutes (2012-2013), by dispensing controlled substances to himself for reasons outside of the course of the professional practice of pharmacy.

6. Section 465.016(1)(r), Florida Statutes (2012-2013), subjects a pharmacist to discipline, including restriction, for "[v]iolating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto."

7. Section 456.072(1)(b), Florida Statutes (2012-2013), subjects a pharmacist to discipline, including restriction, for "[m]aking misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession."

8. Mr. Bishara violated Section 465.016(1)(r), Florida Statutes (2012-2013), by violating Section 456.072(1)(b), Florida Statutes (2012-2013), by obtaining medication by acting as if a doctor had called in an order prescribing it.

9. Section 120.60(6), Florida Statutes (2012-2013), authorizes the Department to restrict a pharmacist's license if the Department finds that the pharmacist presents an immediate, serious danger to the public health, safety, or welfare.

10. Mr. Bishara's continued practice as a pharmacist constitutes an immediate serious danger to the health, safety, and welfare of the public and this summary procedure is fair under the circumstances to adequately protect the public.

WHEREFORE, in accordance with Section 120.60(6), Florida Statutes (2012-2013), it is **ORDERED THAT**:

1. The license of Magdi Mikhail Bishara, R.Ph., license number PS 47410, is hereby immediately restricted to prohibit him from practicing pharmacy until such time as PRN recommends to the Department that Mr. Bishara is safe to practice pharmacy.

2. A proceeding seeking formal discipline of the license of Magdi Mikhail Bishara to practice as a pharmacist will be promptly instituted and acted upon in compliance with Sections 120.569 and 120.60(6), Florida Statutes (2012-2013).

DONE and ORDERED this 4th day of September, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

PREPARED BY:
R. Shaffer Claridge, Esq.
Florida Bar No. 0095549
Assistant General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(P) 850-245-4444, extension 8166
(F) 850-245-4662
(E) shaffer_claridge@doh.state.fl.us

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Sections 120.60(6), and 120.68, Florida Statutes, this Order is judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Proceedings are commenced by filing a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, with the District Court of Appeal, accompanied by a filing fee prescribed by law, and a copy of the Petition with the Agency Clerk of the Department within 30 days of the date this Order is filed.

Complaint Cost Summary

Complaint Number: 201309121

Subject's Name: BISHARA, MAGDI MIKHAIL

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	1.50	$82.35
Investigation:	14.90	$953.29
Legal:	8.90	$944.35
Compliance:	0.15	$5.00
	**********	**********
Sub Total:	25.45	$1,984.99
Expenses to Date:		$1,600.00
Prior Amount:		$0.00
Total Costs to Date:		$3,584.99

HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201212301

PRAVEEN ANANTHULA,
RESPONDENT.

NOTICE

TO: PRAVEEN ANANTHULA
11413 WAKEWORTH STREET
ORLANDO, FL 32836

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins

Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201212301

PRAVEEN ANANTHULA,
RESPONDENT.

NOTICE

TO: PRAVEEN ANANTHULA
3952 TOWNSHIP SQ BLVD APT 1212
ORLANDO, FL 32837

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Florida Department of Health
4052 Bald Cypress Way, Bin #
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Florida HEALTH

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201212301

PRAVEEN ANANTHULA,
RESPONDENT.

NOTICE

TO: PRAVEEN ANANTHULA
3800 TOWNSHIP SQ BLVD APT 511
ORLANDO, FL 32837

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201212301

PRAVEEN ANANTHULA,
RESPONDENT.

NOTICE

TO: CHRISTOPHER BROWN
1101 DOUGLAS AVENUE
ALTAMONTE SPRINGS, FL 32714

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY = on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Settlement Agreement

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CERTIFICATE OF SERVICE

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

HEALTH

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PERSONAL AND CONFIDENTIAL

January 14, 2014

CRAZIANO A. MANCINI
147 ATHABASCA DRIVE
KISSIMMEE, FL 34759

Re: DOH v. Praveen Ananthula
Case # 201212301

Dear Craziano A. Mancini:

I am writing to you concerning the Department of Health's review of certain health care provided by the above named health care practitioner. That review included a full investigation and the filing of an Administrative Complaint. That review is nearing a conclusion and Board of Pharmacy is scheduled to take final disciplinary action in the matter on Wednesday, February 12, 2014.

This is one of several matters that will be part of the public meeting. You are welcome to attend this public meeting, but you are not required to attend, and this is not a request that you attend the meeting. Cases shown on the agenda may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled to begin at 9 a.m.; therefore, if you choose to attend it is imperative that you arrive promptly at 9 a.m. and be prepared to remain until the case is heard as cases may be heard in a different order than they appear on the agenda.

Florida law provides that the person who made the complaint to the Department ("complainant") is entitled to provide oral or written communication to the Board concerning the alleged violation or the appropriate penalty. Likewise, the patient/legal representative in the case who was not the "complainant" may request that the Board allow them the same opportunity to provide such written or oral communication. The Board has granted such requests. If you have any questions concerning this matter, please contact the Department's Prosecution Services Unit prior to the meeting at (850)245-4640. Please reference the above case number when calling.

All final disciplinary actions of the Board are reflected in written orders which are available on the Department's website at: www.flhealthsource.com. Please allow 30-60 days after the board meeting for the posting of these orders.

Sincerely,

for Tammy Collins
Executive Director
Board of Pharmacy

Florida Department of Health
Division of Medical Quality Assurance
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3260
PHONE: (850) 245-4444 • FAX : (850) 245-4791

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Kristal Beharry, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Praveen Ananthula, R.PH.
DOH Case Number 2012-12301
DATE: December 5, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Praveen Ananthula, R.PH.
Subject's Address of Record:	11413 Wakeworth Street Orlando, FL 32836
Enforcement Address:	3952 Township Square Blvd., Apt 1212 Orlando, FL 32837
Additional Address:	3800 Township Square Blvd., Apt 511 Orlando, FL 32837
Subject's License No:	42006 **Rank:** PS
Licensure File No:	33661
Initial Licensure Date:	12/29/2006
Board Certification:	None
Required to Appear:	Yes
Current IPN/PRN Contract:	No
Allegation(s):	Section 465.016(1)(g), F.S. (2012)
Prior Discipline:	None
Probable Cause Panel:	October 24, 2013 Fallon & Glass
Subject's Attorney:	Christopher Brown, Esq. The Health Law Firm 1101 Douglas Avenue Altamonte Springs, FL 32714
Complainant/Address:	G.M.

Materials Submitted:

Memorandum to the Board
Settlement Agreement
Exhibit A - Administrative Complaint
Board Notification Letter
Election of Rights
Cost Summary Report
PCP Memo
456 materials
456 Request
Letters/response
Confidentiality Agreement (signed)
Final Investigative Report with Exhibits 1 - 11

GUIDELINES:
Section 465.016(1)(g), F.S. – **$250 fine and completion of approved CE course in the prevention of medication errors of no less than (8) hours <u>up to</u> Revocation**

<u>PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT</u>

This is a one count administrative complaint alleging that Respondent violated Section 465.016(1)(g), Florida Statutes (2012), by furnishing upon prescription an ingredient or article different in any manner from the ingredient or article prescribed.

At all times material to the Administrative Complaint, Respondent was the prescription department manager of record of CVS Pharmacy Store #7973, located in Kissimmee, Florida. On or about August 4, 2011, a prescription for Prinzide 20-25 mg was ordered for Patient G.M. On or about November 11, 2011, and/or March 3, 2012, Respondent dispensed Lisinopril-HCTZ 20-12.5 mg to Patient G.M.

Terms of Settlement:
-Appearance at Board meeting required
-Administrative fine of $1,000
-Costs not to exceed $2,600
-CE in Prevention of Medical Errors (8 hour course)

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-12301**

PRAVEEN ANANTHULA, R.PH.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, PRAVEEN ANANTHULA, R.PH., was a licensed pharmacist in the state of Florida, having been issued license number PS 42006. Respondent's mailing address of record is 3800 Township Square Boulevard, Apartment 511, Orlando, Florida 32837.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **ONE THOUSAND DOLLARS ($1,000).** The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-**

6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND SIX HUNDRED DOLLARS ($2,600.00).** Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

4. **CE Course-** Respondent shall successfully complete a Continuing Education Course on the subject of PREVENTION OF MEDICAL ERRORS consisting of eight (8) hours of credit, which has approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. These continuing education hours shall be in addition to the hours required for license renewal. Within ten (10) days of completion of the course and/or receipt of

the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

5. **Future Conduct** - Respondent shall not violate Chapter 456, 465, 499, or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms** - It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order** - It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement** - This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent

authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings** - Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs** - Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights** - Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses** - Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

13. **Time of the Essence** - Time is of the essence in all respects concerning this agreement.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 12TH day of NOVEMBER, 2013

PRAVEEN ANANTHULA, R.PH.
CASE NO. 2012-12301

STATE OF FLORIDA

COUNTY OF ORANGE

Before me personally appeared PRAVEEN ANANTHULA, whose identity is known to me or by FDL. (type of identification), and who, under oath, acknowledges that his/her signature appears above.

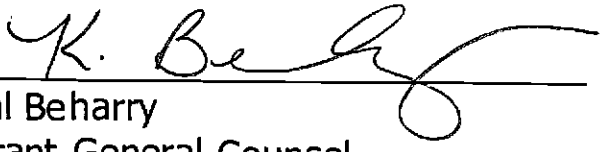
Sworn to and subscribed before me this 12TH day of NOVEMBER, 2013.

MICHAEL J. GLANZMANN
Notary Public, State of Florida
Commission# EE 170895
My comm. expires Feb. 19, 2016

Notary Public
My Commission Expires: FEB 19, 2016

APPROVED this 18th day of December, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health



Kristal Beharry
Assistant General Counsel

Counsel for Petitioner
Kristal Beharry
Florida Bar No. 0078070
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 245-4444
Fax: (850) 245-4683
Email: Kristal.Beharry@flhealth.gov

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-12301**

PRAVEEN ANANTHULA, R.PH.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Praveen Ananthula, R.Ph., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the State of Florida, having been issued license number PS 42006.

EXHIBIT
A

3. Respondent's address of record is 3800 Township Square Boulevard, Apartment 511, Orlando, Florida 32837.

4. At all times material to this Administrative Complaint, Respondent was the prescription department manager ("PDM") of record of CVS Pharmacy Store #7973, a community pharmacy located in Kissimmee, Florida.

5. On or about August 4, 2011, a prescription for Prinzide 20-25 mg was ordered for Patient G.M.

6. On or about November 11, 2011, and/or March 3, 2012, Respondent dispensed Lisinopril-HCTZ 20-12.5 mg to Patient G.M.

7. Section 465.016(1)(g), Florida Statutes (2011), provides that using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed constitutes grounds for disciplinary action by the Board of Pharmacy.

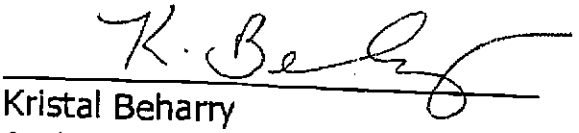
8. As set forth above, Respondent furnished upon prescription an ingredient or article different from the ingredient or article prescribed by furnishing Lisinopril-HCTZ 20-12.5 mg to Patient G.M., instead of the prescribed Prinzide 20-25 mg.

9. Based on the foregoing, Respondent has violated Section 465.016(1)(g), Florida Statutes (2012), by furnishing upon prescription an ingredient or article different in any manner from the ingredient or article prescribed.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 24th **day of** October**, 2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health



Kristal Beharry
Assistant General Counsel
Fla. Bar No. 0078070
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: Kristal_Beharry@doh.state.fl.us

/KB

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE OCT 2 4 2013

PCP: 10/24/13
PCP Members: Glass & Fallon

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

December 18, 2013

Christopher Brown, J.D.
The Health Law Firm
1101 Douglas Avenue
Altamonte Springs, FL 32714

Re: DOH vs. Praveen Ananthula, R.PH.
DOH Case Number: 2012-12301

Dear Mr. Brown:

I am in receipt of the settlement agreement executed by your client on November 12, 2013 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next regularly scheduled meeting of the Florida Board of Pharmacy. You will receive official notification from the Board of the date and time your client's case is set for hearing approximately two weeks prior to the date of the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

K. Beharry

Kristal Beharry
Assistant General Counsel

KB/cmn

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Complaint Cost Summary

Complaint Number: 201212301

Subject's Name: ANANTHULA, PRAVEEN

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.80	$46.10
Investigation:	17.90	$1,121.54
Legal:	4.80	$506.28
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	23.50	$1,673.92
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,673.92

MEMORANDUM OF FINDING OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy
RE: **DOH v. Praveen Ananthula, R.Ph.**
DOH Case Number 2012-12301

MEMBERS: Leo J. "Lee" Fallon, BPharm, Ph.D and Glass

DATE OF PCP: **October 24, 2013** **AGENDA ITEM: A1**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative report, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1) (g), Florida Statutes (2012)

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **Other** _____

Linda Glass RPh 10/24/13
Chair, Probable Cause Panel Date
Board of Pharmacy

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

January 15, 2013

Christopher Brown, Esq.
The Health Law Firm
1101 Douglas Avenue
Altamonte Springs, FL 32714

Certified Article Number
7196 9008 9111 4171 4711
SENDERS RECORD

Re: Complaint Name: Praveen Ananthula, R.PH.
Complaint Number: 2012-12301

Dear Mr. Brown:

Pursuant to section 456.073(10), Florida Statutes, enclosed is a copy of the Department's complete investigative file in this matter. Section 456.073(10), Florida Statutes provides in part:

> . . . Upon completion of the investigation and a recommendation by the department to find probable cause, and pursuant to a written request by the subject or the subject's attorney, the department shall provide the subject an opportunity to inspect the investigative file or, at the subject's expense, forward to the subject a copy of the investigative file. Notwithstanding s. 456.057, the subject may inspect or receive a copy of any expert witness report or patient record connected with the investigation if the subject agrees in writing to maintain the confidentiality of any information received under this subsection until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to s. 456.057. The subject may file a written response to the information contained in the investigative file. Such response must be filed within 20 days of mailing by the department, unless an extension of time has been granted by the department. . . .

Also enclosed is an invoice for copying charges. Please send a copy of the invoice, along with payment, to the Department of Health, Finance and Accounting, 4052 Bald Cypress Way, B-01.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

Finally, when opening your disc you will be prompted to enter a password. The password to be entered is: 456.
If you have any questions, please call me at (850) 245-4640.

Respectfully,

Kristal Beharry
Assistant General Counsel

KB/tr

Enclosures: Investigative File #: 2012-12301
Invoice #: MQPR13-358

Prosecution Services Unit
4052 Bald Cypress Way, Bin C65 • Tallahassee, Florida 32399-3265
Phone: (850) 245-4640 • Fax: (850) 245-4683• https://www.floridashealth.com

PROSECUTION SERVICES UNIT
4052 BALD CYPRESS WAY, BIN # C65
TALLAHASSEE FLORIDA 32399-3265

PHONE: (850) 245-4640

TO The Health Law Firm
1101 Douglas Avenue
Altamointe Springs Florida 32714

INVOICE NUMBER MQPR13-358

DATE January 9, 2013

SERVICES RENDERED

		AMOUNT
(copy) ___	Pages @$.15 Per Page	$
___	Pages @$.75 Per Page (Color Copied)	$
1	CD @ $8.00 Each	$ 8.00
	Charge to Certify Above Copies	$
	X-Ray Duplication Charge:	$
	Research Charge (if over one half hour) At $__per hour x __hours	$
	Postage & Handling Fees:	$
	TOTAL AMOUNT DUE UPON RECEIPT	$ 8.00

Payment Options: Cashier Check or Money Order made payable to:

Florida DOH, Division of MQA

Please reference the INVOICE NUMBER on your Payment—Mail to the above address.

Organization Code: 64-22-10-01-022

Expense Code: 497000

EO Code: PA

Profession: Pharmacy

Case Name: Praveen Ananthula

Case Number: 2012-12301

2. Article Number

7196 9008 9111 4171 4711

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly) Rebecca Horn

B. Date of Delivery 1/19/13

C. Signature

x Rebecca Horn

☐ Agent
☐ Addressee

D. Is delivery address different from item 1?
If YES, enter delivery address below:

☐ Yes
☐ No

3. Service Type **CERTIFIED MAIL™**

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Christopher Brown, Esq.
The Health Law Firm
1101 Douglas Ave
Altamonte Springs, FL 32714

2013 JAN 30 AM 8:

Behary
12-12301

PS Form 3811, January 2005 Domestic Return Receipt

May 9, 2013

Certified Article Number
7196 9008 9111 8827 4070
SENDERS RECORD

Christopher E. Brown, Esq.
The Health Law Firm
1101 Douglas Avenue
Altamonte Springs, FL 32714

Re: Complaint No. 2012-12301
DOH v. Praveen Ananthula, R.Ph.

Dear Mr. Brown:

I have enclosed an updated copy of the investigative file for your review. The updated disk includes all additional materials received after you were initially provided a copy of the above referenced case file.

Pursuant to section 456.073(10), Florida Statutes, enclosed is a copy of the Department's complete investigative file in this matter. Section 456.073(10), Florida Statutes provides in part:

> . . . Upon completion of the investigation and a recommendation by the department to find probable cause, and pursuant to a written request by the subject or the subject's attorney, the department shall provide the subject an opportunity to inspect the investigative file or, at the subject's expense, forward to the subject a copy of the investigative file. Notwithstanding s. 456.057, the subject may inspect or receive a copy of any expert witness report or patient record connected with the investigation if the subject agrees in writing to maintain the confidentiality of any information received under this subsection until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to s. 456.057. The subject may file a written response to the information contained in the investigative file. Such response must be filed within 20 days of mailing by the department, unless an extension of time has been granted by the department. . . .

Finally, when opening your disc you will be prompted to enter a password. The password to be entered is: **456**.

If you have any questions, please call me at (850) 245-4444 extension 8218.

Respectfully,

K. Beharry

Kristal Beharry
Assistant General Counsel

KB/cmn

Enclosures: Investigative File # 2012-12301

7196 9008 9111 8827 4070

TO:

456 Disk Additional Material
Cassandra/Beharry
Date Mailed 5/8/2013
2012-12301

SENDER:

REFERENCE:

PS Form 3800, January 2005

RETURN RECEIPT SERVICE		
	Postage	
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

USPS®
Receipt for Certified Mail™
No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

2. Article Number

7196 9008 9111 8827 4070

3. Service Type CERTIFIED MAIL™

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Christopher E. Brown, J.D.
The Health Law Firm
1101 Douglas Avenue
Altamonte Springs, FL 32714
Tampa, FL 33612

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly) Rebecca Horn

B. Date of Delivery 5/11/13

C. Signature

x Rebecca Horn ☐ Agent ☐ Addressee

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

Reference Information

456 Disk Additional Material 2012-12301
Cassandra/Beharry

Anarithula
PA 88

PS Form 3811, January 2005 Domestic Return Receipt

BRANCH OFFICE
37 N. ORANGE AVENUE, SUITE 500
ORLANDO, FLORIDA 32801

BRANCH OFFICE
201 E. GOVERNMENT STREET
PENSACOLA, FLORIDA 32501
TELEPHONE: (850) 439-1001

BRANCH OFFICE
155 E. BOARDWALK DRIVE, SUITE 424
FORT COLLINS, COLORADO 80525
TELEPHONE: (970) 416-7456
TELEFAX: (866) 203-1464

THE HEALTH LAW FIRM®
"THE PHYSICIAN'S ADVOCATES"
RESPOND ONLY TO MAIN OFFICE:
1101 DOUGLAS AVENUE
ALTAMONTE SPRINGS, FLORIDA 32714
TELEPHONE: (407) 331-6620
TELEFAX: (407) 331-3030
WWW.THEHEALTHLAWFIRM.COM

GEORGE F. INDEST III, J.D., M.P.A., LL.M.
FLA., LA. AND D.C.
BOARD CERTIFIED BY THE FLORIDA BAR IN HEALTH LAW

MICHAEL L. SMITH, J.D.
FLA.
REGISTERED RESPIRATORY THERAPIST
BOARD CERTIFIED BY THE FLORIDA BAR IN HEALTH LAW

JOANNE KENNA, R.N., J.D.
FLA.
REGISTERED NURSE (ILL.)

CAROLE C. SCHRIEFER, R.N., J.D.
FLA. AND COLO.
REGISTERED NURSE (COLO.)

CHRISTOPHER E. BROWN, J.D.
FLA.

LANCE D. LEIDER, J.D.
FLA.

MATTHEW R. GROSS, J.D., P.A.
FLA.
(OF COUNSEL)

April 29, 2013

CONFIDENTIAL

Kristal Beharry, Esquire
Assistant General Counsel
Department of Health
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399

Re: Department of Health vs. Praveen Ananthula, R.Ph.
DOH Complaint No. 2012-12301
Our File No.: 1508/001
REQUEST FOR COPY OF SUPPLEMENTAL DOH INVESTIGATION FILE

Dear Ms. Beharry:

We have been advised that the above-referenced matter is again under investigation.

In accordance with Chapter 456, Florida Statutes, and the applicable Florida Administrative Code (F.A.C.) rules, we are specifically requesting a copy of any supplemental investigation of this matter. The copy of the supplemental file should include, but not be limited to any additional: medical records, summaries of interviews with witnesses, witness statements, receipts, investigator's notes, internal correspondence and memoranda, all notes, expert reviews, external correspondence sent or received, and anything and everything else that may be included in the file. We will, of course, agree to keep the matters contained therein confidential as required by law.

A release/authorization form executed by our client authorizing us to receive information and documents from the Department of Health on this matter is attached. We are also enclosing a DOH Acknowledgment of and Agreement to Maintain Patient Confidentiality signed by our client.

THE HEALTH LAW FIRM IS CERTIFIED AS A SERVICE-DISABLED VETERAN OWNED BUSINESS AND A CERTIFIED BUSINESS ENTERPRISE BY THE FLORIDA OFFICE OF SUPPLIER DIVERSITY.
THE HEALTH LAW FIRM IS CERTIFIED AS A SERVICE-DISABLED VETERAN OWNED SMALL BUSINESS BY THE U.S. DEPARTMENT OF VETERANS AFFAIRS.

It is our client's intention to exercise his statutory right to receive and review a copy of the supplemental investigation report and file in this matter before it is forwarded to the Probable Cause Panel.

In addition, our client may desire, after he reviews the supplemental investigation to provide additional documents and information, if considered necessary, before this matter is considered by the Probable Cause Panel. This is his right under Florida law. He desires to exercise his right.

After we have had an opportunity to consult with our client and review his documents, we will decide whether or not he will submit a supplemental written response to you for inclusion in the investigation.

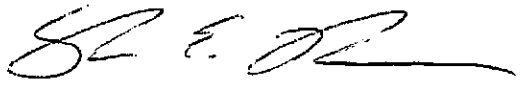
Again, since you are now aware that the health care provider is represented by counsel, please do not attempt to contact or communicate with the health care provider or any of his employees except through this firm.

Should you desire to discuss this matter further, you may reach me at the numbers indicated above. If I am not available, please feel free to speak with George F. Indest III, Esquire, another attorney with this firm, who is also familiar with this case.

Thank you very much for your cooperation in this matter.

Sincerely,

THE HEALTH LAW FIRM, by:



CHRISTOPHER E. BROWN

encls: (1) DOH Agreement to Maintain Confidentiality
(2) Release and Authorization

cc: Praveen Ananthula, R.Ph. (w/out encl)
CEB/ceb S:\1500-1599\1508\001\310-Letters-Drafts\DOH-Beharry-5.wpd

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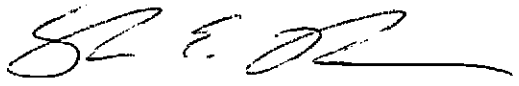
Sincerely,

THE HEALTH LAW FIRM, by:



CHRISTOPHER E. BROWN

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(2) Release and Authorization

cc: Praveen Ananthula, R.Ph. (w/out encl)
CEB/ceb S:\1500-1599\1508\001\310-Letters-Drafts\DOH-Beharry-5.wpd

Acknowledgment of and
Agreement to Maintain Patient Confidentiality

I, Praveen Ananthula, am the Subject of an investigation by the Department of Health. As the Subject of such an investigation, I am entitled to inspect or receive a copy of the investigative report, including any expert witness report or patient records connected with the investigation pursuant to Section 456.073(10), Florida Statutes, if I agree in writing to maintain the confidentiality of any information received under this provision, until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to section 456.057, F.S. I was provided with a copy of section 456.072, F.S. and understand my duty to maintain the confidentiality of patient's records that I received and or inspected.

I understand the cost associated with duplicating x-rays and ~~I want ( )~~ do not want (X) to receive a copy of any x-rays that are contained within the investigative file.

SIGNED this 3rd day of September, 2012

Printed Name: Praveen Ananthula.

Before me personally appeared Praveen Ananthula whose identity is known to be by Florida Drivers License (type of identification), and who under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed by Respondent before me this 3rd day of September, 2012.

Notary Public

GEORGE F. INDEST III
Commission # EE 076324
Expires June 23, 2015
Bonded Thru Troy Fain Insurance 800-385-7019

My Commission Expires:

AUTHORIZATION TO REPRESENT AND FOR RELEASE OF DOCUMENTS AND INFORMATION

TO: **Records Custodian of the Department of Health (and any of its professional boards) and the State of Florida, or any of its agencies**

I HEREBY REQUEST and authorize you to disclose to my legal counsel:

George F. Indest III
The Health Law Firm
1101 Douglas Avenue
Altamonte Springs, Florida 32714
(or any other member/employee of this firm)

Any and all files on me including but not limited to the following:

- Licensure Files (including applications),
- Reports, Complaints or Investigations,
- Probable Cause Panel file and transcript, if any,
- Any and all other files or documents of any kind you may have on me,
- Any correspondence, memos or documents concerning the above.

THIS AUTHORIZATION also applies to the release of any and all records of any kind that my counsel may request on my behalf. I hereby expressly consent to the release of any Psychiatric/Mental Health Records, HIV/AIDS testing records, and Drug/Alcohol/Substance Abuse treatment or counseling records. I hereby expressly waive any privacy rights or any objection to the release of the information or documents described above that I may have pursuant to state or federal laws including but not limited to the Federal Privacy Act, The Buckley Amendment (Privacy in Education Act), Florida Public Records Act, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, or any other law for the sole and limited purpose of allowing my counsel to receive a copy of my records.

I authorize you to freely discuss this matter with my attorneys indicated above.

A photostatic or telefax copy of this Authorization for the Release of Documents and Information shall be considered as effective and valid as the original.

Signature: x _____ / 09/03/2012
(Signature) / date

Name (print): PRAVEEN ANANTHULA

Soc. Sec. No.: _____ Date of Birth: _____

CONFIDENTIAL

THE HEALTH LAW FIRM®
1101 DOUGLAS AVENUE
ALTAMONTE SPRINGS, FLORIDA 32714

ORLANDO FL 328

CONFIDENTIAL

Kristal Beharry, Esquire
Assistant General Counsel
Department of Health
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399

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32399701752

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area VI Tampa	Date of Case: 08/21/2012	Case Number: 2012-12301

Subject: **PRAVEEN ANANTHULA, PS** 3952 Township Square Blvd. Apt #1212 Orlando, FL 32837 386-496-1994	Source: **G.M.**

Prefix: PS	License #: 42006	Profession: Pharmacist	Board: Pharmacy	Report Date: 10/04/2012

Period of Investigation: 08/29/12 through 10/04/12	Type of Report: FINAL

Alleged Violation: F.S. 465.072(1)(dd), 465.016(1)(g)(i)(r), F.S.; Rules 64B16-27.1001(1)(c)(3),) and 64B16-27.810(1)(d), F.A.C. Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy. Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed..., Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto...

Synopsis: This investigation is predicated upon receipt of a Case Summary (Exhibit #1) based upon a complaint from G.M. a 56 year old male patient. G.M. alleges that ANANTHULA a Pharmacy Manager at CVS Pharmacy Store #7973 located at 4500 Pleasant Hill Rd. Kissimmee, FL 34746 dispensed a misfilled prescription. On 11-11-11 and 03-03-12 ANANTHULA allegedly changed the dosage of G.M.'s prescription for Linsinopril-HCTZ from 20-25mg to 20-12.5mg. G.M. claims to have had numerous adverse reactions from the mistake.

ANANTHULA was notified of the investigation by letter (Exhibit #2) dated 08-29-12 to the address of record and was provided a copy of the case summary and original documents that initiated the complaint.

A check of DOH computer licensure records revealed ANANTHULA is currently licensed as a Pharmacist.

The patient notification letter was not necessary since the source is the patient in this case.

ANANTHULA is represented by Attorney GEORGE INDEST III, Esq., 1101 Douglas Ave. Altamonte Springs, FL 32714, 407-331-6620. INDEST sent a letter of representation dated 09/03/2012 (Exhibit #4). <u>INDEST also requests a copy of the completed investigative report.</u>

The source was notified via letter (Exhibit #3), dated 08-29-12.

As of the date of this report, there has been no statement from ANANTHULA /INDEST.

Related Case(s): 2012-12402

Investigator/Date: 10/04/12 Terrence Dawkins, TI-141 Investigation Specialist II	Approved By/Date: 10-04-12 Babette S. Agett, TI-115 Investigation Supervisor Babette S Agett

Distribution: HQ/ISU

RECEIVED-LEGAL
12 OCT -8 AM 10: 34

Received
Investigative Services
OCT 05 2012
DOH/MQA
Tallahassee HQ

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Interview of R.M. (Witness) 4
Interview of Attorney GEORGE INDEST, Legal Counsel for ANANTHULA (Source) 4

IV. EXHIBITS

* 1. Case Summary and attachments 5-16

* 2. Copy of subject notification letter and attachments, dated 08-29-12 17-30

* 3. Copy of source notification letter, dated 08-29-12 31

4. Letter of Representation from Attorney INDEST, dated 09-03-12 32-37

* 5. Copy of Subject Notification Letters and attachments sent to ANANTHULA's Attorney GEORGE INDEST III, dated 09-14-12 and 10-02-12 38-67

* 6. Copy of Letter Directed to the records custodian for PAMELA WARREN, MS, PA requesting patient G.M.'s original prescription 68

* 7. Copy of Prescriptions for G.M. from WARREN's office 69-72

* 8. Copy of Letter sent to CVS Corporate Privacy Office requesting G.M.'s Patient profile and internal incident documentation 73-75

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***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES**

INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit #1 is a copy of the case summary and attachments submitted by G.M.. The attachments include; a statement from G.M., a signed Patient Authorization for release of records and copies of CVS Pharmacy labels for G.M. were included showing the correctly and incorrectly dispensed medication dosages.

Exhibit #4 is a letter of representation for ANANTHULA from Attorney GEORGE INDEST III, dated 09-03-12. In the letter INDEST requests a copy of the completed investigative report. INDEST explains after the completed investigative report is reviewed with ANANTHULA it will be determined if they will submit a response or not.

Exhibit #7 is a copy of the original prescriptions issued by PAMELA WARREN, MS, PA at Dr. MONGELLUZZO's office, M.G.'s primary care physician in Waterbury, CT. There are three prescriptions dated 08-04-11, 12-27-11 & 06-01-12. The prescriptions are written for Prinzide (Linsinopril) 20-25mg tabs.

Exhibit #9 is a copy of G.M.'s Patient Prescription Record faxed by CVS's Pharmacy Privacy Office. The records include G.M.'s patient profile record for store# 7973 for November 2011 through February 2012. The record indicates prescriptions filled for G.M. on 11-11-11 and 03-03-12 was for Linsinopril-HCTZ 20-12.5MG tabs and not Prinzide (Linsinopril) 20-25MG tabs as prescribed by his physician.

Exhibit #10 is a copy of the last three Pharmacy Inspections completed by the Florida Department of Health. Inspections passed and were completed on: 04/22/2010, 09/24/2010 and 11/29/11.

Exhibit #11 is the Confidential Index.

Interview of G.M. (Source)

On 08-30-12, Investigator DAWKINS interviewed G.M. via telephone. G.M. advised he wished for his wife R.M. to be interviewed about this incident, that she could explain easier as to what his complaint was. G.M. advised she was a witness to the whole incident and was with him through every step of this process so far. G.M. stated he would be on the phone line and interject if he needed to add any other statements.

Interview of R.M. (Witness)

On 08-30-12, Investigator DAWKINS interviewed R.M. via telephone. R.M. stated that her husband G.M. was prescribed Linsinopril HCTZ 20-25MG for many years by his primary care doctor in Connecticut. R.M. stated during the month of November in 2011 she picked up her husband's medication as she had done many times in the past and this time it looked different, after asking the pharmacy if there was a change she was assured the medicine was fine and the pills might look different since they switched suppliers. R.M. stated around January of 2012 another

prescription was filled and again the pills looked different. R.M. noticed G.M. began to gain weight, had shortness of breath and swelling in his extremities. Around this time G.M. was contacted by his primary care physician and inquired why CVS was contacting them to obtain a new prescription for Linsinopril HCTZ 20-12.5MG because they had not changed the dosage nor did they want to. R.M. stated she was alarmed and checked the previous prescriptions G.M. had been receiving and was shocked to discover the last two fills were a different dosage. R.M. stated that after they went to another CVS location and received the correct dosage G.M. dropped 40lbs, swelling was reduced, and he no longer had trouble breathing. R.M. stated G.M. is still in possession of the leftover misfilled prescriptions. R.M. stated they had an initial incident with ANANTHULA and this CVS location dealing with the availability of a prescription prior to this incident with the misfill, to which she stated they were told not to speak of and were asked to sign a confidentiality agreement and paid an undisclosed amount of money from CVS corporate. R.M. also added she has been contacted by CVS Corporate Risk Manager Deborah Rodriguez this time regarding this current incident but R.M. refuses to speak with her and won't take an offered settlement. R.M. refused to give any more details or circumstances regarding the first incident with CVS. R.M. stated she and her husband really would like to see this particular pharmacy loose their license along with any pharmacist working at this location.

Investigator's Note: An attempt was made to contact Risk Manager Deborah Rodriguez at CVS Corporate for comment; however the risk management office declined to comment and referred all questions to the CVS Corporate Attorney EDWIN BAYO. EDWIN BAYO is not representing ANANTHULA and directed questions to Attorney INDEST.

Interview of Attorney GEORGE INDEST III (Source/Counsel)
1101 Douglas Ave.
Altamonte Springs, FL 32714
407-331-6620

On 10-02-12, Investigator DAWKINS made contact with INDEST via telephone. INDEST stated he was fully aware of the complaint against his client and he would possibly submit a statement pending the completion and review of this initial investigation. INDEST stated he was unaware of any other incidents involving his client ANANTHULA and G.M. or R.M. but he would do some checking and figure out if he could find out what they were referencing too. This is all INDEST had to state at this time.

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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INSPECTION#_____

ROUTINE ☐ CHANGE LOC ☐ NEW ☑ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

INSPECTION AUTHORITY – CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT	PERMIT NUMBER	EXPIRATION DATE	DATE OF INSPECTION
Holiday CVS, LLC	Not. Appli.	Not Appli.	4-22-2010

DOING BUSINESS AS	TELEPHONE NUMBER	EXTENSION
CVS Pharmacy 7973	407-944-9030	

STREET ADDRESS	CITY	COUNTY	STATE	ZIP
4500 Pleasant Hill Road	Kissimmee	Osceola	FL	34746

DEA NUMBER	EXPIRATION DATE
Pending	

PRESCRIPTION DEPARTMENT MANAGER NAME	PDM NOTIFICATION DATE	LICENSE NUMBER	
Praveen Ananthula	3-26-2010	PS42006	9-30-2011
VENDOR WHOLESALER-PHARMACY	VENDOR LICENSE NUMBER		
CVS Orlando Distrib. Ctr			

REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE NUMBER	
1 N.A.	N.A.	N.A.
2 N.A.	N.A.	N.A.
3 N.A.	N.A.	N.A.

		SATISFACTORY	NA	YES	NO
1.	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.] 8-10 M-F 8-6 Sat 10-6 Sun			✓	
2.	Pharmacy technicians properly identified and supervised, approval date. [64B16-27.410, F.A.C.]			✓	
3.	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			✓	
4.	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035F.A.C.] [64B16-27.400(6), F.A.C.]* Coming in truck - will send photo				✓
5.	Written and verbal offer to counsel patients. [64B16-27.820(1), F.A.C.]			✓	
6.	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			✓	
7.	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			✓	
8.	Proper equipment and references as required. [64B16-28.102, F.A.C.]			✓	
9.	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			✓	
10.	CQI Policy and Procedures and quarterly meetings. [64B16-27.300, F.A.C. [766.101, F.S.]		✓		
11.	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1) (c) 6, F.S.] [64B16-28.140(3) (b), F.A.C.]			✓	
12.	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	✓			
13.	Controlled substance records readily retrievable. [893.07 (4)(B), F.S.]	✓			
14.	All controlled substance prescriptions contain information required. [893.04(1) (c), F.S.]	✓			
15.	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1) (g), F.S.] [64B16-28.114, F.A.C.]	✓			
16.	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1) (a), F.S.]	✓			
17.	DEA 222 order forms properly completed. [893.07(2), F.S.]	✓			
18.	Controlled substance Rx information in computer system is retrievable. [21CFR 1306.22] [893.07, F.S] [64B16-28.140, F.A.C.]*	✓			
19.	Controlled substance records maintained for 2 years. [21CFR 1304.04][21CFR 1306.22] [893.07(4) (b), F.S.]	✓			
20.	Certified daily log OR printout maintained as required by section. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	✓			
21.	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.] *	✓			
22.	Compounding records properly maintained. [64B16-27.700, F.A.C.] [64B16-28.140(4), F.A.C.]*	✓		✓	
23.	Unit dose records properly maintained. [465.016(1) (l), F.S.][64B16-28.118, F.A.C.] *	✓			
	** Questions with (*) may be answered n/a (not applicable)*				

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks:

REPORT EXHIBIT # 10

PAGES

I have read and have had this inspection report and the laws and regulations concerned explained, and the information given is true and correct to the best of my knowledge.

Signature of Pharmacist

Date 4/22/10

Diana S. Coumbe, RPh
Investigator/Sr. Pharmacist Signature/ID Number

CORY D KLINE PS35531
Print Name

OI 117

INV 359 Revised 06/09 05/07; 5/06, Replaces 12/02, 12/00

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0082

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
WWW.DOH.STATE.FL.US

FLORIDA DEPARTMENT OF HEALTH

COMMUNITY PHARMACY

FILE# 17424

INSPECTION# _____

ROUTINE ☒ CHANGE LOC ☐ NEW ☐ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

INSPECTION AUTHORITY – CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT: HOLLAAY CVS	PERMIT NUMBER: 24618	EXPIRATION DATE: 2/28/11	DATE OF INSPECTION: 9/24/10
DOING BUSINESS AS: CVS #2573	TELEPHONE NUMBER: 407-944-9030	EXTENSION:	
STREET ADDRESS: 4500 PLEASANT HILL rd.	CITY: KISSIMMEE	COUNTY: OSCEOLA	STATE: FL ZIP: 34746
DEA NUMBER: FH1952503			EXPIRATION DATE: 12-31-10
PRESCRIPTION DEPARTMENT MANAGER NAME: PRAVEEN ANANTHULA	PDM NOTIFICATION DATE:	LICENSE NUMBER: 42006	4-30-11
VENDOR WHOLESALER PHARMACY:	VENDOR LICENSE NUMBER:		
REGISTERED PHARMACIST/INTERN/TECHNICIAN 1: ANA CARDOA	LICENSE NUMBER: RPH 20176		12-31-12
2: ABDEL ARFAOUI	PJ 44425		9-30-11
3:			

	SATISFACTORY	NA	YES	NO
1. Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			✓	
2. Pharmacy technicians properly identified and supervised, approval date. [64B16-27.410, F.A.C.]			✓	
3. Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			✓	
4. Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035F.A.C.] [64B16-27.400(6), F.A.C.]*			✓	
5. Written and verbal offer to counsel patients. [64B16-27.820(1), F.A.C.]			✓	
6. Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			✓	
7. Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			✓	
8. Proper equipment and references as required. [64B16-28.102, F.A.C.]			✓	
9. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			✓	
10. CQI Policy and Procedures and quarterly meetings. [64B16-27.300, F.A.C. [766.101, F.S.]			✓	
11. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1) (c) 6, F.S.] [64B16-28.140(3) (b), F.A.C.]			✓	
12. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			✓	
13. Controlled substance records readily retrievable. [893.07 (4)(B), F.S.]			✓	
14. All controlled substance prescriptions contain information required. [893.04(1) (c), F.S.]			✓	
15. Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1) (g), F.S.] [64B16-28.114, F.A.C.]			✓	
16. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1) (a), F.S.]				
17. DEA 222 order forms properly completed. [893.07(2), F.S.]			✓	
18. Controlled substance Rx information in computer system is retrievable. [21CFR 1306.22] [893.07, F.S] [64B16-28.140, F.A.C.]*			✓	
19. Controlled substance records maintained for 2 years. [21CFR 1304.04][21CFR 1306.22] [893.07(4) (b), F.S.]			✓	
20. Certified daily log OR printout maintained as required by section. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			✓	
21. Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.] *			✓	
22. Compounding records properly maintained. [64B16-27.700, F.A.C.] [64B16-28.140(4), F.A.C.]*		✓		
23. Unit dose records properly maintained. [465.016(1) (l), F.S.][64B16-28.118, F.A.C.] *		✓		
** Questions with (*) may be answered n/a (not applicable)*				

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: _____

I have read and have had this inspection report and the laws and regulations concerned explained, and the information given is true and correct to the best of my knowledge.

Signature of Pharmacist: [signature] Date: 9/24/10 Investigator/Sr. Pharmacist Signature/ID Number: [signature] OF-111

Print Name: [signature]

INV 359 Revised 06/09 05/07, 5/08, Replaces 12/02, 12/00

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

File # 17424
Insp # 103181

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT: HOLIDAY CVS	PERMIT NUMBER: 24618	DATE OF INSPECTION: 11/29/11
DOING BUSINESS AS: CVS #7973	DEA NUMBER: 407-944-8030	PRESCRIPTION DEPARTMENT MANAGER: PRAVEEN ANANJHULA
STREET ADDRESS: 4500 PLEASANT HILL Rd	TELEPHONE #:	EXT.:
CITY: KISSIMMEE / COUNTY: OSCEOLA	STATE/ZIP: FLA 34746	PRESCRIPTION DEPARTMENT MANAGER LICENSE #: 4006

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8:00	8:00	8:00	8:00	8:00	8:00	10:00
Close	10:00	10:00	10:00	10:00	10:00	6:00	6:00

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. MAX BEAUVOIR — PS 47601
2. LUIS TORRES — RPT-23536
3. STEPHANIE RAMOS — RPT-39128

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			✓	
2	Pharmacy technicians properly identified and supervised. [64B16-27.410, F.A.C.]			✓	
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			✓	
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			✓	
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			✓	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			✓	
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			✓	
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			✓	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			✓	
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			✓	
11	COI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			✓	
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]			✓	
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) & F.S.] [64B16-28.140(3)(b), F.A.C.]			✓	
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			✓	
15	All controlled substance prescriptions contain information required. [893.04, F.S.]			✓	
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			✓	
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			✓	
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]			✓	
19	DEA 222 order forms properly completed. [893.07, F.S.]			✓	
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			✓	
21	Controlled substance records maintained for 4 years. [456.022, F.S.]			✓	
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			✓	
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]			✓	
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.]			✓	
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]			✓	
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]	✓			
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]			✓	
28	Compounding records properly maintained. [64B16-27.797, F.A.C.]*	✓			
29	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]	✓			
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]	✓			

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT: MAX BEAUVOIR — Max Beauvoir

Max Beauvoir — Date 11/29/11 — Investigator/Sr. Pharmacist Signature

ID 02-14

Institutional Representative

INV 359 Revised 9/11, 10/10, 10/09, 5/08, 12/02, 12/00

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CONFIDENTIAL AND EXEMPT MATERIALS

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201218539

SERENITY PHARMACY, CORP,
RESPONDENT.

NOTICE

TO: SERENITY PHARMACY, CORP
23 SW 8TH AVENUE
MIAMI, FL 33130

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Serenity Pharmacy, Corp.
DOH Case Number 2012-18539
DATE: December 30, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Serenity Pharmacy, Corp.
Subject's Address of Record:	23 SW 8th Avenue Miami, FL 33130
Enforcement Address:	23 SW 8th Avenue Miami, FL 33130
Subject's License No:	26021 **Rank:** PH
Licensure File No:	19007
Initial Licensure Date:	3/22/2012
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No
Allegation:	Section 465.023(1)(c), F.S. (2012) by violating Section 499.005(18), F.S. (2012) by violating Rule 61N-1.012(1)(a), F.A.C.
Prior Discipline:	None
Probable Cause Panel:	June 20, 2013 Jeffrey J. Mesaros and Lorena Risch
Subject's Attorney:	Pro Se

Complainant/Address: DOH/ISU Miami

Materials Submitted: Memorandum to the Board
Settlement Agreement
Exhibit A – Administrative Complaint
Election of Rights
Notification Letter
Cost Summary
Defense Documents dated 11-07-13
PCP Memorandum
Final Investigative Report
Exhibits 1 thru 9

GUIDELINES: No Guideline

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

On or about December 7, 2012 and on or about December 10, 2012, the Department inspector found the prescription department to be closed during posted business hours.

As part of a January 31, 2013 inspection, the Department inspector also conducted an audit of the legend drugs Lidoderm patches and Advair 250/50.

From on or about January 15, 2013 through on or about January 30, 2013, Respondent could not provide documentation to account for receipt of six boxes of Lidoderm Patches and three boxes of Advair 250/50.

Terms of Settlement:

- Appearance
- $5,000 Fine
- Costs limited to $2,500
- Probation – One year
- Eight hour continuing education course in the prevention of medication errors.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-18539**

SERENITY PHARMACY CORP.,

RESPONDENT.

2013 SEP 10 PM 12:03
PRACTITIONER REGULATION
LEGAL

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Serenity Pharmacy Corp., was a licensed pharmacy in the state of Florida, having been issued license number PH 26021. Respondent's mailing address of record is 23 S.W. 8th Avenue, Miami, Florida 33130.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

5000.00

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **FIVE THOUSAND FIVE DOLLARS ($5,000).** The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs-** The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND FIVE HUNDRED DOLLARS ($2,500).** Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

4. **Probation-** Respondent shall be placed on **1** year of probation. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. The Department shall conduct semi-annual inspections to ensure compliance with the laws and rules at Respondent's physical location at Respondent's cost.

b. Respondent shall make a mandatory appearance before the Board of Pharmacy during the last three (3) months of probation.

5. **Correction of Alleged Deficiencies** - At its sole expense, but without admitting any specific deficiency or violation, Respondent shall immediately, or at least forthwith, correct and address all deficiencies and violations listed or alleged in the Administrative Complaint, to the extent necessary to comply with Florida law.

6. **Future Conduct** - Respondent shall not violate Chapter 456, 465, 499, or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

7. **Violation of Terms** - It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

8. **No Force or Effect until Final Order** - It is expressly understood that this Settlement Agreement is subject to approval by the

Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

9. **Purpose of Agreement** - This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

10. **Not Preclude Additional Proceedings** - Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional

proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

11. **Waiver of Attorney's Fees and Costs** - Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

12. **Waiver of Procedural Rights** - Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

13. **Current Addresses** - Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

14. **Time of the Essence** - Time is of the essence in all respects concerning this agreement.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-18539**

SERENITY PHARMACY CORP.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Serenity Pharmacy Corp., was a licensed pharmacy in the state of Florida, having been issued license number PH 26021. Respondent's mailing address of record is 23 S.W. 8th Avenue, Miami, Florida 33130.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

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PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **FIVE THOUSAND FIVE DOLLARS ($5,000).** The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs-** The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND FIVE HUNDRED DOLLARS ($2,500).** Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

4. **Probation-** Respondent shall be placed on **1** year of probation. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. The Department shall conduct semi-annual inspections to ensure compliance with the laws and rules at Respondent's physical location at Respondent's cost.

b. Respondent shall make a mandatory appearance before the Board of Pharmacy during the last three (3) months of probation.

5. **Correction of Alleged Deficiencies** - At its sole expense, but without admitting any specific deficiency or violation, Respondent shall immediately, or at least forthwith, correct and address all deficiencies and violations listed or alleged in the Administrative Complaint, to the extent necessary to comply with Florida law.

6. **Future Conduct** - Respondent shall not violate Chapter 456, 465, 499, or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

7. **Violation of Terms** - It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

8. **No Force or Effect until Final Order** - It is expressly understood that this Settlement Agreement is subject to approval by the

Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

9. **Purpose of Agreement** - This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

10. **Not Preclude Additional Proceedings** - Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional

proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

11. **Waiver of Attorney's Fees and Costs** - Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

12. **Waiver of Procedural Rights** - Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

13. **Current Addresses** - Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

14. **Time of the Essence** - Time is of the essence in all respects concerning this agreement.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 6 day of Sept, 2013

Serenity Pharmacy Corp.
CASE NO. 2012-18539

STATE OF Florida

COUNTY OF Dade

Before me personally appeared LETICIA MORO, whose identity is known to me or by Florida Driver License - (type of identification), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 6TH day of September, 2013.

Notary Public
My Commission Expires:

BEATRIZ CARREON
MY COMMISSION # EE118933
EXPIRES November 06, 2015
(407) 398-0153 FloridaNotaryService.com

APPROVED this 30 day of December, 2013.

John H. Armstrong, MD
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel

Counsel for Petitioner
Matthew G. Witters
Florida Bar No. 0091245
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 245-4444
Fax: (850) 245-4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-18539**

SERENITY PHARMACY CORP.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Serenity Pharmacy Corp., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a permitted community pharmacy within the state of Florida, having been issued permit number PH 26021.

EXHIBIT A

3. Respondent's address of record is 23 S.W. 8th Avenue, Miami, Florida 33130.

4. On or about December 7, 2012 and on or about December 10, 2012, a Department inspector attempted to conduct an inspection of Respondent at 23 S.W. 8th Avenue, Miami, Florida 33130.

5. On or about December 7, 2012 and on or about December 10, 2012, the Department inspector found the prescription department to be closed during posted business hours.

6. On or about January 31, 2013, the Department inspector conducted a routine inspection of Respondent.

7. As part of January 31, 2013 inspection, the Department inspector also conducted an audit of the legend drugs Lidoderm patches and Advair 250/50.

8. Lidoderm patches are a local anesthetic. It works by stopping nerves from transmitting painful impulses to the brain.

9. Advair is used to control and prevent symptoms (wheezing and shortness of breath) caused by asthma or ongoing lung disease (such as COPD). It contains 2 medications: fluticasone and salmeterol. Fluticasone belongs to a class of drugs known as corticosteroids. It works by reducing

the irritation and swelling of the airways. Salmeterol belongs to the class of drugs known as long-acting beta agonists. It works by opening airways in the lungs to make breathing easier.

10. According to Respondent's purchasing records, to include invoices and receipts, from on or about January 17, 2013 through on or about January 25, 2013, Respondent purchased the following quantities of Lidoderm and Advair:

Drug	Total Quantity Purchased
Lidoderm	4 Boxes
Advair 250/50	3 Boxes

11. According to Respondent's dispensing records, from on or about January 15, 2013 through on or about January 30, 2013, Respondent dispensed the following quantities of Lidoderm and Advair 250/50:

Drug	Total Quantity Dispensed
Lidoderm	10 Boxes
Advair 250/50	6 Boxes

16. As set forth in paragraphs twelve (12), Respondent cannot provide documentation to account for receipt of six (6) boxes of Lidoderm Patches and three (3) boxes of Advair 250/50.

17. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating Section 499.005(18), Florida Statutes (2012), by violating Rule 61N-1.012(1)(a), Florida Administrative Code, which requires that records to document the movement of drugs, devices or cosmetics must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 20 day of June, 2013.

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel
Fla. Bar No. 0091245
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: matthew_witters@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE JUN 20 2013

PCP: June 20, 2013
PCP Members: Mesaros and Risch

CONFIDENTIAL AND EXEMPT MATERIALS

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

December 30, 2013

VIA US MAIL

Serenity Pharmacy, Corp.
23 S.W. 8th Avenue
Miami, Florida 33130

Re: DOH vs. Serenity Pharmacy, Corp.
DOH Case Number: 2012-18539

Dear Serenity Pharmacy, Corp.:

I am in receipt of the settlement agreement executed by you on September 6, 2013 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for February 12, 2014 in Orlando, Florida. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office at 850-245-4444, ext. 8172.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

cc: file

Complaint Cost Summary

Complaint Number: 201218539

Subject's Name: SERENITY PHARMACY, CORP

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.60	$32.94
Investigation:	25.90	$1,657.09
Legal:	11.70	$1,242.67
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	38.20	$2,932.70
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$2,932.70

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MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Serenity Pharmacy Corp., (MGW)**
Case Number: 2012-18539

MEMBERS: **Gavin Meshad ~~and Michele~~ Weizer** Mesaros / Risch

DATE OF PCP: **June 20, 2013** **AGENDA ITEM: A-05**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(c), Florida Statutes (2012), by violating Section 499.005(18), Florida Statutes (2012), by violating Rule 61N-1.012(1)(a), Florida Administrative Code;

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss

___ **other**:

2013 JUN -5 PM 2:23

6/20/13

Chair, Probable Cause Panel
~~Board of Pharm~~acy

Date

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Received
Investigative Services
FEB 11 2013
DOH/MQA
Tallahassee HQ

Office: Miami XI	Date of Case: 12/18/2012	Case Number: PH 2012-18539

Subject: **SERENITY PHARMACY CORP, (PH 26021)** 23 SW 8th Avenue Miami, FL 33130 (305) 325-1885 (W)	Source: **DOH/INVESTIGATIVE SERVICES UNIT-MIAMI**

Prefix:	License #:	Profession:	Board:	Report Date:
2205	26021	Pharmacy	Pharmacy	02/08/13

Period of Investigation: 12/21/12 – 02/08/13	Type of Report: FINAL

Alleged Violation of SS. 456.072 (1) (dd) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken: Violating any provision of this...; F.S. 465.016(1)(r) The following acts constitute grounds for denial of a license or disciplinary action...; Compounding, dispensing, or distributing a legend drug, including any controlled substance...; F.S. 465.023(1)(c) The department or the board may revoke or suspend the permit of any pharmacy...; Violated any of the requirements of this chapter or any of the rules...; F.A.C., 64B16.28.1081 Any person who receives a community pharmacy permit...; Pharmacy technicians may perform duties in addition to...;Rule 64B16-27.420 All registered pharmacy technicians shall identify themselves as registered pharmacy technicians by wearing a type of identification badge that is clearly visible...; Rule 64B16-28.109 The prescription department of any community pharmacy permittee shall be considered closed...;

Synopsis: This investigation is predicated upon receipt of an inspection in regards to SERENITY PHARMACY CORP (Case Summary and Initiating Documents Exhibit #1). A routine inspection was attempted on 12/07/12 at SERENITY PHARMACY CORP (PH 26021) a Community Pharmacy, located at 23 SW 8th Avenue, Miami, FL 33130. The pharmacy was closed with a note on the door informing there was an emergency. On 12/10/12 another routine inspection was attempted but the doors were locked to the public. The owner of the pharmacy stated she already got her DEA permit but they haven't bought any prescribed meds yet, because they are still waiting to get the insurance companies. It was clarified with the owner that a pharmacist must be there at all times when they buy prescribed medication. Since the pharmacy already had their Pharmacy and DEA permits, as result pharmacy must buy medication for any incoming patients and be open 40 hours a week.

SERENITY PHARMACY CORP was notified of the investigation by letter, dated 12/21/12 (Exhibit #2) and was provided a copy of the case summary and initiating documents from (Exhibit #1).

A search of the DOH licensure database reveals SERENITY PHARMACY CORP is currently licensed as a Community Pharmacy.

Patient(s) were identified, thus patient notification was not required.

SERENITY PHARMACY CORP is not currently represented by an attorney at this time.

On 01/09/13, this Investigator received a written response (via Certified Mail) from SERENITY PHARMACY CORP owner, LETICIA MORO. MORO neither admits nor denies the allegations (Exhibit #5).

Related Case(s): PS 2012-18537

Investigator/Date: February 8, 2013 Jeneice Mayers, Investigation Specialist II	Approved By/Date: February 8, 2013 Caridad Rodriguez, Investigator Supervisor

Distribution: HQ/ISU

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***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10) (a), FLORIDA STATUTES**

INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit 3: Contains the Florida Department of State Division of Corporations, listing LETICIA MORO as the Registered Agent/Director of SERENITY PHARMACY CORP
Status: Active

Exhibit 4: Contains a written response from PDM, ALLAN CAO dated 01/01/13 (including CV), received in the Miami Investigative Service Unit Office (via fax) on 01/07/13 and (via Certified Mail) on 01/09/13.

Exhibit 5: Contains a written response from pharmacy owner, LETICIA MORO dated 12/29/12, received in the Miami Investigative Service Unit office (via Certified Mail) on 01/02/13; which contains the following documentation:

- Photo of SERENITY PHARMACY CORP with a note on the door stating the reason they were closed
- MIAMI CHILDREN's HOSPITAL Emergency Department letter from SERENITY PHARMACY CORP owner, LETICIA MORO

Exhibit 6: Documentation that were obtained from SERENITY PHARMACY CORP on 01/31/13 by Inspector WARSHOFSKY, which contains the following:

- Change of SERENITY PHARMACY CORP Prescription Department Manager from ALLAN CAO to SILVIA RODRIGUEZ
- Delivery Sheet for patient PT date 01/23/13 & 01/25/13; patient RC date 01/30/13 & photos
- SERENITY PHARMACY CORP Delivery Sheet Invoice for date 01/23/13 & 01/30/13
- Drug Utilization Report (Detail) pulled from 10/01/12 to 01/31/13
- Drug Utilization Report (Summary) pulled from 10/01/12 to 01/31/13
- ANDA Invoice for order date 01/17/13 & order date 01/21/13
- The HARVARD DRUG GROUP Invoice; invoice date 01/17/13
- VERTICAL SOURCE Invoice; invoice date 01/25/13
- Audit done for Lidorderm & Advair patient script was pulled for those drugs filled

Exhibit 7: Contains documentation from SERENITY PHARMACY CORP owner, LETICIA MORO received in Miami Investigative Service Unit Office (via e-mail) on 02/04/13, which contains the following documents:

- Copy of SERENITY PHARMACY CORP Controlled Substance Fraud Policy and Procedure
- HD SMITH WHOLESALE DRUG Invoice; invoice date 02/03/13
- ANDA Invoice for order date 01/31/13

Exhibit 8: Contains copies of SERENITY PHARMACY CORP, Inspection Reports for the following dates:

- 03/16/12 – (Satisfactory) New Routine Inspection
- 12/12/12 – (Unsatisfactory) Routine Inspection
- 01/31/13 – (Unsatisfactory) Routine Re-Inspection

INTERVIEW OF SILVIA LEON, MIAMI ISU INSPECTOR – (Source)
DOH/MIAMI INVESTIGATIVE SERVICES
8350 NW 52nd Terrace, Ste 400
Miami, FL 33166
(305) 499-5895 (W)

On 01/28/13, this Investigator interviewed SILVIA LEON at the Miami ISU office. LEON reiterated the violations that specified within page two of the Healthcare Practitioner Form, LEON submitted to DOH/Consumer Services Unit (Exhibit #1).

INTERVIEW of SILVIA RODRIGUEZ, CURRENT PDM (LICENSE #36084) – (Witness)
Residential Address:
18517 NW 19 Street
Pembroke Pines, FL 33029
(305) 331-6490 (C)

On 01/31/13, this Investigator and Inspector, MALDONADO-CANATE presented to SERENITY PHARMACY CORP to conduct a re-inspection on the facility and conducted an interview with PDM, SILVIA RODRIGUEZ. RODRIGUEZ essentially stated the following: I became the PDM for SERENITY PHARMACY CORP on 01/14/13 (Exhibit #6 pg. 30). RODRIGUEZ also stated that she is aware that SERENITY PHARMACY CORP has investigations going on with DOH regarding allegations of possible violations that were cited on 12/07/12 & 12/10/12 (Exhibit #1 pg. 7). RODRIGUEZ also stated to this Investigator that SERENITY PHARMACY CORP just received approval by RX SOLUTION on 01/10/13 and that the pharmacy filled their first script on 01/11/13 (see Drug Utilization Report Exhibit #6 pp. 38-58).

INTERVIEW/STATEMENT OF ALLAN CAO, PDM – (Witness)
Residential Address:
12515 Palm Rd
North Miami, FL 33181
(786) 547-3240 (C)

On 01/07/13, this Investigator received a written response from ALLAN CAO, SERENITY PHARMACY CORP PDM (Exhibit #4). In summary CAO stated the following: "I became SERENITY

PHARMACY CORP pharmacy manager on 11/20/12 when I was approached by the owners, because they were having all sorts of difficulties and they stated that they needed to sell the pharmacy and I wanted to do my due diligence prior to purchase. CAO stated that the pharmacy did no have a manager, patients, prescription medication, and no insurance in order to operate. So in order to make the pharmacy in compliant, I begun by assuming the manager position. CAO also stated that he began working on getting the pharmacy up to standard, including CQI, necessary insurances, etc. As we began to work, owners ran out of money (stating that the DEA approval took about 7 months) and could not pay a pharmacist 40 hours. Because of this I began the process of requesting to minimize pharmacist hours with the Board of Pharmacy. The Board advised me that meetings for approval of reduction of hours were held every 2 months and the next meeting is in 02/28/13. But due to the circumstances with the DOH and the owner's financial issues, I have removed myself as PDM from SERENITY PHARMACY (Exhibit #6 pg. 30). COA further stated that the pharmacy did not have any prescription drugs, no dispensing of any kind, no patients, and no insurances to bill.

STATEMENT LETICIA MORO, PHARMACY OWNER – (Subject/Exhibit #5)

Employment Address:
SERENITY PHARMACY CORP
23 SW 8th Avenue
Miami, FL 33130
(305) 325-1885 (W)

On 01/02/13, this Investigator received a written response from LETICIA MORO, SERENITY PHARMACY CORP owner (Exhibit #5). MORO stated the following: Please accept our most sincere apology for the difficulties and inconvenience that the recent visit to SERENITY PHARMACY CORP has caused. We assure you that this issue is not common problem through out internal review process and we believe the cause has strive from lack of experience in this field and considering that this is our first time being a owner of a local business.

On the other hand we are facing some financial difficulties and also the application for our DEA permit took us 7 months to get approve. MORO further stated that they accept full responsibility for the inconvenience and assure they are taking the necessary steps to prevent this situation from happening again in the near future.

INVESTIGATOR NOTE:

On 01/22/13 at approximately 11:50 am, this Investigator and Miami Inspector WARSHOFSKY presented at the address of SERENITY PHARMACY CORP for a routine investigative visit and to conduct a re-inspection on the facility. This Investigator obtained copies of wholesaler invoices (Exhibit #6 pp. 57-60). Inspector WARSHOFSKY also conducted an audit for the month of 01/13 by using the Drug Utilization Reports from SERENTIY PHARMACY CORP dated 10/01/12 -01/31/13 (Exhibit #6 pp. 38-56); and Invoice from ANDA, The HARVARD DRUG GROUP, & VERTICAL SOURCE (Exhibit #6 pp. 57-60) on Lidoderm and Advair. SERENITY PHARMACY CORP purchased 4 boxes of Lidorderm and none were on the shelves, but the amount billed/dispensed was 10 boxes.

SERENITY PHARMACY CORP also purchased 3 boxes of Advair and none were on the shelves, but amount billed/dispensed was 6 boxes. Pedigree records were no retrievable at the time of the Inspections (see Exhibit #8 pp. 85-87 for inspection details). This Investigator and Inspector WARSHOFSKY went through the invoices and highlighted in yellow Lidoderm and Advair which were the medications that was audited (Exhibit #6 pp. 38, 45, 54, 55, 58, 59, & 60). Also this Investigator and Inspector WARSHOFSKY observed two bags of Medication containing prescription for patient PT date 01/23/13 & 01/25/13 and patient RC dated 01/30/13 for delivery. The delivery sheet for patient PT stated that he will receive 10 medications but the bags only had 3 medications inside (see Exhibit #6 pp. 31-33 and photos of medication pg. 34) and the delivery sheet for patient RC dated 01/30/13 stated that he will receive 7 medications but the bags only had 2 medications inside (see Exhibit #6 pp. 35-36 and photos of medication pg. 37). On 02/04/13 SERENITY PHARMACY CORP OWNER, LETICIA MORO e-mailed inspector WARSHOFSKY, SERENITY PHARMACY CORP's Substance Fraud Policy Procedure, Invoice from HD SMITH WHOLESALE DRUG, and ANDA Invoice, but medication was still short for Lidoderm and Advair (Exhibit #7 pp. 79- 82).

Confidential Index of Name is Exhibit 9.

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FLORIDA DEPARTMENT OF STATE
DIVISION OF CORPORATIONS

Detail by Entity Name

Florida Profit Corporation

SERENITY PHARMACY, CORP

This detail screen does not contain information about the 2013 Annual Report.

Click here to determine if a 2013 Annual Report has been filed.

Filing Information

Document Number	P11000086364
FEI/EIN Number	453507336
Date Filed	09/30/2011
State	FL
Status	ACTIVE

Principal Address

23 SW 8TH AVE
MIAMI FL 33130

Mailing Address

23 SW 8TH AVE
MIAMI FL 33130

Registered Agent Name & Address

MORO, LETICIA L
23 SW 8TH AVE
MIAMI FL 33130

Officer/Director Detail

Name & Address

Title D

MORO, LETICIA I
23 SW 8TH AVE
MIAMI FL 33130

Annual Reports

Report Year	Filed Date
2012	03/28/2012

Document Images

03/28/2012 -- ANNUAL REPORT | View Image in PDF format

09/30/2011 -- Domestic Profit | View image in PDF format

EXHIBIT 3

CONFIDENTIAL

Note: This is not official record. See documents if question or conflict.

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State of Florida, Department of State

2012 FOR PROFIT CORPORATION ANNUAL REPORT

FILED
Mar 28, 2012
Secretary of State

DOCUMENT# P11000086364

Entity Name: SERENITY PHARMACY, CORP

Current Principal Place of Business:

23 SW 8TH AVE
MIAMI, FL 33130

New Principal Place of Business:

Current Mailing Address:

23 SW 8TH AVE
MIAMI, FL 33130

New Mailing Address:

FEI Number: 45-3507336 **FEI Number Applied For ( )** **FEI Number Not Applicable ( )** **Certificate of Status Desired ( )**

Name and Address of Current Registered Agent:

MORO, LETICIA L
23 SW 8TH AVE
MIAMI, FL 33130 US

Name and Address of New Registered Agent:

The above named entity submits this statement for the purpose of changing its registered office or registered agent, or both, in the State of Florida.

SIGNATURE: _____

Electronic Signature of Registered Agent Date

OFFICERS AND DIRECTORS:

Title: D
Name: MORO, LETICIA I
Address: 23 SW 8TH AVE
City-St-Zip: MIAMI, FL 33130

I hereby certify that the information indicated on this report or supplemental report is true and accurate and that my electronic signature shall have the same legal effect as if made under oath; that I am an officer or director of the corporation or the receiver or trustee empowered to execute this report as required by Chapter 607, Florida Statutes; and that my name appears above, or on an attachment with all other like empowered.

SIGNATURE: LETICIA MORO OWNE 03/28/2012

Electronic Signature of Signing Officer or Director Date

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

File # 18947 -,
Insp # 113267

ROUTINE ☐ CHANGE LOC ☐ NEW ☒ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
MEDZDIRECT, INC		2/15/2012
DOING BUSINESS AS	DEA NUMBER	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS: 1065 NE 125TH ST SUITE 207	TELEPHONE #: 3058910050 / EXT.	SCOTT SEGAL
CITY: NORTH MIAMI / COUNTY: 23	STATE/ZIP: 33161	PRESCRIPTION DEPARTMENT MANAGER LICENSE #

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1. SSEGAL@COMPASS.MD	
Open	9AM	9AM	9AM	9AM	9AM	CLOSED	CLOSED	2. SSEGAL0721@AOL.COM	
Close	5PM	5PM	5PM	5PM	5PM	CLOSED	CLOSED	3.	

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			☒	
2	Pharmacy technicians properly identified and supervised. [64B16-27.410, F.A.C.]	☒			
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	☒			
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			☒	
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			☒	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]	☒			
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			☒	
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			☒	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	☒			
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	☒			
11	CQI Policy and Procedures and quarterly meetings. [786.101, F.S.] [64B16-27.300, F.A.C.]			☒	
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	☒			
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) & F.S.] [64B16-28.140(3)(b), F.A.C.]	☒			
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	☒			
15	All controlled substance prescriptions contain information required. [893.04, F.S.]	☒			
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	☒			
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]	☒			
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	☒			
19	DEA 222 order forms properly completed. [893.07, F.S.]	☒			
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	☒			
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	☒			
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	☒			
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	☒			
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	☒			
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	☒			
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]	☒			
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]	☒			
28	Compounding records properly maintained. [64B16-27.700, F.A.C.]*	☒			
29	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]	☒			
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]	☒			

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: All no responses are not applicable at this time. This is an initial pharmacy inspection. PDM for this facility is Peter Day (PS 18276), although it shows the owners name Scott Segal. Appointment set for 12/17/2012 at 9:30 am. The pharmacist will email me the test label next week.

EXHIBIT 8

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT PDM 18276

Peter Day — Institutional Representative

02-17-2012 — Date

Investigator/Sr. Pharmacist Signature

ID mi187

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

CONFIDENTIAL

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 18947

Insp # 113877

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
MEDZDIRECT, INC	25969	12/19/2012
DOING BUSINESS AS	DEA NUMBER	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS: 1065 NE 125TH ST SUITE 207	TELEPHONE #: 3058910050 / EXT.	PETER DAY
CITY: NORTH MIAMI / COUNTY: 23	STATE/ZIP: 33161	PRESCRIPTION DEPARTMENT MANAGER LICENSE #: 18276

PRESCRIPTION DEPARTMENT HOURS	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open							
Close							

REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
1.	
2.	
3.	

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]				X
2	Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]				X
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]				X
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]				X
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]				X
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]				X
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]				X
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]				X
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]				X
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]				X
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]				X
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]				X
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]				X
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]				X
15	All controlled substance prescriptions contain information required. [893.04, F.S.]				X
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].				X
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]				X
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]				X
19	DEA 222 order forms properly completed. [893.07, F.S.]				X
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]				X
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]				X
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]				X
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]				X
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]				X
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]				X
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]				X
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]				X
28	Compounding records properly maintained. [64B16-28.140(4), F.A.C.]*				X
29	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]				X
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]				X

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks:

Inspector Mi212 conducted visit for routine inspection. Pharmacy permit was approved since 02/2012 and DEA no issued since 10/2012. As pharmacy manager Peter Day who now claims to be a consultant for this pharmacy no medication could be purchased yet.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Silvia Leon

N/A

Institutional Representative

12-19-2012

Date

Investigator/Sr. Pharmacist Signature

ID mi212

INV 359 Revised 5/12, 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # _____

Insp # _____

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
Serenity Pharmacy Corp	26021	1/31/2013
DOING BUSINESS AS	DEA NUMBER FS3566215	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 23 SW 8th Ave	TELEPHONE # (305)325-1885 / EXT.	
CITY Miami / COUNTY 23	STATE/ZIP 33130	PRESCRIPTION DEPARTMENT MANAGER LICENSE #

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1. Silvia Rodriguez, PS 36084	
Open	9:00A	9:00A	9:00A	9:00A	9:00A	Closed	Closed	2.	
Close	5:00P	5:00P	5:00P	5:00P	5:00P	Closed	Closed	3.	

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2	Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]		X		
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			X	
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			X	
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]		X		
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]				X
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15	All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]		X		
19	DEA 222 order forms properly completed. [893.07, F.S.]		X		
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]		X		
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			X	
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]			X	
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]			X	
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]			X	
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]		X		
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]		X		
28	Compounding records properly maintained. [64B16-28.140(4), F.A.C.]*		X		
29	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]		X		
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]				X
31	Preparation time does not exceed 1 hour when preparing, and adminstration begins not later than 1 hour following start of immediate use CSPs. [64B16-27.797(1)(j), F.A.C.]		X		
32	Preparation is properly labeled if preparer does not administer or witness administration when preparing immediate-use CSPs. [64B16-27.797(1) (j), F.A.C.]		X		

* Note: If establishment is engaged in sterile compounding, a separate inspection form should be completed.

Remarks: All N/A's are not applicable at this time.
Wholesaler is API, Verticle, and Harvard.
No control II at this time at this location.
#10 No expired medication.
#22 Reviewed daily print out for the last month.
#12 and #30 See additional remarks page.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Silvia Rodriguez, PS 36084

Institutional Representative

01-31-2013
Date

Investigator/Sr. Pharmacist Signature

ID mi200

INV 359 Revised 12/12, 5/12, 12/11, 10/11, 9/11, 10/10, 10/09, 5/08, 12/02, 12/00

STATE OF FLORIDA
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE - ISU

FLORIDA DEPARTMENT OF HEALTH

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ADDITIONAL REMARKS

CORPORATE NAME Serenity Pharmacy Corp	INSPECTION NUMBER	TYPE OF PERMIT 2205	DATE OF INSPECTION 1/31/2013
DOING BUSINESS AS	FILE NUMBER	LICENSE # 26021	
STREET ADDRESS 23 SW 8th Ave		TELEPHONE # (305)325-1885	EXT #
CITY Miami	COUNTY MIAMI-DADE	STATE/ZIP 33130	

Remarks:

#12 No control fraud policy available for review.

#30: Inspector MI 200 conducted an audit on the following medication for the month of January 2013.

Lidoderm Patches #30:

Amount purchased from various wholesalers during January was 4 boxes. None are in stock at this time. Amount billed out is 10 boxes.

Advair 250/50 #30

Amount purchased from various wholesalers during January was 3 boxes. None are in stock at this time. Amount billed out is 6.

Page: Of:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Silvia Rodriguez, PDM

ID mi200

Institutional Representative

01-31-2013
Date

Investigator/Sr. Pharmacist Signature

INV 416 Revised 12/11, 10/11, 01/07, 07/03

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

FLORIDA DEPARTMENT OF HEALTH

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Pharmacy/Dispensing Practitioner Data Collection Form

File # _____

Insp # _____

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.073, FLORIDA STATUTES AND 64b16-30.002 F.A.C.

NAME OF ESTABLISHMENT Serenity Pharmacy Corp		PERMIT NUMBER 26021	DATE OF INSPECTION 1/31/2013
DOING BUSINESS AS		DEA NUMBER	PRESCRIPTION DEPARTMENT MANAGER/ CONSULTANT PHARMACIST
STREET ADDRESS 23 SW 8th Ave		TELEPHONE # (305)325-1885 / EXT.	
CITY Miami	COUNTY MIAMI-DADE	STATE/ZIP 33130	LICENSE #

101. Pharmacy is compounding nonsterile products.	[ ]
103. Pharmacy is compounding sterile products.	[ ]
105. Pharmacy is compounding sterile products without a prior INV 797 inspection form.	[ ]
106. Pharmacy operates as Internet pharmacy only.	[ ]
110. Pharmacy is in the same location within a pain management clinic or weight loss clinic.	[ ]
111. Pharmacy technicians are NOT properly registered.	[ ]
125. Pharmacy is accepting cash only for pain medication.	[ ]
126. Dispensing practitioner is dispensing controlled drugs.	[ ]
128. Dispensing practitioner is dispensing CII and CIII drugs pursuant to F.S. 465.0276.	[ ]
129. Dispensing practitioner is dispensing at a location not listed as a practice or satellite location in the licensing module of COMPAS.	[ ]
130. Inspector has obtained copies of prescriptions or patient profiles from dispensing practitioner or pharmacy.	[ ]
131. None of the above statements apply.	[ ]

NOTE

The purpose of this form is to collect data for internal use for the ISU ONLY. It will be used at different intervals to assess statewide trends in pharmacy and dispensing practitioners. This form will not be issued to the licensee and is separate from the inspection and inspection form that is provided at the completion of the site visit. This information does not exclude the inspector/investigator from notification of any immediate issues or concerns initiated at the inspection. The appropriate protocol must be followed when any immediate issue is identified, to include documentation of same on the inspection form.

Remarks:
No compounding at this time.

PRINT NAME D. Warshofsky

ID mi200

Investigator/Sr. Pharmacist sign here also

01-31-2013
Date

Investigator/Sr. Pharmacist Signature

INV 373 Revised 06/12, 01/07 Replaces 12/02

CONFIDENTIAL AND EXEMPT MATERIALS

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

HEALTH

Rick Scott
Governor

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201216087

CANTONMENT PHARMACY INC,
RESPONDENT.

NOTICE

TO: CANTONMENT PHARMACY INC
433 HIGHWAY 29 SOUTH
CANTONMENT, FL 32533

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Determination of Walver

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida Department of Health
Division of Medical Quality Assurance
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3260
PHONE: (850) 245-4444 • FAX : (850) 245-4791

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

PERSONAL AND CONFIDENTIAL

January 14, 2014

PRESTON E MCDONALD
5740 WESTMONT ROAD
MILTON, FL 32583

Re: DOH v. Cantonment Pharmacy Inc
Case # 201216087

Dear Preston E Mcdonald:

I am writing to you concerning the Department of Health's review of certain health care provided by the above named health care practitioner. That review included a full investigation and the filing of an Administrative Complaint. That review is nearing a conclusion and Board of Pharmacy is scheduled to take final disciplinary action in the matter on Wednesday, February 12, 2014.

This is one of several matters that will be part of the public meeting. You are welcome to attend this public meeting, but you are not required to attend, and this is not a request that you attend the meeting. Cases shown on the agenda may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled to begin at 9 a.m.; therefore, if you choose to attend it is imperative that you arrive promptly at 9 a.m. and be prepared to remain until the case is heard as cases may be heard in a different order than they appear on the agenda.

Florida law provides that the person who made the complaint to the Department ("complainant") is entitled to provide oral or written communication to the Board concerning the alleged violation or the appropriate penalty. Likewise, the patient/legal representative in the case who was not the "complainant" may request that the Board allow them the same opportunity to provide such written or oral communication. The Board has granted such requests. If you have any questions concerning this matter, please contact the Department's Prosecution Services Unit prior to the meeting at (850)245-4640. Please reference the above case number when calling.

All final disciplinary actions of the Board are reflected in written orders which are available on the Department's website at: www.flhealthsource.com. Please allow 30-60 days after the board meeting for the posting of these orders.

Sincerely,

for Tammy Collins

Executive Director
Board of Pharmacy

Florida Department of Health
Division of Medical Quality Assurance
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3260
PHONE: (850) 245-4444 • FAX : (850) 245-4791

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Ana Gargollo-McDonald, Assistant General Counsel
RE: Determination of Waiver
SUBJECT: DOH v. Cantonment Pharmacy Inc
DOH Case Number 2012-16087
DATE: November 26, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Cantonment Pharmacy Inc
Subject's Address of Record:	433 Highway 29 S Cantonment, FL 32533-1401
Enforcement Address:	433 Highway 29 South Cantonment, FL 32533
Subject's License No:	2748 **Rank:** PH
Licensure File No:	498
Initial Licensure Date:	
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	465.023(1)(c), FS (2012) 465.015(2)(c), FS (2012)
Prior Discipline:	None
Probable Cause Panel:	September 5, 2013; Mesros & Glass
Subject's Attorney:	Pro Se
Complainant/Address:	Preston E McDonald 5740 Westmont Road Milton, FL 32583
Materials Submitted:	Memorandum to the Board Motion For Determination of Waiver Exhibit A - Administrative Complaint Exhibit B – Copy of Certified Mail Receipt Exhibit C – Affidavit of Service Exhibit D – Board Affidavit

Exhibit E – Clerks Affidavit
Motion to Assess Costs with Attachments
Exhibit A – Affidavit of Fees and Costs Expended
Exhibit 1 – Complaint Cost Summary
Exhibit 2 – Itemized Cost by Complaint
Supplemental Investigative Report dated 7/31/13
Supplemental Investigative Report dated 10/29/13
Probable Cause Memorandum
Correspondence
Final Investigative Report with Exhibits 1-9

Disciplinary Guidelines:
456.023(1)(c), Florida Statutes (2012):
From an administrative fine of up to $1,500.00 and 1 year probation, to $5,000 fine and 1 year suspension.

PRELIMINARY CASE REMARKS: DETERMINATION OF WAIVER

This is a one-count administrative complaint alleging Respondent violated Section 456.023(1)(c), Florida Statutes (2012), by violating Section 465.015(2)(c), Florida Statutes, (2012), by selling or dispensing drugs as defined in s. 465.003(8) without first being furnished with a prescription.

RECOMMENDATION OF THE DEPARTMENT

- Fine of $2,000.00
- Costs.

CONSIDERATIONS SUPPORTING THE DEPARTMENT'S RECOMMENDATION

- The recommendation is consistent with the disciplinary guidelines.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. **CASE NO. 2012-16087**

CANTONMENT PHARMACY, INC.,
Respondent.
_____/

MOTION FOR DETERMINATION OF WAIVER AND FOR FINAL ORDER BY HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

Petitioner, Department of Health, by and through counsel, moves the Board of Pharmacy to find that Respondent has waived his/her right to elect a method of disposition of the pending Administrative Complaint, to determine that no material facts are in dispute, to conduct a hearing not involving disputed issues of material fact, and to enter a Final Order. As grounds therefore, Petitioner states:

1. An Administrative Complaint was filed against Respondent on September 5, 2013. A copy of said Administrative Complaint is attached hereto as Petitioner's Exhibit A.

2. Copies of the Administrative Complaint, Explanation of Rights form, and Election of Rights forms were sent to Respondent, via certified US mail delivery, on September 18, 2013 (7196 9008 9111 1387 0964). A signed

green receipt card was not returned. A copy of the certified mail receipt is attached as Petitioner's Exhibit B.

3. Thereafter, the Department requested personal service on Respondent, which was completed on October 29, 2013. The affidavit of personal service is attached as Petitioner's Exhibit C.

4. Respondent has not filed with either the Department of Health or the Board of Pharmacy, an Election of Rights form or other responsive pleading in this case within the twenty-one (21) day period to dispute the allegations contained in the Administrative Complaint. Copies of affidavits supporting the same are attached hereto as Petitioner's Exhibits D and E.

5. Rule 28-106.111(2), Florida Administrative Code, provides in pertinent part that:

> . . . persons seeking a hearing on an agency decision which does or may determine their substantial interests shall file a petition for hearing with the agency within 21 days of receipt of written notice of the decision.

6. Rule 28.106.111(4), Florida Administrative Code, provides in pertinent part that:

> . . . any person who received written notice of an agency decision and who fails to file a written request for a hearing within 21 days waives the right to request a hearing on such matters.

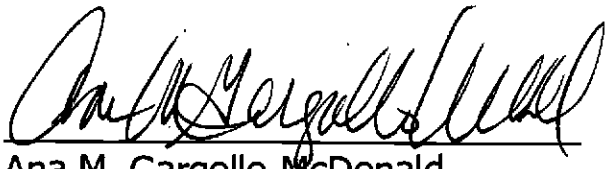
7. Respondent has been advised, by a copy of this motion sent to his/her address of record, that a copy of the investigative file in this case shall be furnished to the Board to establish a prima facie case regarding the violations as set forth in the Administrative Complaint.

8. The Department has determined that there are no material facts in dispute and has concluded that Respondent has waived his/her right to elect the method of resolution.

9. The Department requests that this Motion and a hearing be placed on the agenda for the next regularly scheduled meeting of the Board of Pharmacy.

WHEREFORE, Petitioner respectfully requests that the Board find that Respondent has waived his/her right to elect a method of resolution of this matter, find that there are no material facts in dispute, hold a hearing not involving material issues of disputed fact based on the information contained in the investigative file, find that Respondent violated Chapters 456 and 465, Florida Statutes, as alleged in the Administrative Complaint, impose discipline in accordance with the disciplinary guidelines, and enter a Final Order.

Respectfully submitted,



Ana M. Gargollo-McDonald
Assistant General Counsel
Florida Bar No. 85907
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4681
Email: ana.gargollo-mcdonald@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion for Determination of Waiver and for Final Order by Hearing Not Involving Disputed Issues of Material Fact has been furnished via U.S. mail this 9th day of December, 2013, to Cantonment Pharmacy, Inc., 433 Highway 29 South, Cantonment, Florida 32533.

Ana M. Gargollo-McDonald
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. CASE NO. 2012-16087

CANTONMENT PHARMACY, INC.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Cantonment Pharmacy, Inc., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a permitted pharmacy within the State of Florida, having been issued license number PH 2748.

EXHIBIT
A

3. Respondent's address of record is 433 Highway 29 South, Cantonment, Florida 32533.

4. On or about February 4, 2013, the Department of Health Investigator went to Respondent's address of record at 433 Highway 29 South, Cantonment, Florida 32533, and obtained six (6) azithromycin 250 mg tablets, a prescription only medication, without a valid prescription.

5. Section 465.015(2)(c), Florida Statutes (2012), it is unlawful for any person to sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription.

6. Azithromycin is an antibiotic that fights bacteria and is a prescription drug.

7. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee, if the permittee, or any affiliated person, partner, officer, director, or agent of the permittee, violates any of the requirements of Chapter 465, Florida Statutes, Chapter 893, Florida Statutes, or any of the rules of the Board of Pharmacy.

8. As set forth above in paragraph 4, on or about February 4, 2013, Respondent, or any affiliated person, partner, officer, director, or agent of Respondent violated Section 465.015(2)(c), Florida Statutes (2012).

9. Based on the foregoing, Respondent, or any affiliated person, partner, officer, director, or agent of Respondent, has violated Section 465.023(1)(c), Florida Statutes (2012), by violating Section 465.015(2)(c), Florida Statutes (2012), by selling or dispensing drugs as defined in s. 465.003(8) without first being furnished with a prescription.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 5th **day of** September, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Ana M. Gargollo-McDonald
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No. 0085907
Telephone: (850) 245-4444 Ext. 8133
Facsimile: (850) 245-4683
ana_gargollo-mcdonald@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Angela Sanders
DATE: SEP 0 5 2013

/AGM

PCP: 9/5/2013
PCP Members: Mesros & Glass

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

7196 9008 9111 1387 0964

TO:

Cantonment Rx
2012-16087
AM/ab/Stip Pk
Sent 9/18/2013

Cantonment Pharmacy, Inc.
433 Highway 29 South
Cantonment, FL 32533

RECEIPT SERVICE		
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

USPS®
Receipt for Certified Mail™

No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

EXHIBIT
B

English Customer Service USPS Mobile Register / Sign In

USPS.COM

Search USPS.com or Track Packages

Quick Tools
Track
Enter up to 10 Tracking # Find
Find USPS Locations
Buy Stamps
Schedule a Pickup
Calculate Postage
Find a Zip Code
Hold Mail
Change of Address

Ship a Package Send Mail Manage Your Mail Shop Business Solutions

USPS Tracking™

Customer Service ›
Have questions? We're here to help.

Tracking Number: 71969008911113870964

Requested label is archived.

Restore Archived Details ›

Product & Tracking Information

Postal Product:

Features:
Certified Mail™

[redacted]

September 25, 2013 , 9:32 am	Delivered	CANTONMENT, FL 32533

Available Options

Track Another Package

What's your tracking (or receipt) number?

Track It

LEGAL
Privacy Policy ›
Terms of Use ›
FOIA ›
No FEAR Act EEO Data ›

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Government Services ›
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Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

AFFIDAVIT OF SERVICE

DEPARTMENT OF HEALTH
Petitioner

vs

Case No. PH 2012-16087

CANTONMENT PHARMACY
Respondent

COMES NOW, the affiant, who first being duly swom, deposes and states:

1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That from 10/28/13-10/29/13, Affiant made a diligent effort to locate Respondent, to serve XX Administrative Complaint and related papers; _____ Order compelling examination(s); ____ Subpoena(s); _____Final order; _____Notice to cease and desist; ____ ESO/ERO and related papers.

3) Check applicable answer below:

XX Affiant made personal service on 10/29/13 by serving the AC to GENE R. LACHNEY, RPh at Cantonment Pharmacy located at 433 Hwy 29 South, Cantonment, FL 32533.

_____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

Affiant

State Of Florida
County Of Escambia

Before me, personally appeared Ben Lanier whose identity is known to me by Personally known _____ (type of identification) and who, acknowledges that his/her signature appears above.

Swom to or affirmed by Affiant before me this 29th day of October, 2013.

LORA BOYD
Commission # EE 869098
Expires January 27, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

Notary Public-State of Florida

My Commission Expires

Type or Print Name

Florida Department of Health
Division of Medical Quality Assurance • Bureau of Enforcement
5016 N. Davis Hwy • Pensacola, FL 32503
PHONE: (850) 475-5474• FAX (850) 475-5475

www.FI

FACEBO

Exhibit S2-2

EXHIBIT
C

Affidavit of Non-Receipt

I, Tommy Collins, hereby certify in my official capacity as custodian for the Board's licensure files that the Board of Pharmacy as of 26 Nov 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **Cantonment Pharmacy, Inc.; 2012-16087**, which would affect the Subject's substantial interests or rights.

Tommy Collins
Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Tommy Collins, whose identity is known to me personally and who, under, oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 5 day of Dec, 2013.

HELAINE ROBISON
MY COMMISSION # EE 138625
EXPIRES: November 17, 2015
Bonded Thru Notary Public Underwriters

Notary Public
My commission expires:

EXHIBIT
D

AFFIDAVIT

I, Amy Carraway, Deputy Clerk for the Department Clerk's Office, hereby certify in my official capacity as custodian for the Department Clerk's records, that the Department Clerk's Office has not received an Election of Rights form or other responsive pleading, which requests a hearing prior to any Department action regarding **Cantonment Pharmacy, Inc.; 2012-16087**, which would affect the Respondent's substantial interests or rights.

Amy Carraway
Custodian of Record
Department Clerk's Office

Before me, personally appeared Amy Carraway, whose identity is known to me personally and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 27th day of November, 2013.

Angela Barton
Notary Public
My Commission Expires:

ANGELA BARTON
Notary Public - State of Florida
My Comm. Expires Sep 1, 2017
Commission # FF 49339
Bonded Through National Notary Assn.

EXHIBIT
E

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. CASE NO. 2012-16087

CANTONMENT PHARMACY, INC.,
Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or

> after July 1, 2001, pursuant to this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto.

3. The investigation and prosecution of this case has resulted in costs in the total amount of $1,421.71, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	Costs
Complaint:	0.60	$32.94
Investigation:	13.50	$846.78
Legal:	5.10	$541.99
Compliance:	0.00	$0.00
Sub Total:	19.20	$1,421.71
Expenses to Date:		$0.00
Prior		$0.00

Amount:		
Total Costs to Date:		$1,421.71

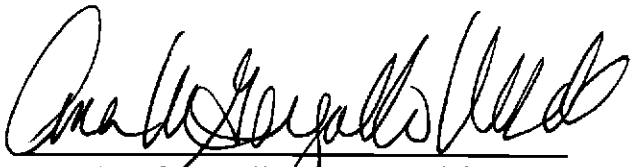
Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $879.72 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $879.72 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $879.72.

DATED this 9th day of December, 2013.



Ana M. Gargollo-McDonald
Assistant General Counsel
Fla. Bar No. 85907
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: ana.gargollo-mcdonald@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 9th day of December, 2013, to Cantonment Pharmacy, Inc., 433 Highway 29 South, Cantonment, Florida 32533.

Ana M. Gargollo-McDonald
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2012-16087** (Department of Health v. **CANTONMENT PHARMACY, INC.**) are **ONE THOUSAND FOUR HUNDRED TWENTY-ONE DOLLARS AND SEVENTY-ONE CENTS ($1,421.71).**

6) The costs for DOH case number(s) **2012-16087** (Department of Health v. **CANTONMENT PHARMACY, INC.**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case number(s) **2012-16087** (Department of Health v. **CANTONMENT PHARMACY, INC.**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to keep track of their time in six-minute increments (e.g., investigators

EXHIBIT
A

and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of her knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 2nd day of December, 2013, by Shane Walters, who is personally known to me.

Notary Signature

TOWANDA B. BURNETT
Commission # EE 838342
Expires September 25, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

Towanda Burnett

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

Complaint Cost Summary

Complaint Number: 201216087

Subject's Name: CANTONMENT PHARMACY INC

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.60	$32.94
Investigation:	13.50	$846.78
Legal:	5.10	$541.99
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	19.20	$1,421.71
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,421.71

EXHIBIT

Exhibit 1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216087

Report Date 12/02/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA115	0.50	$54.90	$27.45	10/30/2012	7	PRELIMINARY INVESTIGATION
HA115	0.50	$54.90	$27.45	04/11/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HA115	0.10	$54.90	$5.49	05/16/2013	144	CSU INVESTIGATIVE WORK
Sub Total	**1.10**		**$60.39**			
INVESTIGATIVE SERVICES UNIT						
BI35	0.10	$61.19	$6.12	11/16/2012	7	PRELIMINARY INVESTIGATION
BI35	0.20	$61.19	$12.24	11/20/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$61.19	$6.12	11/26/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$61.19	$6.12	11/27/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$61.19	$6.12	11/30/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$61.19	$6.12	11/30/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$63.98	$6.40	12/05/2012	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	12/11/2012	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	12/13/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$63.98	$6.40	12/19/2012	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	01/08/2013	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	01/09/2013	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	01/11/2013	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	01/11/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	01/17/2013	7	PRELIMINARY INVESTIGATION
BI35	0.10	$63.98	$6.40	01/28/2013	7	PRELIMINARY INVESTIGATION
BI35	0.10	$63.98	$6.40	01/31/2013	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	02/04/2013	58	TRAVEL TIME
BI35	0.10	$63.98	$6.40	02/04/2013	7	PRELIMINARY INVESTIGATION
BI35	0.50	$63.98	$31.99	02/05/2013	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	02/08/2013	7	PRELIMINARY INVESTIGATION
BI35	0.10	$63.98	$6.40	03/28/2013	7	PRELIMINARY INVESTIGATION

EXHIBIT
2

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216087

Report Date 12/02/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
BI35	0.30	$63.98	$19.19	04/01/2013	76	REPORT PREPARATION
BI35	0.30	$63.98	$19.19	04/05/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	04/17/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.10	$63.98	$6.40	04/17/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	04/18/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.10	$63.98	$6.40	04/18/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	05/02/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	05/02/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/06/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	05/06/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/10/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/14/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/15/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.10	$63.98	$6.40	05/15/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	05/16/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.10	$63.98	$6.40	05/17/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	05/17/2013	76	REPORT PREPARATION
BI35	0.40	$63.98	$25.59	05/30/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.40	$63.98	$25.59	05/30/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	06/05/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	06/14/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.30	$63.98	$19.19	06/14/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	06/26/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	06/26/2013	76	REPORT PREPARATION
BI35	0.40	$63.98	$25.59	06/27/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.30	$63.98	$19.19	06/27/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	06/28/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	06/28/2013	76	REPORT PREPARATION
BI35	0.70	$63.98	$44.79	07/01/2013	76	REPORT PREPARATION
BI35	0.30	$63.98	$19.19	07/02/2013	76	REPORT PREPARATION
BI35	0.50	$63.98	$31.99	07/03/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	07/08/2013	76	REPORT PREPARATION
BI35	0.60	$63.98	$38.39	07/22/2013	6	SUPPLEMENTAL INVESTIGATION

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
BI35	0.10	$63.98	$6.40	07/30/2013	6	SUPPLEMENTAL INVESTIGATION
BI35	0.60	$63.98	$38.39	07/30/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	07/31/2013	76	REPORT PREPARATION
BI35	0.10	$46.35	$4.64	10/29/2013	6	SUPPLEMENTAL INVESTIGATION
BI35	0.30	$46.35	$13.91	10/29/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
BI35	0.20	$46.35	$9.27	10/30/2013	6	SUPPLEMENTAL INVESTIGATION
Sub Total	**13.00**		**$819.33**			

PROSECUTION SERVICES UNIT

HLL106A	0.70	$106.35	$74.45	07/12/2013	25	REVIEW CASE FILE
HLL106A	0.20	$106.35	$21.27	07/15/2013	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFF
HLL106A	0.10	$106.35	$10.64	07/15/2013	35	TELEPHONE CALLS
HLL106A	0.20	$106.35	$21.27	07/15/2013	35	TELEPHONE CALLS
HLL106A	0.20	$106.35	$21.27	07/16/2013	35	TELEPHONE CALLS
HLL106A	0.20	$106.35	$21.27	07/16/2013	35	TELEPHONE CALLS
HLL106A	0.30	$106.35	$31.91	07/16/2013	36	PREPARATION OR REVISION OF LETTER
HLL106A	0.20	$106.35	$21.27	07/22/2013	115	CONTACT WITH INVESTIGATORS
HLL106A	0.10	$106.35	$10.64	07/30/2013	35	TELEPHONE CALLS
HLL106A	0.10	$106.35	$10.64	07/30/2013	35	TELEPHONE CALLS
HLL106A	0.20	$106.35	$21.27	08/02/2013	103	REVIEW SUPPLEMENTAL REPORT
HLL106A	1.10	$106.35	$116.99	08/02/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL106A	0.10	$106.35	$10.64	09/06/2013	37	REVIEW LETTER
HLL106A	0.90	$106.35	$95.72	09/18/2013	90	POST PROBABLE CAUSE PROCESSING
HLL106A	0.20	$106.35	$21.27	10/07/2013	25	REVIEW CASE FILE
HLL106A	0.20	$106.35	$21.27	10/07/2013	25	REVIEW CASE FILE
HLL106A	0.10	$101.95	$10.20	10/28/2013	37	REVIEW LETTER
Sub Total	**5.10**		**$541.99**			

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216087

Report Date 12/02/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
Total Cost			**$1,421.71**			

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 12/02/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description
	SubTotal			
	Total Expenses			

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area I, Pensacola	Date of Case: 4/8/13	Case Number: PH 2012-16087

Subject:	Source:
CANTONMENT PHARMACY, INC 433 Highway 29 South Cantonment, FL 32533 (850) 968-2489	**PRESTON MCDONALD, RPH** 5740 Westmont Road Milton, FL 32583 (850) 983-0916

Prefix:	License #:	Profession:	Board:	Report Date:
PH	2748	PHARMACY	PHARMACY	7/31/13

Period of Investigation: 7/17/13-7/31/13	Type of Report: SUPPLEMENTAL 1

Alleged Violation: **FS 456.072(1)(k)** Failing to perform any statutory or legal obligation placed upon a licensee. **(n)** Exercising influence on the patient or client for the purpose of financial gain **(dd)** Violating any provision of this chapter, **FS 465.015(2)** It is unlawful for any person: **(c)** To sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription. **FS 465.016(1)(i)** Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. **(r)** Violating any provision of this chapter .... **and FS 465.023(1)** The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline **(c)** Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy;

Synopsis: This supplemental report is predicated upon receipt of a PSU Request Form on 7/17/13 from BLONDELL HELLER-HUTCHINSON for ANA GARGOLLO-MCDONALD, Attorney, requesting the Chloraspetic with Lidocaine added purchased on 3/28/13 be tested for the drug. **(EXHIBIT S1-1)**.

INTERVIEW OF ED HUDSON, SUPERVISOR–WITNESS:
Employment: FDLE
1301 N. Palafox Street
Pensacola, FL 32501
(850) 595-2006

On 7/15/13, Investigator Supervisor CATHY MARTIN contacted HUDSON by telephone to inquire who to speak with about testing the evidence in their lab. HUDSON referred Investigator Supervisor MARTIN to the FDLE Chemistry Supervisor, JOEY GRAVES.

INTERVIEW OF JOEY GRAVES, LAB SUPERVISOR–WITNESS:
Employment: FDLE
1301 N. Palafox Street
Pensacola, FL 32501
(850) 595-2077

On 7/15/13, Investigator Supervisor MARTIN attempted to telephone GRAVES; however, his voice mail message stated he was out and would not return until the following week.

RECEIVED-LEGAL
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CONTINUED ...

Related Cases: RPT 2012-16092, RPT 2012-16089, PS 2012-16091, PS 2012-16088, PS 2012-16090, PS 2013-06754

Investigator/Date:	Approved By/Date:
Ben Lanier 7/31/13	Cathy Martin 7/31/13
Ben Lanier, BI-35, Investigator	Cathy Martin, Investigator Supervisor

Received
Investigative Services
AUG 01 2013

Distribution: HQ/ISU

DOH/MQA
Tallahassee HQ

On 7/22/13, Investigator Supervisor CATHY MARTIN contacted GRAVES by telephone and asked about the possibility of testing for Lidocaine in the bottle of Chloraseptic. GRAVES stated Lidocaine was not a controlled substance and he therefore would only be able to confirm whether Lidocaine was in the Chloraseptic, but not the quantity. He stated he would need an Originating Agency Identifier (ORI) for intake of the Chloraseptic. Investigator Supervisor MARTIN explained DOH was not a law enforcement agency and probably did not have an ORI. GRAVES stated he would check and call back. He did so shortly after and stated he confirmed DOH did not have an ORI and he therefore could not accept and analyze the Chloraseptic. GRAVES referred Investigator Supervisor MARTIN to NMS labs.

INTERVIEW OF DANIELLE FARINA, STAFF–WITNESS:
Employment: NMS Labs
2300 Strattford Ave
Willengrove, PA19090
(866) 522-2216

On 7/22/13, Investigator LANIER interviewed FARINA by telephone. FARINA stated they could test Chloraseptic for Lidocaine. FARINA stated the lab could simply test for the presence of Lidocaine and the testing code was 72101LI.. FARINA stated the cost would be $369.00 and the turnaround time was about two weeks. FARINA stated the lab could also test for the quantity of Lidocaine in the bottle. FARINA stated the cost would be $576.00 and the turnaround time was about three weeks. FARINA stated there would also be a fee to return the specimen if it was needed. FARINA stated if the Chloraseptic was going to be sent to them then the proper forms would be need to be filled out which could be found at nmslabs.com.

INVESTIGATOR'S NOTE: On 7/22/13, Investigator LANIER called the local Quest Diagnostics lab and staff informed they only test patients and not evidence. On the same date, Investigator LANIER searched for other labs that might offer to test the Lidocaine. Investigator LANIER telephoned Avomeen lab at (800) 930-5450 and staff informed they do not perform those test regularly, but that it could be done for about $2,500.00. On the same date, Investigator LANIER telephoned Central Florida Testing Lab and staff informed that test could not be performed in their lab. On the same date, Investigator LANIER attempted to speak with staff at OAS lab at (800) 695-7222; however, no one answered the call and a voicemail message was left requesting a return call. As of the completion of this report the call was not returned.

On 7/22/13, Investigator LANIER provided the cost information to PSU and was informed the matter would be reviewed and a decision made whether to proceed with the testing.

On 7/30/13, Investigator LANIER followed up with PSU and was informed the testing would not be necessary at this time due to the cost.

EXHIBITS:
S1-1. PSU Request Form **(p. 3)**

Department of Health

FLORIDA DEPARTMENT OF HEALTH

JUL 17 2013

PSU REQUEST FORM

ISU/Pensacola

BL35

FROM: Blondell Heller-Hutchison for Ana Gargollo-McDonald, Esq.	TO: ISU Cathy Martin
Date: 7/17/2013	TO: CSU
Phone #: (850) 245-4444 ext. 8133	CC: Ben Lanier, Investigator

Case Number: 2012-16087
Subject: **Cantonment Pharmacy, Inc.**
Requested Completion Date: **8/17/2013**
Board: **Pharmacy**
HL Code: **HLL106A**
Status: **67**

(PSU) TYPE OF REQUEST: (describe details below)

- ☐ Process Service* (**Activity Code 160**)
- ☒ Additional Information Requested (**Activity Code 145**)
- ☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Attorney Ana M. Gargollo-McDonald is requesting the Investigator to obtain a requesting for the Chloraseptic that was purchased on March 28, 2013, be tested to find out if any substance, chemical, or drug was added. If the investigator has any additional questions concerning this request please contact attorney Ana Gargollo-McDonald at (850) 245-4444 ext. 8133. Thanking you in advance,

*The following additional information is needed for each service request:
Last Known Address: **433 Highway 29 South, Cantonment, Florida 32533**
Last Known Name & Phone Number: **(850) 968-2489**
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☒** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
IF YES, please send a copy of the original Investigative Report without attachments.

(ISU/CSU) RESPONSE:

- ☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)
- ☑ Additional Info Sent to Legal (Activity Code 156)
- ☐ Supp. Investigation Request Cancelled (Activity Code 157)

RECEIVED-LEGAL
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INV FORM 376, Revised 1/12. 10/11, 6/10, 06/09, 4/09, 11/08 Created 4/05

Exhibit S1-1

Heller-Hutchison, Blondell

From: Heller-Hutchison, Blondell
Sent: Wednesday, July 17, 2013 3:24 PM
To: DL MQA Inv Serv Priority Mail Area1 (BI) Pensacola
Cc: Martin, Cathy S; Lanier, Ben O; Gargollo-McDonald, Ana
Subject: Additional Information Request
Signed By: Blondell_Heller-Hutchison@doh.state.fl.us
Attachments: Cantoment Pharmacy, Inc., (PH, 12-16087) Additional Information Request.doc

Cathy,
Please see the attached additional information request. If you have ony further questions or concerns concerning this request please contact Attorney Ana M. Gargollo-McDonald at (850) 245-4444 ext. 8133 or myself at (850) 245-4444 ext 8109.

Thanking you in advance,

Blondell Heller-Hutchison, MSW, Regulatory Specialist, II
Assistant to Casey L. Cowon & Lauren A. Leikom
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
(850) 245-4444 ext. 8109
(850) 245-4683 Fax Number:
blondell_heller-hutchison@doh.state.fl.us

Please note: Florida has o very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.

However, if this e-mail concerns anticipated or current litigation or odversarial administrative proceeding to which the Florido Department of Health is a party, this email is an attorney-client communication, and is, therefore, a limited access public document exempt from the provisions of Chapter 119, Florida Statutes. See Section 119.071(d)1., Florida Statutes (2010).

DOH Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.

Vision statement: Healthiest State in the Nation.

DOH Values: I.C.A.R.E.

Innovation: We search for creative solutions and manage resources wisely.

Collaboration:We use teamwork to achieve common goals & solve problems.

Accountability:We perform with integrity & respect.

Responsiveness:We achieve our mission by serving our customers & engaging our partners.

Excellence:We promote quality outcomes through learning & continuous performance improvement.

Please visit www.CEAtRenewal.com to learn more.

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

FROM: Blondell Heller-Hutchison for Ana Gargollo-McDonald, Esq.	TO: ISU Cathy Martin
Date: 7/17/2013	TO: CSU
Phone #: (850) 245-4444 ext. 8133	CC: Ben Lanier, Investigator

Case Number: 2012-16087
Subject: **Cantonment Pharmacy, Inc.**
Requested Completion Date: **8/17/2013**
Board: **Pharmacy**
HL Code: **HLL106A**
Status: **67**

(PSU) TYPE OF REQUEST: (describe details below)

- ☐ Process Service* (**Activity Code 160**)
- ☒ Additional Information Requested (**Activity Code 145**)
- ☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Attorney Ana M. Gargollo-McDonald is requesting the Investigator to obtain a requesting for the Chloraseptic that was purchased on March 28, 2013, be tested to find out if any substance, chemical, or drug was added. If the investigator has any additional questions concerning this request please contact attorney Ana Gargollo-McDonald at (850) 245-4444 ext. 8133. Thanking you in advance,

*The following additional information is needed for each service request:
Last Known Address: **433 Highway 29 South, Cantonment, Florida 32533**
Last Known Name & Phone Number: **(850) 968-2489**
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☒** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

- ☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)
- ☐ Additional Info Sent to Legal (Activity Code 156)
- ☐ Supp. Investigation Request Cancelled (Activity Code 157)

FLORIDA DEPARTMENT OF HEALTH

Email to: Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area I, Pensacola	Date of Case: 4/8/13	Case Number: PH 2012-16087

Subject:	Source:
CANTONMENT PHARMACY, INC 433 Highway 29 South Cantonment, FL 32533 (850) 968-2489	**PRESTON MCDONALD, RPH** 5740 Westmont Road Milton, FL 32583 (850) 983-0916

Prefix:	License #:	Profession:	Board:	Report Date:
PH	2748	PHARMACY	PHARMACY	10/29/13

Period of Investigation: 10/28/13-10/29/13	Type of Report: SUPPLEMENTAL 2

Alleged Violation: **FS 456.072(1)(k)** Failing to perform any statutory or legal obligation placed upon a licensee. (n) Exercising influence on the patient or client for the purpose of financial gain **(dd)** Violating any provision of this chapter, **FS 465.015(2)** It is unlawful for any person: **(c)** To sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription. **FS 465.016(1)(i)** Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. **(r)** Violating any provision of this chapter ... **and FS 465.023(1)** The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline **(c)** Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy;

Synopsis: This supplemental report is predicated upon receipt of a PSU Request Form on 10/28/13 from BLONDELL HELLER-HUTCHINSON for ANA GARGOLLO-MCDONALD, Attorney, requesting hand service of the Administrative Complaint (AC) and related documents to CANTONMENT PHARMACY **(EXHIBIT S2-1)**.

INTERVIEW OF GENE R. LACHNEY, RPH–WITNESS:

Employment: Cantonment Pharmacy
433 Highway 29 South
Cantonment, FL 32533
(850) 968-2489

On 10/28/13, Investigator LANIER called CANTONMENT PHARMACY and spoke to LACHNEY. Investigator LANIER informed LACHNEY that an AC needed to be served to CANTONMENT PHARMACY. On the same date, Investigator LANIER provided the AC and related documents for CANTONMENT PHARMACY to LACHNEY at CANTONMENT PHARMACY. LACHNEY stated he would provide the pharmay's documentation to JOHN READING, Owner, PDM. An Affidavit of Service is included as **Exhibit S2-2**.

RECEIVED-LEGAL
13 OCT 31 PM 2:59

EXHIBITS:

S2-1. PSU Request Form with AC and related documents **(pp. 2-23)**
S2-2. Affidavit of Service **(p. 24)**

Related Cases: RPT 2012-16092, RPT 2012-16089, PS 2012-16091, PS 2012-16088, PS 2012-16090, PS 2013-06754

Investigator/Date:	Approved By/Date:
Ben Lanier 10/29/13	Cathy Martin 10/30/13
Ben Lanier, BI-35, Investigator	Cathy Martin, Investigator Supervisor

Received
Investigative Services
OCT 31 2013

Distribution: HQ/ISU

Tallahassee HQ

Department of Health

FLORIDA DEPARTMENT OF HEALTH

OCT 28 2013

ISU/Pensacola

PSU REQUEST FORM

B1.35

FROM: Blondell Heller-Hutchison for Ana M. Gargollo-McDonald, Esq.	TO: ISU Cathy Martin
Date: 10/28/2013	TO: CSU
Phone #: (850) 245-4444 ext. 8133	CC: Ben Lanier, Investigator

Case Number: 2012-16087
Subject: **Cantonment Pharmacy, Inc.**
Requested Completion Date: **11/28/2013**

Board: **Pharmacy**
HL Code: **HLL106a** Status: **87**

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: **Please have the attached Administrative Complaint, Election of Rights and Stipulation hand served. The respondent's mail is being returned "attempt not known". If the Subject cannot be located, please have a supplemental prepared within thirty (30) days of receipt of this memo along with an affidavit of diligent service/search. Please check the licensure screen as well for hand service. Please complete an Accurint check on this respondent if she cannot be located at the address above. Please state in the affidavit the type of method you used to identify the respondent. Thanking you in advance**

*The following additional information is needed for each service request:
Last Known Address: **433 Highway 29 South, Cantonment, Florida 32533**
Last Known Name & Phone Number: **(850) 968-2489**
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☐; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☒** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
IF YES, please send a copy of the original Investigative Report without attachments.

(ISU/CSU) RESPONSE:

☒ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

INV FORM 376, Revised 1/12, 10/11, 6/10, 06/09, 4/09, 11/08 Created 4/05

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Exhibit S2-1

2

FLORIDA DEPARTMENT OF HEALTH

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Email to:										
Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Contonment Pharmacy, Inc. (AMM)**
Case Number: 2012-16087

MEMBERS: **Cy~~nthia Griffin~~ Glass, PharmD and Jeffrey Mesaros**

DATE OF PCP: **September 5, 2013** **AGENDA ITEM: A-15**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(c), Florida Statutes (2012), by violating Section 465.015(1)(c), Florida Statutes (2012);

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss

___ **other** +

9/5/13

Chair, Probable Cause Panel
Board of Pharmacy

Date

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-16087**

CANTONMENT PHARMACY, INC.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Cantonment Pharmacy, Inc., was a permitted pharmacy within the State of Florida, having been issued license number PH 2748. Respondent's mailing address of record is 433 Highway 29 South, Cantonment, Florida 32533.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

3. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

4. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

5. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

6. **Fine**- The Board of Pharmacy shall impose an administrative fine of **TWO THOUSAND DOLLARS** ($2,000.00). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

7. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND TWO HUNDRED AND FORTY-FIVE DOLLARS** ($2,245.00). Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

8. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

9. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute

a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

10. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

11. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice

the Board or any of its members from further participation, consideration, or resolution of these proceedings.

12. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

13. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

14. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

15. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 2nd day of December, 2013.

CANTONMENT PHARMACY, INC.
CASE NO. 2012-16087

STATE OF Florida

COUNTY OF Escambia

Before me personally appeared John T. Reeding, SR, whose identity is known to me or by _____ (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 2nd day of December, 2013.

Notary Public

My Commission number:

My Commission Expires:

BENJAMIN V. FENN
Commission # EE 855488
Expires March 31, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

APPROVED this _____ day of _____, 2013.

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

_____
Ana M. Gargollo-McDonald
Assistant General Counsel

Counsel for Petitioner
Ana M. Gargollo-McDonald
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Facsimile: (850) 245-4683
ana_gargollo-mcdonald@doh.state.fl.us

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

!! CONFIDENTIAL

Office: Area I, Pensacola	Date of Case: 4/8/13	Case Number: PH 2012-16087

Subject:	Source:
CANTONMENT PHARMACY, INC 433 Highway 29 South Cantonment, FL 32533 (850) 968-2489	**PRESTON MCDONALD, RPH** 5740 Westmont Road Milton, FL 32583 (850) 983-0916

Prefix:	License #:	Profession:	Board:	Report Date:
PH	2748	PHARMACY	PHARMACY	7/8/13

Period of Investigation: 4/17/13-7/8/13	Type of Report: FINAL

Alleged Violation: **FS 456.072(1)(k)** Failing to perform any statutory or legal obligation placed upon a licensee. **(n)** Exercising influence on the patient or client for the purpose of financial gain **(dd)** Violating any provision of this chapter, **FS 465.015(2)** It is unlawful for any person: **(c)** To sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription. **FS 465.016(1)(i)** Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. **(r)** Violating any provision of this chapter ... and **FS 465.023(1)** The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline **(c)** Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy;

Synopsis: This investigation is predicated upon receipt of a complaint (Case Summary and Attachments) **(EXHIBIT 1)** submitted by MCDONALD in regard to CANTONMENT PHARMACY. MCDONALD, a former pharmacist at CANTONMENT PHARMACY, alleged staff there are dispensing prescription medications without a prescription including antibiotics, erectile dysfunction oral tablets (Viagra), albuterol inhalers, and possibly non-controlled medications. Allegedly customers come to the pharmacy on a daily basis to purchase Penicillin, Amoxicillin, Flagyl, Diflucan, and cough syrup with codeine without a prescription from a physician. On 2/4/13, a Pensacola investigator went to CANTONMENT PHARMACY and purchased a "Z-Pak" (six Azithromycin 250mg tablets, prescription only medication) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Tripolidine Hydrochloride 2.5mg) tablets. On 3/28/13, another Pensacola ISU staff member went to the pharmacy and purchased Chloraseptic with Lidocaine added (which requires a prescription) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Tripolidine Hydrochloride 2.5mg) tablets. The pharmacist was not identified on 2/4/13 or 3/28/13.

CANTONMENT PHARMACY was notified of the investigation by letter dated 4/17/13 **(EXHIBIT 2)** and was provided a copy of the Case Summary and originating documents from Exhibit 1.

A check of DOH computer licensure records revealed CANTONMENT PHARMACY is currently licensed as a PHARMACY.

No patients were identified; therefore, patient notification was not required.

CANTONMENT PHARMACY is not known to be represented by an attorney in this matter.

On 5/21/13 by US mail, Investigator LANIER received a statement from JOHN T. READING JR on behalf of CANTONMENT PHARMACY **(EXHIBIT 8)**. On behalf of CANTONMENT PHARMACY, READING denied the allegations.

Related Cases: RPT 2012-16092, RPT 2012-16089, PS 2012-16091, PS 2012-16088, PS 2012-16090, PS 2013-06754

Investigator/Date:	Approved By/Date:
Ben Lanier 7/8/13	John M. Sh for 7/8/13
Ben Lanier, BI-35, Investigator	Cathy Martin, Investigator Supervisor

Received
Investigative Services
JUL 09 2013

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JUL 9 PM 3:09

Distribution: HQ/ISU

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Tallahassee HQ

!! CONFIDENTIAL

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INVESTIGATIVE DETAILS

On 2/4/13, Investigator LANIER drove to Cantonment Pharmacy. Upon entering the pharmacy, "EMILY" the cashier asked how she could help. Investigator LANIER stated he had a sinus infection and EMILY told Investigator LANIER to go to the pharmacy consultation window. Investigator LANIER walked to the consultation window and a man, without a name tag, presumably the pharmacist, with short brown hair and a goatee asked how he could help. Investigator LANIER told him that he had a sinus infection and a swollen throat. Investigator LANIER told him that a friend of his had the same thing recently and a Z-pak seemed to help. The pharmacist asked if Investigator LANIER wanted a Z-pak and Investigator LANIER told him yes. The pharmacist asked if Investigator LANIER was taking any kind of Antihistamine and Investigator LANIER told him no. The pharmacist told Investigator LANIER to also purchase an Antihistamine to clear up his sinuses. Investigator LANIER told him that funds were limited and the man said it would be roughly $31.00 in total. There was no counseling offered on how to take either the Z-pak or Antihistamine. EMILY assisted Investigator LANIER check out and asked for Investigator LANIER's driver's license. EMILY wrote down Investigator LANIER's name, address, and driver's license number in a book. Then Investigator LANIER signed the log and left the pharmacy. While in the pharmacy Investigator LANIER did not see a sign offering the sale of Viagra. A "Z-pak" (six Azithromycin 250mg tablets, prescription only medication) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets were provided by the pharmacist.

On 3/28/13, Investigator Supervisor CATHY MARTIN presented to Cantonment Pharmacy with complaints of lingering cough and sore throat. The cashier immediately instructed Investigator Supervisor MARTIN to go the pharmacy window. A man with short brown hair and a goatee, presumably the pharmacist but with no name tag, asked what symptoms were present. The symptoms were repeated to the pharmacist, and he instructed Investigator Supervisor MARTIN to select a bottle of Chloraseptic. He stated, with a wink, that he would add an ingredient to relieve the symptoms. He asked if Investigator Supervisor MARTIN was taking any decongestants, and Investigator Supervisor MARTIN responded no. He asked no other questions. A selection of the orange flavored Chloraseptic was made and Investigator MARTIN returned to the pharmacy window. The pharmacist stated that the orange flavor was not very good and to go back and get the red bottle. Investigator MARTIN did so. The pharmacist took the bottle, and a few minutes later he passed a white paper bag with contents to the cashier. The pharmacist stated that he added Lidocaine to the Chloraseptic. The cashier instructed Investigator MARTIN to approach the counter and provide a driver license. Investigator Supervisor MARTIN did so, and the cashier copied information from the driver license to a worn green ledger. The cashier then instructed Investigator Supervisor MARTIN to enter address information in the log and sign where indicated. Investigator MARTIN did so. During this process, Investigator MARTIN asked what the purpose of the log was, and the cashier stated it was for the Sudafed pills being provided. Investigator MARTIN also asked for the pharmacist's name, and the cashier provided a first name of "Gene." She informed the total was $11.10, and Investigator Supervisor MARTIN provided the cashier a $50 bill. Change of $38.90 was provided, and Investigator Supervisor MARTIN thanked the cashier and the pharmacist and left. The cost of the Chloraseptic was $5.12, and a blue bottle with 24 small white pills was also provided for a cost of $5.98. No prescriptions were presented to the pharmacy, and no instructions for taking the medications were provided. Chloraseptic with Lidocaine added (which requires a prescription) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets were provided by the pharmacist. The pharmacist was not identified on 2/4/13 or 3/28/13.

Thirteen pictures of these medications and receipts from both purchases are provided on CD and included as **EXHIBIT 6**.

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

EXHIBIT 1 is information forwarded by the Consumer Services Unit (CSU) with the complaint. This information consists of a Case Summary, corrected Case Summary, complaint form by MCDONALD, and the following:

- Complaint narrative by MCDONALD noting he was previously employed at Winn-Dixie pharmacy located nearby CANTONMENT PHARMACY. While at work on many occasions, he would have customers ask if he could sell them antibiotics. It was explained to them that a prescription was required, and their response was always that they could obtain them from CANTONMENT PHARMACY. MCDONALD did not believe the customers for the most part, contributing it to CANTONMENT PHARMACY selling something to the customers and telling them it worked almost as good as antibiotics. Through diverging circumstances, MCDONALD became employed at CANTONMENT PHARMACY as a pharmacist. The very first day at work not long after they opened, a customer came up and asked him for antibiotics. MCDONALD told the customer that he had to have a prescription for antibiotics. Throughout the day about six different customers asked him for antibiotics and without fail, every day to this date, they had customers telling him they had purchased antibiotics in the past from one registered pharmacy technician (RPT1) or sometimes another registered pharmacy technician (RPT2) was mentioned, and that they would like to purchase some more. MCDONALD refused and always told the customers that a prescription was required. Antibiotics mentioned to MCDONALD that customers had purchased in the past included Penicillin, Amoxicillin, Z-Pak, Keflex, Flagyl, and Diflucan. As corroborating evidence of this practice of selling antibiotics without a prescription to customers, there are large bottles of Penicillin, Amoxicillin, and SMZ-TMP on a counter near the counseling window, which is outside of the area of stock of all other medications, and separate from its normal location (for filling prescriptions).

  MCDONALD also had several male customers ask to purchase Viagra tablets, stating that they had bought them in the past from RPT1 or sometimes RPT2 and wanted some more. MCDONALD refused and always told the customers a prescription was required. MCDONALD stated there are handwritten signs above/below the Viagra tablets on the prescription stock area of "$24" which indicated that customers are charged $24.00 for each Viagra tablet (sold without a prescription). MCDONALD also had a customer come to the counseling window and ask him for an Albuterol inhaler. After MCDONALD explained that a prescription was needed, the customer stated that he had purchased them before from RPT1 and RPT2, and he became irate that MCDONALD would not sell him an Albuterol inhaler.

  Finally, MCDONALD alleged there is a well-known practice in the community that CANTONMENT PHARMACY sells a "cough syrup" that is mixed at the pharmacy which contains codeine. This is a C-V medication that can be legally sold without a prescription, but it can only be sold by a pharmacist. MCDONALD had several customers tell him they wanted that special "cough syrup" they got from RPT1 or RPT2 in the past. MCDONALD witnessed it being sold to customers by a clerk without consultation of the pharmacist on duty. MCDONALD stated it was a common practice for RPT1 to give medical advice to customers and otherwise infer to customers that he was a licensed pharmacist, and to also sell them prescription medications without a prescription. This was also the case for RPT2, although to a lesser extent.

  MCDONALD listed the licensed employees of the pharmacy who were allegedly guilty of dispensing medications without a prescription. These employees allowed RPT1 to portray himself as a licensed

practitioner prescriber or pharmacist. This technician was allowed to perform duties only allowed by law to be performed by a licensed practitioner prescriber or pharmacist such as 1) diagnosing patients and prescribing prescription medications by virtue of selling the prescription medications to customers without a valid prescription, 2) giving medical advice to customers without consultation of a licensed pharmacist, 3) holding himself as a pharmacist, 4) acting/speaking as a pharmacist over the telephone to other pharmacists in the transfer of prescriptions, without identifying himself as a pharmacy technician, 5) individually selling C-V medications (i.e., cough syrup with codeine) to customers without involvement, consultation, and approval of a pharmacist. MCDONALD noted that the primary principal or violator was RPT1, who had for many years acted as a pharmacist and performed pharmacist-only duties. The owner of the pharmacy is listed as the pharmacist-in-charge, who has a legal responsibility in developing and enforcing policies and procedures for the pharmacy. It is extremely difficult to believe that the owner, although absent from the day to day operations of the pharmacy, is not aware of the violations occurring on a daily basis. The two most recent pharmacists employed by the pharmacy are also participants in these violations by virtue of allowing them to occur while on duty and failing to report them. MCDONALD did not know if those two pharmacists were guilty of selling medications that require a prescription without one, or just knowingly allowed such. MCDONALD stated the pharmacy technicians were not identifying themselves when answering or speaking on the phone and did not regularly wear name tags/badges that readily identify themselves as pharmacy technicians. MCDONALD stated the pharmacy is also in violation by not having an easily accessible sink near the prescription counter.

EXHIBIT 3 is a copy of a letter dated 4/17/13 to MCDONALD informing him of the status of the case.

EXHIBIT 4 is a copy of a letter dated 5/16/13 to CANTONMENT PHARMACY providing a corrected Case Summary. The original Case Summary made two references to Hydrocodone which should have read Hydrochloride.

EXHIBIT 5 is copies of three previous inspection forms dated 9/22/09, 10/18/10, and 1/23/12 for inspections conducted at CANTONMENT PHARMACY printed by Investigator LANIER on 4/18/13. The three previous inspections indicate passing results; however, the inspection form dated 9/22/09 indicated there were some improperly labeled medications found.

EXHIBIT 6 is a copy of thirteen pictures placed on CD by Investigator LANIER. The pictures are of prescription medications purchased from CANTONMENT PHARMACY by Pensacola ISU staff on 2/4/13 and 3/28/13, and the respective receipts, dispensed without providing a prescription. The medications consist of a "Z-pak" (six Azithromycin 250mg tablets, prescription only medication), 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets, Chloraseptic with Lidocaine added (which requires a prescription), and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets.

EXHIBIT 7 is a copy of the formula for the "Cantonment Wine" provided by [redacted] on 4/26/13 to Investigator LANIER at the Pensacola ISU office.

INTERVIEW OF PRESTON MCDONALD, RPH (PS 33121)–SOURCE:
Address of Record:
5740 Westmont Road
Milton, FL 32583
(850) 983-0916

On 11/26/12, Investigator LANIER interviewed MCDONALD by telephone. MCDONALD stated he quit working at CANTONMENT PHARMACY close to a month prior. MCDONALD stated the pharmacy did not keep a record of the medications that customers were buying. MCDONALD stated the cough syrup did not contain full strength codeine and it did not require a prescription, but a pharmacist had to be involved. MCDONALD stated Registered Pharmacy Technicians were also providing the cough syrup to customers. MCDONALD stated he could not specifically remember any patient names to whom prescription medications were sold.

INTERVIEW OF
Address of Record:

Employment: Cantonment Pharmacy
433 Highway 29 South
Cantonment, FL 32533
(850) 968-2489

INTERVIEW OF SUSAN HALFEN, RPH (PS 32697)–WITNESS:
Employment: Winn-Dixie
1550 Hwy 29 North
Cantonment, FL 32533
(850) 968-3318

On 5/10/13 and 5/14/13, Investigator LANIER attempted to telephone HALFEN; however, she was not available and voicemail messages were left requesting a return call.

On 5/15/13, HALFEN returned the call and left a voicemail message for Investigator LANIER stating she was working all day on this date, but that she should be available for Investigator LANIER to call. On the same date, Investigator LANIER returned the call. HALFEN stated she had been a pharmacist at Winn-Dixie for about six years and that their location was very close to CANTONMENT PHARMACY. HALFEN stated that since she started working at Winn-Dixie pharmacy, one to two customers come in every month or so to try and get prescription medications without a prescription. HALFEN stated these customers were mainly seeking antibiotics and told her that they had gotten them in the past without a prescription from CANTONMENT PHARMACY. HALFEN stated she also knew CANTONMENT PHARMACY provided a cough syrup. HALFEN stated she knew pharmacists were allowed to sell the cough syrup. HALFEN stated that was all she really knew about CANTONMENT PHARMACY's operation.

INTERVIEW/STATEMENT OF JOHN T. READING, JR., ON BEHALF OF CANTONMENT PHARMACY, INC., PHARMCY–SUBJECT:
Address of Record:
433 Highway 29 South
Cantonment, FL 32533
(850) 968-2489

On 5/17/13, Investigator LANIER interviewed JOHN T. READING by telephone. Investigator LANIER asked READING who would be responding on behalf of the pharmacy and READING stated he would provide a response for the pharmacy in the near future.

On 5/21/13 by US mail, Investigator LANIER received READING statement on behalf of CANTONMENT PHARMACY. READING stated this letter came as a result of the telephone conversation last week. READING stated he would go through the complaint in the same order that MCDONALD had written it.

FS 456.072(1)(k)(n)(dd), FS 465.016 (1)(i)(r), and FS 465.023 (1)(c) all pertain to dispensing without a legitimate prescription. The allegations were denied to each with the exception that for 45 years they have sold many antibiotics for animals (almost exclusively Penicillin injections) and generic Septra DS tablets for horses. CANTONMENT PHARMACY carries a fairly extensive line of almost everything one would need for animals and there is a veterinarian across the street that calls in prescriptions to them **[INVESTIGATOR'S NOTE:** On 7/2/13, Investigator LANIER spoke with Senior Pharmacist JOHN TAYLOR, who informed that a pharmacist could fill a prescription for an animal if they wanted to, but that a prescription was still required. Any medication that would be required for a human would still be required for an animal.]

READING stated that on 2/4/13, he did not believe he was working at the pharmacy and therefore must claim that he is without knowledge of what went on. On 3/28/13, READING was able to establish that he was definitely not working as that was a long weekend off for him. READING typically works every day until 1:00pm and he is off every other Thursday through Sunday. READING could not say what happened on that date. One of the allegations is that 24 Aprodine were sold to an ISU Investigator and the allegation is that the formula is Pseudoephedrine Hydrocodone 60 mgm and Triprolidine Hydrochloride 2.5 mgm. For sinus decongestant, CANTONMENT PHARMACY sells almost exclusively Aprodine; however, it is always signed for and it has absolutely no Hydrocodone in it. READING stated that if someone wanted to examine their signature log, they would find that the ISU investigator did sign for it as the law required. READING stated the Hydrocodone listed as an ingredient was probably a typographical error in the Case Summary. Everyone at CANTONMENT PHARMACY is periodically tested on the amount of Pseudoephedrine that could be sold at a time and they have never exceeded that quantity.

If a Z-Pak was sold, READING had no knowledge of it, and after questioning, he was no further to answering the question. In regard to the purchase of Chloraseptic with Lidocaine, Chloraseptic is one of their most recommended products. They do not suggest adding anything to it, but frequently suggest getting an item from the grocery store to reduce any swelling that is apparent in their throat. That item is artificial lemon juice and is a standard, well known in the "home remedies" book of most pharmacies. Variations of that theme also include a shot of whiskey and/or a shot of honey. The pharmacy recommends neither of them as they believe that the benefits accrued from the astringent quality of the juice and anything else would dilute that quality. Digging in to the matter, READING was more successful as noted in the answer of another response. Apparently MCDONALD was present that day and their Lidocaine viscous is stored appropriately in the back and at the

bottom of their antibiotic section. READING stated that he had already determined that he was not there on the particular date and perhaps his answer should have just been a simple "denial, or without knowledge."

READING stated no pharmacist ever worked directly with MCDONALD; however, both pharmacy technicians worked quite a bit with MCDONALD, and both deny his allegations. If something as alleged had occurred, it would have been in relatively tight quarters with MCDONALD and so MCDONALD should have stopped anything like he said. When MCDONALD was working for CANTONMENT PHARMACY and people came to the counseling window, MCDONALD was almost always called over to be introduced to the patient and be involved with any discussions.

Every employee, not just technicians and pharmacists, is checked for name tags every day that READING is present. READING stated that over the past inspections, they have never been citied for failure to wear a name tag and only on one occasion have they been asked to do something additional to the prescription files. No inspector has ever said anything about the location of the sink in the prescription department. Leading to it is a doorway that is always open and they have a large opening that the data entry person can look through and see the sink.

Allegations of selling Viagra are probably confused with other pills that they sell a great number of that do not require a prescription. They are not represented as Viagra but they are blue capsules. The name is Orexis and they order them from Amazon.com. They are very popular and are more expensive each time the pharmacy buys them. The pharmacy has other tablets that are generally referred to as "nature pills, for men." They sell a great deal more of them than the Orexis. They have two versions, one is called Bomba and the other is called Bomba-365. None of them require a prescription, but they keep them behind the counter as the men coming to the counseling window do not generally wish for the ladies in the store to know what they are purchasing. The product is placed in a sack with the price on it and the customer takes it to the cash register.

Antibiotic bottles that are kept near the ordering computer and not in the regular section are usually items that they are shopping their suppliers on prices for and usually contain only a few tablets. Two examples are Penicillin and Doxycycline, which have had huge price increases this year. Controlling inventory is key to correct market pricing of prescriptions.

MCDONALD made one allegation of a single request from a customer for an Albuterol inhaler saying that he bought it from the pharmacy in the past without a prescription. Albuterol inhalers were taken off the market about two years ago and replaced with three much more expensive alternatives. Because older generic albuterol was taken off the market, READING did not know what to say other than it was likely that someone might have asked for an Albuterol inhaler. Many if not most of their customers come in and ask for their medications by name and if they know their Rx numbers they usually call them in so that the medications will be ready when they come into the pharmacy.

The pharmacy does have a cough syrup that they make up and have sold for years which does contain codeine and every sale is recorded. It is a combination of generic Robitussin AC mixed with plain over the counter generic Benadryl. When they mix this they are diluting the legal codeine concentration of the cough syrup. The cough syrup is labeled appropriately and they do not make it more than one or two liters at a time depending on whether it is cold and allergy season. The pharmacy had a manufacturing license and found that they did not sell enough of anything to justify the license and so they do not make more than one or two

days' supply at a time. The lot number and expiration date is put on the label according to which ingredient has the codeine in it.

MCDONALD stated that he did not know if the other pharmacists violated any statutes but he had thrown them in for good measure. MCDONALD focused on RPT1 and RPT2 because almost everyone knows their names and calls them by name, as they call their customers by name. RPT 1 has been at CANTONMENT PHARMACY for over 40 years.

[INVESTIGATOR'S NOTE: On 6/26/13, Investigator LANIER interviewed READING by telephone. READING stated he was closing CANTONMENT PHARMACY on 7/8/13, for good.]

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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April 17, 2013

CONFIDENTIAL

Preston E. McDonald, RPH
5740 Westmont Road
Milton, FL 32583

Reference Number: PH 2012-16087
Subject: Cantonment Pharmacy Inc.

Dear Mr. McDonald:

Please be advised that the Investigative Services Unit is conducting an investigation on Cantonment Pharmacy Inc., and I am the investigator assigned to your case.

Florida law requires that all information in a complaint remain confidential until 10 days after probable cause is found. Patient names and records are never released to the public.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please call me at (850) 475-5470. In addition, if you have any concerns or suggestions about our complaint process, please fill-out our *Customer Concerns or Suggestions* form at www.floridashealth.com/mqa/survey.html.

Sincerely,

Ben Lanier
Investigator

CONFIDENTIAL AND EXEMPT MATERIALS

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

File # 498

Insp # 86062

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT CANTONMENT PHARMACY INC	PERMIT NUMBER 2748	DATE OF INSPECTION 9/22/2009
DOING BUSINESS AS	DEA NUMBER AC5573767	PRESCRIPTION DEPARTMENT MANAGER JOHN T READING
STREET ADDRESS 433 HIGHWAY 29 S	TELEPHONE # 850-968-2489 EXT.	
CITY CANTONMENT / COUNTY 27	STATE/ZIP 32533-1401	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 10065

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	6pm	6pm	6pm	6pm	6pm	3pm	

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Benjamin Fenn PS 13028
2. Johnny Reading PTech
3. Karen Bonanno PTech

	SATISFACTORY	N/A	YES	NO
1 Current pharmacy permit displayed. [465.015(1)(a),F.S.]			X	
2 Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]			X	
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4 Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]			X	
5 Intems properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]			X	
6 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			X	
7 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]			X	
8 Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]			X	
9 Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.			X	
10 Generic drug sign displayed. [465.025(7),F.S.]			X	
11 Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]			X	
12 Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*		X		
13 Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]			X	
14 Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]			X	
15 Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]			X	
16 Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			X	
17 Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]			X	
18 Prescription department clean and safe. [64B16-28.105,F.A.C.]			X	
19 Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]			X	
20 Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]			X	
21 Medication properly labeled [64B16-27.101,F.A.C.]				X
22 All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]			X	
23 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]			X	
24 Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]			X	
25 "Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]			X	
26 All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]			X	
27 Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]			X	
28 Complete pharmacy prescription records. [64B16-28.140,F.A.C.]			X	
29 Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]			X	
30 Controlled substance records readily retrievable. [893.07,F.S.]			X	
31 Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]			X	
32 Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]			X	
33 Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			X	
34 Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]			X	
35 All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			X	
36 Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]			X	
37 Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			X	
38 Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]			X	
39 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]			X	
40 DEA 222 order forms properly completed. [893.07(2),F.S.]			X	
41 Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*			X	
42 Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]			X	
43 Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]			X	
44 Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *			X	
45 Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *		X		
46 Compounding records properly maintained [64B16-28.140(4),F.A.C.] *		X		
47 Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *		X		

** Questions with (*) may be answered n/a (not applicable).*

Remarks: Missy Shores PTech. #3 DEA expires 8-31-2011. #5 NA. #7 Tech ratio letter 6-22-1994. #21 Two bottles of OTC drug in pharmacy stock without expiration date. #23 Last CQI meeting 9-15-2009. #39 CS inventory 5-1-2009. #44 Logbook. Rx drug purchases from Smith Drug, AmerisourceBergen, Masters, & Top Rx.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Benjamin Fenn, RPh

ID: ci20

Institutional Representative

09-22-2009
Date

Investigator/Sr. Pharmacist Signature

INV 359 Revised 01/07 Replaces 12/02

Exhibit 5

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 498

Insp # 94915

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT CANTONMENT PHARMACY INC		PERMIT NUMBER 2748	DATE OF INSPECTION 10/18/2010
DOING BUSINESS AS		DEA NUMBER AC5573767	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 433 HIGHWAY 29 S		TELEPHONE # 850-968-2489 EXT.	JOHN T READING
CITY CANTONMENT	COUNTY 27	STATE/ZIP 32533-1401	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 10065

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	6pm	6pm	6pm	6pm	6pm	3pm	

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Benjamin Fenn PS 13028
2. Wilton Glover PS 7751
3. Melissa Shores RPT 21008

	SATISFACTORY	N/A	YES	NO
1 Current pharmacy permit displayed. [465.015(1)(a),F.S.]			X	
2 Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]			X	
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4 Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]			X	
5 Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]			X	
6 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			X	
7 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]			X	
8 Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]			X	
9 Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.			X	
10 Generic drug sign displayed. [465.025(7),F.S.]			X	
11 Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]			X	
12 Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*		X		
13 Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]			X	
14 Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]			X	
15 Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]			X	
16 Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			X	
17 Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]			X	
18 Prescription department clean and safe. [64B16-28.105,F.A.C.]			X	
19 Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]			X	
20 Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]			X	
21 Medication properly labeled [64B16-27.101,F.A.C.]			X	
22 All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]			X	
23 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]			X	
24 Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]			X	
25 "Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]			X	

	SATISFACTORY	N/A	YES	NO
26 All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]			X	
27 Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]			X	
28 Complete pharmacy prescription records. [64B16-28.140,F.A.C.]			X	
29 Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]			X	
30 Controlled substance records readily retrievable. [893.07,F.S.]			X	
31 Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]			X	
32 Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]			X	
33 Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			X	
34 Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]			X	
35 All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			X	
36 Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]			X	
37 Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			X	
38 Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]			X	
39 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]			X	
40 DEA 222 order forms properly completed. [893.07(2),F.S.]			X	
41 Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*			X	
42 Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]			X	
43 Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]			X	
44 Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *			X	
45 Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *			X	
46 Compounding records properly maintained [64B16-28.140(4),F.A.C.] *			X	
47 Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *			X	

** Questions with (*) may be answered n/a (not applicable).*

Remarks: Leslie Johnson RPT 21005; John Reading, Jr. RPT 21007. #3 DEA expires 8-31-2011. #5 NA. #7 Tech ratio letter 6-22-1994. #23 Last CQI meeting #39 CS inventory #43 Book - OK. #44 Logbook. Rx drug purchases from Smith Drug-Valdosta and AmerisourceBergen-Orlando.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Benjamin Fenn, RPh

Institutional Representative

10-18-2010
Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

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File # 498

Insp # 103821

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
CANTONMENT PHARMACY INC	2748	1/23/2012
DOING BUSINESS AS	DEA NUMBER Ac5573767	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 433 HIGHWAY 29 S	TELEPHONE # 850-968-2489 EXT.	JOHN T READING
CITY CANTONMENT / COUNTY 27	STATE/ZIP 32533-1401	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 10065

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1. Joseph Gibson PS 26203	
Open	9am	9am	9am	9am	9am	9am	closed	2. Benjamin Fenn PS 13028	
Close	6pm	6pm	6pm	6pm	6pm	3pm		3. Melissa Shores RPT 21008	

	SATISFACTORY	N/A	YES	NO
1 Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2 Pharmacy technicians properly identified and supervised. [64B16-27.410, F.A.C.]			X	
3 Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4 Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			X	
5 A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6 Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7 Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			X	
8 Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9 Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10 Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11 CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			X	
12 Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]		X		
13 Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
14 Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15 All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16 Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
17 Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]			X	
19 DEA 222 order forms properly completed. [893.07, F.S.]			X	
20 Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
21 Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]			X	
22 Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			X	
23 Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]			X	
24 Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	X			
25 Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	X			
26 Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]			X	
27 Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]	X			
28 Compounding records properly maintained. [64B16-27.700, F.A.C.]*	X			
29 Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]	X			
30 Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			X	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: Adam Bass RPT 21001; John Reading RPT 21007; Karin Bonano RPT 21006; Leslie Johnson RPT 21005. DEA expires 8-31-2014. #2 Tech ratio letter 6-22-1994. #11 Last CQI meeting 9-1-2011. #12 Future requirement. #18 CS inventory 5-1-2011. #22 Logbook. #23 One incident - Escambia CSO. #24 None since 7-1-2011.
CII prescription file survey (60Rxs): Local Practitioner - 97%; Local Patient - 100%; Pain Therapy - 78%; Non-pain Therapy - 22%.
No batch compounding. No compounding for practitioner office stock.
Rx drug suppliers: Smith Drug-Valdosta; AmericansourceBergen-Orlando.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Joseph Gibson, RPh

Institutional Representative

01-23-2012
Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

DOH CASE # PH 2012-16087

CANTONMENT PHARMACY

CD containing 13 pictures of medications

Exhibit 6

35-47

Manufactured by:
Wockhardt Limited,
Mumbai, INDIA.

*Each film-coated tablet contains azithromycin anhydrous equivalent to 250 mg of azithromycin.

Usual Dosage: See accompanying prescribing information.

This blister card package is not child-resistant.

RECOMMENDED STORAGE: Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].

Your healthcare provider has been provided with full prescribing information for azithromycin.

Affix pharmacy label here.

Distributed by:
Wockhardt USA LLC.
20 Waterview Blvd.
Parsippany, NJ 07054
USA.

LOT LM10588
EXP APR 2015

Rev.131010

211282

MH/DRUGS/101

NDC 64679-961-04

Azithromycin 250 mg*
Tablets

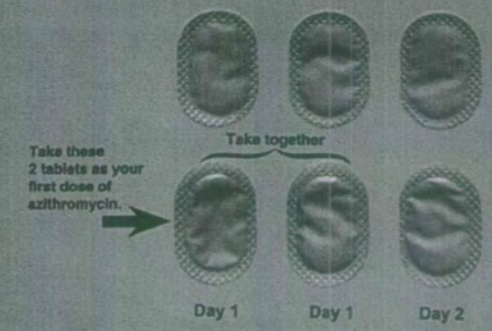
A full course of antibiotic therapy in just 5 doses

Rx only

WOCKHARDT

1 Card x Six 250 mg* Tablets

To remove, push tablets through from other side.



Manufactured by:
Wockhardt Limited,
Mumbai, INDIA.

*Each film-coated tablet contains azithromycin anhydrous equivalent to 250 mg of azithromycin.

Usual Dosage: See accompanying prescribing information.

This blister card package is not child-resistant.

RECOMMENDED STORAGE: Store at 20°-25°C (68°-77°F) [See USP Controlled Room Temperature].

Your healthcare provider has been provided with full prescribing information for azithromycin.

Distributed by:
Wockhardt USA LLC.
20 Waterview Blvd.
Parsippany, NJ 07054
USA.

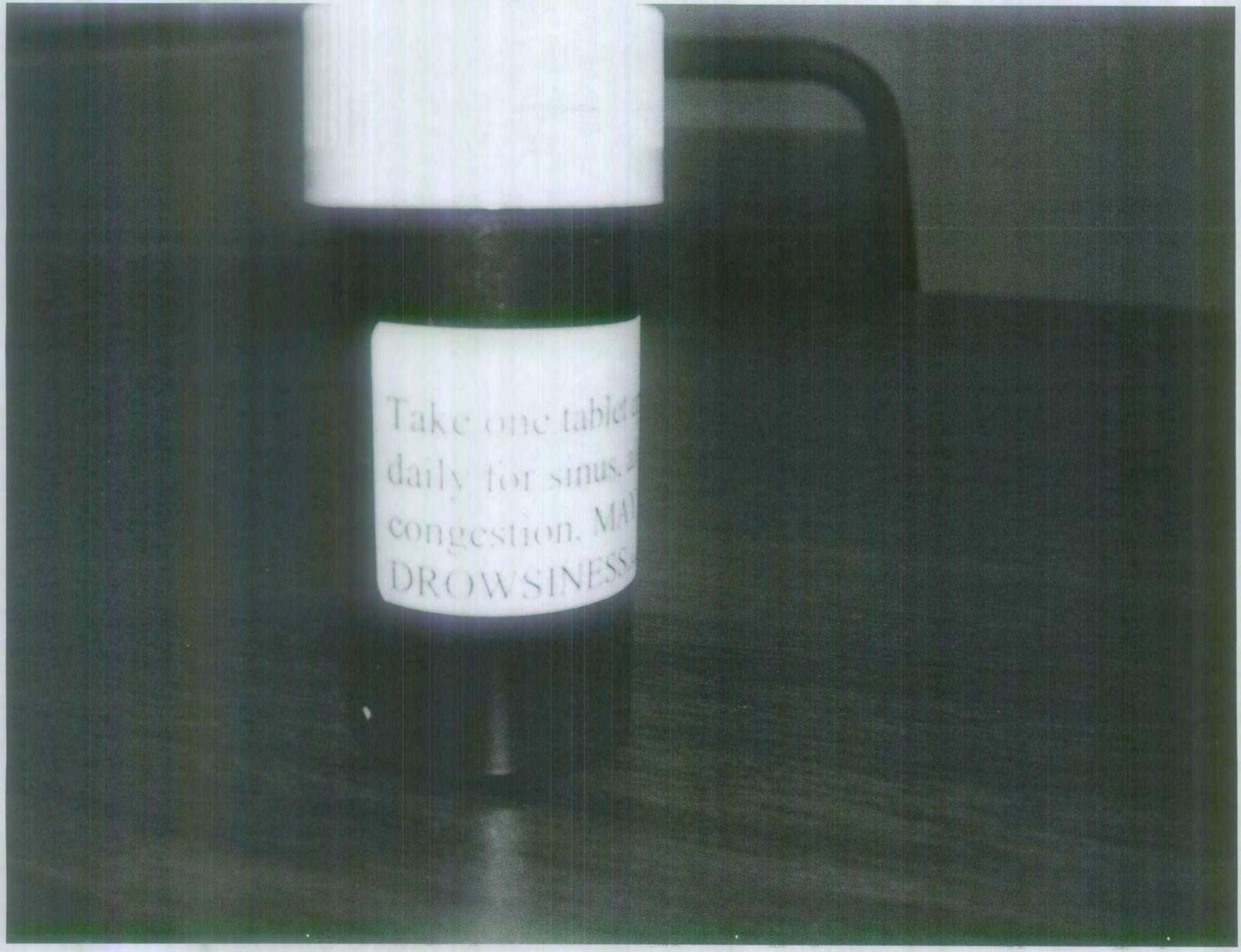
Rev.131010

Affix pharmacy label here.

LOT LM10656
EXP APR 2015

211282

MH/DRUGS/101


Take one tablet
daily for sinus
congestion. MA
DROWSINESS

CANTONMENT PHARMACY
433 HIGHWAY 29 SOUTH
CANTONMENT,FL 32533
850-968-2489

Description	Qty	Total
NON-TAXABLE	1	24.98
NON-TAXABLE	1	5.98

(F) = ELIGIBLE FLEXIBLE SPENDING ACCOUNT ITEM (FSA)

Discounts	0.00
SubTotal	30.96
Tax	0.00
Total	30.96
CASH	40.00

Change Due $9.04
Items 2

Receipt # 95235
Register #
DateTime: 2/4/2013 5:38:21PM

THANK YOU SO MUCH AND COME BACK AND SEE US!!!!!

NDC 64679-961-04

Azithromycin
Tablets

250 mg*

A full course of antibiotic therapy in just 5 doses

Rx only

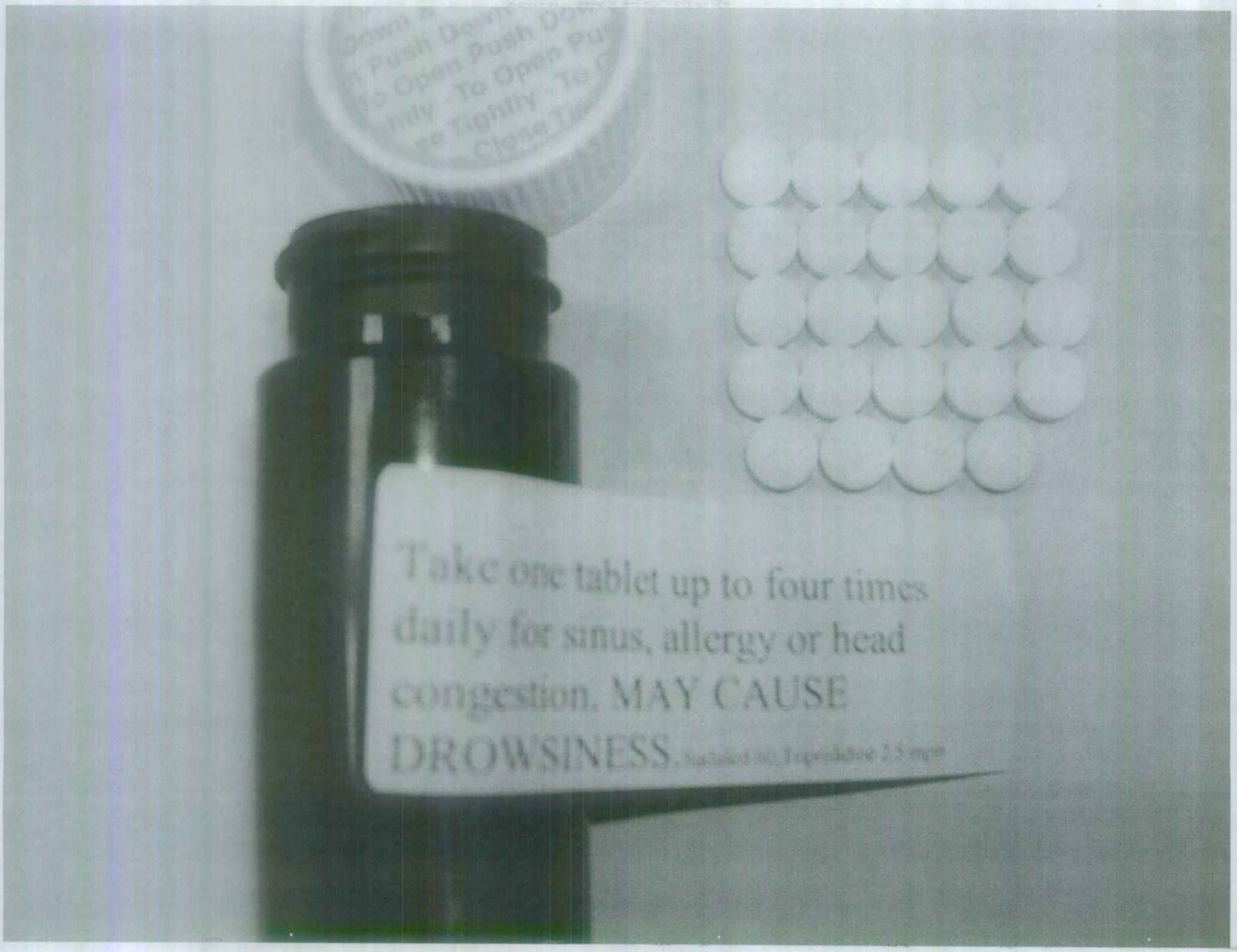
WOCKHARDT

1 Card x Six 250 mg* Tablets

Get to know your neighbor.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

ABC# 786614


Take one tablet up to four times
daily for sinus, allergy or head
congestion. MAY CAUSE
DROWSINESS.

One Touch Relief.
The Chloraseptic Touch.
#1
Chloraseptic
SORE THROAT
Real Relief. Real Fast
Relieves Sore Throat Pain
CHERRY | 6 fl oz (177mL)
Total
5.12
5.98

PRESCRIPTIONS

SAVE FOR TAX OR INSURANCE RECORDS

DATE _____

FOR _____

ADDRESS _____

DOCTOR _____

Rx No. _____ $ _____

Rx No. _____ $ _____

Rx No. _____ $ _____

Rx No. _____ $ _____

PHARM. _____ TAX $ _____

Thank You TOTAL $ _____

HealthWise PHARMACY

Take one tablet up to four times daily for sinus, allergy or head congestion. MAY CAUSE DROWSINESS. Sudafed 60, Triprolidine 2.5 mgm

CANTONMENT PHARMACY
433 HIGHWAY 29 SOUTH
CANTONMENT, FL 32533
850-968-2489

Description	Qty	Total
CHLORSEPTC SF	1	5.12
NON-TAXABLE	1	5.98

(F) = ELIGIBLE FLEXIBLE SPENDING ACCOUNT ITEM (FSA)

Discounts	0.00
SubTotal	11.10
Tax	0.00
Total	11.10
CASH	50.00

Change Due $38.90
Items 2

Receipt # 98983
Register #
DateTime: 3/27/2013 5:40:59PM

THANK YOU SO MUCH AND COME BACK AND SEE US!!!!!

Touch Relief.
Chloraseptic
SORE THROAT
Real Relief.
Relieves Sore Throat Pain
CHERRY | 6 fl oz (177mL)

PRESCRIPTIONS

SAVE FOR TAX OR INSURANCE RECORDS

DATE _____

FOR _____

ADDRESS _____

DOCTOR _____

Rx No. _____ $ _____

Rx No. _____ $ _____

Rx No. _____ $ _____

Rx No. _____ $ _____

PHARM. _____ TAX $ _____

Thank You TOTAL $ _____

HealthWise PHARMACY

Take one tablet up to four times daily for sinus, allergy or head congestion. MAY CAUSE DROWSINESS. Sudafed 60, Triprolidine 2.5 mgm

CANTONMENT PHARMACY
433 HIGHWAY 29 SOUTH
CANTONMENT, FL 32533
850-968-2489

Description	Qty	Total
CHLORSEPTC SF	1	5.12
NON-TAXABLE	1	5.98

(F) = ELIGIBLE FLEXIBLE SPENDING ACCOUNT ITEM (FSA)

Discounts	0.00
SubTotal	11.10
Tax	0.00
Total	11.10
CASH	50.00

Change Due $38.90
Items 2

Receipt # 98983
Register #
DateTime 3/27/2013 5:40:59PM

THANK YOU SO MUCH AND COME BACK AND SEE US!!!!!

modified formula WKRP Formula

SK&F

Tuss-Ornade®

Each capsule contains 40 mg. of caramiphen edisylate and 75 mg. of phenylpropanolamine HCl

Spansule® ℞ AGOS Radio 1620

brand of sustained release capsules

– Roger Hitchcock

Healthy MAN

TUES – 4/23/13 8:45 pm

– 1-800-530-6595

Advertisement

– 40 VIAGRA for $300/Each

1-877 – Roger 70437

Formula for the '80s

See back for complete prescribing information

1-877847 – 6437

Exhibit 1

00048

(5) **SCHEDULE V** – A substance, compound, mixture, or preparation of a substance in Schedule V has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.

(a) Substances controlled in Schedule V include any compound, mixture, or preparation containing any of the following limited quantities of controlled substances, which shall include one or more active medicinal ingredients which are not controlled substances in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the controlled substance alone:

1. **Not more than 200 milligrams of codeine per 100 milliliters** or per 100 grams. = 120 mg/120 cc
2. Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.
3. Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.
4. **Not more than 2.5 milligrams of diphenoxylate** and not less than 25 micrograms of atropine sulfate per dosage unit.

- CHERATUSSIN AC NDC 0603-1075-58
  - 10 mg/5 cc Codeine phosphate, USP (cough suppressant)
  - 100 mg/5 cc Guaifenesin, USP (Expectorant)

2 g = 60 cc

~~8 mg / 60 cc~~ ~~10 mg / 5 cc~~ x mg = 120 mg

Cut with/Add 2 g of Benadryl (Bonadryl Oral Soln) 12.5 g/5 cc Diphenhydramine HCL, USP

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

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Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201302904

GULF MEDICAL SERVICES INC,
RESPONDENT.

NOTICE

TO: GULF MEDICAL SERVICES INC
6776 CAROLINE STREET
MILTON, FL 32570

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Determination of Waiver

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Mary Miller, Assistant General Counsel
RE: Determination of Waiver
SUBJECT: DOH v. Gulf Medical Services, Inc.
DOH Case Number 2013-02904
DATE: December 13, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Gulf Medical Services, Inc.
Subject's Address of Record:	6776 Caroline Street Milton, FL 32570
Enforcement Address:	6776 Caroline Street Milton, FL 32570
Subject's License No:	18700 **Rank:** PH
Licensure File No:	10801
Initial Licensure Date:	8/12/2002
Board Certification:	None
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Count 1: Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-27.797(1)(i)(4), F.A.C. Count 2: Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-27.797(1)(i)7, F.A.C.
Prior Discipline:	None
Probable Cause Panel:	June 27, 2013 Fallon and Glass
Subject's Attorney:	Pro Se
Complainant/Address:	Department of Health/Investigative Services Unit-Tallahassee

Materials Submitted:

Memorandum to the Board
Motion for Determination of Waiver
Exhibit A – Administrative Complaint
Exhibit B – Copy of certified mail receipt
Exhibit C – Board affidavit
Exhibit D – Clerk affidavit
Prosecutor's documents
Motion to Assess Costs with
Exhibit A – Affidavit of Fees and Costs Extended
Exhibit 1 – Complaint Cost Summary
Exhibit 2 – Itemized Cost by Complaint
PCP Memo
Final Investigative Report Exhibits 1 – 5

Disciplinary Guidelines:

None.

PRELIMINARY CASE REMARKS: DETERMINATION OF WAIVER

On or about 2/11/13, the Department conducted a routine inspection of Respondent. On or about 2/11/13, the Department's inspector noted the Respondent's sterilized high-risk preparations did not pass a sterility test or were not properly stored as required by board rule. The Department's inspector also noted that the Respondent's high-risk compounding personnel had not completed a media-filled test with a high-risk test kit on a semi-annual basis, as required by board rule.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-02904**

GULF MEDICAL SERVICES, INC.,

Respondent.
_____/

MOTION FOR DETERMINATION OF WAIVER AND FOR FINAL ORDER AFTER A HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

PETITIONER, the Florida Department of Health, by and through the undersigned counsel, hereby moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore Petitioner states:

1. An Administrative Complaint was filed against Respondent on June 27, 2013. A copy of said Administrative Complaint is attached hereto as Petitioner's Exhibit A.

2. Copies of the Administrative Complaint, Explanation of Rights form, and Election of Rights form were successfully served on Respondent via certified US mail on: October 21, 2013 (7196 9008 9111 8826 3449). A copy of the certified mail receipt is attached as Petitioner's Exhibit B.

3. Rule 28-106.111(2), Florida Administrative Code, provides in pertinent part that:

> . . . persons seeking a hearing on an agency decision which does or may determine their substantial interests shall file a petition for hearing with the agency within 21 days of receipt of written notice of the decision.

4. Rule 28.106.111(4), Florida Administrative Code, provides that:

> Any person who received written notice of an agency decision and who fails to file a written request for a hearing within 21 days waives the right to request a hearing on such matters.

5. Respondent has not filed an Election of Rights form, or any other responsive pleading, with Petitioner or the Board of Pharmacy within the required twenty-one (21) day period of time. Copies of affidavits supporting the same are attached hereto as Petitioner's Exhibits C & D.

6. Based upon the foregoing, Respondent has waived the right to dispute any materials facts contained within the Administrative Complaint. Therefore, there are no disputed issues of material fact to be resolved by the Board.

7. Respondent has been advised by way of this Motion, that a copy of the investigative file in this case will be furnished to the Board, establishing a prima facie case regarding the violations as set forth in the Complaint.

WHEREFORE, Petitioner respectfully requests that the Board find that Respondent has waived the right to dispute any materials facts contained within the Administrative Complaint and enter a Final Order imposing whatever discipline upon Respondent's license that the Board deems appropriate.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Mary S. Miller
Assistant General Counsel
Fla. Bar No. **0784202**
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683
Email: Mary.Miller2@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 16th day of December, 2013, to: Gulf Medical Services, Inc., 6776 Caroline Street, Milton, FL 32570

Mary S. M

Mary S. Miller
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-02904**

GULF MEDICAL SERVICES, INC.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Gulf Medical Services, Inc., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a permitted community pharmacy within the state of Florida, having been issued permit number PH 16983.

EXHIBIT
A

3. Respondent's address of record is 6776 Caroline Street, Milton, Florida 32570.

4. On or about February 11, 2013, a Department inspector conducted an inspection of Respondent at 6776 Caroline Street, Milton, Florida 32570.

5. On or about February 11, 2013, the Department inspector noted the following deficiencies during the inspection:

a. Sterilized high-risk preparations did not pass sterility test or preparations were not properly stored; and/or

b. Personnel authorized to compound high-risk compounded sterile preparations (CSPs), had not completed a media-filled test with high-risk test kit on a semi-annual basis.

COUNT ONE

6. Petitioner realleges and incorporates paragraphs one through five as if fully set forth herein.

7. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy

permittee who violated any of the requirements of Chapter 465, Florida Statutes or any of the rules of the Board of Pharmacy.

8. Rule 64B16-27.797(1)(i)(4), Florida Administrative Code, states the standard of practice for storing High-Risk Level CSPs, in the absence of passing a sterility test, cannot exceed specified time periods enumerated in the rule.

9. On or about February 11, 2013, a Department inspector observed Respondent store High-Risk Level CSPs in the absence of passing a sterility test in time periods exceeding the specified time periods for the standard of practice.

10. Based on the foregoing, Respondent violated Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-27.797(1)(i)(4), Florida Administrative Code, which requires storage of High-Risk Level CSPs to be stored within specified time periods, in the absence of a sterility test for the High-Risk CSPs.

COUNT TWO

11. Petitioner realleges and incorporates paragraphs one through five as if fully set forth herein.

12. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee

and may fine, place on probation, or otherwise discipline any pharmacy permittee who violated any of the requirements of Chapter 465, Florida Statutes or any of the rules of the Board of Pharmacy.

13. Rule 64B16-27.797(1)(i)7, Florida Administrative Code, provides that all compounding personnel are required to demonstrate competency by completing a media-filled test that represents high-level compounding on an semi-annual basis.

14. On or about February 11, 2013, a Department inspector observed Respondent's compounding personnel had not completed a media-filled test that represents high-level compounding on an semi-annual basis.

15. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-27.797(1)(i)7, Florida Administrative Code, which requires that all compounding personnel complete a media-filled test that represents high-level compounding on a semi-annual basis.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand,

placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 27th day of June, 2013.

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and Secretary of Health

Mary S. Miller

Mary S. Miller
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No. 0784202
(850) 245-4444, extension 8104 (telephone)
(850) 245-4683 facsimile
Mary_Miller2@doh.state.fl.us (E-Mail)

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUN 27 2013

PCP: June 27, 2013
PCP Members: Fallon + Glass
/MSM

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

7196 9008 9111 8826 3449

TO:

SA
Pauline/MSM
Date Mailed 10/17/2013
2013-02904

SENDER:

REFERENCE: Gulf Medical Services, Inc

Mr. Michael Halfren
Gulf Medical Services, Inc.
6776 Caroline Street
Milton, Florida 32570

PS Form 3800, January 2005

RETURN RECEIPT SERVICE		
	Postage	
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

USPS®
Receipt for Certified Mail™
No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

2. Article Number

7196 9008 9111 8826 3449

3. Service Type CERTIFIED MAIL™

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Michael Halfren
Gulf Medical Services, Inc.
6776 Caroline Street
Milton, Florida 32570

SA 201302904
Pauline/MSM

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly)

B. Date of Delivery 10/21/13

C. Signature

X

☐ Agent
☐ Addressee

D. Is delivery address different from item 1?
If YES, enter delivery address below:

☐ Yes
☐ No

Reference Information

2013 OCT 23 AM 9:15

PRACTITIONER REGULATION
LEGAL

PS Form 3811, January 2005 Domestic Return Receipt

Gulf Medical Services, Inc.

EXHIBIT
B

7196 9008 9111 1387 2227

TO:

STIP PACK
Pauline/MSM
Date Mailed 10/14/2013
2013-02904

SENDER:

Gulf Medical Services, Inc.

REFERENCE:

Gulf Medical Services, Inc.
6776 Caroline Street
Milton, Florida 32570

PS Form 3800, January 2005

RETURN RECEIPT SERVICE		
	Postage	
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

USPS®
Receipt for Certified Mail™

No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

2. Article Number

7196 9008 9111 1387 2227

3. Service Type **CERTIFIED MAIL™**

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Gulf Medical Services, Inc.
6776 Caroline Street
Milton, Florida 32570

STIP PACK 2013-02904
Pauline/MSM

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly)

B. Date of Delivery 10/16/13

C. Signature

X ☐ Agent ☐ Addressee

D. Is delivery address different from item 1? ☐ Yes ☐ No
If YES, enter delivery address below:

Reference Information

2013 OCT 21 AM 9:35

PRACTITIONER REGULATION
LEGAL

PS Form 3811, January 2005 Domestic Return Receipt

I, Tammy Collins, hereby certify in my official capacity as custodian for the Board of Pharmacy's licensure files that the Board of Pharmacy as of December 10 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **CASE NAME: Gulf Medical Services, Inc., CASE NUMBER: 2013-02904** which would affect the Subject's substantial interests or rights.

Tammy Collins
Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Tammy Collins, whose identity is known to me personally (type of identification) and who, under, oath, acknowledges that his/her signature appears above.

Sworn to and subscribed this 10th day of Dec, 2013.

Lorraine Gail Curry
Notary Public

LORRAINE GAIL CURRY
MY COMMISSION # EE 97887
EXPIRES: May 26, 2015
Bonded Thru Notary Public Underwriters

EXHIBIT
C

AFFIDAVIT

I, Bridget Coates, Deputy Clerk for the Department Clerk's Office, hereby certify in my official capacity as custodian for the Department Clerk's records, that the Department Clerk's Office has not received an Election of Rights form or other responsive pleading, which requests a hearing prior to any Department action regarding **Case Name: Gulf Medical Services, Inc. Case No.: 2013-02904**, which would affect the Respondent's substantial interests or rights.

Bridget Coates
Custodian of Record
Department Clerk's Office

Before me, personally appeared Bridget Coates whose identity is known to me by personally known (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 9th day of December, 2013.

Angela Barton
Notary Public

My Commission Expires:

ANGELA BARTON
Notary Public - State of Florida
My Comm. Expires Sep 1, 2017
Commission # FF 49339
Bonded Through National Notary Assn.

EXHIBIT
D

STATE OF FLORIDA
DEPARTMENT OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-02904**

GULF MEDICAL SERVICES, INC.,

Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or after July 1,

> 2001, pursuant to this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. . . .

3. The investigation and prosecution of this case has resulted in costs in the total amount of $530.62, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**0.20**	**$10.98**
Investigation:	**4.90**	**$243.13**
Legal:	**2.60**	**$276.51**
Compliance:	**0.00**	**0.00**
Sub Total:	**7.70**	**$530.62**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$530.62**

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $254.11 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $254.11 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $254.11.

DATED this 16th day of December, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Mary S. Miller
Assistant General Counsel
Fla. Bar No. **0784202**
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: Mary.Miller2@flheath.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 16th day of December, 2013, to: Gulf Medical Services, Inc., 6776 Caroline Street, Milton, FL 32570.

Mary S. Miller
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2013-02904** (Department of Health v. **GULF MEDICAL SERVICES, INC.**) are **FIVE HUNDRED THIRTY DOLLARS AND SIXTY-TWO CENTS ($530.62).**

6) The costs for DOH case numbers **2013-02904** (Department of Health v. **GULF MEDICAL SERVICES, INC.**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case numbers **2013-02904** (Department of Health v. **GULF MEDICAL SERVICES, INC.**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to

EXHIBIT
A

keep track of their time in six-minute increments (e.g., investigators and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of her knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 10 day of December, 2013, by Shane Walters, who is personally known to me.

Notary Signature

Antoinette Carter

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

ANTOINETTE F. CARTER
MY COMMISSION EXPIRES
September 26, 2015
#EE 132192
Bonded thru
Troy Fain Insurance
NOTARY PUBLIC, STATE OF FLORIDA

Complaint Cost Summary

Complaint Number: 201302904

Subject's Name: GULF MEDICAL SERVICES, INC

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.20	$10.98
Investigation:	4.90	$243.13
Legal:	2.60	$276.51
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	7.70	$530.62
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$530.62

EXHIBIT

tabbies

1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201302904

Report Date 12/10/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA167	0.20	$54.90	$10.98	02/22/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
Sub Total	**0.20**		**$10.98**			
PROSECUTION SERVICES UNIT						
HLL70A	0.40	$106.35	$42.54	05/01/2013	25	REVIEW CASE FILE
HLL70A	1.20	$106.35	$127.62	05/02/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL70A	1.00	$106.35	$106.35	10/11/2013	79	STIPULATION
Sub Total	**2.60**		**$276.51**			
BI27	0.20	$49.62	$9.92	02/27/2013	4	ROUTINE INVESTIGATIVE WORK
BI27	0.60	$49.62	$29.77	03/07/2013	4	ROUTINE INVESTIGATIVE WORK
BI27	0.40	$49.62	$19.85	03/13/2013	76	REPORT PREPARATION
BI27	2.70	$49.62	$133.97	04/17/2013	76	REPORT PREPARATION
BI27	0.80	$49.62	$39.70	04/17/2013	4	ROUTINE INVESTIGATIVE WORK
BI27	0.20	$49.62	$9.92	04/18/2013	76	REPORT PREPARATION
Sub Total	**4.90**		**$243.13**			

Total Cost **$530.62**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201302904

Report Date 12/10/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 12/10/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description
	SubTotal			
	Total Expenses			

October 17, 2013

PERSONAL AND CONFIDENTIAL

Certified Article Number
7196 9008 9111 8826 3449
SENDERS RECORD

Mr. Michael Halfren
Gulf Medical Services, Inc.
6776 Caroline Street
Milton, Florida 32570

RE: Department of Health vs. Gulf Medical Services, Inc.
DOH Case No.: 2013-02904

Dear Mr. Halfren:

Enclosed you will find a copy of the revised Settlement Agreement in your client's case we discussed earlier today. I believe the enclosed Settlement Agreement includes all of the revised terms we discussed earlier today. Please let me know if I overlooked anything.

If the proposed revised Settlement Agreement is acceptable, please have the appropriate person in your corporate office sign it before a notary public and return it to my office at your earliest convenience. If you or someone in your corporate office wishes modify the proposed Settlement Agreement, please call me at (850)-245-4444, extension 8104 to discuss the Settlement Agreement further.

Thank-you for your prompt attention to this matter.

Sincerely,

Mary S. Miller
Assistant General Counsel

MSM/mm

Encl: Settlement Agreement

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-02904**

GULF MEDICAL SERVICES, INC.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Gulf Medical Services, Inc., was a permitted community pharmacy in the state of Florida, having been issued license number PH 18700. Respondent's mailing address of record is 6776 Caroline Street, Milton, Florida 32570.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that it is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **ONE THOUSAND DOLLARS and NO CENTS ($1,000.00).** The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320,**

Tallahassee, Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND FOUR HUNDRED TWENTY FOUR DOLLARS AND TWENTY-SEVEN CENTS ($1,424.27)**. Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

4. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

5. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and

incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice

the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses**- Respondent shall keep current its mailing address and its practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this _____ day of _____, 2013

_____
NAME:
Authorized Representative for
Gulf Medical Services, Inc.
CASE NO. 2013-02904

STATE OF _____

COUNTY OF _____

Before me personally appeared _____, whose identity is known to me or by _____ (type of identification), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this ____ day of _____, 2013.

_____
Notary Public
My Commission Expires:

APPROVED this _____ day of _____, 2013.

John H. Armstrong, MD, FACS
Surgeon General & Secretary
Florida Department of Health

_____

Mary Miller
Assistant General Counsel
Florida Department of Health
Florida Bar Number 0780420
4052 Bald Cypress Way
Tallahassee, Florida 32399-3265
Telephone: 850-245-4444
Fax: 850-245-4683
E-Mail: mary.miller2@flhealth.gov

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Gulf Medical Services, Inc. (MSM)**
Case Number: 2013-02904

MEMBERS: **Lee Fallon and Debra Glass**

DATE OF PCP: **June 27, 2013** **AGENDA ITEM: A-4**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-27.797(1)(i)(4),Florida Administrative Code;

Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B1627.797(1)(i)(7), Florida Administrative Code;

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**

a)
b)
c)

___ Upon **reconsideration**, dismiss

___ **other** _____

6/27/2013

Chair, Probable Cause Panel
Board of Pharmacy

Date

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area I Pensacola	Date of Case: 2/15/13	Case Number: **PH 2013-02904**

Subject:	Source:
GULF MEDICAL SERVICES, INC 6776 Caroline Street Milton, FL 32570 (850) 983-3705	**DOH/ISU TALLAHASSEE** **JOHN TAYLOR, SENIOR PHARMACIST** 4030 Esplanade Way Tallahassee, FL 33901 (850) 519-1181

Prefix:	License #:	Profession:	Board:	Report Date:
PH	18700	COMMUNITY/SPECIAL PE PHARMACY	PHARMACY	4/18/13

Period of Investigation: 2/27/13 – 4/18/13	Type of Report: FINAL

Alleged Violation: **FS 456.072(1)(dd)** Violating any provision of this chapter... **465.016(1)(r)** Violating any provision of this chapter... **465.023 (1)(c)** Violating any of the requirements of this chapter... **FAC 64B16-27.797 (CSPs) (1)(i)** 4. For properly stored sterilized high-risk preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and exposed for not more than 24 hours at controlled room temperature, and for not more than 3 days at a cold temperature (2-8 degrees Celsius) and for not more than 45 days in solid frozen state at -20 degrees celsius or colder.

Synopsis: This investigation is predicated upon receipt of a complaint, and Class II Institutional Pharmacy, Standards of Practice for Compounding Sterile Preparations (CSPs) inspection forms and (Case Summary) **(EXHIBIT 1)** submitted by Senior Pharmacist JOHN TAYLOR in regard to GULF MEDICAL SERVICES (GMS) reporting Senior Pharmacist TAYLOR conducted a routine inspection of GMS, d.b.a. Gulf Medical Pharmacy, a Community Pharmacy located at 6776 Caroline Street, Milton, FL 32570, on 2/11/2013. Findings of inspection alleged violation for failure to provide evidence of sterility for dispensed high risk preparation for which an extended beyond use date (20 days with storage at room temperature) was assigned. Findings further alleged failure to provide evidence that compounders of high risk preparations have successfully completed a high risk media test within the last six months.

The PDM of GMS was notified of the investigation by letter dated 2/27/13 and was provided a copy of the case summary and the originating documentation from EXHIBIT 1 **(EXHIBIT 2)**.

A check of Department computer records revealed GMS is currently licensed as a Community Special PE pharmacy.

There was no patient involved in this case; therefore, notification was not required.

GMS is not know to be represented by attorney in this matter.

On 3/13/13, by hand served letter by MICHAEL HALFEN, Pharm. D., PDM to Investigator RICHARD received GMS response statement from KENNETH STEBER, President of GMS **(EXHIBIT 5)**. STEBER acknowledged the allegations and stated immediate steps were taken to correct the allegations.

RECEIVED-LEGAL
13 APR 22 PM 3:11

Related Case: PS 2013-02905

Received
Investigative Services
APR 22 2013

Investigator/Date:	Approved By/Date:
4-18-13 Lloyd E. Richard, BI-27, Investigator	Cathy Martin 4/18/13 Cathy Martin, Investigator Supervisor

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IV. EXHIBITS
* 1. Case Summary, DOH/MQA complaint and pharmacy inspection forms 5-11
2. Copy of notification letter mailed to PDM of GMS dated 2/27/13 with enclosures 12-18
3. Pharmacy inspection forms completed on 3/20/12, 1/10/11 and 12/22/09 19-24
4. CQI meeting for 1st Quarter 2013 25-26
5. President STEBER's response (not dated) received on 3/13/13 with attachments 27-40

*** RECORDS CONTAINS INFORMATION WHICH IDENTIFY PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10) (a), FLORIDA STATUTES.**

INVESTIGATIVE DETAILS

Complaint was found during routine inspections by Senior Pharmacist TAYLOR for Community Pharmacy and Standards of Practice for Compounding Sterile Preparations (CSPs) at Gulf Medical Pharmacy on 2/11/13. Items 1 and 2 were not complied with on the CSPs inspection form.

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

EXHIBIT 1 is information forwarded by the Consumer Services Unit (CSU) to ISU. This information consists of a Case Summary and the following:

- DOH/MQA complaint form completed by the Senior Pharmacist Inspector TAYLOR who provided:
- Community Pharmacy inspection form completed on 2/11/13; no deficiencies.
- Standards of Practice for Compounding Sterile Preparations (CSPs) inspection form completed on 2/11/13; items 1 and 2 were found deficient; item 1 - example found of high risk compounded product dispensed with a five day beyond use date with no evidence of sterility testing of product prior to dispensing; item 2 – compounding staff has not completed high risk media fill testing.
- IV Worksheet on Rx #02001856 for Hydromorphone HCL power 2500 mg / 500 ml dated 2/8/13 compounded with sodium CHL 0.9%
- Medication label for Rx #02001856 for Hydromorphone HCL 2500 mg / 500 ml; no refills, discard after 2/28/13.

EXHIBIT 3 was printed by Investigator RICHARD from COMPAS. Exhibit included:

- Community Pharmacy inspection form completed on 3/20/12; no deficiencies.
- Standards of Practice for CSPs inspection form completed on 3/20/12; no deficiencies.
- Community Pharmacy inspection form completed on 1/10/11; no deficiencies.
- Sterile Products and Special-Parenteral Enteral Compounding Pharmacy form completed on 1/10/11; no deficiencies.
- Community Pharmacy inspection form completed on 12/22/09; no deficiencies.
- Sterile Products and Special-Parenteral Enteral Compounding Pharmacy form completed on 12/22/09; no deficiencies.

All the above inspections passed.

EXHIBIT 4 was provided to Investigator RICHARD by HALFEN on 4/17/13. Exhibit included 1st Quarter CQI meeting notes. No issue with CSPs.

STATEMENT OF KENNETH STEBER, PRESIDENT OF SUBJECT:

Address of business:
GULF MEDICAL SERVICES, INC
D.B.A. GULF MEDICAL PHARMACY
6776 Caroline Street
Milton, FL 32570
Business telephone: (850) 983-3705

On 3/13/13, Investigator RICHARD received a response statement (no date) via hand service by HALFEN for STEBER **(EXHIBIT 5)**.
This letter is in response to the allegations of the pharmacy inspection of 2/11/13 alleging violations to high risk technique testing of employees and beyond use dating of PCA infusions. "In the course of reviewing the personal aseptic technique over the past 3 years the pharmacy has been testing the compounding technicians semi-annually with what was at the time the only PATT (Personal Aseptic Technique) available on the market.

After being notified by the inspector on this second inspection with the new USP formatted form (previous inspection 3/20/12) that this was not satisfactory, research was done by both the pharmacist and infusion suppliers to find a valid high risk media fill kit." These kits were immediately ordered and have been implemented with the compounding technicians (see attachment completion dates).

The pharmacy has substantially increased the testing of their compounding personnel, compounding environment, and products to further insure the safety of their patients.

Attachments to statement:

1. Investigator RICHARD signed receipt of documents from PDM MICHAEL HALFEN on 3/13/13.
2. Testing Schedule 2013 for personnel with dates.
3. Pharmacy Label for Morphine indicating start infusion by dated (example).
4. Certificate of Analysis on Morphine Sulfate 1 mg/ml, lot #2001289; date tested 4/23/12.
5. Certificate of Analysis on Morphine Sulfate 1 mg/ml, lot #2001289; date tested 3/26/12.
6. Certificate of Analysis on Hydromorphone 1 mg/ml, lot #081106H1, received on 8/17/06.
7. Microbiology Report on Hydromorphone 1 mg/ml, lot #081106H1 test results, received on 8/17/06.
8. Certificate of Analysis on Morphine Sulfate 10 mg/ml, lot #081106M10; date tested 8/28/06.
9. Microbiology Report on Morphine Sulfate 10 mg/ml for lot #081106M10; results date tested 9/5/06.
10. Certificate of Analysis on Baclofen 2 mg/ml, lot #071210MH; tested 9/13/10.
11. Microbiology Report on Baclofen 2 mg/ml, lot #071210MH; tested 8/11/10.
12. Blank Testing Schedule (new management form for CSPs testing requirements).

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

File # 10801

Insp # 105809

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT GULF MEDICAL SERVICES, INC		PERMIT NUMBER 18700	DATE OF INSPECTION 3/20/2012
DOING BUSINESS AS GULF MEDICAL PHARMACY		DEA NUMBER BG7912771	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 6776 Caroline Street		TELEPHONE # 850-983-3705 EXT.	MICHAEL W HALFEN
CITY MILTON	COUNTY 67	STATE/ZIP 32570	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 32618

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8am	8am	8am	8am	8am	closed	closed
Close	4:30pm	4:30pm	4:30pm	4:30pm	4:30pm		

REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
1. Donna Pittman PS 8932	
2. George Anderson PS 12203	
3. Tiffany Denham RPT 29518	

	SATISFACTORY	N/A	YES	NO
1 Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2 Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]			X	
3 Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4 Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			X	
5 A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6 Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7 Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			X	
8 Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9 Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10 Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11 CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			X	
12 Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]		X		
13 Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
14 Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15 All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16 Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
17 Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]			X	
19 DEA 222 order forms properly completed. [893.07, F.S.]			X	
20 Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
21 Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]			X	
22 Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			X	
23 Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]		X		
24 Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	X			
25 Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]			X	
26 Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]		X		
27 Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]	X			
28 Compounding records properly maintained. [64B16-27.700, F.A.C.]*			X	
29 Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]			X	
30 Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			X	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: Melissa McGuffey RPT 18664; Joy Patterson RPT 37779; Sharon Fort RPT 27620. Rita Jones - Tech Trainee; Yvonne Lee - Tech Trainee. DEA expires 9-30-2014. #2 Tech ratio letter 11-10-2005. #11 Last CQI meeting 2-3-2012. #12 Future Requirement. #18 CS inventory 1-30-2012. #22 Printout. #23 None since 7-1-2011. #24 None since 7-1-2011.
No outpatient CII prescriptions.
Batch compounding. No compounding for practitioner office stock.
Rx drug suppliers: McKesson-Lakeland, Anda-Weston; Medisca (23:1911).

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Michael Halfen, RPh

M. Halfen

Institutional Representative

03-20-2012

Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

EXHIBIT # 3

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

Standards of Practice for Compounding Sterile Preparations (CSPs)

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 10801

Insp # 105809

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT GULF MEDICAL SERVICES, INC		PERMIT NUMBER 18700	DATE OF INSPECTION 3/20/2012
DOING BUSINESS AS GULF MEDICAL PHARMACY		DEA NUMBER BG7912771	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 6776 Caroline Street		TELEPHONE # 850-983-3705 EXT.	MICHAEL W HALFEN
CITY MILTON	COUNTY 67	STATE/ZIP 32570	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 32618

		SATISFACTORY	N/A	YES	NO
1	Types of sterile compounding prepared (or expected to prepare) per [64B16-27.797, F.A.C.]. Undersigned pharmacist attests:				
	a) High-Risk Level CSPs (If yes, must complete items 5 & 6 - may not answer N/A)			X	
	b) Immediate Use CSPs (If yes, must complete items 7 & 8 - may not answer N/A)				X
	c) Low-Risk Level CSPs (If yes, must complete items 9 & 10 - may not answer N/A)			X	
	d) Medium-Risk CSPs			X	
	e) Antineoplastic Drugs (Cytotoxins) (If yes, must complete items 18, 19, 20 & 22 - may not answer N/A)				X
2	All sterile compounds prepared in barrier isolator? If yes, may answer NA to 3b, 3c, 3d, 4, & 21. [64B16-27.797(5)(e), F.A.C.]	X			
3	Compounding environment appropriate for Risk Level (certification by independent qualified organization).				
	a) Barrier Isolator?	X			
	b) Anteroom/Ante area?			X	
	c) Buffer Area (Clean Room)?			X	
	d) Laminar Air Flow Hood(s)?			X	
4	Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.]			X	
5	Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified in rule. [64B16-27.797(1)(i), F.A.C.]			X	
6	Personnel authorized to compound high-risk-level CSPs completed a media-filled test within the past 6 months (semiannually). [64B16-27.797(1)(i),F.A.C.]			X	
7	Preparation time does not exceed 1 hour when preparing immediate use CSPs. [64B16-27.797(1)(j), F.A.C.]	X			
8	Preparation is properly labeled if preparer does not administer or witness administration when preparing immediate-use CSPs. [64B16-27.797(1)(j), F.A.C.]	X			
9	Storage recommendations in rules are not exceeded when preparing low-risk CSPs. [64B16-27.797(1)(n), F.A.C.]			X	
10	Personnel authorized to compound low-risk level CSPs completed a media-filled test within the past 12 months. [64B16-27.797(1)(n), F.A.C.]			X	
11	P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16.27-797(4), F.A.C.]			X	
12	P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.]			X	
13	P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.]			X	
14	P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.]			X	
15	Appropriate disposal containers. [64B16-27.797(5), F.A.C.]			X	
16	Appropriate temperature and transport devices. [64B16-27.797(5), F.A.C.]			X	
17	Adequate supplies (gloves, mask, etc.) to preserve a suitable environment for aseptic preparation. [64B16-27.797(5), F.A.C.]			X	
18	Spill kits for antineoplastic agent spills if required. [64B16-27.797(5), F.A.C.]	X			
19	Current reference material (hard-copy or on-line). [64B16-27.797(5); and 64B16-27.797(1)(2), F.A.C.]			X	
20	All preparations are compounded in a vertical flow, Class II or biological safety cabinet. [64B16-27.797(6), F.A.C.]	X			
21	Protective apparel requirements are met. [64B16-27.797(6), F.A.C.]			X	
22	Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.]	X			
23	Documented on-going quality assurance. [64B16-27.797(7), F.A.C.]			X	
24	Quality assurance audits at regular planned intervals. [64B16-27.797(7), F.A.C]			X	
25	Compounding personnel skilled and trained based on observation. [64B16-27.797(7), F.A.C]			X	

Remarks: #3 ENV Services Testing & Certification, 4758 Research Drive, San Antonio, TX 78240. (February 15, 2012.)

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Michael Halfen, RPh

M Halfen

Institutional Representative

03-20-2012

Date

Investigator/Sr. Pharmacist Signature

ID cl20

INV 797 Revised 12/11 Created 8/11

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 10801

Insp # 96803

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT GULF MEDICAL SERVICES, INC		PERMIT NUMBER 18700	DATE OF INSPECTION 1/10/2011
DOING BUSINESS AS GULF MEDICAL PHARMACY		DEA NUMBER BG7912771	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 6776 Caroline Street		TELEPHONE # 850-893-3705 EXT.	MICHAEL W HALFEN
CITY MILTON	COUNTY 67	STATE/ZIP 32570	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 32618

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8:30am	8:30am	8:30am	8:30am	8:30am	closed	closed
Close	4:30pm	4:30pm	4:30pm	4:30pm	4:30pm		

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Donna Pittman PS 8932
2. Elliott Roberts PS 8262
3. George Anderson PS 12203

		SATISFACTORY	N/A	YES	NO
1	Current pharmacy permit displayed. [465.015(1)(a),F.S.]			X	
2	Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]			X	
3	Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4	Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]			X	
5	Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]			X	
6	Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			X	
7	Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]			X	
8	Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]			X	
9	Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.			X	
10	Generic drug sign displayed. [465.025(7),F.S.]			X	
11	Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]			X	
12	Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*		X		
13	Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]			X	
14	Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]			X	
15	Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]			X	
16	Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			X	
17	Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]			X	
18	Prescription department clean and safe. [64B16-28.105,F.A.C.]			X	
19	Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]			X	
20	Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]			X	
21	Medication properly labeled [64B16-27.101,F.A.C.]			X	
22	All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]			X	
23	CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]			X	
24	Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]			X	
25	"Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]			X	
26	All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]			X	
27	Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]			X	
28	Complete pharmacy prescription records. [64B16-28.140,F.A.C.]			X	
29	Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]			X	
30	Controlled substance records readily retrievable. [893.07,F.S.]			X	
31	Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]			X	
32	Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]			X	
33	Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			X	
34	Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]			X	
35	All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			X	
36	Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]			X	
37	Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			X	
38	Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]			X	
39	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]			X	
40	DEA 222 order forms properly completed. [893.07(2),F.S.]			X	
41	Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*			X	
42	Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]			X	
43	Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]			X	
44	Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *			X	
45	Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *		X		
46	Compounding records properly maintained [64B16-28.140(4),F.A.C.] *			X	
47	Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *			X	

** Questions with (*) may be answered n/a (not applicable).*

Remarks: Sarah Steele PS 38813. Tiffany Denham RPT29518; Edward Ilano RPT26662; Derek Luke RPT 27889. #3 DEA expires 9-30-2011. #5 NA. #7 Tech ratio letter 11-10-2005. #23 Last CQI meeting 10-14-2010. #39 CS inventory 1-14-2010. #43 NA. #44 Printout. Rx drug purchases McKesson-Lakeland and Medisca.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Michael Halfen, RPh

Michael Halfen — Institutional Representative

01-10-2011 — Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

FLORIDA DEPARTMENT OF HEALTH

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STERILE PRODUCTS AND SPECIAL-PARENTERAL ENTERAL COMPOUNDING PHARMACY

File # 10801

Insp # 96803

ROUTINE ☒ CHANGE LOC ☐ NEW ☐ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT GULF MEDICAL SERVICES, INC	PERMIT NUMBER 18700		DATE OF INSPECTION 1/10/2011
DOING BUSINESS AS GULF MEDICAL PHARMACY	DEA NUMBER BG7912771		PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 6776 Caroline Street	TELEPHONE # 850-893-3705	EXT.	MICHAEL W HALFEN
CITY MILTON / COUNTY SANTA ROSA	STATE/ZIP 32570		PRESCRIPTION DEPARTMENT MANAGER LICENSE # 32618

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8:30am	8:30am	8:30am	8:30am	8:30am	closed	closed
Close	4:30pm	4:30pm	4:30pm	4:30pm	4:30pm		

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. see community inspection form
2.
3.

	SATISFACTORY	N/A	YES	NO
1 Current sterile products and special parenteral/enteralcompounding pharmacy permit displayed. [64B16-28.82, F.A.C.]			☒	☐
2 Board of Pharmacy notified in writing of current Rx department manager. [64B16-28.820(3)(a), F.A.C.]			☒	☐
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			☒	☐
4 Pharmacist license/renewal certificate displayed. [64B16-27.100(1),F.A.C.]			☒	☐
5 Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400,F.A.C.]			☒	☐
6 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410,F.A.C.] [64B16-27.420,F.A.C.]			☒	☐
7 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.][64B16-27.400,F.A.C.]			☒	☐
8 Prescription area set apart for sterile prescriptions from general work/storage area/adequately air-conditioned or under positive pressure. [64B16-28.820(5)(b)1.F.A.C.]			☒	☐
9 Working sink convenient to the clean room. [64B16-28.820(5)(c)3,F.A.C.]			☒	☐
10 Refrigeration/freezer/sink/appropriate waste containers for used needles/ syringes. [64B16-28.820(5)(c)2,4(a),F.A.C.]			☒	☐
11 Gloves/masks/gowns/various standard sizes of needles/syringes/ disinfectant cleaning agent/clean towels. [64B16-28.820(5)(d)1-4,F.A.C.]			☒	☐
12 Bacterial hand-washing materials/vacuum containers and various transfer sets, "spill kits" for cytotoxic agent spills. [64B16-28.820(5)(c)5-F.A.C.]			☒	☐
13 Appropriate waste containers for all cytotoxic waste including apparel used in prescriptions. [64B16-28.820(5)(c)4b,F.A.C.]			☒	☐
14 Certified horizontal or vertical laminar airflow hood(s). [64B16-28.820(3)(e),F.A.C.]			☒	☐
15 Certified vertical laminar airflow hood used for cytotoxins. [64B16-28.820(3)(e),F.A.C.]*		☒	☐	☐
16 Board approved policy and procedure manual available for inspection. [64B1628.820(3)(d.F.A.C.]			☒	☐
17 Separate manual/equipment/handing procedures and protection for personnel if cytotoxic agents are dispensed. (64B16-28.820(3)(e), F.A.C			☒	☐
18 "Practice Guidelines for Personnel Dealing With Cytotoxic Drugs". (64B16-28.820(5)(e)7, F.A.C.			☒	☐
19 Current chapter of Florida Statutes: 465 and 499 and 893, and Board Rules [64B16-28.820(5)(e)1-4,F.A.C.]			☒	☐
20 CurrentUnited StatesPharmacopoeia & National Formulary or Remington Pharmaceutical Sciences or U.S. Dispensatory along with the latest supplementals or an equivalent thereof sufficient in scope to meet the professional practice need of the pharmacy AND a current authoritative therapeutic reference. [64B16-28.820(5)(e)5.F.A.			☒	☐
21 Current edition of the Handbook of Injectable Drugs by American Society of Healthsystem Pharmacists.[64B16-28.820(5)(e)6,F.A.C.]			☒	☐
22 Pharmaceutical stock examined at least every four months and deteriorated or outdated items removed. [64B16-28.11,F.A.C]			☒	☐
23 Medication properly labeled. [64B16-27.101,F.A.C.]			☒	☐
24 "Discard After" date provided on prescription label. [64B1628.402(1)(h),F.A.C.]			☒	☐
25 Written offer to counsel. [64B16-27.820,F.A.C.]			☒	☐
26 Special handling/packing/labeling/delivery of prescriptions with telephone accessibility to pharmacist at all hours. [64B16-28.820(3)(b),F.A.C.]			☒	☐
27 Licensed pharmacist certifies accuracy of final preparation and documents in a manner that responsibility can be traced to the pharmacist. [64B16-27.400(2)(c)(d),F.A.C.]			☒	☐
28 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S] [64B16-27.300,F.A.C.] *		☐	☒	☐
29 Prescriber's name/address/DEA # on all controlled substance prescription. [F.S. 893.04(1)(c)2,F.A.C.]			☒	☐
30 Initials of pharmacist filling controlled substance prescriptions on prescription. [893.04(1)(c)6,F.S.]			☒	☐
31 Controlled substance inventory taken on biennial basis and available for inspection. [893.07(1)(a),F.S.]			☒	☐
32 DEA 222 order forms properly completed. [893.07,F.S.]			☒	☐
33 Certified daily log OR printout maintained as required by section. (64B16-28.140(3)(c) or (e),F.A.C.] *		☐	☒	☐
34 Dispensing done pursuant to prescriptions with patient profiles maintained. (64B16-28.820(3)(c), F.A.C.			☒	☐
35 Results of quality assurance program available for inspection. (64B16-28.820(3)(D), F.A.C			☒	☐

*Questions with *may be answered n/a (not applicable).

Remarks: See community inspection form for details. #12, #13, #15, #17, & #18 - No cytotoxins prepared. Hoods certified 12-29-2010.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Michael Halfen,, RPh

Michael Halfen — Institutional Representative

01-10-2011 — Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 364 Revised 01/07 Replaces 12/02

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 10801

Insp # 88189

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT GULF MEDICAL SERVICES, INC	PERMIT NUMBER 18700	DATE OF INSPECTION 12/22/2009
DOING BUSINESS AS GULF MEDICAL VITAL CARE;GULF MEDICAL PHA	DEA NUMBER BG7912771	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 6776 Caroline Street	TELEPHONE # 850-983-6705 EXT.	MICHAEL W HALFEN
CITY MILTON / COUNTY 67	STATE/ZIP 32570	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 32618

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8:30am	8:30am	8:30am	8:30am	8:30am	closed	closed
Close	4:30pm	4:30pm	4:30pm	4:30pm	4:30pm		

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Amanda McClure PTech
2. Kelly Ward PTech
3. Derek Luke PTech

	SATISFACTORY	N/A	YES	NO
1 Current pharmacy permit displayed. [465.015(1)(a),F.S.]			X	
2 Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]			X	
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4 Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]			X	
5 Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]			X	
6 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			X	
7 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]			X	
8 Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]			X	
9 Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.			X	
10 Generic drug sign displayed. [465.025(7),F.S.]			X	
11 Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]			X	
12 Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*		X		
13 Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]			X	
14 Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]			X	
15 Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]			X	
16 Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			X	
17 Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]			X	
18 Prescription department clean and safe. [64B16-28.105,F.A.C.]			X	
19 Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]			X	
20 Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]			X	
21 Medication properly labeled [64B16-27.101,F.A.C.]			X	
22 All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]			X	
23 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]			X	
24 Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]			X	
25 "Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]			X	
26 All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]			X	
27 Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]			X	
28 Complete pharmacy prescription records. [64B16-28.140,F.A.C.]			X	
29 Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]			X	
30 Controlled substance records readily retrievable. [893.07,F.S.]			X	
31 Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]			X	
32 Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]			X	
33 Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			X	
34 Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]			X	
35 All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			X	
36 Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]			X	
37 Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			X	
38 Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]			X	
39 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]			X	
40 DEA 222 order forms properly completed. [893.07(2),F.S.]			X	
41 Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*			X	
42 Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]			X	
43 Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]			X	
44 Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *			X	
45 Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *		X		
46 Compounding records properly maintained [64B16-28.140(4),F.A.C.] *			X	
47 Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *			X	

** Questions with (*) may be answered n/a (not applicable).*

Remarks: #3 DEA expires 9-30-2011. #5 NA. #7 Tech ratio letter 11-10-2005. #23 Last CQI 10-9-2009. #39 CS inventory 1-20-2009. #43 NA. #44 Printout. Rx drug purchases from McKesson-Lakeland and Medisca.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Michael Halfen, RPh

Institutional Representative

12-22-2009
Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

STERILE PRODUCTS AND SPECIAL-PARENTERAL ENTERAL COMPOUNDING PHARMACY

File # 10801

Insp # 88189

ROUTINE ☒ CHANGE LOC ☐ NEW ☐ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT GULF MEDICAL SERVICES, INC	PERMIT NUMBER 18700	DATE OF INSPECTION 12/22/2009
DOING BUSINESS AS GULF MEDICAL VITAL CARE;GULF MEDICAL PHA	DEA NUMBER BG7912771	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 6776 Caroline Street	TELEPHONE # 850-983-6705 EXT.	MICHAEL W HALFEN
CITY MILTON / COUNTY SANTA ROSA	STATE/ZIP 32570	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 32618

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	8:30am	8:30am	8:30am	8:30am	8:30am	oncall	oncall
Close	4:30pm	4:30pm	4:30pm	4:30pm	4:30pm		

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Amanda McClure PTech
2. Kelly Ward PTech
3. Derek Luke PTech

	SATISFACTORY	N/A	YES	NO
1 Current sterile products and special parenteral/enteralcompounding pharmacy permit displayed. [64B16-28.82, F.A.C.]			☒	☐
2 Board of Pharmacy notified in writing of current Rx department manager. [64B16-28.820(3)(a), F.A.C.]			☒	☐
3 Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			☒	☐
4 Pharmacist license/renewal certificate displayed. [64B16-27.100(1),F.A.C.]			☒	☐
5 Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400,F.A.C.]			☒	☐
6 Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410,F.A.C.] [64B16-27.420,F.A.C.]			☒	☐
7 Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.][64B16-27.400,F.A.C.]			☒	☐
8 Prescription area set apart for sterile prescriptions from general work/storage area/adequately air-conditioned or under positive pressure. [64B16-28.820(5)(b)1,F.A.C.]			☒	☐
9 Working sink convenient to the clean room. [64B16-28.820(5)(c)3,F.A.C.]			☒	☐
10 Refrigeration/freezer/sink/appropriate waste containers for used needles/ syringes. [64B16-28.820(5)(c)2,4(a),F.A.C.]			☒	☐
11 Gloves/masks/gowns/various standard sizes of needles/syringes/ disinfectant cleaning agent/clean towels. [64B16-28.820(5)(d)1-4,F.A.C.]			☒	☐
12 Bacterial hand-washing materials/vacuum containers and various transfer sets, "spill kits" for cytotoxic agent spills. [64B16-28.820(5)(c)5-F.A.C.]			☒	☐
13 Appropriate waste containers for all cytotoxic waste including apparel used in prescriptions. [64B16-28.820(5)(c)4b,F.A.C.]			☒	☐
14 Certified horizontal or vertical laminar airflow hood(s). [64B16-28.820(3)(e),F.A.C.]			☒	☐
15 Certified vertical laminar airflow hood used for cytotoxins. [64B16-28.820(3)(e),F.A.C.]*		☒	☐	☐
16 Board approved policy and procedure manual available for inspection. [64B1628.820(3)(d,F.A.C.]			☒	☐
17 Separate manual/equipment/handing procedures and protection for personnel if cytotoxic agents are dispensed. (64B16-28.820(3)(e), F.A.C			☒	☐
18 "Practice Guidelines for Personnel Dealing With Cytotoxic Drugs". (64B16-28.820(5)(e)7, F.A.C.			☒	☐
19 Current chapter of Florida Statutes: 465 and 499 and 893, and Board Rules [64B16-28.820(5)(e)1-4,F.A.C.]			☒	☐
20 CurrentUnited StatesPharmacopoeia & National Formulary or Remington Pharmaceutical Sciences or U.S. Dispensatory along with the latest supplementals or an equivalent thereof sufficient in scope to meet the professional practice need of the pharmacy AND a current authoritative therapeutic reference. [64B16-28.820(5)(e)5,F.A.			☒	☐
21 Current edition of the Handbook of Injectable Drugs by American Society of Healthsystem Pharmacists.(64B16-28.820(5)(e)6,F.A.C.]			☒	☐
22 Pharmaceutical stock examined at least every four months and deteriorated or outdated items removed. [64B16-28.11,F.A.C]			☒	☐
23 Medication properly labeled. [64B16-27.101,F.A.C.]			☒	☐
24 "Discard After" date provided on prescription label. [64B1628.402(1)(h),F.A.C.]			☒	☐
25 Written offer to counsel. [64B16-27.820,F.A.C.]			☒	☐
26 Special handling/packing/labeling/delivery of prescriptions with telephone accessibility to pharmacist at all hours. (64B16-28.820(3)(b),F.A.C.]			☒	☐
27 Licensed pharmacist certifies accuracy of final preparation and documents in a manner that responsibility can be traced to the pharmacist. [64B16-27.400(2)(c)(d),F.A.C.]			☒	☐
28 CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S] [64B16-27.300,F.A.C.] *		☐	☒	☐
29 Prescriber's name/address/DEA # on all controlled substance prescription. [F.S. 893.04(1)(c)2,F.A.C.]			☒	☐
30 Initials of pharmacist filling controlled substance prescriptions on prescription. [893.04(1)(c)6,F.S.]			☒	☐
31 Controlled substance inventory taken on biennial basis and available for inspection. [893.07(1)(a),F.S.]			☒	☐
32 DEA 222 order forms properly completed. [893.07,F.S.]			☒	☐
33 Certified daily log OR printout maintained as required by section. (64B16-28.140(3)(c) or (e),F.A.C.] *		☐	☒	☐
34 Dispensing done pursuant to prescriptions with patient profiles maintained. (64B16-28.820(3)(c), F.A.C.			☒	☐
35 Results of quality assurance program available for inspection. (64B16-28.820(3)(D), F.A.C			☒	☐

*Questions with *may be answered n/a (not applicable).

Remarks: See community inspection form for details. #12, #13, #15, & #18 NA - No cytotoxins prepared. #14 Hoods certified 10-29-2009.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Michael Halfen, RPh

Michael Halfen — Institutional Representative

12-22-2009 — Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 364 Revised 01/07 Replaces 12/02

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201216646

SAR PHARMACY DISCOUNT, INC,
RESPONDENT.

NOTICE

TO: SAR PHARMACY DISCOUNT, INC
2089 SW 67TH AVE
MIAMI, FL 33155

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Determination of Waiver

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

Mission:
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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201216646

SAR PHARMACY DISCOUNT, INC,
RESPONDENT.

NOTICE

TO: SAR PHARMACY DISCOUNT, INC
11115 W. OKEECHOBEE ROAD UNIT 101
HIALEAH, FL 33018

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Kristal Beharry, Assistant General Counsel
RE: Determination of Waiver
SUBJECT: DOH v. SAR Pharmacy Discount, Inc.
DOH Case Number 2012-16646
DATE: December 17, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	SAR Pharmacy Discount, Inc.
Subject's Address of Record:	2089 SW 67th Avenue Miami, FL 33155
Enforcement Address:	2089 SW 67th Avenue Miami, FL 33155
Additional Address:	11115 W. Okeechobee Road, Unit 101 Hialeah, FL 33018
Subject's License No:	25265 **Rank:** PH
Licensure File No:	18184
Initial Licensure Date:	2/16/2011
Board Certification:	None
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Section 465.023(1)(c), F.S. (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3), F.A.C.
Prior Discipline:	None
Probable Cause Panel:	June 27, 2013 Fallon and Glass
Subject's Attorney:	Pro Se
Complainant/Address:	Department of Health/Investigative Services Unit-Miami

Materials Submitted:

Memorandum to the Board
Motion for Determination of Waiver
Exhibit A - Administrative Complaint
Exhibit B – Copy of certified mail receipt
Exhibit C – Affidavit of diligent search
Exhibit D – Proof of publication
Exhibit E - Affidavit of Non-Receipt - Board Office
Exhibit F - Affidavit of Non-Receipt - Agency Clerk's Office
Motion to assess costs with
Exhibit A – Affidavit of Fees and Costs Extended
Exhibit 1 – Complaint Cost Summary
Exhibit 2 – Itemized Cost by Complaint
Supplemental Investigative Report with Exhibits 9/18/13
PCP Memo
Final Investigative Report with Exhibits 1 – 4

Disciplinary Guidelines:
Section 465.023(1)(c), F.S., by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3)

- $1,500 fine up to Revocation

PRELIMINARY CASE REMARKS: INFORMAL HEARING

This is an Administrative Complaint alleging a violation of Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3), Florida Administrative Code, by failing to notify the Board of Pharmacy in writing as to the effective date of closure, return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy, and/or notify the Board of Pharmacy which permittee is to receive the prescription files.

On or about October 16, October 31, and November 7, 2012, a Department of Health inspector attempted to conduct a routine inspection of Respondent and discovered that Respondent's facility was closed and non-operational.

RECOMMENDATION OF THE DEPARTMENT

- Revocation

CONSIDERATIONS SUPPORTING THE DEPARTMENT'S RECOMMENDATION

- The recommendation is appropriate and within the guidelines

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-16646**

SAR PHARMACY DISCOUNT, INC.,

Respondent.

_____/

MOTION FOR DETERMINATION OF WAIVER AND FOR FINAL ORDER AFTER A HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

PETITIONER, the Florida Department of Health, by and through the undersigned counsel, hereby moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore Petitioner states:

1. An Administrative Complaint was filed against Respondent on June 27, 2013. A copy of said Administrative Complaint is attached hereto as Petitioner's Exhibit A.

2. Copies of the Administrative Complaint, Explanation of Rights form, and Election of Rights form were sent to Respondent via certified US mail on: July 2, 2013 (7196 9008 9111 9326 6121). Service on Respondent via certified mail was not successful. A copy of the certified mail receipt and envelope is attached as Petitioner's Exhibit B.

3. Thereafter, Petitioner requested personal service on Respondent, which was unsuccessful on August 27th, 28th, 29th, September 10th, and 11th, 2013. The affidavit of personal service is attached as Petitioner's Exhibit C.

4. Thereafter, Petitioner requested that the Community Newspapers publish a Legal Notice of Action beginning on October 7, 2013 and appearing consecutively on October 14th, 21st, and 28th, 2013. Petitioner received proof of publication on November 12, 2013, which is attached as Petitioner's Exhibit D.

5. Rule 28-106.111(2), Florida Administrative Code, provides in pertinent part that:

> . . . persons seeking a hearing on an agency decision which does or may determine their substantial interests shall file a petition for hearing with the agency within 21 days of receipt of written notice of the decision.

6. Rule 28.106.111(4), Florida Administrative Code, provides that:

> Any person who received written notice of an agency decision and who fails to file a written request for a hearing within 21 days waives the right to request a hearing on such matters.

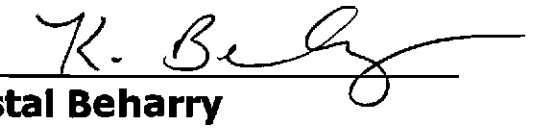
7. Respondent has not filed an Election of Rights form, or any other responsive pleading, with Petitioner or the Board of Pharmacy within the required twenty-one (21) day period of time. Copies of affidavits supporting the same are attached hereto as Petitioner's Exhibits E & F.

8. Based upon the foregoing, Respondent has waived the right to dispute any materials facts contained within the Administrative Complaint. Therefore, there are no disputed issues of material fact to be resolved by the Board.

9. Respondent has been advised by way of this Motion, that a copy of the investigative file in this case will be furnished to the Board, establishing a prima facie case regarding the violations as set forth in the Complaint.

WHEREFORE, Petitioner respectfully requests that the Board find that Respondent has waived the right to dispute any materials facts contained within the Administrative Complaint and enter a Final Order imposing whatever discipline upon Respondent's license that the Board deems appropriate.

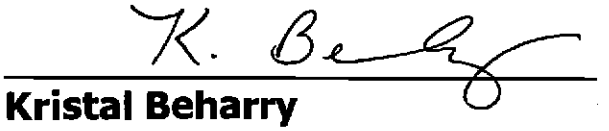
John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health



Kristal Beharry
Assistant General Counsel
Fla. Bar No. **0078070**
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683
Email: Kristal.beharry@doh.state.fl.us

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 19th day of December, 2013, to: SAR Pharmacy Discount, Inc. at 2089 Southwest 67th Avenue, Miami, FL 33155 and 11115 W. Okeechobee Road, Unit 101, Hialeah, FL 33018.



Kristal Beharry
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-16646**

SAR PHARMACY DISCOUNT, INC.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Sar Pharmacy Discount, Inc., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a permitted community pharmacy within the state of Florida, having been issued permit number PH 25265.

EXHIBIT
A

3. Respondent's address of record is 2089 Southwest 67th Avenue, Miami, Florida 33155.

4. On or about February 16, 2011, Respondent was issued a license to operate its pharmacy.

5. On or about October 16, 2012, October 31, 2012, and November 7, 2012, a Department of Health inspector attempted to conduct a routine inspection of Respondent and discovered that Respondent's facility was closed and non-operational.

6. Rule 64B16-28.202(2), Florida Administrative Code, defines "closing of a pharmacy" as the cessation or termination of professional and business activities within a pharmacy for which a permit has been issued under Chapter 465, Florida Statutes.

7. Rule 64B16-28.202(3), Florida Administrative Code, provides that prior to closure of a pharmacy, the permittee shall notify the Board of Pharmacy in writing as to the effective date of closure, return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy, and notify the Board of Pharmacy which permittee is to receive the prescription files.

8. Respondent failed to do one or more of the following prior to closure:

a. Notify the Board of Pharmacy in writing of Respondent's effective date of closure;

b. Return or arrange to return the pharmacy permit; and/or

c. Advise the Board of Pharmacy which permittee is to receive the prescription files.

9. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any of the requirements of Chapter 465, Florida Statutes, or any of the rules of the Board of Pharmacy; of Chapter 499, Florida Statutes; of 21 U.S.C. ss. 301-392; of 21 U.S.C. ss. 821 et. seq.; or Chapter 893, Florida Statutes.

10. As set forth above, Respondent failed to do one or more of the following prior to closure:

a. Notify the Board of Pharmacy in writing of Respondent's effective date of closure;

b. Return or arrange to return the pharmacy permit; and/or

c. Advise the Board of Pharmacy which permittee is to receive the prescription files.

11. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3), Florida Administrative Code, by failing to notify the Board of Pharmacy in writing as to the effective date of closure, return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy, and/or notify the Board of Pharmacy which permittee is to receive the prescription files.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees

billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 27th **day of** June, **20**13.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Kristal Beharry
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Florida Bar # 0078070
Telephone: (850) 245-4444
Facsimile: (850) 245-4683

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUN 27 2013

/KB
PCP: 06/27/13
PCP Members: Fallon & Glass

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

7196 9008 9111 9326 6121

TO:

Stip Pack
Cassandra/Beharry
Date Mailed 7/2/2013
2012-16646

SENDER:

REFERENCE:

Sar Pharmacy Discount

PS Form 3800, January 2005

RETURN RECEIPT SERVICE		
	Postage	
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

USPS®
Receipt for Certified Mail™

No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

EXHIBIT
B

Florida Department of Health
Office of the General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-1701
PHONE: 850/245-4444

7196 9008 9111 9326 6121

FIRST CLASS

UNCLAIMED

Closed
7-6-01

Sar Pharmacy Discount, Inc.
2089 Southwest 67th Avenue
Miami, FL 33155

NIXIE 331553231-1N 07/27/13

RETURN TO SENDER
UNCLAIMED
UNABLE TO FORWARD
RETURN TO SENDER

PRACTITIONER REGULATION
LEGAL
2013 JUL 30 PM 1:10

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

Department of Health
Petitioner

vs

Case No. 2012-16646

Sar Pharmacy-Owner Yoeli Salguiero
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:
1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on 8/27/13, 8/28/13, 8/29/13, 9/10/13, 9/11/13, Affiant made a diligent effort to locate Respondent, to serve Administrative complaint packet and related papers at last known address of 2089 SW 67th Avenue Miami, FL 33155 and a secondary address of 11115 W Okeechobee Road Unit 101 Hialeah, FL 33018.

3) Check applicable answer below:

x Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses

Neil Downs
Affiant

State Of Florida
County Of Miami Dade

Before me, personally appeared Neil Downs whose identity is known to me by personally known (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 18th day of September 2013.

Notary Public-State of Florida

My Commission Expires

ISKRA CAVATORTA
Commission # FF 002218
Expires March 26, 2017
Bonded Thru Troy Insurance, 800 385-7019

ISKRA Cavatorta
Type or Print Name

EXHIBIT C

EXHIBIT S1

INV FORM 321

A FREE AND INDEPENDENT NEWS. ER VOICE

COMMUNITY NEWSPAPERS

PUBLISHED MONDAY
MIAMI, MIAMI-DADE, FLORIDA

RECEIVED-LEGAL

13 NOV 12 AM 9:01

STATE OF FLORIDA
COUNTY OF MIAMI-DADE:

Before the undersigned authority personally appeared **GEORGIA TAIT** who on oath says she is **OFFICE MANAGER** of Legal Advertising of Community Newspapers, published Monday at Miami-Dade, Florida; that the attached copy of advertisement, being a Legal Advertisement of Notice in the Matter of

NOTICE OF ACTION
THE LICENSE TO PRACTICE PHARMACY OF
SAR PHARMACY DISCOUNT, INC.
CASE NO. 2012-16646

in the XXXXX Court, was published in said newspaper in the issue of

10/07, 10/14, 10/21, 10/28/2013

Affiant further says that the said Community Newspaper, published at Miami-Dade County, Florida, and that the newspaper has heretofore been continuously published in said Miami-Dade County, Florida, and has been entered as second class mail matter at the post office in Miami, Florida, Miami-Dade County, and additional mailing offices, for a period of one year next preceding the first publication of the attached copy of advertisement; and affiant further says that she has neither paid nor promised any person, firm or corporation any rebate, commission or refund for the purpose of securing this advertisement for publication in the said newspaper.

PROOF OF PUBLICATION -

AFFIANT Gwen K. Tait

Sworn to and subscribed before me this

28TH day of OCTOBER 2013.

JESUS TOLEDO

(Print or type or stamp commissioned name of Notary Public)

(SEAL)

JESUS C. TOLEDO
Notary Public • State of Florida
My Comm. Expires Apr 10, 2017
Commission # EE 876555
Bonded Through National Notary Assn.

My Commission Expires: _____

Personally known X

NOTICE OF ACTION

BEFORE THE BOARD OF PHARMACY

IN RE: The license to practice pharmacy of

SAR Pharmacy Discount, Inc.
2089 Southwest 67th Avenue
Miami, Florida 33155
&
1115 W. Okeechobee Road
Unit 101
Hialeah, Florida 33018
CASE NO. 2012-16646
LICENSE NO. PH 25265

The Department of Health has filed an Administrative Complaint against you a copy of which may be obtained by contacting: Kristal Beharry, Assistant General Counsel, Prosecution Services Unit, 4052 Bald Cypress Way, Bin #C65, Tallahassee, Florida 32399-3265, (850) 245-4444. If no contact has been made by you concerning the above by November 25, 2013, the matter of the Administrative Complaint will be presented at an ensuing meeting of the Board of Pharmacy. In an informal proceeding.

In accordance with the Americans with Disabilities Act, persons needing a special accommodation to participate in this proceeding should contact the individual or agency sending notice not later than seven days prior to the proceeding at the address given on the notice. Telephone: (850) 245-4640, 1-800-955-8771 (TDD) or 1-800-955-8770(V), via Florida Relay Service.

10/07, 10/14, 10/21, 10/28/2013

Community Newspapers
6796 S.W. 62nd Avenue
South Miami, Florida 33143
305-669-7355 Ext. 228 • Fax: 305-662-6980

EXHIBIT
D

I, Daisy King, hereby certify in my official capacity as custodian for the Board of Pharmacy's licensure files that the Board of Pharmacy as of December 17, 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **CASE NAME: SAR Pharmacy Discount, Inc., CASE NUMBER: 2012-16646** which would affect the Subject's substantial interests or rights.

Daisy King
Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Daisy King, whose identity is known to me personally (type of identification) and who, under, oath, acknowledges that his/her signature appears above.

Sworn to and subscribed this 17th day of Dec, 2013.

LORRAINE GAIL CURRY
MY COMMISSION # EE 97887
EXPIRES: May 26, 2015
Bonded Thru Notary Public Underwriters

Lorraine Gail Curry
Notary Public

EXHIBIT
E

AFFIDAVIT

I, Angel Sanders, Deputy Clerk for the Department Clerk's Office, hereby certify in my official capacity as custodian for the Department Clerk's records, that the Department Clerk's Office has not received an Election of Rights form or other responsive pleading, which requests a hearing prior to any Department action regarding **Case Name: SAR Pharmacy Discount, Inc. Case No.: 2012-16646**, which would affect the Respondent's substantial interests or rights.

Angel Sanders
Custodian of Record
Department Clerk's Office

Before me, personally appeared Angel Sanders, whose identity is known to me by personally known (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 17th day of December, 2013.

Lawanda Bell
Notary Public

My Commission Expires:

LAWANDA M BELL
MY COMMISSION # EE197051
EXPIRES May 09, 2016
(407) 398-0153 FloridaNotaryService.com

EXHIBIT
tabbies
F

STATE OF FLORIDA
DEPARTMENT OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-16646**

SAR PHARMACY DISCOUNT, INC.,

Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or after July 1,

2001, pursuant to this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. . . .

3. The investigation and prosecution of this case has resulted in costs in the total amount of $1,689.02, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**0.80**	**$43.92**
Investigation:	**20.90**	**$1,326.02**
Legal:	**3.00**	**$319.08**
Compliance:	**0.00**	**0.00**
Sub Total:	**24.70**	**$1,689.02**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$1,689.02**

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $1,369.94 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $1,369.94 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $1,369.94.

DATED this 19th day of December, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Kristal Beharry
Assistant General Counsel
Fla. Bar No. **0078070**
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: Kristal.Beharry@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 19th day of December, 201_, to: SAR PHARMACY DISCOUNT, INC., 2089 Southwest 67th Ave., Miami, FL 33155, and 11115 W. Okeechobee Road, Unit 101, Hialeah, FL 33018.

Kristal Beharry
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2012-16646** (Department of Health v. **SAR PHARMACY DISCOUNT, INC.**) are **ONE THOUSAND SIX HUNDRED EIGHTY-NINE DOLLARS AND TWO CENTS ($1,689.02).**

6) The costs for DOH case numbers **2012-16646** (Department of Health v. **SAR PHARMACY DISCOUNT, INC.**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case numbers **2012-16646** (Department of Health v. **SAR PHARMACY DISCOUNT, INC.**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to

EXHIBIT
A

keep track of their time in six-minute increments (e.g., investigators and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of her knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 18th day of December, 2013, by Shane Walters, who is personally known to me.

Bernadette Lawanda Hayes

Notary Signature

Bernadette Lawanda Hayes

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

BERNADETTE LAWANDA HAYES
Commission # EE 838344
Expires September 25, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

Complaint Cost Summary

Complaint Number: 201216646

Subject's Name: SAR PHARMACY DISCOUNT, INC

	***** Cost to Date *****	
	Hours	Costs
Complaint:	0.80	$43.92
Investigation:	20.90	$1,326.02
Legal:	3.00	$319.08
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	24.70	$1,689.02
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,689.02

EXHIBIT

tabbies

1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216646

Report Date 12/17/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA23	0.80	$54.90	$43.92	11/14/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
Sub Total	**0.80**		**$43.92**			
INVESTIGATIVE SERVICES UNIT						
MI207	0.60	$61.19	$36.71	11/21/2012	76	REPORT PREPARATION
MI207	0.70	$61.19	$42.83	11/27/2012	4	ROUTINE INVESTIGATIVE WORK
MI207	1.30	$61.19	$79.55	11/27/2012	58	TRAVEL TIME
MI207	0.80	$61.19	$48.95	11/27/2012	76	REPORT PREPARATION
MI207	0.60	$61.19	$36.71	11/28/2012	4	ROUTINE INVESTIGATIVE WORK
MI207	0.70	$63.98	$44.79	12/05/2012	4	ROUTINE INVESTIGATIVE WORK
MI207	1.30	$63.98	$83.17	12/05/2012	58	TRAVEL TIME
MI207	0.80	$63.98	$51.18	12/05/2012	76	REPORT PREPARATION
MI207	0.70	$63.98	$44.79	12/05/2012	76	REPORT PREPARATION
MI207	0.60	$63.98	$38.39	12/13/2012	76	REPORT PREPARATION
MI207	0.40	$63.98	$25.59	12/27/2012	4	ROUTINE INVESTIGATIVE WORK
MI207	0.60	$63.98	$38.39	01/16/2013	4	ROUTINE INVESTIGATIVE WORK
MI207	2.10	$63.98	$134.36	02/18/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	1.50	$63.98	$95.97	03/15/2013	7	PRELIMINARY INVESTIGATION
MI207	0.60	$63.98	$38.39	08/27/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	1.60	$63.98	$102.37	08/27/2013	58	TRAVEL TIME
MI207	0.60	$63.98	$38.39	08/28/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	1.10	$63.98	$70.38	08/28/2013	58	TRAVEL TIME
MI207	0.70	$63.98	$44.79	08/29/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	0.50	$63.98	$31.99	09/10/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	1.40	$63.98	$89.57	09/10/2013	58	TRAVEL TIME
MI207	0.40	$63.98	$25.59	09/11/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	0.80	$63.98	$51.18	09/11/2013	58	TRAVEL TIME
MI207	0.50	$63.98	$31.99	09/18/2013	6	SUPPLEMENTAL INVESTIGATION

EXHIBIT
exhibit 2

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216646

Report Date 12/17/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
Sub Total	**20.90**		**$1,326.02**			
PROSECUTION SERVICES UNIT						
HLL90A	0.30	$106.35	$31.91	01/18/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL90A	0.30	$106.35	$31.91	02/12/2013	60	MISCELLANEOUS
HLL90A	0.40	$106.35	$42.54	05/03/2013	25	REVIEW CASE FILE
HLL90A	0.90	$106.35	$95.72	05/07/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL90A	0.10	$106.35	$10.64	06/27/2013	68	SIGNING CLOSING ORDERS, ADMINISTRATIVE COMPLAINTS AND REASONAB
HLL90A	0.70	$106.35	$74.45	07/02/2013	90	POST PROBABLE CAUSE PROCESSING
HLL90A	0.10	$106.35	$10.64	08/06/2013	60	MISCELLANEOUS
HLL90A	0.20	$106.35	$21.27	09/24/2013	103	REVIEW SUPPLEMENTAL REPORT
Sub Total	**3.00**		**$319.08**			

Total Cost	**$1,689.02**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 12/17/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description
	SubTotal			
	Total Expenses			

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: MIAMI XI		Date of Case: 11/8/12		Case Number: PH 2012-16646
Subject: **SAR PHARMACY DISCOUNT, INC** 2089 Sw 67th Ave Miami, FL 33155 (305)263-5800			Source: **DOH/ISU-MIAMI**	
Prefix: 2205	License #:25265	Profession: Pharmacy	Board: Pharmacy	Report Date:9/18/13
Period of Investigation: 8/26/13-9/18/13			Type of Report: SUPPLEMENTAL 1	
Alleged violation : SEE FINAL REPORT				

Synopsis:
This supplemental investigation is predicated upon receipt of a request from KRISTAL BEHARRY ESQ, Senior Attorney with DOH PSU. The request was to serve an AC packet and related papers to SAR PHARMACY owner YOELI SALGUIERO at her last known address of 2089 Sw 67th Ave Miami, FL 33155

On 8/27/13, this investigator presented to SARs last known address and was not able to serve owner SALGUIERO as a new business was open at location. A search of various online databases showed a secondary residential address for SALGUIERO of 11115 W Okeechobee Road Unit 101 Hialeah, FL 33018 this address was attempted with no success on 8/28/13, 8/29/13, 9/10/13, and 9/11/13. Phone number found for SALGUIERO 305-888-3284 was attempted, no answer was received when calls were attempted. As of the date of this report no response has been received from SALGUIERO.

Exhibits:
S1- Copy of affidavit of service for SAR PHARMACY (p2)

Related Case(s): 2012-16637

Investigator/Date: September 18, 2013 Neil Downs Investigator MI-207	Approved By/Date: September 18, 2013 Edward Thompson Manager

Distribution: HQ/ISU

13 SEP 23 AM 8:59
RECEIVED-LEGAL
SEP 20

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

Department of Health
Petitioner

vs

Case No. 2012-16646

Sar Pharmacy-Owner Yoeli Salguiero
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:
1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on 8/27/13, 8/28/13, 8/29/13, 9/10/13, 9/11/13, Affiant made a diligent effort to locate Respondent, to serve Administrative complaint packet and related papers at last known address of 2089 SW 67th Avenue Miami, FL 33155 and a secondary address of 11115 W Okeechobee Road Unit 101 Hialeah, FL 33018.

3) Check applicable answer below:

x Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses

Neil Downs
Affiant

State Of Florida
County Of Miami Dade

Before me, personally appeared Neil Downs whose identity is known to me by personally known (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 18th day of September 2013.

Notary Public-State of Florida

My Commission Expires

ISKRA CAVATORTA
Commission # FF 002218
Expires March 26, 2017
Bonded Thru Troy Insurance, 800 385-7019

ISKRA Cavatorta
Type or Print Name

EXHIBIT S1

INV FORM 321

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Sar Pharmacy Discount, Inc., (KB)**
Case Number: 2012-16646

MEMBERS: **Lee Fallon and Debra Glass**

DATE OF PCP: **June 27, 2013** **AGENDA ITEM: A-7**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3), Florida Administrative Code;

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss

___ **other**

Lee J Fallon 6/27/2013

Chair, Probable Cause Panel Date
Board of Pharmacy

DOH INVESTIGATIVE REPORT

Office: MIAMI XI	Date of Case: 11/08/2012	Case Number: PH 2012-16646

Subject:	Source:
SAR PHARMACY DISCOUNT INC 2089 Sw 67th Ave Miami, FL 33155 (305)263-5800	**DOH/ISU**

Prefix:	License #:	Profession:	Prefix:	License #:
2205	25265	Pharmacy	PH	25265

Period of Investigation: 11/16/12-1/15/13	Type of Report: FINAL

Alleged Violation: Possible violation of SS. 456.072(1)(k)(l)(dd), 465.016(1)(j)(r), 465.0123(1)(c), F.S. and Rule 64B16.28.101(1), 64B16-28.1081 and 64B16-28.202(3)(a)(b)(4)(b), F.A.C. Failure to perform statutory/legal obligation; Failure to be available for inspection; Failure to operate 5 days/40 hours per week; Failure to notify Board of closure

Synopsis:

This investigation is predicated upon receipt of an internally generated pharmacy inspection alleging that on 10/16/12, 10/31/12 and 11/7/12 a routine inspection was attempted at SAR Pharmacy and Discount Inc (PH 25265), located at 2089 SW 67th Ave, Miami, FL 33155, the pharmacy was closed and appeared non-operational. The DOH database reflected that a closure had not been reported by the owner YOELI SALGUEIRO who is not licensed.

SAR was notified of the investigation by letter, dated 11/16/12 (Exhibit #2) and was provided a copy of the CASE SUMMARY and initiating documents from Exhibit #1.

No patients were identified thus no notification was necessary

A search of the DOH licensure database reveals that SAR possesses a clear and active license as a community pharmacy.

SAR is not known to be represented by an attorney.

SAR's owner YOELI SALGUEIRO executed a voluntary relinquishment on 12/18/12

Related Case(s): 2012-16637

Investigator/Date: 1/15/13	Approved By/Date: 1/15/13
Neil Downs Investigator MI-207	Edward Thompson Manager

Distribution: HQ/ISU

Received
Investigative Services
JAN 18
DOH
Tallahassee, FL

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Interviews/Statements:
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Statement of YOELI SALGUEIRO, OWNER SAR PHARMACY LLC (SUBJECT) 3

IV. EXHIBITS

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2. Copy of Notification letter, dated 11/16/12 8
3. Copy of letter from property landlord and attached license documents 9-23
4. Copy of executed VR for ACOSTA 24-26

INVESTIGATIVE DETAILS

On 12/18/12 this investigator received a copy of SAR's executed VR (Exhibit #4). Copy of VR was emailed to PSU as per desk guide guidelines on 12/18/12.

On 12/13/12 this investigator was able to speak with landlord BERNIE NAVARRO. NAVARRO provided access to pharmacy location to this investigator. This investigator was able to observe that location contained no medications and appeared abandoned.

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit #1 contains the Case Summary and initiating documents.

Exhibit #2 Copy of Notification letter, dated 11/16/12

Exhibit #3 Copy of Sunbiz profile for SAR

Exhibit #4 Copy of executed VR for ACOSTA

Statement of DAVID WARSHOFSKY, INVESTIGATOR, MIAMI ISU (SOURCE)
Employment
8350 NW 52nd Terrace Suite 400
Miami, FL 33166
(305)470-5800

On 11/16/12, this investigator was able to speak with WARSHOFSKY in the Miami ISU office. He states that she does not have any additional information regarding the initial complaint beyond what is stated in the initial complaint form (Exhibit #1).

Statement of YOELI SALGUEIRO, OWNER SAR PHARMACY LLC (SUBJECT)
Employment
2089 SW 67th Avenue
Miami, FL 33155
(305)263-6632

On 12/18/12 this investigator was able to speak with SALQUIERO when she presented to Miami ISU office. SALGUIERO executed a voluntary relinquishment (Exhibit #4) of the pharmacy license #25266 for SAR PHARMACY LLC.

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Rick Scott
Governor

FLORIDA DEPARTMENT OF HEALTH

John Armstrong M.D.
State Surgeon General

November 16, 2012

CONFIDENTIAL TO:
Yoeli Salgueiro-Owner
Sar Pharmacy Discount Inc
11115 W Okeechobee Rd Unit 101
Hialeah, FL 33018

Case Number: 2012-16646

Dear Sar Pharmacy Discount Inc:

We are currently investigating the enclosed document received by the Department of Health. This investigation was initiated after it was determined that you may have violated the Pharmacy Practice Act.

Within **20 days** of receiving this letter, you may:

- submit a **written response** to the address below; **or**
- call our office to schedule an **interview**.

Please provide a copy of your **curriculum vitae** and identify your **specialty** even if you choose not to submit a response. Include the above-referenced case number in any correspondence that you send.

Florida law requires that this case and all investigative information remain confidential until 10 days after the Probable Cause Panel has determined that a violation occurred or you give up the right to confidentiality. Therefore, the contents of the investigation cannot be disclosed to you or the general public. You may make a written request for a copy of the investigative file and it will be sent to you when the investigation is complete. You may submit an additional written response to the information in the investigative file within 20 days of receipt.

You are not required to answer any questions or give any statement, and you have the right to be represented by an attorney. It is not possible to estimate how long it will take to complete this investigation because the circumstances of each investigation differ.

The mission of the Department of Health is to protect and promote the health of all residents and visitors in the state through organized state and community efforts, including cooperative agreements with counties. If you have any questions please call us at (305)470-5897. In addition, if you have any concerns or suggestions about our complaint process, please fill-out our *Customer Concerns or Suggestions* form at www.floridashealth.com/mqa/survey.html.

Sincerely,

Neil Downs
Medical Malpractice Investigator

/ND
Enclosure

CONFIDENTIAL

EXHIBIT 2 8

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. DOH Case No. 2012-06637 & 2012-16646

SAR PHARMACY DISCOUNT INC

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, SAR PHARMACY DISCOUNT INC license number PH 25266 by and through its owner/officer, YOELI SALGUEIRO, hereby voluntarily relinquishes

Respondent's permit to operate a community pharmacy and special Close Pharmacy in the

State of Florida and states

as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent, by and through its owner/officer, YOELI SALGUEIRO, understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's permit pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent and its owner/officer, YOELI SALGUEIRO, agree to never reapply for a pharmacy permit in the State of Florida.

3. Respondent, by and through its owner/officer, YOELI SALGUEIRO, agrees to voluntarily cease operating as a community pharmacy immediately upon executing this Voluntary Relinquishment. Respondent, by and through its owner/officer, YOELI SALGUEIRO, further agrees to refrain from operating as a community pharmacy until such time as this

EXHIBIT 4

Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, by and through its owner/officer, YOELI SALGUEIRO, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent, by and through its owner/officer, YOELI SALGUEIRO, understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10), Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent, by and through its owner/officer, YOELI SALGUEIRO, agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent, by and through its owner/officer, YOELI SALGUEIRO, hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent, by and through its owner/officer, YOELI SALGUEIRO, authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent, by and through its owner/officer, YOELI SALGUEIRO, agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its

members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 18 day of 12, 2012.

SAR PHARMACY DISCOUNT INC
by and through its Owner/Officer, YOELI SALGUEIRO

STATE OF FLORIDA }
}
COUNTY OF DADE }

Before me, personally appeared YOELI SALGUEIRO, whose identity is known to me by DL (type of identification) and who, under oath, acknowledges that his/her signature appears above. Sworn to and subscribed before me this 18 day of December, 2012.

NOTARY PUBLIC

My Commission Expires:

JENEICE MAYERS
Commission # EE 215645
Expires August 13, 2014
Bonded Thru Troy Fain Insurance 800-432-4254

HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201216637

SAR PHARMACY DISCOUNT, INC,
RESPONDENT.

NOTICE

TO: SAR PHARMACY DISCOUNT, INC
2089 SW 67TH AVE
MIAMI, FL 33155

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Determination of Waiver

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

Rick Scott
Governor

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

John H. Armstrong, MD, FACS
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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201216637

SAR PHARMACY DISCOUNT, INC,
RESPONDENT.

NOTICE

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11115 W. OKEECHOBEE ROAD UNIT 101
HIALEAH, FL 33018

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Kristal Beharry, Assistant General Counsel (KB)
RE: Determination of Waiver
SUBJECT: DOH v. SAR Pharmacy Discount, Inc.
DOH Case Number 2012-16637
DATE: December 18, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	SAR Pharmacy Discount, Inc.
Subject's Address of Record:	2089 SW 67th Avenue Miami, FL 33155
Enforcement Address:	2089 SW 67th Avenue Miami, FL 33155
Additional Address:	11115 W. Okeechobee Road, Unit 101 Hialeah, FL 33018
Subject's License No:	25266 **Rank:** PH
Licensure File No:	18155
Initial Licensure Date:	2/16/2011
Board Certification:	None
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Section 465.023(1)(c), F.S. (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3), F.A.C.
Prior Discipline:	None
Probable Cause Panel:	June 27, 2013 Fallon & Glass
Subject's Attorney:	Pro Se
Complainant/Address:	Department of Health/Investigative Services Unit-Miami

Materials Submitted:

Memorandum to the Board
Motion for Determination of Waiver
Exhibit A – Administrative Complaint
Exhibit B – Copy of certified mail receipt
Exhibit C – Affidavit of diligent search
Exhibit D – Proof of publication
Exhibit E – Board Affidavit
Exhibit F – Clerk Affidavit
Motion to assess costs with
Exhibit A – Affidavit of Fees and Costs
Exhibit 1 – Complaint Cost Summary
Exhibit 2 – Itemized Cost by Complaint
Supplemental Investigative Report 9/18/13
PCP Memo
Final Investigative Report Exhibits 1 – 4

Disciplinary Guidelines:
Section 465.023(1)(c), F.S., by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3)

- $1,500 fine up to Revocation

PRELIMINARY CASE REMARKS: INFORMAL HEARING

This is an Administrative Complaint alleging a violation of Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3), Florida Administrative Code, by failing to notify the Board of Pharmacy in writing as to the effective date of closure, return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy, and/or notify the Board of Pharmacy which permittee is to receive the prescription files.

On or about October 16, October 31, and November 7, 2012, a Department of Health inspector attempted to conduct a routine inspection of Respondent and discovered that Respondent's facility was closed and non-operational.

RECOMMENDATION OF THE DEPARTMENT

- Revocation

CONSIDERATIONS SUPPORTING THE DEPARTMENT'S RECOMMENDATION

- The recommendation is appropriate and within the guidelines

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-16637**

SAR PHARMACY DISCOUNT, INC.,

Respondent.

_____/

MOTION FOR DETERMINATION OF WAIVER AND FOR FINAL ORDER AFTER A HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

PETITIONER, the Florida Department of Health, by and through the undersigned counsel, hereby moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore Petitioner states:

1. An Administrative Complaint was filed against Respondent on June 27, 2013. A copy of said Administrative Complaint is attached hereto as Petitioner's Exhibit A.

2. Copies of the Administrative Complaint, Explanation of Rights form, and Election of Rights form were sent to Respondent via certified US mail on: July 2, 2013 (7196 9008 9111 9326 6114). Service on Respondent via certified mail was not successful. A copy of the certified mail receipt and envelope is attached as Petitioner's Exhibit B.

3. Thereafter, Petitioner requested personal service on Respondent, which was unsuccessful on August 27th, 28th, 29th, September 10th, and 11th, 2013. The affidavit of personal service is attached as Petitioner's Exhibit C.

4. Thereafter, Petitioner requested that the Community Newspapers publish a Legal Notice of Action beginning on October 7, 2013 and appearing consecutively on October 14th, 21st, and 28th, 2013. Petitioner received proof of publication on November 12, 2013, which is attached as Petitioner's Exhibit D.

5. Rule 28-106.111(2), Florida Administrative Code, provides in pertinent part that:

> . . . persons seeking a hearing on an agency decision which does or may determine their substantial interests shall file a petition for hearing with the agency within 21 days of receipt of written notice of the decision.

6. Rule 28.106.111(4), Florida Administrative Code, provides that:

> Any person who received written notice of an agency decision and who fails to file a written request for a hearing within 21 days waives the right to request a hearing on such matters.

7. Respondent has not filed an Election of Rights form, or any other responsive pleading, with Petitioner or the Board of Pharmacy within the required twenty-one (21) day period of time. Copies of affidavits supporting the same are attached hereto as Petitioner's Exhibits E & F.

8. Based upon the foregoing, Respondent has waived the right to dispute any materials facts contained within the Administrative Complaint. Therefore, there are no disputed issues of material fact to be resolved by the Board.

9. Respondent has been advised by way of this Motion, that a copy of the investigative file in this case will be furnished to the Board, establishing a prima facie case regarding the violations as set forth in the Complaint.

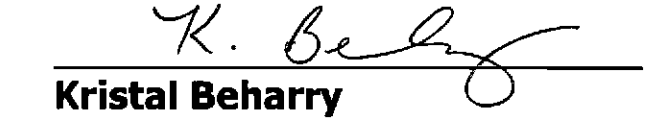
WHEREFORE, Petitioner respectfully requests that the Board find that Respondent has waived the right to dispute any materials facts contained within the Administrative Complaint and enter a Final Order imposing whatever discipline upon Respondent's license that the Board deems appropriate.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Kristal Beharry
Assistant General Counsel
Fla. Bar No. **0078070**
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683
Email: Kristal.beharry@doh.state.fl.us

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 19th day of December, 2012, to: SAR Pharmacy Discount, Inc. at 2089 Southwest 67th Avenue, Miami, FL 33155 and 11115 W. Okeechobee Road, Unit 101, Hialeah, FL 33018.



Kristal Beharry
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. CASE NO. 2012-16637

SAR PHARMACY DISCOUNT, INC.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Sar Pharmacy Discount, Inc., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a permitted special closed system pharmacy within the state of Florida, having been issued permit number PH 25266.

EXHIBIT
A

3. Respondent's address of record is 2089 Southwest 67th Avenue, Miami, Florida 33155.

4. On or about February 16, 2011, Respondent was issued a license to operate its pharmacy.

5. On or about October 16, 2012, October 31, 2012, and November 7, 2012, a Department of Health inspector attempted to conduct a routine inspection of Respondent and discovered that Respondent's facility was closed and non-operational.

6. Rule 64B16-28.202(2), Florida Administrative Code, defines "closing of a pharmacy" as the cessation or termination of professional and business activities within a pharmacy for which a permit has been issued under Chapter 465, Florida Statutes.

7. Rule 64B16-28.202(3), Florida Administrative Code, provides that prior to closure of a pharmacy, the permittee shall notify the Board of Pharmacy in writing as to the effective date of closure, return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy, and notify the Board of Pharmacy which permittee is to receive the prescription files.

8. Respondent failed to do one or more of the following prior to closure:

a. Notify the Board of Pharmacy in writing of Respondent's effective date of closure;

b. Return or arrange to return the pharmacy permit; and/or

c. Advise the Board of Pharmacy which permittee is to receive the prescription files.

9. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any of the requirements of Chapter 465, Florida Statutes, or any of the rules of the Board of Pharmacy; of Chapter 499, Florida Statutes; of 21 U.S.C. ss. 301-392; of 21 U.S.C. ss. 821 et. seq.; or Chapter 893, Florida Statutes.

10. As set forth above, Respondent failed to do one or more of the following prior to closure:

a. Notify the Board of Pharmacy in writing of Respondent's effective date of closure;

b. Return or arrange to return the pharmacy permit; and/or

c. Advise the Board of Pharmacy which permittee is to receive the prescription files.

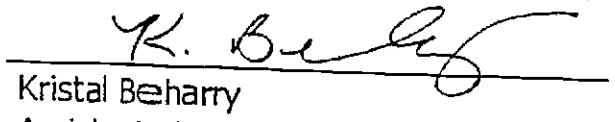
11. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3), Florida Administrative Code, by failing to notify the Board of Pharmacy in writing as to the effective date of closure, return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy, and/or notify the Board of Pharmacy which permittee is to receive the prescription files.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees

billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 27th **day of** June, **2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health



Kristal Beharry
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Florida Bar # 0078070
Telephone: (850) 245-4444
Facsimile: (850) 245-4683

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE JUN 27 2013

/KB
PCP: 06/27/13
PCP Members: Fallon & Glass

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

7196 9008 9111 9326 6114

TO:

Stip Pack
Cassandra/Beharry
Date Mailed 7/2/2013
2012-16637

SENDER:

REFERENCE:

Sar Pharmacy Discount

PS Form 3800, January 2005

RETURN RECEIPT SERVICE	Postage	
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

USPS®
Receipt for Certified Mail™

No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

EXHIBIT
B

Florida Department of Health
Office of the General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-1701
PHONE: 850/245-4444

7196 9008 9111 9326 6114

FIRST CLASS

$07.17⁰
JUL 02 2013
MAILED FROM ZIP CODE 32301

UNCLAIMED

San Pharmacy Discount Inc

07/27/13

NIXIE 331553231-1N

RETURN TO SENDER
UNCLAIMED
UNABLE TO FORWARD
RETURN TO SENDER

7-6
RTS

PRACTITIONER REGULATION
LEGAL
2013 JUL 30 PM 1:10

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

Department of Health
Petitioner

vs

Case No. 2012-16637

Sar Pharmacy-Owner Yoeli Salguiero
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:
1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on 8/27/13, 8/28/13, 8/29/13, 9/10/13, 9/11/13, Affiant made a diligent effort to locate Respondent, to serve Administrative complaint packet and related papers at last known address of 2089 SW 67th Avenue Miami, FL 33155 and a secondary address of 11115 W Okeechobee Road Unit 101 Hialeah, FL 33018.

3) Check applicable answer below:

x Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses

Neil Downs
Affiant

State Of Florida
County Of Miami Dade

Before me, personally appeared Neil Downs whose identity is known to me by ____ personally known (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 18th day of September 2013.

Notary Public-State of Florida

My Commission Expires

ISKRA CAVATORTA
Commission # FF 002218
Expires March 26, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

ISKRA Cavatorta
Type or Print Name

EXHIBIT
C
Initial

EXHIBIT 51

INV FORM 321

A FREE AND INDEPENDENT NEWS ER VOICE

COMMUNITY NEWSPAPERS

PUBLISHED MONDAY
MIAMI, MIAMI-DADE, FLORIDA

RECEIVED-LEGAL

13 NOV 12 AM 9:01

STATE OF FLORIDA
COUNTY OF MIAMI-DADE:

Before the undersigned authority personally appeared **GEORGIA TAIT** who on oath says she is **OFFICE MANAGER** of Legal Advertising of Community Newspapers, published Monday at Miami-Dade, Florida; that the attached copy of advertisement, being a Legal Advertisement of Notice in the Matter of

NOTICE OF ACTION
THE LICENSE TO PRACTICE PHARMACY OF
SAR PHARMACY DISCOUNT, INC.
CASE NO. 2012-16637

in the XXXXX Court, was published in said newspaper in the issue of

10/07, 10/14, 10/21, 10/28/2013

Affiant further says that the said Community Newspaper, published at Miami-Dade County, Florida, and that the newspaper has heretofore been continuously published in said Miami-Dade County, Florida, and has been entered as second class mail matter at the post office in Miami, Florida, Miami-Dade County, and additional mailing offices, for a period of one year next preceding the first publication of the attached copy of advertisement; and affiant further says that she has neither paid nor promised any person, firm or corporation any rebate, commission or refund for the purpose of securing this advertisement for publication in the said newspaper.

PROOF OF PUBLICATION -

AFFIANT Gwen K. Tait

Sworn to and subscribed before me this

28TH day of OCTOBER 2013.

JESUS TOLEDO

(Print or type or stamp commissioned name of Notary Public)

(SEAL)

JESUS C. TOLEDO
Notary Public - State of Florida
My Comm. Expires Apr 10, 2017
Commission # EE 876555
Bonded Through National Notary Assn.

My Commission Expires:

Personally known X

NOTICE OF ACTION

BEFORE THE BOARD OF PHARMACY

IN RE: The license to practice pharmacy of

SAR Pharmacy Discount, Inc.
2089 Southwest 67th Avenue
Miami, Florida 33155
&
11115 W. Okeechobee Road
Unit 101
Hialeah, Florida 33018

CASE NO.: 2012-16637
LICENSE NO.: PH 25266

The Department of Health has filed an Administrative Complaint against you, a copy of which may be obtained by contacting, Kristal Beharry, Assistant General Counsel, Prosecution Services Unit, 4052 Bald Cypress Way, Bin #C65, Tallahassee, Florida 32399-3265, (850) 245-4444. If no contact has been made by you concerning the above by November 25, 2013, the matter of the Administrative Complaint will be presented at an ensuing meeting of the Board of Pharmacy in an informal proceeding.

In accordance with the Americans with Disabilities Act, persons needing a special accommodation to participate in this proceeding should contact the individual or agency sending notice not later than seven days prior to the proceeding at the address given on the notice. Telephone: (850) 245-4640, 1-800-955-8771 (TDD) or 1-800-955-8770(V), via Florida Relay Service.

10/07, 10/14, 10/21, 10/28/2013

Community Newspapers
6796 S.W. 62nd Avenue
South Miami, Florida 33143
305-669-7355 Ext. 228 • Fax: 305-662-6980

EXHIBIT
exhibit
D

I, Daisy King, hereby certify in my official capacity as custodian for the Board of Pharmacy's licensure files that the Board of Pharmacy as of December 19, 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **CASE NAME: SAR Pharmacy Discount, Inc., CASE NUMBER: 2012-16637** which would affect the Subject's substantial interests or rights.

Daisy King
Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Daisy King, whose identity is known to me personally (type of identification) and who, under, oath, acknowledges that his/her signature appears above.

Sworn to and subscribed this 19th day of Dec, 2013.

Lorraine Gail Curry
Notary Public

LORRAINE GAIL CURRY
MY COMMISSION # EE 97887
EXPIRES: May 26, 2015
Bonded Thru Notary Public Underwriters

EXHIBIT
E

AFFIDAVIT

I, Angel Sanders, Deputy Clerk for the Department Clerk's Office, hereby certify in my official capacity as custodian for the Department Clerk's records, that the Department Clerk's Office has not received an Election of Rights form or other responsive pleading, which requests a hearing prior to any Department action regarding **Case Name: SAR Pharmacy Discount, Inc. Case No.: 2012-16637**, which would affect the Respondent's substantial interests or rights.

Angel Sanders
Custodian of Record
Department Clerk's Office

Before me, personally appeared Angel Sanders whose identity is known to me by personally known (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 17th day of December, 2013.

Lawanda Bell
Notary Public

My Commission Expires:

LAWANDA M BELL
MY COMMISSION # EE187051
EXPIRES May 09, 2016
-0153 FloridaNotaryService.com

EXHIBIT
F

STATE OF FLORIDA
DEPARTMENT OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-16637**

SAR PHARMACY DISCOUNT, INC.,

Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or after July 1,

2001, pursuant to this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. . . .

3. The investigation and prosecution of this case has resulted in costs in the total amount of $1,738.23, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**1.00**	**$54.90**
Investigation:	**21.00**	**$1,334.11**
Legal:	**3.30**	**$349.22**
Compliance:	**0.00**	**0.00**
Sub Total:	**25.30**	**$1,738.23**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$1,738.23**

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $1,389.01 as evidenced in the attached affidavit. (Exhibit A).

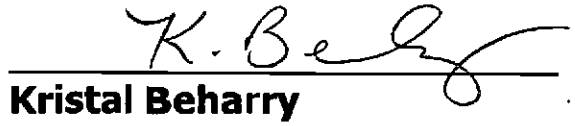
4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $1,389.01 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $1,389.01.

DATED this 19th day of December, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health



Kristal Beharry
Assistant General Counsel
Fla. Bar No.**0078070**
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: Kristal.beharry@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 19th day of December, 201_, to: SAR PHARMACY DISCOUNT, INC., 2089 Southwest 67th Ave., Miami, FL 33155, and 11115 W. Okeechobee Rd., Unit 101, Hialeah, FL 33018.

Kristal Beharry
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

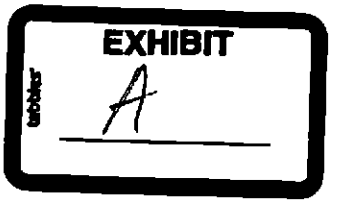
3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2012-16637** (Department of Health v. **SAR PHARMACY DISCOUNT, INC.**) are **ONE THOUSAND SEVEN HUNDRED THIRTY-EIGHT DOLLARS AND TWENTY-THREE CENTS ($1,738.23).**

6) The costs for DOH Case number **2012-16637** (Department of Health v. **SAR PHARMACY DISCOUNT, INC.**) is summarized in Exhibit 1 (Cost Summary Report), which is attached hereto.

7) The itemized costs and expenses for DOH Case number **2012-16637** (Department of Health v. **SAR PHARMACY DISCOUNT, INC.**) is detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.



8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to keep track of their time in six-minute increments (e.g., investigators and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of his knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 18th day of December, 2013, by Shane Walters, who is personally known to me.

Bernadette Lawanda Hayes

Notary Signature

Bernadette Lawanda Hayes

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

BERNADETTE LAWANDA HAYES
Commission # EE 838344
Expires September 25, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

Complaint Cost Summary

Complaint Number: 201216637

Subject's Name: SAR PHARMACY DISCOUNT, INC

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	1.00	$54.90
Investigation:	21.00	$1,334.11
Legal:	3.30	$349.22
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	25.30	$1,738.23
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,738.23

EXHIBIT

Letter 1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216637

Report Date 12/17/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA107	1.00	$54.90	$54.90	11/13/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
Sub Total	**1.00**		**$54.90**			
INVESTIGATIVE SERVICES UNIT						
MI207	0.70	$61.19	$42.83	11/27/2012	4	ROUTINE INVESTIGATIVE WORK
MI207	1.30	$61.19	$79.55	11/27/2012	58	TRAVEL TIME
MI207	0.80	$61.19	$48.95	11/27/2012	76	REPORT PREPARATION
MI207	0.60	$61.19	$36.71	11/28/2012	4	ROUTINE INVESTIGATIVE WORK
MI207	0.70	$63.98	$44.79	11/30/2012	4	ROUTINE INVESTIGATIVE WORK
MI207	1.20	$63.98	$76.78	11/30/2012	58	TRAVEL TIME
MI207	1.10	$63.98	$70.38	12/05/2012	4	ROUTINE INVESTIGATIVE WORK
MI207	1.20	$63.98	$76.78	12/05/2012	58	TRAVEL TIME
MI207	0.60	$63.98	$38.39	12/13/2012	76	REPORT PREPARATION
MI207	0.40	$63.98	$25.59	12/27/2012	4	ROUTINE INVESTIGATIVE WORK
MI207	0.60	$63.98	$38.39	01/16/2013	4	ROUTINE INVESTIGATIVE WORK
MI207	2.10	$63.98	$134.36	02/18/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	1.50	$63.98	$95.97	03/15/2013	7	PRELIMINARY INVESTIGATION
MI207	0.60	$63.98	$38.39	08/27/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	1.60	$63.98	$102.37	08/27/2013	58	TRAVEL TIME
MI207	0.60	$63.98	$38.39	08/28/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	1.10	$63.98	$70.38	08/28/2013	58	TRAVEL TIME
MI207	0.70	$63.98	$44.79	08/29/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	0.50	$63.98	$31.99	09/10/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	1.40	$63.98	$89.57	09/10/2013	58	TRAVEL TIME
MI207	0.40	$63.98	$25.59	09/11/2013	6	SUPPLEMENTAL INVESTIGATION
MI207	0.80	$63.98	$51.18	09/11/2013	58	TRAVEL TIME
MI207	0.50	$63.98	$31.99	09/18/2013	6	SUPPLEMENTAL INVESTIGATION

EXHIBIT
2

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216637

Report Date 12/17/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
Sub Total	**21.00**		**$1,334.11**			
PROSECUTION SERVICES UNIT						
HLL90A	0.30	$106.35	$31.91	01/18/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL90A	0.30	$106.35	$31.91	02/12/2013	60	MISCELLANEOUS
HLL90A	0.40	$106.35	$42.54	05/03/2013	25	REVIEW CASE FILE
HLL90A	0.90	$106.35	$95.72	05/07/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL90A	0.70	$106.35	$74.45	07/02/2013	90	POST PROBABLE CAUSE PROCESSING
HLL90A	0.10	$106.35	$10.64	08/06/2013	60	MISCELLANEOUS
HLL90A	0.20	$106.35	$21.27	09/24/2013	103	REVIEW SUPPLEMENTAL REPORT
HLL90A	0.20	$101.95	$20.39	11/18/2013	60	MISCELLANEOUS
HLL90A	0.20	$101.95	$20.39	11/18/2013	60	MISCELLANEOUS
Sub Total	**3.30**		**$349.22**			

Total Cost	**$1,738.23**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 12/17/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: MIAMI XI	Date of Case: 11/8/12	Case Number: PH 2012-16637
Subject: **SAR PHARMACY DISCOUNT, INC** 2089 Sw 67th Ave Miami, FL 33155 (305)263-5800	Source: **DOH/ISU-MIAMI**	

Prefix: 2205	License #:25266	Profession: Pharmacy	Board: Pharmacy	Report Date:9/18/13

Period of Investigation: 8/26/13-9/18/13	Type of Report: SUPPLEMENTAL 1

Alleged violation : SEE FINAL REPORT

Synopsis:
This supplemental investigation is predicated upon receipt of a request from KRISTAL BEHARRY ESQ, Senior Attorney with DOH PSU. The request was to serve an AC packet and related papers to SAR PHARMACY owner YOELI SALGUIERO at her last known address of 2089 Sw 67th Ave Miami, FL 33155

On 8/27/13, this investigator presented to SARs last known address and was not able to serve owner SALGUIERO as a new business was open at location. A search of various online databases showed a secondary residential address for SALGUIERO of 11115 W Okeechobee Road Unit 101 Hialeah, FL 33018 this address was attempted with no success on 8/28/13, 8/29/13, 9/10/13, and 9/11/13. Phone number found for SALGUIERO 305-888-3284 was attempted, no answer was received when calls were attempted. As of the date of this report no response has been received from SALGUIERO.

Exhibits:
S1- Copy of affidavit of service for SAR PHARMACY (p2)

Related Case(s): 2012-16646

Investigator/Date: September 18, 2013 Neil Downs Investigator MI-207	Approved By/Date: September 18, 2013 Edward Thompson Manager

Distribution: HQ/ISU

13 SEP 23 AM 8:58
RECEIVED-LEGAL

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

Department of Health
Petitioner

vs

Case No. 2012-16637

Sar Pharmacy-Owner Yoeli Salguiero
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:
1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on 8/27/13, 8/28/13, 8/29/13, 9/10/13, 9/11/13, Affiant made a diligent effort to locate Respondent, to serve Administrative complaint packet and related papers at last known address of 2089 SW 67th Avenue Miami, FL 33155 and a secondary address of 11115 W Okeechobee Road Unit 101 Hialeah, FL 33018.

3) Check applicable answer below:

x Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses

Neil Downs
Affiant

State Of Florida
County Of Miami Dade

Before me, personally appeared Neil Downs whose identity is known to me by personally known (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 18th day of September 2013.

Notary Public-State of Florida

My Commission Expires

ISKRA CAVATORTA
Commission # FF 002218
Expires March 26, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

ISKRA Cavatorta
Type or Print Name

EXHIBIT 51

INV FORM 321

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Sar Pharmacy Discount, Inc., (KB)**
Case Number: 2012-16637

MEMBERS: **Lee Fallon and Debra Glass**

DATE OF PCP: **June 27, 2013** **AGENDA ITEM: A-8**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3), Florida Administrative Code;

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss

___ **other**

Lee J. Fallon 6/27/2013
Chair, Probable Cause Panel Date
Board of Pharmacy

DOH INVESTIGATIVE REPORT

Office: MIAMI XI	Date of Case: 11/08/2012	Case Number: PH 2012-16637

Subject:	Source:
SAR PHARMACY DISCOUNT INC 2089 Sw 67th Ave Miami, FL 33155 (305)263-5800	**DOH/ISU**

Prefix:	License #:	Profession:	Prefix:	License #:
2205	25266	Pharmacy	PH	25266

Period of Investigation: 11/16/12-1/15/13	Type of Report: FINAL

Alleged Violation: Possible Violation of SS. 456.072(1)(k)(dd); 465.016(1)(r); 465.023(1)(c), F.S.; Rule 64B16-28.1081; F.A.C. Rule 64B16-28.202, F.A.C., and Rule 64B16-28.203, F.A.C. Violate Statutes/Rules; Fail to perform legal obligations

Synopsis:

This investigation is predicated upon receipt of an internally generated pharmacy inspection alleging that on 10/16/12, 10/31/12 and 11/7/12 a routine inspection was attempted at SAR Pharmacy and Discount Inc (PH 25266), located at 2089 SW 67th Ave, Miami, FL 33155, the pharmacy was closed and appeared non-operational. The DOH database reflected that a closure had not been reported by the owner YOELI SALGUEIRO who is not licensed.

SAR was notified of the investigation by letter, dated 11/16/12 (Exhibit #2) and was provided a copy of the CASE SUMMARY and initiating documents from Exhibit #1.

No patients were identified thus no notification was necessary

A search of the DOH licensure database reveals that SAR possesses a clear and active license as a special closed pharmacy.

SAR is not known to be represented by an attorney.

SAR's owner YOELI SALGUEIRO executed a voluntary relinquishment on 12/18/12

Related Case(s): 2012-16646

Investigator/Date: 1/15/13	Approved By/Date: 1/15/13
Neil Downs Investigator MI-207	Edward Thompson Manager

Distribution: HQ/ISU

Received
Investigative Services
JAN 18 2013
ECM/MQA
Tallahassee FL

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Statement of YOELI SALGUEIRO, OWNER SAR PHARMACY LLC (SUBJECT) 3

IV. EXHIBITS

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2. Copy of Notification letter, dated 11/16/12 8
3. Copy of Sunbiz information for SAR 9
4. Copy of executed VR for ACOSTA 10-12

INVESTIGATIVE DETAILS

On 12/18/12 this investigator received a copy of SAR's executed VR (Exhibit #4). Copy of VR was emailed to PSU as per desk guide guidelines on 12/18/12.

On 12/13/12 this investigator was able to speak with landlord BERNIE NAVARRO via telephone (305)445-5223. NAVARRO provided access to pharmacy location to this investigator. This investigator was able to observe that location contained no medications and appeared abandoned.

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit #1 contains the Case Summary and initiating documents.

Exhibit #2 Copy of Notification letter, dated 11/16/12

Exhibit #3 Copy of Sunbiz profile for SAR

Exhibit #4 Copy of executed VR for ACOSTA

Statement of DAVID WARSHOFSKY, INVESTIGATOR, MIAMI ISU (SOURCE)
Employment
8350 NW 52nd Terrace Suite 400
Miami, FL 33166
(305)470-5800

On 11/16/12, this investigator was able to speak with WARSHOFSKY in the Miami ISU office. He states that she does not have any additional information regarding the initial complaint beyond what is stated in the initial complaint form (Exhibit #1).

Statement of YOELI SALGUEIRO, OWNER SAR PHARMACY LLC (SUBJECT)
Employment
2089 SW 67th Avenue
Miami, FL 33155
(305)263-6632

On 12/18/12 this investigator was able to speak with SALQUIERO when she presented to Miami ISU office. SALGUIERO executed a voluntary relinquishment (Exhibit #4) of the pharmacy license #25266 for SAR PHARMACY LLC.

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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CONFIDENTIAL AND EXEMPT MATERIALS

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v.

DOH Case No. 2012-06637 &
2012-16646

SAR PHARMACY DISCOUNT INC

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, SAR PHARMACY DISCOUNT INC license number PH 25266 by and through its owner/officer, YOELI SALGUEIRO, hereby voluntarily relinquishes

Respondent's permit to operate a community pharmacy and special Close Pharmacy in the

State of Florida and states

as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent, by and through its owner/officer, YOELI SALGUEIRO, understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's permit pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent and its owner/officer, YOELI SALGUEIRO, agree to never reapply for a pharmacy permit in the State of Florida.

3. Respondent, by and through its owner/officer, YOELI SALGUEIRO, agrees to voluntarily cease operating as a community pharmacy immediately upon executing this Voluntary Relinquishment. Respondent, by and through its owner/officer, YOELI SALGUEIRO, further agrees to refrain from operating as a community pharmacy until such time as this

EXHIBIT 4

Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, by and through its owner/officer, YOELI SALGUEIRO, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent, by and through its owner/officer, YOELI SALGUEIRO, understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10), Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent, by and through its owner/officer, YOELI SALGUEIRO, agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent, by and through its owner/officer, YOELI SALGUEIRO, hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent, by and through its owner/officer, YOELI SALGUEIRO, authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent, by and through its owner/officer, YOELI SALGUEIRO, agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its

members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 18 day of 12, 2012.

SAR PHARMACY DISCOUNT INC
by and through its Owner/Officer, YOELI SALGUEIRO

STATE OF FLORIDA }
}
COUNTY OF DADE }

Before me, personally appeared YOELI SALGUEIRO, whose identity is known to me by DL (type of identification) and who, under oath, acknowledges that his/her signature appears above. Sworn to and subscribed before me this 18 day of December, 2012.

NOTARY PUBLIC

My Commission Expires:

JENEICE MAYERS
Commission # EE 218545
Expires August 15, 2014
Bonded Thru Troy Fain Insurance 800-385-7019

HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201312375

LATORIA DENISE JONES,
RESPONDENT.

NOTICE

TO: LATORIA DENISE JONES
274 MAIN STREET
SEBASTIAN, FL 32958

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Determination of Waiver

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201312375

LATORIA DENISE JONES,
RESPONDENT.

NOTICE

TO: LATORIA DENISE JONES
8565 61st DRIVE
WABASSO, FL 32970

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Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

HEALTH

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Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

PERSONAL AND CONFIDENTIAL

January 14, 2014

THERESA W TOLLE
7746 BAY STREET
SEBASTIAN, FL 32958

Re: DOH v. Latoria Denise Jones
Case # 201312375

Dear Theresa W Tolle:

I am writing to you concerning the Department of Health's review of certain health care provided by the above named health care practitioner. That review included a full investigation and the filing of an Administrative Complaint. That review is nearing a conclusion and Board of Pharmacy is scheduled to take final disciplinary action in the matter on Wednesday, February 12, 2014.

This is one of several matters that will be part of the public meeting. You are welcome to attend this public meeting, but you are not required to attend, and this is not a request that you attend the meeting. Cases shown on the agenda may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled to begin at 9 a.m.; therefore, if you choose to attend it is imperative that you arrive promptly at 9 a.m. and be prepared to remain until the case is heard as cases may be heard in a different order than they appear on the agenda.

Florida law provides that the person who made the complaint to the Department ("complainant") is entitled to provide oral or written communication to the Board concerning the alleged violation or the appropriate penalty. Likewise, the patient/legal representative in the case who was not the "complainant" may request that the Board allow them the same opportunity to provide such written or oral communication. The Board has granted such requests. If you have any questions concerning this matter, please contact the Department's Prosecution Services Unit prior to the meeting at (850)245-4640. Please reference the above case number when calling.

All final disciplinary actions of the Board are reflected in written orders which are available on the Department's website at: www.flhealthsource.com. Please allow 30-60 days after the board meeting for the posting of these orders.

Sincerely,

for Tammy Collins
Executive Director
Board of Pharmacy

Florida Department of Health
Division of Medical Quality Assurance
4052 Bald Cypress Way, Bin C10 • Tallahassee, FL 32399-3260
PHONE: (850) 245-4444 • FAX : (850) 245-4791

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM : Louise Wilhite-St. Laurent, Assistant General Counsel
RE: Determination of Waiver
SUBJECT: DOH v. Latoria Denise Jones, R. P.T.
DOH Case Number 2013-12375
DATE: December 18, 2013

Enclosed you will find materials in the above-referenced case to be placed on the **February 12, 2014**, agenda for final agency action for the meeting of the board. The following information is provided in this regard.

Subject: Latoria Denise Jones, R.P.T.
Subject's Address of Record: 8565 61st Drive
Wabasso, FL 32970
772-646-1330 Telephone

Enforcement Address: 274 Main Street
Sebastian, FL 32958

Subject's License No: 45081 **Rank:** RPT
Licensure File No: 46966
Initial Licensure Date: 10/19/2012
Board Certification: None
Required to Appear: No
Current IPN/PRN Contract: None

Allegation(s): 465.016(1)(e), Florida Statutes (2012-2013), by violating Section 893.13, Florida Statutes (2012-2013).

Prior Discipline: None

Probable Cause Panel: Lee Fallon, BPharm, Ph.D. and Debra Glass, BPharm
PCP: October 10, 2013

Subject's Attorney: Pro Se

Complainant/Address: Theresa Tolle, RPH
7746 Bay Street
Sebastian, Florida 32958
(772) 589-2043 Telephone

Materials Submitted:

Memorandum to the Board
Motion for Determination of Waiver
- Exhibit A - Administrative Complaint
- Exhibit B - Copy of Certified Mail Receipt
- Exhibit C – Affidavit of Non-Receipt – Board
- Exhibit D – Affidavit of Non-Receipt – Clerk

Motion to Assess Costs with Attachments
- Exhibit A – Affidavit of Fees & Costs Expended
- Exhibit 1 – Complaint Cost Summary
- Exhibit 2 – Itemized Cost by Complaint

Probable Cause Panel Memorandum
Emergency Suspension Order
- Affidavit of Diligent Search (from investigator)
- Certified mail receipt
- Administrative weekly

Supplemental Investigative Report dated 11/26/2013
Exhibits S4-1 through S4-2
Supplemental Investigative Report dated 10/15/2013
Exhibits S3-1 through S3-3
Supplemental Investigative Report dated 8/22/2013
Exhibits S2-1 through S2-2
Supplemental Investigative Report dated 8/13/2013
Exhibits S1 through S3
Final Investigative Report dated 8/08/2013 with Exhibits 1-7
State Attorney Surveillance Video and Interview of Respondent

DISCIPLINARY GUIDELINES:

- Unlawful Possession of Controlled Substance in violation of Section 893.13, Florida Statutes: **Minimum** of $5,000 fine and 2 years probation; **Maximum** of Revocation.

PRELIMINARY CASE REMARKS: DETERMINATION OF WAIVER

- The Respondent in this case was a registered pharmacy technician volunteering at a pharmacy in Sebastian, Florida. The employees noted that the Roxicodone 30mg count was off by 200 pills on June 31, 2013. On August 3, 2013, Respondent was observed on surveillance camera stealing two, 100 count, bottles of oxycodone 30mg and placing them under her skirt. Respondent admitted to law enforcement that she took the pills for her own pain. Respondent was arrested and charged with grand theft and trafficking in oxycodone.
  - The Department issued an Emergency Suspension Order on September 26, 2013.
  - The Department filed an Administrative Complaint on October 10, 2013.
  - The Administrative Complaint was served on an adult female residing at the Respondent's last known address on November 25, 2013. The woman confirmed that Respondent was a resident of that address and accepted service of the Administrative Complaint and corresponding materials.

RECOMMENDATION OF THE DEPARTMENT

- **The Department recommends that the Respondent's registration be permanently revoked.**

CONSIDERATIONS SUPPORTING THE DEPARTMENT'S RECOMMENDATION

- The Respondent stole at least 300 roxicodone/oxycodone tablets from her employer, possibly even 400 tablets. Although the Respondent admitted to ingesting them herself, according to the police report, she would have ingested 92 tablets within a four-day period. This is highly unlikely the case. The Respondent is facing criminal charges and has eluded the Department's investigator by failing to return messages or contact the investigator after the investigator spoke with three individuals who were either related to the Respondent or residing with the Respondent. The Respondent failed to return an Election of Rights to the Department within the required period and is appearing to take no responsibility for her actions in this case.
- The Department recommends revocation because, based on the Respondent's actions, she cannot be trusted in any pharmacy where she will have access to controlled substance. The egregiousness of the thefts in the quantity of the pills stolen and the number of occasions stolen demonstrate that the Respondent should not be permitted to practice in a pharmacy in the future.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-12375**
Latoria Denise Jones, R.P.T.,

Respondent.
_____/

MOTION FOR DETERMINATION OF WAIVER AND FOR FINAL ORDER BY HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

Petitioner, Department of Health, by and through counsel, moves the Board of Pharmacy to find that Respondent has waived her right to elect a method of disposition of the pending Administrative Complaint, to determine that no material facts are in dispute, to conduct a hearing not involving disputed issues of material face, and to enter a Final Order. As grounds therefore, Petitioner states:

1. An Administrative Complaint was filed against Respondent on October 10, 2013. A copy of said Administrative Complaint is attached hereto as Petitioner's Exhibit A.

2. Copies of the Administrative Complaint, Election of Rights form, and Explanation of Rights form were sent to Respondent, via certified US mail delivery, on October 29, 2013, (article number 7196 9008 9111 5773 9494) and on October 15, 2013, (article number 7196 9008 9111 5773 9449). A copy of the green card receipts and envelope are attached hereto as Petitioner's Exhibit B.

3. Respondent has not filed with either the Department of Health or the Board of Pharmacy, an Election of Rights form or other responsive pleading in this case within the required twenty-one (21) day period to dispute the allegations contained in the Administrative Complaint. Copies of affidavits supporting same are attached hereto as Petitioner's Exhibits C and D.

4. Respondent has been advised, by a copy of this motion sent to her address of record that a copy of the investigative file in this case shall be furnished to the Board to establish a prima facie case regarding the violations as set forth in the Administrative Complaint.

5. The Department requests that this Motion and a hearing be placed on the agenda for the next meeting of the Board of Pharmacy to be held on February 12, 2014, in Orlando, Florida.

WHEREFORE, Petitioner respectfully requests that the Board find that Respondent has waived her right to elect a method of resolution of this matter, find that there are no material facts in dispute, hold a hearing not involving material issues of disputed fact based on the information contained in the investigative file, find that Respondent violated Chapters 456 and 465, Florida Statutes, as alleged in the Administrative Complaint, impose discipline in accordance with the disciplinary guidelines, and enter a Final Order.

DATED this 18th day of December, 2013.

Respectfully Submitted,

Louise Wilhite-St Laurent, Esq.
Florida Bar No. 0091244
Assistant General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
(P) 850-245-4444, extension 8331
(F) 850-245-4662
(E) Louise_StLaurent@doh.state.fl.us

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion for Determination of Waiver and for Final Order by Hearing not Involving Disputed Issues of Material Fact has been provided by U.S. certified Mail to Respondent, Latoria Denise Jones, R.P.T, 8565 61st Drive, Wabasso Florida 32970, this 18th day of December, 2013.

Louise Wilhite-St. Laurent
Assistant General Counsel

LSL/mla

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO.: 2013-12375**

LATORIA DENISE JONES, R.P.T.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through the undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, Latoria Denise Jones, R.P.T., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy and registered pharmacy technicians, pursuant to Chapters 20.43, Florida Statutes (2012-2013), Chapter 456, Florida Statutes (2012-2013) and Chapter 465, Florida Statutes (2012-2013).

2. At all times material to this Administrative Complaint, Respondent was a registered pharmacy technician, pursuant to Chapter

EXHIBIT
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465, Florida Statutes (2012-2013), having been issued license number RPT 45081.

3. Respondent's address of record is 274 Main Street, Sebastian, Florida 32958. Respondent's current address is 8565 61st Drive, Wabasso, Florida 32970.

4. Respondent volunteered as a registered pharmacy technician at Bay Street Pharmacy located at 7746 Bay Street, Sebastian, Florida.

5. On or about June 30, 2013, Respondent stole between 100 and 200 Roxicodone pills from Bay Street Pharmacy.

6. Roxicodone is the brand name for oxycodone, an opioid-class medication commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012-2013), oxycodone is a Schedule II controlled substance.

7. On or about August 3, 2013, Respondent stole 200 oxycodone pills from Bay Street Pharmacy.

8. Respondent stole the Roxicodone and oxycodone pills from Bay Street Pharmacy in order to consume them herself. Respondent did, in fact, consume some of the stolen pills.

9. Section 465.016(1)(e), Florida Statutes (2012-2013), subjects registered pharmacy technicians to discipline for violating Chapter 893, Florida Statutes (2012-2013).

10. Chapter 893.13, Florida Statutes (2012-2013), states in pertinent part:

> (6)(a) It is unlawful for any person to be in actual or constructive possession of a controlled substance unless such controlled substance was lawfully obtained from a practitioner or pursuant to a valid prescription or order of a practitioner while acting in the course of his or her professional practice or to be in actual or constructive possession of a controlled substance except as authorized by this chapter....
>
> (7)(a) A person may not:
> 9. Acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge.

11. Respondent violated Section 465.016(1)(e), Florida Statutes (2012-2013), in one or more of the following ways:

a. By possessing oxycodone and/or Roxicodone in violation of Chapter 893.13(6)(a), Florida Statutes (2012-2013); and/or

b. By acquiring possession of oxycodone and/or Roxicodone by misrepresentation, fraud, forgery, deception or subterfuge in

violation of Chapter 893.13(7)(a)(9), Florida Statutes (2012-2013).

12. Based on the foregoing, Respondent violated Section 465.016(1)(e), Florida Statutes (2012-2013), by violating Chapter 893, Florida Statutes (2012-2013).

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board of Pharmacy deems appropriate.

SIGNED this 10th day of October, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Louise Wilhite-St Laurent
Assistant General Counsel
Florida Bar Number 0091244
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444 x 8331
Facsimile: (850) 245-4662
Email: Louise_StLaurent@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE OCT 10 2013

PCP: October 10, 2013

PCP Members: Leo J. "Lee" Fallon, BPharm, PhD & Debra Glass, BPharm

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

Remailed AC pack

7196 9008 9111 5773 9494

TO: Latoria Denise Jones, RPT
241 8th Avenue
Sebastian, FL 32962

AC-VR
Bennett 2013-12375

SENDER:

REFERENCE:

PS Form 3800, January 2005

RETURN RECEIPT SERVICE		
	Postage	
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

US Postal Service®

Receipt for Certified Mail™

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10/29/13

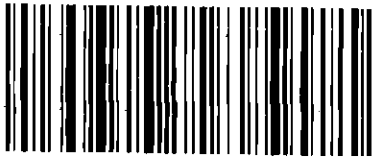
EXHIBIT

B

CERTIFIED MAIL

Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, Florida 32399-3265

PRACTITIONER REGULATION
LEGAL
2013 OCT 28 PM 12:16



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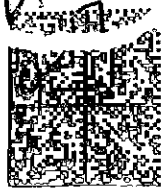
S/U RAA



UNITED STATES POSTAGE
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0004284650 OCT 15 2013
MAILED FROM ZIP CODE 32301

Latoria Denise Jones, RPT
8565 61st Dr.
Wabasso, FL 32970

NIXIE 339 DE 1099 0010/22/13

RETURN TO SENDER
NOT DELIVERABLE AS ADDRESSED
UNABLE TO FORWARD

BC: 32399326599 *0791-09612-15-41

32399-3265

Affidavit of Non-Receipt

I, Daisy King, hereby certify in my official capacity as custodian for the Board of Nursing's licensure files that the Board, as of December 17, 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **Latoria Denise Jones, R.P.T.; 2013-12375,** which would affect the Subject's substantial interests or rights.

Daisy King
Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Daisy King, whose identity is known to me personally and who, under, oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 17th day of December, 2013.

Lorraine Gail Curry
Notary Public Signature
My commission expires:

LORRAINE GAIL CURRY
MY COMMISSION # EE 97887
EXPIRES: May 26, 2015
Bonded Thru Notary Public Underwriters

EXHIBIT
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AFFIDAVIT

I, Angel Sanders, Deputy Clerk for the Department Clerk's Office, hereby certify in my official capacity as custodian for the Department Clerk's records, that the Department Clerk's Office has not received an Election of Rights form or other responsive pleading, which requests a hearing prior to any Department action regarding **Latoria Denise Jones, R.P.T.; 2013-12375**, which would affect the Respondent's substantial interests or rights.

Angel Sanders
Custodian of Record
Department Clerk's Office

Before me, personally appeared Angel Sanders, whose identity is known to me personally and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 18th day of December, 2013.

Renada Conley
Notary Public
My Commission Expires:

RENADA CONLEY
Notary Public - State of Florida
My Comm. Expires Nov 9, 2016
Commission # EE 844542

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-12375**

Latoria Denise Jones, R.P.T.,

Respondent.
_____/

MOTION TO ASSESS COSTS
IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes (2012). As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes (2012), states, in pertinent part, as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or after July 1,

> 2001, under this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is no board, shall assess costs related to the investigation and prosecution of the case. The costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto....

3. As evidenced in the attached affidavit (Exhibit A), the investigation and prosecution of this case has resulted in costs in the total amount of $2,493.19, based on the following itemized statement of costs:

Complaint Cost Summary

Complaint Number: 201312375

Subject's Name: JONES, LATORIA DENISE

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**1.00**	**$54.90**
Investigation:	**31.60**	**$2,020.16**
Legal:	**3.90**	**$414.79**
Compliance:	**0.10**	**$3.34**
	**********	**********
Sub Total:	**36.60**	**$2,493.19**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$2,493.19**

4. The attached affidavit reflects the Department's costs for attorney time in this case as $414.79 (Exhibit A). The cost of obtaining an affidavit from an outside attorney will be greater than $414.79. Therefore, the Department is not seeking costs for attorney time in this case.

5. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

6. Petitioner requests that the Board grant this motion and assess costs in the amount of $2,493.19as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes (2012).

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $2,493.19.

DATED this 18th day of December, 2013.

Respectfully submitted,

Louise Wilhite-St. Laurent
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar # 0091244
Phone (850) 245-4444 x 8331
Fax (850) 245-4662
Louise_StLaurent@doh.state.fl.us

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 18th day of December, 2013 to Latoria Denise Jones, R.P.T., 8565 61st Drive, Wabasso, Florida 32970.

Louise Wilhite- St. Laurent
Assistant General Counsel

LSL/mla

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2013-12375** (Department of Health v. **Latoria Denise Jones, R.P.T.**) are **TWO THOUSAND FOUR HUNDRED NINETY-THREE DOLLARS AND NINETEEN CENTS ($2,493.19).**

6) The costs for DOH case **2013-12375** (Department of Health v. **Latoria Denise Jones, R.P.T**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case numbers **2013-12375** (Department of Health v. **Latoria Denise Jones, R.P.T.**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to keep track of their time in six-minute increments (e.g., investigators

EXHIBIT
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and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of his knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 18th day of December, 2013, by Shane Walters, who is personally known to me.

Bernadette Lawanda Hayes

Notary Signature

Bernadette Lawanda Hayes

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

BERNADETTE LAWANDA HAYES
Commission # EE 838344
Expires September 25, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

Complaint Cost Summary

Complaint Number: 201312375

Subject's Name: JONES, LATORIA DENISE

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.00	$54.90
Investigation:	31.60	$2,020.16
Legal:	3.90	$414.79
Compliance:	0.10	$3.34
	**********	**********
Sub Total:	36.60	$2,493.19
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$2,493.19

EXHIBIT
1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201312375

Report Date 12/18/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
COMPLIANCE MANAGEMENT UNIT						
HC27	0.05	$33.33	$1.67	09/26/2013	125	LICENSE STATUS CHANGE
HC27	0.05	$33.33	$1.67	09/26/2013	129	UPDATING COMPLIANCE RECORDS
Sub Total	**0.10**		**$3.34**			
CONSUMER SERVICES UNIT						
HA115	1.00	$54.90	$54.90	08/05/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
Sub Total	**1.00**		**$54.90**			
INVESTIGATIVE SERVICES UNIT						
WI89	0.90	$63.98	$57.58	08/06/2013	76	REPORT PREPARATION
WI89	2.20	$63.98	$140.76	08/06/2013	4	ROUTINE INVESTIGATIVE WORK
WI89	0.40	$63.98	$25.59	08/06/2013	4	ROUTINE INVESTIGATIVE WORK
WI89	2.20	$63.98	$140.76	08/07/2013	4	ROUTINE INVESTIGATIVE WORK
WI89	1.70	$63.98	$108.77	08/07/2013	76	REPORT PREPARATION
WI89	0.70	$63.98	$44.79	08/08/2013	4	ROUTINE INVESTIGATIVE WORK
WI89	0.10	$63.98	$6.40	08/08/2013	4	ROUTINE INVESTIGATIVE WORK
WI89	2.40	$63.98	$153.55	08/08/2013	76	REPORT PREPARATION
WI89	0.10	$63.98	$6.40	08/09/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	0.20	$63.98	$12.80	08/09/2013	76	REPORT PREPARATION
WI89	0.20	$63.98	$12.80	08/12/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	0.30	$63.98	$19.19	08/12/2013	76	REPORT PREPARATION
WI89	0.20	$63.98	$12.80	08/13/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	0.30	$63.98	$19.19	08/13/2013	76	REPORT PREPARATION
WI89	0.10	$63.98	$6.40	08/22/2013	76	REPORT PREPARATION
WI89	0.90	$63.98	$57.58	09/30/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	0.40	$63.98	$25.59	09/30/2013	76	REPORT PREPARATION

EXHIBIT
2

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201312375

Report Date 12/18/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
WI89	0.70	$63.98	$44.79	10/01/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	0.20	$63.98	$12.80	10/03/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	0.20	$63.98	$12.80	10/07/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	0.30	$63.98	$19.19	10/08/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	5.00	$63.98	$319.90	10/09/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
WI89	0.60	$63.98	$38.39	10/10/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	0.30	$63.98	$19.19	10/11/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	0.40	$63.98	$25.59	10/14/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	0.30	$63.98	$19.19	10/14/2013	76	REPORT PREPARATION
WI89	0.30	$63.98	$19.19	10/15/2013	76	REPORT PREPARATION
WI89	0.20	$63.82	$12.76	11/08/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	1.20	$63.82	$76.58	11/12/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	4.60	$63.82	$293.57	11/15/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
WI89	3.20	$63.82	$204.22	11/25/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
WI89	0.20	$63.82	$12.76	11/25/2013	6	SUPPLEMENTAL INVESTIGATION
WI89	0.40	$63.82	$25.53	11/25/2013	76	REPORT PREPARATION
WI89	0.20	$63.82	$12.76	11/26/2013	76	REPORT PREPARATION
Sub Total	**31.60**		**$2,020.16**			

PROSECUTION SERVICES UNIT

HLL101B	0.30	$106.35	$31.91	08/09/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL101B	0.40	$106.35	$42.54	08/14/2013	25	REVIEW CASE FILE
HLL101B	0.20	$106.35	$21.27	08/14/2013	35	TELEPHONE CALLS
HLL101B	0.10	$106.35	$10.64	08/26/2013	35	TELEPHONE CALLS
HLL101B	0.50	$106.35	$53.18	09/16/2013	103	REVIEW SUPPLEMENTAL REPORT
HLL101B	1.00	$106.35	$106.35	09/17/2013	81	ESO/ERO
HLL101B	0.20	$106.35	$21.27	09/20/2013	81	ESO/ERO
HLL101B	0.10	$106.35	$10.64	09/24/2013	81	ESO/ERO
HLL101B	0.70	$106.35	$74.45	09/26/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL101B	0.20	$106.35	$21.27	10/03/2013	89	PROBABLE CAUSE PREPARATION
HLL101B	0.20	$106.35	$21.27	10/10/2013	63	PRESENTATION OF CASES TO PROBABLE CAUSE PANEL

CONFIDENTIAL

Time Tracking System
Itemized Cost by Complaint

Complaint 201312375

Report Date 12/18/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
Sub Total	**3.90**		**$414.79**			

Total Cost	**$2,493.19**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 12/18/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description
	SubTotal			
	Total Expenses			

MEMORANDUM OF FINDING OF PROBABLE CAUSE

TO: DEPARTMENT OF HEALTH

ADMINISTRATION, GENERAL COUNSEL, PHARMACY SECTION

FROM: CHAIRMAN, PROBABLE CAUSE PANEL

RE: **LATORIA DENISE JONES, R.P.T.** CASE NO. **2013-12375**

DATE OF PROBABLE CAUSE PANEL MEETING: **October 10, 2013**

THIS MATTER WAS BROUGHT BEFORE THE PROBABLE CAUSE PANEL MEMBERSHIP COMPOSED OF **Leo J. "Lee" Fallon, BPharm, PhD & Debra Glass, BPharm** ON THE DATE SET FORTH ABOVE. THE PANEL, HAVING RECEIVED THE COMPLETE INVESTIGATIVE REPORT, HAVING CAREFULLY REVIEWED THAT REPORT, HAVING REVIEWED THE RECOMMENDATION OF THE AGENCY, AND HAVING HAD THE OPPORTUNITY TO INQUIRE OF COUNSEL AND BEING OTHERWISE DULY ADVISED IN THE PREMISES THEREOF, FIND THAT:

_____ PROBABLE CAUSE WAS NOT FOUND IN THIS CASE.

___XXX_ PROBABLE CAUSE WAS FOUND ON THE FOLLOWING STATUTORY AND REGULATORY GROUNDS, INCLUDING BUT NOT LIMITED TO SECTION(S):

465.016(1)(e), Florida Statutes (2012-2013)

Danny Collins for Debra Glass 16 Jan 2014

CHAIRPERSON, PROBABLE CAUSE PANEL
BOARD OF PHARMACY

Final Order No. DOH-13-1863-ESO-MQA
FILED DATE SEP 26 2013
Department of Health
By: [signature]
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the Registration of
Latoria Denise Jones, R.P.T.
Registration Number RPT 45081
Case Number 2013-12375

ORDER OF EMERGENCY SUSPENSION OF LICENSE

John H. Armstrong, MD, FACS, State Surgeon General and Secretary of Health, ORDERS the emergency suspension of the registration of Latoria Denise Jones, R.P.T., ("Ms. Jones") to practice as a registered pharmacy technician in the State of Florida. Ms. Jones holds registration number RPT 45081. Her address of record is 274 Main Street, Sebastian, Florida 32958. Ms. Jones's current address is 8565 61st Drive, Wabasso, Florida 32970. The following Findings of Fact and Conclusions of Law support the emergency suspension of Ms. Jones's registration to practice as a pharmacy technician in the State of Florida.

FINDINGS OF FACT

1. The Department of Health ("Department") is the state agency charged with regulating the practice of pharmacy pursuant to Chapters 20, 456, and 465, Florida Statutes (2013). Section 456.073(8), Florida Statutes (2013), authorizes the State Surgeon General to summarily

suspend Ms. Jones's registration to practice as a registered pharmacy technician in the State of Florida in accordance with Section 120.60(6), Florida Statutes (2013).

2. At all times material to this order, Ms. Jones was a registered pharmacy technician in the State of Florida, pursuant to Chapter 465, Florida Statutes (2013), and worked on a voluntary basis as a registered pharmacy technician at Bay Street Pharmacy located at 7746 Bay Street, Sebastian, Florida.

3. On or about June 31, 2013, employees at Bay Street Pharmacy conducted an internal audit of the medication count in the pharmacy. The employees noted that the count for Roxicodone 30mg was off by 200 pills.

4. Roxicodone is the brand name for oxycodone, an opioid-class medication commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012-2013), oxycodone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of oxycodone may lead to severe psychological or physical dependence.

5. Ms. Jones volunteered in the pharmacy on June 30, 2013, the

day before the audit.

6. The owner of Bay Street Pharmacy contacted law enforcement and a surveillance camera was set up inside the pharmacy.

7. On or about August 3, 2013, Ms. Jones went to Bay Street Pharmacy and asked the pharmacist on duty if she could use the pharmacy's computer to make an insurance payment because Ms. Jones's internet was not working. The pharmacist allowed this, and Ms. Jones used the computer. At approximately 11:23 a.m., shortly after she used the computer, Ms. Jones is seen on surveillance video taking two bottles from a pharmacy shelf and placing them under her skirt. Ms. Jones left the pharmacy at approximately 11:45 a.m.

8. After Ms. Jones left the pharmacy, staff immediately conducted a count of medication in the area Ms. Jones had been and discovered that two 100-count bottles of oxycodone 30mg were missing from the pharmacy. The employees contacted Indian River County Sheriff's Detective G.S., who responded to the location and reviewed the surveillance footage.

9. On or about August 3, 2013, Detective G.S. made contact with Ms. Jones as she was pulling into her driveway. Detective G.S. conducted

an audio-recorded interview of Ms. Jones. Ms. Jones told Detective G.S. that she had sickle cell anemia and she took the pills from the pharmacy for her pain. Ms. Jones stated that she had only taken pills from the pharmacy on two occasions and that she had issues getting additional prescriptions from her doctors. Ms. Jones told Detective G.S. that she had one unopened bottle of oxycodone 30mg in her vehicle, and that she poured the pills from the second bottle that she took on August 3, 2013, into her own prescription pill bottle that contained various other pills.

10. When questioned about the theft of Roxicodone earlier that week, Ms. Jones stated that she only took one 100-count bottle of Roxicodone from the pharmacy and put it in her own pill bottle. Ms. Jones stated that she only takes the pills herself and does not sell them or give them to anyone else.

11. Upon a search of Ms. Jones's vehicle, Detective G.S. found one unopened 100-count bottle of oxycodone 30mg belonging to Bay Street Pharmacy. Detective G.S. also found a prescription bottle with Ms. Jones's name on the bottle containing 200 oxycodone 30mg pills and 8 Roxicodone 30mg pills. Assuming that Ms. Jones was telling the truth in stating that she only took one 100-count bottle of Roxicodone pills earlier in the week

and only ingested the pills herself, Ms. Jones would have ingested 92 Roxicodone pills in a four-day period.

12. On or about August 5, 2013, Ms. Jones was arrested and charged with trafficking in oxycodone, and two counts of grand theft, in Indian River County Case Number 2013CF0971. The charges against Ms. Jones are currently pending resolution.

13. Registered pharmacy technicians assist pharmacists in data entry, and the counting, weighing, measuring, pouring and mixing of prescription medication or stock legend drugs and controlled substances, among various other tasks. Because registered pharmacy technicians are entrusted with such important tasks which include the handling, counting, and reporting of the drugs in the pharmacy, it is imperative that a registered pharmacy technician have good judgment and moral character while working in a pharmacy

14. Ms. Jones's behavior in stealing between 300 and 400 prescription oxycodone or Roxicodone tablets for personal use within a one-week period and her consumption of stolen controlled substances clearly demonstrate that she is lacking the judgment and moral character needed to practice as a registered pharmacy technician.

15. As a result of her employment as a registered pharmacy technician, Mr. Jones was aware that prescription medications and controlled substances may only be dispensed to patients who have valid prescriptions and need the medications for a legitimate health reason. Despite this, Ms. Jones illegally diverted controlled substances for herself when she did not have a valid prescription for the drugs.

16. Mr. Jones's lack of good judgment and moral character, her theft of large quantities of controlled substances from her employer, and her disregard for the laws and rules governing the practice of pharmacy in the State of Florida represent a significant likelihood that Ms. Jones will continue her illegal behavior. This probability constitutes an immediate serious danger to the health, safety, and welfare of the citizens of the State of Florida. Restricting Ms. Jones's registration would not adequately protect the public because the very nature of practicing as a registered pharmacy technician puts Ms. Jones in contact with legend drugs and controlled substances, which creates the risk for further theft of the controlled substances. Additionally, Ms. Jones appears to be ingesting high quantities of oxycodone or Roxicodone herself in short time periods. As a result, nothing short of the immediate suspension of Ms. Jones's

registration to practice as a registered pharmacy technician will protect the public from this danger.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General concludes as follows:

1. The State Surgeon General of the Department of Health has jurisdiction over this matter pursuant to Sections 20.43 and 456.073(8), Florida Statutes (2013), and Chapter 465, Florida Statutes (2013), as set forth above.

2. Section 465.016(1)(e), Florida Statutes (2013), subjects registered pharmacy technicians to discipline, including suspension, for violating Chapter 893, Florida Statutes (2013).

3. Chapter 893.13, Florida Statutes (2013), states in pertinent part:

> (6)(a) It is unlawful for any person to be in actual or constructive possession of a controlled substance unless such controlled substance was lawfully obtained from a practitioner or pursuant to a valid prescription or order of a practitioner while acting in the course of his or her professional practice or to be in actual or constructive possession of a controlled substance except as authorized by this chapter....

(7)(a) A person may not:
9. Acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge.

4. Ms. Jones violated Section 465.016(1)(e), Florida Statutes (2013), in one or more of the following ways:

a. By possessing oxycodone and/or Roxicodone in violation of Chapter 893.13(6)(a), Florida Statutes (2013); and/or

b. By acquiring possession of oxycodone and/or Roxicodone by misrepresentation, fraud, forgery, deception or subterfuge in violation of Chapter 893.13(7)(a)(9), Florida Statutes (2013).

5. Section 120.60(6), Florida Statutes (2013), authorizes the Department to suspend a registered pharmacy technician's registration upon a finding that the registered pharmacy technician presents an immediate, serious danger to the public health, safety or welfare.

6. Ms. Jones's continued ability to practice as a registered pharmacy technician constitutes an immediate serious danger to the health, safety, or welfare of the public and this summary procedure is fair under the circumstances to adequately protect the public.

In accordance with Section 120.60(6), Florida Statutes (2013), it is

ORDERED THAT:

1. The registration of Latoria Denise Jones, registration number RPT 45081, is immediately suspended.

2. A proceeding seeking formal discipline of the registration of Ms. Jones to practice as a registered pharmacy technician will be promptly instituted and acted upon in compliance with Sections 120.569 and 120.60(6), Florida Statues (2013).

DONE and ORDERED this 25th day of September, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

PREPARED BY:
Louise Wilhite-St Laurent
Assistant General Counsel
Fla. Bar No. 0091244
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444 x8331
Facsimile: (850) 245-4662
Email: Louise_StLaurent@doh.state.fl.us

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Sections 120.60(6) and 120.68, Florida Statutes, this Order is judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Review proceedings are commenced by filing a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, with the District Court of Appeal, accompanied by a filing fee prescribed by law, and a copy of the Petition with the Agency Clerk of the Department within 30 days of the date this Order is filed.

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

FLORIDA DEPARTMENT OF HEALTH
Petitioner
vs LATORIA JONES, RPT
Respondent

Case No. 2013-12375

COMES NOW, the affiant, who first being duly swom, deposes and states:

1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on 10/11/13, Affiant made a diligent effort to locate Respondent, to serve___ Administrative Complaint and related papers; _ Order compelling examination(s); Subpoena(s); _____Final order; _____Notice to cease and desist; _XX_ ESO/ERO and related papers.

3) Check applicable answer below:

_____Affiant made personal service on Respondent,

_XX__Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.); any others as detailed in corresponding supplemental report.

Affiant

State Of Florida
County Of Palm Beach
Before me, personally appeared AMY SENIOR whose identity is known to me by Personal Knowledge (type of identification) and who, acknowledges that his signature appears above.

Swom to or affirmed by Affiant before me this 15th day of October, 2013 ___.

Notary Public-State of Florida

My Commission Expires

DARYL FRUTH
Commission # EE 111598
Expires August 23, 2015
Bonded Thru Troy Fain Insurance 800-385-7019

Type or Print Name

EXHIBIT # 53-3

85

MEMORANDUM

TO: Florida Administrative Registry

FROM: Tamia Christopher, Regulatory Specialist I

RE: Latoria Denise Jones, R.P.T., RPT # 45081 (FAW # **13607468**)

CASE NO: 2013-12375

DATE: September 27, 2013

Attached please find notice of the issuance of an **Emergency Suspension** Order for notice in the next issue of the Florida Administrative Register.

On September 26, 2013, the State Surgeon General issued an Order of Emergency Suspension Order with regard to the license of Latoria Denise Jones, R.P.T., RPT # 45081. This Emergency Suspension Order was predicated upon the State Surgeon General's findings of an immediate and serious danger to the public health, safety and welfare pursuant to Sections 456.073(8) and 120.60(6) Florida Statutes (2011). The State Surgeon General determined that this summary procedure was fair under the circumstances, in that there was no other method available to adequately protect the public.

STATE OF FLORIDA

DEPARTMENT OF HEALTH
INVESTIGATIVE REPORT

Office: West Palm Beach	Date of Case: 08/05/2013	Case Number: 2013-12375

Subject: LATORIA DENISE JONES, RPT 274 Main Street Sebastian, FL 32958* (772) 646-1330	Source: THERESA TOLLE, RPH 7746 Bay Street Sebastian, FL 32958 (772) 589-2043

Prefix:	License #:	Profession:	Board:	Report Date:
RPT	45081	Registered Pharmacy Technician	Pharmacy	11/26/2013

Period of Investigation: 11/8/13 – 11/26/13	Type of Report: SUPPLEMENTAL-4

Alleged Violation: F.S. 456.072(1)(k)(dd); 465.016(1)(d)(e)(m)(r); 465.023(1)(c)-Violate Statute/Rule; Failure to perform legal obligation; Impaired from alcohol/drugs/other; Prescription/dispense outside practice...

Synopsis: This SUPPLEMENTAL report is predicated upon receipt of a request from PSU's LOUISE ST. LAURENT, Esq. (EX# S4-1) to hand serve the AC packet and VR upon JONES. The previous supplemental report details prior unsuccessful attempts at locating accurate, current address information for JONES and numerous unsuccessful attempts at contacting and serving JONES.

On 11/12/13 this investigator called JONES at her last known phone number (772) 646-1330, leaving a message requesting her to return the call. There has been no subsequent contact from JONES. On 11/12/13 this investigator called JONES' mother SHIRLEY JONES (772) 646-1030. SHIRLEY JONES stated she was not in town at the moment. I asked if she could tell me how to contact her daughter LATORIA. SHIRLEY stated: "I don't see my daughter much. I really don't know where she is." I reminded SHIRLEY that she previously told me she would call me back to provide LATORIA's newest address. SHIRLEY stated LATORIA moved again since then. I asked SHIRLEY if her statement is that she has no phone number or address or way of contacting her daughter LATORIA. SHIRLEY responded by stating: "My daughter is an adult; we are not close." I reminded SHIRLEY that she previously told me she was Power of Attorney over LATORIA. SHIRLEY stated: "Yah, I have Power of Attorney, but my daughter is an adult, she does her own thing." I asked SHIRLEY if Power of Attorney afforded her the authority to make legal decisions on LATORIA's behalf and she said: "yes." SHIRLEY then asked again "what is this all about anyway." I reminded SHIRLEY that I would be more than happy to discuss the confidential matter with her however she would have to provide me documentation of her Power of Attorney authority over LATORIA, as we previously discussed and she stated she would provide. SHIRLEY hung the phone up abruptly.

On 11/15/13 contact was made with Assistant State Attorney WILLIAM LONG, who is prosecuting JONES in the involved criminal case [(772) 226-3300]. ASA LONG acknowledged that mail sent from the court to JONES to the address of 8565 61st Dr., Wabasso, FL has been returned by the postal service indicating "not deliverable as addressed." LONG confirmed he has no recent accurate address information for JONES. LONG also confirms he will not sign off on any more continuances for JONES in the related criminal matter; if she fails to show up on her next scheduled appearance (docket call on 12/19/13), he will issue a bench warrant for her arrest. LONG has no authority to force JONES' defense attorney to provide locating info for JONES.

SUPPLEMENTAL REPORT CONTINUED.....

Related Cases: 2013-12406

Investigator/Date: 11/26/13 AMY SENIOR, INVESTIGATOR, WI-89	Approved By/Date: 11/26/13 MICELLE MILLER, INV. MANAGER, WI-102

Distribution: HQ/ISU

Received
Investigative Services
NOV 27
DOH/MQA
Tallahassee FL

On 11/12/13 Indian River County Sheriff's Detective GREG STANLEY, who was involved in JONES' arrest, confirms the address at which JONES was arrested and last known to reside as: 8565 61st Dr., Wabasso, FL. He does not know why mail sent to that address by DOH and the court would be returned, claiming it to be a bad address. STANLEY says perhaps there is confusion on GPS map locators as to whether or not this address is actually located in Vero Beach, Sebastian, or Wabasso. STANLEY gave verbal directions to the address at which JONES reportedly lives.

On 11/15/13 this investigator attempted service upon JONES at 8565 61st Dr., Wabasso, FL around 12:45pm. An elderly woman answered the door and confirmed to be JONES' grandmother. She confirmed JONES was just there and left to pick up her sister from school and would return shortly. I asked if she would please give the envelope containing DOH paperwork to JONES upon her return. The woman was reluctant, stating she will just have JONES call me instead and deal with it herself. I gave my business card to her and requested she ask JONES to return my call immediately. The woman confirmed JONES was currently living at this residence. This investigator then surveilled the residence and waited for JONES' return for approximately 45 minutes, without success.

On 11/15/13 this investigator attempted to make personal contact with JONES' criminal defense attorney, but found this office to be closed on Fridays.

On 11/25/13 this investigator made personal contact with an adult female identifying herself as "ABIGAIL", answering the door at 8565 61st Dr., Wabasso, FL. ABIGAIL confirmed she was a resident of this address. ABIGAIL confirmed JONES was a resident of this address, but was not home at the moment. ABIGAIL accepted service of the envelope containing the AC and VR for JONES. ABIGAIL was asked to please give the envelope to JONES, as it contained important, time-pressed information for JONES from the DOH. ABIGAIL agreed.

EXHIBIT

S4-1 PSU Request Form, dated 11/8/13.....p.3
S4-2 Affidavit of service, dated 11/26/13.....p.4

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

Melba L. Apellaniz, RSII for Louise Wilhite-St. Laurent, Esq.	TO: Christopher Ferguson
Date: 11/8/2013	TO: **CSU** ☐
Phone #: 850-245-4640 Ext. 8223	CC: Amy Senior

Case Number: 2013-12375 Board: **Pharmacy**
Subject: **Latoria Denise Jones, R.P.T.** HL Code: **hl146a** Status: **87**
Requested Completion Date: 11/28/13

RECEIVED-LEGAL
13 DEC -2 AM 10:01

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Please hand serve attached Administrative Complaint and proposed Voluntary Relinquishment of License form. Please contact me by November 28, 2013, if you are unable to serve the Subject. Thank you.

*The following additional information is needed for each service request:

Last Known Address: 241 8th Avenue, Sebastian, FL 32962; Last Known Name & Phone Latoria Denise Jones, R.P.T.; (772) 646-1330; Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☒; If Yes, When?
Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☐** No ☒ NOTE: All process service requests need to be sent to appropriate field office.
__IF YES, please send a copy of the original Investigative Report without attachments.**__

(ISU/CSU) RESPONSE:

☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Add'l Info Sent to Legal (Activity Code 156)

☐ Investigative Work Returned to Legal (Activity Code 156)

EXHIBIT #S4-1 P3

INV FORM 376, Revised 10/11, 6/10, 06/09, 4/09,11/08 Created 4/05

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

FLORIDA DEPARTMENT OF HEALTH
Petitioner
vs LATORIA DENISE JONES, RPT
Respondent

Case No. 2013-12375

COMES NOW, the affiant, who first being duly sworn, deposes and states:

1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on 11/25/13, Affiant made a diligent effort to locate Respondent, to serve XX Administrative Complaint and related papers; ____ Order compelling examination(s); Subpoena(s); _____Final order; _____Notice to cease and desist; ____ ESO/ERO and related papers.

3) Check applicable answer below:

XX Affiant made personal service on a person at Respondent's usual place of abode over the age of 15 residing there, on 11/25/2013.

____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.);

Affiant

State Of Florida
County Of Palm Beach
Before me, personally appeared AMY SENIOR whose identity is known to me by Personal Knowledge (type of identification) and who, acknowledges that his signature appears above.

Sworn to or affirmed by Affiant before me this 26th day of November, 2013.

KEVIN LAPHAM
Commission # EE 845076
Expires October 18, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

Notary Public-State of Florida

My Commission Expires

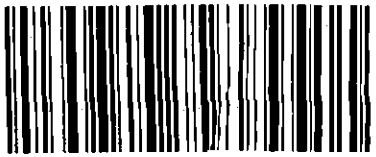
Type or Print Name

[redacted]

EXHIBIT # S4-1 04

CERTIFIED MAIL™

Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, Florida 32399-3265



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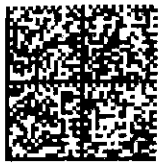


UNITED STATES POSTAGE PITNEY BOWES
02 1M $ 06.51⁰
0004284650 OCT 30 2013
MAILED FROM ZIP CODE 32301

Louise

NSN

Latoria Denise Jones, RPT
241 8th Avenue
Sebastian, FL 32962

2013 NOV -7 PM 12:06
PRACTITIONER REGULATION
LEGAL

NIXIE 339 DE 1009 11/02/13
RETURN TO SENDER
NO SUCH NUMBER
UNABLE TO FORWARD

BC: 32399326599 *1706-00338-02-31

32962\3584 9\08365

Received
Investigative Services
OCT 16 2013
DOH/MQA
Tallahassee HQ

STATE OF FLORIDA

DEPARTMENT OF HEALTH
INVESTIGATIVE REPORT

Office: West Palm Beach	Date of Case: 08/05/2013	Case Number: 2013-12375

Subject: LATORIA DENISE JONES, RPT 274 Main Street Sebastian, FL 32958* (772) 646-1330	Source: THERESA TOLLE, RPH 7746 Bay Street Sebastian, FL 32958 (772) 589-2043

Prefix:	License #:	Profession:	Board:	Report Date:
RPT	45081	Registered Pharmacy Technician	Pharmacy	10/15/2013

Period of Investigation: 9/26/13 – 10/15/13	Type of Report: SUPPLEMENTAL-3

Alleged Violation: F.S. 456.072(1)(k)(dd); 465.016(1)(d)(e)(m)(r); 465.023(1)(c)-Violate Statute/Rule; Failure to perform legal obligation; Impaired from alcohol/drugs/other; Prescription/dispense outside practice...

Synopsis: This SUPPLEMENTAL report is predicated upon receipt of a request from PSU's LOUISE ST. LAURENT, Esq. (EX# S3-1) to hand serve the ESO packet upon JONES. Email contact with ST. LAURENT was made to clarify the provided Wabasso address on the request form, was previously confirmed to be a non-current/non-accurate address. JONES' address of record (above) has also previously been confirmed to no longer be current/accurate. The only known accurate address for JONES is a Post Office Box in Sebastian. Many attempts were made beginning on 9/27/13 to reach JONES and /or her mother (SHIRLEY JONES), and/or her criminal attorney via telephone to acquire a current physical address. On 9/30/13 JONES was reached via her phone number of record (772-646-1330). JONES claims she just left to go out of town this morning for medical reasons and will return 10/6/13. JONES confirms her address of record (274 Main St., Sebastian) is no longer current. JONES claims she recently moved, but does not know her new address. JONES states she will call back this investigator within the hour with that new physical address. JONES was advised of her obligation to update her address with the Board. JONES states she believes her mother picked up the subject notification information mailed by DOH to the Post Office Box of record. It was expressed to JONES that it is important that she be familiar with this information and respond accordingly. It was also explained to JONES that it is critical she provide her physical address to this investigator to accommodate providing her important licensure information in person. JONES confirmed she had a criminal attorney, but was not sure if he would be representing her in the DOH matter. A letter of representation and contact from her attorney was requested. No such letter of representation has been received. Subsequent messages left for JONES to re-contact this investigator have gone unanswered. On 9/27/13 a call was made to SHIRLEY JONES, mother of subject [(772) 646-1030]. Either there was a poor connection, or JONES' mother hung up the call when the Investigator introduced herself. On 10/1/13 telephone contact was made with SHIRLEY JONES who advised that LATORIA JONES is out of town and having medical issues. SHIRLEY JONES stated LATORIA JONES' new, current street address is: "241 8th Avenue, Sebastian 32962." SHIRLEY JONES stated she has Power of Attorney (POA) right now over LATORIA JONES, due to LATORIA's medical issues. SHIRLEY JONES stated she would fax documentation of that POA to this investigator. No such documentation has been received. Many subsequent calls/messages left for SHIRLEY JONES have not been returned.

Contact was made with arresting officer DETECTIVE GREG STANLEY, who confirms he has no updated information regarding JONES' whereabouts or current accurate address. STANLEY also has never been advised by any of the involved parties that JONES' mother has POA over JONES.

SUPPLEMENTAL REPORT CONTINUED.....

RECEIVED 13 OCT 16 PM 12:13 HQ

Related Cases: 2013-12406

Investigator/Date: Amy Senior 10/15/13	Approved By/Date: Chris Ferguson 10/15/13
AMY SENIOR, INVESTIGATOR, WI-89	CHRISTOPHER FERGUSON, INV. SUPERVISOR, WI-100

Distribution: HQ/ISU

Multiple detailed messages have been left with JONES' criminal defense attorney BOBBIE GUTTRIDGE [(772-978-0240] requesting his assistance in providing an accurate street address for JONES. There has been no response from Attorney GUTTRIDGE.

Contact was made with Assistant State Attorney WILLIAM LONG, who is prosecuting JONES in the involved criminal case [(772) 226-3300]. ASA LONG also has no confirmed current locating information for JONES. Since JONES is not on any form of pre-trial or drug-court probationary monitoring; the only court control of JONES is through bond. Unless JONES violates bond, there is no reason for the ASA office's intervention and contact with JONES; therefore JONES has not willingly or cooperatively had reason to be in communication with his office. JONES has a docket call scheduled for 11/4/13 and is ordered to appear in court at 9:00am, unless a stipulated motion is requested for an extension. ASA LONG stated he is not surprised at all by criminal defense attorney GUTTRIDGE's lack of cooperation in this matter.

An Accurint report run on 10/1/13 provided no new address information for JONES. Telephonic and faxed confirmation from the Postal Service (EX# S3-2) provides the street address known to the Postal Service, related to the known PO Box is: 274 Main Street, Sebastian, FL 32958.

On 10/9/13 this investigator attempted to locate JONES at her address of record: 274 Main Street, Sebastian, FL 32978. This residential home was visually confirmed to be vacated. An attempt was then made to locate subject at the new address provided by her mother: "241 8th Avenue, Sebastian 32962." GPS, Mapquest, and Google maps all provide directions in response to a search for this address that results in Brevard County (Roseland area), which is outside of Sebastian. This destination is a non-existent address on a dead end road.

On 10/9/13 this investigator confirmed with the Sebastian Police Department (SPD) that the address of "241 8th Avenue, Sebastian, FL", as provided by JONES mother, is not an existing address in Sebastian; they suggest looking for the same street address in neighboring Vero Beach. SPD checked their records and confirmed during a traffic encounter with LATORIA JONES on 4/19/13, she provided the address of 274 Main St., Sebastian. SPD has no more current address information for JONES.

On 10/9/13 this investigator attempted to locate JONES at 241 8th Avenue, Vero Beach (instead of Sebastian) and discovered there is no such house # on 8th Avenue, Vero Beach. The house numbers went from 235 to 245; no 241.

As of the submission of this report, neither JONES, her mother, or her criminal defense attorney have returned repeat messages requesting contact and/or JONES' current accurate street address. An affidavit of diligent search is being submitted due to LATORIA JONES being unable to be located for ESO service.

EXHIBIT

S3-1 PSU Request Form, dated 9/26/13.....p.3
S3-2 Post Office address request form, received 10/10/13...p.4
S3-3 Affidavit of Diligent Search, dated 10/15/13.....p.5

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

PSU REQUEST FORM

FROM: Tamia Christopher For Louise R. St. Laurent, Esquire	TO: Michelle Miller, Inv. Mngr., (Area 9 (WI)
Date: 9/26/13	TO: CSU
Phone #: 850/245/4444 Ext. 8200	CC: Amy Senior, Investigator, WI-89

Case Number: 2013-12375 Board: Pharmacy
Subject: Latoria Denise Jones, R.P.T. HL Code: HLL101B Status: 90
Requested Completion Date: A.S.A.P.

RECEIVED-LEGAL
13 OCT 16 PM 3:19

(PSU) TYPE OF REQUEST: (describe details below)

- [x] Process Service* (**Activity Code 160**)
- [ ] Additional Information Requested (**Activity Code 145**)
- [ ] Deficiency in Investigative Work (**Activity Code 150**)

Details: **For Hand Service of ESO**
Last Known Address: 8565 61st Drive, Wabasso, Florida 32970
Last Known Name & Phone Number: Latoria Denise Jones, R.P.T., (772) 646-1330
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES [ ] No [x]; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES [ ]** No [ ] NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

- [ ] Process Service Completed (Activity Code 161) [ ] Process Service NOT Completed (Activity Code 162)
- [ ] Additional Info Sent to Legal (Activity Code 156)
- [ ] Supp. Investigation Request Cancelled (Activity Code 157)

Email to: Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

EXHIBIT #S3-1

Florida Department of Health
Division of Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-
PHONE: 850-245-4444 • FAX 850-245-4662

p 3

Mission: To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

REPLY TO: **DEPARTMENT OF HEALTH**
Investigative Services Unit
900 S. U.S. Hwy. 1, Suite #207
Jupiter, FL 33477

To: Postmaster, DOH Case No. 2013-12376

Date: 10/1/2013

ADDRESS INFORMATION REQUEST

Please furnish this Department with the physical street address as recorded on the box holder's application form.

Last Name: JONES

Last Known Post Office Box Address: 780292, Sebastian, FL 32978

274 Main Street Sebastian FL 32958

I certify that the address information for this individual is required for the performance of the DOH's official duties.

Amy Senior, Medical Quality Assurance Investigator
DOH Official

Amy Senior 10/1/13
(signature)

FOR POST OFFICE USE ONLY

(✓) MAIL IS DELIVERED TO ADDRESS GIVEN P.O. Box

( ) NEW ADDRESS: _____

( ) NOT KNOWN AT ADDRESS GIVEN

( ) MOVED, LEFT NO FORWARDING ADDRESS

( ) BOXHOLDER'S STREET ADDRESS: _____

( ) NO SUCH ADDRESS

( ) OTHER (SPECIFY) _____

DOH RETURN ADDRESS LISTED BELOW:

POST MARK/DATE STAMP

USPS OCT 8 2013 Sebastian FL

EXHIBIT #53

Florida Department of Health
Division of Medical Quality Assurance • Bureau of Enforcement
900 S US Highway 1, Suite 207, Jupiter FL 33477
Phone: [redacted] • Fax: 561-741-4581
561-741-4583

www.FloridaHealth.com
TWITTER: HealthyFLA
FACEBOOK: FLDepartmentofHealth
YOUTUBE: fldoh

p4

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

FLORIDA DEPARTMENT OF HEALTH
Petitioner
vs LATORIA JONES, RPT
Respondent

Case No. 2013-12375

COMES NOW, the affiant, who first being duly sworn, deposes and states:

1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on 10/11/13, Affiant made a diligent effort to locate Respondent, to serve___ Administrative Complaint and related papers; _ Order compelling examination(s); Subpoena(s); _____Final order; _____Notice to cease and desist; _XX_ ESO/ERO and related papers.

3) Check applicable answer below:

_____Affiant made personal service on Respondent,

_XX__Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.); any others as detailed in corresponding supplemental report.

Affiant

State Of Florida
County Of Palm Beach
Before me, personally appeared AMY SENIOR whose identity is known to me by Personal Knowledge (type of identification) and who, acknowledges that his signature appears above.

Swom to or affirmed by Affiant before me this 15th day of October, 2013 .

Notary Public-State of Florida

My Commission Expires

DARYL FRUTH
Commission # EE 111598
Expires August 23, 2015
Bonded Thru Troy Fain Insurance 800-385-7019

Type or Print Name

EXHIBIT # 53-3

P5

STATE OF FLORIDA

DEPARTMENT OF HEALTH
INVESTIGATIVE REPORT

Office: West Palm Beach	Date of Case: 08/05/2013	Case Number: 2013-12375

Subject: **LATORIA DENISE JONES, RPT** 274 Main Street Sebastian, FL 32958* (772) 646-1030	Source: **THERESA TOLLE, RPH** 7746 Bay Street Sebastian, FL 32958 (772) 589-2043

Prefix:	License #:	Profession:	Board:	Report Date:
RPT	45081	Registered Pharmacy Technician	Pharmacy	08/22/2013

Period of Investigation: 08/12/13 – 8/22/13	Type of Report: SUPPLEMENTAL-2

Alleged Violation: F.S. 456.072(1)(k)(dd); 465.016(1)(d)(e)(m)(r); 465.023(1)(c)-Violate Statute/Rule; Failure to perform legal obligation; Impaired from alcohol/drugs/other; Prescription/dispense outside professional practice...

Synopsis: This SUPPLEMENTAL report is predicated upon receipt of additional information. On 8/12/13 the "green card" from postal service (EX#S2-1) was returned acknowledging JONES' subject notification was retrieved from the PO Box, Sebastian address. On 8/19/13 the subject notification mailed to a possible address for JONES in Wabasso was returned by the postal service indicating "Not deliverable/Unable to Forward" (EX#S2-2)

EXHIBIT

S2-1 Green postal card returned.....p.2
S2-2 Subject notification letter/envelope returned...p.3

RECEIVED-LEGAL
13 AUG 26 PM 4:19

Related Cases: 2013-12406

Investigator/Date:	Approved By/Date:
8/22/13	8/22/13
AMY SENIOR, INVESTIGATOR, WI-89	MICHELLE MILLER, INV. MANAGER, WI-102

Distribution: HQ/ISU

Received
Investigative Services
AUG 26 2013
DOH/IRA
Tallahassee HQ

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete Item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Latrina Jones
PO BOX 780292
Sebastian FL
32978

COMPLETE THIS SECTION ON DELIVERY

A. Signature

X Tonnie Jones ☐ Agent ☐ Addressee

B. Received by (Printed Name) TONNIE JONES

C. Date of Delivery 12

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

SEBASTIAN FL 32958 USPS

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

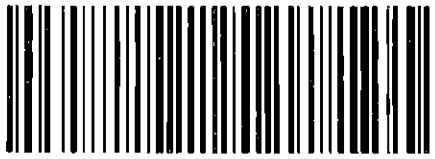
2. Article Number (Transfer from service label) 7009 0820 0001 1731 0821

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

EXHIBIT

Medical Quality Assurance - Investigative Services
900 S. US Highway One, Suite 207
Jupiter, FL 33477
ATTN: A. Senior

RETURN SERVICE REQUESTED



7009 0820 0001 1731 0814

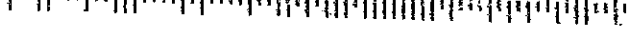
08/08/2013

LATORIA DENISE JONES
8565 61ST DRIVE
WABASSO, FL 32970

PERSONAL (NIXIE 339 4E 1009 0208/14/13

RETURN TO SENDER
NOT DELIVERABLE AS ADDRESSED
UNABLE TO FORWARD

33477 06469 BC: 33477546957 *2506-01090-07-44



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One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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STATE OF FLORIDA

DEPARTMENT OF HEALTH
INVESTIGATIVE REPORT

Office: West Palm Beach	Date of Case: 08/05/2013	Case Number: 2013-12375

Subject: **LATORIA DENISE JONES, RPT** 274 Main Street Sebastian, FL 32958* (772) 646-1030	Source: **THERESA TOLLE, RPH** 7746 Bay Street Sebastian, FL 32958 (772) 589-2043

Prefix:	License #:	Profession:	Board:	Report Date:
RPT	45081	Registered Pharmacy Technician	Pharmacy	08/08/2013

Period of Investigation: 08/06/13 – 08/08/13	Type of Report: FINAL

Alleged Violation: F.S. 456.072(1)(k)(dd); 465.016(1)(d)(e)(m)(r); 465.023(1)(c)-Violate Statute/Rule; Failure to perform legal obligation; Impaired from alcohol/drugs/other; Prescription/dispense outside professional practice...

Synopsis: This investigation is predicated upon a complaint (EX#1) received from THEREA TOLLE, RPH pharmacist/owner of Bay Street Pharmacy in Sebastian alleging JONES stole controlled substances while working in the pharmacy as a pharmacy technician student. On 7/31/13, after JONES had worked in the pharmacy, a discrepancy in the Roxicodone count was off by 200 tablets. Indian River County Sheriffs Office (IRCSO) set up a hidden camera in the pharmacy which captured JONES sliding two bottles of Oxycodone (total quantity 200 pills) under her skirt on 8/2/13. JONES was subsequently arrested by IRCSO for Trafficking Oxycodone and two counts of Felony Grand Theft.

JONES was notified of this investigation via letters dated 8/6/13 and 8/8/13. JONES was also provided a copy of the complaint and a Voluntary Relinquishment form (EX#2).

Per DOH license databank, JONES is licensed as a Registered Pharmacy Technician.

There is no direct patient involvement, thus patient notification is unnecessary.

JONES is not known to be represented by an attorney in this matter.

As of the submission of this report, JONES has not responded to the allegation.

RECEIVED-LEGAL
8 AUG 13 AM 7:26

*Investigation indicates JONES' current mailing address is: PO Box 780292, Sebastian, FL 32978

Related Cases: 2013-12406

Investigator/Date:	Approved By/Date:
Amy Senior 8/8/13	8/8/13
AMY SENIOR, INVESTIGATOR, WI-89	CHRISTOPHER FERGUSON, Inv. Supervisor, WI-100

Distribution: HQ/ISU

Received
Investigative Services
AUG 12 2013
DOH/MQA
Tallahassee HQ

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TARA LYNN KANE, RPT-WITNESS 4-5
CHERYL GRAGE, RPH-WITNESS 5

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***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES**

****These records are sealed pursuant to Section 456.057(10)(a), Florida Statutes and copies of same are not maintained in the West Palm Beach Investigative Services office**

*****This exhibit contains confidential records concerning reports of abuse, neglect or exploitation of the vulnerable adult, including reports made to the central abuse hotline, and is sealed pursuant to section 415.107(1), Florida Statutes**

INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

EX#1 includes copies of sworn witness statements made by Bay Street Pharmacy staff law enforcement.

EX#2 includes copies of all three subject notification letters mailed to JONES' address of record; address in police/arrest records; address provided by JONES' mother to DOH on 8/7/13.

EX#4 is a printout of booking information from the Indian River County Sheriff's Office (IRCSO) jail website confirming JONES' 8/3/13 arrest; that she bonded out on 8/4/13; reported a current address in Wabasso, FL; and has a pending corresponding court date on 9/23/13 (Court case# 2013CF000971A).

EX#5 is the inventory conducted by pharmacy staff on 7/31/13; reflecting 200 Roxicodone pills as missing.

EX#6 is the arrest affidavit dated 8/3/13 charging JONES with Trafficking Oxycodone and two counts of Grand Theft of a Controlled Substance. The affidavit details JONES was caught on video concealing two Oxycodone bottles in her clothes and later admitting to this and a prior theft of pharmacy medication.

STATEMENT OF THERESA TOLLE, RPH-SOURCE

Bay Street Pharmacy
7746 Bay Street
Sebastian, FL 32958
(772) 589-2043

Owner/Pharmacy Department Manager TOLLE's initiating complaint details that she will be out of town/unavailable for interview until after 8/12/13. Her initiating complaint (EX#1) essentially states:

- JONES served as a pharmacy technician student in the pharmacy in 2012. Since completing her education, JONES had volunteered in the pharmacy while she was in between jobs. In her volunteer role she had access to controlled substances.
- An audit conducted on 7/31/13 indicated 200 Roxicodone pills were missing. JONES "had been in the pharmacy on Tuesday 7/30/13 as a volunteer so we immediately suspected her." With the assistance of IRCSO, a hidden video camera was installed in the pharmacy on 8/2/13.
- A controlled substance inventory was conducted on 8/2/13 and first thing in the morning on 8/3/13. On 8/3/13 JONES was in the pharmacy as a volunteer. When she left, another inventory yielded 200 generic Oxycodone pills were missing; (two 100 count bottles).
- The police were called, viewed the video surveillance and could clearly view her stealing two bottles, sliding them up her skirt. JONES was subsequently arrested with the bottles in her possession. JONES admitted to stealing the medication on 8/3/13, as well as previously on 7/30/13.

INTERVIEW OF DETECTIVE GREG STANLEY-WITNESS

Indian River County Sheriff's Office (IRCSO)
41st Avenue
Vero Beach, FL 32960
Main (772) 569-6700/Cell (772) 633-4241

On 8/7/13 and 8/8/13 STANLEY was interviewed by Investigator SENIOR via telephone, essentially stating:

- He was contacted by Bay Street pharmacy staff who suspected JONES of stealing medication based on a discrepancy discovered on 7/31/13. He installed the hidden camera in the pharmacy. On 8/3/13 JONES was in the pharmacy and after she left, the staff determined medication was again missing. JONES was captured on video stealing bottles of Oxycodone and subsequently arrested.

- Upon questioning, JONES admitted to stealing the missing Oxycodone on 8/3/13 as well as the medication that had been documented as missing on/around 7/30/13. JONES' statement was taken via audio recording and was not written. There will be no transcription of the audio statement unless requested by the State Attorney's Office.
  - JONES reported she was taking the medication and ingesting it for her own use. JONES claimed a medical condition, for which the doctors were not prescribing medication adequate enough to address her pain. STANLEY did not observe JONES exhibit any indication of impairment.
  - The informal inventory conducted by pharmacy staff on 8/2/13 and 8/3/13 on small pieces of notepad paper were likely taken into evidence by the arresting officer at the scene. STANLEY will attempt to get copies of these documents out of evidence and forward to DOH in the near future.

INTERVIEW OF TARA LYNN KANE, RPT-WITNESS

Bay Street Pharmacy
7746 Bay Street
Sebastian, FL 32958
(772) 589-2043

On 8/6/13 KANE was interviewed by Investigator SENIOR via telephone, essentially stating:

- Her sworn statement provided to IRCSO (EX#1) is accurate and true. On 7/27/13 KANE was aware that the pharmacy was low on Oxycodone 30mg tablets, so she physically looked on the appropriate shelf and observed for herself that there were four bottles of Roxicodone 30mg tablets.
- On 7/31/13 a count was performed indicating 200 Roxicodone pills were missing (EX#5). KANE physically observed only one sealed bottle and one partially opened 2nd bottle of Roxicodone were now on the shelf; as opposed to KANE personally observing four Roxicodone bottles just days prior.
- First thing in the morning of 8/2/13 KANE performed a controlled substance inventory count. First thing in the morning of 8/3/13 a dispensing report was run and compared to the current inventory; confirming the inventory count was accurate.
- On 8/3/13 JONES arrived while KANE was outside smoking. JONES asked KANE if she could use the pharmacy's computer for a personal matter, since she had no internet. KANE told JONES to ask the pharmacist on duty: CHERYL GRAGE, RPH.
- While in the pharmacy, JONES socialized and showed photos to staff. JONES dropped papers, which scattered all over the floor. In hindsight, KANE realizes this is something JONES has also done previously. When JONES goes in search of collecting her papers scattered all over the floor it gives her access to be in the pharmacy area where the medications in question are kept.
- After JONES left on 8/3/13, GRAGE went to the shelf where Oxycodone are stored, noting bottles were knocked over. An immediate inventory yielded 200 pills were missing (two 100 count bottles).
- JONES interned at this pharmacy July 2012-January 2013. JONES would be present in the pharmacy about four times weekly. After January 2013 JONES was no longer training or considered an intern in this pharmacy; but beginning about six months ago, JONES would pop into the pharmacy about once or twice weekly. JONES would come by to socialize with staff, but mostly to stay in touch with TOLLE, who would try to help JONES get a job and or provide her career guidance. JONES would have access to the pharmacy during these visits, despite her presence was not in any official or formal capacity.

- KANE has never witnessed any obvious signs of JONES being impaired. JONES' previous friendly demeanor did seem to change recently however; she seems to have become less friendly. KANE has not observed any physical signs, symptoms, or indications of impairment by JONES.

INTERVIEW OF CHERYL GRAGE, RPH-WITNESS

Bay Street Pharmacy
7746 Bay Street
Sebastian, FL 32958
(772) 589-2043

On 8/7/13 GRAGE was interviewed by Investigator SENIOR via telephone, essentially stating:

- Her sworn statement provided to IRCSO (EX#1) is accurate and true. GRAGE is a staff pharmacist at Bay Street Pharmacy. JONES was a student intern, performing her internship duties affiliated with her school through January 2013. After January 2013 when her internship was over, she continued to informally volunteer at the pharmacy. JONES had no set volunteer schedule; she was welcome to come into the pharmacy to volunteer whenever she wanted. While volunteering, she would put medication away, help out at the register, and retrieve medications off the shelf for the pharmacist.
- On 7/31/13 a Roxicodone discrepancy was discovered (EX#5). As JONES had been in the pharmacy volunteering the day prior (7/30/13), she was suspected as being the cause of the discrepancy. While JONES had been in on 7/30/13, she told staff she planned on coming back to the pharmacy that Saturday (8/3/13) to show everyone photos from her recent graduation.
- In the interim, IRCSO placed a hidden camera in the pharmacy. On 8/3/13 at 8:40am GRAGE inventoried the Oxycodone; and concluded there were no discrepancies.
- On 8/3/13 at approximately 11:15am JONES came into the pharmacy and asked GRAGE to use the computer in the pharmacy office for a personal task. GRAGE agreed. JONES sat at the desk in the back and then came behind the pharmacy counter to show staff photos.
- Earlier that morning, in anticipation of JONES' arrival, GRAGE purposely laid out medications on the pharmacy filling counter that would normally be put away on the shelf near the Oxycodone. GRAGE instructed staff to not put these medications away; to intentionally leave them out. GRAGE witnessed JONES go over and pick those medications up and proceed to put them away. GRAGE witnessed JONES go into the bay, but GRAGE intentionally did not follow or watch JONES closely, to purposely allow JONES the privacy and room to steal the medication if that was her intention. GRAGE was aware the installed hidden camera would capture any such behavior.
- JONES left the pharmacy at approximately 11:45am. Another inventory was then done. GRAGE noticed Oxycodone bottles knocked over. The inventory yielded 200 Oxycodone pills were missing.
- GRAGE advises that the "before and after" inventories conducted on 8/3/13 were written on small pieces of notepad paper and handed over to the police; the pharmacy kept no copy.
- GRAGE reports never observing any indication of JONES being impaired.

INVESTIGATOR'S NOTE:

On 8/6/13 and 8/7/13 messages were left for JONES on the voice mail of her phone number of record: (772) 646-1330. On 8/7/13 SHIRLEY JONES, identifying herself as JONES' mother returned the messages and provided her own phone number (772) 646-1030. SHIRLEY JONES advised that her daughter, LATORIA JONES has been hospitalized for about 2-3 days for Sickle Cell Disease and was still currently in the hospital. SHIRLEY JONES stated LATORIA JONES is now residing with her and can receive mail at: PO Box 780292, Sebastian, FL 32978. She reports no physical house address is available; only this PO Box. A message was left to please have LATORIA JONES contact this investigator when possible.

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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OPEN / CLOSE

Subject Data

:: field ::	:: value ::
mugshot	
name	Jones, Latoria Denise
date of birth	Tuesday, July 28, 1987 (Age at booking : 26)
address	8565 61ST DRIVE Wabasso, FL 32970

OPEN / CLOSE

Booking Details

:: field ::	:: value ::
arrest date / time	Saturday, August 3, 2013 at 2:07 PM (Eastern)
arrest location	8565 61st Drive Wabasso Fl
arresting agency	Indian River County Sheriff's Office
booking date	Saturday, August 3, 2013 at 5:00 PM (Eastern)
booking number	2013-00003529
case number	2013-00121660

EXHIBIT # 4

30

:: field ::	:: value ::
commissary number	358131
make phone calls	Yes
released	Yes
total bond amount	$0.00

PLEASE NOTE - The Scheduled Release Date is subject to change. Please call Booking Release for an up to date scheduled release date at (772)-978-6373.

OPEN / CLOSE Booking Charges

:: field ::	:: value ::
charge #1	**Traf Oxycodone** **[Bond Number]** 2013-00004151 **[Bond Set Amount]** $75,000.00 **[Bond Set Type]** Cash/Surety **[Disposition / Date]** Posted Bond on Saturday August 3, 2013 **[Court Date / Time]** Monday September 23, 2013 at 8:30 AM **Felony Grand Theft**
charge #2	**[Bond Number]** 2013-00004152 **[Bond Set Amount]** $5,000.00 **[Bond Set Type]** Cash/Surety **[Disposition / Date]** Posted Bond on Saturday August 3, 2013 **[Court Date / Time]** Monday September 23, 2013 at 8:30 AM **[Bond Remarks]** Grand theft controlled substance **Felony Grand Theft**
charge #3	**[Bond Number]** 2013-00004153 **[Bond Set Amount]** $5,000.00 **[Bond Set Type]** Cash/Surety **[Disposition / Date]** Posted Bond on Saturday August 3, 2013 **[Court Date / Time]** Monday September 23, 2013 at 8:30 AM **[Bond Remarks]** Grand theft controlled substance

OPEN / CLOSE Subject Characteristics

:: field ::	:: value ::
eye color	Brown
gender	Female
hair color	Black

31

:: field ::	:: value ::
height	5' 5" (1.7m)
primary language	English
weight	125lbs. (56.8 kg)

OPEN / CLOSE

Release Data

:: field ::	:: value ::
comments	Posted Bond Barnett Bail Bonds # AS6K-411569, AS6K-411568 and AS100K-18528
release date	Sunday August 4, 2013 at 10:39 AM
release reason	Posted Bond
released by	A375 - Dorsett, D.
released to	Posted Bond Barnett Bail Bonds # AS6K-411569, AS6K-411568 and AS100K-18528

Arrest and booking information on our public web site is considered public record information pursuant to Chapter 119, Florida statutes. the information will remain posted absent a court order. FDLE provides a service through which certain criminal records can be expunged (removed from their records) or sealed (placed under highly restricted access). The laws and rules which govern expunction or sealing of criminal history record(s) include : section s.943.0585 - s.943.059, Florida statutes and Chapter 11c-7, Florida administrative code. For more information, forms and the process regarding seal and expungement of arrest records, please refer to the FDLE website.

Data was last modified on at EST.

Print this page •Back a page •Top of page

agency partners

These agencies provide services to the public related to the operations of the IRCSO.

32

inmate tally

This panel lists the current number of inmates residing in the IRCSO Jail.

429

calls for service

This panel lists the current active calls that our 911 dispatchers are handling.

16

*The total number of calls includes incidents that are currently assigned plus any pending incidents that have not been dispatched.

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website legalities|privacy policy|logo linking|user agreement|changelog|employee email

Under Florida law, e-mail addresses are public records. If you do not want your e-mail address released in response to a public-records request, do not send electronic mail to this entity. Instead, contact this office by phone or in writing.

33

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HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307018

BEVERLY LYNN JACKSON,
RESPONDENT.

NOTICE

TO: BEVERLY LYNN JACKSON
4773 CARIBBEAN CIRCLE
KEYSTONE HEIGHTS, FL 32656

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

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BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307018

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115 LAWRENCE BLVD
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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Ana Gargollo-McDonald, Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. Beverly Lynn Jackson, R.P.T.
DOH Case Number 2013-07018
DATE: November 6, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Beverly Lynn Jackson
Subject's Address of Record:	115 Lawrence Blvd Keystone Heights, FL 32656
Enforcement Address:	115 Lawrence Blvd Keystone Heights, FL 32656
Subject's Additional Address:	4773 Caribbean Circle Keystone Heights, FL 32656
Subject's License No:	38762 **Rank:** RPT
Licensure File No:	39802
Initial Licensure Date:	7/22/2011
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	465.016(1)(m), FS (2012)
Prior Discipline:	None
Probable Cause Panel:	August 8, 2013; Griffin & Mesaros
Subject's Attorney:	Pro Se
Complainant/Address:	DOH/ISU-Jacksonville
Materials Submitted:	Memorandum to the Board Voluntary Relinquishment Administrative Complaint Board Notification Letter Supplemental Investigative Report with Exhibits Election of Rights Emergency Suspension Order Order to Compel Examination

Final Investigative Report with Exhibits

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE OCT 28 2013

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v.

DOH Case No. 2013-07018

Beverly Lynn Jackson, R.P.T.,
Respondent.

VOLUNTARY RELINQUISHMENT OF REGISTRATION

Respondent Beverly Lynn Jackson, R.P.T., Registration No. 38762, hereby voluntarily relinquishes her registration as a pharmacy technician in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter "the Board") of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's registration pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for registration as a pharmacy technician in the State of Florida.

3. Respondent agrees to voluntarily cease practicing as a pharmacy technician immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from practicing as a pharmacy technician until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of

the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public per Section 456.073(10), Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 25th day of September, 2013.

Beverly Lynn Jackson

Beverly Lynn Jackson, R.P.T.

STATE OF FLORIDA
COUNTY OF: Clay
Before me, personally appeared Beverly L. Jackson, whose identity is known to me by FLDL identification) and who, under oath, acknowledges that his signature appears above. Sworn to and subscribed before me this 25th day of September, 2013.

Debra B. Suter

NOTARY PUBLIC

My Commission Expires:

DEBRA B. SUTER
MY COMMISSION # DD946720
EXPIRES January 05, 2014
(407) 398-0153 FloridaNotaryService.com

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-07018**

BEVERLY LYNN JACKSON, R.P.T.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, Beverly Lynn Jackson, R.P.T., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes (2012); Chapter 456, Florida Statutes (2012); and Chapter 465, Florida Statutes (2012).

2. At all times material to this Complaint, Respondent was registered to practice as a pharmacy technician pursuant to Chapter 465, Florida Statutes (2012), having been issued registration number RPT

38762.

3. Respondent's address of record is 115 Lawrence Boulevard, Keystone Heights, Florida 32656.

4. At all times material to this Complaint, Respondent was employed by Walgreens Pharmacy ("Walgreens") located at 115 N. Lawrence Boulevard, Keystone Heights, Florida 32656.

5. Between 2012 and 2013, Respondent diverted dosage units of controlled substances from Walgreens, including oxycodone pills.

6. Oxycodone is commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012), oxycodone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of oxycodone may lead to severe psychological or physical dependence.

7. On or about April 18, 2013, H.G., the Walgreens Loss Prevention Manager, contacted Clay County Sheriff's Office and reported Respondent's theft of oxycodone pills from Walgreens.

8. H.G. reported to Officer B.S. that on or about April 9, 2013,

H.G. reviewed Walgreens video surveillance records showing Respondent counting out dosage units of oxycodone and then placing her left hand into her pocket.

9. H.G. stated to Officer B.S. that H.G. obtained additional video surveillance on or about April 15, 2013, and April 16, 2013, showing Respondent pocketing dosage units of oxycodone.

10. On or about April 24, 2013, Officer B.S. interviewed Respondent at Walgreens. Respondent admitted to Officer B.S. that she stole dosage units of oxycodone from Walgreens during the past year of her employment.

11. Respondent signed a sworn statement regarding her involvement in the thefts.

12. Respondent further stated to Officer B.S. that she stole oxycodone pills by counting out extra pills when she filled prescriptions for Walgreens customers and placing the extra pills in her pocket.

13. Respondent stated to Officer B.S. that she has been addicted to oxycodone for the past year and that she diverted oxycodone tablets from Walgreens for her personal use.

14. On or about April 24, 2013, Officer B.S. arrested Respondent and charged her with grand theft of a controlled substance.

15. On or about May 9, 2013, the Department issued an Order to Compel Examination ("Order") against Respondent requiring that she submit to a mental and physical examination at the University of Florida, Florida Recovery Center located in Gainesville, Florida.

16. On or about June 24, 2013, Dr. S.T. evaluated Respondent pursuant to the Order.

17. During Dr. S.T.'s evaluation, Respondent submitted to urine, hair, and blood drug screens. The urine drug screen returned positive for cocaine and oxycodone/oxymorphone.

18. According to Section 893.03(2), Florida Statutes (2012), cocaine is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of cocaine may lead to severe psychological or physical dependence.

19. Oxymorphone is prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012), oxymorphone is a Schedule II

controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of oxymorphone may lead to severe psychological or physical dependence.

20. During Dr. S.T.'s evaluation, Respondent admitted to abusing cocaine, benzodiazepines, opiates, and cannabis.

21. Respondent stated that cocaine and opiates were her drugs of choice and that she used crack cocaine[1] three days prior to Dr. S.T's evaluation.

22. Dr. S.T. diagnosed Respondent with active opioid and cocaine dependence, cannabis dependence in partial remission, and benzodiazepine abuse.

23. Benzodiazepines are a class of drugs that cause sedation and can be habit forming. Most benzodiazepines are Schedule IV controlled substances according to Section 893.03, Florida Statutes (2012) and are typically prescribed to treat anxiety or insomnia.

24. Opiate, or opioid, drugs have similar actions as the drug opium

[1] Crack cocaine is a form of cocaine that has been processed to make rock crystal and is ingested by smoking.

and are typically prescribed to treat pain. While opioid drugs are synthetically manufactured and opiate drugs are naturally occurring, the terms "opioid" and "opiate" are often used interchangeably. Opioid drugs are addictive and subject to abuse.

25. According to Section 893.03(1), Florida Statutes (2012), cannabis is a Schedule I controlled substance that has a high potential for abuse and has no currently accepted medical use in treatment in Florida. Its use under medical supervision does not meet accepted safety standards.

26. As a result of his evaluation, Dr. S.T. determined that Respondent was unable to practice as a registered pharmacy technician with reasonable skill and safety due to her addiction to opioids and cocaine.

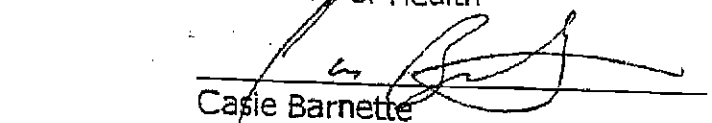
27. Section 465.016(1)(m), Florida Statutes (2012), allows the Board of Pharmacy to impose discipline against a licensee, including suspension, for being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition.

28. Respondent violated Section 465.016(1)(m), Florida Statutes (2012), by being unable to practice pharmacy with reasonable skill and safety to patients due to her drug addiction and abuse of controlled substances including, but not limited to, cocaine, opiates, benzodiazepines, and cannabis.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's registration, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 8 **day of** August **, 2013.**

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health



FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE AUG 08 2013

Casie Barnette
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar # 100159
(P) 850/245-4444 x8102
(F) 850/245-4662
(E) casie_barnette@doh.state.fl.us

PCP: August 8, 2013
PCP Members: Cynthia R. Griffin, PharmD and Jeffrey J. Mesaros, R.Ph.

DOH v. Beverly Lynn Jackson; Case No. 2013-07018

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

November 6, 2013

Beverly Jackson
115 Lawrence Blvd
Keystone Heights, FL 32656

Beverly Jackson
4773 Caribbean Circle
Keystone Heights, FL 32656

Re: DOH vs. Beverly Lynn Jackson, R.P.T.
DOH Case Number: 2013-07018

Dear. Ms. Jackson:

We are in receipt of your executed Voluntary Relinquishment form. As you are aware by signing the Voluntary Relinquishment of License form you agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against your license, pursuant to Section 456.072(1)(f), Florida Statutes;
- you would never reapply for licensure as a registered pharmacy technician in the State of Florida; and
- Voluntarily relinquishing your Florida pharmacy license may have an effect on pharmacy licenses you may hold in other states.

If this is not what you understood, please contact me as soon as possible to discuss, at 850-245-4444. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your request for Voluntary Relinquishment of License at their next regularly scheduled meeting. You are not required to attend the meeting.

Sincerely,

Ana Gargollo-McDonald
Assistant General Counsel

AM/ab

ELECTION OF RIGHTS

DOH v. Beverly Lynn Jackson, R.P.T. Case No. 2013-07018

PLEASE SELECT ONLY 1 OF THE 3 OPTIONS

An Explanation of Rights is attached. If you do not understand these options, please consult with your attorney or contact the attorney for the Prosecution Services Unit at the address/phone number listed at the bottom of this form.

OPTION 1. _____ **I do not dispute the allegations** of fact in the Administrative Complaint, but do wish to be accorded a hearing, pursuant to Section 120.57(2), Florida Statutes, at which time I will be permitted to submit oral and/or written evidence in mitigation of the complaint to the Board.

OPTION 2. ✓ **I do not dispute the allegations** of fact contained in the Administrative Complaint and **waive my right** to object or to be heard. I request that the Board enter a final order pursuant to Section 120.57, Florida Statutes.

OPTION 3. _____ **I do dispute the allegations** of fact contained in the Administrative Complaint and request this to be considered a petition for formal hearing, pursuant to Sections 120.569(2)(a) and 120.57(1), Florida Statutes, before an Administrative Law Judge appointed by the Division of Administrative Hearings. **I specifically dispute the following paragraphs of the Administrative Complaint:**

_____

_____

_____

In addition to the above selection, I also elect the following:

(✓) I accept the terms of the Settlement Stipulation, have signed and am returning the Settlement Stipulation or I am interested in settling this case.

(✓) I do not wish to continue practicing, have signed and returned the voluntary relinquishment of registration form, if it has been provided.

Regardless of which option I have selected, I understand that I will be given notice of time, date, and place when this matter is to be considered by the Board for Final Action. Mediation under Section 120.573, Florida Statutes, is not available in this matter.

(Please sign and complete all the information below.)

Beverly Lynn Jackson
Respondent
Address: 743 Caribbean Circle
Keystone Heights, FL 32656

Lic. No. _____

Phone No. 904-263-7677

Fax No. _____

STATE OF FLORIDA
COUNTY OF Clay

Before me, personally appeared Beverly L. Jackson whose identity is known to me or by FL DL # J250072768550 (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 25th day of September 2013.

Debra B. Suter
Notary Public-State of Florida

Debra B. Suter
Type or Print Name

DEBRA B. SUTER
MY COMMISSION # DD946720
EXPIRES January 05, 2014
(407) 398-0153 FloridaNotaryService.com

PLEASE MAIL AND/OR FAX COMPLETED FORM TO: Casie Barnette, Assistant General Counsel, DOH, Prosecution Services Unit, 4052 Bald Cypress Way, Bin C-65, Tallahassee, Florida 32399-3265. Telephone Number: (850) 245-4640; FAX (850) 245-4662; TDD 1-800-955-877

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Jacksonville	Date of Complaint: 05/02/13	Case Number: RPT 2013-07018
Subject: **BEVERLY LYNN JACKSON, RPT** 115 Lawrence Blvd. Keystone Heights, FL 32656 (B) (352) 473-4621	Source: **DOH / JACKSONVILLE ISU**	

Prefix:	License #:	Profession:	Board:	Report Date:
RPT	38762	Registered Pharmacy Technician	Pharmacy	08/19/13

Period of Investigation: 08/01/13—08/19/13	Type of Report: SUPPLEMENTAL

Alleged Violation: SEE FINAL REPORT

Synopsis:
This supplemental report is predicated upon the receipt of a request from PSU for this office to hand serve the attached Voluntary Relinquishment of Registration, (VR) to JACKSON, and for this office to obtain any and all court documents related to Case # 102013CF000788000AMX against JACKSON, (Exhibit S-1).

On 08/13/13, this Investigator delivered the VR to JACKSON's mother at her current place of residence, 7473 Caribbean Circle, Keystone Heights, FL 32656, while asking for JACKSON to contact this Investigator when she received the VR. On 08/15/13, JACKSON did contact this Investigator, and confirmed she is willing to sign the form and will go to a notary in the neighborhood and sign it at that time. JACKSON stated she would mail it back to this Investigator as soon as possible. As of this writing, the VR has not been received. When it is received, it will be forwarded to PSU.

On 08/16/13, Investigator TODD MCCORMICK of this office presented to the Clay County Clerk of Courts and did obtain the court records related to the case number noted above. The records obtained include:

- Felony Case Summary.
- Application for Criminal Indigent Status.
- Provisional Order Appointing Public Defender.
- Notice to Appear.
- Certified copy of the Order of Drug Offender Probation, including the Plea of Guilty and Negotiated Sentence.
- Copy of the Information.
- Clay County Office of the Sheriff Adult Arrest Report / Adult Notice to Appear.

Attachments:
S-1. Supplemental request and attachments.....2-5
S-2. Court documents.....6-30

Related Complaint: None

Investigator/Date:	Approved By/Date:
Ryan F. Heal MQA Investigator (JI-81) 08/19/13	Charles C. Coats, III District Manager (JI-15) 8-19-13

Received Investigative Services AUG 21 2013

Distribution: HQ/ISU

INV Form 300 7/02

RECEIVED-LEGA 13 AUG 23 AM 8:36

HEAL
8/1/13

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

FROM: Chris Byrne for Casie Barnette, Esq.	TO: ISU Ryan Heal
Date: August 1, 2013	TO: CSU ☐
Phone #: (850) 245-4444X8118	CC: Charles Coats, III

Case Number: 2013-07018
Subject: **Beverly Lynn Jackson, RPT**
Requested Completion Date: **ASAP**
Board: **Pharmacy**
HL Code: **HII105b**
Status: **90**

(PSU) TYPE OF REQUEST: (describe details below)

☐ Process Service* (**Activity Code 160**)

☒ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Please obtain any and all court documents related to Case# 102013CF000788000AMX against Subject. Also, please serve Subject the attached Voluntary Relinquishment of Registration. I am including Subject's address of record below. However, I noticed that you were able to serve Subject previously at her mother's address at 7473 Caribbean Circle, Keystone Heights, Florida 32656. Thank you.

*The following additional information is needed for each service request:
Last Known Address: 115 Lawrence Blvd., Keystone Heights, FL
Last Known Name & Phone Number: Beverly Lynn Jackson; (352) 473-4621 Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☒ No ☐; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☐** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
**__IF YES, please send a copy of the original Investigative Report without attachments.__

(ISU/CSU) RESPONSE:

☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Add'l Info Sent to Legal (Activity Code 156)

☐ Investigative Work Returned to Legal (Activity Code 156)

RECEIVED-LEGAL AUG 23 AM 8:36

INV FORM 376, Revised 10/11, 6/10, 06/09, 4/09, 11/08 Created 4/05

EXHIBIT # 1 PAGE # 2

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FLORIDA DEPARTMENT OF HEALTH

☐ Cancelled by Legal (Activity Code 157) ☐ Cancelled by ISU/CSU (Activity Code 158)

Email to:

Pensacola Tallahassee Alachua Jacksonville St. Pete Tampa Orlando Ft. Myers West Palm Ft. Lauderdale Miami

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v.

DOH Case No. 2013-07018

Beverly Lynn Jackson, R.P.T.,
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF REGISTRATION

Respondent Beverly Lynn Jackson, R.P.T., Registration No. 38762, hereby voluntarily relinquishes her registration as a pharmacy technician in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter "the Board") of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's registration pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for registration as a pharmacy technician in the State of Florida.

3. Respondent agrees to voluntarily cease practicing as a pharmacy technician immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from practicing as a pharmacy technician until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of

the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public per Section 456.073(10), Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this _____ day of _____, 2013.

_____
Beverly Lynn Jackson, R.P.T.

STATE OF FLORIDA
COUNTY OF:
Before me, personally appeared _____, whose identity is known to me by _____ (type of identification) and who, under oath, acknowledges that his signature appears above. Sworn to and subscribed before me this _____ day of _____, 2013.

_____
NOTARY PUBLIC

My Commission Expires:

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CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Jacksonville	Date of Complaint: 05/02/13	Case Number: RPT 2013-07018

Subject: **BEVERLY LYNN JACKSON, RPT** 115 Lawrence Blvd. Keystone Heights, FL 32656 (B) (352) 473-4621	Source: **DOH / JACKSONVILLE ISU**

Prefix:	License #:	Profession:	Board:	Report Date:
RPT	38762	Registered Pharmacy Technician	Pharmacy	06/05/13

Period of Investigation: 05/31/13—06/05/13	Type of Report: SUPPLEMENTAL

Alleged Violation: SEE FINAL REPORT

Synopsis:

This supplemental report is predicated upon the receipt of a request from PSU for this office to hand serve the attached Order Compelling Evaluation to JACKSON, (Exhibit S-1).

On 06/05/13, this Investigator presented to JACKSON's mother's place of residence at 7473 Caribbean Circle, Keystone Heights, FL 32656, and hand served the Order to JACKSON, (Exhibit S-2).

Attachments:

S-1. Supplemental request and attachments.....2-8

S-2. Affidavit of Service.....9

RECEIVED-LEGAL
13 JUN 10 AM 11:59

Related Complaint: None

Investigator/Date:	Approved By/Date:
Ryan F. Heal Medical Malpractice Investigator (JI-81) 06/05/13	Charles C. Coats, III District Manager (JI-15) 6-5-13

Received
Investigative Services
JUN 07 2013

Distribution: HQ/ISU

INV Form 300 7/02

DOH/OIA
Tallahassee, FL

FLORIDA DEPARTMENT OF HEALTH

HEAL 5-31-13

PSU REQUEST FORM

Gwendolyn Swatts, AAII for Casie Barnett, AGC	TO: Charles C. Coats, III, District Manager
Date: 5/31/2013	TO: **CSU** ☐
Phone #: 850-245-4444 Ext. 8214	CC: Ryan F. Heal, MMII (JI-81)

Case Number: 2013-07018 **Board: Pharmacy**
Subject: **Beverly L. Jackson, R.PT** HLCode: **HLL105B** Status: **60**
Requested Completion Date: 6/7/2013

RECEIVED-LEGAL
13 JUN 10 AM 11:59

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Please hand serve the attached Order Compelling Evaluation. Please contact Gwen Swatts at 850-245-4444, Ext 8214 with an update before June 7, 2013 if you are unable to serve the Subject. Thank you.

*The following additional information is needed for each service request:

Last Known Address: 115 Lawrence Blvd., Keystone Heights, FL 32656; Last Known Name & Phone: Beverly L. Jackson, R.PT, (904)263-7667) (Cell) or (352)473-4621(B).
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☒; If Yes, When?
Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☐** No ☒ NOTE: All process service requests need to be sent to appropriate field office.
**__IF YES, please send a copy of the original Investigative Report without attachments.__

(ISU/CSU) RESPONSE:

☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Add'l Info Sent to Legal (Activity Code 156)

☐ Investigative Work Returned to Legal (Activity Code 156)

CONFIDENTIAL

INV FORM 376, Revised 10/11, 6/10, 06/09, 4/09,11/08 Created 4/05

EXHIBIT # S-1 PAGE # 2

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: The Order Compelling Examination of
Beverly Lynn Jackson, RPT
License No: RPT 38762
Case No: 2013-07018

ORDER COMPELLING AN EXAMINATION

The Department of Health (Department) is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes (2012); Chapter 456, Florida Statutes (2012); and Chapter 465, Florida Statutes (2012).

For probable cause shown and pursuant to the authority vested in the Department by Chapters 456 and 465, Florida Statutes (2012), you are hereby ordered to report and submit to a mental and physical examination to be conducted by the following named physician at the date, time and place indicated.

Scott Teitelbaum, M.D.
UF, Florida Recovery Center
4001 SW 13th Street
Gainesville, FL 32606
(352) 265-5549
ON
Friday, June 14, 2013 @ 9:00 a.m.

The above-directed mental and physical examination is for the purpose of obtaining examination reports and expert opinion and testimony concerning

your ability to practice as a registered pharmacy technician with reasonable skill and safety pursuant to Sections 456.072(1)(z) and 465.016(1)(m), Florida Statutes (2012), and for introduction into evidence at any administrative hearing to be conducted on any administrative complaint filed against you which may allege a violation of Section 456.072(1)(z) and/or 465.016(1)(m), Florida Statutes (2012). This Order is predicated upon the following Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

1. At all times material to this Order, Beverly Lynn Jackson, RPT (Ms. Jackson), was a registered pharmacy technician within the state of Florida, having been issued registration number RPT 38762.

2. At all times material to this Order, Ms. Jackson was employed by Walgreens Pharmacy ("Walgreens") at 115 N. Lawrence Boulevard, Keystone Heights, Florida 32656 between 2011 and 2013.

3. Between 2012 and 2013, Ms. Jackson diverted 30 to 40 units of controlled medication from Walgreens, including Oxycodone pills.

4. Oxycodone is commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012), Oxycodone is a Schedule II controlled substance that has a high potential for abuse and has a currently

accepted but severely restricted medical use in treatment in the United States. Abuse of Oxycodone may lead to severe psychological or physical dependence.

5. On or about April 18, 2013, Walgreens' Loss Prevention Manager, H.G., contacted Clay County Sheriff's Office and reported Ms. Jackson's theft of Oxycodone pills from Walgreens.

6. H.G. reported to Officer B.S. that on or about April 9, 2013, H.G. reviewed Walgreens' video surveillance records showing Ms. Jackson counting out dosage units of Oxycodone 5mg and then placing her left hand into her pocket.

7. H.G. stated to Officer B.S. that H.G. obtained additional video surveillance on April 15, 2013, showing Ms. Jackson pocketing two pills of Oxycodone 5mg. H.G. further reported that video surveillance on April 16, 2013, showed Ms. Jackson pocketing two pills of Oxycodone 10mg.

8. On or about April 24, 2013, Officer B.S. interviewed Ms. Jackson at Walgreens. Ms. Jackson admitted to Officer B.S. that she stole 30 to 40 units of Oxycodone 5mg, 10mg, 20mg, and 30mg from Walgreens during the past year of her employment. Ms. Jackson signed a sworn statement regarding her involvement in the thefts.

9. Ms. Jackson further stated to Officer B.S. that she stole Oxycodone

5

pills by counting out extra pills and placing them in her pocket when she filled prescriptions for Walgreens customers.

10. Ms. Jackson stated to Officer B.S. that she has been addicted to Oxycodone for the past year and diverts the Oxycodone pills for personal use.

11. On or about April 24, 2013, Officer B.S. arrested Ms. Jackson and charged her with grand theft of a controlled substance.

12. Section 456.072(1)(z), Florida Statutes (2012), states, in pertinent part, "the department shall have, upon a finding of the State Surgeon General or the State Surgeon General's designee that probable cause exists to believe that the licensee is unable to practice because of the reasons stated in this paragraph, the authority to issue an order to compel a licensee to submit to a mental or physical examination by physicians designated by the department."

CONCLUSIONS OF LAW

1. The Department of Health, by and through the State Surgeon General, has jurisdiction over this matter pursuant to Chapters 456 and 465, Florida Statutes (2012).

2. Ms. Jackson's diversion of 30 to 40 tablets of Oxycodone over the last year and her admitted addiction to Oxycodone gives cause to believe that Ms. Jackson is impaired. Therefore, the State Surgeon General, through his

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undersigned designee, concludes that probable cause exists to believe Ms. Jackson is unable to practice as a registered pharmacy technician with reasonable skill and safety, pursuant to Sections 456.072(1)(z) and 465.016(1)(m), Florida Statutes (2012). A thorough and complete mental and physical examination of Ms. Jackson is necessary to protect the public and ensure that she is able to practice as a registered pharmacy technician with reasonable skill and safety.

3. In accordance with the authority vested in the Department of Health under Chapters 456 and 465, Florida Statutes, the State Surgeon General, through his undersigned designee, concludes that 456.072(1)(z), Florida Statutes (2012), should be enforced.

DONE and ORDERED by the Department of Health on this 9th day of May, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Daniel Hernandez
Deputy General Counsel
Prosecution Services Unit

COUNSEL FOR DEPARTMENT:
Casie Barnette, Esq.
Florida Bar No. 100159
Assistant General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(P) 850-245-4444, extension 8102
(F) 850-245-4662
(E) casie_barnette@doh.state.fl.us

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

DOH
Petitioner

vs

Case No.RPT 2013-07018

BEVERLY L. JACKSON, R.PT
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:
1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on (date) 06/05/13, Affiant made a diligent effort to locate Respondent, to serve _____ Administrative Complaint and related papers; X Order compelling examination(s); Subpoena(s); _____ Final order; _____ Notice to cease and desist; _____ ESO/ERO and related papers.

3) Check applicable answer below:

X Affiant made personal service on Respondent, ~~or on some person~~ at Respondent's usual place of abode over the age of 15 residing there, on (date) 06/05/13.

_____ Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

Affiant

State Of Florida
County Of Duval

Before me, personally appeared Ryan F. Heal whose identity is known to me by Personal Knowledge (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 5th day of June 2013.

William J. Pittman
Notary Public-State of Florida

My Commission Expires

William J. Pittman
Type or Print Name

WILLIAM J. PITTMAN
Commission # DD 915762
Expires August 28, 2013
Bonded Thru Troy Fain Insurance 800-385-7019

INV FORM 321

EXHIBIT # S-2 PAGE # 9

Final Order No. DOH-13-1331-ESO-MQA
FILED DATE - JUL 23 2013
Department of Health
By: Angel Sanders
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the Registration of
Beverly Lynn Jackson, RPT
Registration No.: RPT 38762
Case Number: 2013-07018

ORDER OF EMERGENCY SUSPENSION OF REGISTRATION

John H. Armstrong, MD, FACS, State Surgeon General and Secretary of Health, ORDERS the emergency suspension of the registration of Beverly Lynn Jackson ("Ms. Jackson"), to practice as a pharmacy technician in the State of Florida. Ms. Jackson holds registration number RPT 38762. Her address of record is 115 Lawrence Boulevard, Keystone Heights, Florida 32656. The following Findings of Fact and Conclusions of Law support the emergency suspension of Ms. Jackson's registration to practice as a pharmacy technician in the State of Florida.

FINDINGS OF FACT

1. The Department of Health ("Department") is the state agency charged with regulating registered pharmacy technicians pursuant to Chapters 20, 456 and 465, Florida Statutes (2012). Section 456.073(8), Florida Statutes (2012), authorizes the State Surgeon General to summarily suspend Ms. Jackson's registration to practice as a pharmacy technician in

the State of Florida, in accordance with Section 120.60(6), Florida Statutes (2012).

2. At all times material to this order, Ms. Jackson was a registered pharmacy technician in the State of Florida, pursuant to Chapter 465, Florida Statutes (2012), and she was employed by Walgreens Pharmacy ("Walgreens") located at 115 N. Lawrence Boulevard, Keystone Heights, Florida 32656.

3. Between 2012 and 2013, Ms. Jackson diverted 30 to 40 units of controlled substances from Walgreens, including oxycodone pills.

4. Oxycodone is commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012), oxycodone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of oxycodone may lead to severe psychological or physical dependence.

5. On or about April 18, 2013, H.G., the Walgreens Loss Prevention Manager, contacted Clay County Sheriff's Office and reported Ms. Jackson's theft of oxycodone pills from Walgreens.

5

6. H.G. reported to Officer B.S. that on or about April 9, 2013, H.G. reviewed Walgreens video surveillance records showing Ms. Jackson counting out dosage units of oxycodone 5mg and then placing her left hand into her pocket.

7. H.G. stated to Officer B.S. that H.G. obtained additional video surveillance on April 15, 2013, showing Ms. Jackson pocketing two pills of oxycodone 5mg. H.G. further reported that video surveillance on April 16, 2013, showed Ms. Jackson pocketing two pills of oxycodone 10mg.

8. On or about April 24, 2013, Officer B.S. interviewed Ms. Jackson at Walgreens. Ms. Jackson admitted to Officer B.S. that she stole 30 to 40 units of oxycodone 5mg, 10mg, 20mg, and 30mg from Walgreens during the past year of her employment. Ms. Jackson signed a sworn statement regarding her involvement in the thefts.

9. Ms. Jackson further stated to Officer B.S. that she stole oxycodone pills by counting out extra pills when she filled prescriptions for Walgreens customers and placing the extra pills in her pocket.

10. Ms. Jackson stated to Officer B.S. that she has been addicted to oxycodone for the past year and that she diverted oxycodone tablets from Walgreens for her personal use.

11. On or about April 24, 2013, Officer B.S. arrested Ms. Jackson and charged her with grand theft of a controlled substance.

12. On or about May 9, 2013, the Department issued an Order to Compel Examination ("Order") against Ms. Jackson requiring that she submit to a mental and physical examination at the University of Florida, Florida Recovery Center located in Gainesville, Florida.

13. On or about June 24, 2013, Dr. S.T. evaluated Ms. Jackson pursuant to the Order. During Dr. S.T.'s evaluation, Ms. Jackson submitted to urine, hair, and blood drug screens. The urine drug screen returned positive for cocaine and oxycodone/oxymorphone.

14. According to Section 893.03(2), Florida Statutes (2012), cocaine is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of cocaine may lead to severe psychological or physical dependence.

15. Oxymorphone is prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012), oxymorphone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted

7

but severely restricted medical use in treatment in the United States. Abuse of oxymorphone may lead to severe psychological or physical dependence.

16. During Dr. S.T.'s evaluation, Ms. Jackson admitted to abusing cocaine, benzodiazepines, opiates, and cannabis. Ms. Jackson stated that cocaine and opiates were her drugs of choice. Further, Ms. Jackson stated that she used crack cocaine[1] three days prior to Dr. S.T's evaluation. Dr. S.T. diagnosed Ms. Jackson with active opioid and cocaine dependence, cannabis dependence in partial remission, and benzodiazepine abuse.

17. Benzodiazepines are a class of drugs that cause sedation and can be habit forming. Most benzodiazepines are Schedule IV controlled substances according to Section 893.03, Florida Statutes (2012) and are typically prescribed to treat anxiety or insomnia.

18. Opiate, or opioid, drugs have similar actions as the drug opium and are typically prescribed to treat pain. While opioid drugs are synthetically manufactured and opiate drugs are naturally occurring, the terms "opioid" and "opiate" are often used interchangeably. Opioid drugs are addictive and subject to abuse.

---

[1] Crack cocaine is a form of cocaine that has been processed to make rock crystal and is ingested by smoking.

8

19. According to Section 893.03(1), Florida Statutes (2012), cannabis is a Schedule I controlled substance that has a high potential for abuse and has no currently accepted medical use in treatment in Florida. Its use under medical supervision does not meet accepted safety standards.

20. As a result of his evaluation, Dr. S.T. determined that Ms. Jackson was unable to practice as a registered pharmacy technician with reasonable skill and safety due to her addiction to opioids and cocaine. Further, Dr. S.T. opined that Ms. Jackson requires monitoring and inpatient treatment for cocaine and opioid dependence before returning to practice as a registered pharmacy technician. As of the date of this order, Ms. Jackson has not entered into monitoring or treatment.

21. In the course of their practice, registered pharmacy technicians have access to medications, including controlled substances, which have a high likelihood for abuse and harm. Registered pharmacy technicians must dispense such drugs in a manner that is safe and effective for the patient. Even medications that generally are not considered dangerous may kill or severely harm a patient if that patient is allergic to an ingredient or is taking another medication that may interact adversely with the prescribed medication.

9

22. Because Ms. Jackson is impaired by the use of illegal or controlled substances and, consequently, may not be capable of filling prescriptions for others in a manner that is correct and safe, Ms. Jackson's continued practice as a registered pharmacy technician presents an immediate serious danger to the health, welfare, and safety of the public. Furthermore, Ms. Jackson admitted to stealing controlled substances from her employer. Because Ms. Jackson's abuse of controlled substances, including but not limited to cocaine, opiates, benzodiazepines and cannabis, adversely affects her judgment and ability to practice as a registered pharmacy technician in any manner, it is impossible to craft a restriction that would adequately protect the public from the danger posed by Ms. Jackson's practice of pharmacy. Therefore, complete suspension of her registration is necessary.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General concludes as follows:

1. The State Surgeon General has jurisdiction over this matter pursuant to Sections 20.43 and 456.073(8), Florida Statutes (2012), and Chapter 465, Florida Statutes (2012), as set forth above.

2. Section 465.016(1)(m), Florida Statutes (2012), allows the Board of Pharmacy to impose discipline against a licensee, including suspension, for being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition.

3. Ms. Jackson violated Section 465.016(1)(m), Florida Statutes (2012), by being unable to practice pharmacy with reasonable skill and safety to patients due to her drug addiction and abuse of controlled substances including, but not limited to, cocaine, opiates, benzodiazepines, and cannabis.

4. Section 120.60(6), Florida Statutes (2012), authorizes the State Surgeon General to summarily suspend a pharmacy technician's registration upon a finding that the registered pharmacy technician presents an immediate, serious danger to the public health, safety or welfare.

5. Ms. Jackson's continued practice as a registered pharmacy technician constitutes an immediate, serious danger to the health, safety, or welfare of the citizens of the State of Florida, and this summary procedure is fair under the circumstances to adequately protect the public.

11

WHEREFORE, in accordance with Section 120.60(6), Florida Statutes (2012), it is **ORDERED THAT:**

1. The registration of Ms. Jackson to practice as a pharmacy technician, registration number RPT 38762, is immediately suspended.

2. A proceeding seeking formal discipline of the registration of Ms. Jackson to practice as a pharmacy technician will be promptly instituted and acted upon in compliance with Sections 120.569 and 120.60(6), Florida Statutes (2012).

DONE and ORDERED this 23rd day of July, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

PREPARED BY:
Casie Barnette
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar Number 100159
(P) 850/245-4444, ext 8102
(F) 850/245-4662
(E) casie_barnette@doh.state.fl.us

12

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Sections 120.60(6), and 120.68, Florida Statutes, the Department's findings of immediate danger, necessity, and procedural fairness shall be judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, and accompanied by a filing fee prescribed by law with the District Court of Appeal, and providing a copy of that Petition to the Department of Health within thirty (30) days of the date this Order is filed.

CERTIFIED MAIL

Florida Department of Health
Office of the General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-1701
PHONE: 850/245-4444

7011 1570 0000 0080 3218

UNITED STATES POSTAGE PITNEY BOWES
02 1A $ 06.97⁰
C004371978 JUL 24 2013
MAILED FROM ZIP CODE 32301

UNCLAIMED

7/31/13
JM
8/8

Beverly Lynn Jackson
115 Lawrence, Blvd.
Keystone Hieghts, FL 32656

PRACTITIONER REGULATION
LEGAL
2013 AUG 29 PM 1:22

7011 1570 0000 0080 3218

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Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$

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13-07018

Sent To: Beverly Lynn Jackson, R.P.T.
Street, Apt. No.; or PO Box No.: 115 Lawrence Blvd.
City, State, ZIP+4: Keystone Heights, FL 324

PS Form 3800, August 2006 — See Reverse for Instructions

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

DOH
Petitioner

vs

Case No. RPT 2013-07018

BEVERLY LYNN JACKSON
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:
1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on (date) 07/24/13, Affiant made a diligent effort to locate Respondent, to serve _____ Administrative Complaint and related papers; ___ Order compelling examination(s); Subpoena(s); _____ Final order; _____ Notice to cease and desist; X ESO/ERO and related papers.

3) Check applicable answer below:

X Affiant made personal service on Respondent, or on some person at Respondent's usual place of abode over the age of 15 residing there, on (date) 07/24/13.

_____ Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

Affiant

State Of Florida
County Of Duval

Before me, personally appeared Ryan F. Heal whose identity is known to me by Personal Knowledge (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 25th day of July 2013.

William J. Pittman
Notary Public-State of Florida

8-28-13
My Commission Expires

William J. Pittman
Type or Print Name

WILLIAM J. PITTMAN
Commission # DD 915762
Expires August 28, 2013
Bonded Thru Troy Fain Insurance 800-385-7019

INV FORM 321

EXHIBIT # 5-2 PAGE # 14

Christopher, Tamia L

From: Christopher, Tamia L
Sent: Tuesday, July 23, 2013 2:57 PM
To: zzzz Feedback, MQA_PSU_Operations
Cc: Pope, Berita
Subject: FAW # 13288920

Attachments: FAR Suspension Memorandum_Beverly Lynn Jackson, RPT.doc

Please find attached for your review and records is the FAW memorandum regarding:
DOH Case: Beverly Lynn Jackson, R.P.T.
DOH Case No. : 2013-07018

FAR Suspension
lemorandum_Beve

Thank you.

Tamia L. Christopher, Regulatory Specialist I
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265
(850) 245-4640 ext. 8200

How am I communicating? Please contact my supervisor.
Please note: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.
However, if this e-mail concerns anticipated or current litigation or adversarial administrative proceedings to which the Florida Department of Health is a party, this e-mail is an attorney-client communication, and is, therefore, a limited access public document exempt from the provisions of Chapter 119, Florida Statute.

See Section 119.071(d)1., Florida Statute (2010).

DOH Mission: To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.
Vision: Healthiest State in the Nation
Values: (ICARE)
Innovation: We search for creative solutions and manage resources wisely.
Collaboration: We use teamwork to achieve common goals & solve problems.
Accountability: We perform with integrity & respect.
Responsiveness: We achieve our mission by serving our customers & engaging our partners.
Excellence: We promote quality outcomes through learning & continuous performance improvement.
There have been changes to the license renewal process. Please visit www.CEAtRenewal.com to

MEMORANDUM

TO: Florida Administrative Registry

FROM: Tamia Christopher, Regulatory Specialist I

RE: Beverly Lynn Jackson, R.P.T., Registration # RPT 38762 (FAW # **13288920**)

CASE NO: 2013-07018

DATE: July 23, 2013

Attached please find notice of the issuance of an **Emergency Suspension** Order for notice in the next issue of the Florida Administrative Register.

On July 23, 2013, the State Surgeon General issued an Order of Emergency Suspension Order with regard to the license of Beverly Lynn Jackson, R.P.T., Registration # RPT 38762. This Emergency Suspension Order was predicated upon the State Surgeon General's findings of an immediate and serious danger to the public health, safety and welfare pursuant to Sections 456.073(8) and 120.60(6) Florida Statutes (2011). The State Surgeon General determined that this summary procedure was fair under the circumstances, in that there was no other method available to adequately protect the public.

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

HBH
7-23-13

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

PSU REQUEST FORM

FROM: Tamia Christopher For Casie Barnette, Esq.	TO: Charles C. Coats, III, Investigative Supervisor ISU Jacksonville
Date: 7/23/13	TO: CSU
Phone #: 850/245/4444 Ext. 8200	CC:

Case Number: 2013-07018 Board: Pharmacy
Subject: Beverly Lynn Jackson HL Code: HLL105B Status: 90
Requested Completion Date: A.S.A.P.

(PSU) TYPE OF REQUEST: (describe details below)

RECEIVED-LEGAL
13 JUL 23 AM 6:01

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: **For Hand Service of ESO**
Last Known Address: 115 Lawrence Blvd., Keystone Heights, Florida 32656
Last Known Name & Phone Number: Beverly Lynn Jackson (B) (352) 473-4621
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES ☐** No ☐ NOTE: All process service requests need to be sent to appropriate field office.

****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☑ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Email to: Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

RECEIVED-LEGAL
13 JUL 29 AM 8:01

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Jacksonville	Date of Complaint: 05/02/13	Case Number: RPT 2013-07018

Subject: **BEVERLY LYNN JACKSON, RPT** 115 Lawrence Blvd. Keystone Heights, FL 32656 (B) (352) 473-4621	Source: **DOH / JACKSONVILLE ISU**

Prefix:	License #:	Profession:	Board:	Report Date:
RPT	38762	Registered Pharmacy Technician	Pharmacy	07/25/13

Period of Investigation: 07/23/13—07/25/13	Type of Report: SUPPLEMENTAL

Alleged Violation: SEE FINAL REPORT

Synopsis:

This supplemental report is predicated upon the receipt of a request from PSU for this office to hand serve the attached Emergency Suspension Order and attachments to JACKSON, (Exhibit S-1).

On 07/24/13, this Investigator presented to JACKSON's mother's place of residence at 7473 Caribbean Circle, Keystone Heights, FL 32656, and hand served the Order to JACKSON's father. The father stated he would have JACKSON contact this Investigator via telephone to confirm receipt. On the same date, this Investigator did receive a voicemail from JACKSON stating she had received the ESO, (Exhibit S-2).

Attachments:

S-1. Supplemental request and attachments.....2-13
S-2. Affidavit of Service.....14

RECEIVED-LEGAL
13 JUL 29 AM 8:01

Related Complaint: None

Investigator/Date:	Approved By/Date: 07/25/13
Ryan F. Heal MQA Investigator (JI-81) 07/25/13	Charles C. Coats, III District Manager (JI-15)

Received
Investigative Services
JUL 26 2013
DOH/MQA
Tallahassee HQ

Distribution: HQ/ISU

INV Form 300 7/02

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

HEAL 7-23-13

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

PSU REQUEST FORM

FROM: Tamia Christopher For Casie Barnette, Esq.	TO: Charles C. Coats, III, Investigative Supervisor ISU Jacksonville
Date: 7/23/13	TO: CSU
Phone #: 850/245/4444 Ext. 8200	CC:

Case Number: 2013-07018 Board: Pharmacy
Subject: Beverly Lynn Jackson HL Code: HLL105B Status: 90
Requested Completion Date: A.S.A.P.

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: **For Hand Service of ESO**
Last Known Address: 115 Lawrence Blvd., Keystone Heights, Florida 32656
Last Known Name & Phone Number: Beverly Lynn Jackson (B) (352) 473-4621
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES ☐ ** No ☐ NOTE: All process service requests need to be sent to appropriate field office.

****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Florida Department of Health
Division of Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-
PHONE: 850-245-4444 • FAX 850-245-4662

EXHIBIT #5-1 PAGE # 2

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Email to: Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

July 23, 2013

7011 1570 0000 0080 3218

Beverly Lynn Jackson, R.P.T.
115 Lawrence Blvd
Keystone Hieghts, FL 32656

RE: Department of Health vs. Beverly Lynn Jackson, R.P.T.
Case Number: 2013-07018

Dear Beverly Lynn Jackson:

Enclosed please find an Order of Emergency **Suspension** of Registration filed July 23, 2013, against your registration to practice as a registered pharmacy technician in the State of Florida. You should immediately cease the practice as a registered pharmacy technician according to the enclosed Order of Emergency **Suspension** of Registration.

If you have any questions, please do not hesitate to contact Casie Barnette, Assistant General Counsel at (850) 245-4444.

Sincerely,

Tamia Christopher
Regulatory Specialist I
Prosecution Services Unit

/tc
Enclosure

Final Order No. DOH-13-1331-ESO-MQA
FILED DATE: JUL 23 2013
Department of Health
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the Registration of
Beverly Lynn Jackson, RPT
Registration No.: RPT 38762
Case Number: 2013-07018

ORDER OF EMERGENCY SUSPENSION OF REGISTRATION

John H. Armstrong, MD, FACS, State Surgeon General and Secretary of Health, ORDERS the emergency suspension of the registration of Beverly Lynn Jackson ("Ms. Jackson"), to practice as a pharmacy technician in the State of Florida. Ms. Jackson holds registration number RPT 38762. Her address of record is 115 Lawrence Boulevard, Keystone Heights, Florida 32656. The following Findings of Fact and Conclusions of Law support the emergency suspension of Ms. Jackson's registration to practice as a pharmacy technician in the State of Florida.

FINDINGS OF FACT

1. The Department of Health ("Department") is the state agency charged with regulating registered pharmacy technicians pursuant to Chapters 20, 456 and 465, Florida Statutes (2012). Section 456.073(8), Florida Statutes (2012), authorizes the State Surgeon General to summarily suspend Ms. Jackson's registration to practice as a pharmacy technician in

the State of Florida, in accordance with Section 120.60(6), Florida Statutes (2012).

2. At all times material to this order, Ms. Jackson was a registered pharmacy technician in the State of Florida, pursuant to Chapter 465, Florida Statutes (2012), and she was employed by Walgreens Pharmacy ("Walgreens") located at 115 N. Lawrence Boulevard, Keystone Heights, Florida 32656.

3. Between 2012 and 2013, Ms. Jackson diverted 30 to 40 units of controlled substances from Walgreens, including oxycodone pills.

4. Oxycodone is commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012), oxycodone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of oxycodone may lead to severe psychological or physical dependence.

5. On or about April 18, 2013, H.G., the Walgreens Loss Prevention Manager, contacted Clay County Sheriff's Office and reported Ms. Jackson's theft of oxycodone pills from Walgreens.

6. H.G. reported to Officer B.S. that on or about April 9, 2013, H.G. reviewed Walgreens video surveillance records showing Ms. Jackson counting out dosage units of oxycodone 5mg and then placing her left hand into her pocket.

7. H.G. stated to Officer B.S. that H.G. obtained additional video surveillance on April 15, 2013, showing Ms. Jackson pocketing two pills of oxycodone 5mg. H.G. further reported that video surveillance on April 16, 2013, showed Ms. Jackson pocketing two pills of oxycodone 10mg.

8. On or about April 24, 2013, Officer B.S. interviewed Ms. Jackson at Walgreens. Ms. Jackson admitted to Officer B.S. that she stole 30 to 40 units of oxycodone 5mg, 10mg, 20mg, and 30mg from Walgreens during the past year of her employment. Ms. Jackson signed a sworn statement regarding her involvement in the thefts.

9. Ms. Jackson further stated to Officer B.S. that she stole oxycodone pills by counting out extra pills when she filled prescriptions for Walgreens customers and placing the extra pills in her pocket.

10. Ms. Jackson stated to Officer B.S. that she has been addicted to oxycodone for the past year and that she diverted oxycodone tablets from Walgreens for her personal use.

11. On or about April 24, 2013, Officer B.S. arrested Ms. Jackson and charged her with grand theft of a controlled substance.

12. On or about May 9, 2013, the Department issued an Order to Compel Examination ("Order") against Ms. Jackson requiring that she submit to a mental and physical examination at the University of Florida, Florida Recovery Center located in Gainesville, Florida.

13. On or about June 24, 2013, Dr. S.T. evaluated Ms. Jackson pursuant to the Order. During Dr. S.T.'s evaluation, Ms. Jackson submitted to urine, hair, and blood drug screens. The urine drug screen returned positive for cocaine and oxycodone/oxymorphone.

14. According to Section 893.03(2), Florida Statutes (2012), cocaine is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of cocaine may lead to severe psychological or physical dependence.

15. Oxymorphone is prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012), oxymorphone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted

but severely restricted medical use in treatment in the United States. Abuse of oxymorphone may lead to severe psychological or physical dependence.

16. During Dr. S.T.'s evaluation, Ms. Jackson admitted to abusing cocaine, benzodiazepines, opiates, and cannabis. Ms. Jackson stated that cocaine and opiates were her drugs of choice. Further, Ms. Jackson stated that she used crack cocaine[1] three days prior to Dr. S.T's evaluation. Dr. S.T. diagnosed Ms. Jackson with active opioid and cocaine dependence, cannabis dependence in partial remission, and benzodiazepine abuse.

17. Benzodiazepines are a class of drugs that cause sedation and can be habit forming. Most benzodiazepines are Schedule IV controlled substances according to Section 893.03, Florida Statutes (2012) and are typically prescribed to treat anxiety or insomnia.

18. Opiate, or opioid, drugs have similar actions as the drug opium and are typically prescribed to treat pain. While opioid drugs are synthetically manufactured and opiate drugs are naturally occurring, the terms "opioid" and "opiate" are often used interchangeably. Opioid drugs are addictive and subject to abuse.

---

[1] Crack cocaine is a form of cocaine that has been processed to make rock crystal and is ingested by smoking.

19. According to Section 893.03(1), Florida Statutes (2012), cannabis is a Schedule I controlled substance that has a high potential for abuse and has no currently accepted medical use in treatment in Florida. Its use under medical supervision does not meet accepted safety standards.

20. As a result of his evaluation, Dr. S.T. determined that Ms. Jackson was unable to practice as a registered pharmacy technician with reasonable skill and safety due to her addiction to opioids and cocaine. Further, Dr. S.T. opined that Ms. Jackson requires monitoring and inpatient treatment for cocaine and opioid dependence before returning to practice as a registered pharmacy technician. As of the date of this order, Ms. Jackson has not entered into monitoring or treatment.

21. In the course of their practice, registered pharmacy technicians have access to medications, including controlled substances, which have a high likelihood for abuse and harm. Registered pharmacy technicians must dispense such drugs in a manner that is safe and effective for the patient. Even medications that generally are not considered dangerous may kill or severely harm a patient if that patient is allergic to an ingredient or is taking another medication that may interact adversely with the prescribed medication.

22. Because Ms. Jackson is impaired by the use of illegal or controlled substances and, consequently, may not be capable of filling prescriptions for others in a manner that is correct and safe, Ms. Jackson's continued practice as a registered pharmacy technician presents an immediate serious danger to the health, welfare, and safety of the public. Furthermore, Ms. Jackson admitted to stealing controlled substances from her employer. Because Ms. Jackson's abuse of controlled substances, including but not limited to cocaine, opiates, benzodiazepines and cannabis, adversely affects her judgment and ability to practice as a registered pharmacy technician in any manner, it is impossible to craft a restriction that would adequately protect the public from the danger posed by Ms. Jackson's practice of pharmacy. Therefore, complete suspension of her registration is necessary.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General concludes as follows:

1. The State Surgeon General has jurisdiction over this matter pursuant to Sections 20.43 and 456.073(8), Florida Statutes (2012), and Chapter 465, Florida Statutes (2012), as set forth above.

2. Section 465.016(1)(m), Florida Statutes (2012), allows the Board of Pharmacy to impose discipline against a licensee, including suspension, for being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition.

3. Ms. Jackson violated Section 465.016(1)(m), Florida Statutes (2012), by being unable to practice pharmacy with reasonable skill and safety to patients due to her drug addiction and abuse of controlled substances including, but not limited to, cocaine, opiates, benzodiazepines, and cannabis.

4. Section 120.60(6), Florida Statutes (2012), authorizes the State Surgeon General to summarily suspend a pharmacy technician's registration upon a finding that the registered pharmacy technician presents an immediate, serious danger to the public health, safety or welfare.

5. Ms. Jackson's continued practice as a registered pharmacy technician constitutes an immediate, serious danger to the health, safety, or welfare of the citizens of the State of Florida, and this summary procedure is fair under the circumstances to adequately protect the public.

WHEREFORE, in accordance with Section 120.60(6), Florida Statutes (2012), it is **ORDERED THAT**:

1. The registration of Ms. Jackson to practice as a pharmacy technician, registration number RPT 38762, is immediately suspended.

2. A proceeding seeking formal discipline of the registration of Ms. Jackson to practice as a pharmacy technician will be promptly instituted and acted upon in compliance with Sections 120.569 and 120.60(6), Florida Statutes (2012).

DONE and ORDERED this 23rd day of July, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

PREPARED BY:
Casie Barnette
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar Number 100159
(P) 850/245-4444, ext 8102
(F) 850/245-4662
(E) casie_barnette@doh.state.fl.us

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Sections 120.60(6), and 120.68, Florida Statutes, the Department's findings of immediate danger, necessity, and procedural fairness shall be judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, and accompanied by a filing fee prescribed by law with the District Court of Appeal, and providing a copy of that Petition to the Department of Health within thirty (30) days of the date this Order is filed.

** Transmit Conf. Report **

P.1 Jul 23 2013 02:46pm

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Mission: To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Vision: To be the Healthiest State in the Nation

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

July 23, 2013

The Honorable Robert S. Cohen
Chief Administrative Law Judge
Division of Administrative Hearings
1230 Apalachee Parkway
Tallahassee, FL 32301

RE: Department of Health vs. Beverly Lynn Jackson, R.P.T.
Case Number: 2013-07018

Dear Judge Cohen:

This letter is to advise you that the Department has issued an Emergency Suspension Order concerning the registration of **Beverly Lynn Jackson** to practice as a registered pharmacy technician in the State of Florida. An Administrative Complaint has not been issued in the above case. Therefore, this is not a request for a formal hearing.

This letter is sent to advise you of the action taken by the Department and to advise you of the possibility that the respondent may request an expedited hearing. The Department shall keep you advised of any developments. If you need additional information, please contact Casie Barnette, Assistant General Counsel at (850) 245-4444.

Sincerely,

Tamia Christopher
Regulatory Specialist I
Prosecution Services Unit

/tc

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row • Suite 105
PHONE: 850/245-4444 • FAX 850/245-4662

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fdoh

July 23, 2013

The Honorable Robert S. Cohen
Chief Administrative Law Judge
Division of Administrative Hearings
1230 Apalachee Parkway
Tallahassee, FL 32301

RE: Department of Health vs. Beverly Lynn Jackson, R.P.T.
Case Number: 2013-07018

Dear Judge Cohen:

This letter is to advise you that the Department has issued an Emergency Suspension Order concerning the registration of **Beverly Lynn Jackson** to practice as a registered pharmacy technician in the State of Florida. An Administrative Complaint has not been issued in the above case. Therefore, this is not a request for a formal hearing.

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Sincerely,

Tamia Christopher
Regulatory Specialist I
Prosecution Services Unit

/tc

Christopher, Tamia L

From: Christopher, Tamia L
Sent: Tuesday, July 23, 2013 2:05 PM
To: DL MQA Inv Serv Priority Mail Area4 (JI) Jacksonville
Cc: Pope, Berita
Subject: Request For Hand Serve ESO/Jackson 2013-07018

Attachments: Supplemental Request Form_Beverly Lynn Jackson.doc; DOH 13-1331 ESO 201307018-1 _Beverly Lynn Jackson, RPT.pdf

Correction:

Please hand serve the attached ESO on the Respondent. Thank you.

Supplemental equest Form_BeveO DOH 13-1331 201307018-1_B

Tamia L. Christopher, Regulatory Specialist I
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265
(850) 245-4640 ext. 8200

How am I communicating? Please contact my supervisor.
Please note: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.
However, if this e-mail concerns anticipated or current litigation or adversarial administrative proceedings to which the Florida Department of Health is a party, this e-mail is an attorney-client communication, and is, therefore, a limited access public document exempt from the provisions of Chapter 119, Florida Statute.

See Section 119.071(d)1., Florida Statute (2010).

DOH Mission: To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.
Vision: Healthiest State in the Nation
Values: (ICARE)
Innovation: We search for creative solutions and manage resources wisely.
Collaboration: We use teamwork to achieve common goals & solve problems.
Accountability: We perform with integrity & respect.
Responsiveness: We achieve our mission by serving our customers & engaging our partners.
Excellence: We promote quality outcomes through learning & continuous performance improvement.
There have been changes to the license renewal process. Please visit www.CEAtRenewal.com to learn more.

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

PSU REQUEST FORM

FROM: Tamia Christopher For Casie Barnette, Esq.	TO: Charles C. Coats, III, Investigative Supervisor ISU Jacksonville
Date: 7/23/13	TO: CSU
Phone #: 850/245/4444 Ext. 8200	CC:

Case Number: 2013-07018 Board: Pharmacy
Subject: Beverly Lynn Jackson HL Code: HLL105B Status: 90
Requested Completion Date: A.S.A.P.

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: **For Hand Service of ESO**
Last Known Address: 115 Lawrence Blvd., Keystone Heights, Florida 32656
Last Known Name & Phone Number: Beverly Lynn Jackson (B) (352) 473-4621
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES ☐** No ☐ NOTE: All process service requests need to be sent to appropriate field office.

****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Florida Department of Health
Division of Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 · Tallahassee, FL 32399-
PHONE: 850-245-4444 · FAX 850-245-4662

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MEMORANDUM OF FINDING OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy
RE: **DOH v. Beverly L. Jackson, RPT**
DOH Case Number 2013-07018

MEMBERS: Cynthia R. Griffin, PharmD & Jeffrey J. Mesaros, R.Ph

DATE OF PCP: **August 08, 2013** **AGENDA ITEM: A-2 (CB)**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative report, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1)(m), Florida Statutes (2012)

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **Other** _____

Cynthia R. Griffin, PharmD 8/8/13
Chair, Probable Cause Panel Date
Board of Pharmacy

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Jacksonville	Date of Complaint: 05/02/13	Case Number: RPT 2013-07018

Subject: **BEVERLY LYNN JACKSON, RPT** 115 Lawrence Blvd. Keystone Heights, FL 32656 (B) (352) 473-4621	Source: **DOH / JACKSONVILLE ISU**

Prefix:	License #:	Profession:	Board:	Report Date:
RPT	38762	Registered Pharmacy Technician	Pharmacy	05/15/13

Period of Investigation: 05/03/13—05/15/13	Type of Report: FINAL

Alleged Violation: F.S. 465.016 "Disciplinary actions.— (1) The following acts... (d) Being unfit or incompetent to practice... 2 The misuse or abuse... 3 Any abnormal physical or mental condition... (e) Violating... (i) Compounding, dispensing, or distributing a legend drug, including any controlled substance... (m) Being unable to practice pharmacy with reasonable skill and safety... (r) Violating..." F.S. 456.072 "Grounds for discipline; penalties; enforcement.— (1) The following acts... (a) Making misleading, deceptive, or fraudulent representations... (m) Making deceptive, untrue, or fraudulent representations... (z) Being unable to practice with reasonable skill and safety..."

Synopsis:
This investigation is predicated upon receipt of a complaint submitted by the DOH / JACKSONVILLE ISU in regard to BEVERLY LYNN JACKSON, RPT alleging that on 04/24/13, Jackson was arrested for a felony. JACKSON was involved in diversion and may be impaired, (Exhibit # 1).

JACKSON was notified of the investigation by letter dated 05/03/13 and was provided with a copy of the Department of Health's Uniform Case Summary and a copy of the originating documents submitted by the DOH, (Exhibit # 2).

A check of DOH computer records revealed JACKSON is currently registered as a registered pharmacy technician.

No patient(s) was/were identified, thus patient notification was not required.

JACKSON is not known to be represented by an Attorney in this matter.

On 05/03/13, Investigator TODD MCCORMICK, of this office, hand served the notification letter to JACKSON at her mother's mobile home , located at 4773 Caribbean Circle, Keystone Heights, FL 32656. Voicemail messages were left for JACKSON at her mobile number, (904) 263-7667, on 05/08/13, 05/13/13 and 05/15/13. As of this writing, no further contact has been made with JACKSON.

Related Complaint: None

Investigator/Date:	Approved By/Date:
Ryan F. Heal Medical Malpractice Investigator (JI-81) 05/15/13	Charles C. Coats, III District Manager (JI-15) 5-15-13

Distribution: HQ/ISU

INV Form 300 7/02

Received
Investigative Services
MAY 17 2013
DOH/MQA
Tallahassee HQ
CONFIDENTIAL
13 MAY 20 PM 8:02
RECEIVED-LEGAL

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*** EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES.**

**** THESE RECORDS ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES, AND COPIES ARE NOT MAINTAINED IN THE JACKSONVILLE INVESTIGATIVE SERVICES OFFICE.**

INVESTIGATIVE DETAILS

Summary of Records

Exhibit 1 is the Case Summary and attachments. The attachments include the following:

- The Healthcare Practitioner Complaint Form.
- Clay County Sheriff's Office Incident / Investigation Report, dated 04/24/13, essentially noting the following:
  - The incident took place at Walgreen's Pharmacy in Keystone Heights, FL.
  - The incident was reported to the detective, BA SIMMONS, by HALEY GLISSON, the loss prevention manager for Walgreens.
  - GLISSON stated that in the past several months, Oxycodone 5mg, 10mg, 15mg, 20mg and 30mg pills have gone missing from the pharmacy.
  - GLISSON had placed video surveillance to see who was responsible for the pills being stolen, and also had the pharmacy managers doing counts of the Oxycodone on several occasions to identify which pharmacy employee could be responsible for the stolen pills.
  - GLISSON observed video of JACKSON counting prescriptions for customers and then place her left hand into her pocket with something on 04/19/13.
  - GLISSON observed video on 04/15/13 of two pills of Oxycodone 5mg and on 04/16/13 of two pills of Oxycodone 10mg being taken by JACKSON.
  - The detective contacted JACKSON at her home address on 04/24/13, and the subsequent interview was recorded.
  - JACKSON was read her Constitutional rights, said she understood, and agreed to speak about her involvement.
  - JACKSON stated she had been employed at the pharmacy for two years, and for the last year, she had stolen about 30-40 pills of Oxycodone 5mg, 10mg, 15mg, 20mg and 30mg.
  - When a prescription would come into the pharmacy for Oxycodone, she would count out an extra pill or two at a time, and then place them into her pocket.
  - JACKSON stated she used the pills for personal use and had an addiction for the last year from an accident.
  - JACKSON completed a sworn statement and was arrested.
- Office of the Sheriff, Clay County, Florida, Adult Arrest Report, which essentially notes the information noted above. It additionally notes JACKSON committed the unlawful act of Grand Theft of Controlled Substance.
- Clay County Sheriff's Office Sworn Statement written and signed by JACKSON, which states:
  - She has been taking Oxycodone pills from Walgreens for about a year.
  - It was a bad life decision, and she did it for personal use for her own pains.
  - She does not know how many pills she has taken, but estimates around 30-40 pills.
  - "I only took what I could, when I had the opportunity to do so."

Exhibit 4 is the facsimile response from PRN, which notes, "Ms. JACKSON is not known to PRN."

INTERVIEW OF B.A. SIMMONS

Detective
Clay County Sheriff's Office
PO Box 548
Green Cove Springs, FL 32043
(B) (904) 264-6512

On 05/09/13, this Investigator contacted SIMMONS at the number noted above. Simmons stated that he had no further information at this time, that everything he had was in the incident report. SIMMONS did read his copy of the written statement, so this Investigator could verify what was written as it is a poor quality copy.

INTERVIEW OF HALEY HAMPTON GLISSON

Loss Prevention Manager
Walgreens
922 Clay St.
Green Cove Springs, FL 32043
(B) (904) 487-1832

On 05/09/13, this Investigator interviewed GLISSON via telephone at the number noted above. During the interview, GLISSON essentially stated the following:

- She does not have much to add to the investigation that is not in the police report.
- They were having receiving issues at that store, the monthly CII counts were not correct.
- One of the pharmacists starting noticing "he was short a pill here and there."
- She started ordering reports, but they are not definitive, only showing trends.
- She looked at video, and "got lucky."
- The video is not very good, but it does show JACKSON putting something in her pocket while she was counting Oxycodone on a couple of occasions.
- She interviewed JACKSON, who admitted she had been taking oxycodoen of varying strengths since 2011.
- She is doing an audit now to find exact discrepancies to report to the DEA.
- JACKSON obviously does not know how much she has taken, because she admitted to taking more pills than the pharmacy is missing.
- There are no other loss prevention related disciplinary issues with JACKSON, except she did use sick leave in advance of a day off instead of using vacation leave.

GLISSON had nothing further to add to this investigation at that time.

Investigator's Notes:
On 05/03/13, Investigator TODD MCCORMICK, of this office, hand served the notification letter to JACKSON at her mother's mobile home , located at 4773 Caribbean Circle, Keystone Heights, FL 32656.

Voicemail messages were left for JACKSON at her mobile number, (904) 263-7667, on 05/08/13, 05/13/13 and 05/15/13. As of this writing, no further contact has been made with JACKSON.

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Florida HEALTH

Rick Scott
Governor

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John H. Armstrong, MD, FACS
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Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201305718

PATRICK CARPENTER ,
RESPONDENT.

NOTICE

TO: PATRICK CARPENTER
319 MURTLE AVENUE
ST. AUGUSTINE, FL 32086

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida
HEALTH

Mission:
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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201305718

PATRICK CARPENTER ,
RESPONDENT.

NOTICE

TO: PAUL M. GARBARINI, ESQUIRE
P.O. BOX 1551
NORTHAMPTON, MA 01061

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Jodi-Ann V. Johnson, Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. Patrick Carpenter, PSI
DOH Case Number 2013-05817
DATE: November 12, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Patrick Carpenter, PSI
Subject's Address of Record:	319 Murtle Avenue St. Augustine, FL 32086
Enforcement Address:	319 Murtle Avenue St. Augustine, FL 32086
Subject's License No:	13115 **Rank:** PSI
Licensure File No:	152
Initial Licensure Date:	5/15/2000
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Section 465.06(1)(f)(r), F.S.
Prior Discipline:	None
Probable Cause Panel:	N/A
Subject's Attorney:	Paul M. Garbarini, Esquire P.O. Box 1551 Northampton, MA 01061
Complainant/Address:	Department of Health & Human Services
Materials Submitted:	Memorandum to the Board Motion for Voluntary Relinquishment of License Filed Voluntary Relinquishment Board Notification Letter Final Investigative Report Exhibit 1 - 3

Disciplinary Guidelines

Section 456.016(1)(f)
Min: one year suspension, two years probation, and $5,000 fine.
Max: Revocation.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-05817**

PATRICK CARPENTER, PSI,

Respondent.
_____ /

MOTION FOR FINAL ORDER BASED UPON
A VOLUNTARY RELINQUISHMENT OF LICENSE

PETITIONER, the Florida Department of Health, by and through the undersigned counsel, hereby moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore Petitioner states:

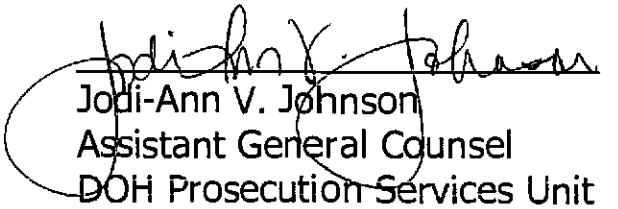
1. On or about **July 1, 2013**, a Complaint was filed with the Department of Health, alleging that Respondent violated provisions of Chapter 465 and/or Chapter 456, Florida Statutes.

2. In lieu of undergoing further disciplinary proceedings, Respondent returned an executed Voluntary Relinquishment of License.

3. Respondent has been advised by way of this Motion, that a copy of the investigative file in this case will be furnished to the Board, establishing a prima facie case regarding the violations as set forth in the Complaint.

WHEREFORE, Petitioner respectfully requests that the Board of enter a Final Order accepting the terms of the Voluntary Relinquishment of License.

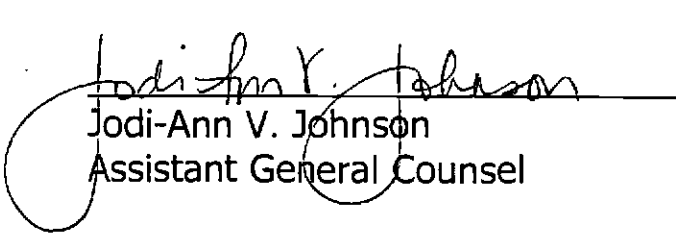
John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health



Jodi-Ann V. Johnson
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar #0073525
(850) 245-4444 telephone
(850) 245-4683 facsimile

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 22nd day of November, 2013, to: Paul M. Garbarini, Esquire, c/o Patrick Carpenter, PSI, P.O. Box 1551, Northampton, MA 01061.



Jodi-Ann V. Johnson
Assistant General Counsel

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE OCT 3 1 2013

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. **CASE NO. 2013-05817**

PATRICK CARPENTER, PSI,

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, Patrick Carpenter, PSI, license number PSI 13115, hereby voluntarily relinquishes his license to practice pharmacy in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for licensure as a pharmacist intern in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy in the state of Florida immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from the practice of pharmacy until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

5. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 17th day of October, 2013.

Patrick Carpenter, PSI
Case No. 2013-05817

STATE OF: MA
COUNTY OF: SUFFOLK

Before me, personally appeared Patrick Carpenter, whose identity is known to me by MASSACHUSETTS DRIVERS LICENSE (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 17 day of OCTOBER, 2013.

NOTARY PUBLIC

My Commission Expires:

RONNIE M. LAMMING
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
December 31, 2015

November 22, 2013

VIA U.S. MAIL

Paul M. Garbarini, Esquire
P.O. Box 1551
Northampton, MA 01061

Re: DOH vs. Patrick Carpenter, PSI
DOH Case Number: 2013-05817

Dear Mr. Garbarini:

We are in receipt of your client's executed Voluntary Relinquishment form. By signing the Voluntary Relinquishment of License form, your client agreed to the following:

- the Voluntary Relinquishment will be considered disciplinary action against your client's license, pursuant to Section 456.072(1)(f), Florida Statutes;
- your client will never reapply for licensure as a Pharmacist Intern in the State of Florida; and
- voluntarily relinquishing your client's Florida Pharmacist Intern license may have an effect on Pharmacist Intern licenses that your client may hold in other states.

If you have any questions or concerns, please contact me as soon as possible to discuss, at 850-245-4444 extension 8113. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up this request for Voluntary Relinquishment of License at their meeting scheduled for February 5, 2014 at the Double Tree by Hilton, 60 South Ivanhoe Boulevard, Orlando, Florida 32804. Your client is not required to attend the meeting.

Sincerely,

Jodi-Ann V. Johnson
Assistant General Counsel

JAVJ/pb

HEALTH

INVESTIGATIVE REPORT

Office: CONSUMER SERVICES	Date of Complaint: July 1, 2013	Case Number: **PSI 2013-05817**

SUBJECT:	SOURCE:
PATRICK CARPENTER, PSI 319 MURTLE AVENUE ST AUGUSTINE, FL 32086 HOME PHONE: (518) 445-7888	**DEPARTMENT OF HEALTH AND HUMAN SERVICES** AMY FLYNN, INVESTIGATION ANALYST OFFICE OF THE INSPECTOR GENERAL 15 NEW SUDBURY STREET, ROOM 2475 BOSTON, MA 02203 HOME PHONE: 617-565-2671

Prefix:	License #:	Profession:	Board:	Report Date:
PSI	13115	Pharmacist Intern	Pharmacy	September 10, 2013

Period of Investigation:	Type of Report:
July 1, 2013 through August 30, 2013	FINAL

Possible violation of S.S. 465.016(1)(f)(r), 456.072(1)(c)(k)(dd), F.S... Having been convicted or found guilty; Violate Statute / Rule of Board; Failure to perform legal obligation; DHHS Medicare Exclusion

Synopsis: This investigation is predicated on the receipt of documentation submitted from **DHHS** which alleged that CARPENTER has been excluded from participation in the Medicare, Medicaid, and all Federal health care programs as a result of the Subject's conviction in the Boston Munipal Court, State of Massachussetts. The action is effective as of March 29, 2013. On May 22, 2013, certified court documents were received from Boston Munipal Court which showed that on Janualry 6, 2010, CARPENTER was arrested by the Boston Police for Drugs - Trafficking in Cocaine. Subject did utter a false prescription and did receive 300 blue pills believed to be Oxycodone within 100 feet of a park. On May 6, 2010, CARPENTER accepted a plea of guilty to Trafficking Class B, Uttering False Instrument, Trafficking in Park Zone (Ex. #1, Case Summary, and attachments).

CARPENTER was notified of this complaint by Regular and Certified USPS letters with two failed attempts. A Regular USPS letter, dated June 1, 2013, and a Certified USPS letter, dated July 1, 2013 to the address of record with the **BOARD OF PHARMACY** were attempted for delivery. Due to a diligent search, a Certified USPS letter was sent to a new address, located at 427 SHAWMUT AVENUE, APARTMENT 5, BOSTON, MA 02118-3828, dated July 1, 2013, which included a copy of the Case Summary, and documents from Boston Munipal Court (Ex. #2).

DOH computer information obtained September 10, 2013, indicates that CARPENTER is licensed to practice as a Pharmacist Intern in the State of Florida. CARPENTER's license is in CLEAR status.

There is no patient involvement; therefore, patient notification was not required.

CARPENTER appears to be represented by Attorney Paul M. Garbarini, R.Ph, P.A., located at P.O. Box 1551, Northampton, MA, 01061, (413) 727-8191. Attorney Garbarini has requested a copy of the investigation.

Counsel for CARPENTER has responded and states that CARPENTER has violated the laws of the profession of Pharmacy. Counsel states that CARPENTER applied for the license so that he could accrue pharmacy intern hours while living in Florida with his parents. CARPENTER assumed that the license had expired, and failed to request that Florida relinquish the license. Counsel for CARPENTER has requested that the license be voluntarily relinquished.

Related Case:

Investigator/Date:	Approved By/Date:
Jacquelynn M. Hakston 9/10/13 Jacquelynn M. Hakston, HA 132 – September 10, 2013 Investigation Specialist II	for Shane Walters, OMC Manager 9-12-13

Distribution: Consumer Services Unit / Prosecution Services Unit

RECEIVED LEGAL SEP 16 AM 11:19

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INVESTIGATIVE DETAILS

SUMMARY OF RECORDS

EXHIBIT 1 contains Court documentation from the Boston Munipal Court, State of Massachussetts which shows that on January 1, 2010, **CARPENTER** was arrested by the Boston Police for Drugs - Trafficking in Cocaine. Subject did utter a false prescription and did receive 300 blue pills believed to be Oxycodone within 100 feet of a park. On May 6, 2010, **CARPENTER** plead guilty to Trafficking Class B, Uttering False Instrument, Trafficking in Park Zone. On May 6, 2010, a Tender of Plea or Admission to Sufficient Facts Waiver of Rights was entered and **CARPENTER** was sentenced in Count A: Possession with Intent (Class D) - Guilty - One (1) day committed; Count B: One (1) day concurrent with Count A; Count C; Two (2) years committed – on and after Count one (1), and assessed a $1,000 fine (Ex. #1, Case Summary, and attachments).

INTERVIEW/STATEMENT OF DEPARTMENT OF HEALTH AND HUMAN SERVICES (DHHS) –SOURCE:

On April 11, 2013, Investigator **HAIRSTON** received documentation from **DHHS** which alleged that **CARPENTER** has been excluded from participation in the Medicare, Medicaid, and all Federal health care programs as a result of the Subject's conviction in the Boston Munipal Court, State of Massachussetts.

INTERVIEW/STATEMENT OF PATRICK CARPENTER, PSI

Address of Record (for Subject):

319 MURTLE AVENUE
ST AUGUSTINE, FL 32086
HOME PHONE: (518) 445-7888

Counsel for CARPENTER has responded on August 30, 2013, and states that **CARPENTER** has violated the laws of the profession of Pharmacy in Florida. Counsel states that **CARPENTER** applied for the license so that he could accrue pharmacy intern hours while living in Florida with his parents. **CARPENTER** assumed that the license had expired, and failed to request that Florida relinquish the license. **Counsel for CARPENTER** has requested that the license be voluntarily relinquished (Ex. 3).

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

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HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307373

SAMUEL E WAHBA,
RESPONDENT.

NOTICE

TO: SAMUEL E WAHBA
4465 LAVENDER DRIVE
PALM HARBOR, FL 34685

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

HEALTH

Rick Scott
Governor

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307373

SAMUEL E WAHBA,
RESPONDENT.

NOTICE

TO: SAMUEL E WAHBA
31201 US HIGHWAY 19N, SUITE 3,
PALM HARBOR, FL 34684

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Jodi-Ann V. Johnson, Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. Samuel E. Wahba, R.Ph.
DOH Case Number 2013-07373
DATE: December 2, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Samuel E. Wahba, R.Ph.
Subject's Address of Record:	4465 Lavender Drive Palm Harbor, FL 34685
Enforcement Address:	31201 US Highway 19N, Suite 3 Palm Harbor, FL 34684
Subject's License No:	27213 **Rank:** PS
Licensure File No:	16250
Initial Licensure Date:	11/22/1991
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Count I: Section 465.016(1)(f), F.S.(2012) Count II: Section 465.016(1)(r), F.S(2012), by violating Section 456.072(1)(ll), F.S(2012)
Prior Discipline:	5010, DOH-06-1599-S; 4022, DOH-02-0619-S
Probable Cause Panel:	November 7, 2013 Meshad and Weizer
Subject's Attorney:	Pro Se
Complainant/Address:	Department of Health/Consumer Services Unit
Materials Submitted:	Board Memorandum Filed Voluntary Relinquishment Administrative Complaint

Board Notification Letter
Election of Rights
ESO packet
PCP Memorandum
Final Investigative Report
Exhibits 1 - 2

Disciplinary Guidelines

Section 456.072(1)(ll)
Min: Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.

Section 465.016(1)(f)
Min: $3,000 fine and one year probation.
Max: Revocation

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE DEC 0 2 2013

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO.: 2013-07373**

SAMUEL E. WAHBA, RPH,

Respondent.

_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent **SAMUEL E. WAHBA, RPH**, license No. **PS 27213**, hereby voluntarily relinquishes Respondent's license to practice Pharmacy in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes. As with any disciplinary action, this relinquishment will be reported to the National Practitioner's Data Bank as

public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 21 day of November, 2013.

SAMUEL E. WAHBA, RPH

STATE OF Florida
COUNTY OF: Pinellas

Before me, personally appeared Samuel E. Wahba, whose identity is known to me by Drivers license, pe of identification) and who, under oath, acknowledges that his signature appears above. Sworn to and subscribed before me this 21 day of November, 2013.

NOTARY PUBLIC

My Commission Expires:

AMY HERRMANN
MY COMMISSION #EE46821
EXPIRES: DEC 06, 2014
Bonded through 1st State Insurance

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v.

CASE NO. 2013-07373

SAMUEL E. WAHBA, R.Ph.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, Samuel E. Wahba, RPH, and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 27213.

3. Respondent's address of record is 4465 Lavender Drive, Palm Harbor, Florida 34685.

4. On or about May 2, 2013, an Information was filed in the United States District Court, Middle District of Florida, Tampa Division, in case number 8:13-CR-232-T-30EAJ, charging Respondent with conspiracy in violation of Title 18 United States Code § 371. Respondent was arrested on May 23, 2013.

5. On or about June 11, 2013, in the United States District Court, Middle District of Florida, Tampa Division, in case number 8:13-CR-232-T-30EAJ, Respondent pled guilty to one count of conspiracy to commit healthcare fraud, in violation of Title 18 United States Code § 371, and was adjudged guilty.

COUNT ONE

6. Petitioner realleges and incorporates paragraphs one (1) through five (5) as if fully set forth herein.

7. Section 465.016(1)(f), Florida Statutes (2012), having been convicted or found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a crime which directly relates to the ability to practice pharmacy or to the practice of pharmacy. A plea of nolo

contendere constitutes a conviction for purposes of this provision. A violation of this statute constitutes grounds for discipline.

8. On or about June 11, 2013, in the United States District Court, Middle District of Florida, Tampa Division, in case number 8:13-CR-232-T-30EAJ, Respondent pled guilty to one count of conspiracy to commit healthcare fraud, in violation of Title 18 United States Code § 371, a crime which directly relates to the ability to practice pharmacy or to the practice of pharmacy.

9. Based on the foregoing, Respondent violated Section 465.016(1)(f), Florida Statutes (2012), by being convicted or found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a crime which directly relates to the ability to practice pharmacy or to the practice of pharmacy.

COUNT TWO

10. Petitioner realleges and incorporates paragraphs one (1) through five (5) as if fully set forth herein.

11. Section 465.016(1)(r), Florida Statutes (2012), provides that violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto, constitutes grounds for discipline.

12. Section 456.072(1)(ll), Florida Statutes (2012), provides that being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud constitutes grounds for discipline.

13. Respondent is licensed pursuant to Chapter 465, Florida Statutes, and is a health care practitioner as defined in Section 456.001(4), Florida Statutes (2012).

14. On or about June 11, 2013, in the United States District Court, Middle District of Florida, Tampa Division, in case number 8:13-CR-232-T-30EAJ, Respondent pled guilty to one count of conspiracy to commit healthcare fraud, in violation of Title 18 United States Code § 371, a crime which relates to health care fraud.

15. Based on the foregoing, Respondent violated Section 465.016(1)(r), Florida Statutes (2012), by violating Section 456.072(1)(ll), Florida Statutes (2012), by being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 7 **day of** November**, 2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Jodi-Ann V. Johnson
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Florida Bar Number 0073525
(850) 245 - 4444 Telephone
(850) 245 - 4683 Facsimile

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Angel Sanders
DATE: NOV 08 2013

/JVJ

PCP Date: November 7, 2013

PCP Members: Meshad and Weizer

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

December 4, 2013

VIA U.S. MAIL

Samuel E. Wahba, R.Ph.
31201 US Highway 19N, Suite 3.
Palm Harbor, Florida 34684

Re: DOH vs. Samuel E. Wahba, R.Ph.
DOH Case Number: 2013-07373

Dear Mr. Wahba:

We are in receipt of your executed Voluntary Relinquishment form. By signing the Voluntary Relinquishment of License form you agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against your license, pursuant to Section 456.072(1)(f), Florida Statutes;
- you would never reapply for licensure as a Pharmacist in the State of Florida; and
- Voluntarily relinquishing your Florida Pharmacist license may have an effect on Pharmacist licenses that you may hold in other states.

If you have any questions or concerns, please contact me as soon as possible to discuss, at 850-245-4444 and extension 8113. Otherwise, this case will proceed as planned, and the Florida Board of Nursing will take up your request for Voluntary Relinquishment of License at their meeting scheduled for February 5, 2014, at the Double Tree by Hilton, 60 South Ivanhoe Boulevard, Orlando, Florida 32804. You are not required to attend the meeting.

Sincerely,

Jodi-Ann V. Johnson
Assistant General Counsel

JAVJ/pb

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Christopher, Tamia L

From: Christopher, Tamia L
Sent: Wednesday, October 23, 2013 11:42 AM
To: DL MQA Inv Serv Priority Mail Area5 (PI) St.Petersburg
Cc: Pope, Berita
Subject: Request for Hand Serve, ERO/Wahba, 13-07373
Attachments: DOH 13-2024 ESO 201307373-1_Samuel E. Wahba, RPh.pdf; Invst. Rpt._Samuel E. Wahba, R.Ph_13-07373.pdf

Please hand serve the attached ESO on the Respondent.

Thank you.

Tamia L. Christopher, Regulatory Specialist I
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
(850) 245-4640 ext. 8200 (Office)
(Mailing Address)
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265
(Physical Address)
2585 Merchants Row, Suite 105
Tallahassee, FL 32399-1701

How am I communicating? Please contact my supervisor.
Please note: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.

However, if this e-mail concerns anticipated or current litigation or adversarial administrative proceedings to which the Florida Department of Health is a party, this e-mail is an attorney-client communication, and is, therefore, a limited access public document exempt from the provisions of Chapter 119, Florida Statute.

See Section 119.071(d)1., Florida Statute (2010).

DOH Mission: To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.

Vision: Healthiest State in the Nation
Values: (ICARE)
Innovation: We search for creative solutions and manage resources wisely.
Collaboration: We use teamwork to achieve common goals & solve problems.
Accountability: We perform with integrity & respect.
Responsiveness: We achieve our mission by serving our customers & engaging our partners.
Excellence: We promote quality outcomes through learning & continuous performance

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

PSU REQUEST FORM

FROM: Tamia Christopher For Jodi-Ann V. Johnson, Esquire	TO: Karen Hanzal, Inv. Supvr., Area 5 (PI) St. Petersburg
Date: 10/23/13	TO: CSU
Phone #: 850/245/4444 Ext. 8200	CC:

Case Number: 2013-07373 Board: Pharmacy
Subject: Samuel E. Wahba, R.Ph. HL Code: HLL79A Status: 90
Requested Completion Date: A.S.A.P.

(PSU) TYPE OF REQUEST: (describe details below)

- [x] Process Service* (**Activity Code 160**)
- [ ] Additional Information Requested (**Activity Code 145**)
- [ ] Deficiency in Investigative Work (**Activity Code 150**)

Details: **For Hand Service of ESO**
Last Known Address: 4465 Lavender Drive, Palm Harbor, Florida 34685.
Last Known Name & Phone Number: Samuel E. Wahba, (727) 787-6382
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES [ ] No [x]; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES [ ]** No [ ] NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

- [ ] Process Service Completed (Activity Code 161) [ ] Process Service NOT Completed (Activity Code 162)
- [ ] Additional Info Sent to Legal (Activity Code 156)
- [ ] Supp. Investigation Request Cancelled (Activity Code 157)

Email to:	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami	Pensacola
	Consumer Services	ULA									

Florida Department of Health
Division of Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-
PHONE: 850-245-4444 • FAX 850-245-4662

7196 9008 9111 5772 5374

TO:

Samuel E. Wahba, R.Ph.
4465 Lavender Drive
Palm Harbor, FL 34685
ESO/13-07373_Jodi-Ann Johnson Esq.
10/23/13

SENDER:

REFERENCE:

PS Form 3800, January 2005

RETURN RECEIPT SERVICE		
	Postage	
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

US Postal Service®

Receipt for Certified Mail™

No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

2. Article Number

7196 9008 9111 5772 5374

3. Service Type **CERTIFIED MAIL™**

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Samuel E. Wahba, R.Ph.
4465 Lavender Drive
Palm Harbor, FL 34685
ESO/13-07373_Jodi-Ann Johnson Esq. 10/23/13

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly)

B. Date of Delivery

C. Signature

X

☐ Agent
☐ Addressee

D. Is delivery address different from item 1?
If YES, enter delivery address below:

☐ Yes
☐ No

2013 NOV -4 AM 10:

PRACTITIONER REGULATION
LEGAL

PS Form 3811, January 2005 Domestic Return Receipt

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Vision: To be the Healthiest State in the Nation

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

October 23, 2013

Certified Article Number
7196 9008 9111 5772 5374
SENDERS RECORD

Samuel E. Wahba, R.Ph.
4465 Lavender Drive
Palm Harbor, FL 34685

RE: Department of Health vs. Samuel E. Wahba, R.Ph.
Case Number: 2013-07373

Dear Mr. Wahba:

Enclosed please find an Order of Emergency **Suspension** of License filed October 23, 2013, against your license to practice as a pharmacist in the State of Florida. You should immediately cease the practice as a pharmacist according to the enclosed Order of Emergency **Suspension** of License.

If you have any questions, please do not hesitate to contact Jodi-Ann Johnson, Assistant General Counsel at (850) 245-4444.

Sincerely,

Tamia Christopher
Regulatory Specialist, I
Prosecution Services Unit

/tc
Enclosure

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row - Suite 105
PHONE: 850/245-4444 • FAX 850/245-4662

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

In Re: Emergency Suspension of the License of
Samuel E. Wahba, R.Ph.
License No.: PS 27213
Case No.: 2013-07373
Final Order No. DOH-13-2024-ESO -MQA
FILED DATE: OCT 23 2013
Department of Health
By: [signature]
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the License of
Samuel E. Wahba, R.Ph.
License No.: PS 27213
Case No.: 2013-07373

ORDER OF EMERGENCY SUSPENSION OF LICENSE

John H. Armstrong, MD, FACS, State Surgeon General and Secretary of Health, ORDERS the emergency suspension of the license of Samuel E. Wahba, R.Ph., to practice as a registered pharmacist in the State of Florida. Mr. Wahba holds license number PS 27213. His address of record is 4465 Lavender Drive, Palm Harbor, Florida 34685. The following Findings of Fact and Conclusions of Law support the emergency suspension of Mr. Wahba's license to practice as a registered pharmacist.

FINDINGS OF FACT

1. The Department of Health (Department) is the state agency charged with regulating the practice of nursing pursuant to Chapters 20, 456, and 465, Florida Statutes. Section 456.074(1), Florida Statutes (2013), authorizes the Department to summarily suspend Mr. Wahba's license to practice as a registered pharmacist.

2. At all times material to this Order, Mr. Wahba was licensed to practice as a registered pharmacist in the State of Florida pursuant to Chapter 465, Florida Statutes (2012).

3. On or about May 2, 2013, an Information was filed in the United States District Court, Middle District of Florida, Tampa Division, in case number 8:13-CR-232-T-30EAJ, charging Mr. Wahba with conspiracy in violation of Title 18 United States Code § 371. Mr. Wahba was arrested on May 23, 2013.

4. On or about June 11, 2013, in the United States District Court, Middle District of Florida, Tampa Division, in case number 8:13-CR-232-T-30EAJ, Mr. Wahba pled guilty to one count of conspiracy to commit healthcare fraud, in violation of Title 18 United States Code § 371, and was adjudged guilty.

5. Section 456.074(1), Florida Statutes (2013), provides that the Department *shall* issue an emergency order suspending the license of any person licensed under Chapter 465, Florida Statutes, who enters a plea of guilty to a misdemeanor or felony under 18 United States Code § 371, regardless of adjudication.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General and Secretary of Health concludes as follows:

1. The Department has jurisdiction pursuant to Sections 20.43 and 456.074(1), Florida Statutes (2013), and Chapter 465, Florida Statutes (2013).

2. The Department is mandated to summarily suspend Mr. Wahba's license to practice as a registered pharmacist in accordance with Section 456.074(1), Florida Statutes (2013).

WHEREFORE, in accordance with Section 456.074(1), Florida Statutes, it is ORDERED THAT:

1. The license of Samuel E. Wahba, R.Ph., license number PS 27213, is immediately suspended.

2. A proceeding seeking formal suspension or discipline of the license of Samuel E. Wahba, R.Ph., to practice as a registered pharmacist will be promptly instituted and acted upon in compliance with Section 120.569, Florida Statutes.

DONE and ORDERED this 22nd day of October, 2013.

John H. Armstrong, MD, FACS
State Surgeon General
and Secretary of Health

PREPARED BY:
Jodi-Ann V. Johnson
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(850) 245 – 4444 Telephone
(850) 245 – 4683 Facsimile
Florida Bar No. 0073525

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Section 120.68, Florida Statutes, this Order is judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Proceedings are commenced by filing a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, with the District Court of Appeal, accompanied by a filing fee prescribed by law, and a copy of the petition with the Agency Clerk of the Department within 30 days of the date this Order is filed.

October 23, 2013

The Honorable Robert S. Cohen
Chief Administrative Law Judge
Division of Administrative Hearings
1230 Apalachee Parkway
Tallahassee, FL 32301

RE: Department of Health vs. Samuel E. Wahba, R.Ph.
Case Number: 2013-07373

Dear Judge Cohen:

This letter is to advise you that the Department has issued an Emergency Suspension Order concerning the license of **Samuel E. Wahba** to practice as a pharmacist in the State of Florida. An Administrative Complaint has not been issued in the above case. Therefore, this is not a request for a formal hearing.

This letter is sent to advise you of the action taken by the Department and to advise you of the possibility that the respondent may request an expedited hearing. The Department shall keep you advised of any developments. If you need additional information, please contact Jodi-Ann Johnson, Assistant General Counsel at (850) 245-4444.

Sincerely,

Tamia Christopher
Regulatory Specialist, I
Prosecution Services Unit

/tc

** Transmit Conf.Report **

P.1

Oct 23 2013 02:41pm

Fax/Phone Number	Mode	Start	Time	Page	Result	Note
99216847	Normal	23:02:40pm	0'29"	1	* O K	

Mission: To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Vision: To be the Healthiest State in the Nation

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

October 23, 2013

The Honorable Robert S. Cohen
Chief Administrative Law Judge
Division of Administrative Hearings
1230 Apalachee Parkway
Tallahassee, FL 32301

RE: Department of Health vs. Samuel E. Wahba, R.Ph.
Case Number: 2013-07373

Dear Judge Cohen:

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Sincerely,

Tamia Christopher
Regulatory Specialist, I
Prosecution Services Unit

/tc

Florida Department of Health
Office of the General Counsel · Prosecution Services Unit
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Express mail address: 2585 Merchants Row · Suite 105
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www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: floh

MEMORANDUM

TO: Florida Administrative Registry

FROM: Tamia Christopher, Regulatory Specialist I

RE: Samuel E. Wahba, R.Ph., PS#: 27213 (FAW # **13721831)**

CASE NO: 2013-07373

DATE: October 23, 2013

Attached please find notice of the issuance of an **Emergency Suspension** Order for notice in the next issue of the Florida Administrative Register.

On October 23, 2013, the State Surgeon General issued an Order of Emergency Suspension Order with regard to the license of Samuel E. Wahba, R.Ph., PS#: 27213. This Emergency Suspension Order was predicated upon the State Surgeon General's findings of an immediate and serious danger to the public health, safety and welfare pursuant to Sections 456.073(8) and 120.60(6) Florida Statutes (2011). The State Surgeon General determined that this summary procedure was fair under the circumstances, in that there was no other method available to adequately protect the public.

Christopher, Tamia L

From: Motes, Alyson
Sent: Wednesday, October 23, 2013 2:07 PM
To: Christopher, Tamia L
Subject: FW: Submit Notice in FAR

* Alyson Motes, Compliance Officer
* Assistant to Therese Savona, Appeals
* & Linda McMullen, Unlicensed Activity
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265
(850) 245-4444 * 8134

* How am I communicating? Please contact my supervisor.

* Please note: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.

* However, if this e-mail concerns anticipated or current litigation or adversarial administrative proceeding to which the Florida Department of Health is a party, this email is an attorney-client communication, and is, therefore, a limited access public document exempt from the provisions of Chapter 119, Florida Statutes.
* See Section 119.071(d)1., Florida Statutes (2010).

* DOH Mission: To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.

* Vision: Healthiest State in the Nation

* Values: (ICARE)
* I nnovation: We search for creative solutions and manage resources wisely.
* C ollaboration: We use teamwork to achieve common goals & solve problems.
* A ccountability: We perform with integrity & respect.
* R esponsiveness: We achieve our mission by serving our customers & engaging our partners.
* E xcellence: We promote quality outcomes through learning & continuous performance improvement.

-----Original Message-----
From: FL-Rules@dos.state.fl.us [mailto:FL-Rules@dos.state.fl.us]
Sent: Wednesday, October 23, 2013 2:06 PM
To: Motes, Alyson
Subject: Submit Notice in FAR

You have successfully submitted a notice for publication in the Florida Administrative Register on 10/23/2013 2:05:44 PM.

Department: Department of Health
Organization: Board of Pharmacy
Notice type: Miscellaneous
Issue: 39/208

Once this notice is published you will be able to view it by clicking the following link:
http://www.FLRules.org/gateway/View_Notice.asp?id=13721831

TRANSMISSION VERIFICATION REPORT

10/1/13

TIME : ~~09/24~~/2013 13:10
NAME :
FAX :
TEL :
SER.# : 000L1N188533

DATE,TIME	09/24 13:10
FAX NO./NAME	618132746358
DURATION	00:00:27
PAGE(S)	01
RESULT	OK
MODE	STANDARD ECM

September 9, 2013

U.S. Attorney's Office
400 North Tampa Street, Suite 3200
Tampa, Fl. 33602

Subject: Samuel E. Wahba, PS
Social Security Number: XXX-XX-6008
Date of Birth: April 2, 1967
DOH Reference Number: 201307373

Dear Sir or Madam:

The above healthcare practitioner was convicted of a crime in your court that may be related to the practice of Pharmacist in Florida. The Department of Health is required to investigate possible violations of the laws and rules regulating this practitioner's profession.

We need the following information so that the department can review this matter and take appropriate action. Please submit a ***certified copy*** of:

- the warrant;
- the Bill of Indictment or Information
- the Judgment or Conviction;
- the Arrest Report; and
- any additional public information that may relate to this practitioner's professional practice.

If there is a charge for these certified copies, please send an itemized invoice with your **Federal Employer Identification number**, the amount per page, and the total number of pages.

Pursuant to Section 28.345 F.S. Exemption from court-related fees and charges.- Notwithstanding any other provision of this chapter or law to the contrary, judges and those court staff acting on behalf of judges, state attorneys, guardians ad litem, public guardians, attorney ad litem. court-appointed private counsel, criminal conflict and civil regional counsel, and public defenders, acting in their official capacity. and state agencies, are exempt from all court-related fees and charges assessed by the clerks of the circuit courts.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please call the Consumer Services Unit at (850) 245-4339. In addition, if you have any concerns or suggestions about our complaint process, please fill out our *Customer Concerns or Suggestions* form at www.floridashealth.com/mqa/survey.html.

Sincerely,

Jacquelynn M. Hairston

Jacquelynn M. Hairston
Investigation Specialist II

JMH/tb
DOH-Form205

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

CLERK'S MINUTES

CASE NO. 8:13-CR-232-T-30EAJ

DATE: May 23, 2013

HONORABLE ELIZABETH A. JENKINS

INTERPRETER N/A
LANGUAGE

UNITED STATES OF AMERICA
v.

AUSA Simon Gaugush
Government Counsel

SAMUEL E. WAHBA
Defendant

Bjorn Brunvand, Esq.
Defense Counsel

COURT RPTR/TAPE Digital

DEPUTY CLERK Cathy Morgan

TIME 11:06 - 11:20

TOTAL ___ COURTROOM 11A

PROCEEDINGS: **INITIAL APPEARANCE/BOND HEARING**

(Circle proceedings that apply)

X Deft provided w/copy of Information
X ARREST DATE: May 23, 2013
X Court summarized charges
X Court advises of Deft's Rule 5 rights
X Govt position on release - signature bond
X Bond: $50,000.00 signature
- X Pretrial Service supervision
- X Travel is enlarged to the State of Florida
- X May travel to Georgia from 5/30 to 6/2
- X Seek and or maintain full time legitimate employment which does not involve reimbursement from medicare or any other federal reimbursement program.
- X Shall not change his address without prior court approval
- X Shall surrender his United States passport to Pretrial Services by 4:00 pm on 5/24/13
- X Shall surrender his Egyptian passport by 5/27/13 at 4:00 pm to Pretrial Services
- X Shall not obtain any passports or travel documents

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

vs

SAMUEL E. WAHBA

Case Number. 8:13-cr-232-T-30EAJ
USM Number: 58658-018

Bjorn Erik Brunvand, Retained

JUDGMENT IN A CRIMINAL CASE

The defendant pleaded guilty to Count One of the Information. Accordingly, the court has adjudicated that the defendant is guilty of the following offense:

Title & Section	Nature of Offense	Date Offense Concluded	Count Number(s)
18 U.S.C. § 371	Conspiracy to Commit Health Care Fraud, to Make False Statements to a Federal Agency, to File False Claims for Payment to Federal Health Care Programs and to Conceal and to Fail to Disclose Exclusion from Federal Health Care Programs in Connection with Claims for Payment	May 2, 2013	One

The defendant is sentenced as provided in the following pages of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

IT IS ORDERED that the defendant shall notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant shall notify the court and United States attorney of any material change in the defendant's economic circumstances.

Date of Imposition of Sentence:

November 7, 2013

JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

November 7, 2013

RECEIVED-LEGAL
13 DEC -2 AM 9:26

IMPRISONMENT

The defendant is hereby committed to the custody of the United States Bureau of Prisons to be imprisoned for a total term of TWENTY-FOUR (24) MONTHS as to Count One of the Information.

The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons as notified by the United States Marshal.

RETURN

I have executed this judgment as follows:

_____

_____

_____

_____

Defendant delivered on _____ to _____

at _____, with a certified copy of this judgment.

_____
UNITED STATES MARSHAL

By: _____
Deputy U.S. Marshal

SUPERVISED RELEASE

Upon release from imprisonment, the defendant shall be on supervised release for a term of THREE (3) YEARS as to Count One of the Information.

The defendant shall report to the probation office in the district to which the defendant is released within 72 hours of release from custody of the Bureau of Prisons.

The defendant shall not commit another federal, state or local crime.

The defendant shall not illegally possess a controlled substance.

For offenses committed on or after September 13, 1994:

The mandatory drug testing requirements of the Violent Crime Control Act are waived. However, the Court orders the defendant to submit to random drug testing not to exceed 104 tests per year.

The defendant shall not possess a firearm, destructive device, or any other dangerous weapon.

If this judgment imposes a fine or a restitution obligation, it shall be a condition of supervision that the defendant pay any such fine or restitution that remains unpaid at the commencement of the term of supervision in accordance with the Schedule of Payments set forth in the Criminal Monetary Penalties sheet of this judgment.

The defendant shall comply with the standard conditions that have been adopted by this court (set forth below).

The defendant shall also comply with the additional conditions on the attached page.

STANDARD CONDITIONS OF SUPERVISION

1. the defendant shall not leave the judicial district without the permission of the court or probation officer;
2. the defendant shall report to the probation officer in a manner and frequency directed by the court or probation officer;
3. the defendant shall answer truthfully all inquiries by the probation officer and follow the instructions of the probation officer;
4. the defendant shall support his or her dependents and meet other family responsibilities;
5. the defendant shall work regularly at a lawful occupation, unless excused by the probation officer for schooling, training, or other acceptable reasons;
6. the defendant shall notify the probation officer **at least ten (10) days prior** to any change in residence or employment;
7. the defendant shall refrain from excessive use of alcohol and shall not purchase, possess, use, distribute, or administer any controlled substance or any paraphernalia related to any controlled substances, except as prescribed by a physician;
8. the defendant shall not frequent places where controlled substances are illegally sold, used, distributed, or administered;
9. the defendant shall not associate with any persons engaged in criminal activity and shall not associate with any person convicted of a felony, unless granted permission to do so by the probation officer;

10. the defendant shall permit a probation officer to visit him or her at any time at home or elsewhere and shall permit confiscation of any contraband observed in plain view by the probation officer;

11. the defendant shall notify the probation officer within **seventy-two (72)** hours of being arrested or questioned by a law enforcement officer;

12. the defendant shall not enter into any agreement to act as an informer or a special agent of a law enforcement agency without the permission of the court;

13. as directed by the probation officer, the defendant shall notify third parties of risks that may be occasioned by the defendant's criminal record or personal history or characteristics, and shall permit the probation officer to make such notifications and to confirm the defendant's compliance with such notification requirement.

ADDITIONAL CONDITIONS OF SUPERVISED RELEASE

1. The defendant shall cooperate in the collection of DNA, as directed by the Probation Officer.

CRIMINAL MONETARY PENALTIES

The defendant shall pay the following total criminal monetary penalties in accordance with the schedule of payments set forth in the Schedule of Payments.

Total Assessment	Total Fine	Total Restitution
$100.00	Waived	N/A

SCHEDULE OF PAYMENTS

Special assessment shall be paid in full and is due immediately.

FORFEITURE

Defendant shall forfeit to the United States those assets previously identified in plea agreement that are subject to forfeiture.

The defendant shall pay interest on any fine or restitution of more than $2,500, unless the fine or restitution is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on the Schedule of Payments may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

*Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18, United States Code, for offenses committed on or after September 13, 1994 but before April 23, 1996.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v. CASE NO. 8:13-cr-232-T-30EAJ

SAMUEL WAHBA

ORDER VACATING THE PRELIMINARY ORDER OF FORFEITURE FOR SUBSTITUTE ASSETS

The United States moves to amend the Forfeiture Money Judgment and Preliminary Order of Forfeiture for Substitute Assets (Doc. 25) by vacating the preliminary order of forfeiture for substitute assets.

Pursuant to 18 U.S.C. §§ 982(a)(7), 981(a)(1)(C), 28 U.S.C. § 2461(c), and Rule 32.2(b)(2), Federal Rules of Criminal Procedure, the court held that the United States was entitled to a forfeiture money judgment against the defendant, and on October 31, 2013 the court entered a forfeiture money judgment in the amount of $5,281,931.00 against defendant Samuel Wahba, representing the amount of proceeds he obtained as a result of the conspiracy to commit health care fraud offenses, in violation of 18 U.S.C. § 1347, 18 U.S.C. § 1001(a)(2) and (a)(3), 18 U.S.C. § 1035(a)(2), and 42 U.S.C. § 1320a-7b(a)(3), all in violation of 18 U.S.C. § 371, as charged in Count One of the Information.

To satisfy the defendant's money judgment, the court further found that the United States was entitled, pursuant to 21 U.S.C. § 853(p), to forfeit any property belonging to the defendant as a substitute asset up to and including the amount of $5,281,931.00.

The court now finds that it is in the best interest of the United States to vacate the Preliminary Order of Forfeiture for the following substitute assets:

a. a 2013 Audi Q7 Quattro 4dr 3.0T S line Prestige, Vehicle Identification No. WA1DGAFE8DD014159;

b. a 1991 Porsche 911 coupe, Vehicle Identification No. WP0AA2960MS480314; and

c. a 2012 Thor Motor Coach, Vehicle Identification No. 1F66F5DY8C0A00325.

Accordingly, it is hereby ORDERED:

1. That the United States' motion is GRANTED.

2. Pursuant to 18 U.S.C. § 982(a)(7), 18 U.S.C § 981(a)(1)(C), 28 U.S.C. § 2461(c), and Rule 32.2(b)(2), Federal Rules of Criminal Procedure, the Forfeiture Money Judgment (Doc. 25) against defendant Samuel Wahba in the amount of $5,281,931.00 shall remain in full force and effect.

3. The Preliminary Order of Forfeiture for the Substitute Assets (Doc. 25) described above is hereby VACATED. The defendant will sell the Audi vehicle and the proceeds will be furnished to the government in partial satisfaction of the defendant's money judgment. The proceeds from the sale of the 1991 Porsche 911 coupe and the 2012 Thor Motor Coach also will be furnished to the United States in partial satisfaction of the defendant's money judgment.

4. The Court retains jurisdiction to enter any further order necessary for the forfeiture and disposition of these assets and any property belonging to the defendant that the government may seek as substitute assets, up to the

value of the money judgment, and to address any third party claim that may be asserted in these proceedings.

5. Upon receipt by the government, the defendant's money judgment will be credited with the proceeds from the sale of the properties described above.

ORDERED in Tampa, Florida, on November 7, 2013

JAMES S. MOODY, JR.
UNITED STATES DISTRICT JUDGE

Copies to:
Counsel/Parties of Record

FILED

13 MAY -2 PM 3:52

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v.

CASE NO. 8:13 CR 232 T 30 EAJ

SAMUEL WAHBA

18 U.S.C. § 371
18 U.S.C. § 982(a)(7) - Forfeiture
18 U.S.C. § 981(a)(1)(C) - Forfeiture
28 U.S.C. § 2461(c) - Forfeiture

INFORMATION

The United States Attorney charges:

COUNT ONE
(Conspiracy - 18 U.S.C. § 371)

Introduction

At all times material to this Information:

A. The Medicaid Program

1. The Medicaid Program ("Medicaid"), as established by the Social Security Act, was a cooperative federal-state health care benefit program that enabled the states to furnish necessary medical benefits, items, and services to indigent families and individuals ("Medicaid beneficiaries") who were unable to meet the costs of the benefits, items, and services.

2. The State of Florida administered Medicaid through the Florida Agency for Health Care Administration ("AHCA").

3. In order to be reimbursed by Medicaid, an entity providing medical benefits and services to Medicaid beneficiaries (the "provider") first had to enter into a Medicaid Provider Enrollment Agreement. This Medicaid Provider Enrollment Agreement was submitted to AHCA for approval.

4. A private corporation under contract with ACHA acted as a "fiscal intermediary" and was authorized to receive and process Medicaid claims on behalf of ACHA. To receive reimbursement for benefits or services provided to a Medicaid beneficiary, the provider transmitted a claim for reimbursement to the fiscal intermediary. Providers were reimbursed with federal funds.

B. <u>The Medicare Program, Part D</u>

5. The Medicare Program ("Medicare") was a federal health care benefit program that provided medical benefits, items and services to persons age 65 and older or with certain disabilities ("Medicare beneficiaries").

6. The Centers for Medicare and Medicaid Services ("CMS"), an agency within the United States Department of Health and Human Services, oversaw and administered Medicare throughout the United States.

7. Medicare included coverage under several components. Part D of Medicare ("Medicare Part D") subsidized the costs of providing prescription drugs to Medicare beneficiaries in the United States. Medicare Part D was enacted as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, which went into effect on January 1, 2006.

8. Private insurance plans administered Medicare Part D benefits (the "Medicare Part D plans"). These Medicare Part D plans then sought reimbursement from Medicare, through CMS, for the benefits provided to Medicare beneficiaries.

9. A pharmacy could contract with one or more Medicare Part D plans to provide covered benefits to Medicare beneficiaries. By contracting with these Medicare Part D plans, a pharmacy could provide covered benefits (*i.e.*, dispense prescription drugs) to Medicare beneficiaries and expect reimbursement from Medicare for providing such benefits. A pharmacy that furnished Medicare Part D benefits could also submit claims for payment to a Medicare Part D plan with which it did not have a contract. In either case, the pharmacy would submit a claim for reimbursement to the particular Medicare Part D plan for prescription benefits provided to the Medicare beneficiary. The pharmacy used the Medicare beneficiary's health insurance claim number and/or the Medicare Plan Identification number to submit a claim for reimbursement to the Medicare Part D plan. Ultimately, the Medicare Part D plan would send a reimbursement check to the pharmacy or initiate an electronic transfer of funds to the pharmacy's bank account for the benefits provided to the beneficiary. The Medicare Part D plan then sought reimbursement from Medicare, through CMS, for payments made to the pharmacy. CMS reimbursed Medicare Part D plans with federal funds.

C. **TRICARE**

10. TRICARE was a triple option health care benefit plan of the United States Department of Defense Military Health System. Eligible TRICARE beneficiaries included members of all seven branches of the Uniformed Services: Army, Air Force, Navy, Marine Corps, National Oceanic Atmospheric Administration, Coast Guard, and the commissioned corps of the Public Health Service. TRICARE received federal funds allocated through the annual Department of Defense Appropriation Acts. A private corporation under contract with TRICARE acted as a "fiscal intermediary" and was authorized to receive and process claims for reimbursement on behalf of TRICARE. Health care service providers (such as pharmacies) were reimbursed with federal funds for benefits and services provided to TRICARE beneficiaries.

D. **The Defendant's Exclusion from All Federal Health Care Programs**

11. **SAMUEL WAHBA** was a pharmacist licensed in the State of Florida and a resident of Pinellas County, Florida.

12. On or about August 10, 2001, SAMUEL WAHBA was convicted of one count of violating the Florida Racketeering Influenced and Corrupt Organization Act (RICO), one count of Medicaid Provider Fraud, one count of Grand Theft (Second Degree), and one count of Grand Theft (Third Degree), in the *State of Florida v. Samuel Wahba*, Case No. CRC00-15237CFANO, in the Circuit Court of the Sixth Judicial Circuit, in and for Pinellas County, Florida (the

"2001 felony convictions"). The 2001 felony convictions arose out of SAMUEL WAHBA's operation of Clover Pharmacy, located at 3325 Tampa Road, in Palm Harbor, Florida.

13. On or about July 31, 2002, SAMUEL WAHBA received notice that he was "excluded in any capacity from participation in the Medicare, Medicaid, and all Federal health care programs as defined in section 1128B(f) of the Social Security Act (Act) for a minimum period of 15 years." (emphasis in original). This exclusion was based on SAMUEL WAHBA's 2001 felony convictions. This exclusion notice also advised SAMUEL WAHBA of the following:

> You are excluded from participation in the Medicare, Medicaid, and all Federal health care programs as defined in section 1128B(f) (42 U.S.C. 1320a-7b) of the Social Security Act. The effect of this exclusion is that no program payment will be made to you for anything that you do, order, or prescribe, or to any employer for anything that you do, order, or prescribe to program patients . . . during the period you are excluded.
>
> This exclusion is global, regardless of your job or location. It applies in all States and in all programs. It applies to all Federal procurement and non-procurement programs and activities.
>
> * * *
>
> Notwithstanding 42 U.S.C. 1395w-4(g)(4), any service you provide is a non-covered service. Therefore, you cannot submit claims or cause claims to be submitted for payment under any Federal health care program. Violations of the conditions of your exclusion may subject you to criminal prosecution, the imposition of civil monetary penalties (42 U.S.C. 1320a-7a – 42 U.S.C. 1320a-7b), and the denial of your reinstatement to the programs.
>
> * * *

> **YOUR REINSTATEMENT IS NOT AUTOMATIC.** You will not be reinstated at the conclusion of the minimum period of exclusion, or anytime thereafter, **UNLESS YOU APPLY TO THE OIG AND ARE GRANTED REINSTATEMENT** to the Medicare and Federal health care programs under the provisions of 42 U.S.C. 1320a-7(g) and 42 CFR 1001.3001–.3005.

(emphasis in original).

E. **The Defendant's Ownership and Operation of St. George Pharmacy**

14. On or about October 15, 2002, approximately two and a half months after his exclusion from participating in all federal health care programs, SAMUEL WAHBA used a nominee (hereinafter referred to as "Nominee I.N.") to register **St. George Pharmacy, Inc. ("St. George Pharmacy")** with the Florida Secretary of State, Division of Corporations. The Electronic Articles of Incorporation listed St. George Pharmacy as being located at 3325 Tampa Road, in Palm Harbor, Florida—the same location as Clover Pharmacy, which SAMUEL WAHBA previously owned and operated. Pursuant to the Articles of Incorporation, Nominee I.N. was the sole incorporator, officer, director, and registered agent of St. George Pharmacy. In truth and in fact, SAMUEL WAHBA was the sole owner and operator of St. George Pharmacy. SAMUEL WAHBA used Nominee I.N. to register St. George Pharmacy with the Florida Secretary of State to conceal his connection with the pharmacy.

15. On or about December 5, 2002, SAMUEL WAHBA and Nominee I.N. opened a corporate signature card account in the name of St. George Pharmacy at Bank of America. SAMUEL WAHBA signed the signature card for

this bank account, representing himself to be the "Manager" of St. George Pharmacy. Nominee I.N. was falsely listed on the signature card as the "President" of St. George Pharmacy.

16. In order to bill Medicaid, a provider was required to first obtain a Medicaid Provider Number. On or about January 6, 2003, AHCA received a Medicaid Provider Enrollment Application from St. George Pharmacy, purportedly signed by Nominee I.N. The Medicaid Provider Enrollment Application required the applicant to "identify all managers, billing agents, officers, directors and principal owners" of St. George Pharmacy. Notwithstanding this requirement, the Medicaid Provider Enrollment Application omitted any mention of SAMUEL WAHBA and falsely represented that Nominee I.N. was a 100% owner of St. George Pharmacy. In addition, the Medicaid Provider Enrollment Application required the applicant to explain whether any of the individuals listed as managers, billing agents, officers, directors and principal owners of St. George Pharmacy had ever been: (a) convicted of a felony, and (b) excluded from Medicare or Medicaid in any state. By omitting SAMUEL WAHBA as a manager and principal owner of St. George Pharmacy, SAMUEL WAHBA was able to conceal from AHCA his 2001 felony convictions and exclusion from participating in Medicaid, Medicare, TRICARE, and all other federal health care programs. As a result, on or about January 6, 2003, AHCA issued a Medicaid Provider Number to St. George Pharmacy and, subsequently, St. George

Pharmacy began submitting claims for reimbursement to Medicaid for prescription services provided to Medicaid beneficiaries.

17. During the course of St. George Pharmacy's operations, it entered into contracts with various pharmacy networks that administered Medicare Part D and TRICARE. By virtue of St. George Pharmacy's participation in these pharmacy networks, St. George Pharmacy was also able to submit claims for reimbursement to Medicare Part D and TRICARE.

18. From on or about October 15, 2002, through the present day, SAMUEL WAHBA has been the sole owner and operator of St. George Pharmacy, notwithstanding his exclusion from participation in all federal health care programs.

19. Between on or about July 28, 2003 and August 1, 2012, St. George Pharmacy—through SAMUEL WAHBA's ownership, direction, and control—submitted thousands of claims for reimbursement to Medicaid, Medicare Part D, and TRICARE (through their respective fiscal intermediaries and pharmacy networks), and, in return, received over $5,000,000.00 in reimbursement from these federal health care programs.

The Conspiracy

20. Beginning on an unknown date, but at least as early as on or about October 15, 2002, and continuing up through the date of this Information, in the Middle District of Florida and elsewhere, the defendant,

SAMUEL WAHBA,

did knowingly and willfully combine, conspire, confederate, and agree with other individuals both known and unknown, to commit certain offenses, that is:

a. to knowingly and willfully execute and attempt to execute, in connection with the delivery of and payment for health care benefits, items, and services, a scheme and artifice to defraud certain health care benefit programs affecting commerce, as defined in Title 18, United States Code, Section 24(b), namely, Medicaid, Medicare Part D, and TRICARE, and to obtain, by means of materially false and fraudulent pretenses, representations, and promises, money and property owned by, and under the custody and control of, Medicaid, Medicare Part D, and TRICARE, in violation of Title 18, United States Code, Section 1347;

b. to knowingly and willfully make a materially false, fictitious, and fraudulent statement and representation and use a false writing and document knowing the same to contain a materially false, fictitious and fraudulent statement and entry, in a matter within the executive branch of the Government of the United States, in particular, the submission of a Medicaid

Provider Enrollment Application to AHCA which falsely represented that Nominee I.N. was the owner and operator of St. George Pharmacy and concealed SAMUEL WAHBA's ownership and operation of St. George Pharmacy, in violation of Title 18, United States Code, Sections 1001(a)(2) and (a)(3);

c. to knowingly and willfully make materially false, fictitious, and fraudulent statements and representations, and make and use materially false writings and documents, knowing the same to contain materially false, fictitious, and fraudulent statements and entries, in connection with the delivery of and payment for health care benefits, items, and services, in a matter involving certain health care benefit programs affecting commerce, namely, Medicaid, Medicare Part D, and TRICARE, in violation of Title 18, United States Code, Section 1035(a)(2); and

d. having knowledge of the occurrence of an event, specifically, that SAMUEL WAHBA had been excluded from participation in any and all federal health care programs for a minimum period of 15 years and was actively participating in the operation of St. George Pharmacy, which affected St. George Pharmacy's initial and continued right to payment under any and all federal health care programs, including, Medicaid, Medicare Part D, and TRICARE, did conceal and fail to disclose such event with the intent fraudulently to secure such payments from Medicaid, Medicare Part D, and TRICARE, when no such

payments were authorized, in violation of Title 42, United States Code, Section 1320a-7b(a)(3).

Manner and Means of the Conspiracy

21. The manner and means by which the conspirators sought to accomplish the objects of the conspiracy included, among other things, the following:

a. It was a part of the conspiracy that SAMUEL WAHBA would and did own and operate St. George Pharmacy;

b. It was further part of the conspiracy that the conspirators would and did form St. George Pharmacy in such a fashion as to conceal SAMUEL WAHBA's ownership and control of the pharmacy from all federal health care programs, including Medicaid, Medicare Part D, and TRICARE;

c. It was further part of the conspiracy that a conspirator would and did submit a Medicaid Provider Enrollment Application to AHCA omitting SAMUEL WAHBA's ownership of and managerial role in the operation of St. George Pharmacy;

d. It was further part of the conspiracy that the conspirators would and did serve as nominee owners of St. George Pharmacy to conceal SAMUEL WAHBA's ownership and operation of St. George Pharmacy from Medicaid, Medicare Part D, and TRICARE;

e. It was further part of the conspiracy that the conspirators would and did submit millions of dollars in claims for reimbursement to Medicaid, Medicare Part D, and TRICARE, notwithstanding SAMUEL WAHBA's exclusion from participation in any and all federal health care programs;

f. It was further part of the conspiracy that the conspirators would and did receive over $5,000,000.00 in reimbursement payments from Medicaid, Medicare Part D, and TRICARE and deposited those fraudulently-obtained federal health care funds into various bank accounts; and

g. It was further part of the conspiracy that conspirators would and did misrepresent, conceal, hide, and cause to be misrepresented, concealed, and hidden, acts done in furtherance of the conspiracy and the purpose of those acts.

Overt Acts

22. In furtherance of the conspiracy and to effectuate the objects thereof, the following overt acts, among others, were committed within the Middle District of Florida, and elsewhere:

a. On or about October 15, 2002, SAMUEL WAHBA used Nominee I.N. to register St. George Pharmacy with the Florida Secretary of State, Division of Corporations;

b. On or about December 5, 2002, SAMUEL WAHBA and Nominee I.N. opened a corporate signature card account in the name of St. George Pharmacy at Bank of America;

c. On or about December 5, 2002, SAMUEL WAHBA submitted, or caused to be submitted, to AHCA a Medicaid Provider Enrollment Application for St. George Pharmacy that fraudulently misrepresented Nominee I.N. as the sole owner of St. George Pharmacy and concealed SAMUEL WAHBA's ownership interest in the pharmacy, his 2001 felony convictions, and his exclusion from participation in all federal health care programs;

d. On or about June 26, 2004, SAMUEL WAHBA caused St. George Pharmacy to submit a claim for reimbursement to Medicaid in the amount of $289.62 for dispensing a prescription of Lidoderm to Medicaid beneficiary M.V.;

e. On or about November 25, 2009, SAMUEL WAHBA caused St. George Pharmacy to submit a claim for reimbursement to TRICARE in the amount of $319.41 for dispensing a prescription of Nexium to TRICARE beneficiary B.T.; and

f. On or about January 25, 2012, SAMUEL WAHBA caused St. George Pharmacy to submit a claim for reimbursement to Medicare Part D in the amount of $103.15 for dispensing a prescription of Plavix to Medicare Part D beneficiary L.O.

All in violation of Title 18, United States Code, Section 371.

FORFEITURE

1. The allegations contained in Count One of this Information are hereby realleged and incorporated by reference for the purpose of alleging forfeiture pursuant to the provisions of Title 18, United States Code, Section 982(a)(7), and Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c).

2. From his engagement in the violations alleged in Count One of this Information, the defendant,

SAMUEL WAHBA,

shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 982(a)(7) any and all right, title, and interest he may have in any property, real or personal, which constitutes or is derived, directly or indirectly, from gross proceeds traceable to such violations and, pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), any property, real or personal, which constitutes or is derived from proceeds traceable to the conspiracy described in Count One of the Information. The property to be forfeited includes, but is not limited to, a forfeiture money judgment in the amount of $5,281,931.00, which represents the amount of proceeds traceable to the conspiracy charged in Count One of the Information.

AO 455 (Rev. 5/85) Waiver of Indictment

13 MAY -2 PM 3:52

FILED

UNITED STATES DISTRICT COURT
FOR THE
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v.

SAMUEL WAHBA

WAIVER OF INDICTMENT

Criminal No. 8:13-CR- 232 + 30 EAJ

I, SAMUEL WAHBA, the above named defendant, who is accused of conspiracy to commit various offenses against the United States, including health care fraud, making false statements to a federal agency, submitting false claims for payment to federal health care programs, and concealing and failing to disclose my exclusion from participation in all Federal health care programs in connection with claims for payment submitted to various Federal health care programs, in violation of 18 U.S.C. § 371, being advised of the nature of the charges, the proposed Information, and of my rights, hereby waive prosecution by Indictment and consent that the proceeding may be by Information rather than by Indictment. Pursuant to Federal Rule of Criminal Procedure 7(b), I will confirm this waiver in open court at arraignment or other hearing.

SAMUEL WAHBA
Defendant

BJORN E. BRUNVAND, ESQ.
Counsel for Defendant

Before _____ 5/23/13
Judicial Officer

September 9, 2013

U.S. Attorney's Office
400 North Tampa Street, Suite 3200
Tampa, Fl. 33602

Subject: Samuel E. Wahba, PS
Social Security Number: XXX-XX-6008
Date of Birth: April 2, 1967
DOH Reference Number: 201307373

Dear Sir or Madam:

The above healthcare practitioner was convicted of a crime in your court that may be related to the practice of Pharmacist in Florida. The Department of Health is required to investigate possible violations of the laws and rules regulating this practitioner's profession.

We need the following information so that the department can review this matter and take appropriate action. Please submit a *certified copy* of:

- the warrant;
- the Bill of Indictment or Information
- the Judgment or Conviction;
- the Arrest Report; and
- any additional public information that may relate to this practitioner's professional practice.

If there is a charge for these certified copies, please send an itemized invoice with your **Federal Employer Identification** number, the amount per page, and the total number of pages.

Pursuant to Section 28.345 F.S. Exemption from court-related fees and charges.- Notwithstanding any other provision of this chapter or law to the contrary, judges and those court staff acting on behalf of judges, state attorneys, guardians ad litem, public guardians, attorney ad litem, court-appointed private counsel, criminal conflict and civil regional counsel, and public defenders, acting in their official capacity, and state agencies, are exempt from all court-related fees and charges assessed by the clerks of the circuit courts.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please call the Consumer Services Unit at (850) 245-4339. In addition, if you have any concerns or suggestions about our complaint process, please fill out our *Customer Concerns or Suggestions* form at www.floridashealth.com/mqa/survey.html.

Sincerely,

Jacquelynn M. Hairston

Please Return This Letter With Your Response.

Jacquelynn M. Hairston
Investigation Specialist II

JMH/tb
DOH-Form205

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Samuel E. Wahba, R.Ph.**
Case Number: 2013-07373

MEMBERS: Meshad and Weizer

DATE OF PCP: **November 7, 2013** **AGENDA ITEM: ESO A-01**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Count I: **Section 465.016(1)(f), Florida Statutes (2012)**

Count II: **Section 465.016(1)(r), Florida Statutes (2012), by violating Section 456.072(1)(ll), Florida Statutes (2012)**

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss

___ **other**

Tony Collins for Michele Weizer 24 Jan 2014
Chair, Probable Cause Panel Date
Board of Pharmacy

FLORIDA DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office:	Date of Complaint:	Case Number:
CONSUMER SERVICES	June 18, 2013	**PH 2013-07373**

SUBJECT:	SOURCE:
SAMUEL E WAHBA, R.PH. 4465 LAVENDER DRIVE PALM HARBOR, FL 34685 HOME PHONE: (727) 787-6382	**DOH CONSUMER SERVICES UNIT** 4052 BALD CYPRESS WAY, BIN C-75 TALLAHASSEE, FL 32399-3275 WORK PHONE: (850) 245-4339

Prefix:	License #:	Profession:	Board:	Report Date:
PH	27213	Registered Pharmacist	Pharmacy	July 2, 2013

Period of Investigation:	Type of Report:
June 27, 2013 through July 2, 2013	FINAL

Possible violation of S.S. 465.016(1)(a)(f)((n)(r), 456.072(1)(b)(c)(h)(k)(m)(dd)(ii)(II), 456.074, F.S...Having been convicted or found guilty; Violating any provision of chapter 465 or chapter 456; Failure to perform legal obligation; Obtaining license through fraud/error; Fraud/deceit in practice of profession; Medicaid Fraud; Failure to report violation/exclusion from Medicaid-Medicare; Mandatory ESO.

Synopsis: This investigation is predicated on the receipt of documentation in the form of a press release by **TBO.COM-THE TAMPA TRIBUNE** and submitted to the **CONSUMER SERVICES UNIT** alleging that on May 3, 2013, **WAHBA** agreed to enter a plea of guilty with conspiracy to commit various offenses against the United States, including: Health care fraud, False statements to a Federal agency, False claims for Payment to Federal Health Care Programs, and concealment and Failure to disclose Exclusion from Federal Health Care Programs in connection with claims for Payment, in violation of 18 U.S.C. s 371. Further review of licensure documentation revealed that **WAHBA** obtained licensure through fraud and failed to report exclusion from Medicaid/Medicare (Ex. #1, Case Summary, and attachments).

WAHBA was notified of this complaint by Certified USPS letter, dated June 27, 2013, to the address of record with the **BOARD OF PHARMACY**, which included a copy of the Case Summary, and documents submitted by the **CONSUMER SERVICES UNIT** (Ex. #2).

DOH computer information obtained July 2, 2013, indicates that **WAHBA** is licensed to practice as a Pharmacist in the State of Florida. **WAHBA's** license is in **Clear/Active** status.

There is no patient involvement; therefore, patient notification was not required.

WAHBA does not appear to be represented by counsel as of the date of this report.

WAHBA has not responded as of this date.

Related Case: **PH 2013-07507**

Investigator/Date:	Approved By/Date:
Jacquelynn M. Hairston 7/2/13 Jacquelynn M. Hairston, HA 132 – July 2, 2013 Investigation Specialist II	Shane Walters Shane Walters, OMC Manager JUL 02 2013

Distribution: Consumer Services Unit / Prosecution Services Unit

RECEIVED-LEGAL
13 JUL -5 AM 8:26

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IV. EXHIBITS

1) Case Summary, and supporting documents .....4 -68

2) Subject Notification Letter, dated June 27, 2013.....69-70

INVESTIGATIVE DETAILS

SUMMARY OF RECORDS

EXHIBIT 1 contains documentation received from **CONSUMER SERVICES UNIT** in the form of a press release by **TBO.COM-THE TAMPA TRIBUNE,** alleging that **WAHBA**, agreed to enter a plea of guilty with conspiracy to commit various offenses against the United States, including: Health care fraud, False statements to a Federal agency, False claims for Payment to Federal Health Care Programs, and concealment and Failure to disclose Exclusion from Federal Health Care Programs in connection with claims for Payment, in violation of 18 U.S.C. s 371. Further review of licensure documentation revealed that **WAHBA** obtained licensure through fraud and failed to report exclusion from Medicaid/Medicare. (Ex. #1, Case Summary, and attachments).

EXHIBIT 2 is a copy of Subject Notification Letter, dated June 27, 2013.

INTERVIEW/STATEMENT OF DEPARTMENT OF HEALTH/CONSUMER SERVICES UNIT–SOURCE:

No additional information has been received by Investigator **HAIRSTON** subsequent to the beginning of this investigation.

INTERVIEW/STATEMENT SAMUEL E. WAHBA, R.PH.

Address of Record (for Subject):

4465 LAVENDER DRIVE
PALM HARBOR, FL 34685
HOME PHONE: (727) 787-6382

SAMUEL E. WAHBA has not submitted a written response to the letter dated June 27, 2013, which served as notification of the allegation that he has been convicted or found guilty of a crime. If a response is received by Investigator **HAIRSTON**, all information will be forwarded to Prosecution Services Unit.

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

June 27, 2013

CONFIDENTIAL
Samuel E. Wahba, PS
4465 Lavender Drive
Palm Harbor, FL 34685

Complaint #: 201307373

Dear Mr. Wahba:

The Consumer Services Unit has received the enclosed complaint against you. We reviewed the complaint or report and determined that you may have violated the practice act that regulates your profession. Therefore, we have opened an investigation into this matter. Please submit a written response to this complaint within 20 days of receipt of this letter.

You may make a written request for a copy of the investigative file. This complaint and all investigative information will remain confidential until 10 days after the probable cause panel has determined that a violation has occurred or you give up the right to confidentiality.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please call the Consumer Services Unit at (850) 245-4339. In addition, if you have any concerns or suggestions about our complaint process, please fill out our *Customer Concerns or Suggestions* form at www.floridashealth.com/mqa/survey.html.

Sincerely,

Jacquelynn M. Hairston
Investigation Specialist II

JMH/tb
Enclosure
CERTIFIED MAIL: 7012 1640 0001 7194 1273

CONFIDENTIAL

DOH-Form300

Florida Department of Health
Division of Medical Quality Assurance• Bureau of Enforcement
4052 Bald Cypress Way, Bin C-75 • Tallahassee, FL 32399-3275
PHONE: (850) 245-4339 • FAX : (850) 488-0796

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7012 1640 0001 7194 1273

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Street, Apt. N or PO Box N
City, State, Z

CONFIDENTIAL
Samuel E. Wahba, PS
4465 Lavender Drive
Palm Harbor, FL 34685
201307373 ha 132

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

CONFIDENTIAL
Samuel E. Wahba, PS
4465 Lavender Drive
Palm Harbor, FL 34685
201307373 ha 132

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) [illegible] C. Date of Delivery 7/8

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

CERTIFIED/RESTRICTED DELIVERY
ADDRESSER ONLY

3. Service Type
☑ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? *(Extra Fee)* ☑ Yes

2. Article Number
(Transfer from service label) 7012 1640 0001 7194 1273

PS Form 3811, February 2004 Domestic Return Receipt

REPORT
EXHIBIT# 2
PAGE# 70

Florida HEALTH

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Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201315021

1ST CHOICE PHARMACY,
RESPONDENT.

NOTICE

TO: 1ST CHOICE PHARMACY
41 E COMMERCIAL BLVD
FT LAUDERDALE, FL 33334

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

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Rick Scott
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John H. Armstrong, MD, FACS
Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel MGW
RE: Voluntary Relinquishment
SUBJECT: DOH v. 1st Choice Pharmacy
DOH Case Number 2013-15021
DATE: December 4, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2013** meeting of the board. The following information is provided in this regard.

Subject:	1st Choice Pharmacy
Subject's Address of Record:	41 E Commercial Blvd Ft Lauderdale, FL 33334
Enforcement Address:	41 E Commercial Blvd Ft Lauderdale, FL 33334
Subject's License No:	24233 **Rank:** PH
Licensure File No:	16958
Initial Licensure Date:	9/3/2009
Board Certification:	No
Required to Appear:	No
Current PRN Contract:	No
Allegation(s):	Waived Probable Cause
Prior Discipline:	None
Probable Cause Panel:	Waived Probable Cause
Subject's Attorney:	Pro Se
Complainant/Address:	DOH/ISU Ft. Lauderdale

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row - Suite 105
PHONE: 850/245-4444 • FAX 850/245-4684

Materials Submitted:

Memorandum to the Board
Motion for Voluntary Relinquishment of License
Voluntary Relinquishment (filed)
Notification Letter
Final Investigative Report
Exhibits 1 thru 5

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-15021**

1st Choice Pharmacy,

Respondent.

_____/

MOTION FOR FINAL ORDER BASED UPON
A VOLUNTARY RELINQUISHMENT OF LICENSE

PETITIONER, the Florida Department of Health, by and through the undersigned counsel, hereby moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore Petitioner states:

1. On or about **October 1, 2013**, a Complaint was filed with the Department of Health, alleging that Respondent violated provisions of Chapter 465 and/or Chapter 456, Florida Statutes.

2. In lieu of undergoing further disciplinary proceedings, Respondent returned an executed Voluntary Relinquishment of License.

3. Respondent has been advised by way of this Motion, that a copy of the investigative file in this case will be furnished to the Board, establishing a prima facie case regarding the violations as set forth in the Complaint.

WHEREFORE, Petitioner respectfully requests that the Board of enter a Final Order accepting the terms of the Voluntary Relinquishment of License.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Matthew G. Witters
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Florida Bar No. **091245**
Telephone: (850) 245-4444, ext. 8172
Facsimile: (850) 245-4683
Email: Matthew.Witters@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 16th day of December, 2013, to: 1st Choice Pharmacy, Attn: Allen Diamond, 41 E. Commercial Boulevard, Ft. Lauderdale, Florida 33334.

Matthew G. Witters
Assistant General Counsel

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Bridget Coates
DATE 11-20-13

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. **CASE NO. 2013-15021**

1ST CHOICE PHARMACY,
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, **1st Choice Pharmacy**, license number **PH 24233**, hereby voluntarily relinquishes its pharmacy permit in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for a pharmacy permit in the State of Florida.

3. Respondent agrees to voluntarily cease operating a pharmacy in the state of Florida immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from operating a pharmacy until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to

otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 17th day of Nov, 2013.

INSTITUTIONAL REPRESENTATIVE FOR
1ST CHOICE PHARMACY
CASE NO. 2013-15021

STATE OF FLORIDA
COUNTY OF Broward

Before me, personally appeared David Carpenter, whose identity is known to me by FL D/L (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 19th day of November, 2013.

SHERRI L. MIMNAGH
Commission # EE 186605
Expires April 4, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

NOTARY PUBLIC

My Commission Expires:

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

December 16, 2013

VIA U.S. MAIL

Attn: Allen Diamond
1st Choice Pharmacy
41 E. Commercial Boulevard
Ft. Lauderdale, Florida 33334

Re: DOH vs. 1st Choice Pharmacy
DOH Case Number: 2013-15021

Dear 1st Choice Pharmacy:

We are in receipt of your executed Voluntary Relinquishment form. As you are aware by signing the Voluntary Relinquishment of License form, you agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against your license, pursuant to Section 456.072(1)(f), Florida Statutes;
- you would never reapply for licensure as a Pharmacy in the State of Florida; and
- Voluntarily relinquishing the Pharmacy's license may have an effect on Pharmacy licenses that you may hold in other states.

If this is not what you understand, please contact me as soon as possible to discuss, at 850-245-4444, ext. 8172. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your request for Voluntary Relinquishment of License at their meeting scheduled for February 5, 2013 in Orlando, Florida 32804. You are not required to attend the meeting.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Fort Lauderdale	Date of Case: 9/23/2013	Case Number: PH 2013-15021

Subject:	Source:
1ST CHOICE PHARMACY 41 East Commercial Blvd Fort Lauderdale, Florida 33334 (954) 332-7885	**DEPARTMENT OF HEALTH/FORT LAUDERDALE ISU**

Prefix:	License #:	Profession:	Board:	Report Date:
2205	24233	Pharmacy	Pharmacy	11/22/2013

Period of Investigation:	Type of Report:
10/9/2013 - 11/22/2013	FINAL

Alleged Violation: SS 465.016 Disciplinary actions (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2): (r) violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto, 465.023 Pharmacy permittee; disciplinary action (1) The department or the board may revoke or suspend the permit of any pharmacy permittee... (c) Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"..., 456.072 Grounds for discipline; penalties; enforcement (1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken (k) Failing to perform any statutory or legal obligation placed upon a licensee... (dd) Violating any provision of this chapter, the applicable practice act, or any rules adopted pursuant thereto, F.S.; Rules 64B16-28.202, 64B16-28.203, F.A.C.; Abandoned Pharmacy; Violate Statute/Rule of Board; Failure to perform legal obligation.

Synopsis: This investigation is predicated upon a complaint (Case Summary & Attachments, Exhibit #1) received from DOH/FORT LAUDERDALE ISU alleging on 9/4/13, an inspection was attempted at 1ST CHOICE PHARMACY (PH 24233) a Community permit pharmacy, located at 41 East Commercial Boulevard, Fort Lauderdale, FL 33331. The pharmacy is located in the same building with South Florida Pain Management Clinic. The premise appeared vacant and it was confirmed that no one had been seen in the pharmacy for weeks. On 9/5/13, a second inspection was attempted and the inspector found the door locked; a call was made to the pharmacy and no one answered. On 9/6/13 and 9/16/13, subsequent attempts were made. It appears that the pharmacy is failing to maintain hours and may have been abandoned.

1ST CHOICE PHARMACY was notified of the investigation by letter dated 10/7/2013 (Exhibit #2), and was provided a copy of the initiating documents. (Exhibit #1).

A check of Department of Health licensure computer records revealed 1ST CHOICE PHARMACY is a licensed Pharmacy since 9/3/2009 with a clear license. (Exhibit #3)

No patients were identified thus patient notification is not required.

1ST CHOICE is not known to be represented by an attorney.

On 11/19/2013 this Investigator met with owner DAVID CARPENTER. CARPENTER signed a Voluntary Relinquishment. (Exhibit #5)

Related Case(s): 2013-15019 & 2013-15018

Investigator/Date: 11/22/2013	Approved By/Date: 11/22/2013
SHERRI MIMNAGH, **Medical Malpractice Investigator LI-102**	**LUIS NIEVES,** **Investigative Supervisor LI-101**

RECEIVED-LEGAL
DEC -2 AM 9:43
Received
Investigative Services
NOV 27 2013
DOH/MQA
Tallahassee HQ

Distribution: HQ/ISU

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***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES.**

**** THESE RECORDS ARE SEALED PURSUANT TO SECTION 456.057(10) (a), FLORIDA STATUTES AND COPIES OF SAME ARE NOT MAINTAINED IN THE FT. LAUDERDALE INVESTIGATIVE OFFICE.**

INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit #1 is the Case Summary and attachments consisting of a statement from MARY CRANE, R.Ph/DOH Senior Pharmacist and a Community Pharmacy inspection form.

CRANE's statement reveals the following in part: 1st CHOICE PHARMACY is located in the same building as SOUTH FLORIDA PAIN MANAGEMENT (PMC 228). CRANE spoke with receptionist of PMC228 who advised that she has not seen anyone in the pharmacy in a couple of weeks. Multiple attempts were made, 9/5/2013 @ 11:34 AM, 9/6/2013 @ 4:30 PM and 9/19/2013 @ 12:25 AM. The posted hours for the pharmacy are 10: AM to 6:00 PM Monday through Friday.

Exhibit #2 is the copy of Subject Notification Letter, dated 10/7/2013.

Exhibit #3 is DOH Licensure Verification for 1ST CHOICE PHARMACY that reveals 1ST CHOICE PHARMACY has been a licensed Pharmacy since 9/3/2009 with a clear license. 1ST CHOICE PHARMACY holds qualifications in Schedule II & III, Community Pharmacy.

Exhibit #4 is a copy of Return Solutions Invoice which indicates that on 10/21/2013 Return Solutions picked up all CII – CV drugs from 1ST CHOICE PHARMACY.

Exhibit #S is the Voluntary Relinquishment signed by 1ST CHOICE PHARMACY owner DAVID CARPENTER on 11/19/2013.

INVESTIGATORS NOTE

The original licenses were received by this Investigator and sent to CMU.

INTERVIEW OF MARY CRANE, R.Ph., SENIOR PHARMACIST, DOH/ISU (WITNESS)

On 10/7/2013 this Investigator interviewed CRANE via telephone. CRANE stated she did not have additional information to add to the initial allegations. CRANE stated that this Investigator would have to contact the owner of the pharmacy because they appear to be closed.

STATEMENT OF DAVID CARPENTER, OWNER OF 1ST CHOICE PHARMACY (SUBJECT)

Residence:
(954) 661-7580

On 10/15/2013 this Investigator spoke with CARPENTER via telephone call. CARPENTER stated he was currently out of town and would be back in approximately one month. CARPENTER stated that they pharmacy had not done any business in more than six months and was having all of the drugs picked up from 1ST CHOICE. CARPENTER stated he would sign the Voluntary Relinquishment and agreed to meet with this Investigator upon his return.

On 11/19/2013 this Investigator and DEA Agent YAYLEENE CALZADA met with CARPENTER and verified there were no drugs on the premises. CARPENTER signed the Voluntary Relinquishment and signed to surrender his DEA number. CARPENTER was in the process of removing all pharmacy signs from the premises.

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

October 7, 2013

CONFIDENTIAL TO:
1st Choice Pharmacy
41 East Commercial Blvd.
Fort Lauderdale, Florida 33334

Case Number: 2013-15021

To Alan Diamond, PDM:

We are currently investigating the enclosed document received by the Department of Health. This investigation was initiated after it was determined that you may have violated your Practice Act.

Within **20 days** of receiving this letter, you may:

- submit a **written response** to the address below; **or**
- call our office to schedule an **interview**.

Please provide a copy of your **curriculum vitae** and identify your **specialty** even if you choose not to submit a response. Include the above-referenced case number in any correspondence that you send.

Florida law requires that this case and all investigative information remain confidential until 10 days after the Probable Cause Panel has determined that a violation occurred or you give up the right to confidentiality. Therefore, the contents of the investigation cannot be disclosed to you or the general public. You may make a written request for a copy of the investigative file and it will be sent to you when the investigation is complete. You may submit an additional written response to the information in the investigative file within 20 days of receipt.

You are not required to answer any questions or give any statement, and you have the right to be represented by an attorney. It is not possible to estimate how long it will take to complete this investigation because the circumstances of each investigation differ.

The mission of the Department of Health is to protect and promote the health of all residents and visitors in the state through organized state and community efforts, including cooperative agreements with counties. If you have any questions please call us at (954) 267-4533. In addition, if you have any concerns or suggestions about our complaint process, please fill-out our *Customer Concerns or Suggestions* form at www.floridashealth.com/mqa/survey.html.

CONFIDENTIAL

Sincerely,
Sherri L. Mimnagh, MMI
Medical Quality Assurance Investigator

Enclosure

EXHIBIT # 2

9

License Verification

Data As Of **10/7/2013**

1ST CHOICE PHARMACY

LICENSE NUMBER: **PH24233**

Profession
PHARMACY

License/Activity Status
CLEAR/

Qualifications
Schedule II & III
Community Pharmacy

Doing Business As Name
1ST CHOICE PHARMACY

License Expiration Date
2/28/2015

License Original Issue Date
09/03/2009

Discipline on File
NO

Public Complaint
NO

Address of Record
41 E COMMERCIAL BLVD
FORT LAUDERDALE, FL 33334

The information on this page is a secure, primary source for license verification provided by The Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

CONFIDENTIAL

EXHIBIT # 3

10

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. **CASE NO. 2013-15021**

1ST CHOICE PHARMACY,
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, **1st Choice Pharmacy**, license number **PH 24233**, hereby voluntarily relinquishes its pharmacy permit in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for a pharmacy permit in the State of Florida.

CONFIDENTIAL

3. Respondent agrees to voluntarily cease operating a pharmacy in the state of Florida immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from operating a pharmacy until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to

otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 17th day of Nov, 2013.

INSTITUTIONAL REPRESENTATIVE FOR
1ST CHOICE PHARMACY
CASE NO. 2013-15021

STATE OF FLORIDA
COUNTY OF Broward

Before me, personally appeared David Carpenter, whose identity is known to me by FL D/L (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 19th day of November, 2013.

NOTARY PUBLIC

My Commission Expires:

AC#5402368

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
03/02/2013	PH 24233	73831

The **PHARMACY** named below has met all requirements of the laws and rules of the state of Florida.
Expiration Date: **FEBRUARY 28, 2015**
1ST CHOICE PHARMACY
1ST CHOICE PHARMACY
41 E COMMERCIAL BLVD
FORT LAUDERDALE, FL 33334

QUALIFICATION(S):
SCHEDULE II & III
COMMUNITY PHARMACY
2:1 PHARMACY TECHNICIAN RATIO APPROVED

Rick Scott
GOVERNOR

John H. Armstrong, MD, FACS
STATE SURGEON GENERAL

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

AC# 5402368

DATE	LICENSE NO.	CONTROL NO.
03/02/2013	PH 24233	73831

The PHARMACY named below has met all requirements of the laws and rules of the state of Florida.
Expiration Date: FEBRUARY 28, 2015
1ST CHOICE PHARMACY

LICENSEE SIGNATURE

QUALIFICATION(S):
Schedule II & III
Community Pharmacy
2:1 Pharmacy Technician Ratio Approved

Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201315019

1ST CHOICE PHARMACY,
RESPONDENT.

NOTICE

TO: 1ST CHOICE PHARMACY
41 E COMMERCIAL BLVD
FT LAUDERDALE, FL 33334

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

Mission:
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Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. 1st Choice Pharmacy
DOH Case Number 2013-15019
DATE: December 4, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2013** meeting of the board. The following information is provided in this regard.

Subject:	1st Choice Pharmacy
Subject's Address of Record:	41 E Commercial Blvd Ft Lauderdale, FL 33334
Enforcement Address:	41 E Commercial Blvd Ft Lauderdale, FL 33334
Subject's License No:	25895 **Rank:** PH
Licensure File No:	18865
Initial Licensure Date:	1/11/2012
Board Certification:	No
Required to Appear:	No
Current PRN Contract:	No
Allegation(s):	Waived Probable Cause
Prior Discipline:	None
Probable Cause Panel:	Waived Probable Cause
Subject's Attorney:	Pro Se
Complainant/Address:	DOH/ISU Ft. Lauderdale

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row - Suite 105
PHONE: 850/245-4444 • FAX 850/245-4684

Materials Submitted:

Memorandum to the Board
Motion for Voluntary Relinquishment of License
Voluntary Relinquishment (filed)
Notification Letter
Final Investigative Report
Exhibits 1 thru 5

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-15019**

1st Choice Pharmacy,

Respondent.
_____/

MOTION FOR FINAL ORDER BASED UPON
A VOLUNTARY RELINQUISHMENT OF LICENSE

PETITIONER, the Florida Department of Health, by and through the undersigned counsel, hereby moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore Petitioner states:

1. On or about **October 1, 2013**, a Complaint was filed with the Department of Health, alleging that Respondent violated provisions of Chapter 465 and/or Chapter 456, Florida Statutes.

2. In lieu of undergoing further disciplinary proceedings, Respondent returned an executed Voluntary Relinquishment of License.

3. Respondent has been advised by way of this Motion, that a copy of the investigative file in this case will be furnished to the Board, establishing a prima facie case regarding the violations as set forth in the Complaint.

WHEREFORE, Petitioner respectfully requests that the Board of enter a Final Order accepting the terms of the Voluntary Relinquishment of License.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Matthew G. Witters
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Florida Bar No. **091245**
Telephone: (850) 245-4444, ext. 8172
Facsimile: (850) 245-4683
Email: Matthew.Witters@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 16th day of December, 2013, to: 1st Choice Pharmacy, Attn: Allen Diamond, 41 E. Commercial Boulevard, Ft. Lauderdale, Florida 33334.

Matthew G. Witters
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Bridget Coates
DATE 11-20-13

DEPARTMENT OF HEALTH,
Petitioner,

v. **CASE NO. 2013-15019**

1ST CHOICE PHARMACY,
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, **1st Choice Pharmacy**, license number **PH 25895**, hereby voluntarily relinquishes its pharmacy permit in the State of Florida and states as follows:

1. Respondent's purpose - in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for a pharmacy permit in the State of Florida.

3. Respondent agrees to voluntarily cease operating a pharmacy in the state of Florida immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from operating a pharmacy until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes.

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DATED this 15 day of Nov, 2013.

INSTITUTIONAL REPRESENTATIVE FOR
1ST CHOICE PHARMACY
CASE NO. 2013-15021

STATE OF FLORIDA
COUNTY OF Broward

Before me, personally appeared David Carpenter, whose identity is known to me by FL D/L (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 19th day of November, 2013.

SHERRI L MIMNAGH
Commission # EE 186605
Expires April 4, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

NOTARY PUBLIC

My Commission Expires:

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

December 16, 2013

VIA U.S. MAIL

Attn: Allen Diamond
1st Choice Pharmacy
41 E. Commercial Boulevard
Ft. Lauderdale, Florida 33334

Re: DOH vs. 1st Choice Pharmacy
DOH Case Number: 2013-15019

Dear 1st Choice Pharmacy:

We are in receipt of your executed Voluntary Relinquishment form. As you are aware by signing the Voluntary Relinquishment of License form, you agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against your license, pursuant to Section 456.072(1)(f), Florida Statutes;
- you would never reapply for licensure as a Pharmacy in the State of Florida; and
- Voluntarily relinquishing the Pharmacy's license may have an effect on Pharmacy licenses that you may hold in other states..

If this is not what you understand, please contact me as soon as possible to discuss, at 850-245-4444, ext. 8172. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your request for Voluntary Relinquishment of License at their meeting scheduled for February 12, 2013 in Orlando, Florida 32804. You are not required to attend the meeting.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Fort Lauderdale	Date of Case: 9/23/2013	Case Number: PH 2013-15019

Subject:	Source:
1ST CHOICE PHARMACY 41 East Commercial Blvd Fort Lauderdale, Florida 33334 (954) 332-7885	**DEPARTMENT OF HEALTH/FORT LAUDERDALE ISU**

Prefix:	License #:	Profession:	Board:	Report Date:
2205	25895	Pharmacy	Pharmacy	11/22/2013

Period of Investigation:	Type of Report:
10/9/2013 - 11/22/2013	FINAL

Alleged Violation: SS 465.016 Disciplinary actions (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2): (r) Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto, 465.023 Pharmacy permittee; disciplinary action (1) The department or the board may revoke or suspend the permit of any pharmacy permittee... (c) Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"..., 456.072 Grounds for discipline; penalties; enforcement (1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken (k) Failing to perform any statutory or legal obligation placed upon a licensee... (dd) violating any provision of this chapter, the applicable practice act, or any rules adopted pursuant thereto, F.S.; Rules 64B16-28.202, 64B16-28.203, F.A.C.; Abandoned Pharmacy; Violate Statute/Rule of Board; Failure to perform legal obligation.

Synopsis: This investigation is predicated upon a complaint (Case Summary & Attachments, Exhibit #1) received from DOH/FORT LAUDERDALE ISU alleging on 9/4/13, an inspection was attempted at 1ST CHOICE PHARMACY (PH 25895) a special closed permit pharmacy, located at 41 East Commercial Boulevard, Fort Lauderdale, FL 33331. The pharmacy is located in the same building with South Florida Pain Management Clinic. The premise appeared vacant and it was confirmed that no one had been seen in the pharmacy for weeks. On 9/5/13, a second inspection was attempted and the inspector found the door locked; a call was made to the pharmacy and no one answered. On 9/6/13 and 9/16/13, subsequent attempts were made. It appears that the pharmacy is failing to maintain hours and may have been abandoned.

1ST CHOICE PHARMACY was notified of the investigation by letter dated 10/7/2013 (Exhibit #2), and was provided a copy of the initiating documents. (Exhibit #1).

A check of Department of Health licensure computer records revealed 1ST CHOICE PHARMACY is a licensed Pharmacy since 1/11/2012 with a clear license. (Exhibit #3)

No patients were identified thus patient notification is not required.

1ST CHOICE is not known to be represented by an attorney.

On 11/19/2013 this Investigator met with owner DAVID CARPENTER. CARPENTER signed a Voluntary Relinquishment. (Exhibit #5)

RECEIVED-LEGAL
13 DEC 2 AM 8:43

Related Case(s): 2013-15021 & 2013-15018

Investigator/Date: 11/22/2013	Approved By/Date: 11/22/2013
SHERRI MIMNAGH, **Medical Malpractice Investigator LI-102**	**LUIS NIEVES,** **Investigative Supervisor LI-101**

Received
Investigative Services
NOV 27 2013

Distribution: HQ/ISU

DOH/MQA
Tallahassee HQ

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***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES.**

**** THESE RECORDS ARE SEALED PURSUANT TO SECTION 456.057(10) (a), FLORIDA STATUTES AND COPIES OF SAME ARE NOT MAINTAINED IN THE FT. LAUDERDALE INVESTIGATIVE OFFICE.**

INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit #1 is the Case Summary and attachments consisting of a statement from MARY CRANE, R.Ph/DOH Senior Pharmacist and a Community Pharmacy inspection form.

CRANE's statement reveals the following in part: 1st CHOICE PHARMACY is located in the same building as SOUTH FLORIDA PAIN MANAGEMENT (PMC 228). CRANE spoke with receptionist of PMC228 who advised that she has not seen anyone in the pharmacy in a couple of weeks. Multiple attempts were made, 9/5/2013 @ 11:34 AM, 9/6/2013 @ 4:30 PM and 9/19/2013 @ 12:25 AM. The posted hours for the pharmacy are 10: AM to 6:00 PM Monday through Friday.

Exhibit #2 is the copy of Subject Notification Letter, dated 10/7/2013.

Exhibit #3 is DOH Licensure Verification for 1ST CHOICE PHARMACY that reveals 1ST CHOICE PHARMACY has been a licensed Pharmacy since 1/11/2012 with a clear license. 1ST CHOICE PHARMACY holds qualifications as a Special Closed System.

Exhibit #4 is a copy of Return Solutions Invoice which indicates that on 10/21/2013 Return Solutions picked up all CII – CV drugs from 1ST CHOICE PHARMACY.

Exhibit #5 is the Voluntary Relinquishment signed by 1ST CHOICE PHARMACY owner DAVID CARPENTER on 11/19/2013.

INVESTIGATORS NOTE

The original licenses were received by this Investigator and sent to CMU.

INTERVIEW OF MARY CRANE, R.Ph., SENIOR PHARMACIST, DOH/ISU (WITNESS)

On 10/7/2013 this Investigator interviewed CRANE via telephone. CRANE stated she did not have additional information to add to the initial allegations. CRANE stated that this Investigator would have to contact the owner of the pharmacy because they appear to be closed.

STATEMENT OF DAVID CARPENTER, OWNER OF 1ST CHOICE PHARMACY (SUBJECT)

Residence:
(954) 661-7580

On 10/15/2013 this Investigator spoke with CARPENTER via telephone call. CARPENTER stated he was currently out of town and would be back in approximately one month. CARPENTER stated that they pharmacy had not done any business in more than six months and was having all of the drugs picked up from 1ST CHOICE. CARPENTER stated he would sign the Voluntary Relinquishment and agreed to meet with this Investigator upon his return.

On 11/19/2013 this Investigator and DEA Agent YAYLEENE CALZADA met with CARPENTER and verified there were no drugs on the premises. CARPENTER signed the Voluntary Relinquishment and signed to surrender his DEA number. CARPENTER was in the process of removing all pharmacy signs from the premises.

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

October 7, 2013

CONFIDENTIAL TO:
1st Choice Pharmacy
41 East Commercial Blvd.
Fort Lauderdale, Florida 33334

Case Number: 2013-15019

To Alan Diamond, PDM:

We are currently investigating the enclosed document received by the Department of Health. This investigation was initiated after it was determined that you may have violated your Practice Act.

Within **20 days** of receiving this letter, you may:

- submit a **written response** to the address below; **or**
- call our office to schedule an **interview**.

Please provide a copy of your **curriculum vitae** and identify your **specialty** even if you choose not to submit a response. Include the above-referenced case number in any correspondence that you send.

Florida law requires that this case and all investigative information remain confidential until 10 days after the Probable Cause Panel has determined that a violation occurred or you give up the right to confidentiality. Therefore, the contents of the investigation cannot be disclosed to you or the general public. You may make a written request for a copy of the investigative file and it will be sent to you when the investigation is complete. You may submit an additional written response to the information in the investigative file within 20 days of receipt.

You are not required to answer any questions or give any statement, and you have the right to be represented by an attorney. It is not possible to estimate how long it will take to complete this investigation because the circumstances of each investigation differ.

The mission of the Department of Health is to protect and promote the health of all residents and visitors in the state through organized state and community efforts, including cooperative agreements with counties. If you have any questions please call us at (954) 267-4533. In addition, if you have any concerns or suggestions about our complaint process, please fill-out our *Customer Concerns or Suggestions* form at www.floridashealth.com/mqa/survey.html.

Sincerely,
Sherri L. Mimnagh, MMI
Medical Quality Assurance Investigator

CONFIDENTIAL

Enclosure

EXHIBIT # 2

9

License Verification

Data As Of **10/7/2013**

1ST CHOICE PHARMACY
LICENSE NUMBER: **PH25895**

Profession
PHARMACY

License/Activity Status
CLEAR/

Qualifications
Special Closed System

Doing Business As Name
1ST CHOICE PHARMACY

License Expiration Date
2/28/2015

License Original Issue Date
01/11/2012

Discipline on File
NO

Public Complaint
NO

Address of Record
41 E COMMERCIAL BLVD
FT LAUDERDALE, FL 33334

The information on this page is a secure, primary source for license verification provided by The Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

CONFIDENTIAL

EXHIBIT # 3

10

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. **CASE NO. 2013-15019**

1ST CHOICE PHARMACY,
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, **1st Choice Pharmacy**, license number **PH 25895**, hereby voluntarily relinquishes its pharmacy permit in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for a pharmacy permit in the State of Florida.

CONFIDENTIAL

3. Respondent agrees to voluntarily cease operating a pharmacy in the state of Florida immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from operating a pharmacy until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to

otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 15 day of Nov, 2013.

INSTITUTIONAL REPRESENTATIVE FOR
1ST CHOICE PHARMACY
CASE NO. 2013-15021

STATE OF FLORIDA
COUNTY OF Broward

Before me, personally appeared David Carpenter, whose identity is known to me by FL D/L (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 19th day of November, 2013.

NOTARY PUBLIC

My Commission Expires:

AC#5402369

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
03/02/2013	PH 25895	73832

The **PHARMACY** named below has met all requirements of the laws and rules of the state of Florida.
Expiration Date: **FEBRUARY 28, 2015**
1ST CHOICE PHARMACY
1ST CHOICE PHARMACY
41 E COMMERCIAL BLVD
FT LAUDERDALE, FL 33334

QUALIFICATION(S):
SPECIAL CLOSED SYSTEM

Rick Scott
GOVERNOR

John H. Armstrong, MD, FACS
STATE SURGEON GENERAL

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA AC# 5402369
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
03/02/2013	PH 25895	73832

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Expiration Date: **FEBRUARY 28, 2015**
1ST CHOICE PHARMACY

LICENSEE SIGNATURE

QUALIFICATION(S):
Special Closed System

HEALTH

Rick Scott
Governor

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201313537

LEYVA CORALIA PEREZ,
RESPONDENT.

NOTICE

TO: LEYVA CORALIA PEREZ
7750 SW 19 STREET
MIAMI, FL 33155

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201313537

LEYVA CORALIA PEREZ,
RESPONDENT.

NOTICE

TO: ARNALDO SURI
10631 NORTH KENDALL DRIVE, STE 150
MIAMI, FL 33176-1559

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

Mission:
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Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel (MW) CRC
RE: Voluntary Relinquishment
SUBJECT: DOH v. Leyva Coralia Perez, P.S.I.
DOH Case Number 2013-13537
DATE: December 16, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Leyva Coralia Perez, P.S.I.
Subject's Address of Record:	7750 SW 19th Street Miami, FL 33155
Enforcement Address:	7750 SW 19th Street Miami, FL 33155
Subject's License No:	21750 **Rank:** PSI
Licensure File No:	9502
Initial Licensure Date:	11/13/2006
Board Certification:	No
Required to Appear:	No
Current PRN Contract:	No
Allegation(s):	Waived Probable Cause
Prior Discipline:	None
Probable Cause Panel:	Waived Probable Cause

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row - Suite 105
PHONE: 850/245-4444 • FAX 850/245-4684

Subject's Attorney:	Arnaldo Suri, Esquire Suite 150 10631 North Kendall Drive Miami, Florida 33176-1559
Complainant/Address:	DOH/CSU/Media
Materials Submitted:	Memorandum to the Board Motion for Voluntary Relinquishment Voluntary Relinquishment – filed Attorney Notification Letter Final Investigative Report Exhibits 1 thru 4

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-13537**

Leyva Coralia Perez, P.S.I.,

Respondent.
_____/

MOTION FOR FINAL ORDER BASED UPON
A VOLUNTARY RELINQUISHMENT OF LICENSE

PETITIONER, the Florida Department of Health, by and through the undersigned counsel, hereby moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore Petitioner states:

1. On or about **August 26, 2013**, a Complaint was filed with the Department of Health, alleging that Respondent violated provisions of Chapter 465 and/or Chapter 456, Florida Statutes.

2. In lieu of undergoing further disciplinary proceedings, Respondent returned an executed Voluntary Relinquishment of License.

3. Respondent has been advised by way of this Motion, that a copy of the investigative file in this case will be furnished to the Board, establishing a prima facie case regarding the violations as set forth in the Complaint.

WHEREFORE, Petitioner respectfully requests that the Board of enter a Final Order accepting the terms of the Voluntary Relinquishment of License.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Matthew G. Witters
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Florida Bar No. **091245**
Telephone: (850) 245-4444, ext. 8172
Facsimile: (850) 245-4683
Email: Matthew.Witters@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 17th day of December, 2013, to: Coralia Leyva Perez, 7750 S.W. 19th Street, Miami, Florida 33155.

Matthew G. Witters
Assistant General Counsel

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE DEC 0 5 2013

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO: 2013-13537**

CORALIA LEYVA PEREZ, P.S.I.,

Respondent.

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, **CORALIA LEYVA PEREZ, P.S.I.**, license No. **PSI 21750,** hereby voluntarily relinquishes Respondent's license to practice as a pharmacist intern in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for licensure as a pharmacist intern in the State of Florida.

12/05/2013 15:02 305-596-4515 JUAN DE J GONZALEZ PAGE 01/04

3. Respondent agrees to voluntarily cease practicing as a pharmacist intern immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from the practicing as a pharmacist intern until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes

12/05/2013 15:02 305-596-4515 JUAN DE J GONZALEZ PAGE 02/04

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the Board does not accept the terms of this Voluntary Relinquishment.

12/05/2013 15:02 305-596-4515 JUAN DE J GONZALEZ PAGE 03/04

DATED this 3rd day of December, year of 2013.

Coralia Leyva Perez, P.S.I.

STATE OF Florida

COUNTY OF Miami-Dade

Before me, personally appeared Coralia Leyva Perez, whose identity is personally known to me or by producing _____ (type of identification) as identification and who acknowledges that her signature appears above.
Sworn to or affirmed by Respondent before me this 3rd day of December, 2013.

My Commission Expires

JUAN DE JESUS GONZALEZ
Notary Public - State of Florida
My Comm. Expires Dec 4, 2015
Commission # EE 128164
Bonded Through National Notary Assn.

NOTARY PUBLIC - STATE OF Florida

Juan de Jesus Gonzalez
Type or Print Notary

12/05/2013 15:02 305-596-4515 JUAN DE J GONZALEZ PAGE 04/04

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

December 17, 2013

VIA U.S. MAIL

Arnaldo Suri, Esquire
Suite 150
10631 North Kendall Drive
Miami, Florida 33176-1559

Re: DOH vs. Coralia Leyva Perez, PSI
DOH Case Number: 2013-13537

Dear Mr. Suri:

We are in receipt of your client's executed Voluntary Relinquishment form. As you are aware by signing the Voluntary Relinquishment of License form, your client agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against your license, pursuant to Section 456.072(1)(f), Florida Statutes;
- you would never reapply for licensure as a Pharmacist in the State of Florida; and
- Voluntarily relinquishing the Pharmacist license may have an effect on Pharmacy licenses that you may hold in other states.

If this is not what you understand, please contact me as soon as possible to discuss, at 850-245-4444, ext. 8172. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your request for Voluntary Relinquishment of License at their meeting scheduled for February 12, 2013 in Orlando, Florida. You are not required to attend the meeting.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

C

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: MIAMI AREA XI	Date of Case: : 08/27/2013		Case Number: PI- 2013-13537	
Subject: **CORALIA LEYVA PEREZ** 7750 SW 19th St Miami, Florida 33155			Source: **DOH- MIAMI-ISU**	
Prefix: 2202	License #:21750	Profession: Pharmacist Intern	Board: Pharmacy	Report Date:11/12/2013
Period of Investigation 08/27/2013-11/12/28/2013			Type of Report: FINAL	

Alleged Violation:456.072(1)(a)(k)(l)(m)(dd) F.S.; (pharmacy) 465.016(1)(j)(r) F.S.
Violation of law/rule; Failure to perform legal obligation; False/misleading representation; Filing a false report; Fraudulent representation;

Synopsis This investigation is predicated upon receipt of a Complaint (Case Summary and Attachments **Exhibit 1**:) an Internally generated complaint states that Miamiherald.com reports that CORALIA PEREZ was arrested on charges of defrauding Medicaid of nearly $600,000. PEREZ is the owner of Patient Pharmacy & Infusion at 5321 W 20th Avenue, where she allegedly submitted fraudulent invoices to the Agency for Health Care Administration to make it appear that the pharmacy had dispensed the correct amount of medications for which they had billed the Medicaid program.

PEREZ was notified of the investigation by letter, dated 08/27/2013 **(Exhibit #2)** and was provided a copy of the case summary and initiating documents **(Exhibit #1).**

A search of the DOH licensure database reveals that CORILIA PEREZ is currently licensed as a Pharmacist Intern.

No patients were identified, thus patient notification are not required.

CORALIA PEREZ is not currently represented by an attorney.

PEREZ has neither admitted or denied the allegations.

Related Case(s):

Investigator/Date: 11/12/2013 George Mulero, MMI-209	Approved By/Date: 11/12/2013 11/14/13 Edward Thompson, Investigative Manager Mi-204

Distribution: HQ/ISU

Received Investigative Services NOV 18 2013 DOH/MQA Tallahassee HQ

INV FORM 300, created 07/02

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3. Copy of Arrest Report and Arrest Affidavit, dated 08/21/2013 8-15
4. Letter and original license from Pharmacy Technician dated 09/13/2013 16-17

INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit #1: Case Summary and Initiating Documents.

Exhibit #2: Copy of Subject notification letter, dated 08/27/2013.

Exhibit #3: Copy of Arrest Report and Arrest affidavit, dated 08/21/2013.

Exhibit #4: Letter and original license which was surrendered by the Pharmacy technician on 09/13/2013.

INVESTIGATOR'S NOTE

On Tuesday, August 27, 2013, this investigator contacted the Miami field office of the Attorney General Medicaid Fraud Control Bureau and obtained a copy of both the ARREST REPORT & ARREST AFFIDAVIT.This investigator did leave a message at the contact phone number for COROLIA PEREZ and there was no return call. The arresting officer in this case was not available for interview at this time. Contact with the Miami-Dade Corrections Department has revealed that PEREZ has bonded out of the County Jail. Several visits were made to the residence of record of the subject, and multiple telephone calls were made as well, messages were provided and no responses were ever returned. On September 13, 2013, this investigator was the recipient of a letter which was signed from CORALIA LEYVA PEREZ which contained her original license and where she expressed that she had not worked in the pharmacy field since March 30, 2012 and had no further intentions of working in the pharmacy industry.

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

August 27, 2013

CONFIDENTIAL TO:

Coralia Perez
7750 SW 19th St
Miami FL 33155

Case Number: 2013-13537

Dear Ms. Perez:

We are currently investigating a case received by the Department of Health. The allegation, if substantiated, would be a violation of (See Attachments).

Within **20 days** of receiving this letter, you may:

- submit a **written response** to the address below; **or**
- call our office to schedule an **interview**.

Please provide a copy of your **resume** and identify the **address of your current employer**, even if you chose not to submit a response. This information, your response (if one is provided) and any other information gathered during the investigation will be considered by the Probable Cause Panel when determining whether a formal administrative complaint should be filed in this matter. Include the above-referenced case number in any correspondence you send.

Florida law requires that this case and all investigative information remain confidential until 10 days after the panel has determined that a violation occurred or you give up the right to confidentiality. Therefore, the contents of the investigation cannot be disclosed to you or the general public.

You are not required to answer any questions or give any statement, and you have the right to be represented by an attorney. It is not possible to estimate how long it will take to complete this investigation because the circumstances of each investigation differ.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county and community efforts. If you have any questions, please callus at (305) 470-5894.

Sincerely,

CONFIDENTIAL

George Mulero, CFE
Medical Malpractice investigator

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Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201112057

JEFFREY ALAN SUSSMAN,
RESPONDENT.

NOTICE

TO: JEFFREY ALAN SUSSMAN
5859 NW 56TH CT
CORAL SPRINGS, FL 33067-2730

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

HEALTH

Mission:
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Vision: To be the **Healthiest State** in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. Jeffrey Alan Sussman, R.Ph.
DOH Case Number 2011-12057
DATE: December 4, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Jeffrey Alan Sussman, R.Ph.
Subject's Address of Record:	5859 NW 56th Court Coral Springs, FL 33067-2730
Enforcement Address:	5859 NW 56th Court Coral Springs, FL 33067-2730
Subject's License No:	18577 **Rank:** PS
Licensure File No:	8148
Initial Licensure Date:	11/6/1980
Board Certification:	No
Required to Appear:	No
Current PRN Contract:	No
Allegation(s):	Section 456.016(1)(i), Florida Statutes (2010-2011)
Prior Discipline:	4013, DOH-02-0032-S
Probable Cause Panel:	April 24, 2012 Risch & Mullins
Subject's Attorney:	Pro Se
Complainant/Address:	Department Of Health/Consumer Services Unit

Materials Submitted:

Memorandum to the Board
Voluntary Relinquishment – filed
Scrivener's Error for Voluntary Relinquishment
Board Notification Letter

Materials Previously Submitted to 04-03-13 Board as Settlement

Memorandum to the Board
Settlement Agreement
    Exhibit A – Administrative Complaint
Board Notification Letter
Election of Rights
Cost Summary Report
Defense Documents
Prosecution Documents
Supplemental Report dated 08-23-11
Supplemental Report dated 08-10-11
Supplemental Report dated 08-04-11
PCP Memorandum
Final Investigative Report
    Exhibits 1 thru 5

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE DEC 0 2 2013

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO: 2011-12057**

JEFFEREY ALAN SUSSMAN, R.Ph.,

Respondent.

_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, **JEFFEREY ALAN SUSSMAN, R.Ph.**, license No. **PS 18577,** hereby voluntarily relinquishes Respondent's license to practice as a registered pharmacist in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for licensure as a registered pharmacist in the State of Florida.

3. Respondent agrees to voluntarily cease practicing as a registered pharmacist immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from the practicing as a registered pharmacist until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the Board does not accept the terms of this Voluntary Relinquishment.

DATED this 26 day of November, year of 2013.

Jeffrey Alan Sussman

Jeffrey ~~Allan~~ Alan Sussman, R.Ph.

STATE OF Florida

COUNTY OF Broward

Before me, personally appeared Jeffrey Alan Sussman, whose identity is personally known to me or by producing FL Drivers License (type of identification) as identification and who acknowledges that her signature appears above.
Sworn to or affirmed by Respondent before me this 26th day of November, 2013.

ROGER S. MCCOY
Commission # EE 160013
Expires January 21, 2015
Bonded Thru Troy Fain Insurance 800-385-7019

My Commission Expires

NOTARY PUBLIC - STATE OF

Roger S McCoy

Type or Print Notary

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE DEC 18 2013

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

CASE NO. 2011-12057

JEFFREY ALAN SUSSMAN, R.Ph.,

RESPONDENT.

_____/

NOTICE OF SCRIVENER'S ERROR

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Notice of Scrivener's Error, and as grounds therefore states:

1. On or about December 2, 2013, the Agency Clerk filed a voluntary relinquishment form for the Respondent.

2. Due to a clerical error, the header of the filed voluntary relinquishment lists the Respondent's name as "JEFFERY ALAN SUSSMAN, R.Ph."

3. The header of the voluntary relinquishment should list the Respondent's name as "JEFFREY ALAN SUSSMAN, R.Ph."

4. The voluntary relinquishment is changed to reflect the proper spelling of the Respondent's first name.

5. The first paragraph on page one of the voluntary relinquishment form lists the Respondent's name as "JEFFERY ALAN SUSSMAN, R.Ph."

6. The first paragraph on page one of the voluntary relinquishment form should list the Respondent's name as "JEFFREY ALAN SUSSMAN, R.Ph."

7. The correction of this error is of no prejudice to Mr. Sussman and makes no substantive change to the voluntary relinquishment.

8. This Notice shall take effect upon its filing with the Clerk of the Department.

WHEREFORE, Petitioner requests that the voluntary relinquishment filed against the License of Jeffrey Alan Sussman, R.Ph., to be amended to reflect these corrections as detailed above.

John H. Armstrong, MD, FACS
State Surgeon and
Secretary of Health

Matthew G. Witters
Assistant General Counsel
Fla. Bar No. 0091245
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: matthew.witters@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Notice of Scrivener's Error has been provided by U.S. mail this 18 day of December, 2013, to Jeffrey Alan Sussman, R.Ph., at 5859 N.W. 56th Court, Coral Springs, Florida 33067.

MATTHEW G. WITTERS
Assistant General Counsel

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

December 18, 2013

VIA U.S. MAIL

Jeffrey Alan Sussman, R.Ph.
5859 Northwest 56th Court
Coral Springs, Florida 33067-2730

Re: DOH vs. Jeffrey Alan Sussman, R.Ph.
DOH Case Number: 2011-12057

Dear Mr. Sussman:

We are in receipt of your client's executed Voluntary Relinquishment form. As you are aware by signing the Voluntary Relinquishment of License form, your client agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against your license, pursuant to Section 456.072(1)(f), Florida Statutes;
- you would never reapply for licensure as a Pharmacist in the State of Florida; and
- Voluntarily relinquishing the Pharmacist license may have an effect on Pharmacy licenses that you may hold in other states.

If this is not what you understand, please contact me as soon as possible to discuss, at 850-245-4444, ext. 8172. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your request for Voluntary Relinquishment of License at their meeting scheduled for February 12, 2013 in Orlando, Florida. You are not required to attend the meeting.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2011-12057**

JEFFREY ALAN SUSSMAN, R.PH.,

RESPONDENT.

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaints, attached as Composite Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Jeffrey Alan Sussman, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 18577. Respondent's mailing address of record is 5859 Northwest 56th Court, Coral Springs, Florida 33067-2730.

2. Respondent was charged by Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaints, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent, Jeffrey Alan Sussman, R.Ph., shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND SEVEN HUNDRED DOLLARS** ($2,700.00). Total costs shall be assessed when the

Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within three years from the date the Final Order is filed with the Department Clerk.

3. **Evaluation and Treatment-** Respondent shall contact the Professional Resource Network (PRN), submit to an evaluation, and comply with all treatment requirements imposed by any contract with PRN.

4. **Probation-** Respondent shall be placed on 1 year probation. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. Respondent shall not function as a prescription department manager in any Florida permitted pharmacy during the probation;

b. Respondent shall not work at or for more than 2 pharmacies during each quarter of the probationary period, unless Respondent obtains prior written approval from the Board;

c. During the period of Respondent's probation, the Department shall conduct semi-annual audits of 5 randomly selected controlled substances at the Respondent's place of employment at Respondent's cost;

d. Respodent shall submit written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall include Respondent's license number, current address, and phone number; current name, address, and phone number of each pharmacy in which Respondent is engaged in the practice of pharmacy; the names of all pharmacists, pharmacy interns, pharmacy technicians, relief pharmacists, and prescription department managers working with Respondent. These reports shall be submitted to the Compliance Officer every 3 months in a manner as directed by the compliance officer;

e. Respondent shall ensure that his employer submits written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance

Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall contain the name, address, license number, and phone number of each pharmacy intern, pharmacy technician, relief pharmacist, and prescription department manager working in the prescription department where Respondent practices, and provide a brief description of Respondent's duties, responsibilities, and working schedule. These reports shall be submitted to the Compliance Officer every 3 months in a manner as directed by the compliance officer;

f. Respondent shall comply with any and all recommendations from PRN;

g. Respondent shall make a mandatory appearance before the Board of Pharmacy during his last year of probation; and

h. Respondent may petition the Board of Pharmacy for early termination of probation after six months.

5. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that

the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses**- Respondent shall keep current his/its mailing address and his/its practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the

Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 19th day of December, 2012.

JEFFREY ALAN SUSSMAN, R.PH.
Case 2011-12057

STATE OF Florida }
COUNTY OF Broward }

Before me personally appeared Jeffrey Alan Sussman, R.PH., whose identity is known to me or by Jeffrey Alan Sussman (type of identification), and who, under oath, acknowledges that his signature appears above. Sworn to and subscribed before me this 19th day of December, 2012.

Notary Public
My Commission Expires: October 06, 2014

MELANIE MAYONE
MY COMMISSION #EE32828
EXPIRES: OCT 06, 2014
Bonded through 1st State Insurance

APPROVED this 11th day of January, 2013.

JOHN H. ARMSTRONG, MD
Surgeon General and Secretary of Health

JOHN J. TRUITT
Assistant General Counsel
Fla. Bar No. 0084752
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683
Email: john_truitt@doh.state.fl.us

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2011-12057**

JEFFREY ALAN SUSSMAN, R.Ph.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Jeffrey Alan Sussman, R.Ph., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 18577.

EXHIBIT
A

3. Respondent's address of record is 5859 Northwest 56th Court, Coral Springs, Florida 33067-2730.

4. At all times material to this Administrative Complaint, Respondent was employed as a pharmacist at CVS Pharmacy, store number 3652, located in Parkland, Florida.

5. CVS Pharmacy loss prevention staff conducted an internal investigation after noting inventory discrepancies that coordinated with Respondent's employment times.

6. On or about July 22, 2011, Respondent signed a statement admitting to taking approximately one-thousand (1,000) Vicoprofen 7.5/200 pills from the CVS pharmacy inventory without permission.

7. Vicoprofen 7.5/200 pills contain a combination of hydrocodone and ibuprofen.

8. According to Section 893.03(3), Florida Statutes, hydrocodone, in the dosages found in Vicoprofin is a Schedule III controlled substance that has a potential for abuse less than the substances in Schedules I and II and has a currently accepted medical use in treatment in the United States. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

9. Respondent did not have a prescription for Vicoprofen on file with CVS pharmacy.

10. Respondent did not have permission or authorization to take Vicoprofen from the stock at the CVS pharmacy for his own personal use.

11. Section 465.016(1)(i), Florida Statutes (2010-2011), provides that compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy, constitutes grounds for disciplinary action by the Board of Pharmacy.

12. As set forth above, Respondent admitted to dispensing or distributing approximately one-thousand tablets of a controlled substance to himself from the stock of his employer without authorization or permission, which is not in the course of the professional practice of pharmacy.

13. Based upon the foregoing, Respondent violated Section 465.016(1)(i), Florida Statutes (2010-2011), by compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties:

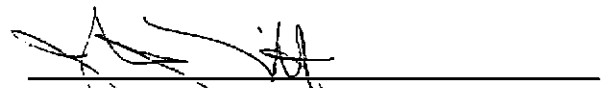
permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 24th **day of** April, **2012.**

STEVEN L. HARRIS, M.D., M.Sc.
Interim State Surgeon General
Florida Department of Health

NICHOLAS W. ROMANELLO
General Counsel
Florida Department of Health

WM. FREEMAN MILLER
Attorney Supervisor
Prosecution Services Unit



JOHN J. TRUITT
Assistant General Counsel
Fla. Bar No. 0084752
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683
Email: john_truitt@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE APR 2 4 2012

PCP: 4/24/2012
PCP Members: Mullins + Risch

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

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Complaint Cost Summary

Complaint Number: 201112057

Subject's Name: SUSSMAN, JEFFREY ALAN

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.10	$5.76
Investigation:	15.50	$1,051.09
Legal:	8.40	$884.71
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	24.00	$1,941.56
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,941.56

(-$884.71) Minus Legal fees

$1,056.85

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MEMORANDUM OF FINDING OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **DOH v. Jeffrey Alan Sussman, R.Ph.**
DOH Case Number 2011-12057

MEMBERS: Lorena Risch, Chair and DeAnn Mullins, BPharm

DATE OF PCP: **April 24, 2012** **AGENDA ITEM: A-3**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative report, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1)(i), Florida Statutes (2010-2011)

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **Other** _____

Lorena M. Risch 4-27-12
Chair, Probable Cause Panel Date
Board of Pharmacy

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Fort Lauderdale	Date of Complaint: 07/28/2011	Complaint Number: PS 2011-12057

Subject: **JEFFREY ALAN SUSSMAN, R.PH.** 5859 NW 56th Ct Coral Springs, FL 33067 (954) 288-8960	Source: **DOH/MQA/CONSUMER SERVICES UNIT**

Prefix: PS	License #:18577	Profession: 2201 Pharmacist	Board: Board of Pharmacy	Report Date: 08/04/2011

Period of Investigation: 07/29/2011 thru 08/04/2011	Type of Report: FINAL

Alleged Violation: F.S. 456.072(1)(b)(m)(z) Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or scheme in or related to the practice of a profession. Being unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. F.S. 465.016(1)(d)2.3.(e)(m)(r), Being unfit or incompetent to practice pharmacy by reason of: 1.Habitual intoxication, 2. The misuse or abuse of any medicinal drug appearing in any schedule set forth in chapter 893, 3. Any abnormal physical or mental condition which threatens the safety of persons to whom she or he might sell or dispense prescriptions, drugs, or medical supplies or for whom she or he might manufacture, prepare, or package, or supervise the manufacturing, preparation, or packaging of, prescriptions, drugs, or medical supplies. Violating chapter 499; 21 U.S.C. ss. 301-392.. Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. A pharmacist affected under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate that she or he can resume the competent practice of pharmacy with reasonable skill and safety to her or his customers. Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto F.S.893.13(6)(a)(7)(a)9 It is unlawful for any person to be in actual or constructive possession of a controlled substance unless such controlled substance was lawfully obtained from a practitioner or pursuant to a valid prescription or order of a practitioner while acting in the course of his or her professional practice or to be in actual or constructive possession of a controlled substance except as otherwise authorized by this chapter. Any person who violates this provision commits a felony of the third degree. It is unlawful for any person to acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.

Synopsis This investigation is predicated upon receipt of a complaint (Case Summary and Attachments, Exhibit #1) from DOH/CSU stating that on 7/28/11 CVS Store #3652 (PH 20291) located at 7621 North State Road 7, Parkland, FL suspended, pending termination of SUSSMAN for drug diversion. The Case Summary alleges that SUSSMAN may be incompetent to practice pharmacy.

SUSSMAN was notified of the investigation via letter from Investigator TRACE WINGATE, dated July 29, 2011 (Exhibit #2). The letter was hand-delivered by Investigator AUDREY PAUL-ROYALE on that date.

A review of the DOH COMPAS licensure report reveals that SUSSMAN is licensed as a Pharmacist, and has been such since 11/06/1980. The license is Clear and Active (Exhibit #3).

No patients were identified in this complaint.

SUSSMAN is not known to be represented by an attorney.

As of this date, SUSSMAN has not responded to the allegations.

Related Complaint: None

Investigator/Date: August 4, 2011 TRACY GLEN WINGATE, Medical Malpractice Investigator LI-97	Approved By/Date: August 4, 2011 PATRICIA A. CALLAHAN, Investigation Manager LI-96

Distribution: HQ/ISU

Received
Investigative Services
AUG 0 8
DOH/MQA

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INVESTIGATIVE DETAILS

SUMMARY OF RECORDS/EXHIBITS/DOCUMENTS:

Exhibit #1 is the Case Summary and attachments, received via email from CSU July 29, 2011, consisting of the following:

Email string, originating with RICHARD MAZZONI, RPH, Director of Regulatory Compliance for CVS CAREMARK, to MARK WHITTEN on July 27, 2011, stating that SUSSMAN (PS18577) was suspended pending termination for diversion of +/- 1000 dosage units of hydrocodone products. MAZZONI stated that SUSSMAN was the Pharmacist-in-Charge (PIC) at Store 3652 in Parkland, FL. MAZZONI stated that a written admission and video evidence is available upon request.

Exhibit #2 is the subject letter of notification to SUSSMAN, dated July 29, 2011, from Investigator Wingate.

Exhibit #3 is the COMPAS licensure printout, revealing SUSSMAN is licensed as a Pharmacist and has been such since November 6, 1980. The license is Clear and Active, but there has been discipline.

Exhibit #4 is a copy of the statement written and signed by SUSSMAN during the Loss Prevention investigation of July 22, 2011.

Review of the statement reveals that SUSSMAN stated:

> "I took handfuls of generic Vicoprofen adding up to around 10 bottles to handle a severe medical condition of psoriatic arthritis. The pain was unbearable on my 13 hour days and I needed relief."

SUSSMAN stated that he had been taking handfuls of generic Vicoprofen (7.5 mg Hydrocodone/ 200mg Ibuprofen) since December 2010, and had taken about 1000 doses without payment or authorization.

SUSSMAN stated he was sorry and promised to pay CVS back the loss, and hoped that he could continue as PIC of Store 3652.

Exhibit #5 is a copy of a Promissory Note signed by SUSSMAN on July 22, 2011, promising to make restitution in the amount of $996.99 to CVS.

INTEVIEWS/STATEMENTS

INTERVIEW OF RICHARD MAZZONI, R.PH. (SOURCE)

National Director of Regulatory Compliance
CVS Caremark
Phoenix, AZ
(401) 665-8321
Cell (602) 501-9388
Fax (401) 216-0064

On August 2, 2011, Investigator WINGATE interviewed RICHARD MAZZONI by telephone. MAZZONI stated that as the National Director of Regulatory Compliance, he is responsible for reporting violations to the proper regulatory agencies, but that he is just the conduit of information and is not directly involved in the investigation. MAZZONI stated that SUSSMAN was caught on surveillance video removing about 1036 tablets of hydrocodone from the pharmacy counter. MAZZONI stated that SUSSMAN later admitted, in writing, to removing the medication and to consuming it throughout the day. MAZZONI stated that there should be no problem making the surveillance video and the written admission available to this Investigator, if this Investigator would send him an email request which would be forwarded to the proper personnel. MAZZONI also provided the name of STEPHANIE ROUSE, the Regional Manager, who would have more information on the details of the incident.

INVESTIGATOR'S NOTE:

According to ADALBERT MARTINEZ, the Regional Loss Prevention Manager for CVS Region 62, the video evidence mentioned by MAZZONI and again, by ROUSE, only showed SUSSMAN ordering the generic vicoprofen from the vendor and did not reveal any explicit activity that would have resulted in criminal prosecution (see Interview of ADALBERT MARTINEZ, CFI, below).

INTERVIEW OF STEPHANIE ROUSE (WITNESS)

Regional Pharmacy Intern Coordinator, Region 62
CVS
7284 Garden Road, Suite 117
Riviera Beach, FL 33404
(561) 841-5288

On August 2, 2011, Investigator WINGATE conducted a phone interview with ROUSE. ROUSE stated she was a witness during the investigation of SUSSMAN for drug diversion. ROUSE stated the investigation began when the Loss Prevention Dept began noticed

inventory discrepancies that coordinated with SUSSMAN's shifts at CVS Store 3652. ROUSE stated that Loss Prevention set up camera surveillance in the pharmacy and monitored it during SUSSMAN's shifts. ROUSE stated that there is video footage of SUSSMAN taking handfuls of hydrocodone/ibuprofen and leaving the pharmacy for long periods of time during his shift. The video footage was reviewed on July 22, 2011 and SUSSMAN was brought in for questioning by Loss Prevention. ROUSE stated SUSSMAN at first denied the allegation that he was diverting but when confronted with the video evidence, he admitted to taking about ten pills per day for horrible back pain he was experiencing. ROUSE denied any complaint about SUSSMAN's behavior or performance prior to the incident, except that co-workers noted that he would leave the pharmacy often during his shift and be gone a little longer than average. ROUSE denied any incidents of misfills or mistakes in filling prescriptions on the part of SUSSMAN. ROUSE stated SUSSMAN, after making a written admission and a promise to make restitution, was terminated from CVS employment on July 26, 2011.

In a follow-up email from ROUSE received by Investigator WINGATE on August 4, 2011, ROUSE stated that the Broward Sheriff's Office was notified of SUSSMAN's actions on July 27, 2011 via a faxed initial notification form and was followed by an official DEA Form 106 on August 3, 2011. ROUSE also stated that SUSSMAN was offered the CVS Employee Assistance Program to help him find a physician to treat his medical condition and with substance abuse counseling. ROUSE stated that SUSSMAN accepted help in finding a physician for his medical condition, but refused substance abuse counseling on the grounds that SUSSMAN stated that he did not have an addition problem.

INTERVIEW OF ADALBERT MARTINEZ, CFI (WITNESS)

Regional Loss Prevention Manager
CVS
3300 N 28th Terrace
Hollywood, FL 33020
(954) 649-2452

On August 3, 2011, Investigator WINGATE conducted a phone interview with MARTINEZ. MARTINEZ stated that the investigation into SUSSMAN was begun when Loss Prevention noted an abnormally large amount of generic Vicoprofen being ordered at Store 3652. MARTINEZ stated that several orders for the medication, each requesting multiple bottles, had been placed to the vendor, while prescription logs indicated that only two (2) or three (3) patients were using that particular medication. MARTINEZ stated he reviewed video footage from the pharmacy and determined that SUSSMAN was the one placing the order for Vicoprofen. MARTINEZ stated he did not have any video footage of SUSSMAN actually taking handfuls of the medication or using the medication, or else he would have alerted law enforcement immediately. MARTINEZ stated he did not have SUSSMAN under any special surveillance and that the video footage is circumstantial at best, merely confirming that

SUSSMAN was ordering the Vicoprofen. MARTINEZ stated that this evidence was just enough to justify conducting an interview with SUSSMAN. MARTINEZ stated that SUSSMAN at first denied the allegations, but later admitted to taking occasional handfuls of generic Vicoprofen for a severe back pain he was having. MARTINEZ stated when confronted with the fact that there were about 17 bottles unaccounted for in the inventory since December, SUSSMAN admitted that he didn't realize that he had been taking that much medication. MARTINEZ stated SUSSMAN admitted to self-medicating for pain, but had no valid reason why he wasn't getting prescriptions through a physician. MARTINEZ stated he took SUSSMAN's written statement, which was signed by SUSSMAN and witnessed by MARTINEZ and ROUSE. MARTINEZ stated SUSSMAN, except for this incident, had behaved in a very professional manner, and had been with CVS around ten (10) years.

INVESTIGATOR'S NOTES:

On July 29, 2011, Investigator WINGATE received the forwarded email documents related to this case and drafted a letter of notification to SUSSMAN (Exhibit #2). Investigator WINGATE contacted SUSSMAN to ensure that he was home. The letter was hand-delivered to SUSSMAN at his home around 4:30 p.m. by Investigator AUDREY PAUL-ROYALE.

On August 1, 2011, the case file was received via FEDEX. Investigator WINGATE contacted MAZZONI, however MAZZONI was unable to take the call due to a meeting at the time and promised to call back.

On August 2, 2011, Investigator WINGATE again contacted MAZZONI for the Interview. MAZZONI gave this Investigator contact information for ROUSE. Investigator WINGATE sent an email to MAZZONI requesting copies of the written admission and the surveillance video footage. Investigator WINGATE then contacted ROUSE for the interview.

Also on August 2, 2011, Investigator WINGATE was contacted by SUSSMAN who stated he wanted to come in for an interview. Investigator WINGATE tried to get SUSSMAN to come in that afternoon, but SUSSMAN stated that he would have to get back to this Investigator. Investigator WINGATE also offered SUSSMAN to come in on August 3, 2011. SUSSMAN did not call back.

On August 3, 2011, Investigator WINGATE received an email from MARTINEZ with attached documents consisting of copies of the written admission (Exhibit #4) and a promissory note signed by SUSSMAN (Exhibit #5). Investigator WINGATE contacted MARTINEZ by phone for the interview.

Also on August 3, 2011, Investigator WINGATE contacted SUSSMAN by phone to try to again convince him to come in for an interview. SUSSMAN declined, stating he was going to hire an attorney to handle the matter.

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HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307508

SANFORD D DUCKMAN,
RESPONDENT.

NOTICE

TO: SANFORD D DUCKMAN
9320 WATER COURSE WAY
BOYNTON BCH, FL 33437

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Hearing - No Disputed Material Facts

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Jodi-Ann V. Johnson, Assistant General Counsel
RE: Hearing - No Disputed Material Facts
SUBJECT: DOH v. Sanford D. Duckman, R.Ph.
DOH Case Number 2013-07508
DATE: December 3, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Sanford D. Duckman, R.Ph.
Subject's Address of Record:	9320 Water Course Way Boynton Bch, FL 33437
Enforcement Address:	9320 Water Course Way Boynton Bch, FL 33437
Subject's License No:	27319 **Rank:** PS
Licensure File No:	16355
Initial Licensure Date:	3/17/1992
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Count I: Section 456.072(1)(k), F.S.(2012) Count II: Section 456.072(1)(k), F.S.(2012) Count III: Section 465.072(1)(k), F.S.(2012) Count IV: Section 456.072(1)(k), F.S.(2012)
Prior Discipline:	None
Probable Cause Panel:	September 5, 2013 Glass and Mesaros
Subject's Attorney:	Pro Se
Complainant/Address:	Department of Health/Investigative Services Unit-Jupiter
Materials Submitted:	Memorandum to the Board

Motion For Hearing Not Involving Disputed Issues of Material Fact for Final Order
Administrative Complaint
Motion to Assess Costs
    Exhibit A – Affidavit of Fees and Costs Expended
    Exhibit 1 – Complaint Cost summary
    Exhibit 2 – Itemized Cost by complaint
Board Notification Letter
Election of Rights
Respondent's Document
PCP Memo
Final Investigative Report
    Exhibits 1-5

Disciplinary Guidelines: **Min:** $2,000 fine
Max: revocation

PRELIMINARY CASE REMARKS:

Respondent was the Prescription Department Manager (PDM) of Franako Pharmacy. On or about April 30, 2013, a Department inspector conducted an inspection of Franako Pharmacy. On or about April 30, 2013, the Department's inspector noted several deficiencies:

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-07508**

SANFORD D. DUCKMAN, R.PH.,

Respondent.
_____/

MOTION FOR FINAL ORDER AFTER HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACTS

PETITIONER, the Florida Department of Health, by and through the undersigned counsel, hereby moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore Petitioner states:

1. Petitioner previously filed an Administrative Complaint against Respondent alleging that Respondent had violated the provisions of Florida Statutes, as set forth therein. Petitioner, by filing the Administrative Complaint, is seeking to discipline Respondent's license to practice nursing, thereby affecting Respondent's substantial interests.

2. On or about September 14, 2013, Petitioner served Respondent with the Administrative Complaint via certified mail, at 9320 Water Course Way, Boynton Beach, Florida 33437. By serving Respondent with the Administrative Complaint, provided Respondent written notice of its decision to seek discipline of the Respondent's license to practice as a Pharmacist.

3. Respondent has filed an Election of Rights Form or other responsive pleading evincing, or has otherwise indicated, that Respondent does not dispute the material facts alleged in the Administrative Complaint.

4. There are no disputed issues of material fact to be resolved by the Board.

5. Respondent has been advised by way of this Motion, that a copy of the investigative file in this case will be furnished to the Board, establishing a prima facie case regarding the violations as set forth in the Complaint.

WHEREFORE, Petitioner respectfully requests that the Board of Nursing, after allowing Respondent the opportunity to present oral and/or written evidence in mitigation of the Administrative Complaint, enter a Final

Order imposing whatever discipline upon Respondent's license that the Board deems appropriate.

Respectfully Submitted,

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Jodi-Ann V. Johnson
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar #0073525
(850) 245-4444 telephone
(850) 245-4683 facsimile

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 4th day of December, 2013, to: Sanford D. Duckman, R.Ph., 9320 Watercourse Way, Boynton Beach, Florida 33437.

Jodi-Ann V. Johnson
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-07508**

SANFORD D. DUCKMAN, R.PH.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through its undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, Sanford D. Duckman, R.Ph., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a licensed pharmacist within the State of Florida, having been issued license number PS 27319.

3. Respondent's address of record is 9320 Water Course Way, Boynton Beach, Florida 33437.

4. At all times material to this Administrative Complaint, Respondent was the Prescription Department Manager (PDM) of Franako Pharmacy (the Permittee) located at 400 South Dixie Highway, Suite 17, Lake Worth, Florida 33460.

5. On or about April 30, 2013, a Department inspector conducted an inspection of Franako Pharmacy.

6. On or about April 30, 2013, the Department's inspector noted the following deficiencies:

a. Pharmacy hours not posted in violation of Rule 64B16-28.1081, Florida Administrative Code;

b. Expired medications found in active stock in violation of Rule 64B16-28.110, Florida Administrative Code;

c. Daily logs missing pharmacists' signatures in violation of Rule 64B16-28.140(3)(d), Florida Administrative Code; and/or

d. Compounding logs not properly maintained in violation of Rule 64B16-28.140(4), Florida Administrative Code.

COUNT ONE

7. Petitioner realleges and incorporates paragraph one (1) through six (6), as if fully set forth herein.

8. Section 456.072(1)(k), Florida Statutes (2012), subjects a licensee to disciplinary action for failing to perform any statutory or legal obligation placed upon a licensee.

9. Section 465.022(11)(a), Florida Statutes (2012), provides, in pertinent part, that the prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

10. Rule 64B16-28.1081, Florida Administrative Code, provides, in pertinent part, that a sign in block letters not less than one inch in height stating the hours the prescription department is open each day shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view.

11. As set forth above, Respondent, as the prescription department manager, failed to ensure the permittee's compliance with the rule

requiring the pharmacy hours to be posted, as required by Rule 64B16-28.1081, Florida Administrative Code.

12. Based on the foregoing, Respondent has violated Section 456.072(1)(k), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes (2012), by failing to ensure a sign in block letters not less than one inch in height stating the hours the prescription department is open each day was displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view, as required by Rule 64B16-28.1081, Florida Administrative Code.

COUNT TWO

13. Petitioner realleges and incorporates paragraph one (1) through six (6), as if fully set forth herein.

14. Section 456.072(1)(k), Florida Statutes (2012), subjects a licensee to disciplinary action for failing to perform any statutory or legal obligation placed upon a licensee.

15. Section 465.022(11)(a), Florida Statutes (2012), provides, in pertinent part, that the prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they

relate to the practice of the profession of pharmacy and the sale of prescription drugs.

16. Rule 64B16-28.140(4), Florida Administrative Code, sets forth the requirements for maintaining a written record for each batch/sub-batch of a compounded product under the provisions of Rule 64B16-27.700, F.A.C.

17. As set forth above, Respondent, as the prescription department manager, failed to ensure the permittee's compliance with Rule 64B16-28.140(4), Florida Administrative Code, by failing to properly maintain a written record of the compounded products when the records failed to note the lot numbers, the expiration dates, and the registered pharmacist's certification.

18. Based on the foregoing, Respondent has violated Section 456.072(1)(k), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes (2012), by failing to ensure that the written record for each batch/sub-batch of a compounded product under Rule 64B16-27.700, F.A.C. included all the required information, as required by Rule 64B16-28.140(4), Florida Administrative Code.

COUNT THREE

19. Petitioner realleges and incorporates paragraph one (1) through six (6), as if fully set forth herein.

20. Section 456.072(1)(k), Florida Statutes (2012), subjects a licensee to disciplinary action for failing to perform any statutory or legal obligation placed upon a licensee.

21. Section 465.022(11)(a), Florida Statutes (2012), provides, in pertinent part, that the prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

22. Rule 64B16-28.140(3)(d), Florida Administrative Code, provides that each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document within seven days from the date of dispensing.

23. As set forth above, Respondent, as the prescription department manager, failed to ensure the permittee's compliance with Rule 64B16-28.140(3)(d), Florida Administrative Code, by failing to properly maintain a

daily log when permittee's daily logs were missing the pharmacists' signatures.

24. Based on the foregoing, Respondent has violated Section 456.072(1)(k), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes (2012), by failing to ensure that each individual pharmacist who dispenses or refills a prescription drug order verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document within seven days from the date of dispensing, as required by Rule 64B16-28.140(3)(d), Florida Administrative Code.

COUNT FOUR

25. Petitioner realleges and incorporates paragraph one (1) through six (6), as if fully set forth herein.

26. Section 456.072(1)(k), Florida Statutes (2012), subjects a licensee to disciplinary action for failing to perform any statutory or legal obligation placed upon a licensee.

27. Section 465.022(11)(a), Florida Statutes (2012), provides, in pertinent part, that the prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they

relate to the practice of the profession of pharmacy and the sale of prescription drugs.

28. Rule 64B16-28.110, Florida Administrative Code, states persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.

29. As set forth above, Respondent, as the prescription department manager, failed to ensure the permittee's compliance with the rule requiring removal of deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which has been reached from the stock, as required by Rule 64B16-28.110, Florida Administrative Code..

30. Based on the foregoing, Respondent has violated Section 456.072(1)(k), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes (2012), by failing to ensure that deteriorated pharmaceuticals, or pharmaceuticals which bear upon the

container an expiration date which date has been reached were removed from stock, as required by Rule 64B16-28.110, Florida Administrative Code.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 5th **day of** September**, 2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Vemisha Foster
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Florida Bar # 0092743
Telephone: (850) 245-4444
Facsimile: (850) 245-4683

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE SEP 0 5 2013

/VF
PCP: September 5, 2013
PCP Members: Glass and Mesaros

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-07508**

SANFORD D. DUCKMAN, R.PH.,

Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW, the Department of Health, by and through the undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or after July 1, 2001, pursuant to this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. . . .

3. The investigation and prosecution of this case has resulted in costs in the total amount of $560.86, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.10	$60.39
Investigation:	3.50	$223.93
Legal:	2.60	$276.54
Compliance:	0.00	0.00
Sub Total:	7.20	$560.86
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$560.86

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $284.32 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $284.32 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $284.32.

DATED this 4th day of December, 2013.

Respectfully Submitted,

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Jodi-Ann V. Johnson
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar #0073525
(850) 245-4444 telephone
(850) 245-4683 facsimile

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 4th day of December, 2013, to: Sanford D. Duckman, R.Ph., 9320 Watercourse Way, Boynton Beach, Florida 33437.

Jodi-Ann V. Johnson
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME; the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2013-07508** (Department of Health v. **SANFORD D. DUCKMAN, R.PH.**) are **FIVE HUNDRED SIXTY DOLLARS AND EIGHTY-SIX CENTS ($560.86).**

6) The costs for DOH case numbers **2013-07508**(Department of Health v. **SANFORD D. DUCKMAN, R.PH.**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case numbers **2013-07508** (Department of Health v. **SANFORD D. DUCKMAN, R.PH.**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to

EXHIBIT
tabbies
A

keep track of their time in six-minute increments (e.g., investigators and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of her knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 8 day of October, 2013, by Shane Walters, who is personally known to me.

Notary Signature

Antoinette Carter

Name of Notary Printed

ANTOINETTE F. CARTER
MY COMMISSION EXPIRES
September 26, 2015
#EE 132192
Bonded thru Troy Fain Insurance
NOTARY PUBLIC, STATE OF FLORIDA

Stamp Commissioned Name of Notary Public:

Complaint Cost Summary

Complaint Number: 201307508

Subject's Name: DUCKMAN, SANFORD D

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	1.10	$60.39
Investigation:	3.50	$223.93
Legal:	2.60	$276.54
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	7.20	$560.86
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$560.86

EXHIBIT
1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201307508

Report Date 10/07/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA23	0.50	$54.90	$27.45	05/10/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HA115	0.60	$54.90	$32.94	05/13/2013	2	OFFICE SUPERVISORY DUTIES
Sub Total	**1.10**		**$60.39**			
INVESTIGATIVE SERVICES UNIT						
WI108	1.10	$63.98	$70.38	05/17/2013	4	ROUTINE INVESTIGATIVE WORK
WI108	1.30	$63.98	$83.17	06/18/2013	76	REPORT PREPARATION
WI108	1.10	$63.98	$70.38	06/20/2013	76	REPORT PREPARATION
Sub Total	**3.50**		**$223.93**			
PROSECUTION SERVICES UNIT						
HLL92A	0.50	$106.35	$53.18	07/08/2013	25	REVIEW CASE FILE
HLL92A	0.90	$106.35	$95.72	07/09/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL92A	0.10	$106.35	$10.64	07/09/2013	29	REVIEW ADMINISTRATIVE COMPLAINT
HLL92A	0.20	$106.35	$21.27	07/09/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL92A	0.10	$106.35	$10.64	09/05/2013	68	SIGNING CLOSING ORDERS, ADMINISTRATIVE COMPLAINTS AND REASONAB
HLL92A	0.70	$106.35	$74.45	09/10/2013	79	STIPULATION
HLL79A	0.10	$106.35	$10.64	09/30/2013	25	REVIEW CASE FILE
Sub Total	**2.60**		**$276.54**			

Total Cost **$560.86**

EXHIBIT
2

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201307508

Report Date 10/07/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description

Division of
Medical Quality Assurance

MQA

*** C O N F I D E N T I A L ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 10/07/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description
	SubTotal			
	Total Expenses			

December 4, 2013

VIA U. S. MAIL

Sanford D. Duckman, R.PH.
9320 Watercourse Way
Boynton Beach, Florida 33437

Re: DOH vs. Sanford D. Duckman, R.PH.
DOH Case Number: 2013-07508

Dear Mr. Duckman:

I am in receipt of your election of rights requesting a hearing not involving disputed issues of material fact executed by you on September 29, 2013 concerning the above referenced case. This means that the facts alleged in the Administrative Complaint are uncontested. This is an important distinction because, by law, the Board cannot resolve disputes of material fact in this case or any disciplinary case. Since you are requesting a hearing not involving disputed issues of material fact, you are not admitting the facts alleged in the Administrative Complaint, however, you are agreeing not to contest these facts and to limit presentation to legal argument, if any, and to matters in mitigation or extenuation.

Our office is now preparing this case to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for February 5, 2014, at the Doubletree by Hilton, 60 S. Ivanhoe Boulevard, Orlando, Florida 32804. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank you for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Jodi-Ann V. Johnson
Assistant General Counsel

JAVJ/pb

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

DEPARTMENT OF HEALTH CASE # 2013-07508

TO WHOM IT MAY CONCERN:

I AM A 72 YEAR OLD PHARMACIST, WHO HAS BEEN LICENSED FOR OVER 47 YEARS WITH NO VIOLATION. I AM LIVING ON SOCIAL SECURITY AND CAN'T AFFORD TO RETAIN AN ATTORNEY OR ATTEND THE VIOLATION MEETING. I WAS THE PHARMACY MANAGER AT FRANAKO PHARMACY WHEN THE STORE WAS INSPECTED. I VISITED THE STORE AT LEAST 1-2 TIMES A WEEK, CHECKING FOR VIOLATIONS.

THE VIOLATIONS WERE:

1. PROPER PHARMACY HOURS SIGN NOT VISIBLE

I MADE SURE THE PHARMACY HOURS SIGN WAS VISIBLE...ONE OF THE VITAMIN VENDORS HAD POST THEIR SIGN AND IT OBSURE OUR SIGN...THE SIGN WAS IMMEDIATELY REMOVED AND PHARMACY SIGN IS NOW FULLY VISIBLE. **ALL VENDORS HAVE BEEN ADVISED AND EDUCATED ON THE IMPORTANCE OF THE PHARMACY SIGN...PHARMACIST MUST ENDORSE ALL DISPLAYS OF SIGNS BY VENDORS.**

2. EXPIRED MEDICATION FOUND IN ACTIVE STOCK

THE PHARMACY HAS A COLOR CODING SYSTEM TO IDENTIFY SOON – TO-EXPIRED MEDICATION ON THE SHELVES, THERE APPEARS TO HAVE BEEN SOME MISCOMMUNICATION AMONG THE STAFF. ALL EXPIRED MEDICATION WAS TO BE PULLED FROM THE SHELVES AND ALL SOON-TO-EXPIRED MEDICATION WAS TO BE COLOR CODED. INSTEAD ALL THE SOON TO EXPIRE AND EXPIRED WERE COLOR CODED BUT NOT TAKEN OFF THE SHELVES, AS WAS THE CASE OF THE INSPECTION OF APRIL 30, 2013.

REVISED TO TAG AND INCLUDE MEDICATION 4 MONTHS BEFORE EXPIRATION. ALL EXPIRED MEDICATION HAVE BEEN REMOVED FROM THE ACTIVE STOCK AND SCHEDULED FOR SHIPMENT THROUGH THIRD PARTY VENDOR.

3. CERTIFIED DAILY LOG OR PRINT OUT NOT MAINTAINED

EVERY PHARMACIST WORKING AT FRANAKO PHARMACY IS REQUIRED TO SIGN INTO THE PHARMACY OPERATING SYSTEM ON A DAILY BASIS. THE PROCESS ALLOWS THE SYSTEM TO CAPTURE AND KEEP A COMPREHENSIVE RECORD OF ALL ATTENDING PHARMACISTS. A REPORT CAN BE GENERATED FOR ANY POINT OF TIME FOR THE ATTENDING PHARMACIST. **MORE PROMPTS HAVE BEEN ADDED TO OUR OPEN/CLOSING PROCEDURE TO REMIND THE STAFF TO SIGN IN/OUT OF THE DAILY LOG.**

4. COMPOUNDING RECORDS NO PROPERLY MAINTAINED

THE PHARMACY MAINTAINS A COMPOUNDING LOG FOR ALL COMPOUNDED PRESCRIPTIONS. A COUPLE OF SIGNATURES WERE MISSING FROM THE PREVIOUS LOG.

ALL COMPOUNDED PRESCRIPTIONS HAVE BEEN TRANSCRIBED AND ALL SIGNATURES ARE IN PLACE. A NEW MODIFIED LOG IS NOW BEING USED.

I WOULD APPRECIATE YOUR PROMPT ATTENTION TO THIS MATTER.

THANK YOU FOR YOUR CO-OPERATION

SANFORD DUCKMAN

PS27319 FLORIDA LICENSE

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: **Department of Health, Prosecution Services Unit**

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Sanford D. Duckman, R.Ph. (VF)**
Case Number: 2013-07508

MEMBERS: **Cy~~nthia Griffin~~ Glass, PharmD and Jeffrey Mesaros**

DATE OF PCP: **September 5, 2013** **AGENDA ITEM: A-7**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 456.072(1)(k), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes (2012);

Section 456.072(1)(k), Florida Statutes (2012) by violating Section 465.022(11)(a), Florida Statutes (2012), by failing to ensure that the written record for each batch/sub-batch of a compounded product under Rule 64B16.27.700, Florida Administrative Code, included all the required information, as required by Rule 64B16.28.140(4), Florida Administrative Code;

Section 465.072(1)(k), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes (2012);

Section 456.072(1)(k), Florida Statutes (2012), by violating Sectioin 465.022(11)(a), Florida Statutes (2012);

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss

____ **other**

9/5/13

Chair, Probable Cause Panel
Board of Pharmacy

Date

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

File # 18526

Insp # 115783

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
FRANAKO PHARMACY INC	25600	6/15/2012
DOING BUSINESS AS	DEA NUMBER	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS: 400 SOUTH DIXIE HWY SUITE 17	TELEPHONE #: 561-588-0707 / EXT.	SANFORD D DUCKMAN
CITY: LAKE WORTH / COUNTY: 60	STATE/ZIP: 33460	PRESCRIPTION DEPARTMENT MANAGER LICENSE #: 27319

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1. Kwame Kyermaten-Afrani	PS35409
Open	8	8	8	8	on cal	on cal	8	2. Bruce Greenbarg	PS32836
Close	8	8	8	12	on cal	on cal	12	3.	

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2	Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]		X		
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			X	
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			X	
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			X	
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]			X	
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]		X		
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15	All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]			X	
19	DEA 222 order forms properly completed. [893.07, F.S.]		X		
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]				X
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]			X	
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			X	
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]			X	
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]		X		
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]			X	
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]			X	
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]		X		
28	Compounding records properly maintained. [64B16-28.140(4), F.A.C.]*		X		
29	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]		X		
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]		X		

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: Re inspection conducted with relief RPH Bruce Greenbarg PS32836 (provided by staffing agency Healthcare Consultants)
Upon entering RPh Greenbarg was not properly identified. Advised that RPH name tags must be worn during working hours.
#4: Pharmacy hours posted were posted in standard hours. (Note: Friday hours posted indicate "on Call". Re inspection was conducted on Friday. Pharmacy was open. Licenses were visible to the public
#7: Upon entering Temperature was posted at 70 degrees.
#11: CQI minutes for 9/5/11, 1/5/12 and 4/9/12 were seen and copies taken.
#19: DEA 222 completed forms were not available. Per RPh Greenbarg they are stored in controlled substance safe which was not accessible at time of inspection.
#22: Daily logs were completed and copies from 1/2/12 to 6/14/12 were taken.

#20:A controlled substance movement report from 4/6/12 to 6/15/12 was requested and provided for scheduled II-V.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Bruce Greenbarg RPh

Bruce Greenbarg

Institutional Representative

06-15-2012

Date

Investigator/Sr. Pharmacist Signature

ID wi95

EXHIBIT # 3

INV 359 Revised 5/12, 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

File # _____

Insp # _____

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT FRANAKO PHARMACY INC		PERMIT NUMBER 25600	DATE OF INSPECTION 4/6/2012
DOING BUSINESS AS		DEA NUMBER FF2785206	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 400 SOUTH DIXIE HWY SUITE 17		TELEPHONE # 5615880707 EXT.	SANFORD DUCKMAN
CITY LAKE WORTH	COUNTY 60	STATE/ZIP 33460	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 27319

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1. KWAME KYEREMATEN-AFRANI	PS35409
Open	6A	9A	5	5P	X	X	7P	2. SIMON JEAN SIMON	RPT 38399
Close	11P	9P	11P	11P	X	X	11P	3. EDWARD KATZ	PS10052

	SATISFACTORY	N/A	YES	NO
1 Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2 Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]	X			
3 Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4 Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]				X
5 A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6 Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7 Prescription department clean and safe. [64B16-28.102(4), F.A.C.]				X
8 Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9 Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10 Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11 CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]				X
12 Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	X			
13 Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
14 Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15 All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16 Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
17 Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	X			
19 DEA 222 order forms properly completed. [893.07, F.S.]				X
20 Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
21 Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	X			
22 Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]				X
23 Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	X			
24 Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	X			
25 Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]			X	
26 Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]	X			
27 Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]	X			
28 Compounding records properly maintained. [64B16-27.700, F.A.C.]*	X			
29 Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.116, F.A.C.]	X			
30 Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			X	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: ROUTINE INSPECTION CONDUCTED WITH KWAME KYEREMATEN-AFRANI
SEE ADDITIONAL REMARKS PAGE

CONTROLLED SUBSTANCE OBSERVATIONS:
A RANDOM REVIEW OF SCHEDULE II CONTROLLED SUBSTANCES RX'S INDICATED THE DISPENSING OF OXYCODONE TO PATIENTS IN THEIR 20'S-40'S WHO HAVE VISITED PAIN CLINICS OUTSIDE THE AREA AND AS FAR AWAY AS MIAMI/DADE COUNTY. PATIENTS SEEN WITH ONLY IDENTIFICATION CARDS, PAYING CASH, HAVING ONLY CONTROLLED SUBSTANCES FILLED WITH THE ADDITION OF "FILLER RX'S", IE, IBUPROFEN WITH INAPPROPRIATE DIRECTIONS FOR USE (ONE DAILY). MANY RX'S OBSERVED WITHOUT PRESCRIBER VERIFICATION INDICATED.
ADVISED RPH TO REVEIW 64B16-27.831

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT KWAME KYEREMATEN-AFRANI

Institutional Representative

04-06-2012
Date

Investigator/Sr. Pharmacist Signature

ID wi95

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

STATE OF FLORIDA
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE - ISU

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US/MQA

ADDITIONAL REMARKS

CORPORATE NAME FRANAKO PHARMACY INC	INSPECTION NUMBER	TYPE OF PERMIT 2205	DATE OF INSPECTION 4/6/2012
DOING BUSINESS AS	FILE NUMBER	LICENSE # 25600	
STREET ADDRESS 400 SOUTH DIXIE HWY SUITE 17		TELEPHONE # 5615880707	EXT #
CITY LAKE WORTH	COUNTY PALM BEACH	STATE/ZIP 33460	

Remarks:

UPON ENTERING THE RPH ON DUTY WAS NOT PROPERLY IDENTIFIED.

#4: PHARMACY HOURS WRITTEN IN MILITARY HOURS. ADVISED TO CHANGE TO STANDARD HOURS FOR THE GENERAL PUBLIC TO READ

LICENSES NOT VISIBLE TO THE PUBLIC. ADVISED RPH THAT PUBLIC MUST BE ABLE TO READ LICENSES.

#7: UPON ENTERING PHARMACY THE TEMPERATURE WAS 80 DEGREES.
ADVISED THIS TEMPERATURE MAY COMPROMISE THE INTEGRITY OF THE MEDICATIONS. ADVISED TO ADDRESS.

#11: ONLY 2 CQI MEETINGS HAVE BEEN HELD SINCE THIS LICENSE WAS GRANTED IN JULY 2011. MEETINGS WERE HELD 9/5/11 AND 1/5/12 AND BOTH INDICATED DUPLICATE MINUTES. ADVISED MEETINGS MUST BE HELD QUARTERLY AND RELATE TO QRE'S AND THEIR ACTIONS OF CORRECTION.

#19: ELECTRONIC DEA 222 FORMS WERE NOT PROPERLY COMPLETED.

#22: DAILY LOGS MISSING SIGNATURES SINCE 3/29/12

NOTE
THIS PHARMACY HAS HAD SEVERAL PHARMACY MANAGERS IN THE LAST 9 MONTH PERIOD INCLUDING RUBEN GARZON, (PS21325), BENJAMIN LEVY(PS47936), DAVID MACKARAY(PS24599), EDWARD KATZ (PS10052) AND SANFORD DUCKMAN (PS27319).

DAILY LOGS DO NOT INDICATE GARZON WORKED ON ANY DAYS.
DAILY LOGS INDICATE DUCKMAN ONLY WORKED ON 10/24/11.
DALIY LOGS INDICATE MACKARAY ONLY WORKED 3 DAYS ON 10/4,10/10 AND 9/19/2011
DAILY LOGS DO NOT INDICATE LEVY WORKED ON ANY DAYS
DAILY LOGS DO NOT INDICATE KATZ WORKED ON ANY DAYS

AN OFFICAL RECEIPT WAS GIVEN TO KYEREMATEN-AFRANI FOR RECORDS REMOVED FOR COPYING.
A REQUEST FOR PATIENT PROFILES WAS GIVEN AS WELL FOR SELECT RX'S INDICATED ON THE OFFICIAL RECEIPT TO BE PROVIDED WITHIN 72 HOURS.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT KWAME KYEREMATEN-AFRANI

Institutional Representative

04-06-2012
Date

Investigator/Sr. Pharmacist Signature

ID wi95

INV 416 Revised 12/11, 10/11, 01/07, 07/03

11

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
WWW.DOH.STATE.FL.US

FLORIDA DEPARTMENT OF HEALTH

COMMUNITY PHARMACY

FILE# 18526

INSPECTION# _____

ROUTINE ☐ CHANGE LOC ☐ NEW ☑ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

INSPECTION AUTHORITY – CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT: FRANAKO PHARMACY	PERMIT NUMBER	EXPIRATION DATE	DATE OF INSPECTION: 7/20/11
DOING BUSINESS AS	TELEPHONE NUMBER	EXTENSION	
STREET ADDRESS: 400 So. Dixie Hwy #17	CITY: LAKE WORTH	COUNTY: Palm Bch	STATE: FL. ZIP: 33460
DEA NUMBER			EXPIRATION DATE
PRESCRIPTION DEPARTMENT MANAGER NAME: RUBEN GARZON	PDM NOTIFICATION DATE	LICENSE NUMBER: 21325	9/30/11
VENDOR WHOLESALER PHARMACY	VENDOR LICENSE NUMBER		
REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE NUMBER		
1 KWAME KYEREMATEN-AFRANI	PS 35409		
2			
3			

	SATISFACTORY	NA	YES	NO
1. Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			✓	
2. Pharmacy technicians properly identified and supervised, approval date. [64B16-27.410, F.A.C.]		✓		
3. Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]		✓		
4. Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035F.A.C.] [64B16-27.400(6), F.A.C.]*			✓	
5. Written and verbal offer to counsel patients. [64B16-27.820(1), F.A.C.]		✓		
6. Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			✓	
7. Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			✓	
8. Proper equipment and references as required. [64B16-28.102, F.A.C.]			✓	
9. Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]		✓		
10. CQI Policy and Procedures and quarterly meetings. [64B16-27.300, F.A.C. [766.101, F.S.]		✓		
11. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1) (c) 6, F.S.] [64B16-28.140(3) (b), F.A.C.]		✓		
12. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]		✓		
13. Controlled substance records readily retrievable. [893.07 (4)(B), F.S.]		✓		
14. All controlled substance prescriptions contain information required. [893.04(1) (c), F.S.]		✓		
15. Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1) (g), F.S.] [64B16-28.114, F.A.C.]		✓		
16. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1) (a), F.S.]		✓		
17. DEA 222 order forms properly completed. [893.07(2), F.S.]		✓		
18. Controlled substance Rx information in computer system is retrievable. [21CFR 1306.22]-[893.07, F.S] [64B16-28.140, F.A.C.]*		✓		
19. Controlled substance records maintained for 2 years. [21CFR 1304.04][21CFR 1306.22] [893.07(4) (b), F.S.]		✓		
20. Certified daily log OR printout maintained as required by section. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]		✓		
21. Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.] *		✓		
22. Compounding records properly maintained. [64B16-27.700, F.A.C.] [64B16-28.140(4), F.A.C.]*		✓		
23. Unit dose records properly maintained. [465.016(1) (i), F.S.][64B16-28.118, F.A.C.] *		✓		
** Questions with (*) may be answered n/a (not applicable)*		✓		

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: New Pharmacy opening Inspection. Currently NO ADEQUATE Filing AREA FOR Rx's. Advised to Address. Per PDM, Delivery plans to patients will start at opening. NO COMPOUNDING to BE DONE. Reviewed + Provided 64B16-27.831

I have read and have had this inspection report and the laws and regulations concerned explained, and the information given is true and correct to the best of my knowledge.

Signature of Pharmacist

Date 7/20/11

Investigator/Pharmacist Signature/ID Number

RUBEN GARZON
Print Name

INV 359 Revised 06/09 05/07; 5/06, Replaces 12/02, 12/00

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201218263

LA PERLA PHARMACY, INC,
RESPONDENT.

NOTICE

TO: LA PERLA PHARMACY, INC
11180 WEST FLAGLER ST STE 2
MIAMI, FL 33174

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Hearing - No Disputed Material Facts

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

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RESPONDENT.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Yolonda Green, Assistant General Counsel
RE: Hearing - No Disputed Material Facts
SUBJECT: DOH v. La Perla Pharmacy, Inc.
DOH Case Number 2012-18263
DATE: October 28, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	La Perla Pharmacy, Inc.
Subject's Address of Record:	11180 West Flagler St, Ste 2 Miami, FL 33174
Enforcement Address:	11180 West Flagler St #2 Miami, FL 33174
Subject's License No:	24200 **Rank:** PH
Licensure File No:	16855
Initial Licensure Date:	8/7/2009
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	465.023(1)(c), FS (2012) 64B16-28.109, FAC
Prior Discipline:	None
Probable Cause Panel:	March 28, 2013 Meshad & Weizer
Subject's Attorney:	Pro Se
Complainant/Address:	DOH/ISU-Miami
Materials Submitted:	Memorandum to the Board Motion for Hearing and Final Order Administrative Complaint Motion to Assess Costs Exhibit A – Affidavit of Fees and Costs Expended Exhibit 1 – Complaint Cost Summary

Exhibit 2 – Itemized Cost
Board Notification Letter
Prosecutor's Document
Election of Rights
Probable Cause Memorandum
Final Investigative Report with Exhibits 1-5

YG/bhh

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. CASE NO. 2012-18263

LA PERLA PHARMACY, INC.,
Respondent.
_____/

MOTION FOR HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACTS

COMES NOW, the Petitioner, by and through its undersigned counsel, and moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore, the Petitioner would state the following:

1. Petitioner previously filed an Administrative Complaint against Respondent alleging that Respondent had violated the provisions of Florida Statutes, as set forth therein. The Department, by filing the Administrative Complaint, is seeking to discipline the Respondent's license to practice as a pharmacy, thereby affecting the Respondent's substantial interests.

2. On or about September 9, 2013, Petitioner served Respondent with the Administrative Complaint via Respondent's address of record with

the Department of Health. The Department, by serving the Respondent with the Administrative Complaint, provided the Respondent written notice of its decision to seek discipline of the Respondent's license to practice as a pharmacy.

3. On or about June 18, 2013, Respondent filed an Election of Rights Form electing a formal hearing. However, Respondent failed to dispute issues of material fact alleged in the Administrative Complaint.

4. The Department placed this case on the agenda for the August 14, 2013, Board of Pharmacy agenda. The Board tabled the case to permit the Respondent a final opportunity to dispute specific issues of material fact alleged in the Administrative Complaint.

5. On or about September 5, 2013, the Department served a letter notifying Respondent that it had 10 days to properly dispute issues of material facts alleged in the Administrative Complaint. (See Exhibit A)

6. Respondent has not filed a new Election of Rights or other responsive pleading evincing, or otherwise indicating, that Respondent disputes issues of material facts alleged in the Administrative Complaint.

7. Therefore, there are no disputed issues of material fact to be resolved by the Board.

8. Respondent has been advised, by a copy of this Motion, that a copy of the investigative file in this case shall be furnished to the Board to establish a prima facie case regarding the violations as set forth in the Administrative Complaint.

WHEREFORE the parties respectfully request the Board of Pharmacy, after allowing the Respondent the opportunity to present oral and/or written evidence in mitigation of the Administrative Complaint, enter a Final Order imposing whatever discipline upon the Respondent's license that the Board deems appropriate.

Respectfully Submitted,

Yolonda Y. Green
Assistant General Counsel
Fla. Bar No. 738115
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: yolonda.green@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 17th day of December, 2013, to La Perla Pharmacy, 11180 West Flagler Street, Suite 2, Miami, FL 33174.

Yolonda Y. Green
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-18263**

LA PERLA PHARMACY, INC.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, La Perla Pharmacy, Inc., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a permitted community pharmacy within the state of Florida, having been issued permit number PH 24200.

3. Respondent's address of record is 11180 West Flagler Street #2, Miami, Florida 33174.

4. On or about December 10, 2012, a Department investigator conducted a routine inspection of Respondent.

5. The Department investigator observed Y.P.S., a registered pharmacy technician, in the prescription department.

6. The Department investigator observed the pharmacy door was kept slightly open after Y.P.S. left the prescription department.

7. The Department investigator observed Y.P.S. discussing work related issues with customers on the telephone.

8. Respondent did not have a licensed pharmacist on its premises when it was open and inspected by the Department investigator on or about December 10, 2012.

9. Due to not having a licensed pharmacist on its premises, Respondent's prescription department should have been closed during the Department investigator's on-site visit on or about December 10, 2012.

10. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy

permittee who has violated any of the requirements of Chapter 465, Florida Statutes or any of the rules of the Board of Pharmacy.

11. Rule 64B16-28.109, Florida Administrative Code, provides as follows:

> (1) The prescription department of any community pharmacy permittee shall be considered closed whenever the establishment is open and a pharmacist is not present and on duty. A sign with bold letters not less than two (2) inches in width and height, shall be displayed in a prominent place in the prescription department so that it may easily be read by patrons of that establishment. The sign shall contain the following language: "Prescription Department Closed."
>
> (2) The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purpose of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, taking a meal break pursuant to Rule 64B16-27.1001, Florida Administrative Code, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.
>
> (3) At all times when the prescription department is closed, either because of the absence of a pharmacist or for any other reason, It shall be separated from the remainder of the establishment by partition or other means of enclosure, thereby preventing access to the prescription department by persons not licensed in Florida to practice the profession of pharmacy.
>
> (4) The partition or other means of enclosure shall be securely locked or padlocked and only a pharmacist shall have the means to gain access to the prescription department.

(5) Whenever the prescription department of any community pharmacy establishment is closed, no person other than a pharmacist shall enter, be permitted to enter or remain in the prescription department.

12. Respondent violated the pharmacy prescription department requirements as set forth in Rule 64B16-28.109, Florida Administrative Code, in one or more of the following ways:

a. By failing to display a sign with bold letters not less than two (2) inches in width and height with the language "Prescription Department Closed" in a prominent place in the prescription department so that it may easily be read by patrons of that establishment as required by Rule 64B16-28.109(1), Florida Administrative Code;

b. By failing to securely lock or padlock Respondent's prescription department and ensure only a pharmacist had the means to gain access to the prescription department as required by Rule 64B16-28.109(4), Florida Administrative Code;

c. By having persons other than a licensed pharmacist enter Respondent's prescription department when Respondent's

pharmacy was closed as required by Rule 64B16-28.109(5), Florida Administrative Code.

13. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.109, Florida Administrative Code.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 28th **day of** March**, 2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Michael G. Lawrence, Jr.

MICHAEL G. LAWRENCE, JR.
Assistant General Counsel
Fla. Bar No. 0011265
Florida Department of Health
Office of the General Counsel

4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683
Email: michael_lawrence@doh.state.fl.us

/MGL

PCP: March 28, 2013
PCP Members: Meshad & Weizer

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE MAR 28 2013

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. CASE NO. 2012-18263

LA PERLA PHARMACY, INC.,
Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or after July 1, 2001, pursuant to this section or

discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. .

3. The investigation and prosecution of this case has resulted in costs in the total amount of $1,748.78, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.00	$54.90
Investigation:	17.00	$1,087.66
Legal:	5.70	$606.22
Compliance:	0.00	$0.00
Sub Total:	23.70	$1,748.78
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,748.78

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $1,142.56 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $1,142.56 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $1,142.56.

DATED this 17th day of December, 2013.

Respectfully submitted,

Yolonda Y. Green
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar # 738115
(850) 245-4444 Telephone
(850) 245-4683 Fax

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 17th day of December, 2013, to La Perla Pharmacy, 11180 West Flagler St, #2, Miami, FL 33174.

Yolonda Y. Green
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2012-18263** (Department of Health v **LA PERLA PHARMACY**) are **ONE THOUSAND SEVEN HUNDRED FORTY-EIGHT DOLLARS AND SEVENTY-EIGHT CENTS ($1,748.78).**

6) The costs for DOH case number(s) **2012-18263** (Department of Health v **LA PERLA PHARMACY**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case number(s) **2012-18263** (Department of Health v **LA PERLA PHARMACY**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to keep track of their time in six-minute increments (e.g., investigators

EXHIBIT
A

and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of her knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 30 day of October, 2013, by Shane Walters, who is personally known to me.

Notary Signature

Antoinette Carter

Name of Notary Printed

ANTOINETTE F. CARTER
MY COMMISSION EXPIRES
September 26, 2015
#EE 132192
Bonded thru
Troy Fain Insurance
NOTARY PUBLIC, STATE OF FLORIDA

Stamp Commissioned Name of Notary Public:

Complaint Cost Summary

Complaint Number: 201218263

Subject's Name: LA PERLA PHARMACY, INC

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	1.00	$54.90
Investigation:	17.00	$1,087.66
Legal:	5.70	$606.22
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	23.70	$1,748.78
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,748.78

EXHIBIT

1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201218263

Report Date 10/29/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA107	1.00	$54.90	$54.90	12/13/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
Sub Total	**1.00**		**$54.90**			
INVESTIGATIVE SERVICES UNIT						
MI209	1.00	$63.98	$63.98	12/18/2012	76	REPORT PREPARATION
MI209	1.00	$63.98	$63.98	01/08/2013	76	REPORT PREPARATION
MI209	3.00	$63.98	$191.94	01/09/2013	76	REPORT PREPARATION
MI209	2.00	$63.98	$127.96	01/11/2013	76	REPORT PREPARATION
MI209	1.00	$63.98	$63.98	01/16/2013	76	REPORT PREPARATION
MI209	1.00	$63.98	$63.98	01/18/2013	4	ROUTINE INVESTIGATIVE WORK
MI209	2.00	$63.98	$127.96	01/22/2013	76	REPORT PREPARATION
MI209	1.00	$63.98	$63.98	01/23/2013	76	REPORT PREPARATION
MI209	5.00	$63.98	$319.90	02/01/2013	76	REPORT PREPARATION
Sub Total	**17.00**		**$1,087.66**			
PROSECUTION SERVICES UNIT						
HLL38B	1.30	$106.35	$138.26	02/18/2013	25	REVIEW CASE FILE
HLL38B	0.80	$106.35	$85.08	02/18/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL38B	0.10	$106.35	$10.64	03/28/2013	68	SIGNING CLOSING ORDERS, ADMINISTRATIVE COMPLAINTS AND REASONAB
HLL38B	0.40	$106.35	$42.54	04/07/2013	79	STIPULATION
HLL38B	0.40	$106.35	$42.54	04/08/2013	79	STIPULATION
HLL38B	0.60	$106.35	$63.81	04/22/2013	25	REVIEW CASE FILE
HLL38B	0.50	$106.35	$53.18	04/25/2013	79	STIPULATION
HLL38B	0.40	$106.35	$42.54	05/29/2013	25	REVIEW CASE FILE
HLL38B	0.50	$106.35	$53.18	06/04/2013	91	BOARD MEETING PREPARATION
HLL38B	0.40	$106.35	$42.54	06/19/2013	36	PREPARATION OR REVISION OF LETTER

EXHIBIT
2

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201218263

Report Date 10/29/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
HLL38B	0.20	$106.35	$21.27	09/05/2013	36	PREPARATION OR REVISION OF LETTER
HLL38B	0.10	$106.35	$10.64	09/16/2013	25	REVIEW CASE FILE
Sub Total	**5.70**		**$606.22**			

Total Cost	**$1,748.78**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 10/29/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description
	SubTotal			
	Total Expenses			

December 17, 2013

La Perla Pharmacy, Inc.
11180 West Flagler St. #2
Miami, FL 33174

Re: DOH vs. La Perla Pharmacy, Inc.
DOH Case Number: 2012-18263

Dear Sir/Madam:

I am in receipt of your election of rights requesting a hearing involving disputed issues of material fact executed by you on June 11, 2013, concerning the above referenced case. You failed to dispute the allegations of fact contained in the Administrative Complaint within the 10 days provided to you pursuant to the Department's letter dated September 5, 2013.

Our office is now preparing this case to be presented at the next regularly scheduled meeting of the Florida Board of Pharmacy. Please be advised your case will be set at the convenience of the Department and/or the Board and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Yolonda Y. Green
Assistant General Counsel

YG/ab

September 5, 2013

La Perla Pharmacy, Inc.
11180 W. Flagler Street, #2
Miami, Florida 33174

Certified Article Number
7198 9008 9111 9325 9260
SENDERS RECORD

RE: Department of Health v. La Perla Pharmacy, Inc.
Case No. 2012-18263

Dear Sir/Madam:

The Department of Health is in receipt of your Election of Rights form sent to my office on June 12, 2013. You again failed to dispute the allegations of fact contained in the Administrative Complaint. Your case was heard at the August 2013 Board of Pharmacy meeting as in informal hearing. The Board of Pharmacy elected to table your case and give you a final opportunity to properly dispute specific issues of material fact contained in the Administrative Complaint.

Please feel free to contact me if you wish to discuss this matter. At minimum, please return documentation indicating the specific paragraph numbers in the Administrative Complaint that you are disputing. If you have any documentation that you want me to consider regarding this matter, please forward it to my attention at your earliest convenience.

You have **ten (10) days** from receipt of this package to return the Election of Rights in which you dispute specific issues of material fact contained in the Administrative Complaint to my office. If I fail to receive the form within this time frame, your case will be forwarded to the Board of Pharmacy for an informal hearing.

If you have any questions about this letter or any other questions relating to your case, please feel free to contact me by telephone at (850) 245-4444, extension 8199.

Sincerely,

Michael G. Lawrence, Jr.
Assistant General Counsel

MGL
Enclosures: Administrative Complaint
Election of Rights form
Explanation of Rights
Settlement Agreement

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **La Perla Pharmacy, Inc.**
Case Number: 2012-18263

MEMBERS: **Gavin Meshad and Michele Weizer**

DATE OF PCP: **March 28, 2013** **AGENDA ITEM: A-3**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.109, Florida Administrative Code;

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**
a)
b)
c)

___ Upon **reconsideration**, dismiss

___ **other** _____

Michele Weizer, PharmD, BCPS 3/28/13
Chair, Probable Cause Panel Date
Board of Pharmacy

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: MIAMI AREA XI	Date of Case: 12/12/2013	Case Number: PH 2012-18263

Subject: **LA PERLA PHARMACY, INC** 11180 West Flagler St # 2 Miami , Florida 33174 (305) 551-8419- Business	Source: **DOH- MIAMI-ISU**

Prefix: 2205	License # 24200	Profession: Pharmacy	Board: Pharmacy	Report Date: 02/05/2013

Period of Investigation: 12/12/2012- 02/05/2013	Type of Report: FINAL

Alleged Violation: Possible Violation of F.S. 456.056(1)(k)(dd); 465.016(1)(r); 465.023 (1)(c), F.S.; Rule 64B16- 28.109, F.A.C. Violate Statute/Rule; Failure to perform legal obligation.

Synopsis: : This investigation was predicated upon receipt of an inspection submitted by the Department of health Miami ISU on 12/10/12, in regards to a routine inspection was conducted at La Perla Pharmacy, Inc, a Community Pharmacy (PH24200), located at 11180 West Flagler St, S-2, Miami, FL 33174. The investigator went to the pharmacy and found it opened and no pharmacist was present /on duty. In addition, the door to the drug department was unlocked.

LA PERLA PHARMACY was notified of the investigation by letter, dated 12/18/2012 **(Exhibit #2)** and was provided a copy of the case summary and initiating documents **(Exhibit #1).**

A search of the DOH licensure database reveals that LA PERLA PHARMACY is currently licensed as a Pharmacy.

No patients were identified, thus patient notification is not required.

LA PERLA PHARMACY is not currently represented by an Attorney.

LA PERLA PHARMACY initially denied the allegations. However admitted to the allegations in an affidavit which was sent to the Miami Field Office.

Related Case(s): NONE

Investigator/Date: February 5, 2013 George Mulero, MMI-209	Approved By/Date: February 5, 2013 Caridad Rodriguez, Investigative Supervisor MI-176

Distribution: HQ/ISU

Received
Investigative Services
FEB 07 2013
DOH/MQA
Tallahassee HQ

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INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit #1: Case Summary and Initiating Documents.

Exhibit #2: Copy of Subject notification letter, dated 12/18/2012.

Exhibit #3: Copy of Report from the FLORIDA DEPARTMENT OF STATE, DIVISION OF CORPORATIONS which delineates owner as ANGEL A. SANCHEZ dated 12/18/2012.

Exhibit#4: Copy of AFFIDAVIT from Pharmacy owner, AFFIDAVIT from Pharmacy Technician And other documents provided by the pharmacy CONSULTANT received on 01/18/2013.

Exhibit #5: Copy of AFFIDAVIT, STOCK PURCHASE AGREEMENT and ARTICLES OF INCORPORATION received on 01/24/2013.

INTERVIEW OF MR. SCOTT CRAIG MAAS- PHARMACIST LICENSE PS 15162- (WITNESS)
Employer- La Perla Pharmacy
11180 West Flagler Street # 2
Miami, Florida 33147
(305) 551-8419

On 1/18/2013, when this investigator arrived at LA PERLA PHARMACY, he observed two women working inside the dispensing area along with a gentleman who identified himself as SCOTT CRAIG MASS the pharmacist. However, he was sitting down reading a bible while the two ladies worked. This investigator asked MAAS how long he has been employed as a pharmacist with LA PERLA and MAAS responded by stating that he was hired approximately two weeks ago which was in early January of 2013. MAAS had no further information to provide relative to the investigation.

INTERVIEWOF MS.JUANA ELVIRA GARCIA NARANJO-LICENSE RPT39367-(WITNESS)
Employer- La Perla Pharmacy
11180 West Flagler Street # 2
Miami, Florida 33147
(305) 551-8419

On 1/18/2013, this investigator interviewed NARANJO upon arrival to LA PERLA and she stated that she has been working at this pharmacy as a REGISTERED PHARMACY TECHNICIAN for approximately one (1) week. She also stated that she previously worked at the HEALTH STAFF

PHARMACY in the South West area of Miami. She also stated that she has no information relative to any incidents in the pharmacy prior to her commencement date of 01/10/2013.

INTERVIEW OF MS. YUNET PELLON SOLER-LICENSE RPT40486-(WITNESS)
Employer- La Perla Pharmacy
11180 West Flagler Street # 2
Miami, Florida 33147
(305) 551-8419

On 1/18/2013, this investigator interviewed SOLER while conducting an investigation relative to the compliant and allegation which was received in our Miami field office. SOLER stated that she has been employed at LA PERLA since April 2012. She recalls that on 12/10/2012, she was the technician inside the dispensing area. She was both on the computer and on the telephone with ABACUS obtaining information from them to fill out appropriate applications. She also stated that there was a pharmacist present on that day. However, after discussing with the owner SANCHEZ The compensation amount for his services, according to SOLER the pharmacist left the premises. Thus, following that event the pharmacist did not have a pharmacist present for the remainder of the day.

INTERVIEW OF MS. SONIA RODRIGUEZ-(WITNESS)
President- Capital-One Consultant Health Care
2500 NW 79th Avenue Suite 261
Miami, Florida 33122
(305) 477-6507

On 1/18/2013, this investigator made contacted with Ms. RODRIGUEZ via telephone and she stated that she had been the recipient of the notification from our office and some how this item was misplaced and an appropriate response was not provided prior to this date 01/18/2013. RODRIGUEZ responded to the allegation and compliant in behalf of LA PERLA by stating that on 12/10/2012 the Pharmacy Technician had gone into the prescription area to obtain a copy of the new contract from ABACUS software.

INTERVIEW OF MS. ZUZETTE DE LA RUA-CO-OWNER
Co-Owner –La Perla Pharmacy, Inc
11180 West Flagler St # 2
Miami, Florida 33147
(305) 551-8419

On 1/18/2013, this investigator interviewed LA RUA who identified herself as the wife and co-owner of the pharmacy. She stated that she was not aware of any notifications which were sent to the pharmacy by this investigator. She asked her husband SANCHEZ, "why didn't you provided me with a the document which arrived. During the interview with his wife he then recalls that he had sent the

notification to his pharmacy consultant Ms. SONIA RODRIGUEZ. LA RUA stated and confirmed that she never observed the notification and also had no knowledge that it had arrived. LA RUA also stated that a pharmacist was present and had to leave however, when asked to provide that name and phone number of the pharmacist who present on 12/10/2012 neither could provide the information relative to the pharmacist.

INTERVIEW OF MR. ANGEL SANCHEZ- OWNER- (SUBJECT)
Owner-La Perla Pharmacy
11180 West Flagler St # 2
Miami, Florida 33174
(305) 551-8419

On 1/18/2013, this investigator visited LA PERLA PHARMACY and interviewed Mr. SANCHEZ who provided an identification card which listed his photograph, name, address and DOB as 12/04/1969. This investigator provided him with a copy of subject notification and case summary which is dated 12/18/2012 and requested to ascertain why a response had not been submitted to my attention at the Miami Field office. According to SANCHEZ he recalls having been the recipient of the letter and having placed it in his office and that's all he remembers. SANCHEZ was also asked why he never called in response to the communication and he could not provide an answer. SANCHEZ was also questioned about the initial compliant he stated that there was pharmacists present on 12/10/12. According to SANCHEZ a Pharmacist arrived and they were allegedly discussing compensation for the days services and that the pharmacist did not accept the offer for compensation and left the premises. However, SANCHEZ did not recall the name of the pharmacist.

INVESTIGATOR'S NOTE

On 01/18/2013, when this investigator returned to the Miami field office a package had been delivered to this investigator's attention. Upon inspection it contained several documents which are enclosed as exhibits in this case. On 01/24/2013, a second set of documents had arrived apparently sent by the pharmacy consultant SONIA RODRIGUEZ.

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

December 18, 2012

CONFIDENTIAL TO:
Mr. Angel A. Sanchez
c/o La Perla Pharmacy Inc
11180 West Flagler St # S2
Miami, Florida 33174

Case Number: 2012-18263

Dear Mr. Sanchez:

We are currently investigating a case received by the Department of Health. The allegation, if substantiated, would be a violation of «statutes/rules».

Within **20 days** of receiving this letter, you may:

- submit a **written response** to the address below; **or**
- call our office to schedule an **interview**.

Please provide a copy of your **resume** and identify the **address of your current employer**, even if you chose not to submit a response. This information, your response (if one is provided) and any other information gathered during the investigation will be considered by the Probable Cause Panel when determining whether a formal administrative complaint should be filed in this matter. Include the above-referenced case number in any correspondence you send.

Florida law requires that this case and all investigative information remain confidential until 10 days after the panel has determined that a violation occurred or you give up the right to confidentiality. Therefore, the contents of the investigation cannot be disclosed to you or the general public.

You are not required to answer any questions or give any statement, and you have the right to be represented by an attorney. It is not possible to estimate how long it will take to complete this investigation because the circumstances of each investigation differ.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county and community efforts. If you have any questions, please call me at (305) 470-5894.

Sincerely,

George Mulero, CFE
Medical Malpractice Investigator

FLORIDA DEPARTMENT OF STATE
DIVISION OF CORPORATIONS

Detail by Entity Name

Florida Profit Corporation

LA PERLA PHARMACY, INC

Filing Information

Document Number	P09000022385
FEI/EIN Number	264436984
Date Filed	03/10/2009
State	FL
Status	ACTIVE
Last Event	AMENDMENT
Event Date Filed	12/06/2012
Event Effective Date	NONE

Principal Address

11180 WEST FLAGLER SUITE #2
MIAMI FL 33174

Mailing Address

11180 WEST FLAGLER SUITE #2
MIAMI FL 33174

Registered Agent Name & Address

SANCHEZ, ANGEL A
11180 WEST FLAGLER SUITE #2
MIAMI FL 33174 US

Name Changed: 12/03/2012

Officer/Director Detail

Name & Address

Title PSD

SANCHEZ, ANGEL A
11180 WEST FLAGLER SUITE #2
MIAMI FL 33174

Title VP

DE LA RUA, ZUZETTE
11180 WEST FLAGLER ST., STE 2
MIAMI FL 33174

Annual Reports

Report Year	Filed Date
2010	07/13/2010
2011	04/27/2011
2012	04/30/2012

Document Images

12/06/2012 -- Amendment | View image in PDF format

Exhibit 3

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

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RECEIVED

JAN 18 2013

DOH/MIAMI
INVESTIGATIVE SERVICES

La Perla Pharmacy Inc
11180 West Flagler Street, Unit 2
Miami Florida 33174

Open from 9am to 5pm

Mission:
La Perla Pharmacy Inc mission is to provide innovative services to treat illness and disease and promote the improvement of personal health.

Florida Agency for Health Care Administration
Division of Medical Quality Assurance, Investigative Services Unit
8350 NW 52 Ter, Suite 400
Doral Florida 33166
George Mulero, CFE, Medical Malpractice Investigator

Re: La Perla Pharmacy Inc
License No: PH24200
DOH Complaint No. 2012-18263

CONFIDENTIAL

Exhibit 4

January 10, 2013

Florida Agency for Health Care Administration
Division of Medical Quality Assurance, Investigative Services Unit
8350 NW 52 Ter, Suite 400
Doral Florida 33166
George Mulero, CFE, Medical Malpractice Investigator

Re: La Perla Pharmacy Inc
License No: PH24200
DOH Complaint No. 2012-18263

Dear Mr. Muleroi

On the allegations unknown since we are missing the CASE SUMMARY
Please mail or fax to La Perla Pharmacy Inc
11180 West Flagler Street, Unit 2
Miami, Fl 33174

Explanation

> *On the possible allegations on violating (Unknown awaiting second letter with the Case Summary and copy of the inspector notes). La Perla Pharmacy only received the letter of 20 days.*

On December 7,2012 Board of Pharmacy Inspector came in for a routine inspection and found that the Technician was inside the prescription department and no pharmacist on hand.

Explanation

The technician had gone into the prescription department to obtain a copy of the new contract from Abucus software.

Evidence

Affidavit from Technician (Exhibit 1)

Affidavit from owner (Exhibit 2)

Copy of the Abucus Software (Exhibit 3)

Purchase agreement and changes done to the Florida Board of Pharmacy. (Exhibit 4)

Any question pleases call or visit our pharmacy.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

December 18, 2012

CONFIDENTIAL TO:
Mr. Angel A. Sanchez
c/o La Perla Pharmacy Inc
11180 West Flagler St # S2
Miami, Florida 33174

Case Number: 2012-18263

Dear Mr. Sanchez:

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- submit a **written response** to the address below; **or**
- call our office to schedule an **interview**.

Please provide a copy of your **resume** and identify the **address of your current employer**, even if you chose not to submit a response. This information, your response (if one is provided) and any other information gathered during the investigation will be considered by the Probable Cause Panel when determining whether a formal administrative complaint should be filed in this matter. Include the above-referenced case number in any correspondence you send.

Florida law requires that this case and all investigative information remain confidential until 10 days after the panel has determined that a violation occurred or you give up the right to confidentiality. Therefore, the contents of the investigation cannot be disclosed to you or the general public.

You are not required to answer any questions or give any statement, and you have the right to be represented by an attorney. It is not possible to estimate how long it will take to complete this investigation because the circumstances of each investigation differ.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county and community efforts. If you have any questions, please call me at (305) 470-5894.

Sincerely,

George Mulero, CFE
Medical Malpractice Investigator

Affidavit

Date December 30, 2012

Name Yunet Pellon

Address 1180 West Flagler Street, Unit #2.

City/State/Zip Miami Fl 33174

December 7, 2012

I Yunet. P. technician for La Perla Pharmacy on the day of the routine inspection open the door of the prescription to pickup the contracts from Abacus Software was the new owner was standing next to the door waiting for me to pickup the contract.

Sincerely

This person is produced the following identification: _____

Subscribed and sworn to or affirmed before me this 14 day of JANUARY 2013

NOTARY STATE SEAL:

BEATRIZ CARREON
MY COMMISSION # EE118933
EXPIRES November 06, 2015
(407) 398-0153 FloridaNotaryService.com

Notary Public Name

11/06/2015
My Commission Expires

RX CLAIMS, INC.
ELECTRONIC e-CLAIM SYSTEM PRICING
ABACUS SOFTWARE

SCRIP FEE: 8¢ per Transaction (Bundle up to 4 Rx/transaction)
ONE-TIME SET-UP FEE(S): **Free**
CUSTOMER HOTLINE SUPPORT: **Free**
TRANSACTION MAINTENACE: **Free**
ELECTRONIC FUNDS TRANSFER: Customers must sign an ACH agreement. The agreement can be cancelled at anytime.

THIS IS TO ACKNOWLEDGE THAT A SEPARATE CHARGE FOR PRESCRIPTION CLAIMS BILLED ELECTRONICALLY TO ANY THIRD PARTY CARRIER WILL BE CHARGE AS OUTLINED ABOVE, AND THAT YOU AGREE TO PAY SUCH CHARGES UPON RECEIPT OF INVOICE.

X _____
SIGNATURE

_____
DATE

SUSETTE ALEJANDRO
NAME (Print or type)

(305) 551-8419
(Area code) TELEPHONE

LA PERLA PHARMACY, INC.
PHARMACY NAME

_____
MEDICAID PROVIDER NUMBER

1265664080
NPI#

1048126
NABP#

11180 WEST FLAGLER SUITE 2
ADDRESS

MAIL ALL CORRESPONDENCE TO:

8000 S.W. 117 Ave PH-G
MIAMI, FL 33183
Phone (305) 220-0400

MIAMI, FL 33174-1216
City, State, Zip code

YOUR CUSTOMER # IS 20093091

THE AUTHORIZATION FOR PRE-ARRANGED PAYMENTS FORM MUST BE ATTACHED

R X C L A I M S, I N C.
AUTHORIZATION FOR PRE-ARRANGED PAYMENTS
THIS FORM MUST BE COMPLETED AND RETURNED

As a more convenient method of payment, Rx Claims, Inc. ask for your participation in our Automated Clearing House (ACH) program. ACH is an electronic billing mechanisum which deducts from a banking institution account all monies due Rx Claim, Inc. for services rendered.

As a safeguard against error, an itemized activity statement that notifies you of the exact charges is generated and sent to each office prior to the scheduled collection date. This statement covers activity routed through the network and specifies the total amount that will be collected. The debit to the account will occur on or about the 25th of the month.

The ACH agreement is necessary for the processing of your contract, please send all forms completed to avoid delay of your location being set up on the Rx Claim, Inc. network. The switch processing fee is $¢ per transaction.

THIS IS NOT AN OPTION. THIS FORM MUST BE CORRECTLY COMPLETED (signed where indicated and voided check attached) BEFORE YOUR CONTRACT CAN BE PROCESSED AND BE REGISTERED ON THE SWITCH.

ACCOUNT NAME La Perla Pharmacy, Inc. Account# 20093091

ADDRESS 11180 West Flagler Suite 2 Miami, FL 33174-1216

I HEREBY AUTHORIZE RX CLAIMS, INC., HEREINAFTER CALLED "COMPANY", TO INITIATE DEBIT ENTRIES TO OUR CHECKING ACCOUNT INDICATED BELOW AND THE FINANCIAL INSTITUTION NAMED BELOW, HEREINAFTER CALLED "DEPOSITORY", TO DEBIT THE SAME TO SUCH ACCOUNT.

FINANCIAL INSTITUTION _____

BRANCH _____

CITY _____ STATE _____ ZIP _____

TRANSIT/ABA NO. 067014822 ACC. NO. 4271290515

THIS AUTHORITY IS TO REMAIN IN FULL FORCE AND EFFECT UNTIL COMPANY AND DEPOSITORY HAVE RECEIVED WRITTEN NOTIFICATION FROM ME OF IT'S TERMINATION IN SUCH TIME AND IN SUCH MANNER AS TO AFFORD COMPANY AND DEPOSITORY A REASONABLE OPPORTUNITY TO ACT ON IT PRIOR CHARGING ACCOUNT. AFTER ACCOUNT HAS BEEN CHARGED, I HAVE THE RIGHT TO HAVE THE AMOUNT OF AN ERRONEOUS DEBIT IMMEDIATELY CREDITED TO MY ACCOUNT BY DEPOSITORY, PROVIDED I SEND WRITTEN NOTICE OF SUCH DEBIT ENTRY IN ERROR TO DEPOSITORY WITHIN 15 DAYS FOLLOWING ISSUANCE OF THE STATEMENT OF 30 DAYS AFTER POSTING, WHICHEVER OCCURS FIRST.

SIGNATURE X _____ DATE _____

NAME (PRINT) Susette Alejandro TITLE _____

PHARMACY NAME La Perla Pharmacy, Inc. PHONE # (305) 551-8419

*** PLEASE ATTACH A VOIDED CHECK DRAWN ON THE ABOVE ACCOUNT ***

PLACE VOIDED CHECK HERE

TRANSIT/ABA NO.- is a nine-digit number located on bottom of check. If you assistants, please contact your bank.
ACCOUNT NO. - is located on bottom of check or deposit slip. If you assistants, please contact your bank.

A B A C U S R X, I N C.
AUTHORIZATION FOR PRE-ARRANGED PAYMENTS
THIS FORM MUST BE COMPLETED AND RETURNED

ACCOUNT NAME La Perla Pharmacy, Inc.

ADDRESS 11180 West Flagler Suite 2 Miami, FL 33174-1216

I HEREBY AUTHORIZE ABACUS RX, INC., HEREINAFTER CALLED "COMPANY", TO INITIATE DEBIT ENTRIES TO OUR CHECKING ACCOUNT INDICATED BELOW AND THE FINANCIAL INSTITUTION NAMED BELOW, HEREINAFTER CALLED "DEPOSITORY", TO DEBIT THE SAME TO SUCH ACCOUNT.

FINANCIAL INSTITUTION _____

BRANCH _____

CITY _____ STATE _____ ZIP _____

TRANSIT/ABA NO. 067014822 ACC. NO. 4271290515

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SIGNATURE X _____ DATE _____

NAME (PRINT) Susette Alejandro TITLE _____

PHARMACY NAME La Perla Pharmacy, Inc. PHONE # (305) 551-8419

*** PLEASE ATTACH A VOIDED CHECK DRAWN ON THE ABOVE ACCOUNT ***

PLACE VOIDED CHECK HERE

Abacus Rx, Inc.
8000 SW 117 Ave PH-G
Miami, FL 33183
(305) 220-0400
Fax (305) 220-4900

Visit our web site at
www.AbacusRx.com

Change form

Type of change: ☑New Owner ☐New address ☐New contact ☐New Corp name ☐New Phone/Fax

Former Company name: La Perla Pharmacy, Inc

LOCATION:

Company name: La Perla Pharmacy, Inc ☑Inc ☐Corp ☐LLC
D/B/A: La Perla Pharmacy

Address: 11180 West Flagler St #2

City, State & Zip: Miami FL 33174

Phone: (305) 551-8419 Fax: (305) 551-8420

Contact: Suselte Phone:

Owner/Officer: Suselte Alejandro Phone:

BILL TO: ☑Same as above

Company name:

Address:

City, State & Zip:

Contact:

Phone: Fax:

AUTHORIZATION:

Name: Alejandro Sorolay Signature: X Date: 12/5/12

[redacted]

SOFTWARE MAINTENANCE/SUPPORT AGREEMENT

THIS AGREEMENT ("Agreement") dated December 6, 2012 between Abacus Rx, Inc. ("Company"), 8000 S.W. 117 Avenue PH-G, Miami, Florida 33183, its successors and assigns, and LA PERLA PHARMACY, INC. and its heirs, successors, administrators and assigns, hereinafter called ("Customer").

WHEREAS, Company offers the Customer a special price on the use of a computer program called Pharmacy Plus ("Software") that was specially designed and customized for the Customer, with the understanding that the Customer desires and is willing to pay for software maintenance and support.

WHEREAS, Customer desires maintenance and support for the SOFTWARE in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the premises and the mutual promises in this Agreement, the parties agree as follows:

1. OVERVIEW. This Agreement shall be freely assignable by company and shall be binding upon and inure to the benefit of the parties, their heirs, executors, administrators, successors and assigns. In the event Customer's business is transferred, Customer will notify Company at least thirty days before the transfer and the transferee shall be notified of the existence of this Agreement. Failure of Customer to secure an assumption of this Agreement by the transferee shall not serve to relieve the transferee of its obligation hereunder. This Agreement shall survive any sale, assignment, or other transfer of the demised premises. Customer agrees to obtain a waiver of any liens in form supplied by Company. Failure to exercise this option shall not constitute a waiver of Company's other causes of action under law. If any litigation results in connection with this Agreement, the successful party shall be entitled to reasonable attorney's fees. This Agreement is entered into by Customer/owner or through its duly authorized agent with full knowledge of the contents hereof and acquiescent there to by the owner of the demised premises.

2. TERM. This Agreement shall be for an initial term of TWENTY SIX (36) months from the effective date above. This Agreement shall thereafter be automatically renewed for successive terms of the same duration, unless either party terminates the Agreement in writing, at least ninty (90) days prior to the expiration of the term then in force.

3. FEE. Customer agrees to pay the specified monthly fee of $141.95, for software maintenance and telephone support at the location listed below, for the duration of this Agreement. The customer agrees that the above monthly fee is due and payable on the first (1st) of the month, and is delinquent after the twentieth (20th) of the month. Customer agrees to pay Company before the 1st of the Month. Payments received after the 20th of the Month, will be subject to a $15 late fee or 1.5% of the balance due if greater. Dishonored checks are subject to a $25 fee. Failure to pay the amount due within thirty (30) days of the due date may result in refusal and temporary disconnection of service. Customer agrees to pay any and all applicable collection costs, attorneys fees, court cost and interest accrued. In the event that the Customer wants to cancel this agreement, the Customer agrees to pay the remaining months on the Agreement.

4. PROTECTION OF SOFTWARE. Customer acknowledges that the Company retains all title, copyright and other proprietary rights in and to the software. Customer agrees to treat the software furnished to Customer as a valuable asset of the Company and shall adopt reasonable measures to prevent unauthorized access to the software. In the event that the Agreement is terminated by either party for any reason, Customer shall promptly remove the software from its computer(s) and return all copies of the software and documentation to the Company. Customer grants the Company full access to its computer(s) to inspect any violation of this agreement.

5. SUPPORT SERVICES. The Company will provide telephone support and future enhancements of the Software, at no cost to the Customer, as part of this agreement, provided that the enhancements were not requested and made exclusively for the Customer. Company shall in no case be required to perform any on-site support services, unless otherwise specified under separate agreement.

6. WARRANTIES AND LIMITATIONS. The Company makes no warranty of any kind, express or implied, including without limitation, any warranties of fitness for a particular purpose. In no event shall the Company be liable for any computer equipment or software failure resulting in loss of information or labor hours, loss of profits or loss of business, including special, incidental or consequential damages, even if Company has been advised of the possibility of such damages.

7. GENERAL. This agreement shall be interpreted under, and governed by, the Laws of the State of Florida. The parties hereto agree that any action relating to this Agreement shall be instituted and prosecuted in the courts of the County of Miami-Dade, State of Florida, and each party hereto waives the right to change of venue or trial by jury. This Agreement contains the entire agreement between the parties whereto and may not be modified except in writing, signed by duly authorized representative of both parties. If any provision hereof is held invalid by a court of competent jurisdiction, it shall be automatically deleted and all remaining provisions shall remain in full force and effect.

COMPANY

Signature: _____

Name: Orlando Alberro

Title: SALES MANAGER

Date: _____

WITNESS

Signature: _____

Name: _____

CUSTOMER

Signature: _____

Name: SUSEITE ALEJANDRO

Title: _____

LOCATION OF SOFTWARE

Organization: _____

Address: 11180 WEST FLAGLER SUITE 2

City,State,Zip: MIAMI, FL 33174-1216

Telephone: (305) 551-8419

Owner/Contact: SUSEITE ALEJANDRO

Capital-One Consultant Health Care
2500 NW 79 Ave, Suite 261
Miami Fl 33122
305-477-6507
305-477-6518 Fax

To BETH RANNE Sonia Rodriguez

Fax 1-850-413-6982

Phone: Date: 12/5/2012

_X_Urgent __For Review __Please Comment __Please Reply –Please Recycle

Sonia Rodriguez
305-477-6507

Fingerprint Technologies

Fingerprint Technologies
5200 SW 8 St.
Suite 204-B
Coral Gables, FL 33134 US

(305)443-9148
idenrios@aol.com

Sales Receipt

Date	Sale #
12/06/2012	56109

Sold To

Board of Pharmacy
4052 Bald Cypress Way
Tallahassee, FL 32399
Zuzette De La Rua
Angel Sanchez

Date	Activity	Quantity	Rate	Amount
12/06/2012	FDLE Level II / Board of Pharmacy	2	60.00	120.00

FDLE 850-410-8161
DCF 5-7 Days
BGS1116@DCF.STATE.FL.US
AHCA results 5-7 Days
AHCA 850-412-4503
TCN: 70CA360000040561-40562

Total	$120.00
Amount Received	$120.00
Balance Due	$0.00

Transmittals are good for 6 months

www.fingerprints4all.com

Not responsible for results after 6 months

: 00026

Capital One Health Care Corp
2500 NW 79 Ave, Suite 261
Doral Florida 33122
305-477-6507
305-477-6518 Fax

December 3, 2012

Florida Board of Pharmacy
4052 Bald Cypress Way, BIN #C-04
Tallahassee, Florida 321399
1-850-245-4292

Re: Stock Transfer
License Number PH24200
La Perla Pharmacy Inc
11180 West Flagler Street
Suite 2
Miami Fl 33174

Dear Florida Department of Pharmacy

*The purpose of this letter is to inform you the Florida Board of Pharmacy that there has been a change in the stockholders of **La Perla Pharmacy Inc,** effective November 30, 2012. The ownership of the shares shall be as follows:*

Angel A Sanchez 100% of the shares of the corporation
Address: 69 Suffolk Ave
Hialeah Fl 33012
DOB12/04/1969
Social Security number 594-53-0873
President

Vice President Zuzette De La Rua
Address: 1305 West 46 Street, 232
Hialeah Fl 33012
DOB 07/06/1980
Social Security Number 594-53-5820
Vice-President

Please note this change for your records. Should you have any questions please contact me immediately.

Attach copy of the Articles of Corporation, Bill of Sale

Copy of the Finger prints for both president/vice president

ARTICLES OF AMENDMENT
TO
ARTICLES OF INCORPORATION
OF
LA PERLA PHARMACY INC

Pursuant to the provisions of section 607.1006 of the Florida Statutes, the above referenced corporation hereby adopts the following Articles of Amendment to its Articles of Incorporation:

1. The date of the filing of the Articles of Incorporation of was March 10, 2009 and assigned document number P000022385.

2. The following Amendment to the Articles of Incorporation was adopted by the corporation:

Maria Isabel Bohbot is hereby *deleted* as Director and President.

Angel Alejandro Sanchez of 11180 West Flagler Street, Suite 2, Miami, Florida 33174 is hereby *added* as Director, President and Secretary.

CHANGE OF REGISTERED AGENT/REGISTERED OFFICE:

Angel Alejandro Sanchez of 11180 West Flagler Street, Suite 2, Miami, Florida 33174 shall be added as Registered Agent/Registered Office.

Maria Isabel Bohbot shall be *deleted* as the Registered Agent/Registered Office.

The Amended Articles and each Amendment described herein were approved by the shareholders. The number of votes cast for the amendments by the shareholders were sufficient for approval. The Amendments are hereby adopted and shall be effective as of the date written below.

The Amended Articles were adopted by a majority of the Corporation's Directors and Shareholders on the date written below.

SIGNED, this 30th day of November, 2012.

ANGEL ALEJANDRO SANCHEZ, President

I hereby accept the appointment as registered agent and agree to act in this capacity. I further agree to comply with the provisions of all statutes relative to the proper and complete performance of my duties, and I am familiar with and accept the obligation of my position as registered agent. Or, if this document is being filed merely to reflect a change in the registered offiee address, I hereby confirm that the corporation has been notified in writing of this change.

ANGEL ALEJANDRO SANCHEZ

ADDENDUM TO

LA PERLA PHARMACY

STOCK PURCHASE AGREEMENT

THIS ADDENDUM TO STOCK PURCHASE AGREEMENT is made and entered into this 30th day of November, 2012 by and between Maria Isabel Bohbot, hereinafter referred to as the "Seller," and Angel Alejandro Sanchez, hereinafter referred to as the "Buyer."

RECITALS:

A. The Seller and Buyer entered into a stock Purchase Agreement for the sale and purchase of La Perla Pharmacy, Inc. ("La Perla Pharmacy") is a Florida corporation in good standing.

B. The Seller and Buyer desire to add additional terms to the Stock Purchase Agreement as set forth herein.

THEREFORE, in consideration of the mutual promises contained herein and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

Federal and State Licenses and Regulatory Notices.

(a) Florida State Pharmacy Permit. Buyer hereby agrees to prepare and submit all required notifications and applications relative to the La Perla Pharmacy's pharmacy permit and license in connection with the transactions contemplated hereby. Said notifications and applications shall be submitted by Buyer within 10 days from the date of this Addendum and a copy of such shall be simultaneously provided to Seller and Seller's attorney.

(b) Medicare. Buyer hereby agrees to notify Medicare of this transaction in accordance with Federal law. Said notifications shall be submitted by Buyer within 10 days from the date of this Addendum and a copy of such shall be simultaneously provided to Seller and Seller's attorney.

IN WITNESS WHEREOF, the parties have executed this Agreement on the day and year first above written.

Witnesses:

Seller:

Maria Isabel Bohbot

Buyer:

Angel Alejandro Sanchez

BILL OF SALE

KNOW ALL MEN BY THESE PRESENTS, that MARIA ISABEL BOHBOT, party of the first part and as sole stockholders of LA PERLA PHARMACY, INC., a Florida corporation, in consideration of the sum of Ten and NO/100 ($10.00) Dollars, lawful money of the United States paid to him by ANGEL ALEJANDRO SANCHEZ, party of the second part, the receipt whereof is hereby acknowledged, has/have granted, bargained, sold, transferred and delivered, and by these presents does/do grant, bargain, sell, transfer and deliver unto the said party of the second part, his/her/their executors, administrators and assigns, under the terms and conditions of the Stock Purchase Agreement, the following goods and chattels:

100 Shares representing 100% ownership interest and stock in and to LA PERLA PHARMACY, INC., a Florida corporation.

TO HAVE AND TO HOLD the same unto the said party of the second part, his/her/their executors, administrators and assigns forever.

AND I/we do, for ourselves, heirs, executors and administrators, covenant to and with the said party of the second part, his/her/their executors, administrators, covenant to and with the said party of the second part, our executors, administrators and assigns, that we are the lawful owners of the said goods and chattels; that they are free from all encumbrances; that we have good right to sell the same aforesaid, and that we will warrant and defend the sale of the said property, goods and chattels hereby made, unto the said party of the second part, our executors, administrators and assigns against the lawful claims and demands of all persons whomsoever.

IN WITNESS WHEREOF, I/We have hereunto set my/our hand and seal this 30th day of November, 2012.

Signed sealed and delivered
in the presence of:

MARIA ISABEL BOHBOT

RESIGNATION

Gentlemen:

I hereby tender my resignation as Director and President of La Perla Pharmacy, Inc., a Florida corporation, as well as any other office or position with said company, effective November 30, 2012.

DATED AS OF: November 30, 2012.

MARIA ISABEL BOHBOT

CLOSING STATEMENT

SELLER : Maria Isabel Bohbot
BUYER : Angel Alejandro Sanchez
CLOSING DATE : November 30, 2012
DESCRIPTION : 100% Sale of Stock of La Perla Pharmacy, Inc.

	Buyer	Seller
Purchase Price	$ 70,000.00	$70,000.00
Sales Commission	$ 0	

TOTAL CASH FROM BUYER TO SELLER AT CLOSING: $70,000.00

I have carefully reviewed the settlement statement and to the best of my knowledge and belief it is a true statement of all the receipts and disbursements made on my account or by me in this transaction. I further certify that I have received full payment from the buyer and a copy of this settlement statement.

SELLER:

Maria Isabel Bohbot

Dated: 11/30/12, 2012

BUYER:

Angel Alejandro Sanchez

Dated: 11/30/12, 2012

Notice to Parties in Regulated Health Care Transactions

La Perla Pharmacy, Inc.

Please be advised that most transactions involving health care facilities in the State of Florida are subject to various notice requirements. Additionally, if the facility has a Medicare provider number, any changes in the officers and/or owners must be reported to Medicare within 30 days of said change. There are additional notice requirements for pharmacies related to the DEA. It is imperative that these notices be completed in an accurate fashion and reported to the proper agencies.

You are hereby notified that your failure to report these transactions as required by state and federal law may lead to various administrative remedies that include license suspension and termination of your provider number and even criminal prosecution.

If you have any questions as to the reporting requirement specifically related to your transaction, please ask your attorney before closing.

THIS OFFICE DOES NOT PERFORM POST TRANSACTION LICENSING AND CHANGE OF OWNERSHIP SERVICES. IT IS THE BUYER'S AND SELLER'S RESPONSIBILITY TO NOTIFY THE APPROPRIATE GOVERNMENT AGENCIES OR BODIES.

I attest that I have read and understand the reporting requirements for my regulated transaction and understand the penalties for failing to comply with state and federal reporting requirements.

Dated this 3 day of November, 2012 by:

BUYER ANGEL ALEJANDRO SANCHEZ

SELLER MARIA ISABEL BOHBOT

MINUTES OF MEETING OF

BOARD OF THE SHAREHOLDER AND DIRECTORS OF

LA PERLA PHARMACY, INC.

The meeting of Shareholders and Directors was held as of November 30, 2012 at 4:00 P.M.

The following were present: Maria Isabel Bohbot, the sole shareholder and director of the company and Angel Alejandro Sanchez the purchaser of the Company.

The secretary then presented a Stock Purchase Agreement between Maria Isabel Bohbot and Angel Alejandro Sanchez, dated November 30, 2012.

RESOLVED, that the Stock Purchase Agreement is hereby ratified and the contemplated stock transfer approved and it is ordered that the Agreement be appended to the minutes of this meeting and that, upon Closing, the Shares in the name of Maria Isabel Bohbot be cancelled and that Shares representing all of the outstanding interest in the company be issued to Angel Alejandro Sanchez.

The secretary then presented a resignation executed by Maria Isabel Bohbot the Director and President of the company dated November 30, 2012.

RESOLVED that the resignation of the Director and Officer listed above is hereby approved and accepted and that the resignation as executed by said officer and director be appended to these minutes.

The chairman then stated that this meeting would be considered as the annual meeting of members and to transact such business as may properly come before the meeting.

The chairman of the meeting called for the election of directors. The following person was nominated: Angel Alejandro Sanchez.

.No further nominations being made nominations were closed and a vote was taken.

After the vote had been counted, the chairman declared that the foregoing named nominee was elected Director of the company.

The chairman of the meeting called for the election of the officers. The following person was nominated: Angel Alejandro Sanchez, President and Secretary.

No further nominations being made nominations were closed and a vote was taken.

After the vote had been counted, the chairman declared that the foregoing named nominee was elected President and Secretary of the company.

The chairman then stated that the newly elected director and officer would assume his responsibilities immediately, and that this meeting would be considered as the annual meeting of shareholders and directors and to transact such business as should properly come before the meeting.

To facilitate the business of the Company, it was further RESOLVED that Angel Alejandro Sanchez, as the President, be authorized as the sole signatory on the bank account in the name of the Company.

Upon motion duly made, seconded and carried, it was,

RESOLVED, that the signing of these minutes shall constitute full ratification thereof and waiver of notice of the meeting by the signatories.

There being no further business before the meeting, on motion duly made, seconded and carried, the meeting was adjourned.

Witnesses:

MARIA ISABEL BOHBOT

ANGEL ALEJANDRO SANCHEZ

LA PERLA PHARMACY, INC

Certificate No 01 For 100 Shares

Issued to Lazaro J. Reinoso Haramboure

Dated March 11 20 09

From whom transferred N/A

Dated 20

No. Of Original Certificate	No. Of Original Shares	No. Of Shares Transferred
01	100	—

Received Certificate No 01

For 100 Shares

on March 11 20 09

CERTIFICATE No 01

INCORPORATED UNDER THE LAWS OF THE STATE OF FLORIDA

SHARES

LA PERLA PHARMACY, INC

100 SHARES COMMON STOCK

This Certifies that Lazaro J. Reinoso Haramboure

is hereby issued 100 (One Hundred)

fully paid and non-assessable Shares of Common Stock of La Perla Pharmacy, Inc. transferable only on the books of the Corporation by the holder hereof, in person or by duly authorized Attorney, upon surrender of this Certificate properly endorsed.

In Witness Whereof, La Perla Pharmacy, Inc has caused this Certificate to be signed by its duly authorized officers and its Corporate Seal to be hereunto affixed as of this 11th day of March 20 09

PRESIDENT

SECRETARY

LAZARUS CORPORATE FILING SERVICES (305) 552-5973

For Value Received, I hereby sell, assign and transfer unto Maria I. Bohbot

Shares represented by the within certificate and do hereby irrevocably constitute and appoint

Maria I. Bohbot Attorney to transfer the said Shares on the books of the within named Corporation with full power of substitution in the premises.

Dated November 5th 20 10

In presence of

Ralph Fonseca

Lazaro J. Reinoso Harambure

NOTICE: THE SIGNATURE OF THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE, IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT, OR ANY CHANGE WHATSOEVER.

LA PERLA PHARMACY, INC

Certificate No 02 For 100 Shares

Issued to Maria I. Bohbot

Dated November 5 2010

From whom transferred
Lazaro J. Reinoso Haramboure

Dated March 11 2009

No. Of Original Certificate	No. Of Original Shares	No. Of Shares Transferred
01	100	100

Received Certificate. No 01

For 100 Shares

on March 9 2009

CERTIFICATE No 02

INCORPORATED UNDER THE LAWS OF THE STATE OF FLORIDA

SHARES 100

LA PERLA PHARMACY, INC

100 SHARES COMMON STOCK

This Certifies that Maria I. Bohbot

is hereby issued 100 (ONE HUNDRED)

fully paid and non-assessable Shares of Common Stock of La Perla Pharmacy, Inc, transferable only on the books of the Corporation by the holder hereof, in person or by duly authorized Attorney, upon surrender of this Certificate properly endorsed.

In Witness Whereof, La Perla Pharmacy, Inc has caused this Certificate to be signed by its duly authorized officers and its Corporate Seal to be hereunto affixed as of this 5th day of November 2010

PRESIDENT

SECRETARY

LAZARUS CORPORATE FILING SERVICES (305) 552-5973

For Value Received, I *hereby sell, assign and transfer unto* Angel Alejandro Sanchez

One Hundred (100) ——— *Shares represented by the within certificate and do hereby irrevocably constitute and appoint*

Manuel R. Lopez *Attorney to transfer the said Shares on the books of the within named Corporation with full power of substitution in the premises.*

Dated November 30 2012

In presence of

Maria I. Bohbot

NOTICE: THE SIGNATURE OF THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE, IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT, OR ANY CHANGE WHATSOEVER.

AC#3544447

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
08/08/2009	**PH 24200**	**48505**

The **PHARMACY** named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: **FEBRUARY 28, 2011**

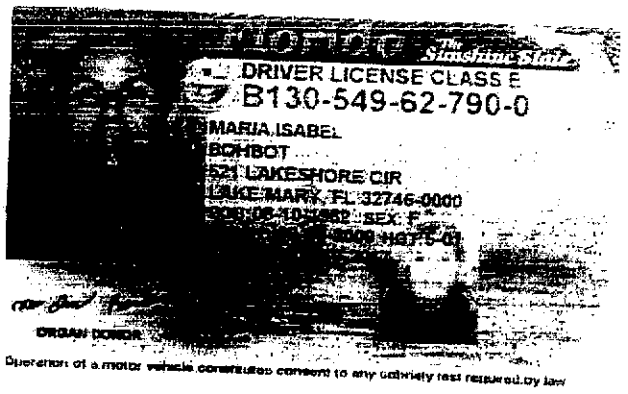
LA PERLA PHARMACY, INC
11180 WEST FLAGLER ST
STE 2
MIAMI, FL 33174

QUALIFICATION(S):
COMMUNITY PHARMACY

Charlie Crist
GOVERNOR

Ana M. Viamonte Ros, M.D., M.P.H.
STATE SURGEON GENERAL

DISPLAY IF REQUIRED BY LAW


The Sunshine State
DRIVER LICENSE CLASS E
B130-549-62-790-0
MARIA ISABEL
BOHBOT
521 LAKESHORE CIR
LAKE MARY, FL 32746-0000
SEX: F
ORGAN DONOR
Operation of a motor vehicle constitutes consent to any sobriety test required by law

Sunshine State
ORGAN DONOR
SAFE DRIVER
Operation of a motor vehicle constitutes consent to any sobriety test required by law

LA PERLA PHARMACY

STOCK PURCHASE AGREEMENT

THIS AGREEMENT is made and entered into this 30th day of November, 2012 by and between Maria Isabel Bohbot, hereinafter referred to as the "Seller," and Angel Alejandro Sanchez, hereinafter referred to as the "Buyer."

RECITALS:

A. La Perla Pharmacy, Inc. ("La Perla Pharmacy") is a Florida corporation in good standing.

B. The Seller owns 100 shares of common capital stock of La Perla Pharmacy, comprising one-hundred percent (100%) of all of the issued and outstanding stock of La Perla Pharmacy.

C. The Seller desires to one hundred percent (100%) of the shares of the stock and the Buyer desires to purchase the same (hereafter referred to as the "Stock") at Closing.

THEREFORE, in consideration of the mutual promises contained herein and other good and valuable consideration, the sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. SALE OF STOCK. Subject to the provisions of this Agreement, the Seller agrees to sell the Stock to the Buyer. In connection therewith, the Seller agrees to deliver the Stock to the Buyer at Closing, with all certificates duly endorsed to the Buyer, free and clear of all liens, claims and encumbrances, and ready for transfer. The Seller further agrees to execute such additional documents and take such additional actions as the Buyer deems necessary to perfect

the Buyer's title to the Stock, both before and after Closing. In turn, the Buyer agrees to tender payment of the Purchase Price in accordance with this Agreement.

2. PURCHASE PRICE. The purchase price (the "Purchase Price") to be paid for the Stock shall be the sum of Seventy Thousand ($70,000.00) Dollars. The parties hereto acknowledge that the Purchase Price accurately represents the current fair market value of the Stock. The Purchase Price shall be paid on the Closing Date.

3. EXECUTION AND CLOSING DATE. The Execution date shall be on the date the last party has executed this Agreement. The Closing Date under this Agreement shall be November 30, 2012.

4. CLOSING DOCUMENTS. All documents relative to Closing shall be executed at Closing.

5. REPRESENTATIONS AND WARRANTIES. The Buyer and the Seller make the following representations and warranties to each other:

(a) Recitals. The recitals in the preamble to this Agreement are true and are hereby incorporated in this Agreement as representations of the Seller.

(b) Title. The Seller has good, absolute, and marketable title to the Stock, free from all liens, claims, and encumbrances. The Seller has the unfettered right, power, and authority to sell all of the Stock pursuant to this Agreement. Delivery of the Stock to the Buyer as contemplated by this Agreement will vest unencumbered title to the Stock in the Buyer.

(c) Taxes. La Perla Pharmacy has filed all required federal, state, and local tax returns and has fully paid all federal, state, and local taxes due. In the event La Perla Pharmacy incurs a tax deficiency related to any events that occurred prior to the Closing, irrespective of when the same was determined or assessed, the Seller shall be responsible for any such deficiency. In the event La Perla Pharmacy incurs a tax deficiency related to any events that occurred subsequent to the Closing, irrespective of when the same was determined or assessed, the Buyer shall be responsible for any such deficiency.

(d) Litigation and Claims. There is no litigation, arbitration, or other legal, judicial, administrative, or governmental action currently pending against La Perla Pharmacy. There are no other pending claims, asserted or unasserted, against La Perla Pharmacy. Seller is not aware of any facts that may give rise to any such proceedings, actions, or claims.

(e) Compliance with Applicable Laws. La Perla Pharmacy has complied with all applicable federal, state and local laws.

(f) Compliance with Corporate Instruments. La Perla Pharmacy has complied with all provisions of its articles of incorporation, bylaws and resolutions in the operation and conduct of its business.

(g) Authority of Seller. Seller and its signatory hereunder have full power and authority to enter into this Agreement and consummate the transaction contemplated thereby.

(h) Corporate Records. The books and records of La Perla Pharmacy are complete and accurate and reflect all transactions of La Perla Pharmacy that properly should have been set forth therein.

(i) Full Disclosure. Seller has made full disclosure to Buyer of all material facts relating to the operation of La Perla Pharmacy and has provided full access to all property, books, records, contracts, and documents of La Perla Pharmacy.

(j) Licenses. La Perla Pharmacy is the holder of any and all licenses and authorizations currently necessary for operation thereof.

(k) Medicare Provider Status. La Perla Pharmacy is authorized to bill Part D under private insurance for Medicare patients.

(l) Assets. The assets of La Perla Pharmacy are the licenses to operate a pharmacy, inventory and good sold at the pharmacy. All assets are free and clear of any and all liens and encumbrances.

(m) Other Liabilities. La Perla Pharmacy has no outstanding liabilities.

(n) Current Lease. The lease at the premises occupied by the pharmacy is is current and in good standing.

(o) Pharmaceutical Inventory at Closing. Seller represents that the inventory is paid and that ~~Buyer acknowledges the amount of inventory at time of Closing~~ AS

6. NOTICES. All notices to be given under this Agreement shall be in writing and sent by registered or certified mail, return receipt requested.

7. ENTIRE AGREEMENT. The parties acknowledge and represent that this Agreement contains the entire understanding between the parties and that there are no other agreements between them as to the matters described herein.

AS

8. GOVERNING LAW. The parties agree that this Agreement shall be deemed made and entered into in the State of Florida and shall be governed and construed in accordance with the laws of the State of Florida.

9. INDEMNIFICATION.

(a) Seller hereby agrees to indemnify and hold La Perla Pharmacy and Buyer harmless from any and all liability, loss, damages, claims, demands, costs and judgments, including without limitation all costs of defense, litigation, and attorney's fees (collectively "Damages"), asserted against, imposed upon, or incurred by La Perla Pharmacy and Buyer, by reason of, resulting from, arising in connection with or due to (a) any and all misrepresentations, breaches of warranty, or the nonfulfillment of any agreement, covenant or other obligation on the part of Seller under this Agreement or any agreement, instrument or documents related hereto including, without limitation, under Section 5 hereof; (b) any conduct, action or inaction on the part of the Seller occurring or arising from or relating to, or any event or circumstance relating to, the operation, management or ownership of La Perla Pharmacy on or prior to the Closing Date; and (c) any and all liabilities of the La Perla Pharmacy of any nature including without limitation any tax, environmental, or other regulatory liabilities whether accrued, absolute, contingent or otherwise, and whether known or unknown, existing at the Closing Date.

(b) The Buyer and La Perla Pharmacy, pursuant to a corporate resolution approving the transaction contemplated hereby, agree to indemnify and hold the Seller harmless from any and all liability, loss, or damages, including all costs of defense, litigation, and attorney's fees, resulting from any claims, demands, costs and judgments arising from (a) any and all misrepresentations, breaches of warranty, or the nonfulfillment of any agreement, covenant or other obligation on the part of Buyer or La Perla Pharmacy under this Agreement or

any agreement, instrument or documents related hereto (b) any conduct, action or inaction on the part of the Buyer or La Perla Pharmacy occurring or arising from or relating to, or any event or circumstance relating to, the operation, management or ownership of La Perla Pharmacy after the Closing Date; and (c) any and all liabilities of La Perla Pharmacy arising after the Closing Date provided that such liabilities do not arise from events, acts or omissions occurring prior to the Closing Date.

10. CONFIDENTIALITY. This Agreement and the terms thereof shall remain confidential and shall not be disclosed to anyone for any purpose whatsoever without the written consent of the parties hereto.

11. REPRESENTATION AND TRANSACTION FEES. Each party shall bear their own legal fees and costs in connection with this transaction. The Seller hereby acknowledges and understands that the law firm of Manuel Lopez & Associates, P.A. is solely and exclusively acting as counsel to the Buyer in the transaction contemplated hereby and further acknowledges and understands that neither said attorneys nor any other attorney or law firm utilized by the Buyer serves as legal counsel to the Seller in the subject transaction.

12. SURVIVAL. The provisions of this Agreement shall survive the closing of the transaction contemplated hereby.

13. ATTORNEY'S FEES. In the event of any legal action to enforce the terms and conditions of this Agreement or related to a breach thereof, the prevailing party shall be entitled to recover all costs of such actions, including attorney's fees and paralegal fees and all other legal expenses and costs at all pre-suit, trial and appellate levels.

14. RECEIVABLES. Any and all receivables from sales prior to the Closing date are the property of the Seller after payment of all costs and expenses associated with the sales.

Buyer shall pay to Seller all monies received from theses receivables within 3 days of clearance of funds.

15. PATIENT RECORDS. As of the Closing Date, Buyer shall become the custodian of all patient records for all patients who received goods or services from the Pharmacy at any time up to and including the Closing Date. Buyer shall maintain such patient records for a period of at least seven (7) years OR LONGER AS REQUIRED BY LAW, following the Closing Date and shall provide Seller with access to same during normal business hours upon receipt of a written request for access from Seller. Buyer shall at all times keep Seller informed as to the location of the patient records and shall immediately notify Seller in writing in the event there is a change in such location. In maintaining the patient records, Buyer will comply with the Standards for Privacy of Individually Identifiable Health Information, 45 C.F.R., Parts 160 through 164 and the Security Standards for the Protection of Electronic Protected Health Information, 45 C.F.R., Part 164 (collectively the "HIPAA Regulations") and agrees not to use or further disclose any protected health information as defined in 42 USC Section 1320d ("Protected Health Information") concerning Seller's patients other than as permitted by this Agreement and the requirements of HIPAA or regulations promulgated thereunder. Buyer will implement appropriate safeguards to prevent the inappropriate use or disclosure of Protected Health Information.

16. ADDITIONAL DOCUMENTS. Buyer and Sellers agree to execute in an expeditious manner all instruments in writing and to do all other things necessary to effectuate the purpose of this Agreement.

17. ADDITIONAL TERMS. Buyer and seller agree that Seller Maria Isabel Bohbot, upon closing, will return for cancellation to the DEA her certificate of registration and that this transaction is being consummated with the understanding that La Perla Pharmacy will discontinue

business altogether with respect to controlled substances. Buyer understands and agrees that Seller will have no responsibility to Buyer, nor to any other person regarding future efforts by Buyer or anyone other person regarding any future efforts by Buyer or anyone else to obtain a DEA registration, or nay attempts by La Perla Pharmacy to resume any business activity related to controlled substances.

IN WITNESS WHEREOF, the parties have executed this Agreement on the day and year first above written.

Witnesses:

Seller:

Maria Isabel Bohbot 11/30/12

Buyer:

Angel Alejandro Sanchez 11/30/12

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Florida HEALTH

Rick Scott
Governor

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307506

FRANAKO PHARMACY INC,
RESPONDENT.

NOTICE

TO: FRANAKO PHARMACY INC
400 SOUTH DIXIE HWY SUITE 17
LAKE WORTH, FL 33460

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Hearing - No Disputed Material Facts

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307506

FRANAKO PHARMACY INC,
RESPONDENT.

NOTICE

TO: FRANAKO PHARMACY INC
P O BOX 222821
WEST PALM BCH, FL 33422

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Hearing - No Disputed Material Facts

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Christopher A. Jurich, Assistant General Counsel CJ 12/18/13 CRC
RE: Hearing - No Disputed Material Facts
SUBJECT: DOH v. Franako Pharmacy, Inc.
DOH Case Number 2013-07506
DATE: December 17, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Franako Pharmacy, Inc.
Subject's Address of Record:	P O Box 222821 West Palm Bch, FL 33422
Enforcement Address:	400 South Dixie Hwy Suite 17 Lake Worth, FL 33460
Subject's License No:	25600 **Rank:** PH
Licensure File No:	18526
Initial Licensure Date:	7/26/2011
Board Certification:	No
Required to Appear:	No
Current PRN Contract:	No

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row • Suite 105
PHONE: 850/245-4444 • FAX 850/245-4684

Allegations:	**Count I:** Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.1081, F.A.C. **Count II:** Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.140(4), F.A.C. under Rule 64B16-27.700, F.A.C. **Count III:** Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.140(3)(d), F.A.C. **Count IV:** Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.110, F.A.C.
Prior Discipline:	None
Probable Cause Panel:	September 5, 2013 Debra Glass & Jeffrey Mesaros
Subject's Attorney:	Pro Se
Complainant/Address:	DOH/ISU West Palm Beach
Materials Submitted:	Memorandum to the Board Motion for Hearing Not Involving Disputed Issues Administrative Complaint Motion to Assess Costs Exhibit A – Affidavit of Fees and Costs Expended Exhibit 1 – Complaint Cost Summary Exhibit 2 – Itemized Costs by Complaint Election of Rights Board Notification Letter PCP Memorandum

CAJ/crl

Disciplinary Guidelines:

Count I: Minimum of $500 fine and 12 hours Laws Rules or MPJE to a maximum of 1 year probation and $2,000 fine.

Count II: Minimum of $500 fine for possession and $1,000 fine for dispensing to a maximum of revocation.

Count III: Minimum of $1,000 fine to a maximum of revocation.

Count IV: Minimum of $1,000 fine to a maximum of revocation.

PRELIMINARY CASE REMARKS: INFORMAL HEARING

On or about April 30, 2013, the Department conducted a routine inspection of the Respondent. During the course of this inspection, the following deficiencies were noted: pharmacy hours were not posted, expired medications were found in active stock, daily logs were missing pharmacists' signatures, and compounding logs were not properly maintained.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-07506**

Franako Pharmacy, Inc.,

Respondent.

_____/

MOTION FOR FINAL ORDER AFTER HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACTS

COMES NOW, the Petitioner, by and through its undersigned counsel, and moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore, the Petitioner would state the following:

1. Petitioner previously filed an Administrative Complaint against Respondent alleging that Respondent had violated the provisions of Florida Statutes, as set forth therein. The Department, by filing the Administrative Complaint, is seeking to discipline the Respondent's license to practice as a **Pharmacy** thereby affecting the Respondent's substantial interests.

2. On or about September 19, 2013, Petitioner served Respondent with the Administrative Complaint via Respondent's address of record with the Department of Health. The Department, by serving the Respondent with the Administrative Complaint, provided the Respondent written notice of its decision to seek discipline of the Respondent's license to practice as a **Pharmacy**.

3. The Respondent has filed an Election of Rights Form or other responsive pleading evincing, or has otherwise indicated, that Respondent does not dispute the material facts alleged in the Administrative Complaint.

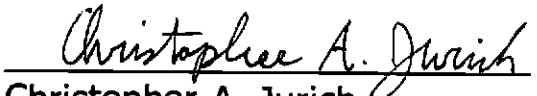
4. There are no disputed issues of material fact to be resolved by the Board.

5. Respondent has been advised, by a copy of this Motion, that a copy of the investigative file in this case shall be furnished to the Board to establish a prima facie case regarding the violations as set forth in the Administrative Complaint.

WHEREFORE, the parties respectfully request the Board of Pharmacy, after allowing the Respondent the opportunity to present oral and/or written evidence in mitigation of the Administrative Complaint, enter a Final Order imposing whatever discipline upon the Respondent's license that the Board deems appropriate.

Respectfully Submitted,

John H. Armstrong, MD, FACS
Surgeon General and Secretary of Health



Christopher A. Jurich
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Florida Bar No. **0099014**
Telephone: (850) 245-4444, ext. 8174
Facsimile: (850) 245-4683
Email: Christopher.Jurich@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 18th day of December, 2013, to: Attn. Mr. Afrani, Franako Pharmacy, Inc., 400 South Dixie Highway, Suite 17, Lake Worth, Florida 33460.

Christopher A. Jurich

Christopher A. Jurich
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-07506**

FRANAKO PHARMACY, INC.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through its undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, Franako Pharmacy, Inc., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a permitted community pharmacy within the state of Florida, having been issued permit number PH 25600.

3. Respondent's address of record is Post Office Box 222821, West Palm Beach, Florida 33422. Respondent's physical address is 400 South Dixie Highway, Suite 17, Lake Worth, Florida 33460.

4. On or about April 30, 2013, a Department inspector conducted an inspection of Respondent at 400 South Dixie Highway, Suite 17, Lake Worth, Florida 33460.

5. On or about April 30, 2013, the Department's inspector noted the following deficiencies:

a. Pharmacy hours not posted in violation of Rule 64B16-28.1081, Florida Administrative Code;

b. Expired medications found in active stock in violation of Rule 64B16-28.110, Florida Administrative Code;

c. Daily logs missing pharmacists' signatures in violation of Rule 64B16-28.140(3)(d), Florida Administrative Code; and/or

d. Compounding logs not properly maintained in violation of Rule 64B16-28.140(4), Florida Administrative Code.

COUNT ONE

6. Petitioner realleges and incorporates paragraph one (1) through five (5), as if fully set forth herein.

7. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any of the requirements of Chapter 465, Florida Statutes or any of the rules of the Board of Pharmacy.

8. Rule 64B16-28.1081, Florida Administrative Code, provides, in pertinent part, that a sign in block letters not less than one inch in height stating the hours the prescription department is open each day shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view.

9. Respondent failed to ensure that a sign stating the hours was displayed in a clear and unobstructed view either at the main entrance of the establishment or at or near the place where prescriptions are dispensed.

10. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-28.1081, Florida Administrative Code, by failing to ensure a sign in block letters not less than one inch in height stating the hours the prescription department is open each day was displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view.

COUNT TWO

11. Petitioner realleges and incorporates paragraph one (1) through five (5), as if fully set forth herein.

12. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any of the requirements of Chapter 465, Florida Statutes or any of the rules of the Board of Pharmacy.

13. Rule 64B16-28.140(4), Florida Administrative Code, sets forth the requirements for maintaining a written record for each batch/sub-batch of a compounded product under the provisions of Rule 64B16-27.700, F.A.C.

14. Respondent failed to properly maintain a written record of the compounded products when the records failed to note the lot numbers, the expiration dates, and the registered pharmacist's certification.

15. Based on the foregoing, Respondent violated Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-28.140(4), Florida Administrative Code, by failing to ensure that the written record for each batch/sub-batch of a compounded product under Rule 64B16-27.700, F.A.C. included all the required information.

COUNT THREE

16. Petitioner realleges and incorporates paragraph one (1) through five (5), as if fully set forth herein.

17. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any of the requirements of Chapter 465, Florida Statutes or any of the rules of the Board of Pharmacy.

18. Rule 64B16-28.140(3)(d), Florida Administrative Code, provides that each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard-copy printout is

correct, by dating and signing such document in the same manner as signing a check or legal document within seven days from the date of dispensing.

19. Respondent failed to properly maintain a daily log when Respondent's daily logs were missing the pharmacists' signatures.

20. Based on the foregoing, Respondent violated Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-28.140(3)(d), Florida Administrative Code, by failing to ensure that each individual pharmacist who dispenses or refills a prescription drug order verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document within seven days from the date of dispensing.

COUNT FOUR

21. Petitioner realleges and incorporates paragraph one (1) through five (5), as if fully set forth herein.

22. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy

permittee who has violated any of the requirements of Chapter 465, Florida Statutes or any of the rules of the Board of Pharmacy.

23. Rule 64B16-28.110, Florida Administrative Code, states persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.

24. Respondent failed to ensure the removal of deteriorated pharmaceutical, or pharmaceuticals which bear upon the container an expiration date which has been reached from the stock.

25. Based on the foregoing, Respondent violated Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-28.110, Florida Administrative Code, by failing to ensure that deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached were removed from stock.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 5th **day of** September**, 2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Vernisha Foster
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Florida Bar # 0092743
Telephone: (850) 245-4444
Facsimile: (850) 245-4683

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE SEP 0 5 2013

/VF
PCP: September 5, 2013
PCP Members: Glass and Mesaros

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-07506**

Franako Pharmacy, Inc.,

Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW, the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or after

July 1, 2001, pursuant to this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. . . .

3. The investigation and prosecution of this case has resulted in costs in the total amount of $1,195.60 based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**1.10**	**$60.39**
Investigation:	**8.60**	**$550.24**
Legal:	**5.50**	**$584.97**
Compliance:	**0.00**	**$0.00**
Sub Total:	**15.20**	**$1,195.60**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$1,195.60**

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $610.63 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $610.63 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $610.63.

DATED this 18th day of December, 2013.

Respectfully Submitted,

John H. Armstrong, MD, FACS
Surgeon General and Secretary of Health

Christopher A. Jurich

Christopher A. Jurich
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Florida Bar No. **0099014**
Telephone: (850) 245-4444, ext. 8174
Facsimile: (850) 245-4683
Email: Christopher.Jurich@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Motion to Assess Cost has been provided by U.S. mail this 18th day of December, 2013, to: Attn: Mr. Afrani, Franako Pharmacy, Inc., 400 South Dixie Highway, Suite 17, Lake Worth, Florida 33460.

Christopher A. Jurich

Christopher A. Jurich
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number **2013-07506** (Department of Health v. **FRANAKO PHARMACY, INC.**) are **ONE THOUSAND ONE HUNDRED NINETY-FIVE DOLLARS AND SIXTY CENTS ($1,195.60).**

6) The costs for DOH case number **2013-07506** (Department of Health v. **FRANAKO PHARMACY, INC.**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case number **2013-07506** (Department of Health v. **FRANAKO PHARMACY, INC.**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to keep track of their time in six-minute increments (e.g., investigators

EXHIBIT A

and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of her knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 2nd day of December, 2013, by Shane Walters, who is personally known to me.

Notary Signature

TOWANDA B. BURNETT
Commission # EE 838342
Expires September 25, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

Towanda Burnett

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

Complaint Cost Summary

Complaint Number: 201307506

Subject's Name: FRANAKO PHARMACY INC

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	1.10	$60.39
Investigation:	8.60	$550.24
Legal:	5.50	$584.97
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	15.20	$1,195.60
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,195.60

EXHIBIT 1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201307506

Report Date 12/02/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA23	0.50	$54.90	$27.45	05/10/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HA115	0.60	$54.90	$32.94	05/13/2013	2	OFFICE SUPERVISORY DUTIES
Sub Total	**1.10**		**$60.39**			
INVESTIGATIVE SERVICES UNIT						
WI108	1.20	$63.98	$76.78	05/17/2013	4	ROUTINE INVESTIGATIVE WORK
WI108	0.70	$63.98	$44.79	05/28/2013	4	ROUTINE INVESTIGATIVE WORK
WI108	1.00	$63.98	$63.98	06/14/2013	4	ROUTINE INVESTIGATIVE WORK
WI108	0.80	$63.98	$51.18	06/14/2013	76	REPORT PREPARATION
WI108	3.20	$63.98	$204.74	06/17/2013	76	REPORT PREPARATION
WI108	0.70	$63.98	$44.79	06/18/2013	76	REPORT PREPARATION
WI108	1.00	$63.98	$63.98	06/20/2013	76	REPORT PREPARATION
Sub Total	**8.60**		**$550.24**			
PROSECUTION SERVICES UNIT						
HLL92A	0.50	$106.35	$53.18	07/08/2013	25	REVIEW CASE FILE
HLL92A	1.30	$106.35	$138.26	07/08/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL92A	0.10	$106.35	$10.64	09/05/2013	68	SIGNING CLOSING ORDERS, ADMINISTRATIVE COMPLAINTS AND REASONAB
HLL92A	0.80	$106.35	$85.08	09/10/2013	79	STIPULATION
HLL92A	0.10	$106.35	$10.64	09/17/2013	35	TELEPHONE CALLS
HLL104B	0.50	$106.35	$53.18	10/07/2013	25	REVIEW CASE FILE
HLL104B	0.20	$106.35	$21.27	10/07/2013	29	REVIEW ADMINISTRATIVE COMPLAINT
HLL104B	0.20	$106.35	$21.27	10/08/2013	25	REVIEW CASE FILE
HLL104B	0.50	$106.35	$53.18	10/08/2013	35	TELEPHONE CALLS
HLL104B	0.40	$106.35	$42.54	10/08/2013	60	MISCELLANEOUS
HLL104B	0.20	$106.35	$21.27	10/08/2013	36	PREPARATION OR REVISION OF LETTER

EXHIBIT
2

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201307506

Report Date 12/02/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
HLL104A	0.30	$106.35	$31.91	10/16/2013	35	TELEPHONE CALLS
HLL104A	0.10	$106.35	$10.64	10/16/2013	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFF
HLL104B	0.20	$106.35	$21.27	10/18/2013	35	TELEPHONE CALLS
HLL104B	0.10	$106.35	$10.64	10/18/2013	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFF
Sub Total	**5.50**		**$584.97**			

Total Cost **$1,195.60**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 12/02/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

December 18, 2013

VIA U.S. MAIL

Attn: Mr. Afrani
Franako Pharmacy, Inc.
Suite 17
400 South Dixie Highway
Lake Worth, Florida 33460

Re: DOH vs. Franako Pharmacy, Inc.
DOH Case Number: 2013-07506

Dear Mr. Afrani/Franako Pharmacy, Inc.:

I am in receipt of your election of rights requesting a hearing not involving disputed issues of material fact executed by you on October 4, 2013 concerning the above referenced case. This means that the facts alleged in the Administrative Complaint are uncontested. This is an important distinction because, by law, the Board cannot resolve disputes of material fact in this case or any disciplinary case. Since your client is requesting a hearing not involving disputed issues of material fact, he is not admitting the facts alleged in the Administrative Complaint, however, your client is agreeing not to contest these facts and to limit presentation to legal argument, if any, and to matters in mitigation or extenuation.

Our office is now preparing this case to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for **February 12, 2014** in Orlando, Florida. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and your office will receive notification of the date and time approximately two weeks prior to the meeting.

Thank you for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office at 850-245-4444, ext. 8174.

Sincerely,

Christopher A. Jurich

Christopher A. Jurich
Assistant General Counsel

CAJ/crl

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: **Department of Health, Prosecution Services Unit**

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Franako Pharmacy, Inc., (VF)**
Case No. 2013-07506

MEMBERS: **~~Cynthia Griffin~~, PharmD and Jeffrey Mesaros**
Glaro

DATE OF PCP: **September 5, 2013** **AGENDA ITEM: A-06**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-28.1081, Florida Administrative Code;

Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-28.140(4), Florida Administrative Code;

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss

___ **other**:

9/5/13

Chair, Probable Cause Panel
Board of Pharmacy

Date

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

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CONFIDENTIAL AND EXEMPT MATERIALS

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10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

May 17, 2013

CONFIDENTIAL TO:
Franako Pharmacy, Inc
400 South Dixie Hwy, Suite 17
Lake Worth, FL 33460

Case Number: 2013-07506

Dear Franako Pharmacy

We are currently investigating the enclosed document received by the Department investigation was initiated after it was determined that you may have violated the Pha Act.

Within **20 days** of receiving this letter, you may:

- submit a **written response** to the address below; **or**
- call our office to schedule an **interview**.

Florida law requires that this case and all investigative information remain confidential after the Probable Cause Panel has determined that a violation occurred or you give u confidentiality. Therefore, the contents of the investigation cannot be disclosed to you public. You may make a written request for a copy of the investigative file and it will b when the investigation is complete. You may submit an additional written response to information in the investigative file within 20 days of receipt.

You are not required to answer any questions or give any statement, and you have represented by an attorney. It is not possible to estimate how long it will take to investigation because the circumstances of each investigation differ.

The mission of the Department of Health is to protect, promote & improve the heal people in Florida through intregrated state, couny and community efforts. If you h questions please call me at (561) 275 8095. In addition, if you have any concerns o about our complaint process, please fill-out our *Customer Concerns or Suggestion* www.floridashealth.com/mqa/survey.html.

Sincerely,

Kevin Lapham
Investigative Specialist

EXHIBIT # 2

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 18526

Insp # 115783

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
FRANAKO PHARMACY INC	25600	6/15/2012
DOING BUSINESS AS	DEA NUMBER	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS: 400 SOUTH DIXIE HWY SUITE 17	TELEPHONE #: 561-588-0707 / EXT.	SANFORD D DUCKMAN
CITY: LAKE WORTH / COUNTY: 60	STATE/ZIP: 33460	PRESCRIPTION DEPARTMENT MANAGER LICENSE #: 27319

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1. Kwame Kyermaten-Afrani	PS35409
Open	8	8	8	8	on cal	on cal	8	2. Bruce Greenbarg	PS32836
Close	8	8	8	12	on cal	on cal	12	3.	

	SATISFACTORY	N/A	YES	NO
1 Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2 Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]		X		
3 Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4 Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			X	
5 A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6 Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7 Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			X	
8 Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9 Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10 Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11 CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			X	
12 Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]		X		
13 Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
14 Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15 All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16 Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].		X		
17 Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18 Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]		X		
19 DEA 222 order forms properly completed. [893.07, F.S.]				X
20 Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
21 Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]			X	
22 Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			X	
23 Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]		X		
24 Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]		X		
25 Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]			X	
26 Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]		X		
27 Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]		X		
28 Compounding records properly maintained. [64B16-28.140(4), F.A.C.]*		X		
29 Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]		X		
30 Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			X	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: Re inspection conducted with relief RPH Bruce Greenbarg PS32836 (provided by staffing agency Healthcare Consultants)
Upon entering RPh Greenbarg was not properly identified. Advised that RPH name tags must be worn during working hours.
#4: Pharmacy hours posted were posted in standard hours. (Note: Friday hours posted indicate "on Call". Re inspection was conducted on Friday. Pharmacy was open. Licenses were visible to the public
#7: Upon entering Temperature was posted at 70 degrees.
#11: CQI minutes for 9/5/11, 1/5/12 and 4/9/12 were seen and copies taken.
#19: DEA 222 completed forms were not available. Per RPh Greenbarg they are stored in controlled substance safe which was not accessible at time of inspection.
#22: Daily logs were completed and copies from 1/2/12 to 6/14/12 were taken.

#20:A controlled substance movement report from 4/6/12 to 6/15/12 was requested and provided for scheduled II-V.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Bruce Greenbarg RPh

Bruce Greenbarg — Institutional Representative

06-15-2012 — Date

Investigator/Sr. Pharmacist Signature

ID wi95

EXHIBIT # 3

INV 359 Revised 5/12, 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # _____

Insp # _____

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT FRANAKO PHARMACY INC		PERMIT NUMBER 25600	DATE OF INSPECTION 4/6/2012
DOING BUSINESS AS		DEA NUMBER FF2785206	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 400 SOUTH DIXIE HWY SUITE 17		TELEPHONE # 5615880707 EXT.	SANFORD DUCKMAN
CITY LAKE WORTH	COUNTY 60	STATE/ZIP 33460	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 27319

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1. KWAME KYEREMATEN-AFRANI	PS35409
Open	6A	9A	5	5P	X	X	7P	2. SIMON JEAN SIMON	RPT 38399
Close	11P	9P	11P	11P	X	X	11P	3. EDWARD KATZ	PS10052

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2	Pharmacy technicians properly identified and supervised. [64B16-27.420, F.A.C.]		X		
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]				X
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]				X
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]				X
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	X			
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15	All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	X			
19	DEA 222 order forms properly completed. [893.07, F.S.]				X
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	X			
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]				X
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	X			
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	X			
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]			X	
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]	X			
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]	X			
28	Compounding records properly maintained. [64B16-27.700, F.A.C.]*	X			
29	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]	X			
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			X	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: ROUTINE INSPECTION CONDUCTED WITH KWAME KYEREMATEN-AFRANI
SEE ADDITIONAL REMARKS PAGE

CONTROLLED SUBSTANCE OBSERVATIONS:
A RANDOM REVIEW OF SCHEDULE II CONTROLLED SUBSTANCES RX'S INDICATED THE DISPENSING OF OXYCODONE TO PATIENTS IN THEIR 20'S-40'S WHO HAVE VISITED PAIN CLINICS OUTSIDE THE AREA AND AS FAR AWAY AS MIAMI/DADE COUNTY. PATIENTS SEEN WITH ONLY IDENTIFICATION CARDS, PAYING CASH. HAVING ONLY CONTROLLED SUBSTANCES FILLED WITH THE ADDITION OF "FILLER RX'S", IE, IBUPROFEN WITH INAPPROPRIATE DIRECTIONS FOR USE (ONE DAILY). MANY RX'S OBSERVED WITHOUT PRESCRIBER VERIFICATION INDICATED.
ADVISED RPH TO REVEIW 64B16-27.831

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT KWAME KYEREMATEN-AFRANI

Institutional Representative

04-06-2012
Date

Investigator/Sr. Pharmacist Signature

ID wi95

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

STATE OF FLORIDA
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE - ISU

FLORIDA DEPARTMENT OF HEALTH

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ADDITIONAL REMARKS

CORPORATE NAME FRANAKO PHARMACY INC	INSPECTION NUMBER	TYPE OF PERMIT 2205	DATE OF INSPECTION 4/6/2012
DOING BUSINESS AS	FILE NUMBER	LICENSE # 25600	
STREET ADDRESS 400 SOUTH DIXIE HWY SUITE 17		TELEPHONE # 5615880707	EXT #
CITY LAKE WORTH	COUNTY PALM BEACH	STATE/ZIP 33460	

Remarks:

UPON ENTERING THE RPH ON DUTY WAS NOT PROPERLY IDENTIFIED.

#4: PHARMACY HOURS WRITTEN IN MILITARY HOURS. ADVISED TO CHANGE TO STANDARD HOURS FOR THE GENERAL PUBLIC TO READ

LICENSES NOT VISIBLE TO THE PUBLIC. ADVISED RPH THAT PUBLIC MUST BE ABLE TO READ LICENSES.

#7: UPON ENTERING PHARMACY THE TEMPERATURE WAS 80 DEGREES.
ADVISED THIS TEMPERATURE MAY COMPROMISE THE INTEGRITY OF THE MEDICATIONS. ADVISED TO ADDRESS.

#11: ONLY 2 CQI MEETINGS HAVE BEEN HELD SINCE THIS LICENSE WAS GRANTED IN JULY 2011. MEETINGS WERE HELD 9/5/11 AND 1/5/12 AND BOTH INDICATED DUPLICATE MINUTES. ADVISED MEETINGS MUST BE HELD QUARTERLY AND RELATE TO QRE'S AND THEIR ACTIONS OF CORRECTION.

#19: ELECTRONIC DEA 222 FORMS WERE NOT PROPERLY COMPLETED.

#22: DAILY LOGS MISSING SIGNATURES SINCE 3/29/12

NOTE
THIS PHARMACY HAS HAD SEVERAL PHARMACY MANAGERS IN THE LAST 9 MONTH PERIOD INCLUDING RUBEN GARZON, (PS21325), BENJAMIN LEVY(PS47936), DAVID MACKARAY(PS24599), EDWARD KATZ (PS10052) AND SANFORD DUCKMAN (PS27319).

DAILY LOGS DO NOT INDICATE GARZON WORKED ON ANY DAYS.
DAILY LOGS INDICATE DUCKMAN ONLY WORKED ON 10/24/11.
DALIY LOGS INDICATE MACKARAY ONLY WORKED 3 DAYS ON 10/4,10/10 AND 9/19/2011
DAILY LOGS DO NOT INDICATE LEVY WORKED ON ANY DAYS
DAILY LOGS DO NOT INDICATE KATZ WORKED ON ANY DAYS

AN OFFICAL RECEIPT WAS GIVEN TO KYEREMATEN-AFRANI FOR RECORDS REMOVED FOR COPYING.
A REQUEST FOR PATIENT PROFILES WAS GIVEN AS WELL FOR SELECT RX'S INDICATED ON THE OFFICIAL RECEIPT TO BE PROVIDED WITHIN 72 HOURS.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT KWAME KYEREMATEN-AFRANI

Institutional Representative

04-06-2012
Date

Investigator/Sr. Pharmacist Signature

ID wi95

INV 416 Revised 12/11, 10/11, 01/07, 07/03

11

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
WWW.DOH.STATE.FL.US

FLORIDA DEPARTMENT OF HEALTH

COMMUNITY PHARMACY

FILE# 18526

INSPECTION# _____

ROUTINE ☐ CHANGE LOC ☐ NEW ☒ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

INSPECTION AUTHORITY – CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT: FRANAKO PHARMACY	PERMIT NUMBER	EXPIRATION DATE	DATE OF INSPECTION: 7/20/11
DOING BUSINESS AS	TELEPHONE NUMBER	EXTENSION	
STREET ADDRESS: 400 So. Dixie Hwy #17	CITY: LAKE WORTH	COUNTY: Palm Bch	STATE: FL. ZIP: 33460
DEA NUMBER		EXPIRATION DATE	
PRESCRIPTION DEPARTMENT MANAGER NAME: RUBEN GARZON	PDM NOTIFICATION DATE	LICENSE NUMBER: 21325	9/30/11
VENDOR WHOLESALER PHARMACY	VENDOR LICENSE NUMBER		
REGISTERED PHARMACIST/INTERN/TECHNICIAN 1 KWAME KYEREMATEN-AFAANI	LICENSE NUMBER: PS 35409		
2			
3			

	SATISFACTORY	NA	YES	NO
1. Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			✓	
2. Pharmacy technicians properly identified and supervised, approval date. [64B16-27.410, F.A.C.]		✓		
3. Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]		✓		
4. Proper signs displayed. [465.025(7). F.S.] [64B16-28.109(1). F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035F.A.C.] [64B16-27.400(6), F.A.C.]*			✓	
5. Written and verbal offer to counsel patients. [64B16-27.820(1). F.A.C.]	✓			
6. Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			✓	
7. Prescription department clean and safe. [64B16-28.102(4). F.A.C.]			✓	
8. Proper equipment and references as required. [64B16-28.102, F.A.C.]			✓	
9. Medication properly labeled. [465.0255. F.S.] [64B16-28.109. F.A.C.]	✓			
10. CQI Policy and Procedures and quarterly meetings. [64B16-27.300, F.A.C. [766.101, F.S.]			✓	
11. Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1) (c) 6. F.S.] [64B16-28.140(3) (b), F.A.C.]		✓		
12. Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	✓			
13. Controlled substance records readily retrievable. [893.07 (4)(B). F.S.]	✓			
14. All controlled substance prescriptions contain information required. [893.04(1) (c), F.S.]	✓			
15. Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1) (g). F.S.] [64B16-28.114. F.A.C.]	✓			
16. Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1) (a). F.S.]	✓			
17. DEA 222 order forms properly completed. [893.07(2), F.S.]	✓			
18. Controlled substance Rx information in computer system is retrievable. [21CFR 1306.22] [893.07. F.S] [64B16-28.140. F.A.C.]*	✓			
19. Controlled substance records maintained for 2 years. [21CFR 1304.04][21CFR 1306.22] [893.07(4) (b), F.S.]	✓			
20. Certified daily log OR printout maintained as required by section. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b). F.A.C.]	✓			
21. Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.] *	✓			
22. Compounding records properly maintained. [64B16-27.700, F.A.C.] [64B16-28.140(4), F.A.C.]*	✓			
23. Unit dose records properly maintained. [465.016(1) (l), F.S.][64B16-28.118, F.A.C.] *	✓			
** Questions with (*) may be answered n/a (not applicable)*				

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: New Pharmacy opening Inspection, Currently NO ADEQUATE Filling AREA FOR Rx's. Advised to Address Per PDM, Delivery plans to patients will start at opening. NO COMPOUNDING to BE DONE. Reviewed + Provided 64B16-27.831

I have read and have had this inspection report and the laws and regulations concerned explained, and the information given is true and correct to the best of my knowledge.

Signature of Pharmacist _____ Date 7/20/11 _____ Investigator/Sr. Pharmacist Signature/ID Number

RUBEN GARZON
Print Name

INV 359 Revised 06/09 05/07; 5/06, Replaces 12/02, 12/00

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CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201019143

JAMES M. MAISTER,
RESPONDENT.

NOTICE

TO: JAMES M. MAISTER
4810 DIAMONDS PALM LOOP
WESLEY CHAPEL, FL 33543

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, February 12, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at The Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809.

The purpose of the hearing is to consider a motion for: Hearing - No Disputed Material Facts

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 14th day of January, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Casey Cowan, Assistant General Counsel
RE: **Hearing - No Disputed Material Facts**
SUBJECT: DOH v. James M. Maister, R.PH.
DOH Case Number: 2010-19143
DATE: December 19, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **February 12, 2014** meeting of the board. The following information is provided in this regard.

Subject:	James M. Maister, R.PH.
Subject's Address of Record:	4810 Diamonds Palm Loop Wesley Chapel, FL 33543 CLC
Enforcement Address:	4810 Diamonds Palm Loop Wesley Chapel, FL 33543
Subject's License No:	34202 **Rank:** PS
Licensure File No:	23211
Initial Licensure Date:	7/19/1999
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Violated Section 465.016(1)(e), Florida Statutes (2010) by violation of 893.13(7)(a)9, Florida Statutes (2009)
Prior Discipline:	4000, DOH-02-1355-FOI; 5020, DOH-02-1354-FOI
Probable Cause Panel:	Meshad & Weizer March 28, 2013
Subject's Attorney:	Pro Se
Complainant/Address:	Department Of Health

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row - Suite 105
PHONE: 850/245-4444 • FAX 850/245-4683

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Materials Submitted:

Memorandum to the Board
Motion for Hearing Not Involving Disputed Issues of Material Fact for Final Order
Administrative Complaint
Motion to Assess Costs
Exhibit A-Affidavit of Fees and Cost
Exhibit 1-Complaint Cost Summary
Exhibit 2-Itemized Cost by Complaint
Board Notification Letter
Election of Rights
Supplemental Investigative Report dated 4/18/2013
PCP Memo
PRN Letter
456 Materials
456 Request
Letters/Response
Confidentiality Agreement (signed)
Final Investigative Report
Exhibits 1-17

CLC/bhh

Disciplinary Guidelines: Section 465.016(1)(e), Florida Statutes (2010)- $1,500 fine and one (1) year probation up to $5,000 fine and one (1) year suspension.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

One count AC alleging a violation of Section 465.016(1)(e), Florida Statutes (2010), by a violation of 893.13(7)(a)9, Florida Statutes (2009), by attempting to obtain a controlled substance by fraud, a third degree felony.

On or about August 17, August 29, and September 8, 2010, Respondent filled a fraudulent prescription for hydrocodone/APAP, at a Target Pharmacy #1382, located in Wesley Chapel, Florida. On or about September 30, 2010, the Pasco County Sheriff's Office arrested Respondent and charged him with three (3) counts of attempting to obtain a controlled substance by fraud, a third degree felony in violation of Section 893.13(7)(a)9, Florida Statutes.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2010-19143**

JAMES M. MAISTER, R.PH.,

Respondent.

_____/

MOTION FOR FINAL ORDER AFTER A HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACTS

PETITIONER, the Florida Department of Health, by and through the undersigned counsel, hereby moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore Petitioner states:

1. Petitioner previously filed an Administrative Complaint against Respondent alleging that Respondent had violated the provisions of Florida Statutes, as set forth therein. Petitioner, by filing the Administrative Complaint, is seeking to discipline Respondent's license to practice Pharmacy, thereby affecting Respondent's substantial interests.

2. On or about April 2, 2013, Petitioner served Respondent with the Administrative Complaint via Certified Mail at 4810 Diamonds Palm Loop, Wesley Chapel, Florida 33543. Petitioner, by serving Respondent with the Administrative Complaint, provided Respondent written notice of its decision to seek discipline of the Respondent's license to practice pharmacy.

3. Respondent has filed an Election of Rights Form or other responsive pleading evincing, or has otherwise indicated, that Respondent does not dispute the material facts alleged in the Administrative Complaint.

4. There are no disputed issues of material fact to be resolved by the Board.

5. Respondent has been advised by way of this Motion, that a copy of the investigative file in this case will be furnished to the Board, establishing a prima facie case regarding the violations as set forth in the Complaint.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy, after allowing Respondent the opportunity to present oral and/or written evidence in mitigation of the Administrative Complaint, enter

a Final Order imposing whatever discipline upon Respondent's license that the Board deems appropriate.

Respectfully submitted,

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

CASEY L. COWAN
Assistant General Counsel
Fla. Bar No. **0035536**
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: **casey_cowan**@doh.state.fl.us

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 23rd day of August, 2013, to: **JAMES M. MAISTER, R.PH., at 4810 DIAMONDS PALM LOOP, WESLEY CHAPEL, FLORIDA 33543.**

CASEY L. COWAN
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. CASE NO. 2010-19143

JAMES M. MAISTER, RPH,

RESPONDENT.

ADMINISTRATIVE COMPLAINT

Petitioner Department of Health, by and through its undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, James M. Maister, R.Ph., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 34202.

3. Respondent's address of record is 4810 Diamonds Palm Loop, Wesley Chapel, Florida 33543.

4. On or about August 17, 2010, Respondent filled a fraudulent prescription for hydrocodone/APAP, at a Target Pharmacy #1382, located in Wesley Chapel, Florida.

5. Hydrocodone/APAP contains hydrocodone and acetaminophen, or Tylenol and is prescribed to treat pain. According to Section 893.03(3), Florida Statutes, hydrocodone, in the dosages found in hydrocodone/APAP is a Schedule III controlled substance that has a potential for abuse less than the substances in Schedules I and II and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

6. On or about August 29, 2010, Respondent filled a fraudulent prescription for hydrocodone/APAP, at a Target Pharmacy #1382, located in Wesley Chapel, Florida.

7. On or about September 8, 2010, Respondent filled a fraudulent prescription for hydrocodone/APAP, at a Target Pharmacy #1382, located in Wesley Chapel, Florida.

8. On or about September 30, 2010, the Pasco County Sheriff's Office arrested Respondent and charged him with three (3) counts of attempting to obtain a controlled substance by fraud, a third degree felony in violation of Section 893.13(7)(a)9, Florida Statutes.

9. Section 465.016(1)(e), Florida Statutes (2010), provides that a pharmacist can be disciplined, including suspension, for violating a provision of Chapter 893, Florida Statutes.

10. Section 893.13(7)(a)9, Florida Statutes (2010), provides that it is unlawful for any person to acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.

11. As set forth above, on or about September 30, 2010, the Pasco County Sheriff's Office arrested Respondent and charged him with three (3) counts of attempting to obtain a controlled substance by fraud, a third degree felony in violation of Section 893.13(7)(a)9, Florida Statutes.

12. Based on the foregoing, Respondent violated Section 465.016(1)(e), Florida Statutes (2010), by a violation of 893.13(7)(a)9, Florida Statutes (2009), by attempting to obtain a controlled substance by fraud, a third degree felony.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 28th **day of** March, **20**13.

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and Secretary of Health

Casey L. Cowan

Casey L. Cowan
Assistant General Counsel
Fla. Bar No. 0035536
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683
Email: casey_cowan@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE MAR 28 2013

PCP: 3/28/13
PCP Members: Weizer + Meshad

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2010-19143**

JAMES M. MAISTER, R.PH.,

Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or

> after July 1, 2001, pursuant to this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. . . .

3. The investigation and prosecution of this case has resulted in costs in the total amount of $4, 393.92, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**1.60**	**$92.19**
Investigation:	**30.90**	**$2,072.88**
Legal:	**20.60**	**$2,228.85**
Compliance:	**0.00**	**0.00**
Sub Total:	**53.10**	**$4,393.92**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$4, 393.92**

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $2,165.07 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

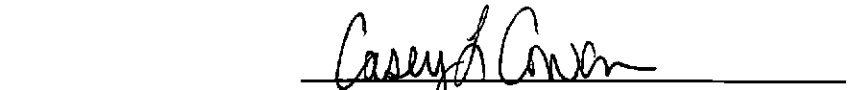
5. Petitioner requests that the Board grant this motion and assess costs in the amount of $2,165.07 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $2,165.07.

DATED this 23rd day of August, 2013.

Respectfully Submitted,

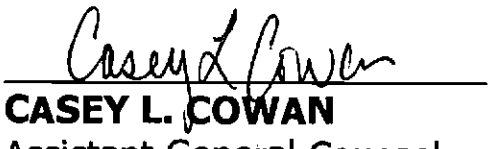
John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health



CASEY L. COWAN
Assistant General Counsel
Florida Bar No.: **0035536**
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 23rd day of August, 2013, to: **JAMES M. MAISTER, R.PH., 4810 DIAMOND PALM LOOP, WESLEY CHAPEL, FLORIDA 33543**.



CASEY L. COWAN
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2010-19143** (Department of Health v. **JAMES M. MAISTER, R.PH.**) are **FOUR THOUSAND THREE HUNDRED NINETY-THREE DOLLARS AND NINETY-TWO CENTS ($4, 393.92).**

6) The costs for DOH case numbers **2010-19143** (Department of Health v. **JAMES M. MAISTER, R.PH.**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case numbers **2010-19143** (Department of Health v. **JAMES M. MAISTER, R.PH.**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to

EXHIBIT
tabbies
A

keep track of their time in six-minute increments. (e.g., investigators and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of her knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 19 day of August, 2013, by Shane Walters, who is personally known to me.

Notary Signature

Antoinette Carter

Name of Notary Printed

ANTOINETTE F. CARTER
MY COMMISSION EXPIRES
September 26, 2015
#EE 132192
Bonded thru
Troy Fain Insurance
NOTARY PUBLIC, STATE OF FLORIDA

Stamp Commissioned Name of Notary Public:

Complaint Cost Summary

Complaint Number: 201019143

Subject's Name: MAISTER, JAMES M

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.60	$92.19
Investigation:	30.90	$2,072.88
Legal:	20.60	$2,228.85
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	53.10	$4,393.92
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$4,393.92

EXHIBIT

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1

Division of
Medical Quality Assurance

MQA

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Time Tracking System
Itemized Cost by Complaint

Complaint 201019143

Report Date 08/16/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
COMPLIANCE MANAGEMENT UNIT						
HA17	0.10	$57.62	$5.76	11/24/2010	1	ROUTINE ADMINISTRATIVE DUTIES
HA17	0.10	$57.62	$5.76	11/29/2010	1	ROUTINE ADMINISTRATIVE DUTIES
Sub Total	**0.20**		**$11.52**			
CONSUMER SERVICES UNIT						
HA107	0.80	$57.62	$46.10	10/05/2010	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HA107	0.60	$57.62	$34.57	02/22/2012	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFF
Sub Total	**1.40**		**$80.67**			
INVESTIGATIVE SERVICES UNIT						
TI123	1.10	$65.23	$71.75	10/08/2010	4	ROUTINE INVESTIGATIVE WORK
TI123	1.80	$65.23	$117.41	10/12/2010	4	ROUTINE INVESTIGATIVE WORK
TI123	1.30	$65.23	$84.80	10/13/2010	4	ROUTINE INVESTIGATIVE WORK
TI123	0.20	$65.23	$13.05	10/13/2010	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
TI123	2.00	$67.81	$135.62	10/15/2010	58	TRAVEL TIME
TI123	7.50	$67.81	$508.58	10/15/2010	4	ROUTINE INVESTIGATIVE WORK
TI123	1.00	$67.81	$67.81	10/19/2010	58	TRAVEL TIME
TI123	1.00	$67.81	$67.81	10/19/2010	4	ROUTINE INVESTIGATIVE WORK
TI123	2.10	$67.81	$142.40	10/26/2010	4	ROUTINE INVESTIGATIVE WORK
TI123	2.00	$67.81	$135.62	10/26/2010	76	REPORT PREPARATION
TI123	3.00	$67.81	$203.43	10/27/2010	4	ROUTINE INVESTIGATIVE WORK
TI123	1.50	$67.81	$101.72	10/27/2010	58	TRAVEL TIME
TI123	1.00	$67.81	$67.81	10/28/2010	4	ROUTINE INVESTIGATIVE WORK
TI123	1.50	$67.81	$101.72	10/28/2010	58	TRAVEL TIME
TI123	1.00	$67.81	$67.81	10/28/2010	76	REPORT PREPARATION
TI123	0.30	$63.98	$19.19	04/16/2013	6	SUPPLEMENTAL INVESTIGATION

tabbies EXHIBIT 2

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
TI141	1.00	$63.98	$63.98	04/17/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
TI141	0.60	$63.98	$38.39	04/18/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
TI123	1.00	$63.98	$63.98	04/18/2013	6	SUPPLEMENTAL INVESTIGATION
Sub Total	**30.90**		**$2,072.88**			

PROSECUTION SERVICES UNIT

HLL81B	2.60	$111.56	$290.06	11/12/2010	25	REVIEW CASE FILE
HLL81B	0.10	$111.56	$11.16	11/15/2010	25	REVIEW CASE FILE
HLL81B	0.40	$111.56	$44.62	11/15/2010	35	TELEPHONE CALLS
HLL81B	0.80	$111.56	$89.25	11/18/2010	25	REVIEW CASE FILE
HLL81B	0.50	$111.56	$55.78	11/18/2010	25	REVIEW CASE FILE
HLL81B	0.40	$111.56	$44.62	11/18/2010	26	PREPARE OR REVISE MEMORANDUM
HLL81B	0.50	$111.56	$55.78	11/22/2010	25	REVIEW CASE FILE
HLL81B	0.60	$111.56	$66.94	11/22/2010	26	PREPARE OR REVISE MEMORANDUM
HLL67B	0.20	$111.56	$22.31	09/09/2011	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL67B	0.20	$111.56	$22.31	09/09/2011	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL67B	1.30	$111.56	$145.03	10/03/2011	25	REVIEW CASE FILE
HLL67B	0.30	$111.56	$33.47	10/03/2011	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFF
HLL67B	0.30	$111.56	$33.47	10/03/2011	36	PREPARATION OR REVISION OF LETTER
HLL67B	0.20	$111.56	$22.31	10/03/2011	46	LEGAL RESEARCH
HLL67B	0.40	$111.56	$44.62	10/03/2011	81	ESO/ERO
HLL67B	0.40	$111.56	$44.62	10/03/2011	46	LEGAL RESEARCH
HLL67A	0.30	$111.56	$33.47	10/03/2011	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFF
HLL67B	0.20	$111.56	$22.31	10/05/2011	26	PREPARE OR REVISE MEMORANDUM
HLL67B	0.20	$111.56	$22.31	10/05/2011	81	ESO/ERO
HLL67B	0.20	$111.56	$22.31	10/05/2011	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL67B	0.20	$102.41	$20.48	02/05/2012	37	REVIEW LETTER
HLL67B	0.30	$102.41	$30.72	02/05/2012	46	LEGAL RESEARCH
HLL67B	0.20	$102.41	$20.48	02/22/2012	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFF
HLL67B	1.30	$102.41	$133.13	02/22/2012	36	PREPARATION OR REVISION OF LETTER
HLL67B	0.30	$102.41	$30.72	07/06/2012	37	REVIEW LETTER

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201019143

Report Date 08/16/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
HLL67B	0.20	$102.41	$20.48	09/11/2012	46	LEGAL RESEARCH
HLL67B	0.10	$102.41	$10.24	09/18/2012	37	REVIEW LETTER
HLL67B	0.20	$102.41	$20.48	09/18/2012	25	REVIEW CASE FILE
HLL67B	0.30	$102.41	$30.72	09/18/2012	46	LEGAL RESEARCH
HLL67B	0.20	$102.41	$20.48	09/18/2012	36	PREPARATION OR REVISION OF LETTER
HLL67B	0.20	$102.41	$20.48	09/21/2012	37	REVIEW LETTER
HLL67B	0.20	$102.41	$20.48	09/21/2012	46	LEGAL RESEARCH
HLL67B	0.20	$106.35	$21.27	12/10/2012	37	REVIEW LETTER
HLL67B	0.20	$106.35	$21.27	12/10/2012	25	REVIEW CASE FILE
HLL67B	0.20	$106.35	$21.27	12/10/2012	46	LEGAL RESEARCH
HLL67B	0.20	$106.35	$21.27	01/02/2013	46	LEGAL RESEARCH
HLL67B	0.60	$106.35	$63.81	01/02/2013	25	REVIEW CASE FILE
HLL67B	0.40	$106.35	$42.54	01/02/2013	31	PREPARE OR REVISE CLOSING ORDER
HLL67B	0.20	$106.35	$21.27	01/02/2013	32	REVIEW CLOSING ORDER
HLL67A	0.20	$106.35	$21.27	01/14/2013	35	TELEPHONE CALLS
HLL67A	0.20	$106.35	$21.27	01/15/2013	35	TELEPHONE CALLS
HLL67A	0.40	$106.35	$42.54	01/15/2013	35	TELEPHONE CALLS
HLL67A	0.20	$106.35	$21.27	02/20/2013	35	TELEPHONE CALLS
HLL67A	0.80	$106.35	$85.08	02/20/2013	25	REVIEW CASE FILE
HLL67A	0.50	$106.35	$53.18	02/20/2013	31	PREPARE OR REVISE CLOSING ORDER
HLL67A	0.50	$106.35	$53.18	02/21/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL67A	0.30	$106.35	$31.91	04/02/2013	35	TELEPHONE CALLS
HLL67A	0.30	$106.35	$31.91	04/15/2013	35	TELEPHONE CALLS
HLL67A	0.30	$106.35	$31.91	04/19/2013	35	TELEPHONE CALLS
HLL67A	0.50	$106.35	$53.18	04/19/2013	40	PREPARATION OF OR REVISION OF A PLEADING
HLL67A	0.20	$106.35	$21.27	04/19/2013	36	PREPARATION OR REVISION OF LETTER
HLL67A	0.40	$106.35	$42.54	05/01/2013	35	TELEPHONE CALLS
Sub Total	**20.60**		**$2,228.85**			

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201019143

Report Date 08/16/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
Total Cost			$4,393.92			

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 08/16/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

August 20, 2013

VIA U. S. MAIL

JAMES M. MAISTER
4810 DIAMOND PALM LOOP
WESLEY CHAPEL, FLORIDA 33543

Re: DOH vs. JAMES M. MAISTER, R.PH.
DOH Case Number: 2010-19143

Dear Mr. MAISTER:

I am in receipt of your election of rights requesting a hearing not involving disputed issues of material fact executed by you on **May 3, 2013,** concerning the above referenced case. This means that the facts alleged in the Administrative Complaint are uncontested. This is an important distinction because, by law, the Board cannot resolve disputes of material fact in this case or any disciplinary case. Since you are requesting a hearing not involving disputed issues of material fact, you are not admitting the facts alleged in the Administrative Complaint, however, you are agreeing not to contest these facts and to limit presentation to legal argument, if any, and to matters in mitigation or extenuation.

Our office is now preparing this case to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for **October 9, 2013, at the Wyndham bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, Florida 32408**. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Casey L. Cowan

CASEY L. COWAN
Assistant General Counsel

CLC/bhh

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Cowan, Casey

From: Cowan, Casey
Sent: Friday, April 19, 2013 4:02 PM
To: 'jimborph@verizon.net'
Subject: Proposed settlement agreement/confidentiality agreement

Attachments: Maister, James (2010-19143).pdf

Mr. Maister,

Per our conversation this afternoon please find the proposed settlement offer and confidentiality agreement attached to this email. Please confirm that you received this email. If you had any trouble opening the attachments please contact my office and we will mail you a paper copy. Upon receipt of the signed confidentiality agreement we will provide you with a copy of the complete investigative file. If you have any further questions or concerns please contact me at the number listed below.

Maister, James (2010-19143).pd...

Thank you,

Casey L. Cowan, Assistant General Counsel
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265
(850) 245-4444 ext. 8103

Please note: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure. However, if this e-mail concerns anticipated or current litigation or adversarial administrative proceeding to which the Florida Department of Health is a party, this email is an attorney-client communication, and is, therefore, a limited access public document exempt from the provisions of Chapter 119, Florida Statutes. See Section 119.071(d)1., Florida Statutes (2010).

DOH Mission: To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.

Vision: Healthiest State in the Nation

Values: (ICARE)
I nnovation: We search for creative solutions and manage resources wisely.
C ollaboration: We use teamwork to achieve common goals & solve problems.
A ccountability: We perform with integrity & respect.
R esponsiveness: We achieve our mission by serving our customers & engaging our partners.
E xcellence: We promote quality outcomes through learning & continuous performance improvement.

Please consider the environment before printing this e-mail. Go Green!

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2010-19143**

JAMES M. MAISTER, RPH,

RESPONDENT.

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, James M. Maister, RPH, was a licensed pharmacist in the state of Florida, having been issued license number PS 34202. Respondent's mailing address of record is 4810 Diamonds Palm Loop, Wesley Chapel, Florida 35543.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **two thousand seventeen dollars and ninety-two cents** ($2,017.92). Total costs shall be assessed

when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement.

3. **CE Course-** Respondent shall successfully complete a Continuing Education Course on the subject of Laws and Rules consisting of 12 hours of credit, which has approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. These continuing education hours shall be in addition to the hours required for license renewal. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

4. **Evaluation and Treatment-** Respondent shall contact the Professional Resource Network (PRN), submit to an evaluation, and comply with all treatment requirements imposed by any contract with PRN.

5. **Probation-** Respondent shall be placed on probation for five (5) years. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. Respondent shall not function as a prescription department manager in any Florida permitted pharmacy during the probation;

b. Respondent shall not work at or for more than 2 pharmacies during each quarter of the probationary period, unless Respondent obtains prior written approval from the Board;

c. During the first year of Respondent's probation, the Department shall conduct semi-annual audits of 5 randomly selected controlled substances at the Respondent's place of employment at Respondent's cost;

d. Respodent shall submit written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall include Respondent's license number, current address, and phone

number; current name, address, and phone number of each pharmacy in which Respondent is engaged in the practice of pharmacy; the names of all pharmacists, pharmacy interns, pharmacy technicians, relief pharmacists, and prescription department managers working with Respondent. These reports shall be submitted to the Compliance Officer every 3 months in a manner as directed by the compliance officer;

e. Respondent shall ensure that his employer submits written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall contain the name, address, license number, and phone number of each pharmacy intern, pharmacy technician, relief pharmacist, and prescription department manager working in the prescription department where Respondent practices, and provide a brief description of Respondent's duties, responsibilities, and working schedule. These reports shall be submitted to the Compliance Officer every 3 months in a manner as directed by the compliance officer;

f. Respondent shall comply with any and all recommendations from PRN; and

g. Respondent shall make a mandatory appearance before the Board of Pharmacy during his last three (3) months of probation. The Board retains the right to extend Respondent's term of probation or to impose additional restrictions, conditions or limitations on Respondent's license.

6. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

7. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

8. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the

Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

9. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

10. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional

proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

11. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

12. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

13. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this _____ day of _____, 2013

_____

James M. Maister, RPH
CASE NO. 2010-19143

STATE OF _____

COUNTY OF _____

Before me personally appeared _____, RPH, whose identity is known to me or by _____ (type of identification), and who, under oath, acknowledges that her signature appears above.

Sworn to and subscribed before me this ____ day of _____, 2013.

_____
Notary Public
My Commission Expires:

APPROVED this _____ day of _____, 2013.

JOHN H. ARMSTRONG, MD, FACS
Surgeon General and Secretary of Health

_____
Casey L. Cowan
Assistant General Counsel

Counsel for Petitioner
Casey L. Cowan
Florida Bar No. 0035536
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: 850.245.4640 ext. 8103
Fax: 850.245.4683

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area VI Tampa	Date of Case: 10-05-10	Case Number: 201019143

Subject: **JAMES M. MAISTER, R.PH** 4810 Diamonds Palm Loop Wesley Chapel, Florida 33543 813-545-9446 (C)	Source: **DEPARTMENT OF HEALTH**

Prefix:	License #:	Profession:	Board:	Report Date:
2201	34202	Pharmacist	Pharmacy	04-18-13

Period of Investigation: 04-17-13 through 04-18-13	Type of Report: Supplemental -1

Alleged Violation: 465.016(1)(d)2.3.(e)(i)(m)(r), F.S., s. 456.072(1)(a)(m)(z), F.S.: 2.The misuse or abuse of any medicinal drug appearing in any schedule set forth in chapter 893. 3. Any abnormal physical or mental condition which threatens the safety of persons to whom she or he might sell or dispense prescriptions, drugs... (e)Violating chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act;... (i)Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy... (m)Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition... (r)Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto... (a)Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession... (m)Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or scheme in or related to the practice of a profession... (z)Being unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals...

Synopsis: This supplemental investigation is predicated upon receipt of a PSU Request Form requesting for Service (Exhibit #S1-1) of Administrative Complaint and related papers from CASEY L. COWAN, Esq.

On Wednesday, April 17, 2013 Investigator TERRENCE DAWKINS hand served Administrative Complaint and related papers to adult female who identified herself as the spouse of JAMES M. MAISTER, R.PH 4810 Diamonds Palm; Wesley Chapel, Florida 33543.

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13 APR 22 AM 8:38

EXHIBITS:

S1-1 PSU Request Form, pp. 2-3
S1-2 Affidavit of Service, p. 4

Related Case(s): 2010-19119

Investigator/Date: 04-18-13 Victor R. Troupe Medical Malpractice Investigator, TI-123	Approved By/Date: 4-18-13 Babette S. Agett, TI – 115 Investigation Supervisor

Distribution: HQ/ISU

Received
Investigative Services
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DOH/MQA
Tallahassee HQ

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AFFIDAVIT OF SERVICE

Florida Department of Health
Petitioner

vs

Case No. 2010-19143

JAMES M. MAISTER, R.Ph.
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:
1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on 04-17-13, Affiant made a diligent effort to locate respondent & to serve an Administrative Complaint Packet.

3) Check applicable answer below:

X Affiant made personal service to MAISTER's Wife on behalf of JAMES MAISTER, R.Ph. at his residence of 4810 Diamonds Palm, Wesley Chapel, FL 33543, on (date) 04-17-13.

_____ Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

Affiant

State Of Florida
County Of Hillsborough

Before me, personally appeared Terrence Dawkins whose identity is known to me by (personally known) _____ (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 18th day of April, 2013.

Notary Public-State of Florida

My Commission Expires

Type or Print Name

VICTOR R. TROUPE
Commission # DD 922813
Expires September 3, 2013
Bonded Thru Troy Fain Insurance 800-385-7019

EXHIBIT#
S1 Exh 2

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

June 19, 2013

James Maister
4810 Diamonds Palm Loop
Wesley Chapel, Florida 33543

Re: Complaint Name: James Maister, R.PH.
Case Number: 2010-19143

Dear Mr. Maister:

Pursuant to section 456.073(10), Florida Statutes, enclosed is a copy of the Department's complete investigative file in this matter. We are providing you with a copy of the investigative file for **Case Number: 2010-19143, James Maister, R.PH.**, pursuant to the rules of discovery. We are sure that you will respect the confidentiality of the patient records pursuant to Chapter 456, Florida Statutes.

If you have any questions please give me a call at (850) 245-4444 ext. 8103. The CD is password protected, the password is **456.**

Respectfully,

Casey L. Cowan

Casey L. Cowan
Assistant General Counsel

CLC/bhh
Enclosures: Investigative File #: **2010-19143**
Invoice #: **MQPR13-681**

Acknowledgement of and
Agreement to Maintain Patient Confidentiality

I, JAMES MAISTER, am the Subject of an investigation by the Department of Health. As the Subject of such an investigation, I am entitled to inspect or receive a copy of the investigative report, including any expert witness report or patient records connected with the investigation pursuant to Section 456.073(10), Florida Statutes, if I agree in writing to maintain the confidentiality of any information received under this provision, until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to Section 456.057, Florida Statutes.

I understand the cost associated with duplicating x-rays and I want ( ) do not want ( ) to receive a copy of any x-rays that are contained within the investigative file.

SIGNED this 3 day of MAY, 2013.

James Maister

James M. Maister, R.Ph.
2010-19143

James Maister
4810 Diamonds Palm Loop
Wesley Chapel, Florida 33543

TAMPA FL 335
SAINT PETERSBURG FL
09 MAY 2013 PM 5 L

Casey L Cowan, Assistant General Counsel
Dept of Health, Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265

32399326599

April 19, 2013

James M. Maister, R.Ph.
4810 Diamonds Palm Loop
Wesley Chapel, Florida 33543

Re: Complaint No. 2010-19143
Respondent: James M. Maister, R.Ph.

Dear Mr. Maister:

Pursuant to section 456.073(10), Florida Statutes, you requested a copy of the Department's investigative file. Section 456.073(10), Florida Statutes, provides in part:

> The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) until 10 days after probable cause has been found to exist by the probable cause panel or by the department, or until the regulated professional or subject of the investigation waives his or her privilege of confidentiality, whichever occurs first. Upon completion of the investigation and a recommendation by the department to find probable cause, and pursuant to a written request by the subject or the subject's attorney, the department shall provide the subject an opportunity to inspect the investigative file or, at the subject's expense, forward to the subject a copy of the investigative file. Notwithstanding s. 456.057, the subject may inspect or receive a copy of any expert witness report or patient record connected with the investigation if the subject agrees in writing to maintain the confidentiality of any information received under this subsection until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to s. 456.057. . . .

Attached for your review is an Acknowledgement of and Agreement to Maintain Patient Confidentiality. Please sign and return the enclosed form to my office as soon as possible. The signed confidentiality agreement will be placed in our file. If you have any questions, please give me a call at (850) 245-4444 x 8103.

Respectfully,

Casey L. Cowan

Casey L. Cowan
Assistant General Counsel

Enclosure: Confidentiality Agreement

Acknowledgement of and
Agreement to Maintain Patient Confidentiality

I, _____, am the Subject of an investigation by the Department of Health. As the Subject of such an investigation, I am entitled to inspect or receive a copy of the investigative report, including any expert witness report or patient records connected with the investigation pursuant to Section 456.073(10), Florida Statutes, if I agree in writing to maintain the confidentiality of any information received under this provision, until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to Section 456.057, Florida Statutes.

I understand the cost associated with duplicating x-rays and I want ( ) do not want ( ) to receive a copy of any x-rays that are contained within the investigative file.

SIGNED this ____ day of _____, 2013.

_____
James M. Maister, R.Ph.
2010-19143

CC

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **James M. Maister, R.Ph.**
Case Number: 2010-19143

MEMBERS: **Gavin Meshad and Michele Weizer**

DATE OF PCP: **March 28, 2013** **AGENDA ITEM: A-7**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

X **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1)(e), Florida Statutes (2010), by a violation of 893.13(7)(a)9, Florida Statutes (2009);

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**
a)
b)

___ Upon **reconsideration,** dismiss

___ **other:**

Michele Weizer, PharmD, BCPS 3/28/13
Chair, Probable Cause Panel Date
Board of Pharmacy

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area VI Tampa	Date of Case: 10-05-10	Case Number: 201019143

Subject: **JAMES M. MAISTER, R.PH** 4810 Diamonds Palm Loop Wesley Chapel, Florida 33543 813-545-9446 (C)	Source: **DEPARTMENT OF HEALTH**

Prefix:	License #:	Profession:	Board:	Report Date:
2201	34202	Pharmacist	Pharmacy	10-28-10

Period of Investigation: 10-08-10 through 10-28-10	Type of Report: FINAL

Alleged Violation: 465.016(1)(d)2.3.(e)(i)(m)(r), F.S., s. 456.072(1)(a)(m)(z), F.S.: 2.The misuse or abuse of any medicinal drug appearing in any schedule set forth in chapter 893. 3. Any abnormal physical or mental condition which threatens the safety of persons to whom she or he might sell or dispense prescriptions, drugs... (e)Violating chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act;... (i)Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy... (m)Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition... (r)Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto... (a)Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession... (m)Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or scheme in or related to the practice of a profession... (z)Being unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals...

Synopsis: This investigation is predicated upon receipt of a Case Summary, Exhibit #1, based upon complaint from Department of Health. On 09-30-10 JAMES M. MAISTER, R.PH (PS 34202) was arrested for felony under Ch 893.13(7)(a)9. FS (Obtain controlled substance by fraud). In August and September, 2010 MAISTER presented and had filled prescriptions for Norco at a pharmacy in Wesley Chapel, Florida. The physician noted on the prescriptions denied writing them.

MAISTER was notified of the investigation by letter dated 10-08-10(Exhibit #2) to the address of record and was provided a copy of the Case Summary and original documents that initiated the complaint.

A check of DOH computer licensure records revealed MAISTER is currently licensed as a pharmacist. A copy of MAISTER's licensure printout is attached, Exhibit #3.

The patient notification letter was not sent since there was no direct patient involvement.

MAISTER is not represented by an attorney.

On 10-27-10 Investigator TROUPE conducted an interview of MAISTER and in summary the allegations were concured.

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Related Case(s): 2010-19119

Investigator/Date: 10-28-10 Victor R. Troupe Medical Malpractice Investigator, TI-123	Approved By/Date: 10-28-10 Babette S. Agett, TI – 115 Investigation Supervisor

Distribution: HQ/ISU

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Investigative Services

OCT 29 2010

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* 5. Copy of Subpoena Duces Tecum A-0065688 directed to University Community Hospital Human Resources Department for copies of JAMES M. MAISTER's, R.Ph personnel records 17-23

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* 17. Florida Department of Health Physician Prescription Affidavits **176-179**

***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES**

****These records are sealed pursuant to Section 456.057(10)(a), Florida Statutes and copies of same are not maintained in the Tampa Investigative Services office**

INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit #4 is a facsimile request to PRN to determine if MAISTER has enrolled in, or is participating in the PRN program. PRN response via facsimile on 10-27-10 is that "Yes, Mr. MAISTER is under contract with PRN".

Exhibit #5 is a copy of Subpoena Duces Tecum A-0065688 directed to University Community Hospital Human Resources Department for copies of JAMES M. MAISTER's, R.Ph personnel records.

Exhibit #6 is JAMES M. MAISTER's, R.Ph personnel records received via United States Postal Service on 10-22-10 with certification of completeness of records. Pertinent documents consist of:

- Termination Notification Form of MAISTER with an effective date of 10-18-10.
- Letter of resignation by MAISTER dated 10-18-10 addressed to CAROL PAZOS, Director of Human Resources.
- Typed statement from unsigned writer. Statement documents: "...Adminstration has reviewed the situation including the theft of our prescription pad and the illegal use of that prescription pad. The decision of the organization is to terminate employment at the end of the FMLA. That means that Tuesday, 10/19 will be last date of employment... ... Jim asked if he could resign and I told him I would accept his resignation..."
- Typed unsigned and undated statement: "At 8 am on Thursday 9/23, Mr. JAMES MAISTER, presented himself to me with a request to self-report a drug addiction. Mr. MAISTER has been employed as a full-time pharmacist since 06-12-07. At the time of his hire he presented documentation that his petition to terminate probation was to be heard by the Board of Pharmacy and Drugs for a past reported issue.

  During our meeting, he confessed he had a drug problem with hydrocodone. He stated that he had forged Dr. CANNELLA's signature on two occasions using UCH prescription pads totaling 150 pills. He stated he had not diverted any drugs from UCH...

  I contacted PRN and via speaker phone, Mr. MAISTER self-reported to the board. He was given the names of 3 psychiatrists and instructed to contact one of them for an evaluation. I told him that he could not return to work until he could present a contract from PRN and that I would contact ELAINE COPELAND for FMLA paperwork. And should his FMLA expire prior to obtaining a contract, he would be terminated and his future employment eligibility would be considered. He said he had used a good amount of FMLA already due to care for his wife and his own health issues. He then left my office..."
- University Community Hospital Policy on prescription pad dispensing and control

Exhibit #7 is documents obtained from Target Pharmacy #1382 on 10-15-10: Documents consist of:

- Pharmacy profile of MAISTER

Date Rx Written	Fill Date	Drug	Physician	Quantity
08-16-2010	08-17-2010	Hydrococ / APAP 10-325 Tab	XAVIER CANNELLA	90
08-16-2010	08-29-2010	Hydrococ / APAP 10-325 Tab	XAVIER CANNELLA	90
09-07-2010	09-08-2010	Hydrococ / APAP 10-325 Tab	XAVIER CANNELLA	90

- Photo copies of prescriptions
  - Dated 08-16-10 for Norco 10/325mg #90. One by mouth every six hours as needed. Refill documented as one.
  - Dated 09-07-10 for Norco 10/325mg #90. One by mouth every six hours as needed. Refill documented as two.
  - Pharmacy Signature Retrieval Signature Reports.

Exhibit #8 is are documents obtained from KATHY A. MOORMAN, R.Ph. / Pharmacy Director of University community Hospital; Tampa, Florida. Documents is a PYXIS report of MAISTER from 10-01-10 to 10-15-10. No narcotics noted as retrieved by MAISTER.

Exhibit #9 is JAMES MATTHEW MAISTER Individual Charge Report for date of arrest 09-30-10. Report documents MAISTER was arrested on 09-30-10 for obtaining controlled substance by fraud.

Exhibit #10 is a Pasco Sheriff's Office Offense Incident Report of JAMES MATTHEW MAISTER Individual Charge Report Number 10-059683-01. Report documents: "...On the dates of August 17 and September 8, 2010, the suspect, JAMES MAISTER presented and had filled, two forged prescriptions for Norco (Hydrocodone) at the Target Pharmacy located at 1201 Bruce B. Downs Blv. In Wesley Chapel, Florida. Additionally, on August 29, he presented the forged prescription of August 17 for a refill at the same Target Pharmacy. MAISTER paid for and picked up the medications as forged on the prescription forms, leaving the Target Pharmacy..."

Exhibit #11 is a document obtained from Pasco County Courthouse; Dade City, Florida on 10-15-10. Document consists of a Pasco County Complaint Affidavit for arrest of MAISTER on 09-30-10. Report documents: "...JAMES MAISTER admitted that he forged three prescriptions, signing as the doctor and did acquired possession of Norco (Hydrocodone) a controlled substance, by misrepresentation, fraud, forgery, contrary to Florida Statutes form the Target store Pharmacy, located at 1201 Bruce B. Downs in Wesley Chapel, Florida, Pasco County..."

Exhibit #12 is JAMES MATTHEW MAISTER Individual Charge Report for date of arrest 10-08-02. Report documents MAISTER was arrested on 10-08-02 for obtaining controlled substance by fraud.

- Case Number 2002-CF-016551 Count One obtaining controlled substance by fraud.
- Criminal Report Affidavit / Notice to Appear.
- Uniform Plea, Acknowledgement and Waiver of rights form.
- Judgment form. Form indicates MAISTER entered a plea of guilty and that adjudication of guilt was withheld and was placed on Drug offender probation for 18 months.

Exhibit #13 is a document obtained from Hillsborough County Courthouse; Tampa, Florida on 10-19-10.

- Case Number 99-CM-024577
  - Offense date: 09-06-1999
  - Battery (Domestic Violence)
  - Plea: No plea entered
- Case Number 99-CM-02575
  - Offense date: 03-06-1999
  - Obtaining property for worthless check
  - Plea: Nolo Centendere
  - Suspended dep. Closed

- Case 00-CM-006684
  - Offense date: 03-03-1999
  - Obtaining property for worthless check
  - Plea: Not guilty
  - Finding: Nolle-Prosequi

Exhibit #14 is a document obtained from Hillsborough County Courthouse; Tampa, Florida on 10-15-10. Document is a No Information form. Form states: "The State Attorney, having taken testimony under oath at a State Attorney investigation, concludes that the facts and circumstances revealed do not warrant prosecution at this time".

Exhibit #15 is JAMES MATTHEW MAISTER Individual Charge Report for date of arrest 09-06-99. Report documents MAISTER was arrested on 09-06-99 for obtaining controlled substance by fraud.

Exhibit #16 are certified documents obtained from Pasco County Courthouse; Dade City, Florida on 10-15-10 for Case Number 9901120MMAES. Form is a No Information from and documents: "The State Attorney, having taken testimony under oath at a State Attorney investigation, concludes that the facts and circumstances revealed do not warrant prosecution at this time".

Exhibit #17 are Florida Department of Health Physician Prescription Affidavits signed by XAVIER CANNELLA, M.D. documenting prescriptions dated 09-07-10 for Norco 10/325 #90 and prescription 08-16-10 for Norco 10/325 # made to JAMES MAISTER are forgeries.

INTERVIEW OF KATHY A. MOORMAN, R.Ph (Witness)
University Community Hospital
3100 East Fletcher Avenue
Tampa, Florida 33613-4688
813-615-7114

On Friday, October 15, 2010 Investigator TROUPE met with and interviewed KATHY A. MOORMAN at her place of employment University Community Hospital. MOORMAN stated that she is the Pharmacy Director.

MOORMAN was asked to explain in detail her knowledge of this incident concerning JAMES M. MAISTER, R.Ph. She replied she was informed by the Human Resource that MAISTER had self reported himself for obtaining a prescription pad. MOORMAN said she was informed that MAISTER had obtained a hospital prescription pad and filled in a doctor's name and used the forged prescription to obtain control substances.

MOORMAN said she questioned MOORMAN in the presence of a human resource personnel. She said MOORMAN stated he had used the prescription pad on two separate occasions. MOORMAN said MAISTER stated he had contacted the physician and self reported himself to PRN. She said MAISTER was very apologetic. MOORMAN said she thanked MAISTER.

MOORMAN was asked how did MAISTER obtain the prescriptions pad. She said MAISTER obtained the prescription pads from the hospital. MOORMAN said she has not seen the forged script. She said the scripts belonged to Dr. XAVIER CANNERLA. MOORMAN was asked if MAISTER mentioned pharmacies the prescriptions were used at. She said the pharmacy location was mentioned in the news and police report. MOORMAN was asked how long is/was MAISTER employed with University Community Hospital. She replied MAISTER was hired on 06-17-07 and is currently still employed as of today (October 15, 2010). MOORMAN said she hired MAISTER knowing he had been in the PRN program. MOORMAN was asked if MAISTER had any problems. She stated MAISTER adopted a five year old girl; sold his house; bought a new house; his wife was diagnosed with a serious illness and has been in & out of the hospital; he was in the hospital very sick with heart problems; wife can't drive and figured out was to get his wife around.

MOORMAN was asked if there were any noted missing narcotics associated with MAISTER. She replied none associated with MAISTER. MOORMAN was asked if there were any narcotic discrepancies associated with MAISTER. She replied no PYXIS discrepancies associated with MAISTER. MOORMAN was asked if MAISTER had access to narcotics. She replied as a role the pharmacist never go into the system unless it is an emergency. MOORMAN said the pharmacist techs pulls drugs and places in bag and then initials and scan drug name. She said the pharmacist verify the correct drug, strength, amount and scan initials and then puts in a bin. She said the pharmacy tech then pulls the drug out of the bin and take to the floor. MOORMAN said when the tech arrives to the floor they scan the PYXIS machine and the correct draw opens and the tech counts the number of drugs currently present which is a blind count. She said the PYXIS either accepts or denies the number enters. MOORMAN said a second attempt is given and if the correct the product is closed in the draw. She said if incorrect the pharmacy tech notifies the leader of the unit and pharmacy director. MOORMAN said the Nurse Manager determines who had prior actions and if warrant an investigation is initiated. She said usually the count is correct. MOORMAN said the PYXIS system is a very safe system. MOORMAN said the PYXIS is very good in preventing diversion.

INTERVIEW OF JAMES M. MAISTER, R.PH. (Subject)
4810 Diamonds Palm Loop
Wesley Chapel, Florida 33543
813-545-9446 (C)

On Wednesday, October 27, 2010 Investigator TROUPE conducted a telephone interview with JAMES M. MAISTER, R.Ph. MAISTER said he has been a pharmacist for approximately 25 years. He said he was last employed with University Community Hospital Tampa for three years. MAISTER said currently he is not working and is enrolled in the PRN program. He said he initially called PRN on 23 September 2010 and received an evaluation the day after and withdrew from practice. MAISTER was asked if he planned on continuing practicing as a pharmacist. He replied "yes" once/if PRN clears him. MAISTER said he would like to work in a non-dispensing role.

MAISTER was asked to explain in detail his knowledge of this complaint. He replied he wrote prescriptions for himself to have filled and was wrong. MAISTER said he was enrolled in PRN from 2002 through 2007 and continued to be in compliance until early June 2010.

MAISTER said he had dental procedures which consisted of two root canals, extraction and bridge. He said he was prescribed Vicodin. MAISTER said at the end of June 2010 he was hospitalized for hypertension crisis and a minor stroke. He said he was also diagnosed with severe central and obstructed sleep apnea. MAISTER said while in the hospital he fell and injured his ankle and back and was given Vicodin while in the hospital and upon discharge. He said at this point is when his addiction took off. MAISTER said then he felt as though he needed the medication. He said his addiction was in charge and he did what he did. MAISTER said he wrote prescriptions for himself. MAISTER was asked how many prescriptions did he wrote. He replied he wrote two prescriptions with one with a refill.

MAISTER stated that he is sorry for what he did. He said he knows what he needs to do to stay clean and sober and is more than willing to do so. MAISTER said he will do what he needs to do to stay clean.

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CONFIDENTIAL

PATIENT INFORMATION

RECORDS SEALED

Patient Records that identify by name are sealed pursuant to Section 456.057(10)(a),F.S.

COMPLAINT #: PS 2010-19143

PATIENT: ___

SUBJECT: JAMES M. MAISTER, R.Ph.

INVESTIGATOR: Victor R. Troupe

EXHIBIT: 1,2,4,5,6,7,8,9,12,15 & 17

One of Six

Received
Investigative Services
OCT 29 2010
BOARDQA

Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

October 8, 2010

CONFIDENTIAL TO:
James M. Maister, R.Ph.
4810 Diamonds Palm Loop
Wesley Chapel, Florida 33543

Case Number: PS 2010-19143

Dear Mr. Maister:

We are currently investigating the enclosed document received by the Department of Health. This investigation was initiated after it was determined that you may have violated the Pharmacy Practice Act.

Within **20 days** of receiving this letter, you may:

- submit a **written response** to the address below; **or**
- call our office to schedule an **interview**.

Please provide a copy of your **curriculum vitae** and identify your **specialty** even if you choose not to submit a response. Include the above-referenced case number in any correspondence that you send.

Florida law requires that this case and all investigative information remain confidential until 10 days after the Probable Cause Panel has determined that a violation occurred or you give up the right to confidentiality. Therefore, the contents of the investigation cannot be disclosed to you or the general public.

You may make a written request for a copy of the investigative file and it will be sent to you when the investigation is complete. You may submit an additional written response to the information in the investigative file within 20/45 days of receipt. Your response (if one is provided), along with the information in the file, will be considered by the panel when determining whether a formal administrative complaint should be filed in this matter.

You are not required to answer any questions or give any statement, and you have the right to be represented by an attorney. It is not possible to estimate how long it will take to complete this investigation because the circumstances of each investigation differ.

The mission of the Division of Medical Quality Assurance is to protect the public through healthcare licensure, enforcement and information. If you have any questions, please call us at 813-871-7443.

Sincerely,

Victor R. Troupe
Medical Malpractice Investigator

2/VRT
Enclosure

CONFIDENTIAL

FLORIDA DEPARTMENT OF HEALTH

Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., MPH
State Surgeon General

Received
OCT 07 2010
DOH/MQA
Jacksonville IS

CASE SUMMARY

CONFIDENTIAL

Case No: 201019143
Please use this number in all correspondence with the Department concerning this matter.

RESPONDENT INFORMATION

License No: 34202 Profession: 2201 Pharmacist
Name: James M Maister
Address: 4810 DIAMONDS PALM LOOP
Wesley Chapel, FL 33543
Home Phone:

SOURCE OF INFORMATION

Name: Department Of Health
Address:
Home Phone:

RECEIVED
OCT 08 2010
By

REPORTED INFORMATION

Receive Date: 10/05/2010 Source Code: 5 Form Code: 1
Responsible Party: ha107 Status Code: 10 Priority: 1
Classification Code: Incident Date: 09/30/2010

Patient Name:

Possible Code(s): 33

Summary:
Possible violation of, s. 465.016(1)(d)2.3.(e)(i)(m)(r), F.S., s. 456.072(1)(a)(m)(z), F.S.

On 9/30/10 Subject (PS 34202) was arrested for felony under Ch 893.13(7)(a)9. FS (Obtain controlled substance by fraud). Subject may be impaired. Analyzed by: Leo Paulson, 10/5/10

Leo Paulson

2010-1919

Nc

St. Petersburg Times
tampabay.com

October 1, 2010

Wesley Chapel pharmacist accused of fraud

Times staff

WESLEY CHAPEL - A pharmacist is accused of using stolen and forged prescription forms to get hydrocodone.

James M. Maister, 45, of Wesley Chapel was arrested Thursday and charged with three counts of attempting to obtain controlled substances by fraud.

The Florida Department of Health shows Maister's pharmacy license is clear and active and that he works at University Community Hospital.

Documents state Maister's license was revoked in 2002 for fraudulently obtaining Buprenex, a narcotic controlled substance, and his license was reinstated in 2003.

Maister's told a deputy he has an addiction problem and has enrolled in a treatment program, according to a report from the Pasco County Sheriff's Office.

He was released from the Pasco County jail on $6,000 bail.

St. Petersburg Times

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January 23, 2014

Michael Alan Donato
1305 Tradition Circle #308
Melbourne, FL 32901

RE: Pharmacist Examination Application

Dear Mr. Donato:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, it is encouraged that you do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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2201 F-44245

11/07/2013 295.00
ID: 44245 Type: F
BT: 3009073
VL: 913025018

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.doh.state.fl.us/mqa/pharmacy

Florida HEALTH

ITEM #2 –PHARMACIST EXAMINATION APPLICATION FOR U.S. AND PUERTO RICO GRADUATES
FEE: $295.00

Please print or type legibly.

1. Biographical data			
Last name	**First name**	**Middle name**	
DONATO	MICHAEL	ALAN	
Street address (ML – Mailing Address)	**City**	**State**	**Zip**
1305 TRADITION CIRCLE #308	MELBOURNE	FL	32901
Work address (PL – Practice Location)	**City**	**State**	**Zip**
Home phone number	**Business phone number**	**E-mail address**	
321-266-9648		MIKRX1@YAHOO.COM	
Date of birth	**Place of birth**		
8/18/1972	BETHPAGE, NEW YORK		

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☑ Male ☐ Female
RACE: ☑ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. Have you ever changed your name through marriage or through action of a court or have you ever been known by any other name? If yes, list name(s) and date(s) of the change(s) below. *Use a separate sheet, if necessary.*

Yes _____ No X

Name	**Date**

4. Name of University, College or School of Pharmacy attended

ST. JOHN'S UNIVERSITY, COLLEGE OF PHARMACY

5. Date of graduation	**6. Type of degree earned**	**7. Have you ever been licensed as an intern in Florida?**
MAY 21, 1995	BS PHARMACY	Yes _____ No X Intern License number: _____

RECEIVED
NOV 05 2013
Licensing and Auditing Services

WL

8. Are you planning to transfer your NAPLEX® score to Florida? If yes, please indicate approximate date of transfer.	9. Did you transfer your NAPLEX® score to Florida within the past three (3) years?
Yes X Date of transfer: 10/21/2013 No _____	Yes _____ Date of exam: _____ No X

10. Would you be willing to provide health services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disasters?

Yes X No _____

11. Have you ever applied to take the Florida Pharmacist Examination? If yes, please indicate the date.

Yes X No _____ Date 1996

12. List all experience earned as an intern. If you have been a registered pharmacist for at least one (1) year, list only your pharmacist experience. If you graduated after January 1, 2001 with a Pharm.D. Degree, it is not necessary to complete this section. Note: you must submit one (1) Internship or Work Experience Form - Form B (Item #4) for each employer listed below. ***Use a separate sheet, if necessary.***

Dates	Employer	Location	Intern or pharmacy experience	Total hours
2008-2011	CVS/PHARMACY	ROCKLEDGE, FL	PHARMACY	4,480

13. List all state(s) in which you have held or currently hold a pharmacist license. Note: you must submit one (1) Licensure Verification Form (Item #5) for each state listed below. ***Use a separate sheet, if necessary.***

State	License number	Date issued
NEW YORK	043731	9/5/1995
NEVADA	13949	11/26/1997

14. Special testing accommodations – please indicate if you require special testing accommodations due to a disability, or if you have a religious conflict with the scheduled examination date. **If yes, complete the "Application for Candidates Requesting Special Testing Accommodations in Accordance with the Americans with Disabilities Act," form DH-MQA 4000, 6/08, which may be downloaded from the Department's website at http://www.doh.state.fl.us/mqa/exam/spectest.htm, or you may contact Testing Services by phone at (850) 245-4252 for detailed information and an application. All requests must be in writing and include supporting documents.**

Yes _____ No X

15. Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense?

Yes X No _____

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

20. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state?
Yes X ____ No ____
21. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes ____ No X ____
22. Are you presently being investigated or is any disciplinary action pending against you?
Yes ____ No X ____
23. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If no, go to question #25.)
Yes X IN FLORIDA ONLY No ____
24. If "yes" to 23, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes ____ No ____
24a. If "yes" to 23, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6) (a), Florida Statutes).
Yes ____ No X ____
24b. If "yes" to 23, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes ____ No X ____
24c. If "yes" to 23, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes ____ No X ____
25. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?
Yes ____ No X ____
25a. If "yes" to 25, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes ____ No ____
26. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 27.)

Yes _____ No X _____
27. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No _____
28. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 28a and 28b.)   Yes _____ No X _____
28a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes X _____ No _____
28b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
29. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?
Yes _____ No X _____ (If yes, provide supporting documentation)
30. If "yes" to any of the questions 23 through 29 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)   Yes X _____ No _____
All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 16-29, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacist's license may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

Applicant Signature _____ Date 10/14/2013

NOTE: Please check to be sure that you have answered all of the questions above.

*THIS BEEN HAS SENT DIRECTLY TO FL BOP

HEALTH

FLORIDA BOARD OF PHARMACY
4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254
Phone: (850) 245-4292 • www.doh.state.fl.us/mqa/pharmacy

ITEM #3 - CERTIFICATE OF PHARMACY EDUCATION (FORM A)

Please print or type legibly.

Part I. – To be completed by applicant and forwarded to the College of Pharmacy for completion of Part II below.

Last Name	First Name	Middle Name
DONATO	MICHAEL	ALAN

Maiden Name/Surname	Date of Graduation
	MAY 21, 1995

Mailing Address	City	State	Zip
1305 TRADITION CIR #308	MELBOURNE	FL	32901

Part II. – To be completed by an official of the university

Name of School/College of Pharmacy

St. John's University

Mailing Address	City	State	Zip
8000 Utopia Parkway	Queens	NY	11439

Type of Degree Awarded	Date Degree Awarded	Dates of Attendance
Bachelor of Science in Pharmacy	5/21/1995	From: 9/1/90 To: 5/21/95

The information recorded above is true and correct according to the official records of this institution. Failure to include the school seal may result in a delay in processing the applicant's application.

Joanne Llerandi
Print Name
Joanne A. Llerandi
University Registrar
Title

Signature

8/21/2013
Date

(SCHOOL SEAL)

NOTE: Please check to be sure that you have answered all of the questions above.

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY
BIN #C-04
TALLAHASSEE, FL 32399-3254

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

File: 44245

1956600

RECEIVED

DEC 05 2013

Florida Board of Pharmacy

HEALTH

FLORIDA BOARD OF PHARMACY
4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254
Phone: (850) 245-4292 • www.doh.state.fl.us/mqa/pharmacy

ITEM #4 – INTERNSHIP OR WORK EXPERIENCE FORM (FORM B)

Please print or type legibly.

1. Biographical information			
Applicant name	**Intern/pharmacist license number**	**Phone number**	
MICHAEL ALAN DONATO	PS 31230	321-266-9648	
Street address	**City**	**State**	**Zip**
1305 TRADITION CIR. #308	MELBOURNE, FL 32901		
2. Have you submitted an application for the Florida Pharmacist Examination? If yes, please indicate date.			
Yes _____ No X _____ Date _____			

I HEREBY APPLY FOR INTERNSHIP OR WORK EXPERIENCE CREDIT AS OUTLINED BELOW UNDER THE SUPERVISION OF:

3. Pharmacy information			
Supervising Pharmacist's name		**License number**	
STEVE BERES		PS32506	
Pharmacy name		**Permit number**	
CVS / PHARMACY		PH21175	
Street address	**City**	**State**	**Zip**
1696 FISKE BLVD	ROCKLEDGE	FL	32955
Phone number	**4. Dates of experience**		
321-631-2939	From: 08/01/2008 To: 03/21/2011 (28 MONTHS)		
5. Average number of hours per week	**6. Total hours of experience**		
40	4,480		
(No more than 50 hours per week if you are a student and no more than 60 after graduation is allowed)			

Applicant's Signature _____ Date 10/14/2013

This report is a correct statement of fact. The above information was taken from the records of the above named pharmacy and are available for inspection by the Board of Pharmacy.

Preceptor/Supervisor's Signature _____ Date 12/02/2013

NOTE: Please check to be sure that you have answered all of the questions above.

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY
BIN #C-04
TALLAHASSEE, FL 32399-3254

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
DIVISION OF PROFESSIONAL LICENSING SERVICES
89 WASHINGTON AVENUE
ALBANY, NEW YORK 12234

FL 1926678

This is to certify that according to the records of the Division of Professional Licensing Services, New York State Education Department Albany, New York, DONATO MICHAEL ALAN
was issued license/certificate number 043731 for the practice of PHARMACY on 09/05/95.

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DEC 17 2013
Florida Board of Pharmacy

Our records also indicate the following information:
Date of birth: 08/18/72
School attended: ST JOHN'S UNIVERSITY-MAIN
Date of graduation: 05/21/95
Degree earned: BS

Program was acceptable in accordance with the NYS Regulations of the Commissioner of Education. Requirements met at the time of licensure.

Basis of licensure:

DATE	*PT 1	PT 2	PT 3
06/95	00114	00088	00086

AT LEAST SIX MONTHS EXPERIENCE

*NABPLEX
EXMS TAKEN=01

A license is valid during the life of the holder unless revoked, annulled or suspended by the Board of Regents. A licensee must register periodically with this Department to practice in this state.

Currently Registered: NO Last reg period ended: 07/31/01
Address: 4007 ESTANCIA WAY
MELBOURNE FL 32934-0000
Disciplinary information: No charges have been preferred against this licensee
Comments:

I, Cathy Hanczaryk, Principal Clerk, Division of Professional Licensing Services of the New York State Education Department, do hereby state that as Principal Clerk of said Division, I have legal custody of the official records of the Division of Professional Licensing Services and to the best of my knowledge, the aforesaid information is true and correct.

SEAL

Cathy Hanczaryk 10/18/13
Principal Clerk

RECEIVED
OCT 28 2013
Florida Board of Pharmacy

Board of Pharmacy

License Details

Press "Previous Record" to display the previous license.

Press "Next Record" to display the next license.

Press "Search Results" to return to the Search Results list.

Press "New Search Criteria" to do another search of this type.

Press "New Search" to start a new search.

License Number: 13949 ***Current Date: 12/***

Name:	**Donato, Michael Alan**
License Type:	**Registered**
License Status:	**Closed**
Expiry Date:	**10/31/2003**
1st License Date:	**11/26/1997**
Disciplinary Status:	**None**

If the information indicates that the person or business has 'Yes' and you would like additional information regarding the disciplinary action, please co shunting@pharmacy.nv.gov or at (800) 364-2081.

Grossman, Furlow & Bayó, LLC
ATTORNEYS AT LAW

ALLEN R. GROSSMAN
FILE NO.: 81759

a.grossman@gfblawfirm.com

November 5, 2013

VIA HAND DELIVERY

Florida Board of Pharmacy
C/O Mark Whitten
Executive Director
4052 Bald Cypress Way, Bin C-04
Tallahassee, Florida 32314-3254

RECEIVED
NOV 05 2013
Licensing and Auditing Services

Re: Application of Michael Donato, R.Ph.

Dear Mr. Whitten:

Enclosed is the application of Michael Donato, R.Ph. for licensure as a pharmacist by examination. Mr. Donato was previously licensed as a pharmacist in Florida in 1996. Unfortunately, in January of 2012, Mr. Donato entered a guilty plea to a single count of possession of hydrocodone pursuant to section 893.13(6)(a), Florida Statutes, a third degree felony. Shortly after his arrest and during the pendency of his criminal case, Mr. Donato entered into the Professionals Resource Network (PRN) program and successfully completed treatment at the Florida Recovery Center (UF/Shands), in Gainesville, Florida. In July 2012, Mr. Donato's pharmacist's license was disciplined by the Florida Board of Pharmacy as a result of the conduct related to his August 2011 arrest and his January 2012 criminal plea. (DOH Case No. 2012-02328) The Board's Final Order imposed an administrative fine of $2,000; costs of $1500; a requirement for him to successfully participate in PRN; a suspension of licensure until such time as Mr. Donato established his ability to practice safely; and a five year period of probation with terms. Based upon the report of the Medical Director of PRN, who described Mr. Donato as a model of recovery, the Board of Pharmacy voted at the same meeting to reinstate Mr. Donato's license and permit him to immediately return to practice under the probationary terms imposed. In July of this year, the Florida Department of Health denied renewal of Mr. Donato's Florida license pursuant to section 456.0635, Florida Statutes. He is now applying for a new pharmacy license in Florida pursuant to section 456.036(14), Florida Statutes, which provides that licensees denied renewal pursuant to section 456.0635, Florida Statutes, may re-establish licensure by applying for a new Florida license and the exemption provided in section 456.0635(2), Florida Statutes, for applicants for a license who were enrolled in an educational or training program on or before July 1, 2009.

In addition to the other required documentation and payment of the $295.00 application fee (check #1246.), Mr. Donato has enclosed with his completed application supplemental answers addressing his impairment issues, his criminal matter (which has been ordered sealed by the Circuit Court) and his prior Florida disciplinary action. He has also provided copies of

certificates for more than 45 hours of approved CE, a copy of the notice of the Department of Health's denial of his application for renewal, a copy of the Board of Pharmacy's previous disciplinary Final Order, documentation of the underlying criminal matter, and a copy of his PRN contract. Documentation required directly from primary sources has also been requested. Please let us know if any additional documentation is required.

Mr. Donato has remained in compliance with PRN and we have requested that PRN provide a letter in support of Mr. Donato's application for licensure. Such letter will be provided directly by PRN under separate cover.

Mr. Donato's story is one of unfortunate circumstances stemming from an undiagnosed addiction. His actions under the influence of that addiction brought to a screeching halt the previously unblemished career of a respected and capable pharmacist. His story also includes his successful completion of treatment and rehabilitation and his enrollment and participation in PRN. He now seeks the opportunity to complete his return to being a significant contributor to the betterment of society as a pharmacist in Florida.

Mr. Donato considers himself to be extremely fortunate to have made it through his course of addiction without ever having implicated the safety of his patients and has always considered himself to be a competent and ethical pharmacist. He practiced in Florida for over fifteen years before falling victim to his addiction and looks forward to the opportunity to return to his chosen career. Prior to his unfortunate experience with addiction and his inappropriate actions to feed that addiction, Mr. Donato had never been the subject of any civil, criminal or disciplinary action in any jurisdiction and as a result of that experience he has dedicated himself not only to his own continuing recovery, but also to re-establishing himself as a contributor to society both on a personal and a professional level.

Thank you for taking the time and effort to handle and consider this matter fully.

Sincerely,

Allen R. Grossman

enclosures

cc: Michael Donato, R.Ph.
Penelope Ziegler, M.D., Medical Director, PRN

Dear Board of Pharmacy,

I was initially prescribed hydrocodone several years ago when I was diagnosed with a painful foot condition called congenital tarsal coalition. My feet were always in pain, especially after standing or walking a great deal. The medication certainly helped, but it also ignited the disease of addiction in me. As a result, I was no longer able to get prescriptions to cover my increasing need. It has been postulated that being diagnosed as azoospermic and the depression that resulted from being told I could not father children may have also been a factor in this as well. I know that these things alone, should not lead a person to having a drug problem. However, added to having this previously undiagnosed disease of addiction, these issues sent my life into a tailspin. The medication served to kill the physical and emotional pain in my life. The situation spiraled out of control until I just couldn't take enough pills to numb the pain anymore. I needed help but, as with most people in my situation, never really had intention of getting it until something came along to stop the insanity.

On August 23, 2011, as an employee of Publix Pharmacy, I was confronted by my supervisor, after I closed the pharmacy for the day. My boss, Don Pickens, suspected that I was diverting hydrocodone from the pharmacy department. He was correct. I had a large quantity of pills hidden on my person and I was arrested and initially charged with theft, possession and trafficking and spent the night in Brevard County jail. A phone call from the jail that night was the first time my wife and family learned about a problem I had been hiding from them. As terrible and humiliating as it was to have to spend the night in jail, there was a strange peace knowing that the suffering was finally over.

Three days later on August 26, 2011, I checked myself into Florida Recovery Center's addiction program for healthcare professionals in Gainesville, FL. This is a minimum of a 90-day program and one of the leading programs in the country. It was "the greatest experience I never want to have again." I missed my wife, 7-month old daughter, and family terribly, but I am so very grateful that I was fortunate to have the opportunity most people with this problem don't get. The program taught me how to effectively cope with physical and emotional pain and how to accept life on life's terms. I was introduced to the AA program and realized the power of the AA fellowship. Putting it simply, I learned how to live again and how to enjoy life. My treatment culminated in serving 5 weeks as Senior Peer. The Senior Peer is the "leader" of the treatment community and he assists the treatment team in making treatment decisions. I completed my treatment and "graduated" on December 16, 2011.

I then returned to my home in Melbourne, FL and signed a 5-year PRN monitoring contract and began to face my consequences. After investigating my case, the assigned prosecuting attorney reduced my charges to third degree theft and possession and required that I enter drug court. However, he was overruled by his supervisor, Wayne Holmes, who refused to offer drug court out of what is understood to be a personal aversion to the drug court process. Therefore, I was obliged to plead guilty to the third degree charges which consequently has resulted in my application for renewal of my pharmacy license being denied. Upon entering a guilty plea, adjudication was withheld and I was given 12 months of probation. After six months, my probation was terminated early for good behavior/compliance and then my arrest record was subsequently sealed. My pharmacy license was temporarily suspended. After appearing before

the Board of Pharmacy in June 2012, my license was reinstated and placed on probation for 5 years. Knowing that renewal of my license might be a problem, I chose not to reenter practice until my licensure issues were sorted out. In order to obtain medical insurance for my family, I secured a job as a barista at Starbucks in April 2012. I am still employed there today and I feel that the job is another important factor in the success of my recovery although it does not come close to meeting my financial needs. Therefore, I very much want to return to practice as a pharmacist which is my chosen profession.

As of this writing, I have been clean and sober for over 2 years. I have been in full compliance with my PRN contract and the terms of my settlement agreement with the Department of Health. I have shed almost 80 pounds over this time in order to reduce the weight burden on my feet and obtained braces for both feet/ankles to wear when I anticipate having to stand for long periods of time. I have also continued to use meditation techniques I learned in treatment as a mechanism to relax and escape pain in a healthy way. I've attached a "recovery resume" that I put together. I feel that this could be helpful in summarizing key factors that are pertinent to my successful recovery.

Sincerely,

Michael Alan Donato

Michael Donato: Recovery Resume

1) Having pleaded guilty to third degree theft and possession in January 2012, adjudication was withheld and I was placed on 12 month probation and was released from probation after just six months for 100% compliance and voluntary service.

2) I have made full restitution to Publix.

3) My records have been sealed.

4) I have been clean & sober for over 2 years. My sobriety date is August 27, 2011. My new life started by completing a 3-month treatment program for medical professionals at Florida Recovery Center (UF/Shands) in Gainesville, FL. I graduated and was "coined out" on December 16, 2011.

5) My treatment culminated in serving 5 weeks as the senior peer of the treatment community. The senior peer serves as a mentor for the other men and assists the treatment team in making treatment decisions.

6) I have been dutifully employed at Starbucks since April 2012 in order to provide medical coverage for my wife and child.

7) Owing to the uncertainties associated with my circumstances, I have not practiced pharmacy since voluntarily surrendering my license in August 2011. However, I am most desirous of resuming my professional career so that I may recover from the serious financial hardships I have caused myself and those who have supported me.

8) I have complied with all the terms of my five year PRN contract which runs concurrently with my DOH probation.

9) I became an election official for Brevard County elections in October 2012.

10) I have donated 19 double units of platelets since April 2013.

11) I currently volunteer with the Sea Turtle Preservation Society.

12) I currently sponsor 3 men, all healthcare professionals, in recovery (PH, RS, and AB) and help them stay sober.

13) In addition, I am proud to say that I helped to save the life of JM and her unborn child after receiving a random call for help from her attorney. I encouraged JM to enter treatment and sign a PRN contract. Against the odds, JM and her baby are alive and well today.

15) At my initial appearance before the Board of Pharmacy, Dr. J. Rivenbark, (Medical Director of PRN) testified that I was a "model of recovery". The Board eventually reinstated my license to practice pharmacy in June 2012.

16) In addition to the required (30) CE credits for the biennium, I have completed numerous additional CE credits.

Final Order No. DOH-12-1349-S -MQA
FILED DATE JUL 03 2012
Department of Health
By [signature]
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
Petitioner,

vs.

MICHAEL ALAN DONATO, R.PH.,
Respondent.

CASE NO.: 2012-02328
LICENSE NO.: PS 31230

FINAL ORDER APPROVING SETTLEMENT AGREEMENT

THIS CAUSE came before the Board of Pharmacy (hereinafter the "Board") pursuant to Section 120.57(4), Florida Statutes, on June 5, 2012 in Deerfield Beach, Florida, for consideration of a Settlement Agreement (attached hereto as Exhibit A) entered into between the parties in the above-styled cause. Upon consideration of the Settlement Agreement, the documents submitted in support thereof, and being otherwise advised in the premises, it is hereby ordered and adjudged:

(1) The Settlement Agreement as submitted is hereby approved, adopted and incorporated herein by reference. Accordingly, the parties shall adhere to and abide by all the terms of the Settlement Agreement.

(2) Respondent's license was reinstated at the Board meeting and he was placed on probation pursuant to the terms of the agreement.

(3) As authorized by the Settlement Agreement the Board finds that the costs of investigation and prosecution are $1500.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 27th day of June, 2012.

BOARD OF PHARMACY

Daisy King, Program Operations Administrator for
Cynthia Griffin, PharmD, Chair

NOTICE OF RIGHT TO JUDICIAL REVIEW UNLESS WAIVED

A PARTY WHO IS ADVERSELY AFFECTED BY THIS ORDER IS ENTITLED TO JUDICIAL REVIEW, UNLESS WAIVED, PURSUANT TO SECTION 120.68, FLORIDA STATUTES. PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF THE NOTICE OF APPEAL WITH THE AGENCY CLERK OF THE DEPARTMENT OF HEALTH AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEALS, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by U.S. Mail to Michael Alan Donato, R.Ph. at 4007 Estancia Way, Melbourne, Florida 32934; Edwin Bayo at Grossman, Furlow and Bayo LLC, 2022 Raymond Diehl Rd # 2, Tallahassee, Florida 32308-3881 by interoffice delivery to John Truitt, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, FL 32399-3265, and by interoffice delivery to Allison Dudley, Assistant Attorney General, Department of Legal Affairs, The Capitol, PL-01, Tallahassee, Fl 32399-1050 this 3rd day of

July, 2012.

Angel Sanders

Deputy Agency Clerk

PRACTITIONER REGULATION
LEGAL
12 MAY -2 AM 9:16

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-02328**

MICHAEL ALAN DONATO, R.PH.,

RESPONDENT.

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaints, attached as Composite Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, MICHAEL ALAN DONATO, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 31230. Respondent's mailing address of record is 4007 Estancia Way, Melbourne, Florida 32934.

2. On or about March 7, 2012, Respondent was suspended by Emergency Suspension Order pursuant to Section 456.074(1), Florida Statutes, (2011) for entering a plea to a felony under Chapter 893.

STIPULATED LAW

1. Respondents admit that they are subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10), Florida Statutes. Respondent further stipulates to the issuance by the Department and the inclusion of the attached Administrative Complaint as part of this settlement.

3. Respondent admits that the allegations in the Administrative Complaints, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent, MICHAEL ALAN DONATO, R.Ph., shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **TWO THOUSAND DOLLARS** ($2,000.00). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND FIVE HUNDRED DOLLARS** ($1,500.00). Total costs shall be assessed when the

Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

4. **Evaluation and Treatment-** Respondent shall enter and successfully participate in a Professional Resource Network (PRN) contract.

5. **Suspension-** Respondent's license shall be indefinitely suspended until such time as Respondent petitions and appears before the Board to demonstrate his ability to practice pharmacy with reasonable skill and safety to patients and shall provide a practice plan detailing his pharmaceutical employment intentions for the Board's approval. Such demonstration of his ability to practice shall include an evaluation by a board approved treatment provider, and Respondent shall answer any questions asked by the Board. Such practice plan shall include the location of Respondent's intended practice, the type of practice, the number of employees (both professional and support), supervision delineations, and protocol for the handling of controlled substances. Said petition may be filed to be heard at the same time as the settlement agreement is

presented, but may also be filed at a later time. During the period of suspension, Respondent shall in no way participate in the preparation of medicinal drugs for dispensing or in the actual dispensing of medicinal drugs.

6. **Probation-** Upon reinstatement of licensure, Respondent shall be placed on a minimum of 5 years probation. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. Respondent shall not function as a prescription department manager in any Florida permitted pharmacy during the first 2 years of probation;

b. Respondent shall not work at or for more than 2 pharmacies during each quarter of the probationary period, unless Respondent obtains prior written approval from the Board;

c. During the period of Respondent's probation, the Department shall conduct semi-annual audits of 5 randomly selected controlled substances at the Respondent's place of employment at Respondent's cost;

d. Respodent shall submit written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall include Respondent's license number, current address, and phone number; current name, address, and phone number of each pharmacy in which Respondent is engaged in the practice of pharmacy; the names of all pharmacists, pharmacy interns, pharmacy technicians, relief pharmacists, and prescription department managers working with Respondent. These reports shall be submitted to the Compliance Officer every 3 months in a manner as directed by the compliance officer;

e. Respondent shall ensure that his employer submits written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall contain the name, address, license number, and phone number of each pharmacy intern, pharmacy technician, relief pharmacist, and prescription department manager

working in the prescription department where Respondent practices, and provide a brief description of Respondent's duties, responsibilities, and working schedule. These reports shall be submitted to the Compliance Officer every 3 months in a manner as directed by the compliance officer;

f. Respondent shall comply with any and all recommendations from PRN; and

g. Respondent shall make a mandatory appearance before the Board of Pharmacy during his last year of probation.

7. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

8. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

9. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

10. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

SIGNED this 18TH day of April, 2012.

MICHAEL ALAN DONATO, R.PH.
Case 2012-02328

STATE OF Florida }
}
COUNTY OF Brevard }

Before me personally appeared MICHAEL ALAN DONATO, R.PH., whose identity is known to me or by Drivers License (type of identification), and who, under oath, acknowledges that hissignature appears above. Sworn to and subscribed before me this 18 day of April, 2012.

ANDREW DIER
Notary Public - State of Florida
My Comm. Expires Jul 17, 2015
Commission # EE 113024

Notary Public
My Commission Expires: 07/17/2015

CONFIDENTIAL

DOH v. Michael Alan Donato, RPh
Case No. 2012-02328

APPROVED this 1st day of May, 2012.

STEVEN L. HARRIS, M.D., M.Sc.
Interim State Surgeon General
Florida Department of Health

NICHOLAS W. ROMANELLO
General Counsel
Florida Department of Health

WM. FREEMAN MILLER
Attorney Supervisor
Prosecution Services Unit

JOHN J. TRUITT
Assistant General Counsel
Fla. Bar No. 0084752
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683
Email: john_truitt@doh.state.fl.us

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. CASE NO. 2012-02328

MICHAEL ALAN DONATO, R.PH.,

RESPONDENT.

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through its undersigned counsel, hereby files this Administrative Complaint before the Board of Pharmacy against Respondent, MICHAEL ALAN DONATO, R.PH., and in support thereof alleges:

1. The Department of Health (Department) is the state agency charged with regulating the practice of registered pharmacy technicians pursuant to Chapters 20, 456 and 465, Florida Statutes (2011).

2. At all times material to this Complaint, Respondent, MICHAEL ALAN DONATO, R.PH., held license number PS 31230, as a

licensed pharmacist in the State of Florida pursuant to Chapter 465, Florida Statutes.

3. On or about January 26, 2012, in the Circuit Court of the Eighteenth Judicial Circuit in and for Brevard County, Florida, in case number 05-2011-CF-38613-AXXX-XX, Mr. Donato entered a plea of guilty to one count of possession of hydrocodone, a third-degree felony, in violation of Section 893.13(6)(a), Florida Statutes(2011).

4. The Department was notified of these pleas by a self-report letter from Mr. Donato's legal counsel received February 1, 2012.

5. Section 456.072(1)(c), Florida Statutes (2011), subjects a licensee to discipline, including suspension or denial of a license, for being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

6. On or about January 26, 2012, in the Circuit Court of the Eighteenth Judicial Circuit in and for Brevard County, Florida, in case number 05-2011-CF-38613-AXXX-XX, Mr. Donato entered a plea of

guilty to one count of possession of hydrocodone, a third-degree felony, in violation of Section 893.13(6)(a), Florida Statutes.

7. By entering such plea, Respondent entered a plea of guilty to a crime which relates to the practice of, or the ability to practice, a licensee's profession.

8. Respondent violated Section 456.072(1)(c), Florida Statutes (2011), by entering a plea of guilty to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board

deems appropriate.

SIGNED this 10th **day of** April, **2012.**

STEVEN L. HARRIS, M.D., M.Sc.
Interim State Surgeon General
Florida Department of Health

NICHOLAS W. ROMANELLO
General Counsel
Florida Department of Health

WM. FREEMAN MILLER
Attorney Supervisor
Prosecution Services Unit

David C. Bibb
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(850) 245 - 4640 Telephone
(850) 245 - 4683 Facsimile
Florida Bar No: 190330
E-mail: David_Bibb@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUL 02 2012

PCP: waived
PCP Members: n/a

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena *duces tecum* issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUL 24 2013

NOTICE OF AGENCY ACTION
DENIAL OF LICENSE RENEWAL

July 22, 2013

Michael Alan Donato
1305 Tradition Circle #308
Melbourne, FL 32901

RE: Application for Pharmacist License No. 31230

Dear Mr. Donato:

This letter is notification that your application for renewal of Pharmacist license no. 31230 is denied.

On or about January 26, 2012 you were were convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 893, Florida Statutes. A copy of the Judgement of conviction or plea is attached hereto, incorporated herein and made a part hereof by reference as Exhibit A.

This conviction, plea, or termination with cause requires denial of renewal of a license as provided in section 456.0635, Florida Statutes, which provides, "Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to issue or renew a license, certificate, or registration to any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has been: were convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 893, Florida Statutes.

This notice is agency action for purposes of section 120.569, Florida Statutes. If you believe your substantial interests have been determined by this action, you have twenty-one (21) days from the date of your receipt of this notice to petition for an administrative hearing pursuant to section 120.57, Florida Statutes, by sending a petition to the Agency Clerk, Department of Health, 4052 Bald Cypress Way, BIN #A-02, Tallahassee, FL 32399-1703 or by delivering a petition to the Agency Clerk, Department of Health, 2585 Merchants Row Blvd., Prather Building, Suite 110, Tallahassee, FL. Such petition must be filed in conformance with Florida Administrative Code Rules 28-106.201 or 28-106.301, as applicable. Mediation is not available. Failure to file a petition within 21 days shall constitute a waiver of the right to a disputed fact hearing on this agency action. Should you choose to waive your right to such a hearing, the Department will move for entry of a final order. Once a final order is entered you have 30 days as provided in section 120.68, Florida Statutes, to file an appeal. Such appeal must be initiated by filing a notice of appeal with the Department of Health agency clerk and a copy to the district court of appeal in accordance with the provisions of Florida Rule of Appellate Procedure 9.110.

DONE and ORDERED this 22nd day of July, 2013 in Tallahassee, Leon County, Florida.

John H. Armstrong, MD
State Surgeon General

By: _____

Mark Whitten
Board Of Pharmacy

Cc: Agency Clerk, Department of Health

_____

_____

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing notice has been provided by certified mail to Michael Alan Donato 1305 Tradition Circle #308 Melbourne, FL 32901 and by interoffice mail to Caryl Kilinsky, Senior Attorney, and the Bureau of Operations, Florida Department of Health this 24th day of July, 2013.

Angel Sanders
Deputy Agency Clerk

7012 3050 0001 9298 4157

May 7, 2013

Mr. Michael Alan Donato
4007 Estancia Way
Melbourne, FL 32934

Final Order filed: July 3, 2012
Case Number: 201202328
License Number: 31230

Dear Mr. Donato:

The Compliance Management Unit has received your payment of the fines and/or costs imposed in the Final Order for Case Number 201202328.

Amount Paid:	$3,500.00
Date Received:	May 1, 2013
Receipt Number:	912058898
Balance:	0

The mission of the Department of Health is to protect, promote, & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please contact me by calling (850) 245-4268.

Sincerely,

Sondra N Allen

Sondra N. Allen
Operations Analyst II

/sna

Division of
Medical Quality Assurance

MQA

Department of Health
Compliance Management Team
4052 Bald Cypress Way, Bin C76
Tallahassee, FL 323399
(850) 245-4268

MAIN TERMS OF THE FINAL ORDER

This summary is provided as a courtesy. It is your responsibility to read and understand the Final Order to ensure compliance with all terms described therein. Please reference the case number listed on all correspondence forwarded to this office pertaining to this case.

CASE INFORMATION	
Case Number:	201202328
Respondent Name:	Michael Alan Donato
Final Order Date:	7/3/2012
Today's Date:	7/3/2012

Licensee:	Michael Alan Donato	**Profession:**	2201 : Pharmacist
Mailing Address:	4007 Estancia Way Melbourne, FL 32934	**File Nbr:**	20241
		License Nbr:	31230
		License Status:	Probation/Active
Attorney:	Allen R. Grossman	**Address:**	2022 Raymond Diehl Road Grossman, Furlow, & Bayo Llc Tallahassee, FL 32308
		Phone:	8503851314
Attorney:	Edwin Bayo	**Address:**	2022 Raymond Diehl Road, Suite 102 Tallahassee, FL 32169
Monitor:	None on Record		
Supervisor:	None on Record		
Appeal:	N		

Discipline Imposed:	Start Date	End Date	Comments
Emergency Suspension	03/12/2012	07/02/2012	
Probation	07/03/2012		Respondent's license was reinstated at the Board meeting and placed on probation pursuant to the terms of the agreement. Upon reinstatement of licensure, Respondent shall be placed on a minimum of 5 years probation

COMPLIANCE MANAGEMENT UNIT
FINE/COSTS INVOICE

Respondent:	Michael Alan Donato		
Profession-License Number:	2201 Pharmacist 31230	Indv/Org #	5018360
File Number:	20241	Case Number:	201202328

Fine:	$ 2,000.00	Due Date: October 3, 2012
Administrative Costs:	$ 1,500.00	Due Date: October 3, 2012
TOTAL:	$ 3,500.00	

To receive credit for your payment attach cashier's check or money order here and return to:
Please make checks payable to the Department of Health

Department of Health
Compliance Management Unit, BIN C-76
P.O. Box 6320
Tallahassee, Florida 32314-6320

Partial payment shall be accepted, however full payment must be made by the due date specified in the Final Order. Each payment must be accompanied by a copy of this invoice. Please make additional copies if needed.

IMPORTANT: Payment in full of all fines and costs imposed by your Final Order are due upon the due date specified by the Final Order. Failure to pay all fines and costs on or before the due date specified will result in the following:

- A referral will be filed with Consumer Services for investigation regarding non-compliance with your Final Order and possible further disciplinary action.
- Failure to pay in full within thirty (30) days of the due date specified by the Final Order will result in the account being deemed "past due". Payment of "past due" accounts will avoid assignment to a collection agency for collection; however it will not result in closing of the referral for non-compliance with your Final Order."

Division of
Medical Quality Assurance

MQA

Department of Health
Compliance Management Team
4052 Bald Cypress Way, Bin C76
Tallahassee, FL 323399
(850) 245-4268

Compliance Record:	Due Date	Cmpl Date	Amt Imposed	Amt Paid
Costs	10/03/2012		1,500.00	0.00
Fine	10/03/2012		2,000.00	0.00
Respondent Report	10/03/2012			
Supervisor's Report	10/03/2012			
Audit	01/03/2013			
Respondent Report	01/03/2013			
Supervisor's Report	01/03/2013			
Respondent Report	04/03/2013			
Supervisor's Report	04/03/2013			
Audit	07/03/2013			
Respondent Report	07/03/2013			
Supervisor's Report	07/03/2013			
Respondent Report	10/03/2013			
Supervisor's Report	10/03/2013			
Audit	01/03/2014			
Respondent Report	01/03/2014			
Supervisor's Report	01/03/2014			
Respondent Report	04/03/2014			
Supervisor's Report	04/03/2014			
Audit	07/03/2014			
Respondent Report	07/03/2014			
Supervisor's Report	07/03/2014			
Respondent Report	10/03/2014			
Supervisor's Report	10/03/2014			
Audit	01/03/2015			
Respondent Report	01/03/2015			
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Supervisor's Report	04/03/2015			
Audit	07/03/2015			
Respondent Report	07/03/2015			
Supervisor's Report	07/03/2015			
Respondent Report	10/03/2015			
Supervisor's Report	10/03/2015			
Audit	01/03/2016			
Respondent Report	01/03/2016			
Supervisor's Report	01/03/2016			
Respondent Report	04/03/2016			
Supervisor's Report	04/03/2016			
Audit	07/03/2016			
Respondent Report	07/03/2016			
Supervisor's Report	07/03/2016			
Respondent Report	10/03/2016			
Supervisor's Report	10/03/2016			
Audit	01/03/2017			

Division of
Medical Quality Assurance

MQA

Department of Health
Compliance Management Team
4052 Bald Cypress Way, Bin C76
Tallahassee, FL 323399
(850) 245-4268

Respondent Report	01/03/2017
Supervisor's Report	01/03/2017
Respondent Report	04/03/2017
Supervisor's Report	04/03/2017
Audit	07/03/2017
Respondent Report	07/03/2017
Supervisor's Report	07/03/2017
PRN Contract	
PRN Evaluation	
Appearances	
Miscellaneous	
Miscellaneous	

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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freeCE.com
PHARMACEUTICAL EDUCATION CONSULTANTS

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

Medication Errors and Public Safety: Tragic Consequences When the System Breaks Down -FL APPROVED/LAW

Accreditation Number: **0798-0000-11-030-H03-P**
Activity Type: **Knowledge**
Date Completed: **Sunday, June 23, 2013**

This activity has been approved for 2 contact hour(s) of continuing education for Pharmacists.

ACPE PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/23/2013**

PHARMACEUTICAL EDUCATION CONSULTANTS, INC.
PHARMCON
1990

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

Statement of Credit

MED ERRORS

Office of Continuing Pharmacy Times Professional Education

6/25/2013

Dear Participant:

Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934

Office of Continuing Pharmacy Times Professional Education

CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

has successfully completed the program

A Pharmacist's Guide to Preventing Vaccine Errors

ACPE Universal Program No. 0290-0000-12-075-H01-P

Type of Activity: Knowledge

and earned 2.0 contact hours (0.20 CEUs) on 6/25/2013

ACPE®

Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

MED ERRORS

ALIVE

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

Medication Errors and Public Safety: Tragic Consequences When the System Breaks Down -FL APPROVED/LAW

Accreditation Number: **0798-0000-11-030-H03-P**
Activity Type: **Knowledge**
Date Completed: **Sunday, June 23, 2013**

This activity has been approved for 2 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/23/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

Medical Marijuana: Real Medication or Just Recreation?

Accreditation Number: **0798-0000-12-099-L01-P**
Activity Type: **Knowledge**
Date Completed: **Wednesday, June 26, 2013**

This activity has been approved for 1 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/26/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

LIVE

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

Endocrine Therapy for Estrogen Receptor Positive Breast Cancer

Accreditation Number: **0798-0000-13-084-L01-P**
Activity Type: **Knowledge**
Date Completed: **Wednesday, June 26, 2013**

This activity has been approved for 1 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/26/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

LIVE

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

What's New in Familial Hypercholesterolemia

Accreditation Number: **0798-0000-13-173-L01-P**
Activity Type: **Knowledge**
Date Completed: **Tuesday, June 25, 2013**

This activity has been approved for 1 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/25/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

PharmCon 404 Main Street Conway, SC 29526 (843) 488-5550 www.freece.com

6/25/2013

Dear Participant:

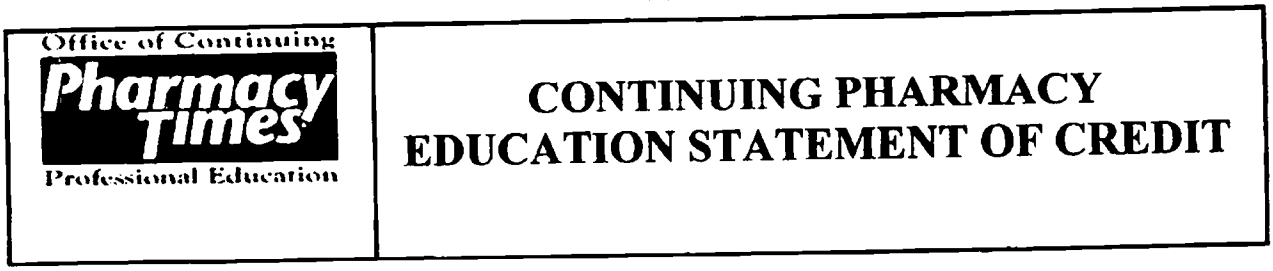
Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934



CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

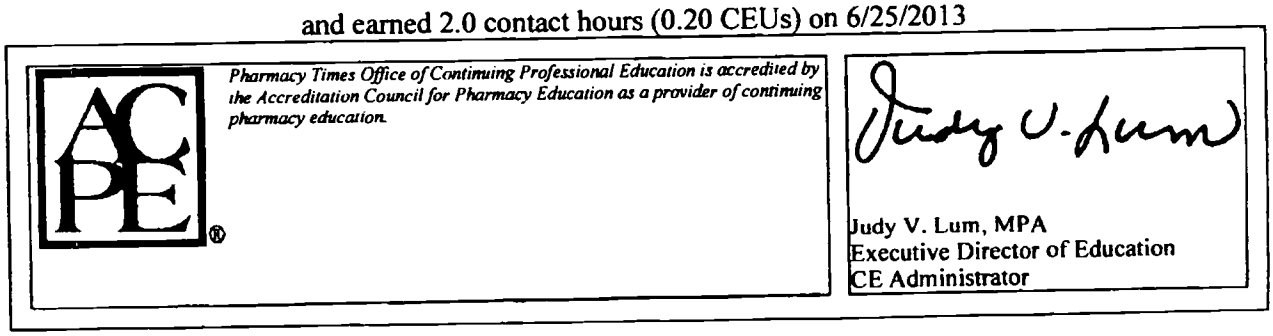
has successfully completed the program

Changing Course: A Pharmacist-Focused Approach to Improving Patient Outcomes in Multiple Sclerosis

ACPE Universal Program No. 0290-0000-12-087-H01-P

Type of Activity: Knowledge

and earned 2.0 contact hours (0.20 CEUs) on 6/25/2013



Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Florida Medical Association
&
Florida Pharmacy Association

Assert that

MICHAEL DONATO

has completed the application-based activity titled

Florida Pharmacists Immunization Course

CE Broker #20-368708 and ACPE UAN #: 0165-9999-12-081-H01-P

on 6/23/2013 and is awarded three (3) continuing education credits.

The Florida Pharmacy Association is accredited by the Accreditation Council on Pharmacy Education as a provider of continuing pharmacy education.

Tian M. Owens, M.S., PharmD

Tian Merren Owens, MS, PharmD

CPE Administrator

6/23/2013

6/6/2013

Dear Participant:

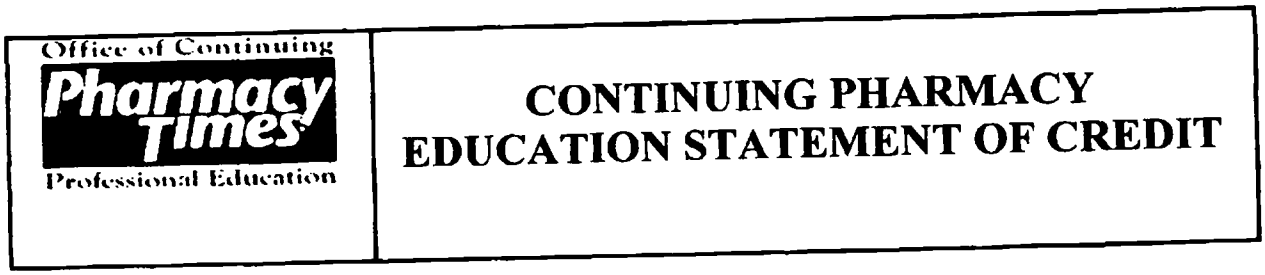
Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934



CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

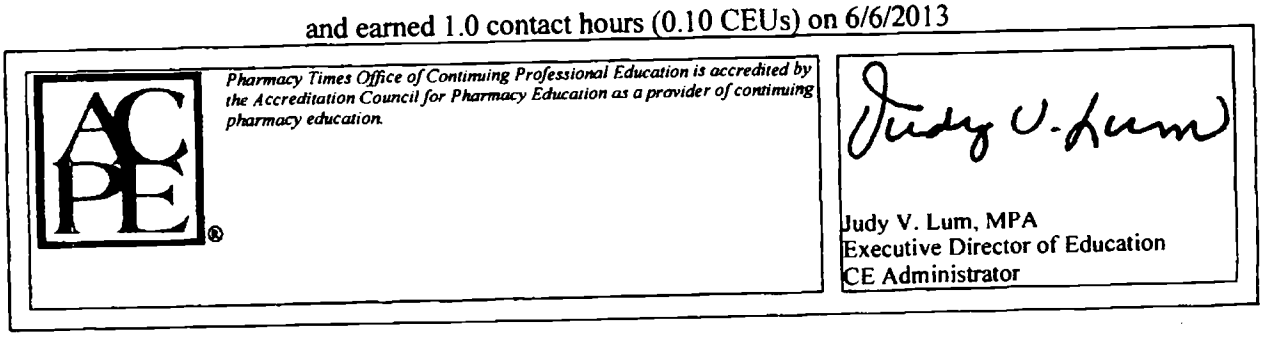
has successfully completed the program

Update on Bowel Preparations: Improving Diagnostic Accuracy and Patient Adherence

ACPE Universal Program No. 0290-0000-13-125-H04-P

Type of Activity: Knowledge

and earned 1.0 contact hours (0.10 CEUs) on 6/6/2013



Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Office of Continuing Pharmacy Times Professional Education

5/25/2013

Dear Participant:

Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934

Office of Continuing Pharmacy Times Professional Education

CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

has successfully completed the program

New Drugs of 2012, Part 1

ACPE Universal Program No. 0290-0000-13-114-H01-P

Type of Activity: Knowledge

and earned 2.0 contact hours (0.20 CEUs) on 5/25/2013

ACPE®

Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

5/31/2013

Dear Participant:

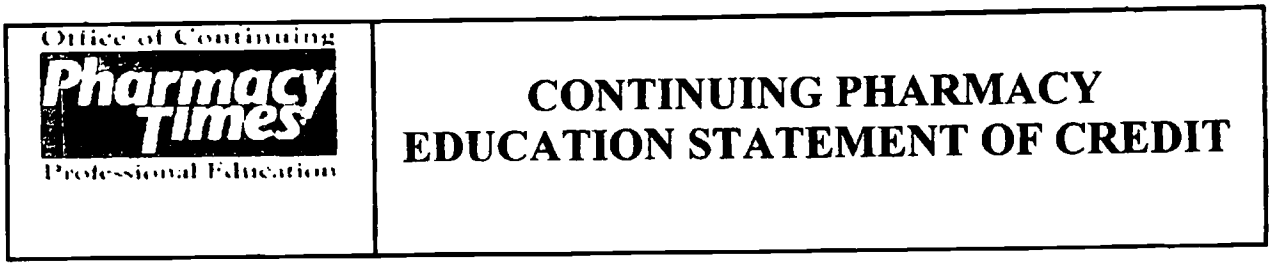
Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934



CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

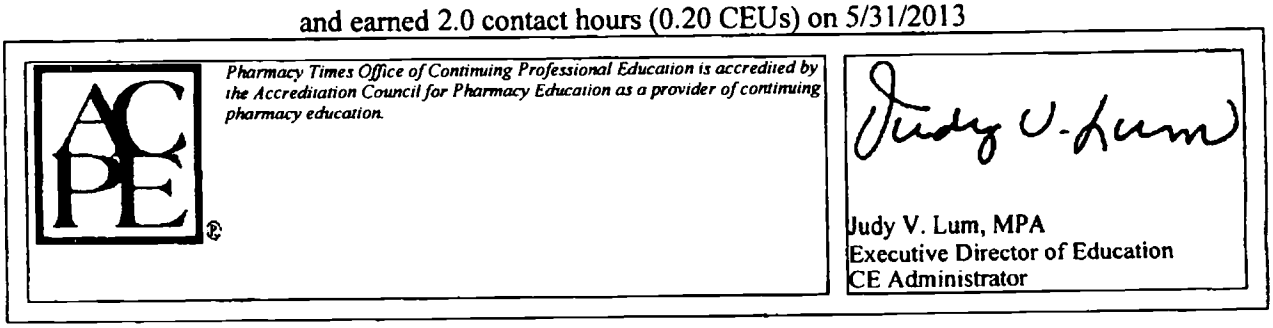
has successfully completed the program

New Drugs of 2012, Part 2

ACPE Universal Program No. 0290-0000-13-117-H04-P

Type of Activity: Knowledge

and earned 2.0 contact hours (0.20 CEUs) on 5/31/2013



Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Office of Continuing Pharmacy Times Professional Education

6/24/2013

Dear Participant:

Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934

Office of Continuing Pharmacy Times Professional Education

CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

has successfully completed the program

Evolving Therapeutic Strategies in Cancer Therapy–Induced Bone Loss: The Pharmacist's Role in Minimizing Fractures

ACPE Universal Program No. 0290-0000-12-082-H01-P

Type of Activity: Knowledge

and earned 2.0 contact hours (0.20 CEUs) on 6/24/2013

ACPE®

Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

LIVE

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

Medication Considerations in Lactation: A Patient-Centered Approach

Accreditation Number: **0798-0000-13-178-L01-P**
Activity Type: **Knowledge**
Date Completed: **Monday, June 24, 2013**

This activity has been approved for 1 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/24/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

PharmCon 404 Main Street Conway, SC 29526 (843) 488-5550 www.freece.com

6/23/2013

Dear Participant:

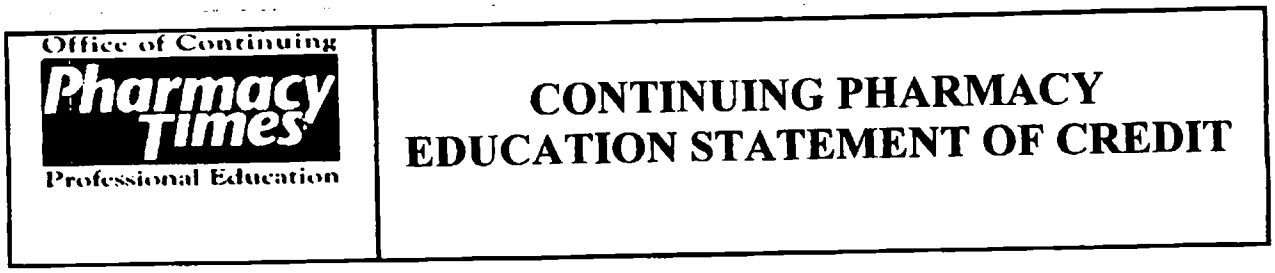
Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934



CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

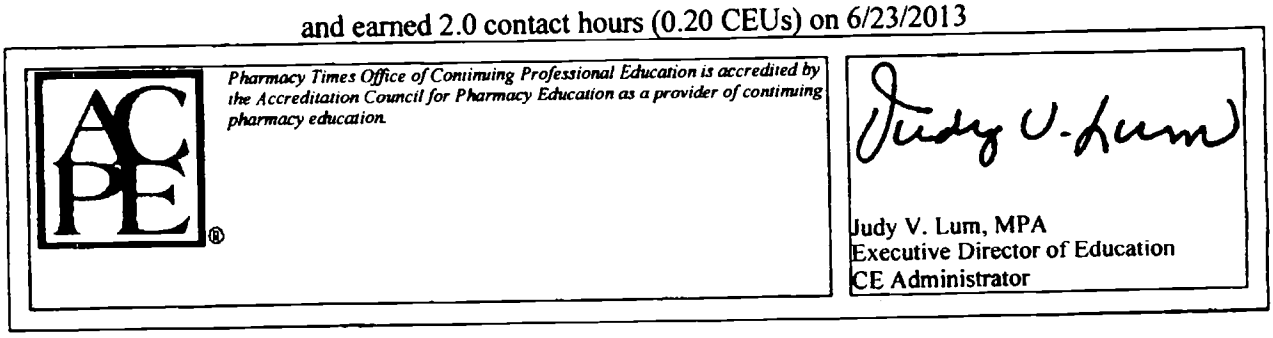
has successfully completed the program

Evaluation and Treatment of Patients with Major Depressive Disorder: Are We Considering All the Options?

ACPE Universal Program No. 0290-0000-12-083-H01-P

Type of Activity: Knowledge

and earned 2.0 contact hours (0.20 CEUs) on 6/23/2013



Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

Taking Control of T2DM: The Role of Incretin Mimetics in Improving Outcomes

Accreditation Number: **0798-0000-12-080-L01-P**
Activity Type: **Knowledge**
Date Completed: **Thursday, June 20, 2013**

This activity has been approved for 1 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/20/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

Office of Continuing Pharmacy Times Professional Education

6/20/2013

Dear Participant:

Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934

Office of Continuing Pharmacy Times Professional Education

CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

has successfully completed the program

New Perspectives on the Pathogenesis and Treatment of Alzheimer's Disease

ACPE Universal Program No. 0290-0000-12-074-H01-P

Type of Activity: Knowledge

and earned 2.0 contact hours (0.20 CEUs) on 6/20/2013

ACPE®

Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

Methadone: An Opioid with Unplumbed Depths

Accreditation Number: **0798-0000-13-148-L01-P**

Activity Type: **Knowledge**

Date Completed: **Wednesday, June 19, 2013**

This activity has been approved for 1 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/19/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

LIVE

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

Appropriate Use of Contraception: Who, What, When, Where, Why and How

Accreditation Number: **0798-0000-12-098-L01-P**
Activity Type: **Knowledge**
Date Completed: **Tuesday, June 18, 2013**

This activity has been approved for 1 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/18/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

Office of Continuing Pharmacy Times Professional Education

6/18/2013

Dear Participant:

Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934

Office of Continuing Pharmacy Times Professional Education

CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

has successfully completed the program

The Impact of Common Neuropsychiatric Conditions on Cognitive Function

ACPE Universal Program No. 0290-0000-12-073-H01-P

Type of Activity: Knowledge

and earned 2.0 contact hours (0.20 CEUs) on 6/18/2013

ACPE®

Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

LEVE

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

Tuberculosis: A Disease of the Past or Continued Public Health Concern?

Accreditation Number: **0798-0000-13-129-L01-P**
Activity Type: **Knowledge**
Date Completed: **Tuesday, June 18, 2013**

This activity has been approved for 1 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/18/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

LIVE

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

The Flu Affair: Unraveling Our Relationship with a Deadly Virus

Accreditation Number: **0798-0000-12-079-L01-P**
Activity Type: **Knowledge**
Date Completed: **Wednesday, June 12, 2013**

This activity has been approved for 1.25 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/12/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

PharmCon 404 Main Street Conway, SC 29526 (843) 488-5550 www.freece.com

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

Better Living Through Bacteria: Probiotics for the Gut and Beyond

Accreditation Number: **0798-0000-13-176-L01-P**
Activity Type: **Knowledge**
Date Completed: **Tuesday, June 11, 2013**

This activity has been approved for 1 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/11/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

LIVE

STATEMENT OF CREDIT

Michael Donato

CPE Monitor ID: 633836

When the Going Gets Tough: The Pharmacist's Role in Managing Treatment Resistant Depression

Accreditation Number: **0798-0000-12-083-L01-P**
Activity Type: **Knowledge**
Date Completed: **Monday, June 10, 2013**

This activity has been approved for 1 contact hour(s) of continuing education for Pharmacists.

PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **6/10/2013**

This Statement of Credit will be retained online by freeCE for a minimum of five (5) years.

6/10/2013

Dear Participant:

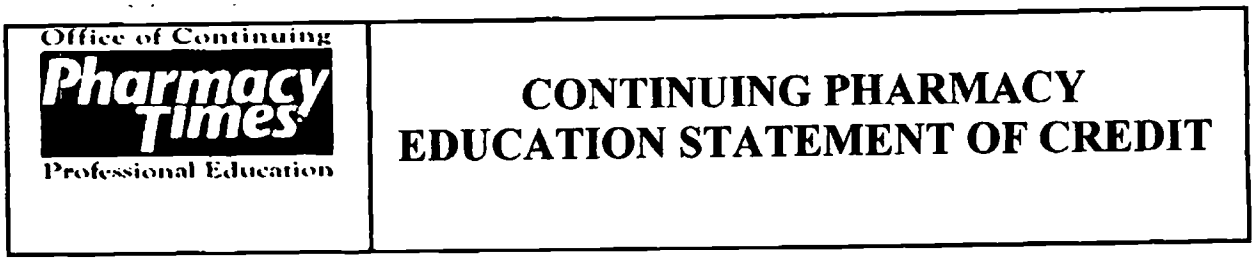
Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934



CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

has successfully completed the program

Learning to Breathe: Optimizing Management of COPD Based on Device Selection

ACPE Universal Program No. 0290-0000-13-123-H01-P

Type of Activity: Knowledge

and earned 2.0 contact hours (0.20 CEUs) on 6/10/2013

Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Office of Continuing Pharmacy Times Professional Education

6/8/2013

Dear Participant:

Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934

Office of Continuing Pharmacy Times Professional Education

CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

has successfully completed the program

Overactive Bladder Management: Challenges and Opportunities

ACPE Universal Program No. 0290-0000-12-066-H01-P

Type of Activity: Knowledge

and earned 1.5 contact hours (0.15 CEUs) on 6/8/2013

ACPE®

Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

6/6/2013

Dear Participant:

Pharmacy Times Office of Continuing Professional Education is pleased to forward your continuing education Statement of Credit. Thank you for participating in this program.

We look forward to your continued interest in pharmacy education and hope we will have the opportunity of serving you again in the future.

Sincerely,

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

Michael A Donato
4007 Estancia Way
Melbourne, FL 32934

CONTINUING PHARMACY EDUCATION STATEMENT OF CREDIT

Michael A. Donato

has successfully completed the program

Preemptive Action: Reducing the Risk of Breast Cancer

ACPE Universal Program No. 0290-0000-12-078-H01-P

Type of Activity: Knowledge

and earned 2.0 contact hours (0.20 CEUs) on 6/6/2013

Pharmacy Times Office of Continuing Professional Education is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Judy V. Lum, MPA
Executive Director of Education
CE Administrator

January 21, 2014

Curtis Michael Drees
19 Miami Street
Fort Loramie, OH 45845

RE: Pharmacist Intern Application

Dear Mr. Drees:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are required to appear per the Board's request. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

November 14, 2013

Curtis Michael Drees
19 Miami Street
Fort Loramie, OH 45845

RE: Pharmacy Intern Application

Dear Mr. Drees:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, December 4, 2013. The meeting is being held at the Hilton Hotel University of Florida, 1714 SW 34th Street, Gainesville, FL 32607, (352) 371-3600. The meeting will begin at 9:00 a.m.

You are required to be present per the Board's request. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE OCT 29 2013

STATE OF FLORIDA BOARD OF PHARMACY

IN RE: APPLICATION FOR PHARMACY INTERN LICENSE	Curtis Michael Dress

ORDER
REQUIRING APPEARANCE

This matter came before the Board of Pharmacy on October, 9, 2013 at a duly noticed public meeting in Panama City Beach, Florida, for review of the application for licensure as a pharmacist intern. By the authority of Section 456.013(3)(c), Florida Statutes, The Board of Pharmacy voted to require your personal attendance at one of either of the next two regularly scheduled board meetings or the application will be denied as a matter of law.

WHEREFORE, it is hereby **ORDERED,** that the applicant will appear at either one of the next two regularly scheduled board meetings or the application will be **DEINED.**

WHEREFORE, it is **ORDERED** that the applicant shall notify the Board Office of which meeting the applicant will be attending 30 days prior to the scheduled date of said meeting.

DONE AND ORDERED this 28 day of October, 2013.

BOARD OF PHARMACY

Mark Whitten
Executive Director *on behalf of*
Albert Garcia, CHAIR

CERTIFICATE OF SERVICE

I **HEREBY CERTIFY** that a true and correct copy of the foregoing has been furnished by Certified mail to **Curtis M. Dress, 19 Miami Street, Fort Loramie , Ohio 45845; and David D. Flynn**, Assistant Attorney General, **david.flynn@myfloridalegal.com**, this 29th day of October, 2013.

Angel Sanders

Deputy Agency Clerk

7012 3050 0001 9149 8341

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

2202

F-19170

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: 850-245-4292
www.doh.state.fl.us/pharmacy/drugs

ITEM #2 – PHARMACY INTERN APPLICATION FOR U.S. PHARMACY STUDENTS/GRADUTES

Rule 64B16-26.400(1), Florida Administrative Code, states, A pharmacy intern is required to be registered with the Department of Health as an intern before being employed as in intern in a pharmacy in Florida. Intern certificates issued by the Florida Board of Pharmacy (the board) are valid for the State of Florida ONLY and must be returned to the board after an intern has become a Registered Pharmacist in the State of Florida. Applicants must complete the information below and forward the application to the College of Pharmacy to be completed by the Dean and returned to the address above.

Please print or type legibly.

1. Biographical Information

Last Name	First Name	Middle Name
Drees	Curtis	Michael

Home Address (Mailing Address – ML)	City	State	Zip
19 Miami St.	Fort Loramie	OH	45845
Work Address (Practice Location – PL)	**City**	**State**	**Zip**
—	—	—	—

Current Phone Number	Home Phone Number	Date of Birth
937-489-9275	937-295-2766	5-3-1989

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☑ Male ☐ Female
RACE: ☑ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. If known, indicate the name and address of the pharmacy where you will intern in Florida.

—

4. Have you ever applied to take the Florida pharmacist examination? If yes, please indicate the date.

Yes _____ No ✓ Date _____

5. Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense?

Yes ✓ No _____

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

10. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state?
Yes _____ No ✓
11. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No ✓
12. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No ✓
13. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #14.)
Yes _____ No ✓
13a. If "yes" to 13, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
13b. If "yes" to 13, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No_____
13c. If "yes" to 13, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes_____ No _____
13d. If "yes" to 13, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes_____ No_____
14. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If no do not answer 14a.)
Yes_____ No ✓

14a. If "yes" to 14, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes_____ No_____
15. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 15a.)
Yes _____ No ___✓___
15a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No _____
16. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 16a and 16b.)
Yes _____ No ___✓___
16a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No _____
16b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
17. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities? (If "yes", please provide documentation)
Yes _____ No ___✓___
18. If "yes" to any of the questions 13 through 17 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes_____ No_____

All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 5-18, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

_____ (SIGNATURE OF APPLICANT)

7-1-13 (DATE)

TO BE COMPLETED BY DEAN OF COLLEGE OF PHARMACY

This is to certify that the above named applicant is entered into the professional curriculum of the University of Toledo College of Pharmacy & Pharmaceutical Sci, as of 8-23-10 ; and is a graduate
(NAME OF SCHOOL) (DATE)

of said professional curriculum as of 5-4-14.
(DATE)

Christine N. Hinko, PhD
(PRINT NAME OF DEAN)

(SCHOOL SEAL)

Christine N. Hinko
(SIGNATURE OF DEAN)

7-22-13
(DATE)

Florida Board of Pharmacy
P.O. Box 6320
Tallahassee, FL 32314-6320

July 1, 2013

To Whom It May Concern:

I have several incidents I wish to report to the Florida Board of Pharmacy in regards to Item 2 on my intern application. The first incident occurred on the night of May 5th, 2007, when I was 17 years old. I was at my cousin's wedding that night, and during the celebration, my parents provided me with alcoholic beverages, including champagne and beer. They did this knowing it was legal in the state of Ohio to provide your child alcohol in a private setting if they are under the age of 18. As it got later into the night, several of my friends and I decided we wanted to go home for the night. We got a sober driver to bring all of us home. However, on the ride home, our vehicle was pulled over for having a dim license plate light. The officer said he could smell alcohol on me and my two friends in the back seat, and after one of my friends lied about his age, he took us in to their station and put us in holding cells. We were charged with underage consumption and waited in our cells until our parents could come pick us up. After taking the case to court, the prosecutor offered a settlement due to the fact that our parents had provided us with the alcohol in a private setting. However, he would not drop the case because, according to the same law, the parents must be present the entire time the child has alcohol in their system. I pleaded guilty to a charge of unruly juvenile and had to take an alcohol class, which I completed through the online class offered by the University of Toledo. I have few regrets about the incident. I know that technically I was not on the right side of the law when the police officer took me in, but I believe the way I obtained the alcohol was legal and was the victim of bad circumstances when my car ride home was pulled over. I was far from intoxicated; rather, I drank socially with my parents and the rest of my extended family at the wedding to celebrate my cousin's marriage. Still, I did put myself in an unfavorable situation by consuming the alcohol at the wedding, and that is something I regret still to this day.

The next incident that occurred was on July 11th, 2008. I was attending an event in my hometown called Country Concert, which is a four-day outdoor concert/festival where you can camp out and see several country music stars. I had gone home to eat and shower before returning to my campsite that day at around 11:30 A.M. I was not drinking at the festival, but several of my friends at my campsite had already begun to drink that morning, all of them under the age of 21. I opted for a Mountain Dew. I sat in a friend's lawn chair, unaware that they had left their open beer in the cup holder on the lawn chair. A few minutes later several undercover cops that patrol the campgrounds stopped at our campsite and arrested anyone who had a beer in hand or near them. Despite me holding a Mountain Dew in hand, they gave me a charge of furnish liquor underage. I pleaded with them that it was not my beer, and asked several times for a breathalyzer to prove my innocence, but they stated the open container in the chair I was sitting in was enough to

charge me. I spoke to a lawyer about the incident, and they told me unless whoever's beer that was in the chair came forward and claimed it as theirs, their was little I could do for myself. In addition, the person whose beer it was did not want to come forward and admit guilt because they themselves did not want to be charged. Therefore, I had to plead bond forfeiture to the charge and had to pay a fine. In retrospect, I should not have placed myself in a situation that could even have caused me to be arrested. I know that the Country Concert is notorious for having undercover officers arresting kids drinking under the age of 21. Although I thought I did enough by simply not drinking, I did not consider the effects of being surrounded by friends who were drinking underage, and I paid the price for that lapse in judgment.

My final and most regrettable incident I would like to inform the Florida Board of Pharmacy about occurred on the night of March 4th, 2010. I had come home for spring break and went with several friends to what is known in our area as a softball dance. Basically, a local softball team that plays in several tournaments throughout the summer throws a dance at a local hall to raise money for their team. They usually hire a DJ or band and sell beer to make their money. After attending this dance, I had realized that my ride had left me there without letting me know they were leaving. I and the others he had left behind were scrambling to find a ride, and eventually did in the bed of another friend's pick-up truck. About halfway through our trip back home, the truck was pulled over for not signaling on a turn. One of the police officers came to the back of the truck bed and asked us to take out our ID's while she talked to the driver. I panicked, because I knew that, though I did not consume alcohol at the dance, I smelled strongly of it because people had been spilling their drinks while dancing as well as throwing them up in the air. In addition, I had been kissing my girlfriend, who had been drinking, and I figured that if I could taste the alcohol on her breath, it was probably on mine as well. Knowing from my previous experiences, these several circumstances were all the cops needed to take me in for underage consumption of alcohol. I also knew I would have to being doing the very thing I am now, applying for an intern license, and another alcohol charge would possibly keep me from obtaining one. As all of this was running through my mind, one of the passengers in the truck bed with me jumped out and began running. Stupidly, I made the same choice. I ran into a field (I live in the country) and did not turn back. However, the police called for backup and they found me in the fields about ten minutes later. During their search of me, they found a fake ID that I had obtained about a month earlier, and charged me with obstruction of justice and prohibited acts.

I had gotten the fake ID about a month previously for two reasons. First, all of my friends at college had already turned 21 and began going out to bars, and just to get into the bar and hang out with them I needed to be 21. Second, I had been planning to go to Florida for spring break and use it to get into bars and buy alcohol. However, I chickened out on going to Florida at the last minute because, and here is the kicker, I did not want to get into any trouble with alcohol before my 21st birthday in May.

I hired a lawyer for the case, and he informed me what I did was not obstruction of justice. He said that the law stated it was only obstruction if they had already had been holding me for suspicion of something and then I ran. Because it was a routine traffic

stop and all they did was ask for ID's, it did not meet the qualifications for being obstruction of justice. In fact, the other passenger who ran was also charged with obstruction and later had his case dropped. However, because of the fake ID they found on me, they gave me a plea bargain where they would drop the prohibited acts if I plead guilty to obstruction of justice. I agreed and plead guilty. I received 5 years probation and a fine, as well as a 30-day jail sentence with all 30 days suspended as long as I do not commit any other crimes within the next 5 years.

I completely regret my acts made in this situation. Instead of trying to simply explain my situation to the police, I panicked and tried to run, which ended up costing more than if I would have stayed in the truck bed. Nevertheless, I promise you it was because I knew my opportunity to continue my path to becoming a pharmacist would suffer if I were to be arrested again. I knew in my previous arrests I was the victim of bad circumstances and figured that would happen again if I stayed in the truck bed.

I would be the first one to tell you that I have put myself in some bad situations over the years. Moreover, it seems every bad situation I have been in has put me into more and more trouble. I can understand that many people would just tell me to avoid these situations completely, get new friends, change your lifestyle, or whatever else to avoid these problems. I agree that these are great solutions, but growing up where I have grown up has made it very difficult to accomplish these things. I am from a small farming community where underage drinking is not only prevalent, but many of the older people encourage it. It is very difficult to go anywhere with your friends around my hometown without being confronted with underage drinking. And eventually, my friends fell into the culture. I could try to get new friends but in such a small town pretty much everyone is your friend and pretty much all of them do start drinking at a young age. My friends don't see it as a problem because that's the way their parents lived, and many of them plan on living in my hometown the rest of their lives, not going to college or ever really leaving at all. They do not have a problem with having any kind of misdemeanor charges on their record because it really will not affect their lives. In addition, I was lulled into that sense of calmness, despite knowing I must hold myself to a higher standard if I want to fulfill my dreams of becoming a pharmacist.

I believe part of the reason I have been in such bad situations involving underage drinking is because I have become desensitized to it after seeing it and being around it since early in high school. I do not view people drinking underage as a blasphemous act, but rather as the norm, and therefore I sometimes see some bad situations I am in also as the norm. I know the reasons I have given for being in bad situations several times in my life are not great ones, but they are the truth.

I am not going to lie and tell you that the only time I have ever drank in my life was at my cousin's wedding. I am not writing this letter to lie to you about having never drunk underage. I have. But it is much less than any other kid from my hometown or many of the kids I go to school with at the University of Toledo have. For the most part, I have tried to stay clean-cut my entire life, because I know what happens in your past can drastically affect your future. I know that all my offenses listed previously have involved

underage drinking, and I hope you take that into consideration when you decide whether I am qualified to receive a pharmacy intern license. I have never been involved in any other type of criminal activity, and have no intentions to start. And now that am I am of legal age to consume alcohol, I can promise you I will never have any more criminal charges in that regard (I had several close friends killed by a drunk driver a few years back, and the thought of stepping behind a wheel of a car after drinking almost makes me sick to my stomach). Furthermore, I have received an intern license from the Ohio State Board of pharmacy and have had no other events I have had to report since receiving said license. I ask that the members of the Florida Board of Pharmacy take all this into account when making a decision about whether or not to grant me an intern license. I am a person who strives to be the best at what they do, and my approach to becoming a pharmacist has been and will continue to be no different. I assure you that you will not regret granting me a license and allowing me to continue my path to becoming a great pharmacist and a great person. I thank you in advance.

Sincerely,

Curtis Drees
19 Miami St.
Ft. Loramie, OH 45845

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Name and Address	[back]
Name	CURTIS MICHAEL DREES
Public Address	OH

License and Registration Information				
License	First Issue Date	Current Issue Date	Expiration Date	Status
INT.06009515	09/23/2010	09/16/2013	09/15/2014	ACTIVE
License Type: Pharmacy Intern **How issued:**				

Formal Action Information
No formal action exists.

This data is an accurate representation of information currently maintained by the Ohio State Board of Pharmacy as of 8/29/2013.

This secure online license verification system conforms with The Joint Commission's current policy on "Primary Source Verification".

This information is otherwise provided as a public service and no user may claim detrimental reliance thereon.

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January 21, 2014

Kaitlyn Nemecek
5050 Graduate Circle
Apt 202-A
Tampa, FL 33617

RE: Pharmacist Intern Application

Dear Ms. Nemecek:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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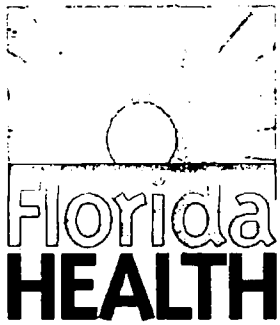

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: 850-245-4292
www.doh.state.fl.us/pharmacy/drugs

ITEM #2 – PHARMACY INTERN APPLICATION FOR U.S. PHARMACY STUDENTS/GRADUTES

Rule 64B16-26.400(1), Florida Administrative Code, states, A pharmacy intern is required to be registered with the Department of Health as an intern before being employed as in intern in a pharmacy in Florida. Intern certificates issued by the Florida Board of Pharmacy (the board) are valid for the State of Florida ONLY and must be returned to the board after an intern has become a Registered Pharmacist in the State of Florida. Applicants must complete the information below and forward the application to the College of Pharmacy to be completed by the Dean and returned to the address above.

2202-19562

Please print or type legibly.

1. Biographical Information				
Last Name	**First Name**		**Middle Name**	
Nemecek	Kaitlyn		Rachel	
Home Address (Mailing Address – ML)		**City**	**State**	**Zip**
5650 Graduate circle Apt 2302A		Tampa	FL	33617
Work Address (Practice Location – PL)		**City**	**State**	**Zip**
Current Phone Number	**Home Phone Number**		**Date of Birth**	
(904) 228-0621	N/A		03-17-1991	

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☐ Male ☑ Female
RACE: ☑ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. If known, indicate the name and address of the pharmacy where you will intern in Florida.

N/A

4. Have you ever applied to take the Florida pharmacist examination? If yes, please indicate the date.

Yes _____ No X Date _____

5. Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense?

Yes _____ No X

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

10. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state?
Yes _____ No X
11. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No X
12. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No X
13. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #14.)
Yes _____ No X
13a. If "yes" to 13, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
13b. If "yes" to 13, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No_____
13c. If "yes" to 13, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes_____ No _____
13d. If "yes" to 13, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes_____ No_____
14. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If no do not answer 14a.)
Yes_____ No X

14a. If "yes" to 14, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes_____ No_____
15. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 15a.)
Yes _____ No X
15a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No _____
16. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 16a and 16b.)
Yes _____ No X
16a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No _____
16b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
17. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities? (If "yes", please provide documentation)
Yes _____ No X
18. If "yes" to any of the questions 13 through 17 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes_____ No X

All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 5-18, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Kathryn [illegible] 03-17-1991

(SIGNATURE OF APPLICANT) (DATE)

TO BE COMPLETED BY DEAN OF COLLEGE OF PHARMACY

This is to certify that the above named applicant is entered into the professional curriculum of the

USF COLLEGE OF PHARMACY, as of AUGUST 26, 2013; and is a graduate
(NAME OF SCHOOL) (DATE)

of said professional curriculum as of May, 2017.
(DATE)

KEVIN B. SNEED, PharmD
(PRINT NAME OF DEAN)

(SCHOOL SEAL)

(SIGNATURE OF DEAN)

August 30, 2013
(DATE)

Norton, Ma'Lasha

From: zzzz Feedback, MQA_Pharmacy_Appstatus
Sent: Thursday, December 26, 2013 7:57 AM
To: Norton, Ma'Lasha
Subject: FW: Kaitlyn Nemecek

Please respond and copy the ZZZZ.

Thank you!

From: kaitlynem@gmail.com [mailto:kaitlynem@gmail.com]
Sent: Monday, December 23, 2013 4:49 PM
To: zzzz Feedback, MQA_Pharmacy_Appstatus
Subject: Fw: Kaitlyn Nemecek

From: kaitlynem@gmail.com
Sent: Monday, December 23, 2013 4:27 PM
To: ma'la.cha_norton@doh.state.fl.us

To whom it may Concern,

In the fall of 2010 I was diagnosed with depression and generalized anxiety disorder. This disorder is apparent as acute gastroenteritis that occurs during periods of stress. I was referred to the USF counseling center for further treatment. On a steady, low dose of fluoxetine, these acute episodes do not occur and the depression is mitigated. The disorder is very well controlled and should not interfere with any actions associated with professional training. If you have any further questions or need additional information, please contact me.

Thank you for your consideration,

Kaitlyn Nemecek
Pharmacy Candidate 2017
(904)228-0621
kaitlynem@gmail.com

In 2001 I was refered to the USF Councling Center for treatment of Depression and Generalized Anxiety disorder. As of Spring 2013, I am continuing treatment as directed.

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January 21, 2014

Rafa Khundkar
14654 SW 140 CT
Miami, FL 33186

RE: Pharmacist Intern Application

Dear Ms. Khundkar:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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2202 F-20080

RIDA DEPARTMENT OF HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.doh.state.fl.us/pharmacy/drugs

ITEM #2 – PHARMACY INTERN APPLICATION FOR U.S. PHARMACY STUDENTS/GRADUTES

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Please print or type legibly.

1. Biographical Information

Last Name	First Name	Middle Name	
KHUNDKAR	RAFA	ZAMAN	
Home Address (Mailing Address – ML)	**City**	**State**	**Zip**
14654 SW 140 CT	MIAMI	FL	33186
Work Address (Practice Location – PL)	**City**	**State**	**Zip**

Current Phone Number	Home Phone Number	Date of Birth
305-677-3954	305-677-3954	07/10/1992

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☐ Male ☒ Female
RACE: ☐ Caucasian ☐ Black ☐ Hispanic ☒ Asian ☐ Native American ☐ Other

3. If known, indicate the name and address of the pharmacy where you will intern in Florida.

4. Have you ever applied to take the Florida pharmacist examination? If yes, please indicate the date.

Yes _____ No ✓ Date _____

5. Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense?

Yes _____ No ✓

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

RECEIVED
OCT 14 2013
Licensing and Auditing Services

10. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state?
Yes _____ No ✓
11. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No ✓
12. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No ✓
13. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #14.)
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13a. If "yes" to 13, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No ✓
13b. If "yes" to 13, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No ✓
13c. If "yes" to 13, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes_____ No ✓
13d. If "yes" to 13, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes_____ No ✓
14. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If no do not answer 14a.)
Yes_____ No ✓

14a. If "yes" to 14, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes _____ No ✓
15. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 15a.)
Yes _____ No ✓
15a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No ✓
16. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 16a and 16b.)
Yes _____ No ✓
16a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No ✓
16b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No ✓
17. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities? (If "yes", please provide documentation)
Yes _____ No ✓
18. If "yes" to any of the questions 13 through 17 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes _____ No ✓

All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 5-18, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Rifa Khaken
(SIGNATURE OF APPLICANT)

08/10/13
(DATE)

TO BE COMPLETED BY DEAN OF COLLEGE OF PHARMACY

This is to certify that the above named applicant is entered into the professional curriculum of the University of Florida (NAME OF SCHOOL), as of August 21, 2013 (DATE); and is a graduate of said professional curriculum as of May 2017 (DATE).

Michael W. McKenzie, PhD, RPh
(PRINT NAME OF DEAN)

(SCHOOL SEAL)

(SIGNATURE OF DEAN)

9/27/13
(DATE)

Attention: Melissa:

December 20th, 2013

Attached, you will find my revised addendum to question 7 on page 3 of 11 of the Florida Board of Pharmacy Intern Application and a letter from my physician.

Thank you,

DEC 20 2013
Florida

Rafa Khundkar
Applicant ID: 20080
Email: rkhundkar@ufl.edu
Phone: (786) 201-7649

Addendum to Page 3 of 11, Question 7:
Rafa Khundkar

On March 21st, 2013, I was admitted to Mercy Hospital Behavioral Health Unit in Miami, Florida. I was treated under the care of Dr. Fernando Salvato and was released from the hospital on March 25, 2013.

Since then, I have been following up with Dr. Salvato in his office on a monthly basis and now am ready and capable of returning to school to start the professional pharmacy program.

A letter from my doctor addressed to the Florida Board of Pharmacy confirming my full recovery, readiness to start professional pharmacy program and obtain pharmacy intern license is enclosed.

For any further questions or concerns, please contact me or Dr. Fernando Salvato, M.D., P.A. at 132 NW 14th Street, Suite 401C, Miami, FL 33125, Phone: 305-324-6440, Fax: 305-324-8050.

Addendum to Page 3 of 11, Question 7:
Rafa Khundkar

On March 21st, 2013 I was admitted to Mercy Hospital Behavioral Health Unit in Miami, Florida. I was treated under the care of Dr. Fernando Salvato and was released from the hospital on March 25, 2013.

I had a period of sleep deprivation which cumulated in a panic attack that needed medical attention. I had an adverse reaction to the benzodiazepines that were subsequently prescribed and only became more agitated with added benzodiazepines. My condition did not improve with other medications but I made a haste recovery soon after all medications, including all benzodiazepines, were halted. Since then, I have been following up with Dr. Salvato in his office. There was no mental illness diagnosis made. Since this experience, I have completed my first semester of pharmacy school at University of Florida consisting of 17 credits with a 4.0 GPA.

A letter from my doctor addressed to the Florida Board of Pharmacy confirming my full recovery, readiness to start a professional pharmacy program and obtain a pharmacy intern license is enclosed.

For any further questions or concerns, please contact me or Dr. Fernando Salvato, M.D., P.A. at 132 NW 14th Street, Suite 401C, Miami, FL 33125, Phone: 305-324-6440, Fax: 305-324-8050.

CONFIDENTIAL AND EXEMPT MATERIALS

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

January 21, 2014

Saige Elizabeth Kaufman
2045 Lee Road 137, Lot #100
Auburn, AL 36832

RE: Pharmacist Intern Application

Dear Ms. Kaufaman:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, it is encouraged that you do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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2202
F-20305

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: 850-245-4292
www.doh.state.fl.us/pharmacy/drugs

ITEM #2 – PHARMACY INTERN APPLICATION FOR U.S. PHARMACY STUDENTS/GRADUTES

Rule 64B16-26.400(1), Florida Administrative Code, states, A pharmacy intern is required to be registered with the Department of Health as an intern before being employed as in intern in a pharmacy in Florida. Intern certificates issued by the Florida Board of Pharmacy (the board) are valid for the State of Florida ONLY and must be returned to the board after an intern has become a Registered Pharmacist in the State of Florida. Applicants must complete the information below and forward the application to the College of Pharmacy to be completed by the Dean and returned to the address above.

Please print or type legibly.

1. Biographical Information

Last Name	First Name	Middle Name	
Kaufman	Saige	Elizabeth	
Home Address (Mailing Address – ML)	**City**	**State**	**Zip**
2045 Lee Rd. 137 Lot#100	Auburn	AL	36832
Work Address (Practice Location – PL)	**City**	**State**	**Zip**

Current Phone Number	Home Phone Number	Date of Birth
(239)280-8888		08/30/1988

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☐ Male ☒ Female
RACE: ☒ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. If known, indicate the name and address of the pharmacy where you will intern in Florida.

4. Have you ever applied to take the Florida pharmacist examination? If yes, please indicate the date.

Yes _____ No X Date _____

5. Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense?

Yes _____ No X

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

10. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state?
Yes X No _____
11. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No X
12. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No X
13. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #14.)
Yes _____ No X
13a. If "yes" to 13, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
13b. If "yes" to 13, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No_____
13c. If "yes" to 13, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes_____ No _____
13d. If "yes" to 13, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes_____ No_____
14. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If no do not answer 14a.)
Yes_____ No X

14a. If "yes" to 14, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes_____ No_____
15. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 15a.)
Yes _____ No X
15a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No X
16. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 16a and 16b.)
Yes _____ No X
16a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No _____
16b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
17. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities? (If "yes", please provide documentation)
Yes _____ No X
18. If "yes" to any of the questions 13 through 17 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes_____ No X

All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 5-18, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

(SIGNATURE OF APPLICANT) 11/11/13 (DATE)

Saige Kaufman

TO BE COMPLETED BY DEAN OF COLLEGE OF PHARMACY

This is to certify that the above named applicant is entered into the professional curriculum of the Auburn University Harrison School of Pharmacy (NAME OF SCHOOL), as of 8-17-2010 (DATE); and is a graduate of said professional curriculum as of May 2014 (DATE).

(SCHOOL SEAL)

R. Lee Evans
(PRINT NAME OF DEAN)

(SIGNATURE OF DEAN)

11-11-2013
(DATE)

November 11, 2013

Dear Florida Board of Pharmacy,

My name is Saige Kaufman and I am writing you regarding my disciplinary action on my current intern license in Alabama. I am a fourth year pharmacy student at the Harrison School of Pharmacy in Auburn, Alabama.

In May of 2011, at the end of my first year of pharmacy school, I was anonymously reported to the Alabama Board of Pharmacy for smoking marijuana. I was further evaluated and it was determined that I had a *minor* dependency to marijuana. As a result, I have been part of the State of Alabama's Wellness Program, formerly known as the Committee On Rehabilitating Impaired Pharmacists. Through this program I gained knowledge about my personal strengths including determination, honesty, and responsibility. I have learned methods of relieving anxiety and stress such as exercising, reading, and jewelry design. I also learned to seek help from others when needed. As a member, I successfully completed a 5-week intensive outpatient rehabilitation program. Currently, I participate in weekly meetings and visit with a private counselor twice a month. Attending meetings allows me to share my personal feelings and welcome support offered by other members. Visits with my counselor allow me to be accountable, reach short and long-term goals for a healthy lifestyle, and discuss life issues in depth in hopes of seeking a resolution.

As a background, I started using marijuana while an undergrad student at the University of Central Florida. Intellectually, I knew it was not the right thing to do and needed to stop. However, due to increased stress and low self-esteem I continued to use marijuana. When I started pharmacy school, I found myself smoking out of habit. I immediately stopped once I was reported to the State Board of Pharmacy of Alabama. At this time, I knew I needed to make changes in my life. I became motivated to achieve my goal in becoming a pharmacist. I began to attend church, surround myself with a different crowd, become more involved in school activities, and take on new hobbies. Over the last few years I have learned a lot about myself and addiction. Being ordered to stop using marijuana and take monthly drugs tests has been the biggest blessing in my life. Being drug free has allowed me to interact socially with peers, live an active lifestyle, and focus more on my academic career.

While in the program, I have come to understand addiction and have been able to put that phase of my life behind me. The first step in my recovery was to take a good look at myself and learn why I was using marijuana. I was always a good student and enjoyed being in school; especially loved science, but never was heavily involved in extracurricular activities. I soon realized that I was surrounding myself with people that were a bad influence. I eliminated these people from my life and urged them to seek help as well. Being clear minded and having

studied and worked the 12 steps in treatment, I was ready to be more involved in my schooling and my future career. I work with counselors on a weekly basis, in group and private settings, and this allows me to have constant support and give constant support to my peers. I am involved in service to the community with the pharmacy school as well as within my fraternity. I have matured tremendously and I truly believe my experience allows me to make a difference in people's lives. Working in the health care field has really helped me to connect with patients and counsel on a daily basis about living a healthy lifestyle and encourage them through making small goals in life; it is a very rewarding practice.

I truly am thankful for the Wellness Program the State of Alabama provided to me. I will be eternally grateful that the State realized my potential and allowed me to continue to pursue my dream of completing pharmacy school. It is my intention to always be a respected pharmacist in the community and provide high-quality patient care. I will continue to work on my rehabilitation in all areas of my life. I am happier than I have ever been and willing to help others needing guidance so they can live happy and healthy lives.

I am looking forward to my future practice in Florida so that I may be close to my family and the friends who have been a positive influence in my life. It is my hope that you will grant me this opportunity.

Please feel free to contact me at (239)280-8888 or by e-mail at sek0017@auburn.edu with any further questions or requests.

Sincerely,

Saige Kaufman
Pharm.D. Candidate 2014

Welcome to the Alabama State Board of Pharmacy Website

Alabama Board of Pharmacy
111 Village St
Hoover, AL 35242
Voice: 205.981.2280
Fax: 205.981.2330
OFFICE HOURS: 8:00AM - 4:00PM CST

Mailing:
P.O. Box 381988
Birmingham, AL 35238-1988

Licensee Verification

Print Copy

Name	SAIGE ELIZABETH KAUFMAN
Filing Type	Intern/Extern License
Status	On Probation
File/License Number	S10060
Original Date	08/23/2010

Discipline on File

License/Permit Effective Period History

Name	Issue Date	Expire Date
Initial	08/23/2010	

Back to Search

Michael C Garver, DMD
19260 North Mobile Street
PO Box 426
Citronelle, AL 36522

fax: 251.252.9112
phone: 251.866-5585
cell phone: 251.605.2883
email: mcg@3mg.com

12.19.2013
Re: Saige Kaufman

Ms. Kaufman has authorized me to tell you that she is under order and contract with the State of Alabama Board of Pharmacy and the Wellness Committee. She has been under contract since February 12, 2012, the date of her order. She has been in compliance with all strictures of her order and contract. All Screens are clean, meeting attendance reported on time, and therapy sessions attended.

Saige has struggled financially to maintain this record of recovery and we are pleased to recommend for licensure in any state.

Please find attached a copy of her order. If I can be of any further service, please let me know

Michael C Garver DMD
File: SK

ALABAMA
BOARD OF PHARMACY

Mailing Address:
P.O. Box 381988
Birmingham, AL 35238-1988

Location:
111 Village Street
Hoover, AL 35242

(205) 981-2280
(205) 981-2330 Fax
www.albop.com

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December 4, 2013
~~November 13, 2013~~

FLORIDA STATE BOARD OF PHARMACY
4052 Bald Cypress Way
Bin C-04
Tallahassee, Florida 32399-3252

RE: ***SAIGE ELIZABETH KAUFMAN***
Alabama Extern/Intern #10060

This is to certify that the undersigned is the duly elected executive officer of the Alabama State Board of Pharmacy. I am in charge of the Board office and all records are made and kept under my direct supervision.

This is to further, certify that the enclosed records are exact copies of those appearing on file regarding ***SAIGE ELIZABETH KAUFMAN.***

Ms. Kaufman's extern/intern license is currently on probation

Mitzi G. Ellenburg
Interim Secretary

Subscribed and sworn before me this **13th** day of **November 2013,** at Birmingham, Alabama, County of Shelby.

Mitzi G. Ellenburg
Notary Public, State-at-Large

My commission expires:
October 22, 2014

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
SAIGE ELIZABETH KAUFMAN	)	
	)	**BOARD OF PHARMACY**
EXTERN/INTERN PERMIT NO: 10060	)	

CONSENT ORDER

THIS CAUSE came before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") in connection with the referral of Saige Elizabeth Kaufman (Kaufman) to UAB Center for Psychiatric Medicine due to her unlawful use and possession of Marijuana and a resulting diagnosis of Cannabis dependence.

Prior to a hearing to determine whether Kaufman's Extern/Intern Permit should be sanctioned, the Board through counsel and Kaufman, pursuant to Code of Alabama (1975), § 41-22-12(f), resolved informally the matters at issue and agree to the entry of this Consent Order, which shall include the following terms:

1. Kaufman acknowledges and agrees that her use of Marijuana violates and she is found to have violated Code of Alabama (1975), § 34-23-33(5).

2. Kaufman's Extern/Intern permit shall be suspended during the time she validly holds the same, with the suspension reverting to probation subject to her compliance with the following conditions:

   (a) The execution of a Monitoring Agreement with the Alabama Board of Pharmacy Wellness Program (Program). Kaufman shall also comply with the recommendations of the Director of the Program and/or the Board.

   (b) In the event Kaufman applies for licensure as a pharmacist and is

otherwise qualified for licensure, the license shall be issued but suspended for a time to be determined by the Board, the suspension immediately reverting to probation subject to her compliance with any and all terms deemed necessary and appropriate by the Board. Kaufman acknowledges and agrees the duration of the above referenced suspension and probation shall be in the sole discretion of the Board.

3. Kaufman expressly waives her rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act, including but not limited to Code of Alabama (1975), § 34-23-34 and § 34-23-92(12) and Code of Alabama (1975), § 41-22-12 and § 40-*22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to a Statement of Charges and Notice of Hearing and the opportunity for a hearing before the Board in connection with any charges against her, the right to counsel and judicial review. Kaufman further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), § 41-22-18.

4. By execution of this Consent Order, Kaufman hereby releases the Board, the Program and their members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order.

5. Kaufman acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board

of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against her license or permit, including, but not limited to revocation.

6. Kaufman acknowledges and agrees that she has read this Consent Order and that she fully understands the terms, conditions and contents of the same. Kaufman acknowledges and agrees that she voluntarily and of her own free will accepts the terms and conditions set out in this Consent Order and had the opportunity to seek legal counsel prior to the execution of this Consent Order.

DONE this the 21 day of February, 2012.

Saige Elizabeth Kaufman

DONE this the 22 day of February, 2012.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Donnie R. Calhoun, RPh, President

_____
James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & WILSON, L.L.C.
2100 Southbridge Parkway, Suite 580
Birmingham, Alabama 35209
(205) 871-5404

PHARMACAL
SCIENCES

AUBURN UNIVERSITY

HARRISON SCHOOL
OF PHARMACY

November 11, 2013

Florida Board of Pharmacy
P.O. Box 6320
Tallahassee, FL 32314-6320

Dear Florida State Board of Pharmacy:

I would like to provide a recommendation for Saige Kaufman, a Pharm. D. candidate 2014 at Auburn University. Saige has been a student in my classes and I also serve as her faculty advisor/mentor in our program.

I have known Saige since she first started pharmacy school in August of 2010. Over this time, I have watched her grow and mature into a professional young lady. She was a member of one of our Pharmacy Practice Experience (PPE) groups that meets every week to discuss health and therapeutics for patients in the community. The group members, both students and faculty, meet with patients on a regular basis to assist, monitor, and inform them on medication and health issues. Saige was an effective leader and contributor in the group activities. In addition, I have been Saige's faculty mentor throughout pharmacy school and meet with her on a regular basis. At mentor meetings, the student and mentor discuss school and personal life activities and issues. With this said, I am well-informed about her current disciplinary status imposed on her intern license.

From my and other faculty's perspective, Saige is an exemplary student that portrays dedication, caring, courage, and determination. Saige continues to be enthusiastic about school and her future career despite a previous setback. Based on our interactions in courses and mentoring, I am confident of her abilities to provide quality patient care. As a third year student, Saige had many responsibilities including being the leader of our weekly meetings and coordinating care with patients. She always has a great attitude and shows sincere concern and admiration for her PPE patients on a consistent basis. From discussions with her and other faculty, Saige appears to be performing exceptionally well in her clerkship rotations.

Saige has openly spoken to me about her stresses at school and that she is constantly working to better herself through professional involvement and devotion to her academic program. I have no doubt that she will be admired and treasured by her future patients and colleagues as she builds her future pharmacy practice. I believe that Saige participates in monthly drug screens and works with a counselor on a monthly basis. She has expressed happiness to have made it to her final year of school and hopes to be working in a retail setting upon graduation.

4306 Walker Building, Auburn, AL 36849-5309; Telephone: 334-844-4037; Fax: 334-844-8331
www.auburn.edu | www.pharmacy.auburn.edu

If you have questions, please feel free to contact me at my office (334-844-8337) or by cell phone (334-703-8045).

Sincerely,

William R. Ravis, RPh, PhD, FCP
Professor of Pharmaceutics
Pharmacal Sciences

January 23, 2014

Dmitriy Matev
2529 Cortez Road
Jacksonville, FL 32246

RE: Pharmacist Intern Application

Dear Mr. Matev:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, it is encouraged that you do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

2202-19902

FLORIDA DEPARTMENT OF HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.doh.state.fl.us/pharmacy/drugs

ITEM #2 – PHARMACY INTERN APPLICATION FOR U.S. PHARMACY STUDENTS/GRADUTES

Administrative Code, states, A pharmacy intern is required to be of Health as an intern before being employed as in intern in a pharmacy sued by the Florida Board of Pharmacy (the board) are valid for the State eturned to the board after an intern has become a Registered Pharmacist ts must complete the information below and forward the application to the College of Pharmacy to be completed by the Dean and returned to the address above.

Please print or type legibly.

1. Biographical Information

Last Name	First Name	Middle Name	
Matev	Dmitriy		
Home Address (Mailing Address – ML)	**City**	**State**	**Zip**
2529 Cortez Road	Jacksonville	FL	32246
Work Address (Practice Location – PL)	**City**	**State**	**Zip**
580 West 8th Street	Jacksonville	FL	32209
Current Phone Number	**Home Phone Number**	**Date of Birth**	
904-305-3062			

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☑ Male ☐ Female
RACE: ☑ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. If known, indicate the name and address of the pharmacy where you will intern in Florida.

4. Have you ever applied to take the Florida pharmacist examination? If yes, please indicate the date.

Yes _____ No ✓ Date _____

5. Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense?

Yes ✓ No _____

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

RECEIVED

OCT 14 2013

Licensing and Auditing Services

10. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state?
Yes _____ No ✓
11. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No ✓
12. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No ✓
13. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #14.)
Yes _____ No ✓
13a. If "yes" to 13, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
13b. If "yes" to 13, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No_____
13c. If "yes" to 13, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes_____ No _____
13d. If "yes" to 13, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes_____ No_____
14. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If no do not answer 14a.)
Yes_____ No ✓

14a. If "yes" to 14, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes_____ No_____
15. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 15a.)
Yes _____ No ✓
15a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No _____
16. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 16a and 16b.)
Yes _____ No ✓
16a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No _____
16b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
17. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities? (If "yes", please provide documentation)
Yes _____ No ✓
18. If "yes" to any of the questions 13 through 17 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes_____ No_____

All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 5-18, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Smith M D — 6-9-13

(SIGNATURE OF APPLICANT) (DATE)

TO BE COMPLETED BY DEAN OF COLLEGE OF PHARMACY

This is to certify that the above named applicant is entered into the professional curriculum of the University of Florida (NAME OF SCHOOL), as of August 21, 2013 (DATE); and is a graduate of said professional curriculum as of May 2017 (DATE).

Michael W. McKenzie, PhD, RPh
(PRINT NAME OF DEAN)

(SCHOOL SEAL)

(SIGNATURE OF DEAN)

9/30/13
(DATE)

2529 Cortez Road
Jacksonville, FL 32246
904-305-3062
dimamatev@gmail.com

To whom it may concern:

I was arrested for underage drinking on March 2nd 2011 in Avery County in North Carolina. I was 20 at the time and decided to drink at a ski resort. I pled guilty and had to pay a $183 fine. On the 29th of December in 2011 I was arrested for DUI in Duval County, Jacksonville, FL. I was charged with a misdemeanor, pled guilty, and spent the next 6 months carrying out my probation. When I turned 21 I started to go out and drink with friends and behave irresponsibly by deciding to drive home afterwards. I felt like I could handle myself on the road regardless of my inebriation. Eventually my recklessness caught up to me on that day when I was driving home and crashed my car into a pole because I was taking a turn too fast. I have stopped drinking alcohol irresponsibly, and I have carried out all the terms of my probation including 50 hours of community service, 10 day vehicle immobilization, DUI School, attending a MADD event, a 12-week alcohol therapy class, and paying $1081 in fines.

I have learned many things from the year 2011; I have learned that I am responsible for my actions, I have learned the real dangers of alcohol, and I have learned that I have the will to do everything I can to amend this terrible mistake I made. During this time I completed my BS in Chemistry at the University of North Florida. Refocusing my goals and gaining a new understanding of responsibility have helped me change for the better and learn from my mistakes.

Sincerely,

Dmitriy Matev
6/9/13

Enclosed: Court Documents

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January 23, 2014

Jonathan James Samuelson
4413 Avalon Suites Terrace
Tampa, FL 33613

RE: Pharmacist Intern Application

Dear Mr. Samuelson:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, it is encouraged that you do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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2202 F-19539

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: 850-245-4292
www.doh.state.fl.us/pharmacy/drugs

ITEM #2 – PHARMACY INTERN APPLICATION FOR U.S. PHARMACY STUDENTS/GRADUTES

Rule 64B16-26.400(1), Florida Administrative Code, states, A pharmacy intern is required to be registered with the Department of Health as an intern before being employed as in intern in a pharmacy in Florida. Intern certificates issued by the Florida Board of Pharmacy (the board) are valid for the State of Florida ONLY and must be returned to the board after an intern has become a Registered Pharmacist in the State of Florida. Applicants must complete the information below and forward the application to the College of Pharmacy to be completed by the Dean and returned to the address above.

Please print or type legibly.

1. Biographical Information			
Last Name	**First Name**	**Middle Name**	
Jamulka	Jonathan	James	
Home Address (Mailing Address – ML)	**City**	**State**	**Zip**
4413 Avalon Suites Terrace K4024	Tampa	Fl	33613
Work Address (Practice Location – PL)	**City**	**State**	**Zip**
/	/	/	/
Current Phone Number	**Home Phone Number**	**Date of Birth**	
727-743-4138	/	Oct. 9 1988	

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☑ Male ☐ Female
RACE: ☑ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. If known, indicate the name and address of the pharmacy where you will intern in Florida.

/

4. Have you ever applied to take the Florida pharmacist examination? If yes, please indicate the date.

Yes _____ No / Date /

5. Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense?

Yes _____ No /

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

10. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state?
Yes _____ No ✓
11. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No ✓
12. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No ✓
13. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #14.)
Yes _____ No ✓
13a. If "yes" to 13, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
13b. If "yes" to 13, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No_____
13c. If "yes" to 13, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes_____ No _____
13d. If "yes" to 13, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes_____ No_____
14. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)? (If no do not answer 14a.)
Yes_____ No ✓

14a. If "yes" to 14, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes_____ No_____
15. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 15a.)
Yes _____ No ✓
15a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No _____
16. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 16a and 16b.)
Yes _____ No ✓
16a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No _____
16b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
17. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities? (If "yes", please provide documentation)
Yes _____ No ✓
18. If "yes" to any of the questions 13 through 17 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes_____ No_____

All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 5-18, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

(SIGNATURE OF APPLICANT) Aug 11 2013 (DATE)

TO BE COMPLETED BY DEAN OF COLLEGE OF PHARMACY

This is to certify that the above named applicant is entered into the professional curriculum of the

USF COLLEGE OF PHARMACY, as of AUGUST 26, 2013; and is a graduate
(NAME OF SCHOOL) (DATE)

of said professional curriculum as of May, 2017.
(DATE)

KEVIN B. SNEED, PharmD
(PRINT NAME OF DEAN)

(SCHOOL SEAL)

(SIGNATURE OF DEAN)

August 30, 2013
(DATE)

Roberson, Akhiem

From: Jonathan S [jsamuels@fastmail.fm]
Sent: Sunday, October 27, 2013 12:39 PM
To: Roberson, Akhiem
Subject: Re: Jonathan Samuelson Pharmacy Intern 19539

I'm terribly sorry -- due to my courseload I didn't read your email in time. I've sent it in anyway, and I hope it's not too late. Again, I sincerely apologize for the oversight.

--

Jonathan J. Samuelson
USF College of Pharmacy
Doctor of Pharmacy Candidate 2017
jsamuels@fastmail.fm

On Sun, Oct 27, 2013, at 02:09 AM, Jonathan S wrote:
> In Fall of 2009 I enrolled in the University of Florida's chemistry
> program. Soon after, I turned 21 & like many students I began drinking.
> Although I did not drink heavily at first it became both more frequent
> and more serious. Although in retrospect my drinking was clearly
> abnormal its progression was incremental, and slow enough that I
> didn't realize what was happening; by the end of my senior year I was
> drinking heavily and near-constantly. Upon realizing that I had
> alienated my friends and family and could not stop drinking I
> purchased Etizolam from an online vendor with the intention of
> combining it with alcohol to commit suicide. This substance was – and
> to my knowledge still is – unregulated in the United States; I
> committed no crimes to obtain it & ordered it legally and openly. When
> the suicide attempt failed I returned to drinking. A nurse at the
> local hospital convinced me to seek help, and a counselor on campus
> arranged for my parents to take me to Windmoor Healthcare -- a detox
> facility – on the 25th of May, 2012. I was diagnosed with depression
> and polysubstance abuse due to my use of both alcohol and Etizolam,
> and released five days later on the 30th. I receive regular
> psychiatric followups and my sponsor (Tom Tucker,
> 727-692-3997) and I attend AA meetings nearly every day (and more
> often, when I can afford the time). The only substances I currently
> take are prescription antidepressants; I have not had a drink or a
> drug of abuse since May 25th of last year, nor have I any desire to
> throw away the second chance I have been given.
>
> --
>
> Jonathan J. Samuelson
> USF College of Pharmacy
> Doctor of Pharmacy Candidate 2017
> jsamuels@fastmail.fm
>
> On Thu, Oct 24, 2013, at 08:35 AM, Akhiem.Roberson@flhealth.gov wrote:
> >
> > Good Morning and thank you for contacting the Board of Pharmacy. We
> > have reviewed your documents and have deemed your application to be
> > reviewed at the next board meeting. We will be sending your file to
> > the December meeting however, in order for us to do that, we must
> > have a complete file as we are missing a personal statement from
> > you. Please email me back with your personal statement. Just include
> > the events and circumstances surrounding the issues at that time.
> > The deadline to make it on the December meeting's agenda is tomorrow
> > by the close of business. Once I receive your personal statement, I
> > will forward it to the organizer so he may include you on the
> > agenda. If you have any other questions or concerns please feel free

> > to contact us back. Thank you and have a great day!
> >
> > Akhiem Roberson
> > Regulatory Specialist I
> > Florida Board of Pharmacy
> > Phone: 850-245-4444
> >
> > Mission: To protect, promote & improve the health of all people in
> > Florida through integrated state, county & community efforts.
> > ~~~~~~
> > Vision: Healthiest State in the Nation
> > ~~~~~~
> > Values: (ICARE)
> > I nnovation: We search for creative solutions and manage resources
> > wisely.
> > C ollaboration: We use teamwork to achieve common goals & solve
> > problems.
> > A ccountability: We perform with integrity & respect.
> > R esponsiveness: We achieve our mission by serving our customers &
> > engaging our partners.
> > E xcellence: We promote quality outcomes through learning &
> > continuous performance improvement.
> > ~~~~~~
> > Special Notice: There have been changes to the license renewal process.
> > Please visit www.CEAtRenewal.com to learn more
> >
> > Please note: Florida has a very broad public records law. Most
> > written communications to or from state officials regarding state
> > business are public records available to the public and media upon
> > request. Your e-mail communications may therefore be subject to public disclosure.
> >
> >
> >
> >
> >
> >
> >
> > -----Original Message-----
> > From: Jonathan S [mailto:jsamuels@fastmail.fm]
> > Sent: Friday, October 18, 2013 4:39 PM
> > To: Roberson, Akhiem
> > Subject: Jonathan Samuelson Pharmacy Intern 19539
> >
> > Attached
> >
> > --
> >
> > Jonathan J. Samuelson
> > USF College of Pharmacy
> > Doctor of Pharmacy Candidate 2017
> > jsamuels@fastmail.fm

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January 21, 2014

Kayla Cerritos
1420 Drew Street
Clearwater, FL 33755

RE: Pharmacist Technician Application

Dear Ms. Cerritos:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, it is encouraged that you do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

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If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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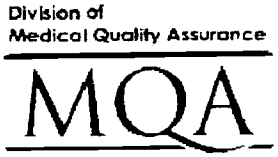
Initial Application for Licensure
Florida Board of Pharmacy



Basic Data

Profession:	REGISTERED PHARMACY TECHNICIAN
Application Type:	REGISTERED PHARMACY TECHNICIAN INITIAL APPLICATION
Name:	KAYLA M CERRITOS
Date of Birth:	05/25/1994
Place of Birth:	SEMINOLE, FL
Email Address:	SACERTIFICATIONS@ULTIMATEMEDICAL.EDU

Mailing Address

1420 DREW STREET
CLEARWATER, FL 33755

Physical Location or Address of Employment

1420 DREW STREET
CLEARWATER, FL 33755

Phone Numbers

Home:	727-953-5225
Business:	727-953-5225

Equal Opportunity Data

Gender:	FEMALE
Race:	HISPANIC

Education History

Course Provider:	OTHER
Course Approved By:	FLORIDA BOARD OF PHARMACY APPROVED
Course Competion Date:	03/26/2013

Other Name History

No Other Name History data entered.

Secondary Work Location

Other State Licenses

License Number:	License Number:
License Type:	License Type:
Licensure Date:	Licensure Date:
Date of Expiration:	Date of Expiration:
Country:	Country:
State:	State:

Mandatory Continue Education

Prevention of Medical Errors

I have completed the Prevention of Medical Errors education required by Florida Statutes, as defined by Rule 64B7-25.001(1)(f), F.A.C.

Provider Number:	
Provider/School Name:	ULTIMATE MEDICAL ACADEMY
Course Name/Title:	PHARMACY TECHNICIAN
Date Completed:	03/26/2013

Criminal History

Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest to, a crime in any jurisdiction other than a minor traffic offense? Your answer: **NO**

Initial Application for Licensure
Florida Board of Pharmacy

Discipline History

Has disciplinary action ever been taken against your pharmacy technician registration, or any other professional license you may have in this state or any other state?	Your answer: **NO**
Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?	Your answer: **NO**
Are you presently under investigation or is any disciplinary action pending against you?	Your answer: **NO**

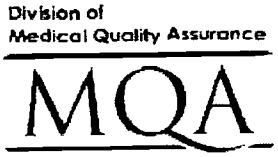
Questions related to Section 456.0635(2), Florida Statutes

Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction?	Your answer: **NO**
For the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?	Your answer: **N/A**
For the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).	Your answer: **N/A**
For the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?	Your answer: **N/A**
Have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed?	Your answer: **N/A**
Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?	Your answer: **NO**
Has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?	Your answer: **N/A**
Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes?	Your answer: **NO**
If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?	Your answer: **N/A**
Have you ever been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program?	Your answer: **NO**
Have you been in good standing with a state Medicaid program for the most recent five years?	Your answer: **N/A**
Did the termination occur at least 20 years before the date of this application?	Your answer: **N/A**
Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?	Your answer: **NO**
On or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health?	Your answer: **N/A**

Additional Information

Availability for Disaster: Will you be available to provide health care services in special needs shelters or help staff disaster medical assistance teams during times of emergency or major disaster?	Your answer: **YES**

Initial Application for Licensure
Florida Board of Pharmacy



Application Statement

☒ Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacy technician registration may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

RE: Personal History for Registered Pharmacy Techician

I, Kayla Cerritos, was hospitalized in September of 2011 as well as December of 2011 while I was under 18 into a Pediatric's Pyschiatric Ward. I was diagnosed with Major Depressive Disorder. I was prescribed two antidepressants to treat my depression. The only documents I was able to find were from that time. I am currently still taking the two antidepressants and am in better health. I have not been admitted to any psychiatric facility since then. I am not currently seeing a licensed professional for the depression, so I am not able to get a letter summarizing my diagnosis. I have enclosed to only documents I was able to obtain. If there are any questions feel free to contact me at 727-225-1751.

Thank You,
Kayla Cerritos
File Number 51118

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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January 23, 2014

Wandey Alexis
289 NW 15th Street
Boca Raton, FL 33431

RE: Pharmacy Technician Application

Dear Ms. Alexis:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, it is encouraged that you do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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2208-43690

FLORIDA HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone 850-245-4292
http://www.doh.state.fl.us/mqa/pharmacy

RECEIVED
NOV 25 2013
Florida Board of Pharmacy

ITEM #2 - Pharmacy Technician Registration Application
FEE: $105.00
Please print or type legibly

1. Biographical data			
Last name	**First name**	**Middle name**	
Alexis	Wandely		
Street address (ML – Mailing Location)	**City**	**State**	**Zip**
289 NW 15th St	Boca Raton	Fl	33431
Work address (PL – Practice Location) (If you are not employed, please list your mailing address below). If you have multiple practice locations, please submit on an additional sheet, attach with application.	**City**	**State**	**Zip**
2390 N Federal Hwy	Boca Raton	Fl	33432
Home phone number	**Business phone number**	**Date of birth**	
954 934 3433		7.1.79	
E-mail address	**Would you be willing to provide health services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disasters?**		
Wandey_Alexis@Yahoo	Yes ✓	No _____	

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☐ Male ☑ Female

RACE: ☐ Caucasian ☑ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. Have you ever changed your name through marriage or through action of a court or have you ever been known by any other name? If yes, list name(s) and date(s) of the change(s) below. *Use a separate sheet, if necessary.*

Yes _____ No ✓

Name	**Date**

DH-MQA PH1183, 09/09
Rule 64B16-26.350, F.A.C.

JL

4. Have you completed a board approved training course according to Rule 64B16-26.351 (3), FA.C.?	
Yes ✓ No _____	If yes, include a copy of your completed course certificate.
5. Have you ever been convicted of, or entered a plea of guilty, nolo contendre, or no contest, to a crime in any jurisdiction other than a minor traffic offense?	
Yes ✓ No _____ **(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)**	
6. Has disciplinary action ever been taken against your pharmacy technician registration, or any other professional license you may have in this state or any other state?	
Yes _____ No ✓	
7. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?	
Yes _____ No ✓	
8. Are you presently under investigation or is any disciplinary action pending against you?	
Yes _____ No ✓	

13. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #14.)
Yes _____ No ✓
13a. If "yes" to 13, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
13b. If "yes" to 13, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No _____
13c. If "yes" to 13, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes_____ No _____
13d. If "yes" to 13, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes _____ No_____
14. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?
Yes_____ No ✓
14a. If "yes" to 14, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes_____ No_____
15. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 15a.)
Yes _____ No ✓
15a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____
16. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 16a and 16b.)
Yes _____ No ✓
16a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes ✓ No _____
16b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
17. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?
Yes_____ No ✓
18. If "yes" to any of the questions 13through 17 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes_____ No ✓
All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 5-16b, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacy technician registration may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

Wandey Alexis
Applicant Signature

NOV, 11, 2013
Date

DH-MQA PH1183, 09/09
Rule 64B16-26.350, F.A.C.

November 11, 2013

I Wandey Alexis is seeking
the opperfunity to continue and
Further my career with Cvs.
A year ago (July 2012) I was
able to with draw my Application
For Pharmacy Technician due
to my back ground. The board
agreed if I was to keep clean
record and Stay out of trouble
I would be able to resubmit
my Application. I've been with
Cvs For 2yrs now and beside
the slight bump in the road
I've grown more with the company.
Looking forward to continue my
Career with Cvs and providing
Great Caring Customer Service
that I have been given as a
employee. Any missing paper
such as letter of Course
certification is in my File.
Looking Forward to hear From

2/2/12

Circumstances behind my charges
I was caught twice stealing
Cloths. Out of the mall. I
was only trying to cloth myself
and my baby I was on the streets
at the time which no excuse.
But I did repay the store and
and did write a letter of apologie.
my other Felony charge I was in
possion of Drugs I was holding
for ~~and~~ an ex Boyfriend I was
leaving with. at the time all of
my offense was Foolish my I did
commit them and have repaid threw
restitution and I'm very remorsful.
But with my last offense that
was a wake up call I was able to
go Back home. I had went Back to
school obtain my Medical Assist.
Diploma. Had I another child and
have straighten up my life. At
32 I'm working 2 jobs maintain
my car and home.

And would love to continue this opportunity to continue to grow at C.S. And show my kids the right way to get want you want in life

Wandey Alexis
954 934 3433

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CVS/pharmacy

Proof of Completion

This document verifies that, in accordance with Florida Board of Pharmacy requirements,

WANDY. ALEXIS
(employee name)

has completed the

Florida Board of Pharmacy Approved CVS/pharmacy® LearnRx Training Program
(CVS/Caremark License Number: RPPT8)

as of

2·3·2012.
(completion date)

Pharmacy Trainer/Pharmacist In-Charge signature

2·3·2012
Date

Lisa Carlin, PharmD.

Pharmacy Manager
CVS Pharmacy #1821
1690 S. Federal Highway
Delray Beach, FL 33483
TEL 561-272-1163 FAX 561-272-6476

February 23, 2012

To Whom It May Concern:

I highly recommend Wandy Alexis as a candidate for the position of Registered Pharmacy Technician. Wandy has been employed with CVS pharmacy since October 2011. Her responsibilities have included but are not limited to: typing and analyzing new prescriptions, processing and filling prescriptions, and problem-solving while updating insurance rejections.

During her time here she has had an amazing impact on the staff and customers. Wandy is highly respected by her co-workers for her willingness to help anyone anytime she can. She has been a great asset to our team and contributes excellent qualities. She is very well organized, reliable, and always on time. Wandy would be an excellent addition to your company and I highly recommend her for company. Please feel free to contact me with any questions or concerns.

Sincerely,

Lisa Carlin

Lisa Carlin, RPh, PharmD

Quest Lending Corp.

1321 S. Dixie Hwy Suite 11E
Pompano Beach, Florida 33060
Tel: 954-788-5899 Fax: 954-788-5898
Email: questlending@yahoo.com

February 6, 2012

To Whom It May Concern:

I highly recommend Wandy Alexis as a candidate for the position of Pharmacy Technician. Wandy was employed with Quest Lending Corp from 2006 – 2008 in which her responsibility included office support (word processing), scheduling appointments, and overseeing clients financials.

Wandy has excellent communication skills. In addition, she is extremely organized and reliable. Wandy can work independently and is able to follow through to ensure that the job gets done. She is flexible and willing to work on any project that is assigned to her.

Wandy would be a tremendous asset for your company and has my highest recommendation. If you have any further questions with regard to her background or qualifications, please do not hesitate to call me 954-788-5899.

Sincerely,

Hudson Celestin
General Manager

1200 NW 51st Street, Boca Raton, FL 33431
(561) 989-1688

RE: Wendy Alexis

Feb 20th, 2012

To Whom It May Concern,

Ms. Wendy Alexis has been working at Yamato 5-Spice Asian Street Market for over 2 years as a customer service personnel. She's a good worker, quick learner, alert, punctual, firm, and does not waste time in getting her job done. I'm certain that she will accomplish any tasks given to her without hesitation.

Sincerely,

Linh Lee
CFO/Adminstrator
Yamato 5-Spice Asian Street Market

43696

1479230

Dear Respected Pharmacy Board Members,

This letter is my personal recommendation for Wandey Alexis.

Wandey is an extremely sharp ,intelligent and enthusiastic team player and has been a valuable contribution to my team.She is highly respected by all of us at work and always makes sure that the customer is taken care of with utmost respect and integrity.

Please feel free to get in touch with me for any questions or concerns.

Kind Regards

Subha Pai

Pharmacy Manager.

06.01.2012.

5147705554

This is with regards to your recent mail about evaluating Regd tech application for Wandey at the Board meeting on June 6th 2012.

Thank you.

Child Development Centers
big hearts helping little ones

Board of Directors

President & Chairman of the Board
Lynn Hover

Executive Vice President
Bernard Finkelstein

Vice Presidents
Kathy Adkins
Robert Robes

Secretary
Mark Scheer

Treasurer
Mark Tabor

Past Presidents
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Sheena Benjamin-Wise
Nancy Brown
Steven Brown
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Rosa Feeney
Jay Foreman
Karen Foreman
Skeets Friedkin
Heidi Johnson
Lauren Johnson
Amy Kazma
Lisa Parks King
Elyssa Kupferberg
Neil Meany
Holly O'Neill
Cornelius Riley
Yulieth Rodriguez
Carrie Rubin
Jason Solodkin
Patty Soltis
Francisco Torres
Rhoda Warren
Sol Zoberman

Chief Executive Officer
Ellyn Okrent

November 5, 2013

To Whom It May Concern,

It is my immense pleasure to write this letter of recommendation for Wandey Alexis. I have known Wandey for over 10 years both professionally and personally. During that time I have grown to respect, admire and trust her. Aside from her strong work ethic, and honesty, she has been a tremendous asset to the Center as a volunteer in her child's class. She has a pleasant and positive demeanor and is considered one of our best team players.

Wandey would be an asset to your company, I recommend her without reservation. Should you have any questions please feel free to contact me.

Very Sincerely,

Mary Henry

Facilities Manager

Florence Fuller Child Development Center

Mhenry@ffcdc.org

P: 561-391-7274 x117

October 22, 2013

To whom it may concern,

Wandey Alexis is an employee at CVS Pharmacy for almost two years. I have been her supervisor for at least one year now, during the time that Wandey and I worked together, I found her to be very efficient and helpful.

I feel confident that she will continue to provide good service to the customers and build her knowledge so she can grow with the company.

Sincerely,

Tamara Jaboin
Tamara Jaboin
ASM Store #770

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUL 05 2012

STATE OF FLORIDA
BOARD OF PHARMACY

IN RE: THE APPLICATION OF

WANDEY ALEXIS
_____/

ORDER ALLOWING WITHDRAWAL OF APPLICATION FOR LICENSURE

This matter came before the Board of Pharmacy (hereinafter the "Board") at a duly noticed public meeting held on June 6, 2012 in Deerfield Beach, Florida, pursuant to the Applicant's request for license. The applicant was present. The Applicant submitted an oral motion to withdraw the application.

The Board considered the request and voted to allow the withdrawal of the application. The application is withdrawn, without prejudice to the Applicant to reapply in the future.

DONE AND ORDERED this 3rd day of July, 2012.

BOARD OF PHARMACY

Mark Whitten, Executive Director *for*
Cynthia Griffin, PharmD, Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by Certified Mail to Wandey Alexis at 6460 N. Dixie Highway, Boca Raton, Florida 33487; by interoffice mail to Allison Dudley, Assistant Attorney General, Office of the Attorney General,

PL-01, The Capitol, Tallahassee, Florida 32399-1050; this 5th day of July, 2012.

Angel Sandoval

Deputy Agency Clerk

7011 2970 0003 1594 3411

January 23, 2014

April B. Watson
5130 Dobson Road
Jay, FL 53982

RE: Pharmacy Technician Application

Dear Ms. Watson:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, it is encouraged that you do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

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If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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2208 - 53982

11/21/2010 · 105.00
ID: 53982 Type: F
BT: 3010093
VL: 913027599

Florida HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone 850-245-4292
http://www.doh.state.fl.us/mqa/pharmacy

RECEIVED
NOV 22 2013
Florida Board of Pharmacy

ITEM #2 - Pharmacy Technician Registration Application
FEE: $105.00
Please print or type legibly

1. Biographical data			
Last name WATSON	**First name**	**Middle name**	
WATSON	APRIL	BURFORD	
Street address (ML – Mailing Location)	**City**	**State**	**Zip**
5130 DOBSON ROAD	JAY	FL	32565
Work address (PL – Practice Location) (If you are not employed, please list your mailing address below). If you have multiple practice locations, please submit on an additional sheet, attach with application.	**City**	**State**	**Zip**
3793 HIGHWAY 4	JAY	FL	32565
Home phone number	**Business phone number**	**Date of birth**	
850-675-5171	850-675-6990	05/12/76	
E-mail address	**Would you be willing to provide health services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disasters?**		
sheppardapothecary@gmail.com	Yes ✓	No _____	

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☐ Male ☒ Female

RACE: ☒ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. Have you ever changed your name through marriage or through action of a court or have you ever been known by any other name? If yes, list name(s) and date(s) of the change(s) below. *Use a separate sheet, if necessary.*

Yes X No _____

Name	**Date**
APRIL SUELLEN BURFORD	JUNE 2002 - MARRIAGE

DH-MQA PH1183, 09/09
Rule 64B16-26.350, F.A.C.

4. Have you completed a board approved training course according to Rule 64B16-26.351 (3), FA.C.?	
Yes ✓ No _____	If yes, include a copy of your completed course certificate.
5. Have you ever been convicted of, or entered a plea of guilty, nolo contendre, or no contest, to a crime in any jurisdiction other than a minor traffic offense?	
Yes ✓ No _____ **(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)**	
6. Has disciplinary action ever been taken against your pharmacy technician registration, or any other professional license you may have in this state or any other state?	
Yes ✓ No _____ License was voluntarily Surrendered	
7. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?	
Yes _____ No ✓	
8. Are you presently under investigation or is any disciplinary action pending against you?	
Yes _____ No ✓	

13. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #14.)
Yes _____ No ✓
13a. If "yes" to 13, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
13b. If "yes" to 13, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No _____
13c. If "yes" to 13, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes_____ No _____
13d. If "yes" to 13, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes _____ No_____
14. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?
Yes_____ No ✓
14a. If "yes" to 14, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes_____ No_____
15. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 15a.)
Yes _____ No ✓
15a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____
16. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 16a and 16b.)
Yes _____ No ✓
16a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No _____
16b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
17. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?
Yes_____ No ✓
18. If "yes" to any of the questions 13through 17 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.) Yes_____ No ✓
All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 5-16b, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacy technician registration may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

April Watson _____ 11/13/13 _____

Applicant Signature Date

DH-MQA PH1183, 09/09
Rule 64B16-26.350, F.A.C.

November 13, 2013

Florida Board of Pharmacy

4052 Bald Cypress Way, Bin #C-04

Tallahassee, FL 32399-3254

To Whom It May Concern:

Enclosed with this application are documents involving my court case beginning in 2009; a letter of explanation, copies of court documents, a copy of my resignation form surrendering my Florida Teaching Certificate, and an unofficial examination report from the PTCB. Please see the attached letter for explanation.

I have completed the pharmacy technician course and have passed the National Pharmacy Technician Certification Exam. I currently work in a pharmacy setting and am requesting that you please consider my application for licensure. Thank you so much for your consideration.

Sincerely,

April B. Watson

April B. Watson

To: Florida State Board of Pharmacy

From: April Watson

Re: Letter of Explanation for Felony Charge

To Whom It May Concern:

My name is April Watson and I am currently applying for the state of Florida Pharmacy Technician License. I have completed a Pharmacy Technician Training Course as well as taken and passed the National Pharmacy Technician Certification Exam. I am looking to obtain my state of Florida license. However, I am a convicted felon and would like to take a few moments to explain my situation and to ask you to please consider my application for licensure.

I have a degree in math education and was a math teacher for ten years. I taught in Georgia and in Florida and truly valued my job as an educator. However, I also suffered from post-partum depression and instead of seeking help; I drank to alleviate the depression. Because of this, I made the biggest mistake of my life in July of 2007. While with a friend and fellow teacher (who was also charged), and while intoxicated, I had sex with a 17 year old male who was visiting. I do not remember the actions, and can only say that I am very sorry for ever being in the wrong place at the wrong time with the wrong people. I was completely embarrassed by my actions and decided it was a huge mistake and to move on with my life.

Two years later, the incident came out to my school board after an anonymous letter was sent. After much investigation, I confessed, was arrested, and was later convicted of unlawful sexual activity with a 16/17 year old. This law came into effect in 2005 in the state of Florida. Regardless, I was sentenced to 15 months in state prison, followed by 5 years of probation which the first 18 months would be on community control. I served my sentence and am now over halfway finished with the probationary period. I have completed required counseling for sexual offenders and was not recommended for drug or alcohol counseling. I have not had a drink in over 4 years.

I am very regretful of making a poor choice, but I also beg of you to consider that I have paid and will continue to pay for my crime. I am a mother of two wonderful children and am still married to my husband of eleven years. It was a very hard time for us, but we made it through. We just want to move on with our lives and not let this incident rule us forever. I am a strong Christian and believe that God will see me through all obstacles of my life including my current one of battling breast cancer. I was diagnosed early this summer while taking my pharmacy technician course and continued with my course because I am very dedicated to this profession.

I have worked for the past year in a compounding pharmacy as an office staff member and truly wish to move forward with my career. I am a hard worker and I strive to do my best in this profession. Please consider all of the above mentioned situations as you consider my application for licensure as a pharmacy technician. It is extremely important to me and I beg of you to give me a chance. Thank you for your consideration.

Sincerely,

April Watson

April Watson

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Before the Education Practices Commission of the State of Florida

FILED
OCT 20 2010
EDUCATION PRACTICES COMMISSION
STATE OF FLORIDA

Final Order

IN RE: Administrative Complaint seeking disciplinary action against the Educator's Certificate of **April Watson**.

EPC CASE NO. 10-0329-RT
INDEX NO. 10-408-FOO

An Administrative Complaint seeking disciplinary action against the educator's certificate of Respondent, **April Watson**, was filed by **DR. ERIC J. SMITH**, as Commissioner of Education on, May 24, 2010.

Respondent, holder of Florida educator's certificate number 942710, was served with a copy of the Administrative Complaint. Respondent has filed an answer to the Administrative Complaint stating that she did not wish to contest the charges, that she waived any further rights to due process or a public hearing, that she surrendered her certificate for permanent revocation, and that all her actions were free and voluntary.

The Administrative Complaint and the answers are incorporated as part of this Order.

In consideration of the foregoing, the Education Practices Commission, as empowered by F.S. 1012.796, hereby **PERMANENTLY REVOKES** educator's certificate number, 942710, held by , **April Watson**.

Reapplication will not be considered.

DONE AND ORDERED this 14th day of October 2010.

Brian T. Donovan

Brian T. Donovan, Chairperson
Education Practices Commission

EXPRESS
TRAINING SERVICES, LLC

"Getting your career on the right track"

This is to certify that

April Burford Watson

Has successfully completed the

Pharmacy Technician Program

Licensed by the Commission for Independent Education (#4878)

Sherri Kalishman, Director of Education

August 23, 2013
Date

National Pharmacy Technician Training Program

Certificate of Completion

This is to certify that the pharmacy technician student listed below has completed the **National Pharmacy Technician Training Program** ("Training Program") offered through the National Healthcareer Association, a division of Assessment Technologies Institute, LLC.

To document satisfactory completion of the **Training Program**, the Competency Assessment form at the end of each chapter of the **Training Program** has been completed. These Competency Assessment forms are maintained on file as indicated below.

Pharmacy technician student to complete	
Last name: WATSON	Date of Birth: 05/12/76
First name: APRIL	
Middle name: BURFORD	Driver's License number: W325-002-76-672-0 State: FL

Instructor to complete	
Last name: Darby	Training start date: April 24 2013
First name: Jolie	Training completion date: Aug 22, 2013
Middle name:	Location of where the Competency Assessments are stored: Pensacola FL
State License No: PS44031	Name of pharmacy or school: Express Training Services Address: Pensacola, FL

Signature of pharmacy technician student: [signature] Date: 8/22/13

Signature of pharmacist/instructor: [signature] Date: 8/22/13

Virginia students only: By signing this certificate of completion, you attest that you have read the Virginia law supplement for the National Pharmacy Technician Training Program on www.atialliedhealth.com.

PLEASE SEND SIGNED ORIGINAL TO: National Pharmacy Technician Training Program, 11161 Overbrook Road, Leawood, KS 66211.

Keep a copy of this form on file, a copy for the student and a copy for the application with the Board of Pharmacy (if required).

Candidate Unofficial Examination Report

CANDIDATE: April B Watson

CANDIDATE ID: 689567 **DATE:** November 7, 2013

REGISTRATION NUMBER: 261539914 **SITE:** 46963

VALIDATION NUMBER: 393258216

EXAM: Pharmacy Technician Certification Examination (PTCE)

SERIES: PTCE

Thank you for participating in the
Pharmacy Technician Certification Examination (PTCE)

Preliminary Result: Pass

The examination result presented above is unofficial, and is subject to modification or invalidation in the event of a testing irregularity, violation of test center rules, or failure to comply with the terms of the Candidate Attestation.

Your official score report will be available online in approximately one to three weeks. It will include your final examination result (pass/fail) and total score. For passing candidates, PTCB will mail a certificate to the address currently on file. If your address has recently changed, please update it online at www.ptcb.org or call 1-800-363-8012.

Note: To ensure the confidentiality of your score information, PTCB will not provide examination results or scores by phone, fax, or email.

January 23, 2014

American Specialty Pharmacy, Inc.
2743 W 15th Street
Plano, TX 75075

RE: Non-Resident Pharmacy Permit Application

Dear American Specialty Pharmacy, Inc.:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, it is encouraged that you do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

2345

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.doh.state.fl.us/mqa/pharmacy

FLORIDA HEALTH

NON-RESIDENT PHARMACY REGISTRATION

RECEIVED
NOV 14 2013
Florida Board of Pharmacy

Application Type – Please choose one of the following:

✓ New Establishment ($255.00 Fee)
___ Change of Location ($100.00 Fee)
___ Change of Ownership (a new permit number will be issued) ($255.00 Fee)
If applicable, list existing permit number: _____

List Federal Employer Identification Number: 27-2824193

1. Corporate Name	**Telephone Number**
American Specialty Pharmacy, Inc.	210-615-7400
2. Doing Business As (d/b/a)	**E-Mail Address**
American Specialty Pharmacy	

3. Mailing Address
2743 W. 15th street

City	**State**	**Zip**
Plano	Texas	75075

4. Physical Address
2414 Babcock Rd, Suite 111

City	**State**	**Zip**
San Antonio	Texas	78229

5. List Prescription Department Manager (PDM)

Name	**License No.**	**Start Date**	**Signature**
Manohar Miryala	48435	4/29/10	Manohar

6. Contact Person	**Telephone Number**
Janet Thorsen	214 919 2520 ext 303

7. DEA Registration Number
FB 4148107

8. Do you have 24 hour access to patient records?
✓ YES ___ NO If no explain on separate sheet

9. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor.

Name	**Telephone Number**	**Permit Number**	
HD Smith	817 335 5761		
Street Address	**City**	**State**	**Zip**
1101 W. Vickery Blvd	Ft. Worth	TX	76104

10. Operating Hours

Prescription Department Hours
Monday-Friday: Open 9 Close: 7
Saturday: Open: closed Close: —
Sunday: Open: closed Close: —

10a. Provide the Toll-Free Telephone number available six days a week for 40 hours below:
(855) 615 - 7400

DH-MQA, 1217, 11/12
Rule 64B16-28.100, F.A.C.

11. Ownership Information

a. Type of Ownership: _____Individual ✓ Corporation _____Partnership

_____Other: _____

NOTE: IF CORPORATION OR LIMITED PARTNERSHIP YOU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE SECRETARY OF STATE'S OFFICE WHERE THE PHARMACY IS LOCATED.

b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes ✓ No _____

c. List each person having an ownership interest of 5 percent or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant ***Attach a separate sheet if necessary.***

Owner/Officer-Title	Date of Birth	Mailing Address	% of Ownership
Abdul Hameed	7/14/68	2743 W. 15th Street Plano TX 75075	100%

Pursuant to Section 456.0635(2), *Florida Statutes*, questions 12 through 18 must be answered. If you answer yes to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.

12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, Chapter 817, or Chapter 893, Florida Statutes; or 21 U.S.C. ss. 801-970 or 42 U.S.C. ss.1395-1396? (If no, do not answer 13.)

Yes _____ No ✓

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

13. If "yes" to 12, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?

Yes _____ No ✓

13a. If "yes" to 12, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).

Yes _____ No ✓

13b. If "yes" to 12, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes_____ No ✓

13c. If "yes" to 12, has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).

Yes _____ No ✓

14. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 15.)

Yes _____ No ✓

15. If the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has been terminated, has the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No ✓ (If yes, explain on a separate sheet providing accurate details)

16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 17 and 18)

Yes _____ No ✓ (If yes, explain on a separate sheet providing accurate details)

17. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

Yes _____ No ✓ (If yes, explain on a separate sheet providing accurate details)

18. Did the termination occur at least 20 years prior to the date of this application?

Yes _____ No ✓ (If yes, explain on a separate sheet providing accurate details)

19. Are you currently registered or permitted in any other states? If yes, provide the state, permit type, and permit number for each permit. *Attach a separate sheet if necessary.*

Yes ✓ No _____

State	Permit Type	Permit Number
Texas	Pharmacy	28002

20. Has the applicant, affiliated persons, partners, officer, directors, or PDM or Consultant Pharmacist of Record ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. *Attach a separate sheet if necessary.*

Yes ✓ No _____ (If yes, explain on a separate sheet providing accurate details)

Pharmacy Name	State	Status
American Specialty Pharmacy	Texas	Active

21. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors or PDM in this state or any other?

Yes _____ No ✓ (If yes, explain on a separate sheet providing accurate details)

22. Is there any other permit issued by the Florida Department of Health located at the physical location address on this application?

Yes _____ No ✓ (If yes, explain on a separate sheet providing accurate details)

23. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?

Yes _____ No ✓

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ TITLE President DATE 10/31/13
Owner/Officer

TEXAS STATE BOARD OF PHARMACY

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Alice G. Mendoza, R.Ph.
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Houston

Charles F. Wetherbee
Boerne

Gay Dodson, R.Ph.
Executive Director/Secretary
Austin

Re:	American Specialty Pharmacy
Address:	2414 Babcock Rd, Suite 111 San Antonio, TX 78229
License No.:	28002
Date Issued:	April 18, 2012
Licensure Status:	Active
Expiration Date:	April 30, 2014
Type of Pharmacy:	Community – Class A
Prior Disciplinary Orders:	No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. As of the date of the receipt of the request for license verification (September 26, 2013), American Specialty Pharmacy, (Texas Pharmacy License #28002) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Allison Benz, R.Ph., M.S.
Director of Professional Services
Texas State Board of Pharmacy

October 18, 2013
Date

The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.

TEXAS STATE BOARD OF PHARMACY

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Houston

Charles F. Wetherbee
Boerne

Gay Dodson, R.Ph.
Executive Director/Secretary
Austin

Re:	Manohar Miryala, R.Ph.
License No.:	48435
Date Issued:	April 29, 2010
Licensure Status:	Active
Expiration Date:	August 31, 2014
Granted by:	Reciprocity
Prior Disciplinary Orders:	No

The Texas State Board of Pharmacy maintains records regarding license and disciplinary action against a licensee. As of the date of the receipt of the request for license verification (September 26, 2013), Manohar Miryala, R.Ph., (Texas Pharmacist License #48435) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Allison Benz, R.Ph., M.S.
Director of Professional Services
Texas State Board of Pharmacy

October 18, 2013
Date

333 Guadalupe Street Suite 3-600 Austin, Texas 78701-3943 512-305-8000(voice) 512-305-8082(fax) www.tsbp.state.tx.us

Pmcy. Lic. #	Expires
28002	4-14

28002 4-14

NOTICE OF INSPECTION

Texas State Board of Pharmacy
333 Guadalupe Street, Suite 3-600
Austin, Texas 78701-3942
(512) 305-8000

Name of Individual: Mirzaei, Masoud	Title: PIC	R.Ph. Lic. # 4845 Expires 8-14
Name of Facility: American Specialty Pharmacy		
Address: 2414 Babcock Road		
City/State: San Antonio, TX	Zip: 78229	Phone # 210 ( ) 6157400
DEA Registration # FP 3186637 Expires 6-15	DPS Registration # N018 8041	Expires 4-14
Date: 8-12-13	Time of Entry: 2:45 pm	

PURPOSE OF INSPECTION

___ (1) Complaint ✓ (2) Routine ___ (3) Preceptor ___ (4) Follow-up to Warning Notice

___ (7) New Pharmacy ___ (8) Change/Owner ___ (15) Pre-Inspection ___ (17) Follow-up to Complaint

___ (18) Follow-up to Theft/Loss Report ___ (12) Other _____

ACKNOWLEDGEMENT

This is to acknowledge that Texas State Board of Pharmacy Agent Sharon Rashell has presented official credentials and this Notice of Inspection citing Sections 554.001, 556.001, 556.051-556.054, and 556.101 of the Texas Pharmacy Act which authorizes an inspection of the above described facility. By my signature, I hereby acknowledge receipt of this Notice of Inspection and certify that:

1. I am the PIC for the above-described facility;
2. I have read this Notice of Inspection and understand its contents and purpose;
3. I have the authority to act in this matter and have signed this Notice of Inspection pursuant to my authority;
4. I have had the purpose of the entry into the above-described facility by the Board's agent stated to me; and
5. I have consented to an inspection of the above-described facility voluntarily and without any manner of threats.

_____
Signature

Witnesses:

Sharon Rashell
Signature

_____
Signature

11/07

TEXAS STATE BOARD OF PHARMACY INSPECTION REPORT

CLASS: (A) B C (BEDS____) D Other _____

Name of Pharmacy American Specialty Phcy

Pharmacist in Charge Manohar Mirpuri

Personnel _____

TSBP License # 28002

Lic 484.35 Exp 8-14

Lic _____ Exp _____

Lic _____ Exp _____

Lic _____ Exp _____

Lic _____ Exp _____

KEY: Circled items need improvement, √ items in Column One Refer to Legal Division (R/L) for review and possible discipline. √ items in Column Two receive a Warning Notice (W/N).

For an explanation of specific violations noted, refer to remarks section of inspection report.

R/L		W/N	
	1		Licenses not posted
	2		Insufficient Equipment
	3		Orderly/Clean
	4		Balance Failed
	5		Equipment Inspection
	6		Inadequate Library
	7		Improper security
	(8)		Environment
	9		Delinquent licenses/certifications
	36		No notification of substitution
	90		No complaint notification
	38		Area for non sterile compounding
	43		Records for non sterile compounding
	47		Out of date/mislabeled drug stock
	48		Improper drug storage
	53		Illegal possession of C/S
	57		Corresponding Responsibility
	59		Improper drug destruction
	(61)		Improper supervision of supportive personnel
	62		Aiding and abetting
	65		Improper registration procedures
	66		Grey Market diversion/ Samples
	78		No PIC
	(34)		Notification Violation
	79	✓	Nametags
	(60)	✓	Improper documentation of training
	92		Improper automated dispensing procedures

R/L		W/N	
			Date of last inventory 4-30-13
	15		No PIC inventory
	69		No annual inventory
	68		No change of ownership inventory
	31		Closed Phcy/Change of owner improper
	17		Incomplete inventory
	18	✓	Records not available
	46		Improper distribution
	54		Improper prepackaging procedures
	24	✓	Theft/Loss not reported 9-12-12
	30		Invoices not dated/initialed
	86		Absence of RPh pick up records
	19		Rx lacks proper information
	25		No documentation of refill authorization
	32		Rx label is incorrect
	40		Non emergency C-II Rx
	26		C II Rx noncompliance
	37		Illegal dispensing
	45		Improper dispensing/ labeling
	44		Refill CIII-V over 5x/6mo
	55		Refill prn past one year
	78		Counseling area
	80		No counseling by RPh
	56		Improper transfer of Rx
	50		Out of state verbal Rx for C/S
	49		Substitution noncompliance
	33		Rx records not in numerical order

R/L		W/N	
	10		Rxs not separated
	35		Invoices not separated
	67		No written information
	21		Computer records incomplete
	22		Computer system noncompliance
	82		PMR Incomplete
	83		PMR Absent
	84		No drug regimen review
	16		No perpetual inventory
	27		Improper inpatient records
	51		Improper ER dispensing
	75		Improper absence of RPh procedures
	70		No P&P manual
	71		Incomplete P&P manual
	72	✓	Improper procedures for IV preparation
	81	✓	Area for preparation of sterile products
	85		Patient Care Guidelines incomplete
	87	✓	Quality Control/Assurance
	88		Cytotoxic/Biohazardous Procedures
	89		Refrigerator Temperature Log
	28		No provision log
	29		Incomplete provision log
	52		Improper provision/ dispensing in Class D
	63		Prohibited drugs in Class D pharmacy
	64		Violation of limited formulary
	91		RPh visits/contact documentation
	73		Formulary not complete

Remarks

(34) notify TSBP of employment within 10 days
(8) clean sink in compounding area
(10) decrease tech ratio to 3 techs to 1 pharmacist
(21) complete documentation of initial training for all techs
IN (60) pharmacist not completed 40 hour ongoing training course was available
IN (38) During inspection, pharmacy unable to provide documentation of written agreements for technician activities pertaining
IN (24) TSBP not notified of 4-12-12 theft of controlled substances
IN (78) Immunizing personnel did not sign logs in pharmacy when entering ISO Class 7 environment and did not follow gowns, shoe covers, etc. when entering or exiting
IN (81) Did not limit use of ISO Class 8 rest room
IN (87) Unable to find media fill testing
IN (79) Have all staff wear name tags at all times

Action Taken

(1) ✓ Inspection
(2) ___ Partial Inspection
(3) ___ Visit
(5) ___ Audit
(10) ___ Pre-Inspection
(9) ___ Other _____

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted. Items marked in Column One will be referred to the Legal Division for review and possible disciplinary action. Items marked in Column Two are conditions that have resulted in the issuance of a Warning Notice and must be corrected to ensure compliance with the laws and rules governing the practice of pharmacy. Circled items need improvement.

I acknowledge that the noted conditions, which are not in compliance, have been explained to me and I have received a copy of this report.

Sharon Eastlake
Agent of the Texas State Board of Pharmacy

Authorized Individual for the Pharmacy

8-12-13
Date

6:45pm
Time of Exit

Marcus Mills
Printed Name and Title of Authorized Individual

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3942
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # _____

Name of Facility _____

Address _____ City _____ Zip _____

Pharmacist License # _____

NAME OF PERSON RESPONSIBLE _____

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule _____

Explanation of violation _____

2. Law/Rule _____

Explanation of violation _____

3. Law/Rule _____

Explanation of violation _____

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before _____, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By _____
Agent, Texas State Board of Pharmacy

Date _____ Signed _____

11/00

RESPONSE TO WARNING NOTICE

Pharmacy License # 28002

Name of Facility American Specialty Pharmacy

Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. **DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.**

Explanation of Correction:

1. [illegible]

2. [illegible] All compounding personnel trained on gowning steps [illegible]

3. [illegible]

Additional comments: _____

9/2/13 _____
Date

[illegible]
Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.)

4 8435
License #

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3942
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # _____

Name of Facility _____

Address _____ City _____ Zip _____

Pharmacist License # _____

NAME OF PERSON RESPONSIBLE _____

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule _____

Explanation of violation _____

2. Law/Rule _____

Explanation of violation _____

3. Law/Rule _____

Explanation of violation _____

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before _____ disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By _____
Agent, Texas State Board of Pharmacy

Date _____

Signed _____

11/00

RESPONSE TO WARNING NOTICE

Pharmacy License # 38002

Name of Facility American Specialty Pharmacy

Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. **DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.**

Explanation of Correction:

1. Located a tested media fill testing for personnel who compound sterile compounds also ongoing media fill testing also available for compounding personnel.

2. _____

3. _____

Additional comments: _____

9/2/13
Date

Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.)

48435
License #

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3942
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # 28002

Name of Facility [illegible]

Address [illegible] City [illegible] Zip [illegible]

Pharmacist License # [illegible]

NAME OF PERSON RESPONSIBLE [illegible]

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule [illegible]

Explanation of violation [illegible]

2. Law/Rule [illegible]

Explanation of violation [illegible]

3. Law/Rule [illegible]

Explanation of violation [illegible]

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before [illegible], disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By [illegible]
Agent, Texas State Board of Pharmacy

Date [illegible]

Signed [illegible]

RESPONSE TO WARNING NOTICE

Pharmacy License # 28002

Name of Facility American Specialty Pharmacy

Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. **DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.**

Explanation of Correction:

1. ordered Magnetic Badges and hung up in the pharmacy

2. Received copy of training certificate from RCA copy attached

3.

Additional comments:

9/3/13
Date

Signature (The person listed in the blank titled "NAME OF PERSON RESPONSIBLE" must sign here.)

4-24-35
License #

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.

Texas State Board of Pharmacy

333 Guadalupe Street, Suite 3-600, Box 21
Austin, Texas 78701-3942
Phone: 512/305-8000

WARNING NOTICE

Pharmacy License # _____

Name of Facility _____

Address _____ City _____ Zip _____

Pharmacist License # _____

NAME OF PERSON RESPONSIBLE _____

Notice is hereby given that you are not complying with the following laws and or rules governing the practice of pharmacy:

1. Law/Rule _____

Explanation of violation _____

2. Law/Rule _____

Explanation of violation _____

3. Law/Rule _____

Explanation of violation _____

Notice is also hereby given that unless the conditions noted above are corrected and a written report detailing the corrections is submitted to the Executive Director/Secretary of the Texas State Board of Pharmacy on or before _____, disciplinary action may be instituted against your license.

I hereby acknowledge that the laws and or rules cited above have been explained to me and that I have received a copy of this notice.

By _____

Agent, Texas State Board of Pharmacy

Date _____ Signed _____

11/00

RESPONSE TO WARNING NOTICE

Pharmacy License # 28002

Name of Facility Connection Specialty Pharmacy

Explain, in the space provided below, how the Unsatisfactory/Warning Notice conditions were corrected. **DO NOT RESPOND UNTIL THE CORRECTIONS HAVE BEEN COMPLETED. CORRECTIONS MUST BE COMPLETED BY THE DATE INDICATED ON THE LEFT SIDE OF THIS FORM.**

Explanation of Correction:

1. Faxed the DEA 106 to TSBP on 8/10/10 [illegible] 512-305-8082

2. _____

3. _____

Additional comments: _____

8/12/10

Date

Signature (The person listed in the blank titled "**NAME OF PERSON RESPONSIBLE**" must sign here.)

45435

License #

Mail entire white copy to Texas State Board of Pharmacy and retain entire yellow copy for your files.

Form 201

Secretary of State
P.O. Box 13697
Austin, TX 78711-3697
FAX: 512/463-5709

Filing Fee: $300

Certificate of Formation
For-Profit Corporation

Filed in the Office of the Secretary of State of Texas
Filing #: 801280272 06/10/2010
Document #: 311366610002
Image Generated Electronically for Web Filing

Article 1 - Entity Name and Type

The filing entity being formed is a for-profit corporation. The name of the entity is:

AMERICAN SPECIALTY PHARMACY, INC

The name must contain the word "corporation," "company," "incorporated," "limited," or an abbreviation of one of these terms. The name must not be the same as, deceptively similar to or similar to that of an existing corporate, limited liability company, or limited partnership name on file with the secretary of state. A preliminary check for "name availability" is recommended.

Article 2 – Registered Agent and Registered Office

☐ A. The initial registered agent is an organization (cannot be corporation named above) by the name of:

OR

☑ B. The initial registered agent is an individual resident of the state whose name is set forth below:

Name:
ABDUL HAMEED

C. The business address of the registered agent and the registered office address is:

Street Address:
1910 SAGEBRUSH TRAIL RICHARDSON TX 75080

Consent of Registered Agent

☐ A. A copy of the consent of registered agent is attached.

OR

☑ B. The consent of the registered agent is maintained by the entity.

Article 3 - Directors

The number of directors constituting the initial board of directors and the names and addresses of the person or persons who are to serve as directors until the first annual meeting of shareholders or until their successors are elected and qualified are set forth below:

Director 1: **ABDUL HAMEED**

Address: **1910 SAGEBRUSH TRAIL RICHARDSON TX, USA 75080**

Article 4 - Authorized Shares

The total number of shares the corporation is authorized to issue and the par value of each of such shares, or a statement that such shares are without par value, is set forth below.

Number of Shares	Par Value (must choose and complete either A or B)	Class	Series
1000000	☑ A. has a par value of **$.001** ☐ B. without par value.		

If the shares are to be divided into classes, you must set forth the designation of each class, the number of shares of each class, and the par value (or statement of no par value), of each class. If shares of a class are to be issued in series, you must provide the designation of each series. The preferences, limitations, and relative rights of each class or series must be stated in space provided for supplemental information.

Article 5 - Purpose

The purpose for which the corporation is organized is for the transaction of any and all lawful business for which corporations may be organized under the Texas Business Organizations Code.

Supplemental Provisions / Information

[The attached addendum, if any, is incorporated herein by reference.]

Effectiveness of Filing

☑ A. This document becomes effective when the document is filed by the secretary of state.

OR

☐ B. This document becomes effective at a later date, which is not more than ninety (90) days from the date of its signing. The delayed effective date is:

Organizer

The name and address of the organizer is set forth below.

ZAHID REZA, CPA **6210 CAMPBELL RD, STE 150, DALLAS, TX 75248**

Execution

The undersigned affirms that the person designated as registered agent has consented to the appointment. The undersigned signs this document subject to the penalties imposed by law for the submission of a materially false or fraudulent instrument and certifies under penalty of perjury that the undersigned is authorized under the provisions of law governing the entity to execute the filing instrument.

ZAHID REZA, CPA

Signature of organizer

FILING OFFICE COPY

Franchise Tax Account Status

As of: 11/01/2013 10:29:31 AM

This Page is Not Sufficient for Filings with the Secretary of State

AMERICAN SPECIALTY PHARMACY, INC	
Texas Taxpayer Number	32042021157
Mailing Address	2743 W 15TH ST PLANO, TX 75075-7525
Right to Transact Business in Texas	ACTIVE
State of Formation	TX
Effective SOS Registration Date	06/10/2010
Texas SOS File Number	0801280272
Registered Agent Name	ABDUL HAMEED
Registered Office Street Address	1910 SAGEBRUSH TRAIL RICHARDSON, TX 75080

IRS DEPARTMENT OF THE TREASURY
INTERNAL REVENUE SERVICE
CINCINNATI OH 45999-0023

Date of this notice: 06-10-2010

Employer Identification Number:
27-2824193

Form: SS-4

Number of this notice: CP 575 A

AMERICAN SPECIALTY PHARMACY INC
1910 SAGEBRUSH TRL
RICHARDSON, TX 75080

For assistance you may call us at:
1-800-829-4933

IF YOU WRITE, ATTACH THE
STUB AT THE END OF THIS NOTICE.

WE ASSIGNED YOU AN EMPLOYER IDENTIFICATION NUMBER

Thank you for applying for an Employer Identification Number (EIN). We assigned you EIN 27-2824193. This EIN will identify you, your business accounts, tax returns, and documents, even if you have no employees. Please keep this notice in your permanent records.

When filing tax documents, payments, and related correspondence, it is very important that you use your EIN and complete name and address exactly as shown above. Any variation may cause a delay in processing, result in incorrect information in your account, or even cause you to be assigned more than one EIN. If the information is not correct as shown above, please make the correction using the attached tear off stub and return it to us.

Based on the information received from you or your representative, you must file the following form(s) by the date(s) shown.

Form 1120 03/15/2011

If you have questions about the form(s) or the due date(s) shown, you can call us at the phone number or write to us at the address shown at the top of this notice. If you need help in determining your annual accounting period (tax year), see Publication 538, *Accounting Periods and Methods*.

We assigned you a tax classification based on information obtained from you or your representative. It is not a legal determination of your tax classification, and is not binding on the IRS. If you want a legal determination of your tax classification, you may request a private letter ruling from the IRS under the guidelines in Revenue Procedure 2004-1, 2004-1 I.R.B. 1 (or superseding Revenue Procedure for the year at issue). Note: Certain tax classification elections can be requested by filing Form 8832, *Entity Classification Election*. See Form 8832 and its instructions for additional information.

IMPORTANT INFORMATION FOR S CORPORATION ELECTION:

If you intend to elect to file your return as a small business corporation, an election to file a Form 1120-S must be made within certain timeframes and the corporation must meet certain tests. All of this information is included in the instructions for Form 2553, *Election by a Small Business Corporation*.

January 23, 2014

Trinity Care Solutions
1731 SW 2nd Avenue, Suite B
Ocala, FL 34471

RE: Special Parenteral and Enteral Pharmacy Permit Application

Dear Trinity Care Solutions:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, it is encouraged that you do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

10/22/2013 255.00
ID: 20419 Type: F
BT: 3007884
VL: 913022193

Florida HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595

SPECIAL PHARMACY PERMIT APPLICATION

Application Type – Please choose one of the following: 2205-20419

_X_ **New Establishment $255 fee**
____ **Change of Location $100 fee** _____ **(existing permit number)**
____ **Change of Ownership (a new permit number will be issued) $255** _____ **(existing permit number)**
____ **Additional Permit Type $255 fee** _____ **(existing permit number)**

Type of Special Pharmacy Permit - Please choose one of the following:
_____Special- Limited Community _X_ Special- Parenteral and Enteral ____ Special- Closed System Pharmacy
_____Special- ESRD ____ Special- Parenteral/Enteral Extended Scope____ Special- ALF
_____Community/Special Parenteral and Enteral _____ Special- Closed System Pharmacy/Parenteral and Enteral

Will the Pharmacy Dispense Schedule II and/or III Controlled Substances? _X_ **Yes** ___ **No**

Please list your Federal Employer Identification Number 20-5909785	
1. Corporate Name	**Telephone Number**
Trinity Care Solutions LLC	1-352-216-1137
2. Doing Business As (d/b/a)	**E-Mail Address**
	fignekann@yahoo.com

3. Mailing Address
1731 SW 2nd Ave, Suite B

City	State	Zip
Ocala	FL	34471

4. Physical Address
Same as above

City	State	Zip

5. List Prescription Department Manager (PDM) or Consultant Pharmacist of Record

Name	License No.	Start Date	Signature
Ann Franck	17256		[signature]

6. Contact Person	**Telephone Number**
Ann Franck	352-216-1137
7. DEA Registration Number	**8. Date ready for inspection (must be within 90 days of the date of the application)**
pending	Oct. 31, 2013

9. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor. If not available you may write in pending.

Name	Telephone Number	Permit Number	
Cardinal	1-800-635-6670	pending	
Street Address	**City**	**State**	**Zip**
2045 Interstate Drive	Lakeland	FL	33805

10. Pharmacy Technician Ratio 2:1 or 3:1 (Optional)

WL

Rule 64B16-27.410, *Florida Administrative Code*, provides that the prescription department manager or consultant pharmacist of record is required to submit a written request and receive approval from the Board of Pharmacy prior to the pharmacy allowing a pharmacist to supervise more than one registered pharmacy technician. If you would like to apply for the Registered Pharmacy Technician 2:1 or 3:1 ratio, you may do so by checking the appropriate selection below. Selecting an option below serves as your written request to the board office for approval to practice with a 2:1 or 3:1 ratio.

_____ 2:1 Ratio _____ 3:1 Ratio

(please attach a brief description of the workflow needs that include the operating hours of the pharmacy, number of pharmacist, registered interns and registered pharmacy technicians employed to justify the ratio request)

11. Operating Hours	**11a. Special- Parenteral & Enteral; Provide Toll-Free Telephone Number Below:**
Prescription Department Hours Monday-Friday: Open 9A Close: 5PM Saturday: Open: — Close: — Sunday: Open: — Close: —	(800) 345 - 9074

12. Ownership Information

a. Type of Ownership: _____Individual X Corporation _____Partnership

_____Other: _____

NOTE: IF CORPORATION OR LIMITED PARTNERSHIP YOU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE FLORIDA SECRETARY OF STATE'S OFFICE

b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes X No _____

c. Does the corporation have more than $100 million of business taxable assets in this state?

Yes _____ No X

If yes, provide attestation from Certified Public Accountant for previous tax year or Florida Corporate Income/Franchise and Emergency Excise Tax Return (F-1120). If no, continue to 12d.

d. List all the owners and officers of the corporation. Each person listed below having an ownership interest of 5 percent or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant including officers and members of the board of directors must submit a set of fingerprints and fees unless you answered yes to 12c. If 12c is yes please list the owners below and only submit fingerprints for the Prescription Department Manager or Consultant Pharmacist of Record. If 12c is yes and the prints are on file with DOH or AHCA and available to the Board of Pharmacy the requirement to submit the prints for this person is met. ***Attach a separate sheet if necessary.***

Owner/Officer-Title	Date of Birth	Mailing Address, City State, Zip Code	% of Ownership
Ann Franck	10/11/55	2324 SE 15th ST. OCALA, FL 34471	100 %
	/ /		%
	/ /		%
	/ /		%
	/ /		%

13. Has anyone listed in 12.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was disciplined, suspended, revoked, or closed involuntarily within the past 5 years?

Yes _____ No X

If yes, please provide a signed affidavit disclosing the reason the entity was closed.

13a Has anyone listed in 12.d had an ownership interest of 5% or more in a pharmacy or any other business permit which was voluntarily relinquished or closed voluntarily within the past 5 years?

Yes _____ No X If yes, please provide a signed affidavit disclosing the reason the entity was closed.

14. Has anyone listed in 12.d ever obtained a pharmacy permit by misrepresentation or fraud or been convicted of, or entered a plea of guilty or nolo contender to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud?

Yes _____ No X If yes, please provide documents concerning this conviction.

Pursuant to Section 456.0635(2) and 465.022(5), *Florida Statutes*, questions 15 through 21 are being asked. If you answer yes to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, Chapter 817, or Chapter 893, Florida Statutes; or a similar felony offense in another state or jurisdiction since July 1, 2009? (If yes, provide court documents concerning this conviction)

Yes_____ No X

15a. If "yes" to 15, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).

Yes_____ No X N/A

15b. If "yes" to 15, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes_____ No_____ N/A

15c. If "yes" to 15, has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).

Yes_____ No_____ N/A

16. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication to a felony under 21 U.S.C. ss.801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009?

Yes_____ No X (If yes, explain on a separate sheet providing accurate details)

16a. If "yes" to 16, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?

Yes_____ No_____ N/A

17. I have been provided and read the statement from the Florida Department of Law Enforcement regarding sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation. (Found on Page 8 of this application.)

Yes X No _____

18. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 19.)

(If yes, explain on a separate sheet providing accurate details)

Yes _____ No X

19. If the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has been terminated, has the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

(If yes, explain on a separate sheet providing accurate details)

Yes _____ No _____ N/A

20. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 21 and 22)

(If yes, explain on a separate sheet providing accurate details)

Yes _____ No X

21. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

(If yes, explain on a separate sheet providing accurate details)

Yes _____ No _____ N/A

22. Did the termination occur at least 20 years prior to the date of this application?

(If yes, explain on a separate sheet providing accurate details)

Yes _____ No _____ N/A

23. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant listed on the United States Department of Health Human Services Office of Inspector General's List of Excluded Individuals and Entities?

Yes _____ No X (If yes, submit proof)

24. Are you currently registered or permitted in any other states? If yes, provide the state, permit type, and permit number for each permit. *Attach a separate sheet if necessary.*

Yes _____ No X

State	Permit Type	Permit Number

25. Has the applicant, affiliated persons, partners, officer, directors, or PDM or Consultant Pharmacist of Record ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. *Attach a separate sheet if necessary.*

Yes _____ No X (If yes, please list them below, you may provide additional sheet)

Pharmacy Name	State	Status

26. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors or Consultant Pharmacist of Record in this state or any other?

Yes _____ No X (If yes, explain on a separate sheet providing accurate details and submit documentation from the licensing agency who took the disciplinary action)

27. Has the applicant, or any officer, member or partner ever been convicted of a felony or misdemeanor, excluding minor traffic convictions?

Yes _____ No X (You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

28. Is there any other permit issued by the Department of Health located at the physical location address on this application?

No X Yes _____ (If yes, explain on a separate sheet providing accurate details)

29. Does the applicant, affiliated person, partner, officer, director have any outstanding fines, liens or overpayments assessed by a final order of the department? If yes, please answer 29a.

No X Yes _____ (If yes, explain on a separate sheet providing accurate details)

29a. Does the applicant, affiliated person, partner, officer, director have a repayment plan approved by the department?

No_____ Yes_____ N/A

30. Is the policy and procedure manual for preventing controlled substance dispensing based on fraudulent representation or invalid practitioner-patient relationship available for inspection by DOH?

No _____ Yes X

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE [signature] TITLE OWNER DATE 10/8/2013

Owner/Officer

63-215-631

6801

PAUL W. FRANCK OR
ANN N. FRANCK
2324 SE 15TH ST
OCALA, FL 34471

10 / 8 20 13

Pay to the order of Florida Board of Pharmacy $ 255.00

Two Hundred Fifty-Five & 00/100 Dollars

PARCHMENT

SUNTRUST
ACH RT 061000104

For

Paul W. Franck

MP

PAY TO TREASURER OF FLORIDA
ACCT 540600106
ACCT 001009070492
LOC 6400167000
DEPARTMENT OF HEALTH
FOR DEPOSIT ONLY
10/22/2013 255.00
ID: 204[illegible] Type: F
BT: 300[illegible]84
VL: 913[illegible]2193

Sec:22 10/23/13 Des:000310 AC:1 Cust:[illegible]

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

TO: Allison Tate, R.Ph., C.Ph., Senior Pharmacist

FROM: Heidi Nitti
Regulatory Specialist II

DATE: December 11, 2013

Please review the attached questionnaire from the pharmacy applicant listed below and return within 30 days. Please return this form by fax to (850) 413-6982.

TRINITY CARE SOLUTIONS LLC
1731 Sw 2nd Ave
SUITE B
Ocala, FL 34471

The above mentioned pharmacy applicant questionnaire is:

☒ APPROVED

☐ DENIED

Allison Tate
Signature

12-11-13
Date

Florida Department of Health
Division of Medical Quality Assurance• Bureau of HCPR
4052 Bald Cypress Way, Bin C04 • Tallahassee, FL 32399
PHONE: (850) 245-4292 • FAX : (850) (850) 413-6982

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One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

FLORIDA DEPARTMENT OF STATE
DIVISION OF CORPORATIONS

Sunbiz

Detail by Entity Name

Florida Limited Liability Company

TRINITY CARE SOLUTIONS, LLC

Filing Information

Document Number	L06000111228
FEI/EIN Number	205909785
Date Filed	11/16/2006
State	FL
Status	ACTIVE
Last Event	LC AMENDMENT
Event Date Filed	10/11/2013
Event Effective Date	NONE

Principal Address

1731 SW 2ND AVENUE
SUITE B
OCALA, FL 34471

Changed: 10/11/2013

Mailing Address

1731 SW 2ND AVENUE
SUITE B
OCALA, FL 34471

Changed: 10/11/2013

Registered Agent Name & Address

FRANCK, ANN
1731 SW 2ND AVENUE
SUITE B
OCALA, FL 34471

Name Changed: 10/11/2013

Address Changed: 10/11/2013

Manager/Member Detail

Name & Address

Title MGRM

FRANCK, ANN
1731 SW 2ND AVENUE, SUITE B
OCALA, FL 34471

Annual Reports

Report Year	Filed Date
2011	03/16/2011
2012	03/16/2012
2013	04/26/2013

Document Images

10/11/2013 -- LC Amendment	View image in PDF format
10/08/2013 -- LC Amendment and Name Change	View image in PDF format
04/26/2013 -- ANNUAL REPORT	View image in PDF format
03/16/2012 -- ANNUAL REPORT	View image in PDF format
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04/15/2008 -- ANNUAL REPORT	View image in PDF format
04/17/2007 -- ANNUAL REPORT	View image in PDF format
11/16/2006 -- Florida Limited Liability	View image in PDF format

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State of Florida, Department of State

State of Florida
Department of State

I certify from the records of this office that TRINITY CARE SOLUTIONS, LLC, is a limited liability company organized under the laws of the State of Florida, filed on November 16, 2006.

The document number of this company is L06000111228.

I further certify that said company has paid all fees due this office through December 31, 2013, that its most recent annual report was filed on April 26, 2013, and its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Tenth day of October, 2013

Ken Detzner

Secretary of State

Authentication ID: CU2647465720

To authenticate this certificate,visit the following site,enter this ID, and then follow the instructions displayed.

https://efile.sunbiz.org/certauthver.html

NUMBER 1

UNITS 100

ORGANIZED UNDER THE LAWS OF THE STATE OF FLORIDA

Trinity Care Solutions, LLC

Authorized to issue Units of Interest

This Certifies that Ann Franck is the owner of One Hundred Units of the above *Limited Liability Company transferable only on the books of the Limited Liability Company by the holder hereof in person or by duly authorized Attorney upon surrender of this Certificate properly endorsed. Transfer of these Units is subject to restrictions in the Operating Agreement/Company Agreement/Regulations for this Limited Liability Company.*

The Company will furnish without charge to each Unit holder who so requests, the powers, designations, preferences and relative participation rights of Unit holders and the qualifications, limitations or restrictions of such rights.

In Witness Whereof, the said Limited Liability Company has caused this Certificate to be signed by its duly authorized Member(s)/Manager(s) and to be sealed with the Seal of the Limited Liability Company.

Dated October 10, 2013

ANN FRANCK MEMBER-MANAGER

MEMBER-MANAGER

L06000111228

(Requestor's Name)

(Address)

(Address)

(City/State/Zip/Phone #)

☐ PICK-UP ☐ WAIT ☐ MAIL

(Business Entity Name)

(Document Number)

Certified Copies _____ Certificates of Status _____

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2013 OCT 11 AM 11:47

J. SAULSBERRY
EXAMINER

OCT 14 2013

DEAN
LAW FIRM LLC

SUITE 300
230 NE 25TH AVENUE
OCALA, FL 34470-7075
TELEPHONE 352.387.8700
FACSIMILE 800.251.9424
www.deanfirm.com

Timothy S. Dean, P.A.
tim@deanfirm.com

October 10, 2013

VIA FEDERAL EXPRESS

Florida Division of Corporations
Attn: Amendments
Clifton Building
2661 Executive Center Circle
Tallahassee, FL 32301

Re: Trinity Care Solutions, LLC – Articles of Amendment
Document No.: L06000111228

To Whom it may Concern:

Enclosed please find the following:

1.) Articles of Amendment to Articles of Organization of Trinity Solutions, LLC;

2.) Check in the amount of $25.00, which represents payment for same.

Please do not hesitate to call if you have any questions.

Thank you in advance for your courtesies.

Sincerely yours,

DEAN LAW FIRM, LLC

Christi Jacquay
Legal Assistant

Enclosures as stated

2013 OCT 11 AM 11:47

ARTICLES OF AMENDMENT
TO
ARTICLES OF ORGANIZATION
OF

Trinity Care Solutions, LLC

(Name of the Limited Liability Company as it now appears on our records.)
(A Florida Limited Liability Company)

The Articles of Organization for this Limited Liability Company were filed on November 16, 2006 and assigned Florida document number L06000111228.

This amendment is submitted to amend the following:

A. If amending name, enter the new name of the limited liability company here:

The new name must be distinguishable and end with the words "Limited Liability Company," the designation "LLC" or the abbreviation "L.L.C."

Enter new principal offices address, if applicable:
(Principal office address MUST BE A STREET ADDRESS)

1731 SW 2nd Avenue, Suite B
Ocala, FL 34471

Enter new mailing address, if applicable:
(Mailing address MAY BE A POST OFFICE BOX)

1731 SW 2nd Avenue, Suite B
Ocala, FL 34471

B. If amending the registered agent and/or registered office address on our records, enter the name of the new registered agent and/or the new registered office address here:

Name of New Registered Agent: Ann Franck

New Registered Office Address: 1731 SW 2nd Avenue, Suite B
Enter Florida street address

Ocala, **Florida** 34471
City *Zip Code*

New Registered Agent's Signature, if changing Registered Agent:

I hereby accept the appointment as registered agent and agree to act in this capacity. I further agree to comply with the provisions of all statutes relative to the proper and complete performance of my duties, and I am familiar with and accept the obligations of my position as registered agent as provided for in Chapter 608, F.S. Or, if this document is being filed to merely reflect a change in the registered office address, I hereby confirm that the limited liability company has been notified in writing of this change.

If Changing Registered Agent, Signature of New Registered Agent

If amending the Managers or Managing Members on our records, enter the title, name, and address of each Manager or Managing Member being added or removed from our records:

MGR = Manager
MGRM = Managing Member

Title	Name	Address	Type of Action
MGRM	Paul W. Franck	202 SW 17th Street	☐ Add
		Ocala, FL 34471	☑ Remove
MGRM	Ann Franck	1731 SW 2nd Avenue, Suite B	☑ Add
		Ocala, FL 34471	☐ Remove
			☐ Add
			☐ Remove
			☐ Add
			☐ Remove
			☐ Add
			☐ Remove
			☐ Add
			☐ Remove

D. If amending any other information, enter change(s) here: *(Attach additional sheets. if necessary.)*

Dated October 10, 2013

Signature of a member or authorized representative of a member

Ann Franck

Typed or printed name of signee

Filing Fee: $25.00

2013 OCT 11 08:11:47

L06000111228

(Requestor's Name)

(Address)

(Address)

(City/State/Zip/Phone #)

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FILED
13 OCT -8 AM 10:43
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

J. SIMMONS OCT 09 2013

mc/ml

January 24, 2014

Douglas N Kassan
201 5th Street S. Apt #10
St. Petersburg, FL 33701

RE: Request for Termination of Probation

Dear Mr. Kassan:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, it is encouraged that you do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Final Order No. DOH-08-1397-S -MQA
FILED DATE - 10-25-08
Department of Health
By: Rachel Rh
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

vs.

Case No.: 2006-42732
License No.: PS 28503

DOUGLAS NEIL KASSAN, R.PH.,

Respondent.

_____/

FINAL ORDER

THIS MATTER came before the Board of Pharmacy (hereinafter "the Board") at a duly noticed public meeting on April 9, 2008, in Orlando, Florida. Petitioner filed an Administrative Complaint seeking disciplinary action against Respondent's license. A copy of the Administrative Complaint is attached to and made a part of this Final Order. Petitioner was represented by Billie Jo Owens. Respondent was present.

Petitioner and Respondent have stipulated to a disposition in this case. The Board voted to adopt the Settlement Agreement as an appropriate settlement of the case.

A copy of the Settlement Agreement is attached to and made a part of this Final Order. The agreed upon costs to be paid by Respondent are two thousand three hundred sixty-six dollars and ninety-six cents **($2,366.96)**. The costs shall be paid prior to Respondent filing a petition for reinstatement.

IT IS THEREFORE ORDERED that the Settlement Agreement is hereby adopted.

This Final Order shall become effective upon filing with the Clerk of the Department of Health.

DONE AND ORDERED this 24 day of June, 2008.

BOARD OF PHARMACY

Rebecca R. Poston

Rebecca R. Poston, R. Ph., Executive Director
Florida Board of Pharmacy
on behalf of Albert Garcia, R.Ph., Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by U.S. Mail to: **Douglas Kassan, R.Ph.**, Suburban Lodge, Room 111, 6500 Ulmerton Road, Largo, Florida 33771; by interoffice mail to **Deborah B. Loucks**, Assistant Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050; and **Billie Jo Owens**, Assistant General Counsel, Department of Health, 4052 Bald Cypress Way, Bin # C-65, Tallahassee, Florida 32399-3265, on 25th June, 2008.

Angel Sanders

Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2006-42732**

DOUGLAS NEIL KASSAN, R.PH.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, DOUGLAS NEIL KASSAN, R.Ph., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. Respondent is, and has been at all times pertinent to this Complaint, a licensed pharmacist pursuant to Chapter 465, Florida Statutes, having been issued license number PS 28503.

3. Respondent's address of record is P.O. Box 3238, St. Petersburg, Florida 33738-3238. The Department has information to believe Respondent may be living at 1417 Reynard Drive, Ft. Myers, Florida 33919.

4. On or about May 4, 2006, Respondent was involved in a single automobile accident in Sarasota County, Florida and found to be exhibiting the indicia of being under the influence of alcohol or/and a controlled substance.

5. On or about May 4, 2006, Respondent was found to be in possession of a controlled substance, Alprazolam without a lawful prescription.

6. Aprazolam is a controlled substance III under Chapter 893, Florida Statutes. A substance listed in Schedule III has a potential for abuse less than the substances contained in Schedule I and II and has a currently accepted medical use in treatment in the United States. Abuse of a Schedule III substance may lead to moderate or low physical dependence or high psychological dependence.

7. On or about August 20, 2007, in the Circuit Court, Sarasota County, in case No. 2006 CF 00822, Respondent entered a plea of guilty to the offense of "DUI and Damage Property – Vehicle", a misdemeanor.

8. Respondent was adjudicated guilty on the allegation listed in paragraph 7 above.

9. Section 465.016(1)(f), Florida Statutes (2006), provides that having been convicted or found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a crime which directly relates to the ability to practice pharmacy or to the practice of pharmacy, constitutes grounds for disciplinary action by the Board of Pharmacy. Entering a plea of guilty constitutes a conviction for purposes of Section 465.016(1)(f), Florida Statutes (2006).

10. Section 465.016(1)(r), Florida Statutes (2006), provides that violating any provision of chapter 465, 456 Florida Statutes or any rules adopted pursuant thereto constitutes grounds for disciplinary action by the Board of Pharmacy.

11. Section 456.072(1)(c), Florida Statutes (2006), provides that being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of or the ability to practice a licensee's profession, constitutes grounds for disciplinary action by the Board of Pharmacy.

12. Driving while under the influence of alcohol or prescription medication is a crime directly related to the practice or to the ability to practice pharmacy.

13. Based on the foregoing, Respondent has violated Section 465.016(1)(f), Florida Statutes (2006), by having been found guilty, regardless of adjudication, in a court of this state of a crime which directly relates to the ability to practice pharmacy or to the practice of pharmacy.

14. Based on the foregoing, Respondent has violated Section 465.016(1)(r), Florida Statutes, (2006) by violating Section 456.072(1)(c), Florida Statutes (2006), by having been found guilty, regardless of adjudication, in a court of this state of a crime which directly relates to the ability to practice pharmacy or to the practice of pharmacy.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees

billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 28th day of November, 2007.

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

Lynne A. QuimbyPennock
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar # 0394572
850.245.4640 ext. 8160
850.245.4682 FAX

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK:
DATE 11-30-07

PCP: 11.28.07
PCP Members: Garcia/Alvarez

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

vs. CASE NO. 2006-42732

DOUGLAS N. KASSAN, R.PH.,

Respondent.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above named parties hereby offer this Settlement Agreement to the Board of Pharmacy as disposition of the Administrative Complaint, attached hereto as Exhibit A, in lieu of any other administrative proceedings. The terms herein become effective only if and when a Final Order accepting this Settlement Agreement is issued by the Board and filed. In considering this Settlement Agreement, the Board may review all investigative materials regarding this case. If this Settlement Agreement is rejected, it, and its presentation to the Board, shall not be used against either party.

STIPULATED FACTS

1. For all times pertinent herein, Respondent was a licensed pharmacist in the State of Florida, having been issued license number PS 28503. Respondent's address of record is P.O. Box 3238, St. Petersburg, Florida 33738-3238.

2. Respondent was charged by an Administrative Complaint filed by the Department and properly served upon Respondent with violations of Chapters 456 and 465, Florida Statutes.

3. Respondent neither admits the factual allegations contained in the Administrative Complaint for the purposes of settlement in these administrative proceedings only.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department of Health and the Board.

2. Respondent admits that the stipulated facts, if proven true, constitute violations of law as alleged in the Administrative Complaint.

PROPOSED DISPOSITION

1. Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and the disposition thereof.

2. The Board of Pharmacy shall impose the administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **THREE THOUSAND DOLLARS** ($3,000.00). Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs are to be paid by Respondent to the **Department of Health, Compliance Management Unit, Pharmacy Compliance Officer, P.O. 6320, Tallahassee, Florida 32314-6320,** payable prior to presentation of Petition for Reinstatement.

3. Respondent shall successfully complete a continuing education course on the laws and rules governing the practice of pharmacy in Florida that is not shorter than twelve (12) hours in length, within one (1) year of entry of the Final Order accepting and adopting this Settlement Agreement ***or*** he shall successfully complete the Multistate Pharmacy Jurisprudence Examination (Florida version) within ONE (1) year of entry of the Final Order accepting and adopting this Settlement Agreement. These continuing education hours shall be in addition to the hours required for

license renewal. Within ten (10) days of completion of the course(s) and/or receipt of the certificate(s) of completion, Respondent shall mail a copy of the continuing education certificate(s) of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above. Respondent shall provide documentation of successful passage of the examination within ten (10) days of receipt of the score. Such documentation shall be provided to the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, Board of Pharmacy, 4052 Bald Cypress Way, Bin C01, Tallahassee, Florida 32399-3251.

4. Respondent shall enter and successfully participate in a Professionals Resource Network (PRN) evaluation, treatment, and monitoring contract the terms and provisions of which shall be determined by PRN. Respondent shall comply with all requirements and recommendations of PRN.

5. Respondent's license shall be suspended until such time as Respondent petitions and appears before the Board to demonstrate his ability to practice pharmacy with reasonable skill and safety to patients and shall provide a practice plan detailing his pharmaceutical employment

intentions for the Board's approval. Such demonstration shall include an evaluation by a Board approved treatment provider and Respondent shall answer any questions asked by the Board. Such practice plan shall include the location of Respondent's intended practice, the type of practice, the number of employees (both professional and support), supervision delineations, and protocol for the handling of controlled substances. Said petition may be filed to be heard at the same time as the settlement agreement is presented, but may also be filed at a later time.

6. Upon reinstatement of his license to practice as a pharmacist, Respondent's license shall be placed on probation for a period of not less than ten (10) years. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. Respondent shall not work at more than two (2) pharmacies without prior written authorization from the Board.

b. Respondent shall submit written reports to the Compliance Officer for the Board of Pharmacy that contain licensee's name, licensee's license number, current address, and phone number; current name, address, and phone number of each pharmacy at which Respondent is engaged in the practice of pharmacy; the names of

all pharmacists, pharmacy interns, pharmacy technicians, relief pharmacists, and prescription department managers working with Respondent. If Respondent works for a placement agency, Respondent's report shall include: the name, address and telephone number of the placement agency and list the pharmacies, including addresses and dates that Respondent worked at each pharmacy, and the name of the supervising or primary pharmacist. These reports shall be submitted to the Compliance Officer every three (3) months in a manner as directed by the Compliance Officer.

c. Respondent shall submit documentation evidencing that his employer, or if employed as a relief or agency pharmacist, his supervising pharmacist(s) and the relief agency, have been provided with a copy of the Final Order describing these probationary terms within ten (10) days of the entry of the Final Order or upon initiation of employment.

d. Respondent shall ensure that his employer or the supervising pharmacist at each pharmacy at which Respondent works, submits written reports to the Compliance Officer for the Board of

Pharmacy. If Respondent is employed by an agency, the written reports must be submitted by the supervising pharmacist at each pharmacy at which Respondent works. These reports shall contain: the name, current address, license number, and telephone number of each pharmacy intern, pharmacy technician, relief pharmacist, and prescription department manager working with Respondent in the prescription department; a brief description of Respondent's duties and responsibilities; and Respondent's work schedule. These reports shall be submitted by the employer to the Compliance Officer every three (3) months in a manner directed by the Department Compliance Officer.

e. The Department shall conduct semi-annual audits of five randomly selected controlled substances. The Department's costs and expenses for the audits shall be paid by Respondent in the manner directed by the Department.

f. The Department shall conduct semi-annual inspections of Respondent's place(s) of employment, at Respondent's cost.

g. Respondent shall not work as a prescription department manager in any Florida licensed pharmacy.

h. If Respondent leaves the State of Florida for a period of thirty (30) days or more, if PRN withdraws Respondent from the practice of pharmacy, or if Respondent ceases the professional practice of pharmacy in the State, Respondent's probation shall be tolled until such time as Respondent returns to the active, professional practice of pharmacy in the State of Florida. The professional practice of pharmacy, for purposes of this settlement agreement only, shall mean working in a licensed pharmacy setting for not less than thirty-five (35) hours a week.

i. Respondent shall comply with any and all requirements and recommendations of PRN.

j. During the last three (3) months of the probationary period, Respondent shall petition and appear before the Board of Pharmacy requesting termination of probation. The Board reserves the right to impose additional conditions or restrictions or extend Respondent's probationary period if deemed appropriate at that time.

7. In the future, Respondent shall not violate Chapter 456, 465, 499, and/or 893, Florida Statutes, the rules promulgated pursuant thereto,

or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

8. It is expressly understood that a violation of the terms of this Settlement Agreement shall be considered a violation of a Final Order of the Board of Pharmacy for which disciplinary action may be initiated pursuant to Chapter 465, Florida Statutes.

9. It is expressly understood that this Settlement Agreement is subject to approval by the Board and Department and has no force or effect until the Board bases an Order upon it.

10. This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular cause. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration

of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

11. Respondent and the Department fully understand that this Settlement Agreement and subsequent Final Order incorporating same will not preclude additional proceedings by the Board and/or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint, attached hereto as Exhibit A.

12. Respondent waives the right to seek any attorney's fees or costs from the Department in connection with this disciplinary proceeding.

13. Respondent waives all rights to appeal and further review of this Settlement Agreement and these proceedings.

WHEREFORE, the parties hereby request that the Board enter a Final Order accepting, adopting, and implementing the terms contained herein.

SIGNED this 14 day of February, 2008.

DOUGLAS N. KASSAN, R.PH.
CASE NO. 2006-42732

N. WANUGHA
Notary Public. State of Florida
Commission# DD 540110
My comm. expires April 3, 2009

D.N.K
D Neil Kassan

STATE OF FL
COUNTY OF Polk

Before me personally appeared Douglas N. Kassan, whose identity is known to me or by FL State ID (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 21st day of February, 2008.

Notary Public
My Commission Expires: 10/8/10

ELIZABETH HARTLEY
Notary Public, State of Florida
Commission# DD586909
My comm. expires Oct. 8, 2010

APPROVED this 25th day of February, 2008.

Ana M. Viamonte Ros, M.D., M.P.H.,
State Surgeon General

Billie Jo Owens,
Assistant General Counsel

Counsel for Petitioner:
Billie Jo Owens
Florida Bar No. 0211958
Assistant General Counsel
Department of Health
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
850.245.4640
850.245.4682 fax

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE SEP 12 2012

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

vs.

Case No.: 2006-42732
License No.: PS 28503

DOUGLAS N. KASSAN, R.PH.,

Respondent.
_____/

ORDER APPROVING REQUEST TO MODIFY FINAL ORDER

THIS MATTER came before the Board of Pharmacy (Board) at the duly-noticed meeting on August 15, 2012 in Tallahassee, Florida, upon Respondent's request to modify the final order to allow Respondent to work as a Prescription Department Manager. Petitioner was present. The Board voted to approve the request.

THEREFORE, Respondent's Final Order is amended to allow Respondent to work as a Prescription Department Manager. No other terms of the Final Order were changed.

This order shall be placed in and become a part of Respondent's official records and shall become effective upon filing with the Clerk of the Department of Health.

DONE and ORDERED, this 12th day of September, 2012.

BOARD OF PHARMACY

Mark Whitten, Executive Director *for*
Cynthia Griffin, PharmD, Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by Certified Mail to Douglas Kassan, 201 5th Street S., Apt 10, Saint Petersburg, Florida 33701; by interoffice mail to Allison Dudley, Assistant Attorney General, Office of the Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050; this 12th day of Sept., 2012.

Angel Sanders

Deputy Agency Clerk

7012 1640 0000 3561 2677

STATE OF FLORIDA
BOARD OF PHARMACY

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE AUG 2 5 2011

DEPARTMENT OF HEALTH,

Petitioner,

vs.

DOH CASE NO.: 2006-42732
LICENSE NO.: PS 28503

DOUGLAS KASSAN, RPH,

Respondent.
_____/

ORDER DENYING REQUEST FOR MODIFICATION OF PROBATION

This matter came before the Board of Pharmacy (hereinafter the "Board") at a duly noticed public meeting held on August 3, 2011 in Orlando, Florida, pursuant to the Respondent's request for modification of probation. The Respondent was not present.

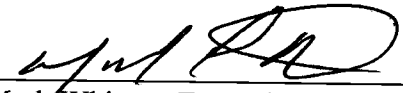
Upon consideration of Respondent's request, the arguments of the parties, and being otherwise advised in the premises,

IT IS HEREBY ORDERED AND ADJUDGED that the Respondent's request to modify probation is DENIED.

This Order shall take effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 25 day of August, 2011.

BOARD OF PHARMACY



Mark Whitten, Executive Director *for*
Carl "Fritz" Hayes, BPharm, Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by Certified Mail to Douglas Kassan, R.Ph.; by interoffice mail to Allison Dudley, Assistant Attorney General, Office of the Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050; this 25th day of August, 2011.

Angel Sanders

Deputy Agency Clerk

7011 1150 0001 4539 9140

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City, State, ZIP+4

PS Form 3800, August 2006 See Reverse for Instructions

Nelson, Sondra

From: Collins, Tammy
Sent: Thursday, December 12, 2013 7:29 PM
To: Nelson, Sondra
Cc: Cumbie, James A
Subject: FW: Contact via Florida | Board of Pharmacy - Appearance befor the Board Request

Hi Sondra,

Would you please let Mr. Kassan know what he needs to do to be presented to the Board in February? We need his file by December 20, 2013 to meet the agenda deadline.

Thank you so much! :)

Tammy Collins, CPM
Acting Executive Director
Florida Department of Health
Board of Pharmacy
Direct line (850) 245-4614
Reception area (850) 245-4292
Direct Fax (850) 413-6982

From: Douglas N Kassan [mailto:dnkassan@outlook.com]
Sent: Sunday, November 17, 2013 12:01 PM
To: info@floridaspharmacy.gov
Subject: Contact via Florida | Board of Pharmacy - Appearance befor the Board Request

From:
Douglas N Kassan - dnkassan@outlook.com

Subject: *Appearance befor the Board Request*

Message Body:
At the last board meeting I attended in August 2012, I was instructed to request an appearance before the Board 3 months prior to the ending of my PRN contract. My contract ends in April 2014. Is there any procedures I should follow, in addition to this request, to appear before the Board at next scheduled meeting available? thank you, Douglas Kassan PS28503 7276562403

Send a Reply ->

--
This mail is sent via the Contact Form on Florida Board of Pharmacy
www.FloridasPharmacy.gov

Douglas Neil Kassan RPh.
Case # 2006-42732
201 5TH ST S, APT 10
SAINT PETERSBURG, FL 33701

FLORIDA DEPARTMENT OF HEALTH
COMPLIANCE MANAGEMENT TEAM
ATTN:SONDRA NELSON-ALLEN4
PHARMACIST COMPLIANCE OFFICER
4052 BALD CYPRESS WAY, BINC76
TALLAHASSEE, FL 32399

CURRENT EMPLOYMENT INFORMATION

RX SPECIALTY PHARMACY/PHARMETRICS
11880 28TH ST N, SUITE 100
SAINT PETERSBURG, FL 33716
727-302-8135

EMPLOYMENT STATUS: FULL-TIME
COMPOUNDING PHARMACY – NON-STERILE PREPARATIONS

LOCATION IS THE SAME BUILDING WHERE THE NEW PHARMACY HAS BEEN OPENED ON FIRST FLOOR.

ASSOCIATES INCLUDE:

KERRY B. EARLYWINE, PHARMACIST-IN-CHARGE LICENSE PS50127
DEAN A. PEDALINO, SENIOR PHARMACIST LICENSE PS19523
FREDDY PAGAN, PHARMACY TECHNICIAN LICENSE RPT29469
NICHOLE JONES, PHARMACY TECHNICIAN LICENSE RPT25900
KARLA BENNTT, PHARMACY TECHNICIAN LICENSE RPT25724

THE NOVEMBER MONITOR/SUPERVISR REPORT ALONG WITH SELF-REPORT WILL BE SUBMITTED FOR BOTH INFUSERVE AND PHARMETRICS TO COVER EMPLOYMENT PERIOD.

Best regards,

DOUGLAS NEIL KASSAN RPH
CASE 3 2006-42376
PH: 727-656-2403

PHARMACIST: DOUGLAS N. KASSAN RPh.

FLORIDA DEPARTMENT OF HEALTH
COMPLIANCE MANAGEMENT TEAM
ATTN: SONDRA NELSON-ALLEN
PHARMACIST COMPLIANCE OFFICER
4052 BALD CYPRESS WAY, BIN C76
TALLAHASSEE, FL 32399

SELF REPORT FOR NOVEMBER 2013

1) DOUGLAS NEIL KASSAN LICENSE PS 28503
2) 201 5TH ST S APT 10 SAINT PETERSBURG, FL 33701
3) LICENSE IS ON PROBATION # 2006-42732
4) PRACTICE LOCATION: 11880 28TH ST N, STE 100, ST PETERSBURG, FL 33716
5) CURRENT PRACTICE: PHARMACY, TOPICALS
6) COMPLIANCE WITH PROBATION TERMS: YES
7) MONITOR/PHARMACY SUPERVISOR
8) NO PROBLEMS
9) CHART REVIEWS; N/A

PHARMETRICS SPECIALTY RX, LLC

PHARMACISTS:

DEAN A. PEDALINO	PS11034
KERRY B. EARLYWINE	PS50127

PHARMACY TECHNICIAN: FREDDY PAGAN	RPT29469
PHARMACY TECHNICIAN: KARLA M. BENNETT	RPT25724
PHARMACY TECHNICIAN: EDA L. STEINBECK	RPT46653

DATES OF EMPLOYMENT -
NOVEMBER 4, 2013 - CURRENT

TARA WILLIS
MY COMMISSION # EE 852549
EXPIRES: February 9, 2017
Bonded Thru Notary Public Underwriters

Tara Willis

SIGNED: DOUGLAS N KASSAN PS28503

11-18-13

PHARMACIST: DOUGLAS N. KASSAN RPh.

FLORIDA DEPARTMENT OF HEALTH
COMPLIANCE MANAGEMENT TEAM
ATTN: SONDRA NELSON-ALLEN
PHARMACIST COMPLIANCE OFFICER
4052 BALD CYPRESS WAY, BIN C76
TALLAHASSEE, FL 32399

SELF REPORT FOR NOVEMBER 2013

1) DOUGLAS NEIL KASSAN LICENSE PS 28503
2) 201 5TH ST S APT 10 SAINT PETERSBURG, FL 33701
3) LICENSE IS ON PROBATION # 2006-42732
4) PRACTICE LOCATION: 11880 28TH ST N, STE 200, ST PETERSBURG, FL 33716
5) CURRENT PRACTICE: PHARMACY INFUSION/PARENTERAL/ENTERAL
6) COMPLIANCE WITH PROBATION TERMS: YES
7) MONITOR/PHARMACY SUPERVISOR
8) NO PROBLEMS
9) CHART REVIEWS; N/A

INFUSERVE AMERICA INC

PHARMACISTS:

DAVID KAZARIAN	PS11034 and PU5398
NANCY KAZARIAN	PS11035 and PU3991
RANDOLPH BRETON	PS27126 and PU5616
ANTHONY WOLFINBARGER	PS26111 and PU4350

PHARMACY TECHNICIAN: ALICIA HAZELTON	RPT46916
PHARMACY TECHNICIAN: TARA WILLIS	RPT34876
PHARMACY TECHNICIAN: ALMA MENENDEZ-RODRIGUEZ	RPT34875

DATES OF EMPLOYMENT -
JUNE 5, 2013 – NOVEMBER 1, 2013

TARA WILLIS
MY COMMISSION # EE 852549
EXPIRES: February 9, 2017
Bonded Thru Notary Public Underwriters

SIGNED: DOUGLAS N KASSAN PS28503

11-18-13

INFUSERVE AMERICA INC.
11880 28TH STREET NORTH, SUITE 200
SAINT PETERSBURG, FL 33716
(727) 573-7847

FLORIDA DEPARTMENT OF HEALTH
COMPLIANCE MANAGEMENT TEAM
ATTN: SONDRA NELSON-ALLEN
PHARMACIST COMPLIANCE OFFICER
4052 BALD CYPRESS WAY, BIN C76
TALLAHASSEE, FL 32399

MONITOR/SUPERVISOR REPORT FOR DOUGLAS NEIL KASSAN, NOVEMER 2013

1) LICENSE CASE # 2006-42732
2) PRACTICE LOCATION: 11880 28TH ST N, STE 200, ST PETERSBURG, FL 33716
3) PRACTICE: PHARMACY, INFUSION/PARENTERAL/ENTERAL
4) COMPLIANCE: QUARTERLY REPORT
5) MONITOR/PHARMACY SUPERVISOR
6) PROBLEMS: N/A
7) CHART REVIEWS: N/A
8) DATE OF CHART REVIEWS: N/A
9) NUMBER OF CHART REVIEWS: N/A

PHARMACY MONITOR/SUPERVISOR:

ANTHONY L WOLFINBARGER RPh, CPh. Pharmacist-in-Charge
email: anthony@infuserveamerica.com

TARA WILLIS
MY COMMISSION # EE 352549
EXPIRES: February 9, 2017
Bonded Thru Notary Public Underwriters

SIGNED: ANTHONY L WOLFINBARGER
11-18-2013

PHARMETRICS SPECIALTY RX
11880 28TH STREET NORTH, SUITE 100
SAINT PETERSBURG, FL 33716
(727) 573-7847

FLORIDA DEPARTMENT OF HEALTH
COMPLIANCE MANAGEMENT TEAM
ATTN: SONDRA NELSON-ALLEN
PHARMACIST COMPLIANCE OFFICER
4052 BALD CYPRESS WAY, BIN C76
TALLAHASSEE, FL 32399

MONITOR/SUPERVISOR REPORT FOR DOUGLAS NEIL KASSAN, NOVEMER 2013

1) LICENSE CASE # 2006-42732
2) PRACTICE LOCATION: 11880 28TH ST N, STE 200, ST PETERSBURG, FL 33716
3) PRACTICE: PHARMACY, COMPOUNDING/TOPICALS
4) COMPLIANCE: QUARTERLY REPORT
5) MONITOR/PHARMACY SUPERVISOR
6) PROBLEMS: N/A
7) CHART REVIEWS: N/A
8) DATE OF CHART REVIEWS: N/A
9) NUMBER OF CHART REVIEWS: N/A

PHARMACY MONITOR/SUPERVISOR:

DEAN A PEDALINE RPh, CPh. Owner/Senior Pharmacist PS261[illegible]1 and PU4350
email: dean.pedalino@pharmetricsrx.net

DEAN A PEDALINO
11/18/13

TARA WILLIS
MY COMMISSION # EE 852549
EXPIRES: February 9, 2017
Bonded Thru Notary Public Underwriters

Tara Willis

CONFIDENTIAL AND EXEMPT MATERIALS

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

January 24, 2014

Michael Shane Miller
189 Hilton Road
Gate City, VA 24251

RE: Request for Board Appearance

Dear Mr. Miller:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are required to appear per Board order. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE APR 30 2013

STATE OF FLORIDA
BOARD OF PHARMACY

IN RE: THE APPLICATION OF

MICHAEL SHANE MILLER
_____/

NOTICE OF INTENT TO APPROVE LICENSE ON CONDITIONS

This matter appeared before the Board of Pharmacy at a duly-noticed public meeting held on April 3, 2013, in St. Petersburg, Florida, for consideration of an application for a license as a pharmacist by endorsement. The applicant was present. Upon consideration of the information provided, and being otherwise advised in the premises, the Board has determined that the application for a license as a pharmacist is conditionally approved with the following conditions and restrictions on licensure:

1. Applicant is entitled to take the pharmacy jurisprudence examination.

2. Upon successful completion of the jurisprudence examination, the applicant's license will be issued by the department one year from the effective date of this order if the applicant does not receive any further discipline in any other jurisdiction for all health licenses the applicant holds and the applicant must take a 12 hour laws and rules continuing education course which has been approved by the board. The applicant must appear before the Board before issuance of license to establish all conditions have been met.

3. If the applicant receives any other discipline in any other jurisdiction or does not complete the laws and rules course, the application for license as a pharmacist is denied.

4. The Board proposes these restrictions or conditions for the following reasons:

a. Pursuant to Section 465.016(1)(h), Florida Statutes (2012), the Board may deny an applicant for having been disciplined by a regulatory agency in another state for any offense that would constitute a violation of this chapter.

b. The applicant has had prior discipline to pharmacy licenses in other jurisdictions.

This Notice shall become effective upon filing with the Clerk of the Department of Health; and will become a Final Order if no further action is taken within the time period stated below.

DONE AND ORDERED this 26 day of April, 2013.

BOARD OF PHARMACY

Mark Whitten
Executive Director *for*
Albert Garcia, Chair

NOTICE OF RIGHT TO HEARING

THIS NOTICE CONSTITUTES A FINAL ORDER AND FINAL AGENCY ACTION IF NO REQUEST FOR A HEARING IS RECEIVED BY THE BOARD ON OR BEFORE THE TWENTY-FIRST DAY AFTER THE APPLICANT'S RECEIPT OF THE NOTICE. THE APPLICANT MAY REQUEST A HEARING BY FILING AN APPROPRIATE PETITION WITH THE EXECUTIVE DIRECTOR OF THE BOARD AT 4052 BALD CYPRESS WAY, BIN # C-04, TALLAHASSEE, FLORIDA 32399-3256. THE APPLICANT MAY PETITION FOR A HEARING INVOLVING DISPUTED ISSUES OF MATERIAL FACT BEFORE AN ADMINISTRATIVE LAW JUDGE PURSUANT TO SECTION 120.57 (1), FLORIDA STATUTES, OR FOR A HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT PURSUANT TO SECTION 120.57 (2) FLORIDA STATUTES.

A PETITION FOR A HEARING INVOLVING DISPUTED ISSUES OF MATERIAL FACT MUST CONTAIN INFORMATION REQUIRED BY RULE 28-106.201, FLORIDA ADMINISTRATIVE CODE, INCLUDING A STATEMENT OF ALL DISPUTED ISSUES OF MATERIAL FACT. THE BOARD MAY REFER A PETITION TO THE DIVISION OF ADMINISTRATIVE HEARINGS FOR ASSIGNMENT OF AN ADMINISTRATIVE LAW JUDGE ONLY IF THE PETITION IS IN SUBSTANTIAL COMPLIANCE WITH THE RULE REQUIREMENTS. A PETITION FOR A PROCEEDING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT MUST CONTAIN INFORMATION REQUIRED BY RULE 28.106.301 FLORIDA ADMINISTRATIVE CODE, INCLUDING A CONCISE STATEMENT OF THE ULTIMATE FACTS ALLEGED, AS WELL AS THE RULES AND STATUTES WHICH ENTITLE PETITIONER TO RELIEF.

IN ACCORDANCE WITH SECTION 120.573, FLORIDA STATUTES MEDIATION IS NOT AVAILABLE.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by Certified Mail to **Michael Shane Miller** at 189 Hilton Road, Gate City, VA 24251; by electronic mail to David D. Flynn, Assistant Attorney General, david.flynn@myfloridalegal.com Office of the Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050; this 30th day of April, 2013.

Angel Sanders

Deputy Agency Clerk

7004 0750 0004 3692 8209

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Michael Shane Miller 1870166

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

PARTICIPANT INFORMATION		PROGRAM INFORMATION	
NAME	University of Florida College of Pharmacy	TITLE	Pharmacy Laws and Rules Course
ACPE I.D. UNIV. PROG. NO.	0012-9999-12-223-H03-P/T, 20-358686 (A)	DATE	8/26/2013

PARTICIPANT INFORMATION

NAME: Shane Miller

ADDRESS: 189 Hilton Road

CITY, STATE, ZIP: Gate City VA 24251

LICENSE NO. (S):

CREDIT INFORMATION

CREDITS ISSUED: 1.2 CEU

OR 12 CONTACT HOURS

DATE: 8/26/2013

AUTHORIZED SIGNATURE: Arthur E Wharton

File

42766

March 13, 2013

Michael Shane Miller
189 Hilton Road
Gate City, VA 24251

RE: Application for Licensure by Endorsement

Dear Mr. Miller:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, April 3, 2013. The meeting is being held at the Hilton Hotel Carillon Park 950 Lake Carillon Drive, St Petersburg, FL 33716, (727) 540-0050. The meeting will begin at 8:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4614.

Sincerely,

Tammy Collins,
Program Operations Administrator

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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12/19/2012 295.00
ID: 42766 Type: F
BT: 3010900
VL: 912033336

FLORIDA DEPARTMENT OF HEALTH

FLORIDA BOARD OF
P.O. Box 6320 • Tallah
Phone: (850) 245-4292
www.doh.state.fl.us/mc

ITEM #2 – PHARMACIST ENDORSEMENT APPLIC.
FEE: $295.00

2201-42764

Please print or type legibly.

1. Biographical Data			
Last Name	**First Name**	**Middle Name**	
MILLER	MICHAEL	SHANE	
Street Address (ML – Mailing Address)	**City**	**State**	**Zip**
189 HILTON RD	GATE CITY	VA	24251
Work Address (PL – Practice Location)	**City**	**State**	**Zip**
1710 Cleveland Hwy	DALTON	GA	30721
Home Phone Number	**Business Phone Number**	**E-Mail Address**	
(276) 386-7669	(276) 494-1124	shanemiller@earthlink.net	
Date of Birth	**Place of Birth**		
10/12/68	Kingsport TN		

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☒ Male ☐ Female
RACE: ☒ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. Have you ever changed your name through marriage or through action of a court or have you ever been known by any other name? If yes, list name(s) and date(s) of the changes below. *Use a separate sheet, if necessary.*

Yes _____ No X

NAME	DATE

4. Name of university, college or school of pharmacy attended:

Medical College of Virginia – VA Commonwealth Univ.

5. Date Of Graduation	**6. Type Of Degree Earned**	**7. Have you ever been licensed as an intern in Florida?**
5/91	Bachelor's	Yes _____ No X Intern License Number: _____

8. Please indicate the date you successfully completed the NAPLEX examination.

Date 6/15/91

9. Would you be willing to provide health services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disasters?

Yes X No _____

10. Method of application - Please select one of the methods of application listed below; you must submit proof that the requirement you choose has been met.

X A. Two years of active practice within two (2) of the last five (5) years.

_____ B. Successful completion of an internship within the immediately preceding two (2) years.

PLEASE NOTE: If you have been licensed in another state in excess of 2 years from the date of your application you must choose A and have completed 30 hours of continuing education in the previous two (2) calendar years. If you choose "B" your internship date will be determined by the Board based on your graduation date, unless the state board of pharmacy where your hours were earned submits the certification of intern hours earned in that state within the preceding two (2) years.

11. List two years work experience if you are applying under 10A Note: you must submit one (1) Internship or Work Experience Form – Form B (Item #4) for each employer listed below. ***Use a separate sheet, if necessary.*** **List internship experience if you are applying under 10B.**

Dates	Employer	Location	Intern Or Pharmacy Experience	Total Hours
2/1/12 -	S+W Pharmacy	Dalton GA	Rx experience	
10/01/09 - 6/23/11	CVS Caremark	Gate City VA	Rx experience	

12. List all jurisdictions in which you have been licensed as a pharmacist. Note: you must submit one (1) Licensure Verification Form (Item #5) for each listed below. ***Use a separate sheet, if necessary.***

State or U.S. Jurisdiction	License Number	Date Issued
See Attached Sheet		

13. Special Testing Accommodations – please indicate if you require special testing accommodations due to a disability, or if you have a religious conflict with the scheduled examination date. **If yes, complete the Request for an Application for Testing Accommodations (item #6) and submit it to Testing Services. You may also contact Testing Services by telephone (850) 245-4252 for detailed information and an application. All requests must be made in writing and include supporting documents.**

Yes _____ No X

14. Have you ever been convicted of, or entered a plea of guilty, nolo contendre, or no contest, to a crime in any jurisdiction other than a minor traffic offense?

Yes _____ No X

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

19. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state or U.S. jurisdiction?
Yes X No _____
20. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No X
21. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No X
22. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If no, do not answer 23 A-C.)
Yes _____ No X
23. If "yes" to 22, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No X
23a. If "yes" to 22, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No X
23b. If "yes" to 22, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No X
23c. If "yes" to 22, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes _____ No X
24. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?
Yes _____ No X
24a. If "yes" to 24, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes _____ No X

25. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 25b.)
Yes _____ No X
25b. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No X
26. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 26a and 26b.)
Yes _____ No X
26a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No X
26b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No X
26. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities? (If "yes", please provide official documentation)
Yes_____ No X
27. If "yes" to any of the questions 22 through 26 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes_____ No X

All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 16-26, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacist's license may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other document, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

Applicant Signature _____ Date 10/2/12

NOTE: Please check to be sure that you have answered all of the questions above.

10/2/2012

Florida Board of Pharmacy
4052 Bald Cypress Way C-04
Tallahassee, FL 32399-3254

In response to item #12 of the Offical Application for Licensure, please find my current license status as:

1) Virginia, license # 10416, issued 6/1991

2) West Virginia, license # RP0007883, issued 6/21/12

3) Tennessee, license # 10287, issued 11/1999

4) Georgia, license # RPH026452, issued 2/27/2012

5) Kentucky, license # 015861, issued 03/20/2012

FLORIDA BOARD OF PHARMACY
4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254
Phone: (850) 245-4292 • www.doh.state.fl.us/mqa/pharmacy

Board of Pharmacy OCT 3 REC'D

42766

ITEM #3 - CERTIFICATE OF PHARMACY EDUCATION (FORM A)

Please print or type legibly.

Part I. – To be completed by applicant and forwarded to the College of Pharmacy for completion of Part II below.

Last name	First name	Middle name
MILLER	MICHAEL	SHANE

Maiden name/surname	Date of graduation
	5/1991

Mailing address	City	State	Zip
189 HILTON Rd	GATE CITY	VA	24251

Part II. – To be completed by College of Pharmacy Dean

Name of School/College of Pharmacy: Virginia Commonwealth University – School of Pharmacy

Mailing address	City	State	Zip
410 North 12th Street	Richmond	VA	23298-0581

Type of degree awarded	Date degree awarded	Dates of attendance
Bachelor of Science in Pharmacy	May 18, 1991	From: 08/23/1989 To: 05/18/1991

The information recorded above is true and correct according to the official records of this institution. Failure to include the school seal may result in a delay in processing the applicant's application.

Thomas Reinders
Print Name

Thomas Reinders
Signature

(SCHOOL SEAL)

Associate Dean for Admissions & Student Services
Title

October 12, 2012
Date

NOTE: Please check to be sure that you have answered all of the questions above.

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY
BIN #C-04
TALLAHASSEE, FL 32399-3254

Board of
OCT 15 REC'D
Pharmacy

42766

FLORIDA DEPARTMENT OF HEALTH

FLORIDA BOARD OF PHARMACY
4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254
Phone: (850) 245-4292 • www.doh.state.fl.us/mqa/pharmacy

ITEM #4 – INTERNSHIP OR WORK EXPERIENCE FORM (FORM B)

Please print or type legibly.

1. Biographical information			
Applicant Name	Intern/Pharmacist License Number	Phone Number	
M. Shane Miller	10416 (VA)	(276) 386-7669	
Street Address	City	State	Zip
189 Hilton Rd	Gate City	VA	24251

2. Have you submitted an application for the Florida Pharmacist Examination? If yes, please indicate date.

Yes _____ No X Date 10/1/12 App submitted for Endorsement

I HEREBY APPLY FOR INTERNSHIP OR WORK EXPERIENCE CREDIT AS OUTLINED BELOW UNDER THE SUPERVISION OF:

3. Pharmacy information			
Supervising Pharmacist's Name		License Number	
Sheila Breedlove		TN-3807	
Pharmacy Name		Permit Number	
CVS #7343		0201 002137	
Street Address	City	State	Zip
241 Gateway Plaza	Gate City, Va. 24251		
Phone Number	4. Dates of Experience		
276-386-6644	From: 09/01/09	To: 6/22/11	
5. Average number of hours per week		6. Total hours of experience	
40		Worked Full Time	

(No more than 50 hours per week if you are a student and no more than 60 after graduation is allowed)

Applicant's Signature _____ Date 10/2/12

This report is a correct statement of fact. The above information was taken from the records of the above named pharmacy and are available for inspection by the Board of Pharmacy.

Sheila Breedlove
Preceptor/Supervisor's Signature _____ Date 10-8-12

NOTE: Please check to be sure that you have answered all of the questions above.

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY
BIN #C-04
TALLAHASSEE, FL 32399-3254

DH-MQA PH100, 02/09
Rule 64B16-26.205, F.A.C.

FLORIDA DEPARTMENT OF HEALTH

FLORIDA BOARD OF PHARMACY
4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254
Phone: (850) 245-4292 • www.doh.state.fl.us/mqa/pharmacy

ITEM #4 – INTERNSHIP OR WORK EXPERIENCE FORM (FORM B)

Please print or type legibly.

1. Biographical information			
Applicant Name	Intern/Pharmacist License Number	Phone Number	
M. Shane Miller	RPH 026452	(276) 386-7669	
Street Address	City	State	Zip
189 Hilton Rd	Gate City	VA	24251

2. Have you submitted an application for the Florida Pharmacist Examination? If yes, please indicate date.

Yes _____ No X Date _____ App. for Endorsement

I HEREBY APPLY FOR INTERNSHIP OR WORK EXPERIENCE CREDIT AS OUTLINED BELOW UNDER THE SUPERVISION OF:

3. Pharmacy information			
Supervising Pharmacist's Name		License Number	
M. Shane Miller		RPH 026452	
Pharmacy Name		Permit Number	
S+W Pharmacy		PHRE 000261	
Street Address	City	State	Zip
1710 Cleveland Hwy	Dalton	GA	30721
Phone Number	4. Dates of Experience		
(706) 259-9787	From: 2/24/12 To: / / Present		
5. Average number of hours per week	6. Total hours of experience		
40	1280 ongoing		

(No more than 50 hours per week if you are a student and no more than 60 after graduation is allowed)

Applicant's Signature _____ Date 10/2/12

This report is a correct statement of fact. The above information was taken from the records of the above named pharmacy and are available for inspection by the Board of Pharmacy.

Preceptor/Supervisor's Signature (owner) Date 10/2/12

NOTE: Please check to be sure that you have answered all of the questions above.

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY
BIN #C-04
TALLAHASSEE, FL 32399-3254

10/02/2012

Florida Board of Pharmacy
4052 Bald Cypress Way C-04
Tallahassee FL 32399-3254

Dear Sirs,

In response to item # 16 of the Official Application for Licensure, please accept the following statement regarding disciplinary action taken against my license in the Commonwealth of Virginia.

From 1996 to 2000, I appeared twice in person before the Virginia Board of Pharmacy for failure to document the required 15 hours of annual CPE. On each occasion I received a monetary penalty and reprimand. In addition, for the second offense I received an 11 day suspension of my license to practice until adequate hard copies of my completed CPE were received and recorded by the Board.

In addition, due to a peer complaint (not a patient or consumer complaint) I appeared before the Board in 2008 and 2010 to defend decisions made in the course of routine pharmacy practice. On both occasions I received a reprimand and monetary penalty for exceeding existing regulations in certain customer service decisions I made. I received praise from the Board committee for my commitment to my patients, but I was made to understand that no matter how pure the motive or how Christian the impulse to help a deserving individual, Board regulations are not to be ignored.

Please see included Order from the Virginia Board as certification that all requirements of the Virginia Board have been met, and I am happy to report that my license to practice in Virginia remains active, clear and free of any restrictions.

Sincerely,

Shane Miller

COMMONWEALTH of VIRGINIA
Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233-1463

Sandra Whitley Ryals
Director

www.dhp.virginia.gov
TEL (804) 367- 4400
FAX (804) 527- 4475

Board of Pharmacy
804/367-4456
804/527-4472 (fax)

January 25, 2008

Michael S. Miller
189 Hilton Road
Gate City, Virginia 24251

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NOTICE

Dear Mr. Miller:

This is official notification that an informal conference will be held before a Special Conference Committee ("Committee") of the Board of Pharmacy on February 21, 2008, at 1:00 p.m., at the Department of Health Professions, Perimeter Center, Commonwealth Conference Center, 9960 Mayland Drive, Suite 201, Richmond, Virginia. **You must sign in with your name and your arrival time to note your appearance. This sign-in sheet will be located on the security desk. The conferences will be held in the time order that you have recorded as present on the sign-in sheet.** Please wait in the designated waiting room and you will be called once the Committee is ready to proceed with the Conference. If you have any additional documents to be presented on your behalf, please bring five (5) copies with you.

In accordance with § 2.2-4019, 2.2-4021 and § 54.1-2400(10) of the Code of Virginia (1950), as amended ("Code"), this conference is being held to review allegations that you may have violated portions of the laws and regulations governing the practice of pharmacy in the Commonwealth of Virginia. More specifically, during the course of your employment at Food City Pharmacy #820, North Weber City, Virginia ("Food City"):

1. You may have violated § 54.1-3316(1), (7) and (13), § 54.1-3410(B)(1) and § 54.1-3411(2) of the Code and 18 VAC 110-20-320(A) of the Board of Pharmacy Regulations ("Regulations") in that on or about April 29, 2006, you refilled an expired prescription for hydrocodone/APAP 10/500 (Schedule III).

2. You may have violated § 54.1-3316(1), (7) and (13), § 54.1-3410(C) and § 54.1-3411(4) of the Code and 18 VAC 110-20-320(B) of the Regulations in that on or about April 22, 2006, you refilled three expired prescriptions for Lopressor (metoprolol tartrate), colchicine and Imdur (isosorbide mononitrate) (all Schedule VI) each with a 30-day supply.

3. You may have violated § 54.1-3316(1) and (7) and (13) and § 54.1-3410(D) of the Code in that between April 18, 2006, and May 1, 2006, you received oral prescriptions without making a written record of the full name of the agent of the prescriber transmitting the prescription.

4. You may have violated § 54.1-3316(1) and (7) and § 54.1-3410 of the Code and 18 VAC 110-20-360(A) of the Regulations in that on or about April 26, 2006, you attempted to transfer a prescription for HCTZ from Broadwater Drug when there were no remaining refills left.

5. You may have violated § 54.1-3316(1) and (7) and § 54.1-3410 of the Code and 18 VAC 110-20-360(B) of the Regulations in that between April 17, 2006, and May 3, 2006, you failed to properly record the required information on prescriptions when you transferred nine prescriptions from other pharmacies to Food City.

The purpose of an informal conference is to allow the Committee, which consists of two members of the Virginia Board of Pharmacy, to inquire into, and discuss with you personally, these allegations. After reviewing the alleged violations with you, the Committee will make a decision regarding appropriate action. The Committee is authorized to take the following actions:

1. If the Committee finds that there is insufficient evidence to warrant further action or that the charges are without foundation, they will so advise and further, you will be notified by mail that your record has been cleared of any charge that might affect your right to practice pharmacy in the Commonwealth;
2. The Committee may place you on probation with such terms as it may deem appropriate;
3. The Committee may reprimand you;
4. The Committee may impose a monetary penalty pursuant to § 54.1-2401 of the Code; or
5. The Committee may refer the case to the Board of Pharmacy or a panel thereof for a formal hearing. If the Committee is of the opinion that a suspension or revocation of your license may be justified, the Committee may offer you a consent order in lieu of a formal hearing.

You have the right to information that will be relied upon by the Committee in making a decision. Therefore, I have enclosed a copy of the documents that will be distributed to the members of the Committee and will be considered by them when discussing the allegations with you and when deliberating upon your case. **These documents are enclosed only with the original notice sent by certified mail and must be claimed at the post office.** Relevant sections of the Administrative Process Act, which govern proceedings of this nature, as well as laws relating to the practice of pharmacy and other healing arts in Virginia cited in this notice can be found on the Internet at http://leg1.state.va.us. To access this information, please click on the *Code of Virginia* for statutes and *Virginia Administrative Code* for regulations.

In its deliberations, the Committee may use the Sanction Reference Points System, as contained in the Sanction Reference Manual. The manual, which is a guidance document of the Board, may be accessed at http://www.dhp.virginia.gov/Pharmacy/. Please click on *guidance documents*, then select #110-21. You may also request a paper copy from the Board office at (804) 367-4456, option #3.

A request to continue this proceeding must be made in writing and directed to me at the address listed on this letter or it may be sent via facsimile transmission to 804/367-4456. Such request must be received by 5:00 p.m. on February 6, 2008. Only one such motion will be considered. Absent critical circumstances, such as personal or family illness, a request for a continuance after February 6, 2008, will not be considered.

You may be represented by an attorney at the informal conference. If you obtain counsel, you should do so as soon as possible, as counsel may find it necessary to request a continuance due to their unavailability. Please have counsel forward a letter of representation to me at the above address or facsimile number. Requests must be received by February 6, 2008, to be considered by the Committee. After that date, such requests will be considered on the basis of whether a good faith effort to obtain counsel within this time parameter was attempted and that you were not successful.

Please inform this office of your intention to appear at the conference at least ten (10) days prior to the scheduled date above. Should you fail to appear at the informal conference, the Committee may proceed in your absence. If you have any questions regarding this notice of informal conference or the procedures involved, please do not hesitate to contact me.

Yours truly,

Cathy M. Reiniers-Day
Deputy Executive Director

Enclosures
cc: David C. Kozera, Committee Chair
Brandon K. Yi, Committee Member
Mykl D. Egan, DHP Adjudication Specialist
Donald M. Jackson, DHP Senior Administrative Investigator (107188)

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: MICHAEL S. MILLER, PHARMACIST
License No.: 0202-010416

ORDER

2008

Pursuant to § 2.2-4019, § 2.2-4021 and § 54.1-2400(10) of the Code of Virginia (1950), as amended ("Code"), a Special Conference Committee ("Committee") of the Virginia Board of Pharmacy ("Board"), composed of David C. Kozera, Pharmacist, and Brandon K. Yi, Pharmacist, met regarding Michael S. Miller on February 21, 2008, in Henrico County, Virginia. Mr. Miller appeared in person at the informal conference and was not represented by counsel. The purpose of the informal conference was to receive and act upon evidence concerning the allegations in the Notice of Informal Conference dated January 25, 2008.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

After consideration of the evidence and statements concerning the allegations, the Committee makes the following findings of fact and conclusions of law:

1. Michael S. Miller holds license number 0202-010416 issued by the Board to practice pharmacy in the Commonwealth of Virginia.

2. During the course of Mr. Miller's employment as a pharmacist at Food City Pharmacy #820, North Weber City, Virginia:

   a. Mr. Miller violated § 54.1-3316(7) and (13), § 54.1-3410(B)(1) and § 54.1-3411(2) of the Code and 18 VAC 110-20-320(A) of the Board of Pharmacy Regulations ("Regulations") in that on April 29, 2006, he refilled an expired prescription for hydrocodone/APAP 10/500 (Schedule III).

   b. Mr. Miller violated § 54.1-3316(7) and (13) and § 54.1-3410(D) of the Code in that between April 18, 2006, and May 1, 2006, he received oral prescriptions without making a written record of the full name of the agent of the prescriber transmitting the

prescription.

c. Mr. Miller violated § 54.1-3316(7) and § 54.1-3410 of the Code and 18 VAC 110-20-360(B) of the Regulations in that between April 17, 2006, and May 3, 2006, he failed to properly record the required information on prescriptions when he transferred nine prescriptions from other pharmacies to Food City.

ORDER

WHEREFORE, on the basis of the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED that Michael S. Miller be issued a REPRIMAND. Further, the Board ORDERS that Mr. Miller shall be assessed a monetary penalty of Five Hundred Dollars ($500.00) to be paid to the Board within ninety (90) days from the date this Order is final. If the monetary penalty is not received within the prescribed deadline, an additional One Hundred Dollars ($100.00) will be assessed weekly, up to a maximum of One Thousand Dollars ($1,000.00). Failure to pay the full fee plus the additional assessed penalty within thirty (30) days of the date the maximum penalty may be assessed shall constitute grounds for the suspension of the license of Mr. Miller, and an administrative proceeding will be convened to determine whether such license shall be suspended.

Pursuant to § 2.2-4023 and § 54.1-2400.2 of the Code, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public release, inspection and copying upon request.

Should Mr. Miller disagree with the Committee's decision, he may request a formal administrative hearing before the Board or a panel thereof, pursuant to § 54.1-2400(10) of the Code, not later than 5:00 p.m. on April 10, 2008, by notifying, in writing, Elizabeth Scott Russell, Executive Director, Board of Pharmacy, Perimeter Center, 9960 Mayland Drive, Suite 300, Richmond, Virginia 23233. Upon the filing with the Executive Director for a request for a formal administrative hearing, this Order shall be vacated.

Therefore, this Order shall become final on April 10, 2008, unless a request for a formal administrative hearing is received as described above.

FOR THE BOARD:

Elizabeth Scott Russell
Executive Director

ENTERED: March 7, 2008

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the foregoing Order was mailed to Michael S. Miller at 189 Hilton Road, Gate City, Virginia 24251, on this 7th day of March, 2008.

Cathy M. Reiniers-Day
Deputy Executive Director

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: MICHAEL S. MILLER, PHARMACIST
License No.: 0202-010416

NOTICE OF HEARING

Pursuant to § 2.2-4020, § 2.2-4021, § 54.1-110, and 54.1-2400(11) of the Code of Virginia (1950), as amended ("Code"), Michael S. Miller is hereby given notice that a formal administrative hearing will be held in the presence of a panel of the Board of Pharmacy ("Board"). The hearing will be held on March 9, 2011, at 1:00 p.m., at the offices of the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Henrico, Virginia, at which time Mr. Miller will be afforded the opportunity to be heard in person or by counsel.

At the hearing, Mr. Miller has the following rights, among others: the right to representation by counsel, the right to have witnesses subpoenaed and to present witnesses on his behalf, the right to present documentary evidence and the right to cross-examine adverse witnesses. If Mr. Miller desires any witnesses to appear on his behalf, he must notify the Director of the Administrative Proceedings Division, Perimeter Center, 9960 Mayland Drive, Suite 300, Henrico, Virginia, 23233-1463, in accordance with the Instructions for Requesting Subpoenas.

The purpose of the hearing is to receive and act upon evidence that Mr. Miller may have violated certain laws and regulations governing the practice of pharmacy in Virginia, as more fully set forth in the Statement of Particulars below.

STATEMENT OF PARTICULARS

The Board alleges that during the course of his employment as the pharmacist-in-charge of CVS/pharmacy #7343, Gate City, Virginia:

1. Mr. Miller may have violated § 54.1-3316(7), and § 54.1-3410.2(B) of the Code and 18 VAC 110-20-270(C) and 18 VAC 110-20-321 of the Board of Pharmacy Regulations ("Regulations") in that, on

several occasions, he provided customers with at least four (4) expired doses of compounded phenergan (promethazine, Schedule VI).

2. Mr. Miller may have violated § 54.1-3316(7) and § 54.1-3462(1) of the Code in that he mixed generic and brand name drugs in the same prescription bottle and mislabeled the bottle in that he did not indicate that both drugs were in the bottle.

3. Mr. Miller may have violated § 54.1-3316(1) and (7), § 54.1-3432 and § 54.1-3434 of the Code and 18 VAC 110-20-190(C) of the Regulations in that, on or about February 19, 2010, as a result of an emergency, he left the premises without securing the pharmacy and leaving the pharmacy technicians unsupervised.

4. Mr. Miller may have violated § 54.1-3316(6) and (7) and § 54.1-3303(A) and (B) of the Code in that:

a. He dispensed drugs without a valid prescription. More specifically, in January 2010, he examined an employee's rash then dispensed one tablet of fluconazole 150mg (Schedule VI) to the employee.

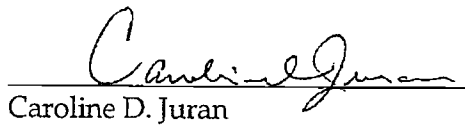
b. Mr. Miller altered the prescription as to amount supplied and number of refills available. More specifically, Mr. Miller attempted to alter the refill amounts for prescriptions written on or about January 7, 2010, for contour test strips from none to "prn" and on nadolol (Schedule VI) from three (3) to "prn."

5. Mr. Miller may have violated § 54.1-3316(1), (7) and (13) and § 54.1-3410(D) of the Code in that between December 2009, and February 2010, he received oral prescriptions without making a written record of the full name of the agent of the prescriber transmitting the prescription.

6. Mr. Miller may have violated § 54.1-3316(1), (7) and (13), § 54.1-3410(B)(1) and § 54.1-3411(2) of the Code and 18 VAC 110-20-320(A) of the Regulations in that he dispensed drugs without authorization from the prescriber. More specifically, on or about December 31, 2009, Mr. Miller issued RX #755662 for Diflucan (fluconazole, Schedule VI), when he did not have authorization to refill the drugs.

7. Mr. Miller may have violated § 54.1-3316(1) and (7) and § 54.1-3410 of the Code and 18 VAC 110-20-360(B) of the Regulations in that on or about January 13, 2010, he failed to properly record all of the required information when he received a prescription from another pharmacy.

FOR THE BOARD



Caroline D. Juran
Acting Executive Director

Entered: January 19, 2011

COMMONWEALTH of VIRGINIA

Dianne L. Reynolds-Cane, M.D.
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
TEL (804) 367- 4400
FAX (804) 527- 4475

Board of Pharmacy
804/367-4456
804/527-4472 (fax)

August 25, 2010

Michael S. Miller
Mailed to the legal address of record
With the Virginia Board of Pharmacy

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NOTICE

Dear Mr. Miller:

This is official notification that an informal conference will be held before a Special Conference Committee ("Committee") of the Board of Pharmacy on September 21, 2010, at 1:00 p.m., at the Department of Health Professions, Perimeter Center, Commonwealth Conference Center, 9960 Mayland Drive, Suite 201, Henrico, Virginia. **You must sign in with your name and your arrival time to note your appearance. This sign-in sheet will be located on the security desk. The conferences will be held in the time order that you have recorded as present on the sign-in sheet.** Please wait in the designated waiting room and you will be called once the Committee is ready to proceed with the conference. If you have any additional documents to be presented on your behalf, please bring five (5) copies with you.

In accordance with § 2.2-4019, § 2.2-4021 and § 54.1-2400(10) of the Code of Virginia (1950), as amended ("Code"), this conference is being held to review allegations that you may have violated portions of the laws and regulations governing the practice of pharmacy in the Commonwealth of Virginia. Specifically, during the course of your employment as pharmacist-in-charge of CVS/pharmacy #7343, Gate City, Virginia:

1. You may have violated § 54.1-3316(7), and § 54.1-3410.2(B) of the Code and 18 VAC 110-20-270(C) and 18 VAC 110-20-321 of the Board of Pharmacy Regulations ("Regulations") in that, on several occasions, you provided customers with at least four (4) expired doses of compounded phenergan (promethazine, Schedule VI).

2. You may have violated § 54.1-3316(1), (2) and (13) of the Code, and 18 VAC 110-20-190(C) of the Regulations in that you allowed an unauthorized person access to the prescription department.

3. You may have violated § 54.1-3316(7) and § 54.1-3462(1) of the Code in that you mixed generic and brand name drugs in the same prescription bottle and mislabeled the bottle in that you did not indicate that both drugs were in the bottle.

4. You may have violated § 54.1-3316(1) and (7), § 54.1-3432 and § 54.1-3434 of the Code and 18 VAC 110-20-190(C) of the Regulations in that, on or about February 19, 2010, as a result of an emergency, you left the premises without securing the pharmacy and leaving the pharmacy technicians unsupervised.

5. You may have violated § 54.1-3316(6) and (7) and § 54.1-3303(A) and (B) of the Code in that:

a. You dispensed drugs without a valid prescription. More specifically:

i. In January 2010, you examined an employee's rash and then dispensed one tablet of fluconazole 150mg (Schedule VI) to the employee;

ii. On or about February 5, 2010, you dispensed RX# 758650 for Ventolin HFA (albuterol, Schedule VI).

iii. On or about February 5, 2010, you dispensed RX# 758619 for Lipitor (atorvastatin, Schedule VI).

iv. On or about February 7, 2010, you dispensed RX# 758704 for promethazine (Schedule VI) when another prescription for promethazine had been issued on January 28, 2010, to the same patient.

v. On or about February 10, 2010, you dispensed RX# 758972 for valacyclovir (Schedule VI).

b. You altered the prescription as to amount supplied and number of refills available. More specifically:

i. On or about February 6, 2010, you dispensed RX# 758699 for Crestor (rosuvastatin, Schedule VI), as a refill but you altered the amount of medication dispensed and the number of refills authorized from the prescription that was written.

ii. You attempted to alter the refill amounts for prescriptions written on or about January 7, 2010, for contour test strips from none to "prn" and on nadolol (Schedule VI) from three (3) to "prn."

6. You may have violated § 54.1-3316(1), (7) and (13) and § 54.1-3410(D) of the Code in that, between December 2009, and February 2010, you received oral prescriptions without making a written record of the full name of the agent of the prescriber transmitting the prescription.

7. You may have violated § 54.1-3316(1), (7) and (13), § 54.1-3410(B)(1) and § 54.1-3411(2) of the Code and 18 VAC 110-20-320(A) of the Regulations in that you dispensed drugs without authorization from the prescriber. More specifically:

a. On or about December 31, 2009, you dispensed RX# 755662 for Diflucan (fluconazole, Schedule VI) when you did not have authorization to refill the drug.

b. On or about December 17, 2009, you dispensed RX# C754685 for hydrocodone/APAP 5/500 (Schedule III) when you did not have authorization to refill the drug.

c. On or about February 7, 2010, you issued RX# C758703 for phendimetrazine ER (Schedule III) when the prescription was on hold.

8. You may have violated § 54.1-3316(1) and (7) and § 54.1-3410 of the Code and 18 VAC 110-20-360(B) of the Regulations in that, on or about January 13, 2010, you failed to properly record all of the necessary information when you received a copy of a prescription from another pharmacy.

The purpose of an informal conference is to allow the Committee that consists of two members of the Virginia Board of Pharmacy, to inquire into, and discuss with you personally, these allegations. After reviewing the alleged violations with you, the Committee will make a decision regarding appropriate action. The Committee is authorized to take the following actions:

1. If the Committee finds that there is insufficient evidence to warrant further action or that the charges are without foundation, they will so advise and further, you will be notified by mail that your record has been cleared of any charge that might affect your right to practice pharmacy in the Commonwealth;
2. The Committee may place you on probation with such terms as it may deem appropriate;
3. The Committee may reprimand you;
4. The Committee may impose a monetary penalty pursuant to § 54.1-2401 of the Code; or

5. The Committee may refer the case to the Board of Pharmacy or a panel thereof for a formal hearing. If the Committee is of the opinion that a suspension or revocation of your license may be justified, the Committee may offer you a consent order in lieu of a formal hearing.

You have the right to information that will be relied upon by the Committee in making a decision. Therefore, I have enclosed a copy of the documents that will be distributed to the members of the Committee and will be considered by them when discussing the allegations with you and when deliberating upon your case. **These documents are enclosed only with the original notice sent by certified mail and must be claimed at the post office.** Relevant sections of the Administrative Process Act, which govern proceedings of this nature, as well as laws relating to the practice of pharmacy and

other healing arts in Virginia cited in this notice can be found on the Internet at http://leg1.state.va.us. To access this information, please click on the *Code of Virginia* for statutes and *Virginia Administrative Code* for regulations.

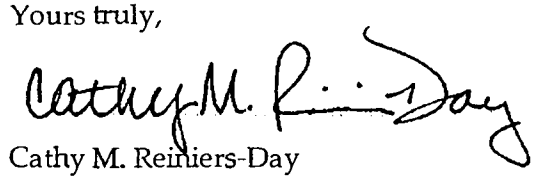
In its deliberations, the Committee may use the Sanction Reference Points System, as contained in the Sanction Reference Manual. The manual, which is a guidance document of the Board, may be accessed at http://www.dhp.virginia.gov/Pharmacy/. Please click on *guidance documents*, then select #110-21. You may also request a paper copy from the Board office at (804) 367-4456, option #3.

A request to continue this proceeding must be made in writing and directed to me at the address listed on this letter or it may be sent via facsimile transmission to 804/527-4472. Such request must be received by 5:00 p.m. on September 14, 2010. Only one such motion will be considered. Absent extraordinary circumstances, such as personal or family illness, a request for a continuance after September 14, 2010, will not be considered.

You may be represented by an attorney at the informal conference. If it is your intention to retain an attorney to represent you at this proceeding, you should do so as soon as possible, as counsel may find it necessary to request a continuance due to their unavailability. Please have counsel forward a letter of representation to me at the above address or facsimile number. Requests must be received by September 14, 2010, to be considered by the Committee. After that date, such requests will be considered on the basis of whether a good faith effort to obtain counsel within this time parameter was attempted and that you were not successful.

Please inform this office of your intention to appear at the conference at least ten (10) days prior to the scheduled date above. Should you fail to appear at the informal conference, the Committee may proceed in your absence. If you have any questions regarding this notice of informal conference or the procedures involved, please do not hesitate to contact me.

Yours truly,



Cathy M. Reiniers-Day
Deputy Executive Director

Enclosures

cc: David C. Kozera, Committee Chair
John O. Beckner, Committee Member
Mykl D. Egan, DHP Adjudication Specialist
Donald M. Jackson, DHP Investigator (#130891)

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: MICHAEL S. MILLER, PHARMACIST
License No.: 0202-010416

ORDER

Pursuant to § 2.2-4019, § 2.2-4021 and § 54.1-2400(10) of the Code of Virginia (1950), as amended ("Code"), a Special Conference Committee ("Committee") of the Virginia Board of Pharmacy ("Board"), composed of David C. Kozera, Pharmacist, and John O. Beckner, Pharmacist, met regarding Michael S. Miller, Pharmacist, on September 21, 2010, in Henrico County, Virginia. Mr. Miller appeared in person at the informal conference and was not represented by counsel. The purpose of the informal conference was to receive and act upon evidence concerning the allegations in the Notice of Informal Conference dated August 25, 2010.

After consideration of the evidence and statements concerning the allegations, the Committee makes the following findings of fact and conclusions of law:

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Michael S. Miller holds license number 0202-010416 issued by the Board to practice pharmacy in the Commonwealth of Virginia. By Order of the Board of Pharmacy ("Board Order") entered May 8, 2002, his license was suspended. Said license was reinstated on May 17, 2002. Mr. Miller was subject to a reprimand and a monetary penalty in a Board Order entered October 30, 1998, for failure to acquire continuing education. He was also reprimanded and given a monetary penalty by a Board Order entered March 7, 2008, for failure to record necessary information on transferred prescriptions and dispensing expired drugs.

2. During the course of his employment as the Pharmacist-in-Charge of CVS/pharmacy #7343, Gate City, Virginia:

a. Mr. Miller violated § 54.1-3316(7) and § 54.1-3410.2(B) of the Code and 18 VAC 110-20-270(C) and 18 VAC 110-20-321 of the Board of Pharmacy Regulations ("Regulations") in that he provided customers with four (4) expired doses of compounded phenergan (promethazine, Schedule VI).

b. Mr. Miller violated § 54.1-3316(7) and § 54.1-3462(1) of the Code in that he mixed generic and brand name drugs in the same prescription bottle and mislabeled the bottle when he failed to indicate that both drugs were in the bottle.

c. Mr. Miller violated § 54.1-3316(1) and (7), § 54.1-3432 and § 54.1-3434 of the Code and 18 VAC 110-20-190(C) of the Regulations in that on February 19, 2010, as the result of an emergency, he left the premises without securing the pharmacy department and left the pharmacy technicians unsupervised.

d. Mr. Miller violated § 54.1-3316(6) and (7) and § 54.1-3303(A) and (B) of the Code in that in January 2010, he examined an employee's rash and dispensed one tablet of fluconazole 150mg (Schedule VI) to the employee to treat the rash. The employee had no prescription for the drug.

e. Mr. Miller violated § 54.1-3316(1), (7) and (13) and § 54.1-3410(D) of the Code in that between December 2009, and February 2010, he received oral prescriptions without making a written record of the full name of the agent of the prescriber transmitting the prescription.

f. Mr. Miller violated § 54.1-3316(1), (7) and (13), § 54.1-3410(B)(1) and § 54.1-3411(2) of the Code and 18 VAC 110-20-320(A) of the Regulations in that on December 31, 2009, he dispensed the full quantity using an expired prescription, RX #755662 for Diflucan (fluconazole, Schedule VI), when he did not have authorization to refill the prescription.

g. Mr. Miller violated § 54.1-3316(1) and (7) and § 54.1-3410 of the Code and 18 VAC 110-20-360(B) of the Regulations in that on January 13, 2010, he failed to properly record all of the necessary information when he received a copy of a prescription from another pharmacy.

ORDER

WHEREFORE, on the basis of the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED that:

1. Michael S. Miller shall be issued a REPRIMAND.

2. Within ninety (90) days from the date this Order is final, Mr. Miller shall provide evidence to the Board that he has taken and passed the Virginia Drug Law Examination.

3. Michael S. Miller shall be assessed a monetary penalty of One Thousand Five Hundred Dollars ($1,500.00) to be paid to the Board within sixty (60) days from the date this Order is final. If the

monetary penalty is not received within the prescribed deadline, an additional One Hundred Dollars ($100.00) will be assessed weekly, up to a maximum of One Thousand Dollars ($1,000.00). Failure to pay the full fee plus the additional assessed penalty within thirty (30) days of the date the maximum penalty may be assessed shall constitute grounds for the suspension of the license of Mr. Miller, and an administrative proceeding will be convened to determine whether such license shall be suspended.

Mr. Miller shall maintain a course of conduct commensurate with the requirements of Chapters 33 and 34, Title 54.1 of the Code. Any violation of these terms or of any law or regulation affecting the practice of pharmacy in the Commonwealth of Virginia shall constitute grounds for the suspension or revocation of his license and an administrative proceeding shall be convened to determine whether such license shall be suspended or revoked.

Pursuant to § 2.2-4023 and § 54.1-2400.2 of the Code, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public release, inspection and copying upon request.

Should Mr. Miller disagree with the Committee's decision, he may request a formal administrative hearing before the Board or a panel thereof, pursuant to § 54.1-2400(10) of the Code, not later than 5:00 p.m. on October 31, 2010, by notifying, in writing, the Executive Director, Board of Pharmacy, Perimeter Center, Commonwealth Conference Center, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233. Upon the filing with the Executive Director for a request for a formal administrative hearing, this Order shall be vacated.

Therefore, this Order shall become final on October 31, 2010, unless a request for a formal administrative hearing is received as described above.

FOR THE BOARD:

Caroline Juran 9/28/10

Caroline D. Juran
Acting Executive Director

Entered: September 28, 2010

0202010416

COMMONWEALTH of VIRGINIA

Dianne L. Reynolds-Cane, M.D.
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

www.dhp.virginia.gov
TEL (804) 367-4400
FAX (804) 527-4475

Board of Pharmacy
804/367-4456
804/527-4472 (fax)

April 8, 2011

Michael S. Miller
189 Hilton Road
Gate City, VA 24251

Dear Mr. Miller:

Pursuant to the Board Order entered September 28, 2010, this will confirm receipt of your personal check in the amount of $1500.00 as payment of your monetary penalty. In addition, this confirms receipt of your passing test score dated November 16, 2010. As you have now fulfilled all the requirements of your Order, monitoring has ceased and your file has been closed.

Please do not hesitate to contact me at 804-367-4645 if you have any questions.

Sincerely,

Susan A. Beasecker, Compliance Case Manager
Board of Pharmacy

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

PARTICIPANT INFORMATION		PROGRAM INFORMATION	
NAME	University of Florida College of Pharmacy	TITLE	Improving Patient Safety & Preventing Medication Errors
ACPE I.D. UNIV. PROG. NO.	0012-0000-11-098-H05-P, 20-314039 (K)	DATE	12/13/2012

PARTICIPANT INFORMATION

NAME Shane Miller

ADDRESS 189 Hilton Road

CITY, STATE, ZIP Gate City VA 24251

LICENSE NO. (S)

CREDIT INFORMATION

CREDITS ISSUED: 0.2 CEU

OR 2 CONTACT HOURS

DATE 12/13/2012

AUTHORIZED SIGNATURE Arthur E. Wheaton

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-11-040-H01-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE:

Benefits of Probiotics in the Management of Gastrointestinal Disorders

RELEASE DATE:

12/20/2011

EXPIRATION DATE:

12/31/2013

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: 13-D, 14-D

STATEMENT ISSUED ON: 1/1/2012

AUTHORIZED SIGNATURE

Susanne Batesko, RN, BSN

29

ID:56703-001781-R2

Creative Educational Concepts, Inc.
116 Dennis Drive, Lexington, KY 40503
(859)260-1717 FAX: (859)276-6118

PROVIDER
Creative Educational Concepts, Inc.

ACPE NO
0245-0000-11-020-H01-P

PROGRAM
Paving a New Path: Avoiding Pain Management Pitfalls in the Community-Based Pharmacy
6/10/2011 - 6/10/2012

ACTIVITY TYPE: Knowledge-Based

Shane Miller
189 HILTON RD
Gate City, Virginia 24251

Contact us online:
http://www.ceconcepts.net

CREDITS ISSUED:

0.1 CEU

1.00 CONTACT HOURS

DATE: 1/1/2012

AUTHORIZED SIGNATURE

27

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-10-042-H01-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE:

Treatment of Otitis Media

RELEASE DATE:

11/1/2010

EXPIRATION DATE:

11/30/2012

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: 16-A, 17-C

STATEMENT ISSUED ON: 1/1/2012

AUTHORIZED SIGNATURE

Susanne Batesko, RN, BSN

26

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-11-031-H03-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE:

Update on Federal Controlled Substance Dispensing Responsibilities

RELEASE DATE:

11/1/2011

EXPIRATION DATE:

11/30/2013

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED

2.00

QUESTIONS MISSED: 4-A, 5-A

STATEMENT ISSUED ON: 1/1/2012

AUTHORIZED SIGNATURE

Susanne Batesko, RN, BSN

24

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-11-039-H01-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE

When Dietary Changes Are Not Enough: A Pharmacist's Guide To Recommending Fiber Supplementation

RELEASE DATE:

12/15/2011

EXPIRATION DATE:

12/31/2013

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: 5-D, 11-B

STATEMENT ISSUED ON: 1/1/2012

AUTHORIZED SIGNATURE

Susanne Bateska, RN, BSN

22

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-10-004-H01-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE:

Insights into the Appropriate Use of Insulin Pens

RELEASE DATE

2/1/2010

EXPIRATION DATE

2/28/2012

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: 16-B, 17-B

STATEMENT ISSUED ON: 1/1/2012

AUTHORIZED SIGNATURE

Susanne Bateskо, RN, BSN

20

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-11-028-H03-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE

Medication Disposal: Current Issues and Legal Considerations for Pharmacists

RELEASE DATE:

10/1/2011

EXPIRATION DATE:

10/31/2013

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED:

STATEMENT ISSUED ON: 1/1/2012

AUTHORIZED SIGNATURE

Susanne Bateska, RN, BSN

18

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

430-000-09-007-H01-P

PROGRAM INFORMATION

TITLE:

Current Treatment Approaches to Common Ocular Disorders Within the Framework of Managed Care: Strategies To Attain Improved Patient Outcomes

EXAM SUBMITTED ON:

1/29/2011

EXAM PROCESSED ON:

1/29/2011

PARTICIPANT INFORMATION

NAME:

Shane S Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, VA 24251

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED:

STATEMENT ISSUED ON: 1/29/2011

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE

Susanne Bateska, RN, BSN

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POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

430-000-09-013-H01-P

PROGRAM INFORMATION

TITLE:

Strategies for Recommending Nonprescription Headache Products for Your Patients

EXAM SUBMITTED ON:

1/29/2011

EXAM PROCESSED ON:

1/29/2011

PARTICIPANT INFORMATION

NAME:

Shane S Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, VA 24251

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED: 7-D,16-D

STATEMENT ISSUED ON: 1/29/2011

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE

Susanne Bateska, RN, BSN

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POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

0430-0000-10-037-H01-P

PROGRAM INFORMATION

TITLE:

Prebiotics: Educating Consumers and Health Care Professionals About an Emerging Health Concept

EXAM SUBMITTED ON:

1/29/2011

EXAM PROCESSED ON:

1/29/2011

PARTICIPANT INFORMATION

NAME:

Shane S Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, VA 24251

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED: 7-C,20-A

STATEMENT ISSUED ON: 1/29/2011

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE

Susanne Batesko, RN, BSN

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POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

430-000-09-005-H03-P

PROGRAM INFORMATION

TITLE:

The Continued Importance of Controlled Substance Management by Health Care Professionals

EXAM SUBMITTED ON:

1/29/2011

EXAM PROCESSED ON:

1/29/2011

PARTICIPANT INFORMATION

NAME:

Shane S Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, VA 24251

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED: 20-D

STATEMENT ISSUED ON: 1/29/2011

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE

Susanne Bateska, RN, BSN

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POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

430-000-09-025-H03-P

PROGRAM INFORMATION

TITLE:

Collaborative Practice Agreements: How They Are Beneficial to Your Practice

EXAM SUBMITTED ON:

1/29/2011

EXAM PROCESSED ON:

1/29/2011

PARTICIPANT INFORMATION

NAME:

Shane S Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, VA 24251

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED:

STATEMENT ISSUED ON: 1/29/2011

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE

Susanne Batesko, RN, BSN

Back to Home

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

0430-0000-09-026-H01-P

PROGRAM INFORMATION

TITLE

Avoiding Acetaminophen Toxicity: The Pharmacist's Role in Safety and Patient Education

EXAM SUBMITTED ON:

1/29/2011

EXAM PROCESSED ON:

1/29/2011

PARTICIPANT INFORMATION

NAME:

Shane S Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, VA 24251

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED:

STATEMENT ISSUED ON: 1/29/2011

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE

Susanne Bateske, RN, BSN

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POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

0430-0000-10-034-H03-P

PROGRAM INFORMATION

TITLE:

Prescription Errors and Their Legal Consequences: Best Practices for Prevention

EXAM SUBMITTED ON:

1/21/2011

EXAM PROCESSED ON:

1/21/2011

PARTICIPANT INFORMATION

NAME:

Shane S Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, VA 24251

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED:

STATEMENT ISSUED ON: 1/21/2011

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE

Susanne Batesko, RN, BSN

Back to Home

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POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

0430-0000-10-045-H01-P

PROGRAM INFORMATION

TITLE:

Over-the-Counter Use of Neuroactive Peptides for the Treatment of Chronic Pain

EXAM SUBMITTED ON:

1/29/2011

EXAM PROCESSED ON:

1/29/2011

PARTICIPANT INFORMATION

NAME:

Shane S Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, VA 24251

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED: 4-B

STATEMENT ISSUED ON: 1/29/2011

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE

Susanne Batesko, RN, BSN

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POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-11-034-H01-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE:

Probiotics Supplementation: What Pharmacists Need to Know to Recommend Safe and Effective Formulations

RELEASE DATE:

11/10/2011

EXPIRATION DATE:

11/30/2013

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: 2-A, 6-D, 19-C, 20-B

STATEMENT ISSUED ON: 1/1/2012

AUTHORIZED SIGNATURE

Susanne Bateska, RN, BSN

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POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-12-032-H01-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE:

Counseling Patients About Over-the-Counter Treatment of Teething Pain

RELEASE DATE:

10/30/2012

EXPIRATION DATE:

10/31/2014

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: 1-B, 2-B, 7-C, 13-D

STATEMENT ISSUED ON: 1/1/2013

AUTHORIZED SIGNATURE

Susanne Bateska, RN, BSN

STATEMENT OF PARTICIPATION

The Postgraduate Institute for Medicine confirms that

Shane Miller

has participated in the educational activity titled

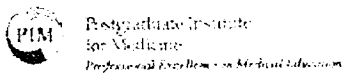
"New Thinking About Insulin Tools: The Long and Short of It"

7/31/2012 - 7/31/2014

The Postgraduate Institute for Medicine designates this continuing education activity for 2.00 contact hour(s) (0.2 CEU's) of the Accreditation Council for Pharmacy Education.

Universal Activity Number - 0809-9999-12-258-H01-P

Activity Type: Knowledge



The Postgraduate Institute for Medicine is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Trace Hutchison, Pharm.D.
Director of Medical Education
Postgraduate Institute for Medicine
367 Inverness Parkway
Englewood, CO 80122
(303) 799-1930
(303) 858-8848 - Fax

Date certificate issued: 1/1/2013

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-12-003-H03-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE:

The Omnibus Budget Reconciliation Act of 1990 (OBRA-90) Mandate: Two Decades Later

RELEASE DATE:

1/15/2012

EXPIRATION DATE:

1/31/2014

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED:

STATEMENT ISSUED ON: 1/1/2013

AUTHORIZED SIGNATURE

Susanne Batesko, RN, BSN

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-12-017-H01-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE:

Complexities of Current Gout Therapy: Reducing Flares While Managing Risk

RELEASE DATE:

7/20/2012

EXPIRATION DATE:

7/31/2014

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED:

STATEMENT ISSUED ON 1/1/2013

AUTHORIZED SIGNATURE

Susanne Bateskb, RN, BSN

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-12-029-H01-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE:

Update on Biosimilars: An Emerging Category of Biologic Drugs

RELEASE DATE:

10/20/2012

EXPIRATION DATE:

10/31/2014

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: 11-C

STATEMENT ISSUED ON: 1/1/2013

AUTHORIZED SIGNATURE

Susanne Balesko, RN, BSN

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-12-035-H01-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE:

Counseling Patients About Heartburn, Constipation, and Intestinal Gas

RELEASE DATE:

12/20/2012

EXPIRATION DATE:

12/31/2014

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: 4-D, 5-A, 10-A, 19-D, 20-A

STATEMENT ISSUED ON: 1/1/2013

AUTHORIZED SIGNATURE

Susanne Batesko, RN, BSN

POWER-PAK C.E.

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITED PROVIDER

NAME:

Postgraduate Healthcare Education, LLC

ACPE UAN

0430-0000-12-038-H01-P

ACTIVITY TYPE

Knowledge

ACTIVITY INFORMATION

TITLE:

Ocular Surface Health in Glaucoma Management: The Pharmacist's Role

RELEASE DATE:

12/20/2012

EXPIRATION DATE:

12/31/2014

PARTICIPANT INFORMATION

NAME:

Shane Miller

ADDRESS:

189 HILTON RD

CITY, STATE, ZIP:

Gate City, Virginia 24251

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: 6-D, 12-B, 13-B, 16-D

STATEMENT ISSUED ON: 1/1/2013

AUTHORIZED SIGNATURE

Susanne Bateska, RN, BSN

January 24, 2014

Joshua Klasinski
4475 Streamside Court
Sarasota, FL 34233

RE: Appeal of Intent to Deny Licensure

Dear Mr. Klasinski:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE OCT 29 2013

STATE OF FLORIDA
BOARD OF PHARMACY

IN RE: THE APPLICATION OF

JOSHUA S. KLASINSKI
_____/

NOTICE OF INTENT TO DENY LICENSE

This matter appeared before the Board of Pharmacy at a duly-noticed public meeting held on October 9, 2013, in Panama City Florida, for consideration of an application for licensure as a Registered Pharmacy Technician. The applicant was not present. Upon consideration of the information provided, and being otherwise advised in the premises, the Board has determined that the application for licensure as Registered Pharmacy Technician is DENIED for the following reasons:

1. Applicant's license to practice as a physician assistant has been disciplined.
2. Pursuant to Section 456.072(1)(f), Florida Statutes, the Board may deny an applicant for having a license or the authority to practice any regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law.
3. Based on the forgoing and pursuant to Sections 456.072(2) and 456.072(1)(f), F.S., the Board denied application for licensure.

This Notice shall be placed in and become a part of the official records and shall become effective upon filing with the Clerk of the Department Health. This Notice of Intent to Deny will become a Final Order if no further action is taken within the time period stated below.

DONE AND ORDERED this 28 day of October, 2013.

BOARD OF PHARMACY

Mark Whitten,
Executive Director *for*
Albert Garcia, BPharm CHAIR

NOTICE OF RIGHT TO HEARING

THIS ORDER CONSTITUTES A FINAL ORDER AND FINAL AGENCY ACTION IF NO REQUEST FOR A HEARING IS RECEIVED BY THE BOARD ON OR BEFORE THE TWENTY-FIRST DAY AFTER THE APPLICANT'S RECEIPT OF THE ORDER. THE APPLICANT MAY REQUEST A HEARING BY FILING AN APPROPRIATE PETITION WITH THE EXECUTIVE DIRECTOR OF THE BOARD AT 4052 BALD CYPRESS WAY, BIN # C-04, TALLAHASSEE, FLORIDA 32399-3256. THE APPLICANT MAY PETITION FOR A HEARING INVOLVING DISPUTED ISSUES OF MATERIAL FACT BEFORE AN ADMINISTRATIVE LAW JUDGE PURSUANT TO SECTION 120.57 (1), FLORIDA STATUTES, OR FOR A HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT PURSUANT TO SECTION 120.57 (2) FLORIDA STATUTES.

A PETITION FOR A HEARING INVOLVING DISPUTED ISSUES OF MATERIAL FACT MUST CONTAIN INFORMATION REQUIRED BY RULE 28-106.201, FLORIDA ADMINISTRATIVE CODE, INCLUDING A STATEMENT OF ALL DISPUTED ISSUES OF MATERIAL FACT. THE BOARD MAY REFER A PETITION TO THE DIVISION OF ADMINISTRATIVE HEARINGS FOR ASSIGNMENT OF AN ADMINISTRATIVE LAW JUDGE ONLY IF THE PETITION IS IN SUBSTANTIAL COMPLIANCE WITH THE RULE REQUIREMENTS. A PETITION FOR A PROCEEDING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT MUST CONTAIN INFORMATION REQUIRED BY RULE 28.106.301 FLORIDA ADMINISTRATIVE CODE, INCLUDING A CONCISE STATEMENT OF THE ULTIMATE FACTS ALLEGED, AS WELL AS THE RULES AND STATUTES WHICH ENTITLE PETITIONER TO RELIEF.

IN ACCORDANCE WITH SECTION 120.573, FLORIDA STATUTES MEDIATION IS NOT AVAILABLE.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by Certified Mail to Joshua S. Klasinski, at 4475 Streamside Court, Sarasota, Florida 34233; by interoffice mail to David D. Flynn, Esquire, Assistant Attorney General, Office of the Attorney General, david.flynn@myfloridalegal.com 32399-1050; this 29th day of October, 2013.

Angel Sanders

Deputy Agency Clerk

7012 3050 0001 9149 8358

To: the Executive Director of the Board of Pharmacy

Re: Petition to Florida Board of Pharmacy (Agency), F.A.C. 28.106.301

(a) Florida Dept. of Health
Board of Pharmacy
4052 Bald Cypress Way, Bin C-04
Tallahassee, FL 32399
File # 51724

Florida Dept. of Health
Board of Medicine
4052 Bald Cypress Way, Bin C-76
Tallahassee, FL 32399
File # 201204092

(b) Joshua S. Klasinski (Petitioner), 4807 Huntleigh Drive Sarasota FL 34233, 813-789-6480, jklasins2002@yahoo.com

(c) Denial of pharmacy license will mean that I am not able to make a living for myself through this means. From year 2002 till year 2008, my primary occupation and means of making a living was as a pharmacy technician. This occupation represents the only viable means, at this time, for me to make a living. In order to obtain and reliably keep a job, that I may pay my bills (including DOH fines, government school loans, etc.) it is imperative that I have the ability to employ my experience and skills as a pharmacy technician,

(d) Notice via letter dated October 29,2013, received by petitioner on

November 2nd, 2013.

(e) Facts alleged are not in dispute:

1. Applicant's license to practice as a PA has been disciplined
2. Pursuant to Section 456.072(1)(f), F.S., the board may deny an applicant for having a license or the authority to practice any regulated profession revoked, suspended, or otherwise acted against, by the licensing authority, for a violation that would constitute a violation under Florida Law.

(f) The petitioner requests modification of the agency's proposed action according to wording in section 456.072(2), F.S. stating the Agency "**MAY** enter an order imposing one or more of the following penalties"; and 456.36 F.S., providing for exemption from disqualification from employment, which agency's proposed action inevitably leads to.

(g) Having had no prior problems during my 7+ years working in pharmacy, instead having full commendation by my employers, and due to my responsibilities in paying my bills I request the ability to work as a pharmacy technician. Other than PA, which I am barred from currently, I have no other solid work experience. Lastly, I would like to bring into consideration the fact that the pharmacy in which I

have completed the required training program, is a long-term care facility having no direct contact with patients. It is my endeavor to work there until the discipline for my PA license has been carried out and I am able to lawfully reenter the PA workforce.

(h) No material facts are in dispute.

sincerely,

Joshua Klasinski

_____ , 11-12-13

CONFIDENTIAL AND EXEMPT MATERIALS

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

FLORIDA BOARD
P.O. Box 6320 • Tal
Phone: (850) 488-0
http://www.doh.stat

06/21/2013 105.00
ID: 51517 Type: F
BT: 3023522
VL: 912068720

ITEM #2 - Pharmacy Technician Registration
FEE: $105.00
Please print or type legibly 2208-51517

1. Biographical data			
Last name	**First name**	**Middle name**	
Klasinski	Joshua	Stephen	
Street address (ML – Mailing Location)	**City**	**State**	**Zip**
4475 Streamside Court	# Sarasota	FL	34238
Work address (PL – Practice Location) (If you are not employed, please list your mailing address below). If you have multiple practice locations, please submit on an additional sheet, attach with application.	**City**	**State**	**Zip**
5736 Clark Rd	Sarasota	FL	34233
Home phone number	**Business phone number**	**Date of birth**	
813-789-6480		6-25-83	
E-mail address	**Would you be willing to provide health services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disasters?**		
jklasins2002@yahoo.com	Yes _____	No ✓	

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☑ Male ☐ Female
RACE: ☑ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. Have you ever changed your name through marriage or through action of a court or have you ever been known by any other name? If yes, list name(s) and date(s) of the change(s) below. *Use a separate sheet, if necessary.*

Yes _____ No ✓

Name	**Date**

DH-MQA PH1183, 09/09
Rule 64B16-26.350, F.A.C.

WL

4. Have you completed a board approved training course according to Rule 64B16-26.351 (3), FA.C.?	
Yes ✓ No _____	If yes, include a copy of your completed course certificate.
5. Have you ever been convicted of, or entered a plea of guilty, nolo contendre, or no contest, to a crime in any jurisdiction other than a minor traffic offense?	
Yes _____ No ✓ (You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)	
6. Has disciplinary action ever been taken against your pharmacy technician registration, or any other professional license you may have in this state or any other state?	
Yes ✓ No _____	
7. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?	
Yes ✓ No _____	
8. Are you presently under investigation or is any disciplinary action pending against you?	
Yes ✓ No _____	

13. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #14.)
Yes _____ No ✓
13a. If "yes" to 13, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
13b. If "yes" to 13, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No _____
13c. If "yes" to 13, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes_____ No _____
13d. If "yes" to 13, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes _____ No_____
14. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?
Yes_____ No ✓
14a. If "yes" to 14, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes_____ No_____
15. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 15a.)
Yes _____ No ✓
15a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____
16. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 16a and 16b.)
Yes _____ No ✓
16a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes ✓ No _____
16b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
17. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?
Yes_____ No ✓
18. If "yes" to any of the questions 13through 17 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes_____ No_____
All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 5-16b, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacy technician registration may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

Applicant Signature _____ Date 6-13-13

DH-MQA PH1183, 09/09
Rule 64B16-26.350, F.A.C.

Certificate of Completion

For successfully completing and passing

PassAssured's Pharmacy Technician Training Course and in compliance with the Florida Board of Pharmacy rules for training technicians.

PassAssured and the Florida Pharmacy Association

presents this award to

Joshua Klasinski

Medisery Pharmacy
Name of Employer Based Training Program Pharmacy

5736 Clark Road
Address

Sarasota FL 34233
City State Zip

RTTP71
Training Program License Number

Employer (Licensed Pharmacist) Signature — **May 25, 2013** Date Completed

Michael O. Jackson
FPhA Signature — **May 25, 2013** Date Completed

PassAssured, LLC
1504 West Park Avenue
Orange, TX 77630

To the Florida Board of Pharmacy, 06-17-13

As required, I, Joshua Klasinski, submit an explanation and the included supporting documents pertaining to questions six thru 8, on page 3 of the Pharmacy Technician Registration application.

Prior to acquiring the license in question (Physician Assistant), my main occupation was certified pharmacy technician. Year 2002, I gained national certification as a pharmacy technician, and thence began a pharmacy work experience lasting from 08/2002 till 08/2008. Year 2008 I enrolled in physician assistant studies and graduated in 2010. Year 2011 to 2012 I worked as a physician assistant at Suncoast Community Health Clinics, licensed and certified at the state and national levels. March 2012 I was terminated from the clinic and subsequently disciplined by the Florida Board of Medicine. Therefore in order to pay the bills, I applied for work at a pharmacy, that being the only occupation I had primary experience in. I was hired at Mediserv LLC in late 2012 and recently finished the training program.

Should you see fit to speak with a prior employer, there are two pharmacists who are able to testify to my work ethic and past employment. Karl Richards RPh (813-376-3941), and Nancy Washmuth RPh (941-377-1838).

sincerely,

Joshua Klasinski

To: the Regulatory Specialist 07-19-2013

RE: file # 51724 Pharmacy Technician application

1. Detailed description of circumstances surrounding disciplinary action:

March 2011, I, Joshua Klasinski, was terminated from Suncoast Community Health Centers as active provider Physician Assistant. During that time, a complaint was filed by one of my female patients, to the DOH. On one occasion during an office visit with aforementioned patient, I made inappropriate comments and lingered during palpation as part of the physical exam. This crossing of the patient/care-giver boundary, was the occasion for said patient's filing of a complaint. Upon my immediate self-reporting, the DOH began the investigation and subsequently required me to stop working as a PA and to appear before the board. February 2012 I appeared before the board and subsequently, the board, and I, agreed to a final order for discipline and future practice.

2. Thorough description of rehabilitative changes in lifestyle since disciplinary action:

Intensive 10 week counseling with two certified counselors at Calvary Chapel, Sarasota. Counseling focused directly on heart of the issue surrounding my actions, and involved daily homework and weekly accountability; formulation of plan for future practice to avoid any such semblance or opportunity for lack of judgment and unethical action on my part, including: accountability partners, active presence of a third party during any physical exam with a female patient; continuing periodic self-evaluation using methods employed during the 10 week counseling.

3. Factors contributing to disciplinary action, what has been learned since that time, changes made:

Major Depression during time of disciplinary action, is in remittance at this time and under the care of Dr. Diego Ramos. Lack of openness and engaging with close social support (e.g. mother, siblings, pastor), which at this time has improved significantly and I continue to form relationships with people at my local church and with my mother and siblings whom I involve myself with on a daily basis. I understand, more than ever, my need for others to be involved in my life and whom I can be held

accountable to, additionally I have reassessed in great detail through contemplation, the importance of maintaining boundaries with a patient and am prepared to act with more discretion as a result of my lack of judgment. My emotional health, is integral to my ability to practice medicine. Therefore I will pursue emotional health, through regular visits with my family doctor and forming healthy habits as advised by family and friends. Currently I have fulfilled 100 hours of CE's for the Physician Assistant career, which has enabled me to stay up-to-date on practice issues.

Sincerely,

Joshua Klasinski PA

Final Order No. DOH-13-0476-S -MQA
FILED DATE - 3-4-13
Department of Health
By: Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF MEDICINE

DEPARTMENT OF HEALTH,

Petitioner,

vs.

DOH CASE NO.: 2012-04092
LICENSE NO.: PA9105912

JOSHUA KLASINSKI, P.A.,

Respondent.
_____/

FINAL ORDER

THIS CAUSE came before the BOARD OF MEDICINE (Board) pursuant to Sections 120.569 and 120.57(4), Florida Statutes, on February 1, 2013, in Jacksonville, Florida, for the purpose of considering a Settlement Agreement (attached hereto as Exhibit A) entered into between the parties in this cause. Upon consideration of the Settlement Agreement, the documents submitted in support thereof, the arguments of the parties, and being otherwise full advised in the premises, the Board rejected the Settlement Agreement and offered a Counter Settlement Agreement which Respondent was given 7 days to accept. By letter dated February 21, 2013, Respondent timely accepted the Board's Counter Settlement Agreement. The Counter Settlement Agreement incorporates the original Settlement Agreement with the following amendments:

1. The costs set forth in Paragraph 3 of the Stipulated Disposition shall be set at $1,244.10.

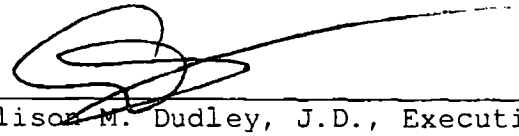
2. The suspension set forth in Paragraph 6 of the Stipulated Disposition shall be amended to require Respondent to be SUSPENDED until such time as he undergoes an evaluation by the Professionals Resource Network (PRN) and personally appears before the Board with said evaluation and the Board determines that Respondent is safe to practice medicine with reasonable skill and safety. The Board retains jurisdiction in this matter to impose terms and conditions of practice based upon the recommendations of Respondent's PRN evaluation, including but not limited to a term of probation, at the time Respondent's license to practice medicine is reinstated.

IT IS HEREBY ORDERED AND ADJUDGED that the Settlement Agreement as submitted be and is hereby approved and adopted in toto and incorporated herein by reference with the amendments set forth above. Accordingly, the parties shall adhere to and abide by all the terms and conditions of the Settlement Agreement as amended.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 4th day of March, 2013.

BOARD OF MEDICINE



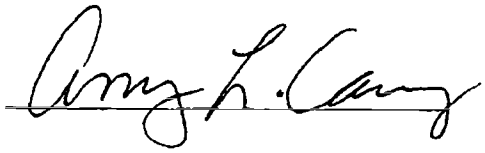
Allison M. Dudley, J.D., Executive Director
For Zachariah P. Zachariah, M.D., Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by **Certified Mail** to JOSHUA KLASINSKI, P.A., 4475 Streamside Court, Sarasota, Florida 34238; and 3211 Beneva Road, Unit 102, Sarasota, Florida 34232; by email to the Professionals Resource Network (PRN) at admin@flprn.org; and by interoffice delivery to Sharmin Hibbert, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, Florida 32399-3253 this 4 day of March, 2013.

3211 Beneva Rd, Unit 102

7012 1010 0002 2383 2301



Deputy Agency Clerk

4475 Streamside Crt.

7012 1010 0002 2383 2318

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE FEB 1 2 2013

STATE OF FLORIDA
BOARD OF MEDICINE

DEPARTMENT OF HEALTH,

Petitioner,

vs.

DOH CASE NO.: 2012-04092
LICENSE NO.: PA9105912

JOSHUA KLASINSKI, P.A.,

Respondent.
_____/

ORDER

THIS CAUSE came before the BOARD OF MEDICINE (Board) pursuant to Sections 120.569 and 120.57(4), Florida Statutes, on February 1, 2013, in Jacksonville, Florida, for the purpose of considering a Settlement Agreement (attached hereto as Exhibit A) entered into between the parties in this cause. Upon consideration of the Settlement Agreement, the documents submitted in support thereof, the arguments of the parties, and being otherwise full advised in the premises, the Board rejected the Settlement Agreement and offered a Counter Settlement Agreement which Respondent was given 7 days to accept. The Counter Settlement Agreement incorporates the original Settlement Agreement with the following amendments:

1. The costs set forth in Paragraph 3 of the Stipulated Disposition shall be set at $1,244.10.

2. The suspension set forth in Paragraph 6 of the Stipulated Disposition shall be amended to require Respondent to be SUSPENDED until such time as he undergoes an evaluation by the Professionals Resource Network (PRN) and personally appears before the Board with said evaluation and the Board determines that Respondent is safe to practice medicine with reasonable skill and safety. The Board retains jurisdiction in this matter to impose terms and conditions of practice based upon the recommendations of Respondent's PRN evaluation, including but not limited to a term of probation, at the time Respondent's license to practice medicine is reinstated.

IT IS HEREBY ORDERED AND ADJUDGED that the Settlement Agreement as submitted is rejected and Respondent shall have 7 days from the date this Order is filed to accept the Board's Counter Settlement Agreement. Acceptance of said Counter Settlement Agreement shall be made in writing to: Edward A. Tellechea, Chief Assistant Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050; or emailed to Ed.Tellechea@myfloridalegal.com.

This Order shall take effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 11th day of February, 2013.

BOARD OF MEDICINE

Allison M. Dudley, J.D., Executive Director
For Zachariah P. Zachariah, M.D., Chair

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Order has been provided by U.S. Mail to JOSHUA KLASINSKI, P.A., 4475 Streamside Court, Sarasota, Florida 34238; and 3211 Beneva Road, Unit 102, Sarasota, Florida 34232; by email to the Professionals Resource Network (PRN) at admin@flprn.org; and by interoffice delivery to Sharmin Hibbert, Department of Health, 4052 Bald Cypress Way, Bin #C-65, Tallahassee, Florida 32399-3253 this 12th day of February, 2013.

Angel Sanders

Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **DOH Case No. 2012-04092**

JOSHUA KLASINSKI, P.A.,

Respondent,

_____/

SETTLEMENT AGREEMENT

Joshua Klasinski, P.A., referred to as the "Respondent," and the Department of Health, referred to as "Department" stipulate and agree to the following Agreement and to the entry of a Final Order of the Board of Medicine, referred to as "Board," incorporating the Stipulated Facts and Stipulated Disposition in this matter.

Petitioner is the state agency charged with regulating the practice of physician assistance pursuant to Section 20.43, Florida Statutes, and Chapter 456, Florida Statutes, and Chapter 458, Florida Statutes.

STIPULATED FACTS

1. At all times material hereto, Respondent was a licensed physician assistant in the State of Florida having been issued license number PA 9105912.

2. The Department charged Respondent with an Administrative Complaint that was filed and properly served upon Respondent with violations of Chapter 458, Florida Statutes, and the rules adopted pursuant thereto. A true and correct copy of the Administrative Complaint is attached hereto as Exhibit A.

3. Respondent neither admits nor denies the allegations of fact contained in the Administrative Complaint for purposes of these proceedings only.

STIPULATED CONCLUSIONS OF LAW

1. Respondent admits that, in his capacity as a licensed physician assistant, he is subject to the provisions of Chapters 456 and 458, Florida Statutes, and the jurisdiction of the Department and the Board.

2. Respondent admits that the facts alleged in the Administrative Complaint, if proven, would constitute violations of Chapter 458, Florida Statutes, as alleged in the Administrative Complaint.

3. Respondent agrees that the Stipulated Disposition in this case is fair, appropriate and acceptable to Respondent.

STIPULATED DISPOSITION

1. **Reprimand** - The Board shall reprimand the license of Respondent.

2. **Fine** - The Board of Medicine shall impose an administrative fine of four thousand dollars **($4,000.00)** against the license of Respondent, to be paid by

Respondent to Payments, Department of Health, Compliance Management Unit, Bin C-76, P.O. Box 6320, Tallahassee, FL 32314-6320, within thirty-days (30) from the date of filing of the Final Order accepting this Agreement. **All fines shall be paid by cashiers check or money order.** The Board office does not have the authority to change the terms of payment of any fine imposed by the Board.

RESPONDENT ACKNOWLEDGES THAT THE TIMELY PAYMENT OF THE FINE IS HIS/HER LEGAL OBLIGATION AND RESPONSIBILITY AND RESPONDENT AGREES TO CEASE PRACTICING IF THE FINE IS NOT PAID AS AGREED TO IN THIS SETTLEMENT AGREEMENT, SPECIFICALLY: IF WITHIN 45 DAYS OF THE DATE OF FILING OF THE FINAL ORDER, RESPONDENT HAS NOT RECEIVED WRITTEN CONFIRMATION THAT THE FULL AMOUNT OF THE FINE HAS BEEN RECEIVED BY THE BOARD OFFICE, RESPONDENT AGREES TO CEASE PRACTICE UNTIL SUCH WRITTEN CONFIRMATION IS RECEIVED BY RESPONDENT FROM THE BOARD.

3. **Reimbursement of Costs** - Pursuant to Section 456.072, Florida Statutes, Respondent agrees to pay the Department for any costs incurred in the investigation and prosecution of this case. Such costs exclude the costs of obtaining supervision or monitoring of the practice, the cost of quality assurance reviews, and the Board's administrative cost directly associated with Respondent's probation, if any. The agreed upon amount of Department costs to be paid in this case is currently ***one thousand eight dollars and fifty-four cents***

($1, 008.54), but shall not exceed two thousand five hundred eight dollars and fifty-four cents ($2,508.54). Respondent will pay costs to Payments, Department of Health, Compliance Management Unit, Bin C-76, P O. Box 6320, Tallahassee, Fl 32314-6320, within thirty-days (30) from the date of filing of the Final Order in this cause. **All costs shall be paid by cashiers check or money order.** Any post-Board costs, such as the costs associated with probation, are not included in this agreement.

RESPONDENT ACKNOWLEDGES THAT THE TIMELY PAYMENT OF THE COSTS IS HIS/HER LEGAL OBLIGATION AND RESPONSIBILITY AND RESPONDENT AGREES TO CEASE PRACTICING IF THE COSTS ARE NOT PAID AS AGREED TO IN THIS SETTLEMENT AGREEMENT, SPECIFICALLY: IF WITHIN 45 DAYS OF THE DATE OF FILING OF THE FINAL ORDER, RESPONDENT HAS NOT RECEIVED WRITTEN CONFIRMATION THAT THE FULL AMOUNT OF THE COSTS NOTED ABOVE HAS BEEN RECEIVED BY THE BOARD OFFICE, RESPONDENT AGREES TO CEASE PRACTICE UNTIL SUCH WRITTEN CONFIRMATION IS RECEIVED BY RESPONDENT FROM THE BOARD.

4. **Continuing Medical Education - "Risk Management"** Respondent may satisfy this requirement by either completing five (5) hours of Continuing Medical Education in "Risk Management" within one (1) year of the date of filing of the Final Order. If Respondent chooses to meet this requirement through Continuing Medical Education, Respondent shall first submit a written

request to the Probation Committee for approval of the course prior to completion of said continuing medical education course(s).

Respondent may also satisfy the requirement for completing (5) five hours of continuing medical education in risk management by attending one full day or eight (8) hours, whichever is more, of disciplinary hearings at a regular meeting of the Board of Medicine. In order to receive such credit, Respondent must sign in with the Executive Director of the Board before the meeting day begins, Respondent must remain in continuous attendance during the full day or eight (8) hours of disciplinary hearings, whichever is more, and Respondent must sign out with the Executive Director of the Board at the end of the meeting day or at such other earlier time as affirmatively authorized by the Board. Respondent may not receive continuing medical education credit in risk management for attending the disciplinary hearings portion of a Board meeting unless, the Respondent is attending the disciplinary hearings portion for the sole purpose of obtaining the continuing medical education credit in risk management. The Respondent may not receive such credit if appearing at the Board meeting for any other purpose, such as pending action against Respondent's medical license.

5. **Permanent Restriction of Practice**-

Respondent's practice is permanently restricted in that Respondent may not examine or treat female patients outside the presence of a Florida licensed health care provider who shall maintain a log of each such patient contact with said log immediately available to a Department Inspector upon request.

6. **Suspension Language:**

(A) Respondent's license shall be suspended for a period of three (3) months. The Board reserves jurisdiction in this matter to impose any additional terms and conditions, including a period of probation, with said terms and conditions of said probation to be determined by the Board at the time of reinstatement of Respondent's license to practice physician assistance. Respondent shall not practice physician assistance in Florida until he petitions the Board for reinstatement, appears before the Board, and has his license reinstated.

STANDARD PROVISIONS

1. **Appearance** Respondent is required to appear before the Board at the meeting of the Board where this Agreement is considered.

2. **No force or effect until final order** - It is expressly understood that this Agreement is subject to the approval of the Board and the Department In this regard, the foregoing paragraphs (and only the foregoing paragraphs) shall have no force and effect unless the Board enters a Final Order incorporating the terms of this Agreement.

3. **Continuing Medical Education** - Unless otherwise provided in this written agreement Respondent shall first submit a written request to the Probation Committee for approval prior to performance of said continuing medical education course(s). Respondent shall submit documentation in the form of certified copies of the receipts, vouchers, certificates, or other papers, such as physician's recognition awards, documenting completion of this medical course within one (1)

year of the date of filing of the Final Order in this matter. All such documentation shall be sent to the Board of Medicine, regardless of whether some or any of such documentation was provided previously during the course of any audit or discussion with counsel for the Department. These hours shall be in addition to those hours required for renewal of licensure. Unless otherwise approved by the Board, said continuing medical education course(s) shall consist of a formal, live lecture format.

4. **Addresses** - Respondent must keep current residence and practice addresses on file with the Board. Respondent shall notify the Board within ten (10) days of any changes of said addresses.

5. **Future Conduct** - In the future, Respondent shall not violate Chapter 456, 458 or 893, Florida Statutes, or the rules promulgated pursuant thereto, or any other state or federal law, rule, or regulation relating to the practice or the ability to practice medicine. Prior to signing this agreement, the Respondent shall read Chapters 456, 458 and 893 and the Rules of the Board of Medicine, at Chapter 64B8, Florida Administrative Code.

6. **Violation of terms considered** - It is expressly understood that a violation of the terms of this Agreement shall be considered a violation of a Final Order of the Board, for which disciplinary action may be initiated pursuant to Chapters 456 and 458, Florida Statutes.

7. **Purpose of Agreement** - Respondent, for the purpose of avoiding further administrative action with respect to this cause, executes this Agreement.

In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to or in conjunction with consideration of the Agreement. Respondent agrees to support this Agreement at the time it is presented to the Board and shall offer no evidence, testimony or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Agreement not be accepted by the Board, it is agreed that presentation to and consideration of this Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration or resolution of these proceedings.

8. **No preclusion of additional proceedings** - Respondent and the Department fully understand that this Agreement and subsequent Final Order incorporating same will in no way preclude additional proceedings by the Board and/or the Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint attached as Exhibit A.

9. **Waiver of attorney's fees and costs** - Upon the Board's adoption of this Agreement, the parties hereby agree that with the exception of costs noted above, the parties will bear their own attorney's fees and costs resulting from prosecution or defense of this matter. Respondent waives the right to seek any attorney's fees or costs from the Department and the Board in connection with this matter.

10. **Waiver of further procedural steps** - Upon the Board's adoption of this Agreement, Respondent expressly waives all further procedural steps and expressly waives all rights to seek judicial review of or to otherwise challenge or contest the validity of the Agreement and the Final Order of the Board incorporating said Agreement.

SIGNED this 18 day of December, 2012

Joshua Klasinski, P. A.

STATE OF FLORIDA
COUNTY OF Sarasota

Before me, personally appeared Joshua Klasinski, whose identity is known to me or by _____ (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 18 day of December 2012.

NOTARY PUBLIC

My Commission Expires:

LORI CALOBREVES
MY COMMISSION # EE 840584
EXPIRES: October 3, 2016
Bonded Thru Notary Public Underwriters

APPROVED this 18th day of December, 2012

H. Frank Farmer, Jr., M.D., Ph.D.
State Surgeon General
Department of Health

By: Sharmin R. Hibbert
Assistant General Counsel
Department of Health

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **DOH CASE NO. 2012-04092**

JOSHUA KLASINSKI, P.A.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, the Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Medicine against Respondent, Joshua Klasinski, P.A., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of Physician Assistance pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 458, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed physician assistant in the State of Florida, having been issued license number PA 9105912.

3. Respondent's address of record is 3211 Beneva Road, Unit 102, Sarasota, Florida 34232.

4. On or about February 16, 2012, Patient D.M., a then fifty-eight year old female, presented to the Ruskin Health Clinic of Suncoast Community Health Center located in Ruskin Florida.

5. Patient D.M. complained of a hard, brown spot on her left leg, self described as knot. The area affected on her leg was approximately five inches from her foot. Patient D.M. was concerned about it being a blood clot.

6. Respondent saw Patient D.M. and asserts to have conducted a physical examination.

7. After placing Patient D.M. on the examination table, Respondent checked Patient D.M.'s heart and lungs through her clothing. Respondent stated he wanted to check Patient D.M.'s heart and lungs again.

8. While using a stethoscope during the examination to check Patient D.M.'s heartbeat, Respondent placed the stethoscope under Patient D.M.'s bra and asked her to pull her bra up further, to which Patient D.M.

stated she couldn't do. Respondent commented that D.M. had an under wire bra on.

9. During this examination Respondent touched Patient D.M.'s leg and her inner thigh in a caressing and inappropriate manner. Respondent touched Patient D.M.'s leg with light pressure asking if it hurt, while continuing to caress/touch Patient D.M.'s leg up her inner thigh.

10. Respondent continued rubbing Patient D.M.'s leg up past her knee in an inappropriate manner.

11. Respondent stated to Patient D.M., "I think I have exactly what you need." Respondent asked Patient D.M. when the last time she had made love was.

12. Respondent continued the conversation by asking Patient D.M. if she lived alone.

13. Respondent left the examination room to print out a prescription and had the medical assistant return with the prescription.

14. Respondent came in before Patient D.M. left and apologized for his conduct stating, "I know I was out of line."

15. On or about March 16, 2012, Patient D.M. reported the incident to administrative staff of the clinic while asking to be transferred to another

provider. Patient D.M. asserts that she felt violated and uncomfortable throughout the course of this visit.

16. Respondent later came in, after seeing Patient D.M., and admitted to his behavior and actions involving Patient D.M. Respondent asserts that it was motivated by lust. Respondent was terminated from the facility.

17. Section 458.347(7)(g), Florida Statutes (2011), provides that the Board of Medicine may impose penalties authorized under sections 456.072 and 458.331(2), Florida Statutes, upon a physician assistant if the physician assistant has been found guilty of or is being investigated for any act that constitutes a violation of Chapter 458 or Chapter 456.

18. Section 456.072(1)(v), Florida Statutes (2011), subjects a licensee to discipline, including suspension or restriction of license, for engaging or attempting to engage in sexual misconduct as defined and prohibited in Section 456.063(1), Florida Statutes.

19. Section 456.063(1), Florida Statutes (2011), defines sexual misconduct in the practice of a health care profession as a violation of the professional relationship through which the health care practitioner uses such relationship to engage or attempt to engage the patient or client, or

an immediate family member, guardian, or representative of the patient or client in, or to induce or attempt to induce such person to engage in, verbal or physical sexual activity outside the scope of the professional practice of such health care profession. Sexual misconduct in the practice of a health care profession is prohibited.

20. Respondent engaged or induced, or attempted to engage or induce Patient D.M. in verbal and/or physical sexual activity that included one or more of the following: inappropriate touching, verbal activity in the form of sexually explicit comments; both of these actions are outside the scope of the professional practice of physician assistance, in violation of Section 456.072(1)(v), Florida Statutes (2011), which prohibits sexual misconduct.

21. Based on the foregoing, Respondent has violated Section 456.072(1)(v), Florida Statutes (2011) by engaging in sexual misconduct with Patient D.M.

WHEREFORE, the Petitioner respectfully requests that the Board of Medicine enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand,

placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 3 day of October, 2012.

JOHN H. ARMSTRONG, MD,
State Surgeon General and Secretary of Health
Florida Department of Health

Sharmin R. Hibbert
Assistant General Counsel
Florida Bar # 032569
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
(850) 245-4640 ext. 8173
(850) 245-4681 FAX

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE OCT 04 2012

SRH/crv

PCP Date: 9/7/12
PCP Members: Rosenberg, Dr. El-Sanadi, Mr. Mullins

DOH v. Joshua Klasinski, P.A. DOH Case No.: 2012-04092

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

Division of
Medical Quality Assurance

MQA

Department of Health
Compliance Management Team
4052 Bald Cypress Way, Bin C76
Tallahassee, FL 323399
(850) 245-4268

MAIN TERMS OF THE FINAL ORDER

This summary is provided as a courtesy. It is your responsibility to read and understand the Final Order to ensure compliance with all terms described therein. Please reference the case number listed on all correspondence forwarded to this office pertaining to this case.

CASE INFORMATION	
Case Number:	201204092
Respondent Name:	Joshua S. Klasinski
Final Order Date:	3/4/2013
Today's Date:	6/24/2013

Licensee:	Joshua S. Klasinski	**Profession:**	1512: Physician Assistant
Mailing Address:	4475 Streamside Court Sarasota, FL 34238	**File Nbr:**	8776
		License Nbr:	9105912
		License Status:	Suspended/Active
Attorney:	Evelyn L. Moya, Esquire	**Address:**	2831 Ringling Blvd. Unit B-105 Sarasota, FL 34237
		Phone:	941-954-3990
Monitor:	None on Record		
Supervisor:	None on Record		
Appeal:	N		

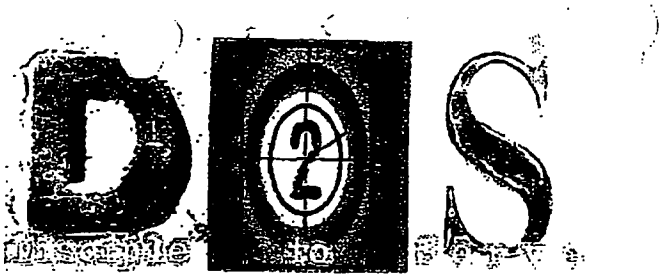
Discipline Imposed:	Start Date	End Date	Comments
Reprimand	03/04/2013		
Suspension	03/04/2013		Until such time as he undergoes an evaluation by the Professionals Resource Network (PRN) and personally appears before the Board with said evaluation and the Board determines that Respondent is safe to practice medicine within reasonable skill and safety.

Compliance Record:	Due Date	Cmpl Date	Amt Imposed	Amt Paid
Costs			1,244.10	0.00
Fine			4,000.00	100.00
Board Retains Jurisdiction				
Permanent Practice Restriction				
PRN Evaluation				
Reinstatement Appearance				

Continuing Education:

Subject Area	Due Dte	Req Hrs	Credit Hrs	Crdt Dte
Risk Management	03/04/2014	5.00		

PRN	Professionals Resource Network, (PRN) P.O. Box 1020, Fernandina Beach, FL 32035-1020 **Telephone Number:** 1 (800) 888-8776; **Fax Number:** (904) 277-8004



D2S Biblical Counseling Ministry
Calvary Chapel Sarasota
3800 27th Parkway
Sarasota, FL 34235
941.365.WORD [9673] ccsrq.cc F#10.2

Completion of Counseling

Counselee Joshua Klamsinski Counselor Carl Caowell
Date of last session 6-18-12
Date of first session 4-2-12
Number of sessions 10
Completion
Mutual YES
Brief specific synopsis of spiritual and/or emotional growth as view by counselor: Excellent growth spiritually

Discipleship follow-up: 1 month 7/18/12

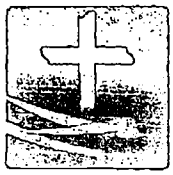
If counselee was referred by another counselor, church, ministry, agency or professional, give name: N/A

Has there been any contact with above party? N/A
If yes, give summary of feedback?

Signature of Counselor 6/18/12 Date

Signature of Counselee 6/18/12 Date

Rev. 12/2011, adapted from FFBCC Policies & Procedures Manual



Calvary Chapel Sarasota

worship & the word... taking it to the world

October 19, 2012

To Whom It May Concern:
RE: Character Reference for Josh Klasinski

I am happy to give a positive reference for Josh. He has attended Calvary Chapel of Sarasota for almost three years. He has worked with our Children's ministry Pastor and has been very involved with the Men's Fellowship at the Church. Josh has built strong accountable relationships with several men in our Church.

Josh came to me when he had a problem regarding his present profession and we talked at length about it. Following my advice he completed a very thorough counseling course with the experienced counselors at the Church here. I am convinced he has handled the experience properly and will not have this problem again.

We are very pleased he is part of our fellowship and will continue to trust him with important ministry positions in the future.

If you have any questions please feel free to call me at 941-809-3244 anytime.

Pastor Carl

Pastor Carl Dixon
Senior Pastor
Calvary Chapel Sarasota

Witnessed before me this 21st day of October 2012 by Carl Dixon, personally known to me, by Karen L. Docter

Karen L. D

Notary Public State of Florida
Karen L Docter
My Commission EE 167809
Expires 02/26/2016

3800 27th Parkway Sarasota, FL 34235-8032 Ph. 941-365-WORD (9673) http://ccsrq.cc

11/22/2012

Jackie Marcelin, MS, ARNP

2814 14th Ave S.E.

Ruskin, FL 33570

(813)751-6713

To whom it may concern

I confirm that I have known Joshua Klasinski for the past year when we both worked as medical providers at Suncoast Community Health Centers, Inc. I must say I was surprised to learn that Joshua was terminated from his employment. I was even baffled when he explained to me why he was released of his duties at work. At all times I have found Joshua to be dependable, hard-working, reliable, honest and soft-spoken. I am happy to provide further information if required.

Sincerely,

Jackie Marcelin, MS, ARNP

STATE OF FLORIDA
COUNTY OF HILLSBOROUGH
The foregoing instrument was acknowledged before me this 11/28/12 by Jackie N. Marcelin, who is personally known to me or who has produced FLDL as identification & who did (did not) take an oath.

Signature of Notary

NOTARY PUBLIC
CARLOS FIGUEROA
Notary Public, State of Florida
Commission# EE 6978
My comm. expires July 7, 2014

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

January 24, 2014

Town & Country Compounding and Consultation Services, LLC
106 Prospect Street
Ridgewood, NJ 07450

RE: Appeal of Intent to Deny Licensure

Dear Town & Country Compounding and Consultation Services, LLC:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

2205-20032

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JAN 2 2 2014

STATE OF FLORIDA
BOARD OF PHARMACY

IN RE: APPLICATION FOR NON-RESIDENT PHARMACY PERMIT OF TOWN AND COUNTRY COMPOUNDING AND CONSULTATION SERVICES

_____/

PETITION FOR HEARING NOT INVOLVING DISPUTED ISSUES OF FACT

COMES NOW Town and Country Compounding and Consultation Services, (hereinafter "Petitioner") by and through the undersigned counsel, and respectfully submits this petition for a hearing not involving disputed issues of material fact pursuant to §§120.569 and 120.57(2), Florida Statutes. As required by Rule 28-106.301, F.A.C., Petitioner states as follows:

1. The agency affected is the Board of Pharmacy, 4052 Bald Cypress Way, Tallahassee, FL 32399 (hereinafter "Board").

2. Petitioner is Town and Country Compounding and Consultation Services. For purposes of this proceeding Petitioner's address and phone number will be that of the undersigned counsel.

3. On or about January 3, 2014, Petitioner received through the U.S. Mail a Notice of Intent to Deny its application for a Non-Resident Pharmacy Permit. A copy of said Notice is attached to this Petition.

4. Petitioner's substantial interests will be affected by the Board of Pharmacy's Notice of Intent to deny its application.

5. Petitioner does not contest the material fact set forth in the Notice of Intent to Deny. Petitioner hereby requests the opportunity to address the Board and to present mitigation and arguments in this matter, including but not limited to, the

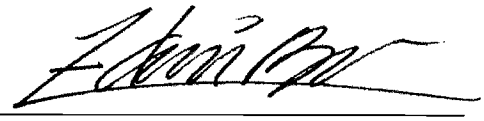
minor nature of the violation in New Jersey and its current good standing with the New Jersey Board of Pharmacy.

WHEREFORE, Petitioner requests that it be granted the opportunity for an informal hearing before the Board of Pharmacy.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by electronic mail and U.S. Mail to Tammy Collins, Acting Executive Director, Florida Board of Pharmacy; and to David Flynn, Assistant Attorney General, Counsel to the Board of Pharmacy on this 22nd day of January, 2014.

Respectfully submitted,



Edwin A. Bayó
Fla. Bar No. 327727
Grossman, Furlow & Bayó
2022-2 Raymond Diehl Road
Tallahassee, FL 32308
(850) 385-1314
fax (850) 385-4240
COUNSEL FOR PETITIONER

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE DEC 30 2013

STATE OF FLORIDA BOARD OF PHARMACY

IN RE: APPLICATION FOR NON-RESIDENT PHARMACY PERMIT	TOWN AND COUNTRY COMPOUNDING AND CONSULTATION SERVICES

NOTICE OF INTENT TO DENY

This matter came before the Board of Pharmacy (hereinafter the "Board") at a duly noticed public meeting held on December, 4 2013 in Gainesville, Florida, pursuant to the Applicant's request for license. The applicant was present.

Applicant is a licensed pharmacy in the state of New Jersey. The applicant's license has been disciplined by the New Jersey Board of Pharmacy.

The board is authorized by Section 456.072(2), Florida Statutes, to deny an applicant that has had a license to practice a profession disciplined by regulatory authority.

Therefore, pursuant to Section 456.072(2), Florida Statutes, the application for a non-resident permit is hereby **DENIED**.

DONE AND ORDERED this 30th day of December, 2013.

BOARD OF PHARMACY

Tammy Collins

Tammy Collins, Acting Executive Director
for Albert Garcia, Chair

NOTICE OF RIGHT TO HEARING

THIS NOTICE CONSTITUTES FINAL AGENCY ACTION IF NO REQUEST FOR A HEARING IS RECEIVED BY THE BOARD ON OR BEFORE THE TWENTY-FIRST DAY AFTER THE APPLICANT'S RECEIPT OF THE NOTICE. THE APPLICANT MAY REQUEST A HEARING BY FILING AN APPROPRIATE PETITION WITH THE EXECUTIVE DIRECTOR OF THE BOARD AT 4052 BALD CYPRESS WAY, BIN # C-04, TALLAHASSEE, FLORIDA 32399-3256. THE APPLICANT MAY PETITION FOR A HEARING INVOLVING DISPUTED ISSUES OF MATERIAL FACT BEFORE AN ADMINISTRATIVE LAW JUDGE PURSUANT TO SECTION 120.57 (1), FLORIDA STATUTES, OR FOR A HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT PURSUANT TO SECTION 120.57 (2) FLORIDA STATUTES.

A PETITION FOR A HEARING INVOLVING DISPUTED ISSUES OF MATERIAL FACT MUST CONTAIN INFORMATION REQUIRED BY RULE 28-106.201, FLORIDA ADMINISTRATIVE CODE, INCLUDING A STATEMENT OF ALL DISPUTED ISSUES OF MATERIAL FACT. THE BOARD MAY REFER A PETITION TO THE DIVISION OF ADMINISTRATIVE HEARINGS FOR ASSIGNMENT OF AN ADMINISTRATIVE LAW JUDGE ONLY IF THE PETITION IS IN SUBSTANTIAL COMPLIANCE WITH THE RULE REQUIREMENTS. A PETITION FOR A PROCEEDING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT MUST CONTAIN INFORMATION REQUIRED BY RULE 28.106.301 FLORIDA ADMINISTRATIVE CODE, INCLUDING A CONCISE STATEMENT OF THE ULTIMATE FACTS ALLEGED, AS WELL AS THE RULES AND STATUTES WHICH ENTITLE PETITIONER TO RELIEF.

IN ACCORDANCE WITH SECTION 120.573, FLORIDA STATUTES MEDIATION IS NOT AVAILABLE.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by Certified Mail to **Town and Country Compounding and Consultation Services, LLC, Attention Rebecca Arnold,** 106 Prospect Street, Ridgewood, New Jersey 07450; by electronic mail to **David D. Flynn**, Assistant Attorney General, david.flynn@myfloridalegal.com ; this 30th day of December, 2013.

Deputy AGENCY CLERK

7012 3050 0001 9149 6125

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

2205 F 20032

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.doh.state.fl.us/mqa/pharmacy

05/20/2013 255.00
ID: 20032 Type: F
BT: 3021296
VL: 912062531

NON-RESIDENT PHARMACY REGISTRATION

Application Type – Please choose one of the following:

____ New Establishment ($255.00 Fee)
____ Change of Location ($100.00 Fee)
____ Change of Ownership (a new permit number will be issued) ($255.00 Fee)
If applicable, list existing permit number: _____

RECEIVED
MAY 17 2013
Florida Board of Pharmacy

List Federal Employer Identification Number:

1. Corporate Name		**Telephone Number**
Town and Country Compounding and Consultation Services		201.447.2020
2. Doing Business As (d/b/a)		**E-Mail Address**
3. Mailing Address		
106 Prospect St		
City	**State**	**Zip**
Ridgewood	NJ	07450
4. Physical Address		
Same as Mailing		
City	**State**	**Zip**

5. List Prescription Department Manager (PDM)

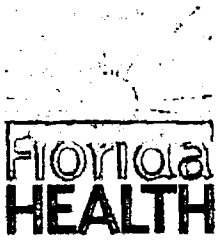
Name	**License No.**	**Start Date**	**Signature**
John J Herr	28RI01804200	April 2000	RPh.

6. Contact Person	**Telephone Number**
Rebecca Arnold	888.290.2244 ext 214
7. DEA Registration Number	**8. Do you have 24 hour access to patient records?**
BT8272229	_X_ YES ___ NO If no explain on separate sheet

9. Please provide the name, address, telephone number, and permit number of your prescription drug wholesale distributor.

Name	**Telephone Number**	**Permit Number**	
Cardinal Health	866.230.0778	430680	
Street Address	**City**	**State**	**Zip**
1120 Commerce Blvd	Swedesboro	NJ	08085

10. Operating Hours	**10a. Provide the Toll-Free Telephone number available six days a week for 40 hours below:**
Prescription Department Hours Monday-Friday: Open 9:00 am Close: 6:00 pm Saturday: Open: 9:00 am Close: 3:00 pm Sunday: Open: _____ Close: _____	(800) 850 - 2101



FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.doh.state.fl.us/mqa/pharmacy

NON-RESIDENT PHARMACY REGISTRATION

Application Type – Please choose one of the following:

_X_ New Establishment ($255.00 Fee)
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If applicable, list existing permit number: _____

List Federal Employer Identification Number:

1. Corporate Name		**Telephone Number**
Town and Country Compounding and Consultation Services,LLC		201.447.2020
2. Doing Business As (d/b/a)		**E-Mail Address**
Town and Country Compounding and Consultation Services		
3. Mailing Address		
106 Prospect St		
City	**State**	**Zip**
Ridgewood	NJ	07450
4. Physical Address		
Same as Mailing		
City	**State**	**Zip**

5. List Prescription Department Manager (PDM)

Name	**License No.**	**Start Date**	**Signature**
John J Herr	28RI01804200	April 2000	

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Prescription Department Hours Monday-Friday: Open 9:00 am Close: 6:00 pm Saturday: Open: 9:00 am Close: 3:00 pm Sunday: Open: _____ Close: _____	(800) 850 - 2101

11. Ownership Information

a. Type of Ownership: _____Individual _____Corporation _____Partnership

__X__Other: LLC

NOTE: IF CORPORATION OR LIMITED PARTNERSHIP YOU MUST INCLUDE WITH YOUR APPLICATION A COPY OF THE ARTICLES OF INCORPORATION ON FILE WITH THE SECRETARY OF STATE'S OFFICE WHERE THE PHARMACY IS LOCATED.

b. Are the applicants, officers, directors, shareholders, members and partners over the age of 18?

Yes __X__ No _____

c. List each person having an ownership interest of 5 percent or greater and any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant ***Attach a separate sheet if necessary.***

Owner/Officer-Title	Date of Birth	Mailing Address	% of Ownership
John J Herr / Manager	05/18/1961	152 Vista Terrace	100 %
		Pompton Lakes, NJ 07442	

Pursuant to Section 456.0635(2), *Florida Statutes*, questions 12 through 18 must be answered. If you answer yes to any of the following questions, explain on a separate sheet providing accurate details and submit copies of supporting documentation.

12. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, Chapter 817, or Chapter 893, Florida Statutes; or 21 U.S.C. ss. 801-970 or 42 U.S.C. ss.1395-1396? (If no, do not answer 13.)

Yes _____ No __X__

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

13. If "yes" to 12, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?

Yes _____ No _____ N/A

13a. If "yes" to 12, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).

Yes _____ **No** _____ N/A

13b. If "yes" to 12, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?

Yes_____ **No**_____ N/A

13c. If "yes" to 12, has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).

Yes _____ **No**_____ N/A

14. I have been provided and read the statement from the Florida Department of Law Enforcement regarding sharing, retention, privacy and right to challenge incorrect criminal history records and the "Privacy Statement" document from the Federal Bureau of Investigation. (Found on Page 7 of this application.)

Yes X **No** _____

15. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 16.)

Yes _____ No X

16. If the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant has been terminated, has the applicant been reinstated and in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details) N/A

17. Has the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 18 and 19)

Yes _____ No X (If yes, explain on a separate sheet providing accurate details)

18. Has the applicant been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

Yes X No _____ (If yes, explain on a separate sheet providing accurate details)

19. Did the termination occur at least 20 years prior to the date of this application?

Yes _____ No _____ (If yes, explain on a separate sheet providing accurate details) N/A

20. Are you currently registered or permitted in any other states? If yes, provide the state, permit type, and permit number for each permit. *Attach a separate sheet if necessary.*

Yes X No _____

State	Permit Type	Permit Number
New York	Pharmacy	031267
Delaware	Pharmacy	A9-0000981
Maryland	Pharmacy	P05724

21. Has the applicant, affiliated persons, partners, officer, directors, or PDM or Consultant Pharmacist of Record ever owned a pharmacy? If yes, provide the name of the pharmacy, the state where the pharmacy is located and the status of the pharmacy. *Attach a separate sheet if necessary.*

Yes X No _____ (If yes, explain on a separate sheet providing accurate details)

Town & Country Apothecary in Ridgewood, NJ. Sold the pharmacy 3 years ago

Pharmacy Name	State	Status
Town & Country Apothecary	NJ	Sold to another R Ph

22. Has any disciplinary action ever been taken against any license, permit or registration issued to the applicant, affiliated persons, partners, officers, directors or PDM in this state or any other?

Yes _____ No X (If yes, explain on a separate sheet providing accurate details)

23. Is there any other permit issued by the Florida Department of Health located at the physical location address on this application?

Yes _____ No X (If yes, explain on a separate sheet providing accurate details)

24. Is the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?

Yes_____ **No** X

ALL QUESTIONS MUST BE ANSWERED OR YOUR APPLICATION WILL BE RETURNED

****

Section 456.013(1), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or conditions stated in the application, which takes place between the initial filing of the application and the final grant or denial of the license, which might affect the decision of the department.

I certify that the statements contained in this application are true, complete, and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations that they deem appropriate and to secure any additional information concerning me, and I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board, or any municipal, county, state, or federal governmental agencies or units, and I understand according to the Florida Board of Pharmacy Statutes that a Pharmacy Permit may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in Section 465.015(2)(a), F.S.

Under penalty of perjury I have read the foregoing document and that the facts stated in it are true. I recognize that providing false information may result in disciplinary action against my license or criminal penalties.

SIGNATURE _____ RPh TITLE President DATE 05/16/2013
Owner/Officer

1899027

Nitti, Heidi

From: Hemalika Gupta [hgupta@licenselogix.com]
Sent: Wednesday, September 25, 2013 3:51 PM
To: Nitti, Heidi
Cc: Shayna Desai
Subject: Re: Town and Country Compounding and Consultation Services

Heidi,

Pursuant to our conversation the EIN is 113679270. You should be receiving the Letter from NJ.

Thanks for all your efforts.

Best,

Hema

• • •

cid:37945405-48

Hemalika Gupta | Client Fulfillment
hgupta@licenselogix.com | www.licenselogix.com

150 Grand St, 4th Floor | White Plains, NY 10601
Office: 800.292.0909 x304 | Fax: 212.672.1105

Joanne Boyer, R.Ph.
Division of Consumer Affairs
Board of Pharmacy
124 Halsey St. 6th floor
Newark, NJ 07102

January 16, 2011

Dear Ms. Boyer,

I apologize for the delay in responding, my wife was hospitalized for an extended period of time and I am now catching up with all of my work. Mr. Lake did the re-inspection of our pharmacy and as always was very professional and courteous to the staff.

I am asking that the board consider my explanation on two of the citations before rendering its final decision.

13:39-11.7(a) I am not sure why this is listed, we only have two pharmacists who prepare sterile products in the clean room and have both received formal training. We do not use any of our Certified Pharmacy Technicians to prepare sterile products. The certificates are on display in the waiting area of the pharmacy. I did show these to Mr. Lake, and have provided photocopies for the board's review, so I can only assume this was an oversight.

13:39-11.24 This was a re-inspection and when I originally opened the pharmacy the board approved the ledge in the anteroom and instructed that I paint it with the same special epoxy paint that was used on the walls. Mr. Lake made a suggestion that I mount plexi-glass so that the 6 inch ledge did not protrude and I would not be in violation in the future. The reason we did not do this when we opened was because we are below ground level and the ledge provides a means of egress from the anteroom in case of emergency. If we were to block this off as suggested we would be in violation of fire codes. We have been in operation in this facility for over eight years now and have had no problems in cleaning and surface testing of any areas in the ante room or clean room.

Everything else has already been corrected and I appreciate the Boards time in considering my explanation on these two points and I again apologize for the delay in responding.

Sincerely,

John J. Herr, R.Ph, FIACP

Date: 11/8/2010
Time entered:
Time departed:

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Report of Inspection

Name of Pharmacy: TOWN + COUNTRY COMPOUNDING AND CONSULTATION SERVICES
Address: 106 PROSPECT STREET, RIDGEWOOD, N.J. 07450

Name and registration number of pharmacist-in-charge:
JOHN MERR 28RI01804200
(If pharmacist-in-charge not present, give name and # of R.P. on duty)

The following deficiencies have been noted:

A. (13:39-5.3(b)) - NAME OF R.P. IN-CHARGE AND HOURS OF OPERATION NOT POSTED AT CONSUMER ENTRANCE

B. (13:39-7.18) (13:39-6.2(b)7) - EIGHT OUTDATED MEDICATIONS FOUND IN ACTIVE DRUG STOCK INVENTORY.
1. FOUR MEDICATIONS WERE OUTDATED BY MORE THAN ONE DAY, BUT LESS THAN FOUR MONTHS
2. FOUR MEDICATIONS WERE OUTDATED BY MORE THAN FOUR MONTHS BUT LESS THAN ONE YEAR

C. (13:39-11.7) THERE WAS NO DOCUMENTATION THAT THE PHARMACIST IN CHARGE AND ALL PERSONNEL INVOLVED IN COMPOUNDING STERILE PREPARATIONS HAVE RECEIVED PRACTICAL OR ACADEMIC TRAINING IN STERILE PREPARATION COMPOUNDING, CLEAN ROOM TECHNOLOGY, LAMINAR FLOW TECHNOLOGY AND QUALITY ASSURANCE TECHNIQUES

D. (13:39-11.7(c)) - THE TESTING OF ASEPTIC TECHNIQUE IS NOT DONE ANNUALLY FOR ALL PERSONNEL INVOLVED IN STERILE PRODUCT COMPOUNDING

E. (13:39-11.17(g)) - THE ANTEROOM HAS A LEDGE

F. (13:39-11.24) - MISSING A CURRENT TEXT PERTINENT TO THE COMPOUNDING OF STERILE PREPARATIONS

This is to acknowledge that I have been present during this inspection and concur with the findings, as so noted, with the following exceptions: if any.

COMMENTS:

(Signature of pharmacist (owner) score)

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
Inventory Quality Assurance Examination

Pharmacy: TOWN + COUNTRY COMPOUNDING AND CONSULTATION SERVICES LLC Date: 11/18/2010
Street Address: 106 PROSPECT ST.
City, State, ZIP: RIDGEWOOD, N.J. 07450
ROBERT LAKE
Inspector

The medications that were present for the filling of prescriptions have been examined for their compliance to the regulatory standards for quality assurance. The medications that were selected to be examined could potentially have been dispensed, and did not include any segments of the inventory that may already have been separated for future return to their respective manufacturers, or had been placed aside for proper disposal. The medications that were found to be in violation of the regulatory disciplines were segregated by the inspector, and then recorded below. The line entries are categorized by the deficiency for which the medication had been set apart, along with the appropriate regulatory cite. It is requested that you accept your option to compare each package of medication that has been separated as deficient against its collateral entry and, if you concur, place your initials in the left-hand column. The inspector will delete any deficiencies for which there are plausible explanations.

Initials of Registered Pharmacist	Quantity or Commercial Package Size	Name and Potency of Item	Manufacturer / Distributor	Lot Number	Expiration Date	Deficiencies [13:39-7.18] [13:39-6.2(f)7] Expired (1 day - 4 months)	Expired (4 months - 1 year)	Expired (more than 1 year)	Misbranded	"Sample" Medications (13:39-7.18)	Improperly Stored (13:39-6.2(f)7 and 8)	Other (See comments)
1. JH	50	PREDNISOLONE	PCCA	[illegible]	11/1/2010	1						
2.	100	VITAMIN D3 LIQUID	PCCA	[illegible]	11/5/2010	1						
3.	17	METHYLCOBALAMIN	—	—	USE BY [illegible]	1						
4.	100	POTASSIUM BROMIDE 50 MG IR CAPSULE	—	100410	4/2010		1					
5.	100	~100 THIRD SOME IR CAPSULE	—	102910F	4/2010		1					
6.	100	~100 THIRD SOME IR CAPSULE	—	102910D	4/2010		1					
7.	100	HYDROXYCOBALAMINE [illegible]	—	100110B	11/2/10	1						
8.	[redacted]		—	[redacted]	[redacted]							
9. JL	44	[illegible] ERYTHRIN	MEDISCA	660518	1/10		1					
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												
18.												
19.												
20.												
		Totals from above										
		Collective Totals from other pages										
		Composite Total on this page										

COMMENTS:

I hereby acknowledge and attest to the accuracy of the inventory deficiencies reported above.

John T. Han
PRINTED NAME OF PHARMACIST

SIGNATURE OF PHARMACIST

EB-23A (1/05)

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF FORMATION OF "TOWN & COUNTRY COMPOUDING AND CONSULTATION SERVICES, L.L.C.", FILED IN THIS OFFICE ON THE TWENTY-THIRD DAY OF JUNE, A.D. 2010, AT 9:03 O'CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

4839807 8100

AUTHENTICATION: 8072374

100681494

DATE: 06-23-10

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 11:16 AM 06/23/2010
FILED 09:03 AM 06/23/2010
SRV 100681494 - 4839807 FILE

CERTIFICATE OF FORMATION
OF
TOWN & COUNTRY COMPOUNDING AND CONSULTATION SERVICES, L.L.C.

This Certificate of Formation of **TOWN & COUNTRY COMPOUNDING AND CONSULTATION SERVICES, L.L.C.** (the "Company") is being filed by the undersigned authorized person to form a limited liability company under the Delaware Limited Liability Company Act, 6 *Del C* § 18-101 *et seq* (the "Act")

1 *Name* The name of the limited liability company formed hereby is **TOWN & COUNTRY COMPOUNDING AND CONSULTATION SERVICES, L.L.C**

2 *Registered Office* The address of the registered office of the Company in the State of Delaware is Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, County of New Castle, Delaware 19808

3. *Registered Agent.* The name and address of the registered agent for service of process on the Company in the State of Delaware, required to be maintained by Section 18-104 of the Act, are Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, County of New Castle, Delaware 19808.

4 *Series Limited Liability Company* The Company is a series limited liability company Separate and distinct records shall be maintained for each such series and the assets associated with each such series shall be held in such separate and distinct records (directly or indirectly, including through a nominee or otherwise) and accounted for in such separate and distinct records separately from the other assets of the Company, or any other series thereof Assets associated with a series may be held directly or indirectly, including in the name of such series, in the name of the Company, through a nominee or otherwise **Notice is hereby given that the debts, liabilities, obligations and expenses incurred, contracted for or otherwise existing with respect to a particular series shall be enforceable against the assets of such series only, and not against the assets of the Company generally or any other series thereof, and none of the debts, liabilities, obligations and expenses incurred, contracted for or otherwise existing with respect to the Company generally or any other series thereof shall be enforceable against the assets of such series.**

IN WITNESS WHEREOF, the undersigned authorized person has executed this Certificate of Formation in accordance with Section 18-204 of the Act

By: Richard J. Lambert
Name: Richard J Lambert
Title: Authorized Person

The 2012 Florida Statutes

Chapter 465 Pharmacy

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465.1901 Practice of orthotics and pedorthics.

465.001 Short Title.—This chapter shall be known as the "Florida Pharmacy Act."
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.002 Legislative findings; intent.—The Legislature finds that the practice of pharmacy is a learned profession. The sole legislative purpose for enacting this chapter is to ensure that every pharmacist practicing in this state and every pharmacy meet minimum requirements for safe practice. It is the legislative intent that pharmacists who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 1, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.003 Definitions.—As used in this chapter, the term:
(1)"Administration" means the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.
(2)"Board" means the Board of Pharmacy.
(3)"Consultant pharmacist" means a pharmacist licensed by the department and certified as a consultant pharmacist pursuant to s. 465.0125.
(4)"Data communication device" means an electronic device that receives electronic information from one source and transmits or routes it to another, including, but not limited to, any such bridge, router, switch, or gateway.
(5)"Department" means the Department of Health.
(6)"Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.
(7)"Institutional formulary system" means a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II institutional pharmacy.
(8)"Medicinal drugs" or "drugs" means those substances or preparations commonly known as "prescription" or "legend" drugs which are required by federal or state law to be dispensed only on a prescription, but shall not include patents or proprietary preparations as hereafter defined.

(9)"Patent or proprietary preparation" means a medicine in its unbroken, original package which is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof and which is not misbranded under the provisions of the Florida Drug and Cosmetic Act.

(10)"Pharmacist" means any person licensed pursuant to this chapter to practice the profession of pharmacy.

(11)(a)"Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.

1.The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2.The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

3.The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4.The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5.The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).

(b)The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

(12)"Pharmacy intern" means a person who is currently registered in, and attending, a duly accredited college or school of pharmacy, or who is a graduate of such a school or college of pharmacy, and who is duly and properly registered with the department as provided for under its rules.

(13)"Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a

prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189.

(14)"Prescription" includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term "prescription" also includes a pharmacist's order for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

(15)"Nuclear pharmacist" means a pharmacist licensed by the department and certified as a nuclear pharmacist pursuant to s. 465.0126.

(16)"Centralized prescription filling" means the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

(17)"Automated pharmacy system" means a mechanical system that delivers prescription drugs received from a Florida licensed pharmacy and maintains related transaction information.

History.—ss. 1, 7, ch. 79-226; s. 322, ch. 81-259; ss. 14, 15, ch. 81-302; ss. 2, 3, ch. 81-318; ss. 1, 2, ch. 82-179; s. 1, ch. 83-101; s. 36, ch. 83-216; s. 3, ch. 83-265; s. 29, ch. 83-329; s. 1, ch. 85-35; ss. 2, 26, 27, ch. 86-256; s. 1, ch. 88-172; s. 1, ch. 89-77; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 123, ch. 94-218; s. 239, ch. 97-103; s. 87, ch. 97-264; s. 118, ch. 99-397; s. 1, ch. 2002-182; s. 1, ch. 2004-25; s. 1, ch. 2004-387; s. 2, ch. 2007-152; s. 2, ch. 2012-60.

465.004 Board of Pharmacy.—

(1)The Board of Pharmacy is created within the department and shall consist of nine members to be appointed by the Governor and confirmed by the Senate.

(2)Seven members of the board must be licensed pharmacists who are residents of this state and who have been engaged in the practice of the profession of pharmacy in this state for at least 4 years and, to the extent practicable, represent the various pharmacy practice settings. Of the pharmacist members, one must be currently engaged in the practice of pharmacy in a community pharmacy, one must be currently engaged in the practice of pharmacy in a Class II institutional pharmacy or a Modified Class II institutional pharmacy, and five shall be pharmacists licensed in this state irrespective of practice setting. The remaining two members must be residents of the state who have never been licensed as pharmacists and who are in

no way connected with the practice of the profession of pharmacy. No person may be appointed as a consumer member who is in any way connected with a drug manufacturer or wholesaler. At least one member of the board must be 60 years of age or older.

(3)As the terms of the members expire, the Governor shall appoint successors for terms of 4 years, and such members shall serve until their successors are appointed.

(4)All provisions of chapter 456 relating to activities of the board shall apply.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 3, 26, 27, ch. 86-256; s. 16, ch. 87-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 124, ch. 94-218; s. 88, ch. 97-264; s. 67, ch. 98-166; s. 124, ch. 2000-160.

465.00 5Authority to make rules.—The Board of Pharmacy has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 4, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 126, ch. 98-200.

465.006 Disposition of fees; expenditures.—All moneys received under this chapter shall be deposited and expended pursuant to the provisions of s. 456.025. All expenditures for duties of the board authorized by this chapter shall be paid upon presentation of vouchers approved by the executive director of the board.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 68, ch. 98-166; s. 125, ch. 2000-160.

465.007 Licensure by examination.—

(1)Any person desiring to be licensed as a pharmacist shall apply to the department to take the licensure examination. The department shall examine each applicant who the board certifies has:

(a)Completed the application form and remitted an examination fee set by the board not to exceed $100 plus the actual per applicant cost to the department for purchase of portions of the examination from the National Association of Boards of Pharmacy or a similar national organization. The fees authorized under this section shall be established in sufficient amounts to cover administrative costs.

(b)Submitted satisfactory proof that she or he is not less than 18 years of age and:

1.Is a recipient of a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Office of Education; or

2.Is a graduate of a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, has demonstrated proficiency in English by passing both the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English (TSE), has passed the Foreign Pharmacy Graduate Equivalency Examination that is approved by rule of the board, and has completed a minimum of 500 hours in a supervised work activity program within this state under the supervision of a pharmacist licensed by the department, which program is approved by the board.

(c)Submitted satisfactory proof that she or he has completed an internship program approved by the board. No such board-approved program shall exceed 2,080 hours, all of which may be obtained prior to graduation.

(2)The department may permit an applicant who has satisfied all requirements of subsection (1), except those relating to age or the internship program, to take the written examination, but the passing of the examination shall confer no rights or

privileges upon the applicant in connection with the practice of pharmacy in this state.

(3)Except as provided in subsection (2), the department shall issue a license to practice pharmacy to any applicant who successfully completes the examination in accordance with this section.

History.—ss. 1, 7, ch. 79-226; ss. 13, 15, 23, 25, 30, 34, 62, ch. 80-406; ss. 2, 3, ch. 81-318; s. 30, ch. 83-329; ss. 5, 26, 27, ch. 86-256; s. 13, ch. 88-205; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 240, ch. 97-103.

465.0075 Licensure by endorsement; requirements; fee.—

(1)The department shall issue a license by endorsement to any applicant who applies to the department and remits a nonrefundable fee of not more than $100, as set by the board, and whom the board certifies:

(a)Has met the qualifications for licensure in s. 465.007(1)(b) and (c);

(b)Has obtained a passing score, as established by rule of the board, on the licensure examination of the National Association of Boards of Pharmacy or a similar nationally recognized examination, if the board certifies that the applicant has taken the required examination;

(c)1.Has submitted evidence of the active licensed practice of pharmacy, including practice in community or public health by persons employed by a governmental entity, in another jurisdiction for at least 2 of the immediately preceding 5 years or evidence of successful completion of board-approved postgraduate training or a board-approved clinical competency examination within the year immediately preceding application for licensure; or

2.Has completed an internship meeting the requirements of s. 465.007(1)(c) within the 2 years immediately preceding application; and

(d)Has obtained a passing score on the pharmacy jurisprudence portions of the licensure examination, as required by board rule.

(2)An applicant licensed in another state for a period in excess of 2 years from the date of application for licensure in this state shall submit a total of at least 30 hours of board-approved continuing education for the 2 calendar years immediately preceding application.

(3)The department may not issue a license by endorsement to any applicant who is under investigation in any jurisdiction for an act or offense that would constitute a violation of this chapter until the investigation is complete, at which time the provisions of s. 465.016 apply.

(4)The department may not issue a license by endorsement to any applicant whose license to practice pharmacy has been suspended or revoked in another state or who is currently the subject of any disciplinary proceeding in another state.

History.—s. 1, ch. 2001-166; s. 1, ch. 2008-216.

465.008 Renewal of license.—

(1)The department shall renew a license upon receipt of the renewal application, verification of compliance with s. 465.009, and receipt of a fee set by the board not to exceed $250.

(2)The department shall adopt rules establishing a procedure for the biennial renewal of licenses.

(3)Any person licensed under this chapter for 50 years or more is exempt from the payment of the renewal or delinquent fee, and the department shall issue a lifetime license to such a person.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 6, 26, 27, ch. 86-256; s. 7, ch. 90-341; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 178, ch. 94-119; s. 32, ch. 2001-277.

465.009 Continuing professional pharmaceutical education.—

(1)No license renewal shall be issued by the department until the licensee submits proof satisfactory to the board that during the 2 years prior to her or his application for renewal the licensee has participated in not less than 30 hours of continuing professional pharmaceutical education in courses approved by the board.

(2)The board shall approve only those courses that build upon the basic courses offered in the curricula of accredited colleges or schools of pharmacy, and the board shall require that the provider meets the educational standards for the program design, administration, and evaluation established by the board.

(3)Upon initial licensure, the department may reduce the number of required hours consistent with the requirements of biennial renewal.

(4)The department may make exception from the requirements of this section in an emergency or hardship case.

(5)The board may adopt rules within the requirements of this section that are necessary for its implementation, including a rule creating a committee composed of equal representation from the board, the colleges of pharmacy in the state, and practicing pharmacists within the state, whose purpose shall be to approve the content of each course offered for continuing education credit prior to the time such course is offered.

(6)Notwithstanding subsections (1)-(5):

(a)Each pharmacist certified to administer a vaccine or epinephrine autoinjection under s. 465.189 must complete a 3-hour continuing education course, which shall be offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category I credit, on the safe and effective administration of vaccines and epinephrine autoinjection as part of biennial relicensure or recertification. This course may be offered in a distance-learning format and must be included in the 30 hours of continuing professional pharmaceutical education specified in subsection (1).

(b)Each pharmacist must submit confirmation of having completed the course specified in paragraph (a) on a form provided by the board when submitting fees for license renewal.

(c)Failure to comply with paragraphs (a) and (b) results in the revocation of the authorization for a pharmacist to administer a vaccine or epinephrine autoinjection under s. 465.189. Such authorization may be restored upon completion of such requirements.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 7, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 241, ch. 97-103; s. 1, ch. 2002-184; s. 3, ch. 2012-60.

465.012 Reactivation of license; continuing education.—

(1)The board shall prescribe by rule continuing education requirements as a condition of reactivating a license. The continuing education requirements for reactivating a license shall be at least 15 classroom hours for each year the license was inactive in addition to completion of the number of hours required for renewal on the date the license became inactive.

(2)The board shall adopt rules relating to application procedures for inactive status, to the biennial renewal of inactive licenses, and to the reactivation of

licenses. The board shall prescribe by rule an application fee for inactive status, a renewal fee for inactive status, a delinquency fee, and a fee for the reactivation of a license. None of these fees may exceed the biennial renewal fee established by the board for an active license. The department may not reactivate a license unless the inactive or delinquent licensee has paid any applicable biennial renewal or delinquency fee, or both, and a reactivation fee.
History.—ss. 1, 7, ch. 79-226; s. 323, ch. 81-259; ss. 2, 3, ch. 81-318; ss. 2, 30, ch. 82-179; s. 3, ch. 83-265; ss. 8, 26, 27, ch. 86-256; s. 8, ch. 90-341; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 179, ch. 94-119.

465.0125 Consultant pharmacist license; application, renewal, fees; responsibilities; rules.—

(1)The department shall issue or renew a consultant pharmacist license upon receipt of an initial or renewal application which conforms to the requirements for consultant pharmacist initial licensure or renewal as promulgated by the board by rule and a fee set by the board not to exceed $250. The consultant pharmacist shall be responsible for maintaining all drug records required by law and for establishing drug handling procedures for the safe handling and storage of drugs. The consultant pharmacist may also be responsible for ordering and evaluating any laboratory or clinical testing when, in the judgment of the consultant pharmacist, such activity is necessary for the proper performance of the consultant pharmacist's responsibilities. Such laboratory or clinical testing may be ordered only with regard to patients residing in a nursing home facility, and then only when authorized by the medical director of the nursing home facility. The consultant pharmacist must have completed such additional training and demonstrate such additional qualifications in the practice of institutional pharmacy as shall be required by the board in addition to licensure as a registered pharmacist.

(2)Notwithstanding the provisions of subsection (1), a consultant pharmacist or a doctor of pharmacy licensed in this state may also be responsible for ordering and evaluating any laboratory or clinical testing for persons under the care of a licensed home health agency when, in the judgment of the consultant pharmacist or doctor of pharmacy, such activity is necessary for the proper performance of his or her responsibilities and only when authorized by a practitioner licensed under chapter 458, chapter 459, chapter 461, or chapter 466. In order for the consultant pharmacist or doctor of pharmacy to qualify and accept this authority, he or she must receive 3 hours of continuing education relating to laboratory and clinical testing as established by the board.

(3)The board shall promulgate rules necessary to implement and administer this section.
History.—s. 31, ch. 83-329; s. 1, ch. 85-65; ss. 9, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 1, ch. 93-231; s. 89, ch. 97-264.

465.0126 Nuclear pharmacist license; application, renewal, fees.—The department shall issue or renew a nuclear pharmacist license upon receipt of an initial or renewal application which conforms to the requirements for nuclear pharmacist initial licensure or biennial renewal as established by the board by rule and receipt of a fee established by the board by rule not to exceed $250, which fee shall be in addition to the initial licensure or biennial renewal fee for pharmacists. The nuclear pharmacist shall be responsible for the compounding and the dispensing of nuclear pharmaceuticals, for maintaining all drug records required by law, for establishing drug handling procedures for the safe handling and storage of radiopharmaceuticals and medicinal drugs, for providing the security of the prescription department, and

for complying with such other rules as relate to the practice of the profession of pharmacy. The nuclear pharmacist must have completed such additional training and must demonstrate such additional qualifications in the practice of nuclear pharmacy as is required by the board by rule in addition to licensure as a registered pharmacist. The board shall adopt rules necessary to implement and administer this section. The requirements of this section do not apply to hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.
History.—s. 2, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.013 Registration of pharmacy interns.—The department shall register as pharmacy interns persons certified by the board as being enrolled in an intern program at an accredited school or college of pharmacy or who are graduates of accredited schools or colleges of pharmacy and are not yet licensed in the state. The board may refuse to certify to the department or may revoke the registration of any intern for good cause, including grounds enumerated in this chapter for revocation of pharmacists' licenses.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.014 Pharmacy technician.—

(1)A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003(13). All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision. A pharmacy registered technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians.

(2)Any person who wishes to work as a pharmacy technician in this state must register by filing an application with the board on a form adopted by rule of the board. The board shall register each applicant who has remitted a registration fee set by the board, not to exceed $50 biennially; has completed the application form and remitted a nonrefundable application fee set by the board, not to exceed $50; is at least 17 years of age; and has completed a pharmacy technician training program approved by the Board of Pharmacy. Notwithstanding any requirements in this subsection, any registered pharmacy technician registered pursuant to this section before January 1, 2011, who has worked as a pharmacy technician for a minimum of 1,500 hours under the supervision of a licensed pharmacist or received certification as a pharmacy technician by certification program accredited by the National Commission for Certifying Agencies is exempt from the requirement to complete an initial training program for purposes of registration as required by this subsection.

(3)A person whose license to practice pharmacy has been denied, suspended, or restricted for disciplinary purposes is not eligible to register as a pharmacy technician.

(4)Notwithstanding the requirements of this section or any other provision of law, a pharmacy technician student who is enrolled in a pharmacy technician training

program that is approved by the board may be placed in a pharmacy for the purpose of obtaining practical training. A pharmacy technician student shall wear identification that indicates his or her student status when performing the functions of a pharmacy technician, and registration under this section is not required.

(5)Notwithstanding the requirements of this section or any other provision of law, a person who is licensed by the state as a pharmacy intern may be employed as a registered pharmacy technician without paying a registration fee or filing an application with the board to register as a pharmacy technician.

(6)As a condition of registration renewal, a registered pharmacy technician shall complete 20 hours biennially of continuing education courses approved by the board or the Accreditation Council for Pharmacy Education, of which 4 hours must be via live presentation and 2 hours must be related to the prevention of medication errors and pharmacy law.

(7)The board shall adopt rules that require each registration issued by the board under this section to be displayed in such a manner as to make it available to the public and to facilitate inspection by the department. The board may adopt other rules as necessary to administer this section.

(8)If the board finds that an applicant for registration as a pharmacy technician or that a registered pharmacy technician has committed an act that constitutes grounds for discipline as set forth in s. 456.072(1) or has committed an act that constitutes grounds for denial of a license or disciplinary action as set forth in this chapter, including an act that constitutes a substantial violation of s. 456.072(1) or a violation of this chapter which occurred before the applicant or registrant was registered as a pharmacy technician, the board may enter an order imposing any of the penalties specified in s. 456.072(2) against the applicant or registrant.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 10, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 242, ch. 97-103; s. 192, ch. 97-264; s. 120, ch. 99-397; ss. 2, 3, 4, ch. 2008-216.

465.015 Violations and penalties.—

(1)It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy:

(a)Which is not registered under the provisions of this chapter.

(b)In which a person not licensed as a pharmacist in this state or not registered as an intern in this state or in which an intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist fills, compounds, or dispenses any prescription or dispenses medicinal drugs.

(2)It is unlawful for any person:

(a)To make a false or fraudulent statement, either for herself or himself or for another person, in any application, affidavit, or statement presented to the board or in any proceeding before the board.

(b)To fill, compound, or dispense prescriptions or to dispense medicinal drugs if such person does not hold an active license as a pharmacist in this state, is not registered as an intern in this state, or is an intern not acting under the direct and immediate personal supervision of a licensed pharmacist.

(c)To sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription.

(d)To sell samples or complimentary packages of drug products.

(3)It is unlawful for any pharmacist to knowingly fail to report to the sheriff or other chief law enforcement agency of the county where the pharmacy is located within 24 hours after learning of any instance in which a person obtained or

attempted to obtain a controlled substance, as defined in s. 893.02, or at the close of business on the next business day, whichever is later, that the pharmacist knew or believed was obtained or attempted to be obtained through fraudulent methods or representations from the pharmacy at which the pharmacist practiced pharmacy. Any pharmacist who knowingly fails to make such a report within 24 hours after learning of the fraud or attempted fraud or at the close of business on the next business day, whichever is later, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. A sufficient report of the fraudulent obtaining of controlled substances under this subsection must contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacist concerning the transaction, such as the name and telephone number of the prescribing physician; the name, description, and any personal identification information pertaining to the person who presented the prescription; and all other material information, such as photographic or video surveillance of the transaction.

(4)(a)It is unlawful for any person other than a pharmacist licensed under this chapter to use the title "pharmacist" or "druggist" or otherwise lead the public to believe that she or he is engaged in the practice of pharmacy.

(b)It is unlawful for any person other than an owner of a pharmacy registered under this chapter to display any sign or to take any other action that would lead the public to believe that such person is engaged in the business of compounding, dispensing, or retailing any medicinal drugs. This paragraph shall not preclude a person not licensed as a pharmacist from owning a pharmacy.

(c)It is unlawful for a person, firm, or corporation that is not licensed or registered under this chapter to:

1.Use in a trade name, sign, letter, or advertisement any term, including "drug," "pharmacy," "prescription drugs," "Rx," or "apothecary," which implies that the person, firm, or corporation is licensed or registered to practice pharmacy in this state.

2.Hold himself or herself out to others as a person, firm, or corporation licensed or registered to practice pharmacy in this state.

(d)It is unlawful for a person who is not registered as a pharmacy technician under this chapter or who is not otherwise exempt from the requirement to register as a pharmacy technician, to perform the functions of a registered pharmacy technician, or hold himself or herself out to others as a person who is registered to perform the functions of a registered pharmacy technician in this state.

(5)Any person who violates any provision of subsection (1) or subsection (4) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. Any person who violates any provision of subsection (2) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In any warrant, information, or indictment, it shall not be necessary to negative any exceptions, and the burden of any exception shall be upon the defendant.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 11, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 91, ch. 91-224; s. 4, ch. 91-429; s. 243, ch. 97-103; s. 121, ch. 99-397; s. 55, ch. 2000-318; s. 2, ch. 2004-25; s. 5, ch. 2008-216; s. 10, ch. 2011-141.

465.0155 Standards of practice.—Consistent with the provisions of this act, the board shall adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and shall be applied by such agencies

when enforcing or implementing any authority granted by any applicable statute, rule, or regulation, whether federal or state.
History.—ss. 12, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.0156 Registration of nonresident pharmacies.—

(1)Any pharmacy which is located outside this state and which ships, mails, or delivers, in any manner, a dispensed medicinal drug into this state shall be considered a nonresident pharmacy, shall be registered with the board, shall provide pharmacy services at a high level of protection and competence, and shall disclose to the board the following specific information:

(a)That it maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed;

(b)The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to residents of this state. This disclosure shall be made within 30 days after any change of location, corporate officer, or pharmacist serving as the prescription department manager for dispensing medicinal drugs to residents of this state;

(c)That it complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the board pursuant to this section. It shall respond directly to all communications from the board concerning emergency circumstances arising from errors in the dispensing of medicinal drugs to the residents of this state;

(d)That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily retrievable from the other business records of the pharmacy and from the records of other medicinal drugs dispensed; and

(e)That during its regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, a toll-free telephone service shall be provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed medicinal drugs.

(2)Applications for nonresident pharmacy registration under this section shall be made on a form furnished by the board. The board may require such information as the board deems reasonably necessary to carry out the purposes of this section. The board may grant an exemption from the registration requirements of this section to any nonresident pharmacy which confines its dispensing activity to isolated transactions. The board may define by rule the term isolated transactions.

(3)The registration fee and the biennial renewal fee shall be the fee specified in s. 465.022.

(4)The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.025 or with any requirement of this section in accordance with the provisions of this chapter.

(5)In addition to the prohibitions of subsection (4) the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with the provisions of this chapter for conduct which causes serious bodily injury or serious psychological injury to a resident of this state if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to investigate within 180 days of the referral.

(6)It is unlawful for any nonresident pharmacy which is not registered pursuant to this section to advertise its services in this state, or for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy which has not registered with the board, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions.

(7)This section does not apply to Internet pharmacies required to be permitted under s. 465.0197.

(8)Notwithstanding s. 465.003(10), for purposes of this section, the registered pharmacy and the pharmacist designated by the registered pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

History.—ss. 13, 27, ch. 86-256; s. 3, ch. 89-218; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 31, ch. 95-144; s. 90, ch. 97-264; s. 2, ch. 2004-387.

465.016 Disciplinary actions.—

(1)The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(a)Obtaining a license by misrepresentation or fraud or through an error of the department or the board.

(b)Procuring or attempting to procure a license for any other person by making or causing to be made any false representation.

(c)Permitting any person not licensed as a pharmacist in this state or not registered as an intern in this state, or permitting a registered intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist, to fill, compound, or dispense any prescriptions in a pharmacy owned and operated by such pharmacist or in a pharmacy where such pharmacist is employed or on duty.

(d)Being unfit or incompetent to practice pharmacy by reason of:

1.Habitual intoxication.

2.The misuse or abuse of any medicinal drug appearing in any schedule set forth in chapter 893.

3.Any abnormal physical or mental condition which threatens the safety of persons to whom she or he might sell or dispense prescriptions, drugs, or medical supplies or for whom she or he might manufacture, prepare, or package, or supervise the manufacturing, preparation, or packaging of, prescriptions, drugs, or medical supplies.

(e)Violating chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or chapter 893.

(f)Having been convicted or found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a crime which directly relates to the ability to practice pharmacy or to the practice of pharmacy. A plea of nolo contendere constitutes a conviction for purposes of this provision.

(g)Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in s. 465.019(6) or s. 465.025.

(h)Having been disciplined by a regulatory agency in another state for any offense that would constitute a violation of this chapter.

(i)Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. For purposes of this paragraph, it shall be legally presumed that the compounding, dispensing, or distributing of legend drugs in excessive or inappropriate quantities is

not in the best interests of the patient and is not in the course of the professional practice of pharmacy.

(j)Making or filing a report or record which the licensee knows to be false, intentionally or negligently failing to file a report or record required by federal or state law, willfully impeding or obstructing such filing, or inducing another person to do so. Such reports or records include only those which the licensee is required to make or file in her or his capacity as a licensed pharmacist.

(k)Failing to make prescription fee or price information readily available by failing to provide such information upon request and upon the presentation of a prescription for pricing or dispensing. Nothing in this section shall be construed to prohibit the quotation of price information on a prescription drug to a potential consumer by telephone.

(l)Placing in the stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient; however, in a hospital, nursing home, correctional facility, or extended care facility in which unit-dose medication is dispensed to inpatients, each dose being individually sealed and the individual unit dose or unit-dose system labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any, the unused unit dose of medication may be returned to the pharmacy for redispensing. Each pharmacist shall maintain appropriate records for any unused or returned medicinal drugs.

(m)Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. A pharmacist affected under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate that she or he can resume the competent practice of pharmacy with reasonable skill and safety to her or his customers.

(n)Violating a rule of the board or department or violating an order of the board or department previously entered in a disciplinary hearing.

(o)Failing to report to the department any licensee under chapter 458 or under chapter 459 who the pharmacist knows has violated the grounds for disciplinary action set out in the law under which that person is licensed and who provides health care services in a facility licensed under chapter 395, or a health maintenance organization certificated under part I of chapter 641, in which the pharmacist also provides services.

(p)Failing to notify the Board of Pharmacy in writing within 20 days of the commencement or cessation of the practice of the profession of pharmacy in Florida when such commencement or cessation of the practice of the profession of pharmacy in Florida was a result of a pending or completed disciplinary action or investigation in another jurisdiction.

(q)Using or releasing a patient's records except as authorized by this chapter and chapter 456.

(r)Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto.

(s)Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.

(t)Committing an error or omission during the performance of a specific function of prescription drug processing, which includes, for purposes of this paragraph:

1.Receiving, interpreting, or clarifying a prescription.

2.Entering prescription data into the pharmacy's record.

3.Verifying or validating a prescription.

4.Performing pharmaceutical calculations.

5.Performing prospective drug review as defined by the board.
6.Obtaining refill and substitution authorizations.
7.Interpreting or acting on clinical data.
8.Performing therapeutic interventions.
9.Providing drug information concerning a patient's prescription.
10.Providing patient counseling.

(2)The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1).

(3)The board shall not reinstate the license of a pharmacist, or cause a license to be issued to a person it has deemed unqualified, until such time as it is satisfied that she or he has complied with all the terms and conditions set forth in the final order and that such person is capable of safely engaging in the practice of pharmacy.

(4)The board shall by rule establish guidelines for the disposition of disciplinary cases involving specific types of violations. Such guidelines may include minimum and maximum fines, periods of supervision or probation, or conditions of probation or reissuance of a license.

History.—ss. 1, 7, ch. 79-226; ss. 13, 15, 24, 25, 30, 34, 62, ch. 80-406; s. 324, ch. 81-259; ss. 2, 3, ch. 81-318; s. 3, ch. 83-101; s. 37, ch. 83-216; ss. 32, 119, ch. 83-329; s. 1, ch. 84-364; ss. 26, 27, ch. 86-256; s. 41, ch. 88-1; s. 20, ch. 88-277; s. 2, ch. 89-77; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 45, ch. 92-149; s. 32, ch. 95-144; s. 244, ch. 97-103; s. 91, ch. 97-264; s. 119, ch. 99-397; s. 126, ch. 2000-160; s. 33, ch. 2001-277; s. 3, ch. 2004-387; s. 10, ch. 2005-240; s. 5, ch. 2008-184; s. 11, ch. 2011-141.

465.0161 Distribution of medicinal drugs without a permit.—An Internet pharmacy that distributes a medicinal drug to any person in this state without being permitted as a pharmacy under this chapter commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—s. 4, ch. 2004-387.

465.017 Authority to inspect; disposal.—

(1)Duly authorized agents and employees of the department shall have the power to inspect in a lawful manner at all reasonable hours any pharmacy, hospital, clinic, wholesale establishment, manufacturer, physician's office, or any other place in the state in which drugs and medical supplies are manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale for the purpose of:

(a)Determining if any of the provisions of this chapter or any rule promulgated under its authority is being violated;

(b)Securing samples or specimens of any drug or medical supply after paying or offering to pay for such sample or specimen; or

(c)Securing such other evidence as may be needed for prosecution under this chapter.

(2)(a)Except as permitted by this chapter, and chapters 406, 409, 456, 499, and 893, records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs shall not be furnished to any person other than to the patient for whom the drugs were dispensed, or her or his legal representative, or to the department pursuant to existing law, or, in the event that the patient is incapacitated or unable to request said records, her or his spouse except upon the written authorization of such patient. Such records may be furnished in any civil or

criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her or his legal representative by the party seeking such records.

(b)The board shall adopt rules to establish practice guidelines for pharmacies to dispose of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules shall be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 1, 2, ch. 85-151; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 125, ch. 94-218; s. 245, ch. 97-103; s. 127, ch. 2000-160; s. 1, ch. 2003-166.

465.018 Community pharmacies; permits.—

(1)Any person desiring a permit to operate a community pharmacy shall apply to the department.

(2)If the board office certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated as the prescription department manager.

(3)The board may suspend or revoke the permit of, or may refuse to issue a permit to:

(a)Any person who has been disciplined or who has abandoned a permit or allowed a permit to become void after written notice that disciplinary proceedings had been or would be brought against the permit;

(b)Any person who is an officer, director, or person interested directly or indirectly in a person or business entity that has had a permit disciplined or abandoned or become void after written notice that disciplinary proceedings had been or would be brought against the permit; or

(c)Any person who is or has been an officer of a business entity, or who was interested directly or indirectly in a business entity, the permit of which has been disciplined or abandoned or become null and void after written notice that disciplinary proceedings had been or would be brought against the permit.

(4)In addition to any other remedies provided by law, the board may deny the application or suspend or revoke the license, registration, or certificate of any entity regulated or licensed by it if the applicant, licensee, registrant, or licenseholder, or, in the case of a corporation, partnership, or other business entity, if any officer, director, agent, or managing employee of that business entity or any affiliated person, partner, or shareholder having an ownership interest equal to 5 percent or greater in that business entity, has failed to pay all outstanding fines, liens, or overpayments assessed by final order of the department, unless a repayment plan is approved by the department, or has failed to comply with any repayment plan.

(5)In reviewing any application requesting a change of ownership or a change of licensee or registrant, the transferor shall, before board approval of the change, repay or make arrangements to repay any amounts owed to the department. If the transferor fails to repay or make arrangements to repay the amounts owed to the department, the license or registration may not be issued to the transferee until repayment or until arrangements for repayment are made.

(6)Passing an onsite inspection is a prerequisite to the issuance of an initial permit or a permit for a change of location. The department must make the inspection within 90 days before issuance of the permit.

(7)Community pharmacies that dispense controlled substances must maintain a record of all controlled substance dispensing consistent with the requirements of s.

893.07 and must make the record available to the department and law enforcement agencies upon request.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 3, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 12, ch. 2011-141.

465.0181 Community pharmacy permit required to dispense Schedule II or Schedule III controlled substances.—In order to dispense controlled substances listed in Schedule II or Schedule III, as provided in s. 893.03, on or after July 1, 2012, a community pharmacy permittee must be permitted pursuant to this chapter, as amended by this act, and any rules adopted thereunder.
History.—s. 13, ch. 2011-141.

465.019 Institutional pharmacies; permits.—

(1)Any institution desiring to operate an institutional pharmacy shall apply to the department. If the board certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit.

(2)The following classes of institutional pharmacies are established:

(a)"Class I institutional pharmacies" are those institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises, except that nursing homes licensed under part II of chapter 400 may purchase medical oxygen for administration to residents. No medicinal drugs may be dispensed in a Class I institutional pharmacy.

(b)"Class II institutional pharmacies" are those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. However, an institutional pharmacy located in an area or county included in an emergency order or proclamation of a state of emergency declared by the Governor may provide dispensing and consulting services to individuals who are not patients of the institution. However, a single dose of a medicinal drug may be obtained and administered to a patient on a valid physician's drug order under the supervision of a physician or charge nurse, consistent with good institutional practice procedures. The obtaining and administering of such single dose of a medicinal drug shall be pursuant to drug-handling procedures established by a consultant pharmacist. Medicinal drugs may be dispensed in a Class II institutional pharmacy, but only in accordance with the provisions of this section.

(c)"Modified Class II institutional pharmacies" are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.

(3)Medicinal drugs shall be stocked, stored, compounded, dispensed, or administered in any health care institution only when that institution has secured an institutional pharmacy permit from the department.

(4)Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the

patient. Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 24-hour period. The board may adopt rules necessary to carry out the provisions of this subsection.

(5)All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist. Every institutional pharmacy that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

(6)In a Class II institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs and proprietary preparations that may be dispensed by the pharmacists employed in such institution. A facility with a Class II institutional permit which is operating under the formulary system shall establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 2, ch. 83-101; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 29, ch. 93-211; s. 244, ch. 98-166; s. 36, ch. 99-397; s. 79, ch. 2001-277; s. 6, ch. 2008-216.

465.0193 Nuclear pharmacy permits.—Any person desiring a permit to operate a nuclear pharmacy shall apply to the department. If the board certifies that the application complies with applicable law, the department shall issue the permit. No permit shall be issued unless a duly licensed and qualified nuclear pharmacist is designated as being responsible for activities described in s. 465.0126. The permittee shall notify the department within 10 days of any change of the licensed pharmacist responsible for the compounding and dispensing of nuclear pharmaceuticals.

History.—ss. 33, 118, ch. 83-329; ss. 15, 26, 27, ch. 86-256; s. 4, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.0196 Special pharmacy permits.—Any person desiring a permit to operate a special pharmacy shall apply to the department for a special pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. A permit may not be issued unless a licensed pharmacist is designated to undertake the professional supervision of the compounding and dispensing of all drugs dispensed by the pharmacy. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs occurs. The permittee shall notify the department within 10 days after any change of the licensed pharmacist responsible for such duties. Each permittee that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

History.—ss. 34, 118, ch. 83-329; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 92, ch. 97-264; s. 122, ch. 99-397; s. 80, ch. 2001-277; s. 5, ch. 2004-387; s. 7, ch. 2008-216.

465.0197 Internet pharmacy permits.—

(1)Any person desiring a permit to operate an Internet pharmacy shall apply to the department for an Internet pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. A permit may not be issued unless a licensed pharmacist is designated as the prescription department manager for dispensing medicinal drugs to persons in this state. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs to persons in this state occurs. The permittee shall notify the department within 30 days after any change of the licensed pharmacist responsible for such duties. A permittee that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

(2)An Internet pharmacy must obtain a permit under this section to sell medicinal drugs to persons in this state.

(3)An Internet pharmacy shall provide pharmacy services at a high level of protection and competence and shall disclose to the board the following specific information:

(a)That it maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed.

(b)The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to persons in this state. This disclosure shall be made within 30 days after any change of location, principal corporate officer, or pharmacist serving as the prescription department manager for dispensing medicinal drugs to persons in this state.

(c)That it complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the board pursuant to this section. It shall respond directly to all communications from the board concerning emergency circumstances arising from errors in the dispensing of medicinal drugs to persons in this state.

(d)That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily retrievable from the other business records of the pharmacy and from the records of other medicinal drugs dispensed.

(e)That during its regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, a toll-free telephone service shall be provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed medicinal drugs.

(4)Notwithstanding s. 465.003(10), for purposes of this section, the Internet pharmacy and the pharmacist designated by the Internet pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

History.—s. 6, ch. 2004-387; s. 8, ch. 2008-216.

465.022 Pharmacies; general requirements; fees.—

(1)The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter. Such rules shall include, but shall not be limited to, rules relating to:

(a)General drug safety measures.

(b)Minimum standards for the physical facilities of pharmacies.

(c)Safe storage of floor-stock drugs.

(d)Functions of a pharmacist in an institutional pharmacy, consistent with the size and scope of the pharmacy.

(e)Procedures for the safe storage and handling of radioactive drugs.

(f)Procedures for the distribution and disposition of medicinal drugs distributed pursuant to s. 499.028.

(g)Procedures for transfer of prescription files and medicinal drugs upon the change of ownership or closing of a pharmacy.

(h)Minimum equipment which a pharmacy shall at all times possess to fill prescriptions properly.

(i)Procedures for the dispensing of controlled substances to minimize dispensing based on fraudulent representations or invalid practitioner-patient relationships.

(2)A pharmacy permit may be issued only to a natural person who is at least 18 years of age, to a partnership comprised of at least one natural person and all of whose partners are at least 18 years of age, to a governmental agency, or to a business entity that is properly registered with the Secretary of State, if required by law, and has been issued a federal employer tax identification number. Permits issued to business entities may be issued only to entities whose affiliated persons, members, partners, officers, directors, and agents, including persons required to be fingerprinted under subsection (3), are not less than 18 years of age.

(3)Any person or business entity, before engaging in the operation of a pharmacy, shall file with the board a sworn application on forms provided by the department. For purposes of this section, any person required to provide fingerprints under this subsection is an affiliated person within the meaning of s. 465.023(1).

(a)An application for a pharmacy permit must include a set of fingerprints from each person having an ownership interest of 5 percent or greater and from any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant, including officers and members of the board of directors of an applicant that is a corporation. The applicant must provide payment in the application for the cost of state and national criminal history records checks.

1.For corporations having more than $100 million of business taxable assets in this state, in lieu of these fingerprint requirements, the department shall require the prescription department manager or consultant pharmacist of record who will be directly involved in the management and operation of the pharmacy to submit a set of fingerprints.

2.A representative of a corporation described in subparagraph 1. satisfies the requirement to submit a set of his or her fingerprints if the fingerprints are on file with the department or the Agency for Health Care Administration, meet the fingerprint specifications for submission by the Department of Law Enforcement, and are available to the department.

(b)The department shall annually submit the fingerprints provided by the applicant to the Department of Law Enforcement for a state criminal history records check. The Department of Law Enforcement shall annually forward the fingerprints to the Federal Bureau of Investigation for a national criminal history records check. The department shall report the results of annual criminal history records checks to wholesale distributors permitted under chapter 499 for the purposes of s. 499.0121(15).

(c)In addition to those documents required by the department or board, each applicant having any financial or ownership interest greater than 5 percent in the subject of the application must submit a signed affidavit disclosing any financial or ownership interest greater than 5 percent in any pharmacy permitted in the past 5 years, which pharmacy has closed voluntarily or involuntarily, has filed a voluntary relinquishment of its permit, has had its permit suspended or revoked, or has had an injunction issued against it by a regulatory agency. The affidavit must disclose the reason such entity was closed, whether voluntary or involuntary.

(4)An application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The board must review the policies and procedures and may deny a permit if the policies and procedures are insufficient to reasonably prevent such dispensing. The department may phase in the submission and review of policies and procedures over one 18-month period beginning July 1, 2011.

(5)The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(a)Has obtained a permit by misrepresentation or fraud.

(b)Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(d)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(e)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(f)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g)Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h)Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i)Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j)Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

(6)The department or board may deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant has violated or failed to comply with any provision of this chapter; chapter 499, the Florida Drug and Cosmetic Act; chapter 893; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; or any rules or regulations promulgated thereunder unless the violation or noncompliance is technical.

(7)After the application has been filed with the board and the permit fee provided in this section has been received, the board shall cause the application to be fully investigated, both as to the qualifications of the applicant and the prescription department manager or consultant pharmacist designated to be in charge and as to the premises and location described in the application.

(8)The Board of Pharmacy shall have the authority to determine whether a bona fide transfer of ownership is present and that the sale of a pharmacy is not being accomplished for the purpose of avoiding an administrative prosecution.

(9)Upon the completion of the investigation of an application, the board shall approve or deny the application. If approved, the permit shall be issued by the department.

(10)A permittee must notify the department, on a form approved by the board, within 10 days after any change in prescription department manager or consultant pharmacist of record.

(11)A permittee must notify the department of the identity of the prescription department manager within 10 days after employment. The prescription department manager must comply with the following requirements:

(a)The prescription department manager of a permittee must obtain and maintain all drug records required by any state or federal law to be obtained by a pharmacy, including, but not limited to, records required by or under this chapter, chapter 499, or chapter 893. The prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

(b)The prescription department manager must ensure the security of the prescription department. The prescription department manager must notify the board of any theft or significant loss of any controlled substances within 1 business day after discovery of the theft or loss.

(c)A registered pharmacist may not serve as the prescription department manager in more than one location unless approved by the board.

(12)The board shall adopt rules that require the keeping of such records of prescription drugs as are necessary for the protection of public health, safety, and welfare.

(a)All required records documenting prescription drug distributions shall be readily available or immediately retrievable during an inspection by the department.

(b)The records must be maintained for 4 years after the creation or receipt of the record, whichever is later.

(13)Permits issued by the department are not transferable.

(14)The board shall set the fees for the following:

(a)Initial permit fee not to exceed $250.

(b)Biennial permit renewal not to exceed $250.

(c)Delinquent fee not to exceed $100.
(d)Change of location fee not to exceed $100.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 36, ch. 82-225; ss. 16, 26, 27, ch. 86-256; s. 6, ch. 88-172; s. 14, ch. 88-205; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 127, ch. 98-200; s. 27, ch. 2009-223; s. 14, ch. 2011-141.

465.023 Pharmacy permittee; disciplinary action.—
(1)The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee if the permittee, or any affiliated person, partner, officer, director, or agent of the permittee, including a person fingerprinted under s. 465.022(3), has:
(a)Obtained a permit by misrepresentation or fraud or through an error of the department or the board;
(b)Attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation;
(c)Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or of chapter 893;
(d)Been convicted or found guilty, regardless of adjudication, of a felony or any other crime involving moral turpitude in any of the courts of this state, of any other state, or of the United States;
(e)Been convicted or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for any offense that would constitute a violation of this chapter;
(f)Been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy;
(g)Been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud; or
(h)Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.
(2)If a pharmacy permit is revoked or suspended, the owner, manager, or proprietor shall cease to operate the establishment as a pharmacy as of the effective date of such suspension or revocation. In the event of such revocation or suspension, the owner, manager, or proprietor shall remove from the premises all signs and symbols identifying the premises as a pharmacy. The period of such suspension shall be prescribed by the Board of Pharmacy, but in no case shall it exceed 1 year. In the event that the permit is revoked, the person owning or operating the establishment shall not be entitled to make application for a permit to operate a pharmacy for a period of 1 year from the date of such revocation. Upon the effective date of such revocation, the permittee shall advise the Board of Pharmacy of the disposition of the medicinal drugs located on the premises. Such

disposition shall be subject to continuing supervision and approval by the Board of Pharmacy.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 38, ch. 83-216; ss. 35, 119, ch. 83-329; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 33, ch. 95-144; s. 7, ch. 2004-387; s. 6, ch. 2008-184; s. 28, ch. 2009-223.

465.0235 Automated pharmacy systems used by long-term care facilities, hospices, or state correctional institutions.—

(1)A pharmacy may provide pharmacy services to a long-term care facility or hospice licensed under chapter 400 or chapter 429 or a state correctional institution operated under chapter 944 through the use of an automated pharmacy system that need not be located at the same location as the pharmacy.

(2)Medicinal drugs stored in bulk or unit of use in an automated pharmacy system servicing a long-term care facility, hospice, or correctional institution are part of the inventory of the pharmacy providing pharmacy services to that facility, hospice, or institution, and drugs delivered by the automated pharmacy system are considered to have been dispensed by that pharmacy.

(3)The operation of an automated pharmacy system must be under the supervision of a Florida-licensed pharmacist. To qualify as a supervisor for an automated pharmacy system, the pharmacist need not be physically present at the site of the automated pharmacy system and may supervise the system electronically. The Florida-licensed pharmacist shall be required to develop and implement policies and procedures designed to verify that the medicinal drugs delivered by the automated dispensing system are accurate and valid and that the machine is properly restocked.

(4)The Legislature does not intend this section to limit the current practice of pharmacy in this state. This section is intended to allow automated pharmacy systems to enhance the ability of a pharmacist to provide pharmacy services in locations that do not employ a full-time pharmacist. This section does not limit or replace the use of a consultant pharmacist.

(5)The board shall adopt rules governing the use of an automated pharmacy system by January 1, 2005, which must specify:

(a)Recordkeeping requirements;

(b)Security requirements; and

(c)Labeling requirements that permit the use of unit-dose medications if the facility, hospice, or institution maintains medication-administration records that include directions for use of the medication and the automated pharmacy system identifies:

1.The dispensing pharmacy;

2.The prescription number;

3.The name of the patient; and

4.The name of the prescribing practitioner.

History.—s. 3, ch. 2004-25; s. 92, ch. 2006-197.

465.024Promoting sale of certain drugs prohibited.—

(1)It is declared that the unrestricted use of certain controlled substances, causing abnormal reactions that may interfere with the user's physical reflexes and judgments, may create hazardous circumstances which may cause accidents to the user and to others, thereby affecting the public health, safety, and welfare. It is further declared to be in the public interest to limit the means of promoting the sale and use of these drugs. All provisions of this section shall be liberally construed to carry out these objectives and purposes.

(2)No pharmacist, owner, or employee of a retail drug establishment shall use any communication media to promote or advertise the use or sale of any controlled substance appearing in any schedule in chapter 893.
(3)This section shall not prohibit the advertising of any medicinal drugs, other than those controlled substances specified in chapter 893, or any patent or proprietary preparation, provided the advertising is not false, misleading, or deceptive.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.0244 Information disclosure.—Every pharmacy shall make available on its Internet website a link to the performance outcome and financial data that is published by the Agency for Health Care Administration pursuant to s. 408.05(3)(k) and shall place in the area where customers receive filled prescriptions notice that such information is available electronically and the address of its Internet website.
History.—s. 39, ch. 2004-297; s. 14, ch. 2006-261.

465.025 Substitution of drugs.—
(1)As used in this section:
(a)"Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler, or distributor.
(b)"Generically equivalent drug product" means a drug product with the same active ingredient, finished dosage form, and strength.
(c)"Prescriber" means any practitioner licensed to prescribe medicinal drugs.
(2)A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product that is:
(a)Distributed by a business entity doing business, and subject to suit and service of legal process, in the United States; and
(b)Listed in the formulary of generic and brand name drug products as provided in subsection (5) for the brand name drug prescribed,

unless the prescriber writes the words "MEDICALLY NECESSARY," in her or his own handwriting, on the face of a written prescription; unless, in the case of an oral prescription, the prescriber expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary; or unless, in the case of a prescription that is electronically generated and transmitted, the prescriber makes an overt act when transmitting the prescription to indicate that the brand name drug prescribed is medically necessary. When done in conjunction with the electronic transmission of the prescription, the prescriber's overt act indicates to the pharmacist that the brand name drug prescribed is medically necessary.

(3)(a)Any pharmacist who substitutes any drug as provided in subsection (2) shall notify the person presenting the prescription of such substitution, together with the existence and amount of the retail price difference between the brand name drug and the drug substituted for it, and shall inform the person presenting the prescription that such person may refuse the substitution as provided in subsection (2).
(b)Any pharmacist substituting a less expensive drug product shall pass on to the consumer the full amount of the savings realized by such substitution.
(4)Each pharmacist shall maintain a record of any substitution of a generically equivalent drug product for a prescribed brand name drug as provided in this section.

(5)Each community pharmacy shall establish a formulary of generic and brand name drug products which, if selected as the drug product of choice, would not pose a threat to the health and safety of patients receiving prescription medication. In compiling the list of generic and brand name drug products for inclusion in the formulary, the pharmacist shall rely on drug product research, testing, information, and formularies compiled by other pharmacies, by states, by the United States Department of Health, Education, and Welfare, by the United States Department of Health and Human Services, or by any other source which the pharmacist deems reliable. Each community pharmacy shall make such formulary available to the public, the Board of Pharmacy, or any physician requesting same. This formulary shall be revised following each addition, deletion, or modification of said formulary.

(6)The Board of Pharmacy and the Board of Medicine shall establish by rule a formulary of generic drug type and brand name drug products which are determined by the boards to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication.

(a)The formulary may be added to or deleted from as the Board of Pharmacy and the Board of Medicine deem appropriate. Any person who requests any inclusion, addition, or deletion of a generic drug type or brand name drug product to the formulary shall have the burden of proof to show cause why such inclusion, addition, or deletion should be made.

(b)Upon adoption of the formulary required by this subsection, and upon each addition, deletion, or modification to the formulary, the Board of Pharmacy shall mail a copy to each manager of the prescription department of each community pharmacy licensed by the state, each nonresident pharmacy registered in the state, and each board regulating practitioners licensed by the laws of the state to prescribe drugs shall incorporate such formulary into its rules. No pharmacist shall substitute a generically equivalent drug product for a prescribed brand name drug product if the brand name drug product or the generic drug type drug product is included in the said formulary.

(7)Every community pharmacy shall display in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign in block letters not less than 1 inch in height which shall read: "CONSULT YOUR PHARMACIST CONCERNING THE AVAILABILITY OF A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG AND THE REQUIREMENTS OF FLORIDA LAW."

(8)The standard of care to be applied to the acts of any pharmacist performing professional services in compliance with this section when a substitution is made by said pharmacist shall be that which would apply to the performance of professional services in the dispensing of a prescription order prescribing a drug by generic name. In no event when a pharmacist substitutes a drug shall the prescriber be liable in any action for loss, damage, injury, or death to any person occasioned by or arising from the use or nonuse of the substituted drug, unless the original drug was incorrectly prescribed.

History.—ss. 1, 7, ch. 79-226; s. 325, ch. 81-259; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 4, ch. 89-218; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 20, ch. 91-220; s. 4, ch. 91-429; s. 246, ch. 97-103; s. 4, ch. 2006-271.

465.0251 Generic drugs; removal from formulary under specified circumstances.—

(1)The Board of Pharmacy and the Board of Medicine shall remove any generic named drug product from the formulary established by s. 465.025(6), if every commercially marketed equivalent of that drug product is "A" rated as

therapeutically equivalent to a reference listed drug or is a reference listed drug as referred to in "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) published by the United States Food and Drug Administration.

(2)Nothing in this act shall alter or amend s. 465.025 as to existing law providing for the authority of physicians to prohibit generic drug substitution by writing "medically necessary" on the prescription.

History.—ss. 1, 2, ch. 2001-146.

465.0255 Expiration date of medicinal drugs; display; related use and storage instructions.—

(1)The manufacturer, repackager, or other distributor of any medicinal drug shall display the expiration date of each drug in a readable fashion on the container and on its packaging. The term "readable" means conspicuous and bold.

(2)Each pharmacist for a community pharmacy dispensing medicinal drugs and each practitioner dispensing medicinal drugs on an outpatient basis shall display on the outside of the container of each medicinal drug dispensed, or in other written form delivered to the purchaser:

(a)The expiration date when provided by the manufacturer, repackager, or other distributor of the drug; or

(b)An earlier beyond-use date for expiration, which may be up to 1 year after the date of dispensing.

The dispensing pharmacist or practitioner must provide information concerning the expiration date to the purchaser upon request and must provide appropriate instructions regarding the proper use and storage of the drug.

(3)This section does not impose liability on the dispensing pharmacist or practitioner for damages related to, or caused by, a medicinal drug that loses its effectiveness prior to the expiration date displayed by the dispensing pharmacist or practitioner.

(4)The provisions of this section are intended to notify the patient receiving a medicinal drug of the information required by this section, and the dispensing pharmacist or practitioner shall not be liable for the patient's failure to heed such notice or to follow the instructions for storage.

History.—ss. 1, 2, ch. 93-44; s. 8, ch. 2004-387.

465.026 Filling of certain prescriptions.—Nothing contained in this chapter shall be construed to prohibit a pharmacist licensed in this state from filling or refilling a valid prescription which is on file in a pharmacy located in this state or in another state and has been transferred from one pharmacy to another by any means, including any electronic means, under the following conditions:

(1)Prior to dispensing any transferred prescription, the dispensing pharmacist must, either verbally or by any electronic means, do all of the following:

(a)Advise the patient that the prescription on file at the other pharmacy must be canceled before it may be filled or refilled.

(b)Determine that the prescription is valid and on file at the other pharmacy and that the prescription may be filled or refilled, as requested, in accordance with the prescriber's intent expressed on the prescription.

(c)Notify the pharmacist or pharmacy where the prescription is on file that the prescription must be canceled.

(d)Record in writing, or by any electronic means, the prescription order, the name of the pharmacy at which the prescription was on file, the prescription number, the

name of the drug and the original amount dispensed, the date of original dispensing, and the number of remaining authorized refills.

(e)Obtain the consent of the prescriber to the refilling of the prescription when the prescription, in the dispensing pharmacist's professional judgment, so requires. Any interference with the professional judgment of the dispensing pharmacist by any pharmacist or pharmacy permittee, or its agents or employees, shall be grounds for discipline.

(2)Upon receipt of a prescription transfer request, if the pharmacist is satisfied in her or his professional judgment that the request is valid, or if the request has been validated by any electronic means, the pharmacist or pharmacy must do all of the following:

(a)Transfer the information required by paragraph (1)(d) accurately and completely.

(b)Record on the prescription, or by any electronic means, the requesting pharmacy and pharmacist and the date of request.

(c)Cancel the prescription on file by electronic means or by recording the word "void" on the prescription record. No further prescription information shall be given or medication dispensed pursuant to the original prescription.

(3)If a transferred prescription is not dispensed within a reasonable time, the pharmacist shall, by any means, so notify the transferring pharmacy. Such notice shall serve to revalidate the canceled prescription. The pharmacist who has served such notice shall then cancel the prescription in the same manner as set forth in paragraph (2)(c).

(4)In the case of a prescription to be transferred from or to a pharmacy located in another state, it shall be the responsibility of the pharmacist or pharmacy located in the State of Florida to verify, whether by electronic means or otherwise, that the person or entity involved in the transfer is a licensed pharmacist or pharmacy in the other state.

(5)Electronic transfers of prescriptions are permitted regardless of whether the transferor or transferee pharmacy is open for business.

(6)The transfer of a prescription for medicinal drugs listed in Schedules III, IV, and V appearing in chapter 893 for the purpose of refill dispensing is permissible, subject to the requirements of this section and federal law. Compliance with federal law shall be deemed compliance with the requirements of this section.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 1, ch. 85-71; ss. 17, 26, 27, ch. 86-256; s. 1, ch. 90-2; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 247, ch. 97-103; s. 93, ch. 97-264; s. 4, ch. 2004-25; s. 9, ch. 2004-387; s. 1, ch. 2006-243.

465.0265 Centralized prescription filling.—

(1)A pharmacy licensed under this chapter may perform centralized prescription filling for another pharmacy, provided that the pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.

(2)Each pharmacy performing or contracting for the performance of centralized prescription filling pursuant to this section must maintain a policy and procedures manual, which shall be made available to the board or its agent upon request. The policy and procedures manual shall include the following information:

(a)A description of how each pharmacy will comply with federal and state laws, rules, and regulations.

(b)The procedure for maintaining appropriate records to identify the pharmacist responsible for dispensing the prescription and counseling the patient.
(c)The procedure for tracking the prescription during each stage of the filling and dispensing process.
(d)The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription.
(e)The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.
(f)The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.
(3)The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription as set forth in s. 465.026 or as a wholesale distribution as set forth in s. 499.003(54).
(4)The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.
History.—s. 2, ch. 2002-182; s. 40, ch. 2008-207; s. 38, ch. 2010-161.

465.0266 Common database.—Nothing contained in this chapter shall be construed to prohibit the dispensing by a pharmacist licensed in this state or another state of a prescription contained in a common database, and such dispensing shall not constitute a transfer as defined in s. 465.026(1)-(6), provided that the following conditions are met:
(1)All pharmacies involved in the transactions pursuant to which the prescription is dispensed are under common ownership and utilize a common database.
(2)All pharmacies involved in the transactions pursuant to which the prescription is dispensed and all pharmacists engaging in dispensing functions are properly licensed, permitted, or registered in this state or another state.
(3)The common database maintains a record of all pharmacists involved in the process of dispensing a prescription.
(4)The owner of the common database maintains a policy and procedures manual that governs its participating pharmacies, pharmacists, and pharmacy employees and that is available to the board or its agent upon request. The policy and procedures manual shall include the following information:
(a)A best practices model detailing how each pharmacy and each pharmacist accessing the common database will comply with applicable federal and state laws, rules, and regulations.
(b)The procedure for maintaining appropriate records for regulatory oversight for tracking a prescription during each stage of the filling and dispensing process, identifying the pharmacists involved in filling and dispensing the prescription and counseling the patient, and responding to any requests for information made by the board under s. 465.0156.
(c)The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.
(d)A quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care through the use of the common database.

Any pharmacist dispensing a prescription has at all times the right and obligation to exercise his or her independent professional judgment. Notwithstanding other provisions in this section, no pharmacist licensed in this state participating in the dispensing of a prescription pursuant to

this section shall be responsible for the acts and omissions of another person participating in the dispensing process provided such person is not under the direct supervision and control of the pharmacist licensed in this state.

History.—s. 2, ch. 2006-243.

465.027 Exceptions.—This chapter shall not be construed to prohibit the sale of home remedies or preparations commonly known as patents or proprietary preparations, when such are sold only in original or unbroken packages, nor shall this chapter be construed to prevent businesses from engaging in the sale of sundries or patents or proprietary preparations.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 18, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.0275 Emergency prescription refill.—In the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication, with the exception of those areas or counties included in an emergency order or proclamation of a state of emergency declared by the Governor, in which the executive order may authorize the pharmacist to dispense up to a 30-day supply, providing that:

(1)The prescription is not for a medicinal drug listed in Schedule II appearing in chapter 893.

(2)The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition.

(3)In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort.

(4)The dispensing pharmacist creates a written order containing all of the prescription information required by this chapter and chapters 499 and 893 and signs that order.

(5)The dispensing pharmacist notifies the prescriber of the emergency dispensing within a reasonable time after such dispensing.

History.—ss. 19, 27, ch. 86-256; s. 3, ch. 89-77; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 30, ch. 93-211.

465.0276 Dispensing practitioner.—

(1)(a)A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.

(b)A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03. This paragraph does not apply to:

1.The dispensing of complimentary packages of medicinal drugs which are labeled as a drug sample or complimentary drug as defined in s. 499.028 to the practitioner's own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (5).

2.The dispensing of controlled substances in the health care system of the Department of Corrections.

3.The dispensing of a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure. The amount dispensed pursuant to the subparagraph may not exceed a 14-day supply. This exception does not allow for the dispensing of a controlled substance listed in Schedule II or Schedule III more than 14 days after the performance of the surgical procedure. For purposes of this subparagraph, the term "surgical procedure" means any procedure in any setting which involves, or reasonably should involve:

a.Perioperative medication and sedation that allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal or tactile stimulation and makes intra- and postoperative monitoring necessary; or

b.The use of general anesthesia or major conduction anesthesia and preoperative sedation.

4.The dispensing of a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial. For purposes of this subparagraph, the term "approved clinical trial" means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the United States Food and Drug Administration.

5.The dispensing of methadone in a facility licensed under s. 397.427 where medication-assisted treatment for opiate addiction is provided.

6.The dispensing of a controlled substance listed in Schedule II or Schedule III to a patient of a facility licensed under part IV of chapter 400.

(2)A practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind, whether direct or indirect, must:

(a)Register with her or his professional licensing board as a dispensing practitioner and pay a fee not to exceed $100 at the time of such registration and upon each renewal of her or his license. Each appropriate board shall establish such fee by rule.

(b)Comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, this chapter and chapters 499 and 893 and all federal laws and federal regulations.

(c)Before dispensing any drug, give the patient a written prescription and orally or in writing advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy.

(3)The department shall inspect any facility where a practitioner dispenses medicinal drugs pursuant to subsection (2) in the same manner and with the same frequency as it inspects pharmacies for the purpose of determining whether the practitioner is in compliance with all statutes and rules applicable to her or his dispensing practice.

(4)The registration of any practitioner who has been found by her or his respective board to have dispensed medicinal drugs in violation of this chapter shall be subject to suspension or revocation.

(5)A practitioner who confines her or his activities to the dispensing of complimentary packages of medicinal drugs to the practitioner's own patients in the regular course of her or his practice, without the payment of fee or remuneration of any kind, whether direct or indirect, and who herself or himself dispenses such drugs is not required to register pursuant to this section. The practitioner must dispense such drugs in the manufacturer's labeled package with the practitioner's name, patient's name, and date dispensed, or, if such drugs are not dispensed in the manufacturer's labeled package, they must be dispensed in a container which bears the following information:

(a)Practitioner's name;

(b)Patient's name;

(c)Date dispensed;
(d)Name and strength of drug; and
(e)Directions for use.
History.—ss. 20, 27, ch. 86-256; s. 1, ch. 88-159; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 95, ch. 92-149; s. 248, ch. 97-103; s. 11, ch. 2010-211; s. 15, ch. 2011-141.

465.035 Dispensing of medicinal drugs pursuant to facsimile of prescription.—
(1)Notwithstanding any other provision of this chapter, it is lawful for a pharmacy to dispense medicinal drugs, including controlled substances authorized under subsection (2), based on reception of an electronic facsimile of the original prescription if all of the following conditions are met:
(a)In the course of the transaction the pharmacy complies with laws and administrative rules relating to pharmacies and pharmacists.
(b)Except in the case of the transmission of a prescription by a person authorized by law to prescribe medicinal drugs:
1.The facsimile system making the transmission provides the pharmacy receiving the transmission with audio communication via telephonic, electronic, or similar means with the person presenting the prescription.
2.At the time of the delivery of the medicinal drugs, the pharmacy has in its possession the original prescription for the medicinal drug involved.
3.The recipient of the prescription shall sign a log and shall indicate the name and address of both the recipient and the patient for whom the medicinal drug was prescribed.
(2)Controlled substances listed in Schedule II as defined in s. 893.03(2) may be dispensed as provided in this section to the extent allowed by 21 C.F.R. s. 1306.11.
History.—s. 5, ch. 90-341; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 8, ch. 91-201; s. 4, ch. 91-429; s. 94, ch. 97-264; s. 5, ch. 99-186.

465.185 Rebates prohibited; penalties.—
(1)It is unlawful for any person to pay or receive any commission, bonus, kickback, or rebate or engage in any split-fee arrangement in any form whatsoever with any physician, surgeon, organization, agency, or person, either directly or indirectly, for patients referred to a pharmacy registered under this chapter.
(2)The department shall adopt rules which assess administrative penalties for acts prohibited by subsection (1). In the case of an entity licensed by the department, such penalties may include any disciplinary action available to the department under the appropriate licensing laws. In the case of an entity not licensed by the department, such penalties may include:
(a)A fine not to exceed $1,000.
(b)If applicable, a recommendation by the department to the appropriate regulatory agency that disciplinary action be taken.
History.—s. 2, ch. 79-106; s. 326, ch. 81-259; s. 2, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 125, ch. 92-149.

465.186 Pharmacist's order for medicinal drugs; dispensing procedure; development of formulary.—
(1)There is hereby created a committee composed of two members of the Board of Medicine licensed under chapter 458 chosen by said board, one member of the Board of Osteopathic Medicine licensed under chapter 459 chosen by said board, three members of the Board of Pharmacy licensed under this chapter and chosen by said board, and one additional person with a background in health care or pharmacology

chosen by the committee. The committee shall establish a formulary of medicinal drug products and dispensing procedures which shall be used by a pharmacist when ordering and dispensing such drug products to the public. Dispensing procedures may include matters related to reception of patient, description of his or her condition, patient interview, patient physician referral, product selection, and dispensing and use limitations. In developing the formulary of medicinal drug products, the committee may include products falling within the following categories:

(a)Any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the United States Food and Drug Administration.

(b)Any medicinal drug recommended by the United States Food and Drug Administration Advisory Panel for transfer to over-the-counter status pending approval by the United States Food and Drug Administration.

(c)Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination.

(d)Any medicinal drug containing fluoride in any strength.

(e)Any medicinal drug containing lindane in any strength.

(f)Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program.

(g)Any topical anti-infectives excluding eye and ear topical anti-infectives.

However, any drug which is sold as an over-the-counter proprietary drug under federal law shall not be included in the formulary or otherwise affected by this section.

(2)The Board of Pharmacy, the Board of Medicine, and the Board of Osteopathic Medicine shall adopt by rule a formulary of medicinal drugs and dispensing procedures as established by the committee. A pharmacist may order and dispense a product from the formulary pursuant to the established dispensing procedure, as adopted by the boards, for each drug in conjunction with its inclusion in the formulary. Any drug product ordered by a pharmacist shall be selected and dispensed only by the pharmacist so ordering, and said order shall not be refilled, nor shall another medicinal drug be ordered for the same condition unless such act is consistent with dispensing procedures established by the committee. Appropriate referral to another health care provider is indicated under such circumstances. On each occasion of such dispensing, the pharmacist shall create and maintain a prescription record in the form required by law.

(3)Affixed to the container containing a medicinal drug dispensed pursuant to this section shall be a label bearing the following information:

(a)The name of the pharmacist ordering the medication.

(b)The name and address of the pharmacy from which the medication was dispensed.

(c)The date of dispensing.

(d)The order number or other identification adequate to readily identify the order.

(e)The name of the patient for whom the medicinal drug was ordered.

(f)The directions for use of the medicinal drug ordered.

(g)A clear, concise statement that the order may not be refilled.

(4)Any pharmacist performing the services authorized by this section shall be eligible for reimbursement by third party prescription programs when so provided by contract or when otherwise provided by such program.

(5)Any person ordering or dispensing medicinal drugs in violation of this section shall be guilty of a misdemeanor of the first degree, and such violation shall be punishable as provided in s. 775.082 or s. 775.083.

History.—ss. 2, 3, ch. 85-35; ss. 26, 27, ch. 86-256; s. 56, ch. 87-225; s. 59, ch. 91-137; s. 21, ch. 91-140; s. 6, ch. 91-156; s. 21, ch. 91-220; s. 92, ch. 91-224; s. 4, ch. 91-429; s. 96, ch. 92-149; s. 249, ch. 97-103; s. 95, ch. 97-264.

465.187 Sale of medicinal drugs.—The sale of medicinal drugs dispensed upon the order of a practitioner pursuant to this chapter shall be entitled to the exemption from sales tax provided for in s. 212.08.
History.—ss. 21, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.188 Medicaid audits of pharmacies.—

(1)Notwithstanding any other law, when an audit of the Medicaid-related records of a pharmacy licensed under chapter 465 is conducted, such audit must be conducted as provided in this section.

(a)The agency conducting the audit must give the pharmacist at least 1 week's prior notice of the initial audit for each audit cycle.

(b)An audit must be conducted by a pharmacist licensed in this state.

(c)Any clerical or recordkeeping error, such as a typographical error, scrivener's error, or computer error regarding a document or record required under the Medicaid program does not constitute a willful violation and is not subject to criminal penalties without proof of intent to commit fraud.

(d)A pharmacist may use the physician's record or other order for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.

(e)A finding of an overpayment or underpayment must be based on the actual overpayment or underpayment and may not be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

(f)Each pharmacy shall be audited under the same standards and parameters.

(g)A pharmacist must be allowed at least 10 days in which to produce documentation to address any discrepancy found during an audit.

(h)The period covered by an audit may not exceed 1 calendar year.

(i)An audit may not be scheduled during the first 5 days of any month due to the high volume of prescriptions filled during that time.

(j)The audit report must be delivered to the pharmacist within 90 days after conclusion of the audit. A final audit report shall be delivered to the pharmacist within 6 months after receipt of the preliminary audit report or final appeal, as provided for in subsection (2), whichever is later.

(k)The audit criteria set forth in this section applies only to audits of claims submitted for payment subsequent to July 11, 2003. Notwithstanding any other provision in this section, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating penalties for Medicaid audits.

(2)The Agency for Health Care Administration shall establish a process under which a pharmacist may obtain a preliminary review of an audit report and may appeal an unfavorable audit report without the necessity of obtaining legal counsel. The preliminary review and appeal may be conducted by an ad hoc peer review panel, appointed by the agency, which consists of pharmacists who maintain an active practice. If, following the preliminary review, the agency or review panel finds that an unfavorable audit report is unsubstantiated, the agency shall dismiss the audit report without the necessity of any further proceedings.

(3)This section does not apply to investigative audits conducted by the Medicaid Fraud Control Unit of the Department of Legal Affairs.

(4)This section does not apply to any investigative audit conducted by the Agency for Health Care Administration when the agency has reliable evidence that the claim that is the subject of the audit involves fraud, willful misrepresentation, or abuse under the Medicaid program.

History.—s. 1, ch. 2003-277; s. 11, ch. 2004-344.

465.189 Administration of vaccines and epinephrine autoinjection.—

(1)In accordance with guidelines of the Centers for Disease Control and Prevention for each recommended immunization or vaccine, a pharmacist may administer the following vaccines to an adult within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459:

(a)Influenza vaccine.

(b)Pneumococcal vaccine.

(2)In accordance with guidelines of the Centers for Disease Control and Prevention, a pharmacist may administer the shingles vaccine within the framework of an established protocol and pursuant to a written or electronic prescription issued to the patient by a physician licensed under chapter 458 or chapter 459.

(3)In order to address any unforeseen allergic reaction, a pharmacist may administer epinephrine using an autoinjector delivery system within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459.

(4)A pharmacist may not enter into a protocol unless he or she maintains at least $200,000 of professional liability insurance and has completed training in administering vaccines authorized under this section.

(5)A pharmacist administering vaccines under this section shall maintain and make available patient records using the same standards for confidentiality and maintenance of such records as those that are imposed on health care practitioners under s. 456.057. These records shall be maintained for a minimum of 5 years.

(6)The decision by a supervising physician licensed under chapter 458 or chapter 459 to enter into a protocol under this section is a professional decision on the part of the practitioner, and a person may not interfere with a physician's decision as to entering into such a protocol. A pharmacist may not enter into a protocol that is to be performed while acting as an employee without the written approval of the owner of the pharmacy. Pharmacists shall forward vaccination records to the department for inclusion in the state registry of immunization information.

(7)Any pharmacist seeking to administer vaccines to adults under this section must be certified to administer such vaccines pursuant to a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a minimum, require that the pharmacist attend at least 20 hours of continuing education classes approved by the board. The program shall have a curriculum of instruction concerning the safe and effective administration of such vaccines, including, but not limited to, potential allergic reactions to such vaccines.

(8)The written protocol between the pharmacist and supervising physician under this section must include particular terms and conditions imposed by the supervising physician upon the pharmacist relating to the administration of vaccines by the pharmacist pursuant to this section. The written protocol shall include, at a minimum, specific categories and conditions among patients for whom the supervising physician authorizes the pharmacist to administer such vaccines. The terms, scope, and conditions set forth in the written protocol between the pharmacist

and the supervising physician must be appropriate to the pharmacist's training and certification for administering such vaccines. Pharmacists who have been delegated the authority to administer vaccines under this section by the supervising physician under the protocol shall provide evidence of current certification by the Board of Pharmacy to the supervising physician. A supervising physician shall review the administration of such vaccines by the pharmacist pursuant to the written protocol between them, and this review shall take place as outlined in the written protocol. The process and schedule for the review shall be outlined in the written protocol between the pharmacist and the supervising physician.

(9)The pharmacist shall submit to the Board of Pharmacy a copy of his or her protocol or written agreement to administer vaccines under this section.

History.—s. 3, ch. 2007-152; s. 1, ch. 2012-60.

465.1901 Practice of orthotics and pedorthics.—The provisions of chapter 468 relating to orthotics or pedorthics do not apply to any licensed pharmacist or to any person acting under the supervision of a licensed pharmacist. The practice of orthotics or pedorthics by a pharmacist or any of the pharmacist's employees acting under the supervision of a pharmacist shall be construed to be within the meaning of the term "practice of the profession of pharmacy" as set forth in s. 465.003(13), and shall be subject to regulation in the same manner as any other pharmacy practice. The Board of Pharmacy shall develop rules regarding the practice of orthotics and pedorthics by a pharmacist. Any pharmacist or person under the supervision of a pharmacist engaged in the practice of orthotics or pedorthics is not precluded from continuing that practice pending adoption of these rules.

History.—s. 3, ch. 2009-202.

CHAPTER 893

DRUG ABUSE PREVENTION AND CONTROL

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893.01Short title.—This chapter shall be cited and known as the "Florida Comprehensive Drug Abuse Prevention and Control Act."

History.—s. 1, ch. 73-331.

893.02Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(1)"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a person or animal.

(2)"Analog" or "chemical analog" means a structural derivative of a parent compound that is a controlled substance.

(3)"Cannabis" means all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin.

(4)"Controlled substance" means any substance named or described in Schedules I-V of s. 893.03. Laws controlling the manufacture, distribution, preparation, dispensing, or administration of such substances are drug abuse laws.

(5)"Cultivating" means the preparation of any soil or hydroponic medium for the planting of a controlled substance or the tending and care or harvesting of a controlled substance.

(6)"Deliver" or "delivery" means the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship.

(7)"Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user.

(8)"Distribute" means to deliver, other than by administering or dispensing, a controlled substance.

(9)“Distributor” means a person who distributes.

(10)“Department” means the Department of Health.

(11)“Homologue” means a chemical compound in a series in which each compound differs by one or more alkyl functional groups on an alkyl side chain.

(12)“Hospital” means an institution for the care and treatment of the sick and injured, licensed pursuant to the provisions of chapter 395 or owned or operated by the state or Federal Government.

(13)“Laboratory” means a laboratory approved by the Drug Enforcement Administration as proper to be entrusted with the custody of controlled substances for scientific, medical, or instructional purposes or to aid law enforcement officers and prosecuting attorneys in the enforcement of this chapter.

(14)“Listed chemical” means any precursor chemical or essential chemical named or described in s. 893.033.

(15)(a)“Manufacture” means the production, preparation, propagation, compounding, cultivating, growing, conversion, or processing of a controlled substance, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging, or labeling of a controlled substance by:

1.A practitioner or pharmacist as an incident to his or her administering or delivering of a controlled substance in the course of his or her professional practice.

2.A practitioner, or by his or her authorized agent under the practitioner’s supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis, and not for sale.

(b)“Manufacturer” means and includes every person who prepares, derives, produces, compounds, or repackages any drug as defined by the Florida Drug and Cosmetic Act. However, this definition does not apply to manufacturers of patent or proprietary preparations as defined in the Florida Pharmacy Act. Pharmacies, and pharmacists employed thereby, are specifically excluded from this definition.

(16)“Mixture” means any physical combination of two or more substances.

(17)“Patient” means an individual to whom a controlled substance is lawfully dispensed or administered pursuant to the provisions of this chapter.

(18)“Pharmacist” means a person who is licensed pursuant to chapter 465 to practice the profession of pharmacy in this state.

(19)“Possession” includes temporary possession for the purpose of verification or testing, irrespective of dominion or control.

(20)“Potential for abuse” means that a substance has properties of a central nervous system

stimulant or depressant or an hallucinogen that create a substantial likelihood of its being:

(a)Used in amounts that create a hazard to the user's health or the safety of the community;

(b)Diverted from legal channels and distributed through illegal channels; or

(c)Taken on the user's own initiative rather than on the basis of professional medical advice.

Proof of potential for abuse can be based upon a showing that these activities are already taking place, or upon a showing that the nature and properties of the substance make it reasonable to assume that there is a substantial likelihood that such activities will take place, in other than isolated or occasional instances.

(21)"Practitioner" means a physician licensed pursuant to chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, a naturopath licensed pursuant to chapter 462, or a podiatric physician licensed pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

(22)"Prescription" means and includes an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting the requirements of s. 893.04. The term also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a state other than Florida, but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness. However, if the physician writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of said prescription. A prescription order for a controlled substance shall not be issued on the same prescription blank with another prescription order for a controlled substance which is named or described in a different schedule, nor shall any prescription order for a controlled substance be issued on the same prescription blank as a prescription order for a medicinal drug, as defined in s. 465.003(8), which does not fall within the definition of a controlled substance as defined in this act.

(23)"Wholesaler" means any person who acts as a jobber, wholesale merchant, or broker, or an agent thereof, who sells or distributes for resale any drug as defined by the Florida Drug and Cosmetic Act. However, this definition does not apply to persons who sell only patent or proprietary preparations as defined in the Florida Pharmacy Act. Pharmacies, and pharmacists

employed thereby, are specifically excluded from this definition.

History.—s. 2, ch. 73-331; s. 1, ch. 75-18; s. 470, ch. 77-147; s. 1, ch. 77-174; s. 184, ch. 79-164; s. 1, ch. 79-325; s. 37, ch. 82-225; s. 169, ch. 83-216; s. 1, ch. 85-242; s. 1, ch. 91-279; s. 1, ch. 92-19; s. 1434, ch. 97-102; s. 104, ch. 97-264; s. 234, ch. 98-166; s. 300, ch. 99-8; s. 10, ch. 99-186; s. 1, ch. 2000-320; s. 3, ch. 2001-55; s. 10, ch. 2002-78; s. 13, ch. 2005-128; s. 1, ch. 2008-184; s. 18, ch. 2010-117; s. 1, ch. 2011-73.

893.03Standards and schedules.—The substances enumerated in this section are controlled by this chapter. The controlled substances listed or to be listed in Schedules I, II, III, IV, and V are included by whatever official, common, usual, chemical, or trade name designated. The provisions of this section shall not be construed to include within any of the schedules contained in this section any excluded drugs listed within the purview of 21 C.F.R. s. 1308.22, styled "Excluded Substances"; 21 C.F.R. s. 1308.24, styled "Exempt Chemical Preparations"; 21 C.F.R. s. 1308.32, styled "Exempted Prescription Products"; or 21 C.F.R. s. 1308.34, styled "Exempt Anabolic Steroid Products."

(1)SCHEDULE I.—A substance in Schedule I has a high potential for abuse and has no currently accepted medical use in treatment in the United States and in its use under medical supervision does not meet accepted safety standards. The following substances are controlled in Schedule I:

(a)Unless specifically excepted or unless listed in another schedule, any of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

1.Acetyl-alpha-methylfentanyl.

2.Acetylmethadol.

3.Allylprodine.

4.Alphacetylmethadol (except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM).

5.Alphamethadol.

6.Alpha-methylfentanyl (N-[1-(alpha-methyl-betaphenyl) ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine).

7.Alpha-methylthiofentanyl.

8.Alphameprodine.

9.Benzethidine.

10.Benzylfentanyl.

11.Betacetylmethadol.

12.Beta-hydroxyfentanyl.

13.Beta-hydroxy-3-methylfentanyl.

14.Betameprodine.

15.Betamethadol.

16.Betaprodine.

17.Clonitazene.

18.Dextromoramide.

19.Diampromide.

20.Diethylthiambutene.

21.Difenoxin.

22.Dimenoxadol.

23.Dimepheptanol.

24.Dimethylthiambutene.

25.Dioxaphetyl butyrate.

26.Dipipanone.

27.Ethylmethylthiambutene.

28.Etonitazene.

29.Etoxeridine.

30.Flunitrazepam.

31.Furethidine.

32.Hydroxypethidine.

33.Ketobemidone.

34.Levomoramide.

35.Levophenacylmorphan.

36.1-Methyl-4-Phenyl-4-Propionoxypiperidine (MPPP).

37.3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide).

38.3-Methylthiofentanyl.

39.3, 4-Methylenedioxymethamphetamine (MDMA).

40.Morpheridine.

41.Noracymethadol.

42.Norlevorphanol.

43.Normethadone.

44.Norpipanone.

45.Para-Fluorofentanyl.

46.Phenadoxone.

47.Phenampromide.

48.Phenomorphan.

49.Phenoperidine.

50.1-(2-Phenylethyl)-4-Phenyl-4-Acetyloxypiperidine (PEPAP).

51.Piritramide.

52.Proheptazine.

53.Properidine.

54.Propiram.

55.Racemoramide.

56.Thenylfentanyl.

57.Thiofentanyl.

58.Tilidine.

59.Trimeperidine.

(b)Unless specifically excepted or unless listed in another schedule, any of the following substances, their salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

1.Acetorphine.

2.Acetyldihydrocodeine.

3.Benzylmorphine.

4.Codeine methylbromide.

5.Codeine-N-Oxide.

6.Cyprenorphine.

7.Desomorphine.

8.Dihydromorphine.

9.Drotebanol.

10.Etorphine (except hydrochloride salt).

11.Heroin.

12.Hydromorphinol.

13.Methyldesorphine.

14.Methyldihydromorphine.

15.Monoacetylmorphine.

16.Morphine methylbromide.

17.Morphine methylsulfonate.

18.Morphine-N-Oxide.

19.Myrophine.

20.Nicocodine.

21.Nicomorphine.

22.Normorphine.

23.Pholcodine.

24.Thebacon.

(c)Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following hallucinogenic substances or that contains any of their salts, isomers, and salts of isomers, if the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

1.Alpha-ethyltryptamine.

2.2-Amino-4-methyl-5-phenyl-2-oxazoline (4-methylaminorex).

3.2-Amino-5-phenyl-2-oxazoline (Aminorex).

4.4-Bromo-2,5-dimethoxyamphetamine.

5.4-Bromo-2,5-dimethoxyphenethylamine.

6.Bufotenine.

7.Cannabis.

8.Cathinone.

9.Diethyltryptamine.

10.2,5-Dimethoxyamphetamine.

11.2,5-Dimethoxy-4-ethylamphetamine (DOET).

12.Dimethyltryptamine.

13.N-Ethyl-1-phenylcyclohexylamine (PCE) (Ethylamine analog of phencyclidine).

14.N-Ethyl-3-piperidyl benzilate.

15.N-ethylamphetamine.

16.Fenethylline.

17.N-Hydroxy-3,4-methylenedioxyamphetamine.

18.Ibogaine.

19.Lysergic acid diethylamide (LSD).

20.Mescaline.

21.Methcathinone.

22.5-Methoxy-3,4-methylenedioxyamphetamine.

23.4-methoxyamphetamine.

24.4-methoxymethamphetamine.

25.4-Methyl-2,5-dimethoxyamphetamine.

26.3,4-Methylenedioxy-N-ethylamphetamine.

27.3,4-Methylenedioxyamphetamine.

28.N-Methyl-3-piperidyl benzilate.

29.N,N-dimethylamphetamine.

30.Parahexyl.

31.Peyote.

32.N-(1-Phenylcyclohexyl)-pyrrolidine (PCPY) (Pyrrolidine analog of phencyclidine).

33.Psilocybin.

34.Psilocyn.

35.*Salvia divinorum*, except for any drug product approved by the United States Food and Drug Administration which contains *Salvia divinorum* or its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, if the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

36.Salvinorin A, except for any drug product approved by the United States Food and Drug Administration which contains Salvinorin A or its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, if the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

37.Tetrahydrocannabinols.

38.1-[1-(2-Thienyl)-cyclohexyl]-piperidine (TCP) (Thiophene analog of phencyclidine).

39.3,4,5-Trimethoxyamphetamine.

40.3,4-Methylenedioxymethcathinone.

41.3,4-Methylenedioxypyrovalerone (MDPV).

42.Methylmethcathinone.

43.Methoxymethcathinone.

44.Fluoromethcathinone.

45.Methylethcathinone.

46.2-[(1R,3S)-3-hydroxycyclohexyl]-5-(2-methyloctan-2-yl)phenol, also known as CP 47,497 and its dimethyloctyl (C8) homologue.

47.(6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo [c]chromen-1-ol, also known as HU-210.

48.1-Pentyl-3-(1-naphthoyl)indole, also known as JWH-018.

49.1-Butyl-3-(1-naphthoyl)indole, also known as JWH-073.

50.1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl) indole, also known as JWH-200.

51.BZP (Benzylpiperazine).

52.Fluorophenylpiperazine.

53.Methylphenylpiperazine.

54.Chlorophenylpiperazine.

55.Methoxyphenylpiperazine.

56.DBZP (1,4-dibenzylpiperazine).

57.TFMPP (3-Trifluoromethylphenylpiperazine).

58.MBDB (Methylbenzodioxolylbutanamine).

59.5-Hydroxy-alpha-methyltryptamine.

60.5-Hydroxy-N-methyltryptamine.

61.5-Methoxy-N-methyl-N-isopropyltryptamine.

62.5-Methoxy-alpha-methyltryptamine.

63.Methyltryptamine.

64.5-Methoxy-N,N-dimethyltryptamine.

65.5-Methyl-N,N-dimethyltryptamine.

66.Tyramine (4-Hydroxyphenethylamine).

67.5-Methoxy-N,N-Diisopropyltryptamine.

68.DiPT (N,N-Diisopropyltryptamine).

69.DPT (N,N-Dipropyltryptamine).

70.4-Hydroxy-N,N-diisopropyltryptamine.

71.N,N-Diallyl-5-Methoxytryptamine.

72.DOI (4-Iodo-2,5-dimethoxyamphetamine).

73.DOC (4-Chloro-2,5-dimethoxyamphetamine).

74.2C-E (4-Ethyl-2,5-dimethoxyphenethylamine).

75.2C-T-4 (2,5-Dimethoxy-4-isopropylthiophenethylamine).

76.2C-C (4-Chloro-2,5-dimethoxyphenethylamine).

77.2C-T (2,5-Dimethoxy-4-methylthiophenethylamine).

78.2C-T-2 (2,5-Dimethoxy-4-ethylthiophenethylamine).

79.2C-T-7 (2,5-Dimethoxy-4-(n)-propylthiophenethylamine).

80.2C-I (4-Iodo-2,5-dimethoxyphenethylamine).

81.Butylone (beta-keto-N-methylbenzodioxolylpropylamine).

82.Ethcathinone.

83.Ethylone (3,4-methylenedioxy-N-ethylcathinone).

84.Naphyrone (naphthylpyrovalerone).

85.N-N-Dimethyl-3,4-methylenedioxycathinone.

86.N-N-Diethyl-3,4-methylenedioxycathinone.

87.3,4-methylenedioxy-propiophenone.

88.2-Bromo-3,4-Methylenedioxypropiophenone.

89.3,4-methylenedioxy-propiophenone-2-oxime.

90.N-Acetyl-3,4-methylenedioxycathinone.

91.N-Acetyl-N-Methyl-3,4-Methylenedioxycathinone.

92.N-Acetyl-N-Ethyl-3,4-Methylenedioxycathinone.

93.Bromomethcathinone.

94.Buphedrone (alpha-methylamino-butyrophenone).

95.Eutylone (beta-Keto-Ethylbenzodioxolylbutanamine).

96.Dimethylcathinone.

97.Dimethylmethcathinone.

98.Pentylone (beta-Keto-Methylbenzodioxolylpentanamine).

99.(MDPPP) 3,4-Methylenedioxy-alpha-pyrrolidinopropiophenone.

100.(MDPBP) 3,4-Methylenedioxy-alpha-pyrrolidinobutiophenone.

101.Methoxy-alpha-pyrrolidinopropiophenone (MOPPP).

102.Methyl-alpha-pyrrolidinohexiophenone (MPHP).

103.Benocyclidine (BCP) or benzothiophenylcyclohexylpiperidine (BTCP).

104.Fluoromethylaminobutyrophenone (F-MABP).

105.Methoxypyrrolidinobutyrophenone (MeO-PBP).

106.Ethyl-pyrrolidinobutyrophenone (Et-PBP).

107.3-Methyl-4-Methoxymethcathinone (3-Me-4-MeO-MCAT).

108.Methylethylaminobutyrophenone (Me-EABP).

109.Methylamino-butyrophenone (MABP).

110.Pyrrolidinopropiophenone (PPP).

111.Pyrrolidinobutiophenone (PBP).

112.Pyrrolidinovalerophenone (PVP).

113.Methyl-alpha-pyrrolidinopropiophenone (MPPP).

114.JWH-007 (1-pentyl-2-methyl-3-(1-naphthoyl)indole).

115.JWH-015 (2-Methyl-1-propyl-1H-indol-3-yl)-1-naphthalenylmethanone).

116.JWH-019 (Naphthalen-1-yl-(1-hexylindol-3-yl)methanone).

117.JWH-020 (1-heptyl-3-(1-naphthoyl)indole).

118.JWH-072 (Naphthalen-1-yl-(1-propyl-1H-indol-3-yl)methanone).

119.JWH-081 (4-methoxynaphthalen-1-yl-(1-pentylindol-3-yl)methanone).

120.JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole).

121.JWH-133 ((6aR,10aR)-3-(1,1-Dimethylbutyl)-6a,7,10,10a-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran)).

122.JWH-175 (3-(naphthalen-1-ylmethyl)-1-pentyl-1H-indole).

123.JWH-201 (1-pentyl-3-(4-methoxyphenylacetyl)indole).

124.JWH-203 (2-(2-chlorophenyl)-1-(1-pentylindol-3-yl)ethanone).

125.JWH-210 (4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone).

126.JWH-250 (2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone).

127.JWH-251 (2-(2-methylphenyl)-1-(1-pentyl-1H-indol-3-yl)ethanone).

128.JWH-302 (1-pentyl-3-(3-methoxyphenylacetyl)indole).

129.JWH-398 (1-pentyl-3-(4-chloro-1-naphthoyl)indole).

130.HU-211 ((6aS,10aS)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).

131.HU-308 ([(1R,2R,5R)-2-[2,6-dimethoxy-4-(2-methyloctan-2-yl)phenyl]-7,7-dimethyl-4-bicyclo[3.1.1]hept-3-enyl] methanol).

132.HU-331 (3-hydroxy-2-[(1R,6R)-3-methyl-6-(1- methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-2,5-cyclohexadiene-1,4-dione).

133.CB-13 (Naphthalen-1-yl-(4-pentyloxynaphthalen-1-yl)methanone).

134.CB-25 (N-cyclopropyl-11-(3-hydroxy-5-pentylphenoxy)-undecanamide).

135.CB-52 (N-cyclopropyl-11-(2-hexyl-5-hydroxyphenoxy)-undecanamide).

136.CP 55,940 (2-[(1R,2R,5R)-5-hydroxy-2-(3-hydroxypropyl)cyclohexyl]-5-(2-methyloctan-2-yl)phenol).

137.AM-694 (1-[(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophenyl)methanone).

138.AM-2201 (1-[(5-fluoropentyl)-1H-indol-3-yl]-(naphthalen-1-yl)methanone).

139.RCS-4 ((4-methoxyphenyl) (1-pentyl-1H-indol-3-yl)methanone).

140.RCS-8 (1-(1-(2-cyclohexylethyl)-1H-indol-3-yl)-2-(2-methoxyphenylethanone).

141.WIN55,212-2 ((R)-(+)-[2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone).

142.WIN55,212-3 ([(3S)-2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone).

(d)Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including any of its salts, isomers, optical isomers, salts of their isomers, and salts of these optical isomers whenever the existence of such isomers and salts is possible within the specific chemical designation:

1.1,4-Butanediol.

2.Gamma-butyrolactone (GBL).

3.Gamma-hydroxybutyric acid (GHB).

4.Methaqualone.

5.Mecloqualone.

(2)SCHEDULE II.—A substance in Schedule II has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States, and abuse of the substance may lead to severe psychological or physical dependence. The following substances are controlled in Schedule II:

(a)Unless specifically excepted or unless listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis:

1.Opium and any salt, compound, derivative, or preparation of opium, except nalmefene or isoquinoline alkaloids of opium, including, but not limited to the following:

a.Raw opium.

b.Opium extracts.

c.Opium fluid extracts.

d.Powdered opium.

e.Granulated opium.

f.Tincture of opium.

g.Codeine.

h.Ethylmorphine.

i.Etorphine hydrochloride.

j.Hydrocodone.

k.Hydromorphone.

l.Levo-alphacetylmethadol (also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM).

m.Metopon (methyldihydromorphinone).

n.Morphine.

o.Oxycodone.

p.Oxymorphone.

q.Thebaine.

2.Any salt, compound, derivative, or preparation of a substance which is chemically equivalent to or identical with any of the substances referred to in subparagraph 1., except that these substances shall not include the isoquinoline alkaloids of opium.

3.Any part of the plant of the species *Papaver somniferum*, *L*.

4.Cocaine or ecgonine, including any of their stereoisomers, and any salt, compound, derivative, or preparation of cocaine or ecgonine.

(b)Unless specifically excepted or unless listed in another schedule, any of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

1.Alfentanil.

2.Alphaprodine.

3.Anileridine.

4.Bezitramide.

5.Bulk propoxyphene (nondosage forms).

6.Carfentanil.

7.Dihydrocodeine.

8.Diphenoxylate.

9.Fentanyl.

10.Isomethadone.

11.Levomethorphan.

12.Levorphanol.

13.Metazocine.

14.Methadone.

15.Methadone-Intermediate,4-cyano-2-dimethylamino-4,4-diphenylbutane.

16.Moramide-Intermediate,2-methyl-3-morpholoino-1,1-diphenylpropane-carboxylic acid.

17.Nabilone.

18.Pethidine (meperidine).

19.Pethidine-Intermediate-A,4-cyano-1-methyl-4-phenylpiperidine.

20.Pethidine-Intermediate-B,ethyl-4-phenylpiperidine-4-carboxylate.

21.Pethidine-Intermediate-C,1-methyl-4- phenylpiperidine-4-carboxylic acid.

22.Phenazocine.

23.Phencyclidine.

24.1-Phenylcyclohexylamine.

25.Piminodine.

26.1-Piperidinocyclohexanecarbonitrile.

27.Racemethorphan.

28.Racemorphan.

29.Sufentanil.

(c)Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts, isomers, optical isomers, salts of their isomers, and salts of their optical isomers:

1.Amobarbital.

2.Amphetamine.

3.Glutethimide.

4.Methamphetamine.

5.Methylphenidate.

6.Pentobarbital.

7.Phenmetrazine.

8.Phenylacetone.

9.Secobarbital.

(3)SCHEDULE III.—A substance in Schedule III has a potential for abuse less than the substances contained in Schedules I and II and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. The following substances are controlled in Schedule III:

(a)Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant or stimulant effect on the nervous system:

1.Any substance which contains any quantity of a derivative of barbituric acid, including thiobarbituric acid, or any salt of a derivative of barbituric acid or thiobarbituric acid, including, but not limited to, butabarbital and butalbital.

2.Benzphetamine.

3.Chlorhexadol.

4.Chlorphentermine.

5.Clortermine.

6.Lysergic acid.

7.Lysergic acid amide.

8.Methyprylon.

9.Phendimetrazine.

10.Sulfondiethylmethane.

11.Sulfonethylmethane.

12.Sulfonmethane.

13.Tiletamine and zolazepam or any salt thereof.

(b)Nalorphine.

(c)Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following controlled substances or any salts thereof:

1.Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

2.Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

3.Not more than 300 milligrams of hydrocodone per 100 milliliters or not more than 15

milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

4.Not more than 300 milligrams of hydrocodone per 100 milliliters or not more than 15 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients that are not controlled substances.

5.Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

6.Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

7.Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

For purposes of charging a person with a violation of s. 893.135 involving any controlled substance described in subparagraph 3. or subparagraph 4., the controlled substance is a Schedule III controlled substance pursuant to this paragraph but the weight of the controlled substance per milliliters or per dosage unit is not relevant to the charging of a violation of s. 893.135. The weight of the controlled substance shall be determined pursuant to s. 893.135(6).

(d)Anabolic steroids.

1.The term “anabolic steroid” means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, that promotes muscle growth and includes:

a.Androsterone.

b.Androsterone acetate.

c.Boldenone.

d.Boldenone acetate.

e.Boldenone benzoate.

f.Boldenone undecylenate.

g.Chlorotestosterone (4-chlortestosterone).

h.Clostebol.

i.Dehydrochlormethyltestosterone.

j.Dihydrotestosterone (4-dihydrotestosterone).

k.Drostanolone.

l.Ethylestrenol.

m.Fluoxymesterone.

n.Formebulone (formebolone).

o.Mesterolone.

p.Methandienone.

q.Methandranone.

r.Methandriol.

s.Methandrostenolone.

t.Methenolone.

u.Methyltestosterone.

v.Mibolerone.

w.Nandrolone.

x.Norethandrolone.

y.Nortestosterone.

z.Nortestosterone decanoate.

aa.Nortestosterone phenylpropionate.

bb.Nortestosterone propionate.

cc.Oxandrolone.

dd.Oxymesterone.

ee.Oxymetholone.

ff.Stanolone.

gg.Stanozolol.

hh.Testolactone.

ii.Testosterone.

jj.Testosterone acetate.

kk.Testosterone benzoate.

ll.Testosterone cypionate.

mm.Testosterone decanoate.

nn.Testosterone enanthate.

oo.Testosterone isocaproate.

pp.Testosterone oleate.

qq.Testosterone phenylpropionate.

rr.Testosterone propionate.

ss.Testosterone undecanoate.

tt.Trenbolone.

uu.Trenbolone acetate.

vv.Any salt, ester, or isomer of a drug or substance described or listed in this subparagraph if that salt, ester, or isomer promotes muscle growth.

2.The term does not include an anabolic steroid that is expressly intended for administration

through implants to cattle or other nonhuman species and that has been approved by the United States Secretary of Health and Human Services for such administration. However, any person who prescribes, dispenses, or distributes such a steroid for human use is considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

(e)Ketamine, including any isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

(f)Dronabinol (synthetic THC) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the United States Food and Drug Administration.

(g)Any drug product containing gamma-hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under s. 505 of the Federal Food, Drug, and Cosmetic Act.

(4)SCHEDULE IV.—A substance in Schedule IV has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, are controlled in Schedule IV:

(a)Alprazolam.

(b)Barbital.

(c)Bromazepam.

(d)Camazepam.

(e)Cathine.

(f)Chloral betaine.

(g)Chloral hydrate.

(h)Chlordiazepoxide.

(i)Clobazam.

(j)Clonazepam.

(k)Clorazepate.

(l)Clotiazepam.

(m)Cloxazolam.

(n)Delorazepam.

(o)Propoxyphene (dosage forms).

(p)Diazepam.

(q)Diethylpropion.

(r)Estazolam.

(s)Ethchlorvynol.

(t)Ethinamate.

(u)Ethyl loflazepate.

(v)Fencamfamin.

1 (w)Fenfluramine.

(x)Fenproporex.

(y)Fludiazepam.

(z)Flurazepam.

(aa)Halazepam.

(bb)Haloxazolam.

(cc)Ketazolam.

(dd)Loprazolam.

(ee)Lorazepam.

(ff)Lormetazepam.

(gg)Mazindol.

(hh)Mebutamate.

(ii)Medazepam.

(jj)Mefenorex.

(kk)Meprobamate.

(ll)Methohexital.

(mm)Methylphenobarbital.

(nn)Midazolam.

(oo)Nimetazepam.

(pp)Nitrazepam.

(qq)Nordiazepam.

(rr)Oxazepam.

(ss)Oxazolam.

(tt)Paraldehyde.

(uu)Pemoline.

(vv)Pentazocine.

(ww)Phenobarbital.

(xx)Phentermine.

(yy)Pinazepam.

(zz)Pipradrol.

(aaa)Prazepam.

(bbb)Propylhexedrine, excluding any patent or proprietary preparation containing propylhexedrine, unless otherwise provided by federal law.

(ccc)Quazepam.

(ddd)Tetrazepam.

(eee)SPA[(-)-1 dimethylamino-1, 2 diphenylethane].

(fff)Temazepam.

(ggg)Triazolam.

(hhh)Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(iii)Butorphanol tartrate.

(jjj)Carisoprodol.

(5)SCHEDULE V.—A substance, compound, mixture, or preparation of a substance in Schedule V has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.

(a)Substances controlled in Schedule V include any compound, mixture, or preparation containing any of the following limited quantities of controlled substances, which shall include one or more active medicinal ingredients which are not controlled substances in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the controlled substance alone:

1.Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

2.Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

3.Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

4.Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

5.Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(b)Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts: Buprenorphine.

(c)Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers: Pyrovalerone.

History.—s. 3, ch. 73-331; s. 247, ch. 77-104; s. 1, ch. 77-174; ss. 1, 2, ch. 78-195; s. 2, ch. 79-325; s. 1, ch. 80-353; s. 1, ch. 82-16; s. 1, ch. 84-89; s. 2, ch. 85-242; s. 1, ch. 86-147; s. 2, ch. 87-243; s. 1, ch. 87-299; s. 1, ch. 88-59; s. 3, ch. 89-281; s. 54, ch. 92-69; s. 1, ch. 93-92; s. 4, ch. 95-415; s. 1, ch. 96-360; ss. 1, 5, ch. 97-1; s. 96, ch. 97-264; s. 1, ch. 99-186; s. 2, ch. 2000-320; s. 1, ch. 2001-55; s. 5, ch. 2001-57; s. 1, ch. 2002-78; s. 2, ch. 2003-10; s. 1, ch. 2008-88; s. 2, ch. 2011-73; s. 1, ch. 2011-90; s. 1, ch. 2012-23.

[1]**Note.**—Section 1, ch. 97-1, added paragraph (4)(w) listing fenfluramine. Section 5, ch. 97-1, repealed paragraph (4)(w) effective upon the removal of fenfluramine from the schedules of controlled substances in 21 C.F.R. s. 1308. The Drug Enforcement Administration of the United States Department of Justice filed a proposed final rule removing fenfluramine from the schedules, *see* 62 F.R. 24620, May 6, 1997.

893.0301Death resulting from apparent drug overdose; reporting requirements.—If a person dies of an apparent drug overdose:

(1)A law enforcement agency shall prepare a report identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV of s. 893.03 which is found on or near the deceased or among the deceased's possessions. The report must identify the person who prescribed the controlled substance, if known or ascertainable. Thereafter, the law enforcement agency shall submit a copy of the report to the medical examiner.

(2)A medical examiner who is preparing a report pursuant to s. 406.11 shall include in the report information identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV of s. 893.03 that was found in, on, or near the deceased or among the deceased's possessions.

History.—s. 6, ch. 2007-156.

893.031Industrial exceptions to controlled substance scheduling.—

(1)For the purpose of this section, the following meanings of terms shall apply:

(a)"Manufacture" means any process or operation necessary for manufacturing a product.

(b)"Distribution" means any process or operation necessary for distributing a product, including, but not limited to, wholesaling, delivery or transport, and storage.

(c)"Manufacturer of 1,4-Butanediol" means a person who is involved in the manufacture of 1,4-Butanediol for use in the manufacture of an industrial product and who provides that manufactured 1,4-Butanediol to a distributor of 1,4-Butanediol or a manufacturer of an industrial product.

(d)"Distributor of 1,4-Butanediol" means a person who is involved in the distribution of 1,4-Butanediol.

(e)"Manufacturer of gamma-butyrolactone (GBL)" means a person who:

1.Is involved in the manufacture of gamma-butyrolactone (GBL) for use in the manufacture of an industrial product and who provides that manufactured gamma-butyrolactone (GBL) to a

distributor of gamma-butyrolactone (GBL) or a manufacturer of an industrial product; and

2.Is in compliance with any requirements to register with the United States Drug Enforcement Administration as a List I Chemical registrant.

(f)“Distributor of gamma-butyrolactone (GBL)” means a person who:

1.Is involved in the distribution of gamma-butyrolactone (GBL); and

2.Is in compliance with any requirements to register with the United States Drug Enforcement Administration as a List I Chemical registrant.

(g)“Manufacturer of an industrial product” means a person who is involved in the manufacture of an industrial product in which that person acquires:

1.1,4-Butanediol from a manufacturer of 1,4-Butanediol or a distributor of 1,4-Butanediol and who possesses that substance for use in the manufacture of an industrial product; or

2.Gamma-butyrolactone (GBL) from a manufacturer of gamma-butyrolactone (GBL) or a distributor of gamma-butyrolactone (GBL) and who possesses that substance for use in the manufacture of an industrial product.

(h)“Distributor of an industrial product” means a person who is involved in the distribution of an industrial product.

(i)“Industrial product” means a nondrug, noncontrolled finished product that is not for human consumption.

(j)“Finished product” means a product:

1.That does not contain either 1,4-Butanediol or gamma-butyrolactone (GBL); or

2.From which neither 1,4-Butanediol nor gamma-butyrolactone (GBL) can be readily extracted or readily synthesized and which is not sold for human consumption.

(2)1,4-Butanediol is excepted from scheduling pursuant to s. 893.03(1)(d)1. when that substance is in the possession of:

(a)A manufacturer of 1,4-Butanediol or a distributor of 1,4-Butanediol;

(b)A manufacturer of an industrial product or a distributor of an industrial product; or

(c)A person possessing a finished product.

(3)Gamma-butyrolactone (GBL) is excepted from scheduling pursuant to s. 893.03(1)(d)2. when that substance is in the possession of:

(a)A manufacturer of gamma-butyrolactone (GBL) or a distributor of gamma-butyrolactone (GBL);

(b)A manufacturer of an industrial product or a distributor of an industrial product; or

(c)A person possessing a finished product.

(4)This section does not apply to:

(a)A manufacturer of 1,4-Butanediol or a distributor of 1,4-Butanediol who sells, delivers, or otherwise distributes that substance to a person who is not a distributor of 1,4-Butanediol or a

manufacturer of an industrial product;

(b)A manufacturer of gamma-butyrolactone (GBL) or a distributor of gamma-butyrolactone (GBL) who sells, delivers, or otherwise distributes that substance to a person who is not a distributor of gamma-butyrolactone (GBL) or a manufacturer of an industrial product;

(c)A person who possesses 1,4-Butanediol but who is not a manufacturer of 1,4-Butanediol, a distributor of 1,4-Butanediol, a manufacturer of an industrial product, a distributor of an industrial product, or a person possessing a finished product as described in paragraph (2)(c) or paragraph (3)(c);

(d)A person who possesses gamma-butyrolactone (GBL) but who is not a manufacturer of gamma-butyrolactone (GBL), a distributor of gamma-butyrolactone (GBL), a manufacturer of an industrial product, a distributor of an industrial product, or a person possessing a finished product as described in paragraph (2)(c) or paragraph (3)(c);

(e)A person who extracts or synthesizes either 1,4-Butanediol or gamma-butyrolactone (GBL) from a finished product as described in subparagraph(1)(j)2. or a person who extracts or synthesizes 1,4-Butanediol or gamma-butyrolactone (GBL) from any product or material, unless such extraction or synthesis is authorized by law; or

(f)A person whose possession of either 1,4-Butanediol or gamma-butyrolactone (GBL) is not in compliance with the requirements of this section or whose possession of either of those substances is not specifically authorized by law.

History.—s. 1, ch. 2003-10.

893.033Listed chemicals.—The chemicals listed in this section are included by whatever official, common, usual, chemical, or trade name designated.

(1)PRECURSOR CHEMICALS.—The term “listed precursor chemical” means a chemical that may be used in manufacturing a controlled substance in violation of this chapter and is critical to the creation of the controlled substance, and such term includes any salt, optical isomer, or salt of an optical isomer, whenever the existence of such salt, optical isomer, or salt of optical isomer is possible within the specific chemical designation. The following are “listed precursor chemicals”:

(a)Anthranilic acid.

(b)Benzaldehyde.

(c)Benzyl cyanide.

(d)Chloroephedrine.

(e)Chloropseudoephedrine.

(f)Ephedrine.

(g)Ergonovine.

(h)Ergotamine.

(i)Hydriodic acid.

(j)Ethylamine.

(k)Isosafrole.

(l)Methylamine.

(m)3, 4-Methylenedioxyphenyl-2-propanone.

(n)N-acetylanthranilic acid.

(o)N-ethylephedrine.

(p)N-ethylpseudoephedrine.

(q)N-methylephedrine.

(r)N-methylpseudoephedrine.

(s)Nitroethane.

(t)Norpseudoephedrine.

(u)Phenylacetic acid.

(v)Phenylpropanolamine.

(w)Piperidine.

(x)Piperonal.

(y)Propionic anhydride.

(z)Pseudoephedrine.

(aa)Safrole.

(2)ESSENTIAL CHEMICALS.—The term "listed essential chemical" means a chemical that may be used as a solvent, reagent, or catalyst in manufacturing a controlled substance in violation of this chapter. The following are "listed essential chemicals":

(a)Acetic anhydride.

(b)Acetone.

(c)Anhydrous ammonia.

(d)Benzyl chloride.

(e)2-Butanone.

(f)Ethyl ether.

(g)Hydrochloric gas.

(h)Hydriodic acid.

(i)Iodine.

(j)Potassium permanganate.

(k)Toluene.

History.—s. 2, ch. 91-279; s. 6, ch. 2001-57; s. 2, ch. 2003-15; s. 1, ch. 2005-128.

893.035Control of new substances; findings of fact; delegation of authority to Attorney General to control substances by rule.—

(1)(a)New substances are being created which are not controlled under the provisions of this

chapter but which have a potential for abuse similar to or greater than that for substances controlled under this chapter. These new substances are sometimes called “designer drugs” because they can be designed to produce a desired pharmacological effect and to evade the controlling statutory provisions. Designer drugs are being manufactured, distributed, possessed, and used as substitutes for controlled substances.

(b)The hazards attributable to the traffic in and use of these designer drugs are increased because their unregulated manufacture produces variations in purity and concentration.

(c)Many such new substances are untested, and it cannot be immediately determined whether they have useful medical or chemical purposes.

(d)The uncontrolled importation, manufacture, distribution, possession, or use of these designer drugs has a substantial and detrimental impact on the health and safety of the people of Florida.

(e)These designer drugs can be created more rapidly than they can be identified and controlled by action of the Legislature. There is a need for a speedy and expert administrative determination of their proper classification under this chapter. It is therefore necessary to delegate to an administrative agency restricted authority to identify and classify new substances that have a potential for abuse, so that they can be controlled in the same manner as other substances currently controlled under this chapter.

(2)The Attorney General shall apply the provisions of this section to any substance not currently controlled under the provisions of s. 893.03. The Attorney General may by rule:

(a)Add a substance to a schedule established by s. 893.03, or transfer a substance between schedules, if he or she finds that it has a potential for abuse and he or she makes with respect to it the other findings appropriate for classification in the particular schedule under s. 893.03 in which it is to be placed.

(b)Remove a substance previously added to a schedule if he or she finds the substance does not meet the requirements for inclusion in that schedule.

Rules adopted under this section shall be made pursuant to the rulemaking procedures prescribed by chapter 120.

(3)(a)The term “potential for abuse” in this section means that a substance has properties as a central nervous system stimulant or depressant or a hallucinogen that create a substantial likelihood of its being:

1.Used in amounts that create a hazard to the user’s health or the safety of the community;

2.Diverted from legal channels and distributed through illegal channels; or

3.Taken on the user’s own initiative rather than on the basis of professional medical advice.

Proof of potential for abuse can be based upon a showing that these activities are already taking place, or upon a showing that the nature and properties of the substance make it reasonable to

assume that there is a substantial likelihood that such activities will take place, in other than isolated or occasional instances.

(b)The terms “immediate precursor” and “narcotic drug” shall be given the same meanings as provided by s. 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 802, as amended and in effect on April 1, 1985.

(4)In making any findings under this section, the Attorney General shall consider the following factors with respect to each substance proposed to be controlled or removed from control:

(a)Its actual or relative potential for abuse.

(b)Scientific evidence of its pharmacological effect, if known.

(c)The state of current scientific knowledge regarding the drug or other substance.

(d)Its history and current pattern of abuse.

(e)The scope, duration, and significance of abuse.

(f)What, if any, risk there is to the public health.

(g)Its psychic or physiological dependence liability.

(h)Whether the substance is an immediate precursor of a substance already controlled under this chapter.

The findings and conclusions of the United States Attorney General or his or her delegee, as set forth in the Federal Register, with respect to any substance pursuant to s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811, as amended and in effect on April 1, 1985, shall be admissible as evidence in any rulemaking proceeding under this section, including an emergency rulemaking proceeding under subsection (7).

(5)Before initiating proceedings under subsection (2), the Attorney General shall request from the Department of Health and the Department of Law Enforcement a medical and scientific evaluation of the substance under consideration and a recommendation as to the appropriate classification, if any, of such substance as a controlled substance. In responding to this request, the Department of Health and the Department of Law Enforcement shall consider the factors listed in subsection (4). The Department of Health and the Department of Law Enforcement shall respond to this request promptly and in writing; however, their response is not subject to chapter 120. If both the Department of Health and the Department of Law Enforcement recommend that a substance not be controlled, the Attorney General shall not control that substance. If the Attorney General determines, based on the evaluations and recommendations of the Department of Health and the Department of Law Enforcement and all other available evidence, that there is substantial evidence of potential for abuse, he or she shall initiate proceedings under paragraph (2)(a) with respect to that substance.

(6)(a)The Attorney General shall by rule exempt any nonnarcotic substance controlled by rule under this section from the application of this section if such substance may, under the Federal

Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

(b)The Attorney General may by rule exempt any compound, mixture, or preparation containing a substance controlled by rule under this section from the application of this section if he or she finds that such compound, mixture, or preparation meets the requirements of either of the following subcategories:

1.A mixture or preparation containing a nonnarcotic substance controlled by rule, which mixture or preparation is approved for prescription use and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

2.A compound, mixture, or preparation which contains any substance controlled by rule, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

(7)(a)If the Attorney General finds that the scheduling of a substance in Schedule I of s. 893.03 on a temporary basis is necessary to avoid an imminent hazard to the public safety, he or she may by rule and without regard to the requirements of subsection (5) relating to the Department of Health and the Department of Law Enforcement schedule such substance in Schedule I if the substance is not listed in any other schedule of s. 893.03. The Attorney General shall be required to consider, with respect to his or her finding of imminent hazard to the public safety, only those factors set forth in paragraphs (3)(a) and (4)(d), (e), and (f), including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(b)The Attorney General may use emergency rulemaking provisions under s. 120.54(4) in scheduling substances under this subsection. Notwithstanding the provisions of s. 120.54(4)(c), any rule adopted under this subsection shall not expire except as provided in subsection (9).

(8)(a)Upon the effective date of a rule adopted pursuant to this section adding or transferring a substance to a schedule under s. 893.03, such substance shall be deemed included in that schedule, and all provisions of this chapter applicable to substances in that schedule shall be deemed applicable to such substance.

(b)A rule adopted pursuant to this section shall continue in effect until it is repealed; until it is declared invalid in proceedings under s. 120.56 or in proceedings before a court of competent jurisdiction; or until it expires under the provisions of subsection (9).

(9)The Attorney General shall report to the Legislature by March 1 of each year concerning the rules adopted under this section during the previous year. Each rule so reported shall expire on the following June 30 unless the Legislature adopts the provisions thereof as an amendment to this chapter.

(10)The repeal, expiration, or determination of invalidity of any rule shall not operate to

create any claim or cause of action against any law enforcement officer or other enforcing authority for actions taken in good faith in reliance on the validity of the rule.

(11)In construing this section, due consideration and great weight should be given to interpretations of the United States Attorney General and the federal courts relating to s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811, as amended and in effect on April 1, 1985. All substantive rules adopted under this part shall not be inconsistent with the rules of the United States Attorney General and the decisions of the federal courts interpreting the provisions of s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811, as amended and in effect on April 1, 1985.

(12)The adoption of a rule transferring a substance from one schedule to another or removing a substance from a schedule pursuant to this section shall not affect prosecution or punishment for any crime previously committed with respect to that substance.

History.—s. 3, ch. 85-242; s. 72, ch. 87-226; s. 255, ch. 94-218; s. 318, ch. 96-410; s. 1826, ch. 97-102; s. 16, ch. 99-186.

893.0355Control of scheduled substances; delegation of authority to Attorney General to reschedule substance, or delete substance, by rule.—

(1)The Legislature has determined that, from time to time, additional testings, approvals, or scientific evidence may indicate that controlled substances listed in Schedules I, II, III, IV, and V hereof have a greater potential for beneficial medical use in treatment in the United States than was evident when such substances were initially scheduled. It is the intent of the Legislature to quickly provide a method for an immediate change to the scheduling and control of such substances to allow for the beneficial medical use thereof so that more flexibility will be available than is possible through rescheduling legislatively.

(2)The Attorney General is hereby delegated the authority to adopt rules rescheduling specified substances to a less controlled schedule, or deleting specified substances from a schedule, upon a finding that reduced control of such substances is in the public interest. In determining whether reduced control of a substance is in the public interest, the Attorney General shall consider the following:

(a)Whether the substance has been rescheduled or deleted from any schedule by rule adopted by the United States Attorney General pursuant to s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811.

(b)The substance's actual or relative potential for abuse.

(c)Scientific evidence of the substance's pharmacological effect, if known.

(d)The state of current scientific knowledge regarding the substance.

(e)The substance's history and current pattern of abuse.

(f)The scope, duration, and significance of abuse.

(g)What, if any, risk there is to the public health.

(h)The substance's psychic or physiological dependence liability.

(3)In making the public interest determination, the Attorney General shall give great weight to the scheduling rules adopted by the United States Attorney General subsequent to such substances being listed in Schedules I, II, III, IV, and V hereof, to achieve the original legislative purpose of the Florida Comprehensive Drug Abuse Prevention and Control Act of maintaining uniformity between the laws of Florida and the laws of the United States with respect to controlled substances.

(4)Rulemaking under this section shall be in accordance with the procedural requirements of chapter 120, including the emergency rule provisions found in s. 120.54. The Attorney General may initiate proceedings for adoption, amendment, or repeal of any rule on his or her own motion or upon the petition of any interested party.

(5)Upon the effective date of a rule adopted pursuant to this section, the rule's rescheduling or deletion of a substance shall be effective for all purposes under this chapter.

(6)Rules adopted pursuant to this section shall be reviewed each year by the Legislature. Each rule shall remain in effect until the effective date of legislation that provides for a different scheduling of a substance than that set forth in such rule.

(7)The adoption of a rule rescheduling a substance or deleting a substance from control pursuant to this section shall not affect prosecution or punishment for any crime previously committed with respect to that substance.

(8)The provisions of this section apply only to substances controlled expressly by statute and not to substances controlled by rules adopted under the authority granted in the provisions of s. 893.035.

History.—s. 4, ch. 85-242; s. 1435, ch. 97-102.

893.0356Control of new substances; findings of fact; "controlled substance analog" defined.—

(1)(a)New substances are being created which are not controlled under the provisions of this chapter but which have a potential for abuse similar to or greater than that for substances controlled under this chapter. These new substances are called "controlled substance analogs," and can be designed to produce a desired pharmacological effect and to evade the controlling statutory provisions. Controlled substance analogs are being manufactured, distributed, possessed, and used as substitutes for controlled substances.

(b)The hazards attributable to the traffic in and use of controlled substance analogs are increased because their unregulated manufacture produces variations in purity and concentration.

(c)Many such new substances are untested, and it cannot be immediately determined whether they have useful medical or chemical purposes.

(d)The uncontrolled importation, manufacture, distribution, possession, or use of controlled

substance analogs has a substantial and detrimental impact on the health and safety of the people of Florida.

(e)Controlled substance analogs can be created more rapidly than they can be identified and controlled by action of the Legislature. There is a need for a speedy determination of their proper classification under this chapter. It is therefore necessary to identify and classify new substances that have a potential for abuse, so that they can be controlled in the same manner as other substances currently controlled under this chapter.

(2)(a)As used in this section, “controlled substance analog” means a substance which, due to its chemical structure and potential for abuse, meets the following criteria:

1.Is substantially similar to that of a controlled substance listed in Schedule I or Schedule II of s. 893.03; and

2.Has a stimulant, depressant, or hallucinogenic effect on the central nervous system or is represented or intended to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to or greater than that of a controlled substance listed in Schedule I or Schedule II of s. 893.03.

(b)“Controlled substance analog” does not include:

1.A controlled substance;

2.Any substance for which there is an approved new drug application;

3.Any compound, mixture, or preparation which contains any controlled substance which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse; or

4.Any substance to which an investigational exemption applies under s. 505 of the Food, Drug, and Cosmetic Act, 21 U.S.C. 355, but only to the extent that conduct with respect to the substance is pursuant to such exemption.

(3)The term “potential for abuse” in this section means that a substance has properties as a central nervous system stimulant or depressant or a hallucinogen that create a substantial likelihood of its being:

(a)Used in amounts that create a hazard to the user’s health or the safety of the community;

(b)Diverted from legal channels and distributed through illegal channels; or

(c)Taken on the user’s own initiative rather than on the basis of professional medical advice.

Proof of potential for abuse can be based upon a showing that these activities are already taking place, or upon a showing that the nature and properties of the substance make it reasonable to assume that there is a substantial likelihood that such activities will take place, in other than isolated or occasional instances.

(4)The following factors shall be relevant to a finding that a substance is a controlled

substance analog within the purview of this section:

(a)Its actual or relative potential for abuse.

(b)Scientific evidence of its pharmacological effect, if known.

(c)The state of current scientific knowledge regarding the substance.

(d)Its history and current pattern of abuse.

(e)The scope, duration, and significance of abuse.

(f)What, if any, risk there is to the public health.

(g)Its psychic or physiological dependence liability.

(h)Its diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(i)Whether the substance is an immediate precursor of a substance already controlled under this chapter.

(5)A controlled substance analog shall, for purposes of drug abuse prevention and control, be treated as a controlled substance in Schedule I of s. 893.03.

(6)In construing this section, due consideration and great weight should be given to interpretations of the United States Attorney General and the federal courts relating to s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811, as amended and in effect on April 1, 1985. New substances controlled under this section shall not be treated in a manner inconsistent with the rules of the United States Attorney General and the decisions of the federal courts interpreting the provisions of s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811, as amended and in effect on April 1, 1985.

(7)The treatment of a new substance as a controlled substance pursuant to this section shall not affect prosecution or punishment for any crime previously committed with respect to that substance.

History.—s. 3, ch. 87-243; s. 11, ch. 99-186; s. 20, ch. 2000-320.

893.04Pharmacist and practitioner.—

(1)A pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances upon a written or oral prescription of a practitioner, under the following conditions:

(a)Oral prescriptions must be promptly reduced to writing by the pharmacist or recorded electronically if permitted by federal law.

(b)The written prescription must be dated and signed by the prescribing practitioner on the day when issued.

(c)There shall appear on the face of the prescription or written record thereof for the controlled substance the following information:

1.The full name and address of the person for whom, or the owner of the animal for which,

the controlled substance is dispensed.

2.The full name and address of the prescribing practitioner and the practitioner's federal controlled substance registry number shall be printed thereon.

3.If the prescription is for an animal, the species of animal for which the controlled substance is prescribed.

4.The name of the controlled substance prescribed and the strength, quantity, and directions for use thereof.

5.The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled.

6.The initials of the pharmacist filling the prescription and the date filled.

(d)The prescription shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of 2 years.

(e)Affixed to the original container in which a controlled substance is delivered upon a prescription or authorized refill thereof, as hereinafter provided, there shall be a label bearing the following information:

1.The name and address of the pharmacy from which such controlled substance was dispensed.

2.The date on which the prescription for such controlled substance was filled.

3.The number of such prescription, as recorded in the prescription files of the pharmacy in which it is filled.

4.The name of the prescribing practitioner.

5.The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed.

6.The directions for the use of the controlled substance prescribed in the prescription.

7.A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

(f)A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by regulation of the Department of Health, such controlled substance may be dispensed upon oral prescription but is limited to a 72-hour supply. A prescription for a controlled substance listed in Schedule II may not be refilled.

(g)A prescription for a controlled substance listed in Schedule III, Schedule IV, or Schedule V may not be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.

(2)(a)A pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient or patient's agent without first determining, in the exercise of her or

his professional judgment, that the order is valid. The pharmacist may dispense the controlled substance, in the exercise of her or his professional judgment, when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent.

(b)Any pharmacist who dispenses by mail a controlled substance listed in Schedule II, Schedule III, or Schedule IV is exempt from the requirement to obtain suitable identification for the prescription dispensed by mail if the pharmacist has obtained the patient's identification through the patient's prescription benefit plan.

(c)Any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon an oral prescription if, before filling the prescription, the pharmacist reduces it to writing or records the prescription electronically if permitted by federal law. Such prescriptions must contain the date of the oral authorization.

(d)Each written prescription prescribed by a practitioner in this state for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and a numerical notation of the quantity of the controlled substance prescribed on the face of the prescription and a notation of the date, with the abbreviated month written out on the face of the prescription. A pharmacist may, upon verification by the prescriber, document any information required by this paragraph. If the prescriber is not available to verify a prescription, the pharmacist may dispense the controlled substance but may insist that the person to whom the controlled substance is dispensed provide valid photographic identification. If a prescription includes a numerical notation of the quantity of the controlled substance or date, but does not include the quantity or date written out in textual format, the pharmacist may dispense the controlled substance without verification by the prescriber of the quantity or date if the pharmacy previously dispensed another prescription for the person to whom the prescription was written.

(e)A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state.

(f)A pharmacist may not knowingly fill a prescription that has been forged for a controlled substance listed in Schedule II, Schedule III, or Schedule IV.

(3)Notwithstanding subsection (1), a pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II, in compliance with the provisions of s. 465.0275.

(4)The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in controlled substances, may sell said stock to a manufacturer, wholesaler, or pharmacy. Such controlled substances may be sold only upon an order form, when such an order form is required for sale by the drug abuse laws of the United States or this state, or regulations pursuant thereto.

History.—s. 4, ch. 73-331; s. 2, ch. 75-18; s. 12, ch. 79-12; s. 2, ch. 90-2; s. 1436, ch. 97-102; s. 301, ch. 99-8; s. 2, ch. 2007-156; s. 5, ch. 2009-202.

893.05Practitioners and persons administering controlled substances in their absence.—

(1)A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may cause the same to be administered by a licensed nurse or an intern practitioner under his or her direction and supervision only. A veterinarian may so prescribe, administer, dispense, mix, or prepare a controlled substance for use on animals only, and may cause it to be administered by an assistant or orderly under the veterinarian's direction and supervision only.

(2)When any controlled substance is dispensed by a practitioner, there shall be affixed to the original container in which the controlled substance is delivered a label on which appears:

(a)The date of delivery.

(b)The directions for use of such controlled substance.

(c)The name and address of such practitioner.

(d)The name of the patient and, if such controlled substance is prescribed for an animal, a statement describing the species of the animal.

(e)A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

(3)Any person who obtains from a practitioner or the practitioner's agent, or pursuant to prescription, any controlled substance for administration to a patient during the absence of such practitioner shall return to such practitioner any unused portion of such controlled substance when it is no longer required by the patient.

History.—s. 5, ch. 73-331; s. 1437, ch. 97-102.

893.055Prescription drug monitoring program.—

(1)As used in this section, the term:

(a)"Patient advisory report" or "advisory report" means information provided by the department in writing, or as determined by the department, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The advisory reports issued by the department are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report; and a person who participates in preparing, reviewing, issuing, or any other activity related to an advisory report may not be permitted or required to testify in any such civil action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with

preparing, reviewing, or issuing such a report.

(b)“Controlled substance” means a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03.

(c)“Dispenser” means a pharmacy, dispensing pharmacist, or dispensing health care practitioner.

(d)“Health care practitioner” or “practitioner” means any practitioner who is subject to licensure or regulation by the department under chapter 458, chapter 459, chapter 461, chapter 462, chapter 464, chapter 465, or chapter 466.

(e)“Health care regulatory board” means any board for a practitioner or health care practitioner who is licensed or regulated by the department.

(f)“Pharmacy” means any pharmacy that is subject to licensure or regulation by the department under chapter 465 and that dispenses or delivers a controlled substance to an individual or address in this state.

(g)“Prescriber” means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner.

(h)“Active investigation” means an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.

(i)“Law enforcement agency” means the Department of Law Enforcement, a Florida sheriff’s department, a Florida police department, or a law enforcement agency of the Federal Government which enforces the laws of this state or the United States relating to controlled substances, and which its agents and officers are empowered by law to conduct criminal investigations and make arrests.

(j)“Program manager” means an employee of or a person contracted by the Department of Health who is designated to ensure the integrity of the prescription drug monitoring program in accordance with the requirements established in paragraphs (2)(a) and (b).

(2)(a)The department shall design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that provides prescription information to a patient’s health care practitioner and pharmacist who inform the department that they wish the patient advisory report provided to them. Otherwise, the patient advisory report will not be sent to the practitioner, pharmacy, or pharmacist. The system shall be designed to provide information regarding dispensed prescriptions of controlled substances and shall not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser acting in good faith and in the course of professional practice. The system shall be consistent with standards of the American Society for Automation in Pharmacy (ASAP). The electronic system shall

also comply with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic protected health information (EPHI), and all other relevant state and federal privacy and security laws and regulations. The department shall establish policies and procedures as appropriate regarding the reporting, accessing the database, evaluation, management, development, implementation, operation, storage, and security of information within the system. The reporting of prescribed controlled substances shall include a dispensing transaction with a dispenser pursuant to chapter 465 or through a dispensing transaction to an individual or address in this state with a pharmacy that is not located in this state but that is otherwise subject to the jurisdiction of this state as to that dispensing transaction. The reporting of patient advisory reports refers only to reports to patients, pharmacies, and practitioners. Separate reports that contain patient prescription history information and that are not patient advisory reports are provided to persons and entities as authorized in paragraphs (7)(b) and (c) and s. 893.0551.

(b)The department, when the direct support organization receives at least $20,000 in nonstate moneys or the state receives at least $20,000 in federal grants for the prescription drug monitoring program, shall adopt rules as necessary concerning the reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the system, including rules for when patient advisory reports are provided to pharmacies and prescribers. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The department shall work with the professional health care licensure boards, such as the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Pharmacy; other appropriate organizations, such as the Florida Pharmacy Association, the Florida Medical Association, the Florida Retail Federation, and the Florida Osteopathic Medical Association, including those relating to pain management; and the Attorney General, the Department of Law Enforcement, and the Agency for Health Care Administration to develop rules appropriate for the prescription drug monitoring program.

(c)All dispensers and prescribers subject to these reporting requirements shall be notified by the department of the implementation date for such reporting requirements.

(d)The program manager shall work with professional health care licensure boards and the stakeholders listed in paragraph (b) to develop rules appropriate for identifying indicators of controlled substance abuse.

(3)The pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance shall submit to the electronic system, by a procedure and in a format established by the department and consistent with an ASAP-approved format, the following information for inclusion in the database:

(a)The name of the prescribing practitioner, the practitioner's federal Drug Enforcement

Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.

(b)The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the database.

(c)The full name, address, and date of birth of the person for whom the prescription was written.

(d)The name, national drug code, quantity, and strength of the controlled substance dispensed.

(e)The full name, federal Drug Enforcement Administration registration number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, federal Drug Enforcement Administration registration number, and address.

(f)The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's National Provider Identification (NPI).

(g)Other appropriate identifying information as determined by department rule.

(4)Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but not more than 7 days after the date the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must meet the reporting requirements of this section by providing the required information concerning each controlled substance that it dispensed in a department-approved, secure methodology and format. Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.

(5)When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:

(a)A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.

(b)A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.

(c)A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.

(d)A practitioner when administering a controlled substance in the emergency room of a licensed hospital.

(e)A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16.

(f)A pharmacist or a dispensing practitioner when dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.

(6)The department may establish when to suspend and when to resume reporting information during a state-declared or nationally declared disaster.

(7)(a)A practitioner or pharmacist who dispenses a controlled substance must submit the information required by this section in an electronic or other method in an ASAP format approved by rule of the department unless otherwise provided in this section. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.

(b)A pharmacy, prescriber, or dispenser shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt information in the database shall be released only as provided in paragraph (c) and s. 893.0551. The program manager, designated program and support staff who act at the direction of or in the absence of the program manager, and any individual who has similar access regarding the management of the database from the prescription drug monitoring program shall submit fingerprints to the department for background screening. The department shall follow the procedure established by the Department of Law Enforcement to request a statewide criminal history record check and to request that the Department of Law Enforcement forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

(c)The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that is confidential and exempt under s. 893.0551. Prior to release, the request shall

be verified as authentic and authorized with the requesting organization by the program manager, the program manager's program and support staff, or as determined in rules by the department as being authentic and as having been authorized by the requesting entity:

1.The department or its relevant health care regulatory boards responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific controlled substance investigation involving a designated person for one or more prescribed controlled substances.

2.The Attorney General for Medicaid fraud cases involving prescribed controlled substances.

3.A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.

4.A patient or the legal guardian or designated health care surrogate of an incapacitated patient as described in s. 893.0551 who, for the purpose of verifying the accuracy of the database information, submits a written and notarized request that includes the patient's full name, address, and date of birth, and includes the same information if the legal guardian or health care surrogate submits the request. The request shall be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate, if the patient's legal guardian or health care surrogate is the requestor. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database.

Information in the database for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the appropriate regulatory board.

(d)The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that contains no identifying information of any patient, physician, health care practitioner, prescriber, or dispenser and that is not confidential and exempt:

1.Department staff for the purpose of calculating performance measures pursuant to subsection (8).

2.The Program Implementation and Oversight Task Force for its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding the prescription drug monitoring program. This subparagraph expires July 1, 2012.

(e)All transmissions of data required by this section must comply with relevant state and federal privacy and security laws and regulations. However, any authorized agency or person under s. 893.0551 receiving such information as allowed by s. 893.0551 may maintain the information

received for up to 24 months before purging it from his or her records or maintain it for longer than 24 months if the information is pertinent to ongoing health care or an active law enforcement investigation or prosecution.

(f)The program manager, upon determining a pattern consistent with the rules established under paragraph (2)(d) and having cause to believe a violation of s. 893.13(7)(a)8., (8)(a), or (8)(b) has occurred, may provide relevant information to the applicable law enforcement agency.

(8)To assist in fulfilling program responsibilities, performance measures shall be reported annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives by the department each December 1, beginning in 2011. Data that does not contain patient, physician, health care practitioner, prescriber, or dispenser identifying information may be requested during the year by department employees so that the department may undertake public health care and safety initiatives that take advantage of observed trends. Performance measures may include, but are not limited to, efforts to achieve the following outcomes:

(a)Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.

(b)Reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit.

(c)Increased coordination among partners participating in the prescription drug monitoring program.

(d)Involvement of stakeholders in achieving improved patient health care and safety and reduction of prescription drug abuse and prescription drug diversion.

(9)Any person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(10)All costs incurred by the department in administering the prescription drug monitoring program shall be funded through federal grants or private funding applied for or received by the state. The department may not commit funds for the monitoring program without ensuring funding is available. The prescription drug monitoring program and the implementation thereof are contingent upon receipt of the nonstate funding. The department and state government shall cooperate with the direct-support organization established pursuant to subsection (11) in seeking federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department so long as the costs of doing so are not considered material. Nonmaterial costs for this purpose include, but are not limited to, the costs of mailing and personnel assigned to research or apply for a grant. Notwithstanding the exemptions to competitive-solicitation requirements under s. 287.057(3)(f), the department shall comply with the competitive-solicitation requirements under

s. 287.057 for the procurement of any goods or services required by this section. Funds provided, directly or indirectly, by prescription drug manufacturers may not be used to implement the program.

(11)The department may establish a direct-support organization that has a board consisting of at least five members to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.

(a)As used in this subsection, the term “direct-support organization” means an organization that is:

1.A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.

2.Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the department in the furtherance of the prescription drug monitoring program.

(b)The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.

(c)The State Surgeon General shall appoint a board of directors for the direct-support organization. Members of the board shall serve at the pleasure of the State Surgeon General. The State Surgeon General shall provide guidance to members of the board to ensure that moneys received by the direct-support organization are not received from inappropriate sources. Inappropriate sources include, but are not limited to, donors, grantors, persons, or organizations that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program.

(d)The direct-support organization shall operate under written contract with the department. The contract must, at a minimum, provide for:

1.Approval of the articles of incorporation and bylaws of the direct-support organization by the department.

2.Submission of an annual budget for the approval of the department.

3.Certification by the department that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the goals and purposes of the prescription drug monitoring program and in the best interests of the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.

4.The reversion, without penalty, to the state of all moneys and property held in trust by the direct-support organization for the benefit of the prescription drug monitoring program if the

direct-support organization ceases to exist or if the contract is terminated.

5.The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.

6.The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications, and an explanation to such donors of the distinction between the department and the direct-support organization.

7.The direct-support organization's collecting, expending, and providing of funds to the department for the development, implementation, and operation of the prescription drug monitoring program as described in this section and s. 2, chapter 2009-198, Laws of Florida, as long as the task force is authorized. The direct-support organization may collect and expend funds to be used for the functions of the direct-support organization's board of directors, as necessary and approved by the department. In addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:

a.Establishing and administering the prescription drug monitoring program's electronic database, including hardware and software.

b.Conducting studies on the efficiency and effectiveness of the program to include feasibility studies as described in subsection (13).

c.Providing funds for future enhancements of the program within the intent of this section.

d.Providing user training of the prescription drug monitoring program, including distribution of materials to promote public awareness and education and conducting workshops or other meetings, for health care practitioners, pharmacists, and others as appropriate.

e.Providing funds for travel expenses.

f.Providing funds for administrative costs, including personnel, audits, facilities, and equipment.

g.Fulfilling all other requirements necessary to implement and operate the program as outlined in this section.

(e)The activities of the direct-support organization must be consistent with the goals and mission of the department, as determined by the department, and in the best interests of the state. The direct-support organization must obtain a written approval from the department for any activities in support of the prescription drug monitoring program before undertaking those activities.

(f)The department may permit, without charge, appropriate use of administrative services, property, and facilities of the department by the direct-support organization, subject to this section. The use must be directly in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would unreasonably interfere with

opportunities for the public to use such facilities for established purposes. Any moneys received from rentals of facilities and properties managed by the department may be held in a separate depository account in the name of the direct-support organization and subject to the provisions of the letter of agreement with the department. The letter of agreement must provide that any funds held in the separate depository account in the name of the direct-support organization must revert to the department if the direct-support organization is no longer approved by the department to operate in the best interests of the state.

(g)The department may adopt rules under s. 120.54 to govern the use of administrative services, property, or facilities of the department or office by the direct-support organization.

(h)The department may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.

(i)The direct-support organization shall provide for an independent annual financial audit in accordance with s. 215.981. Copies of the audit shall be provided to the department and the Office of Policy and Budget in the Executive Office of the Governor.

(j)The direct-support organization may not exercise any power under s. 617.0302(12) or (16).

(12)A prescriber or dispenser may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under this subsection for accessing or failing to access such information.

(13)To the extent that funding is provided for such purpose through federal or private grants or gifts and other types of available moneys, the department shall study the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting that respects the privacy of the patient, the prescriber, and the dispenser. Such a study shall be conducted in order to further improve the quality of health care services and safety by improving the prescribing and dispensing practices for prescription drugs, taking advantage of advances in technology, reducing duplicative prescriptions and the overprescribing of prescription drugs, and reducing drug abuse. The requirements of the National All Schedules Prescription Electronic Reporting (NASPER) Act are authorized in order to apply for federal NASPER funding. In addition, the direct-support organization shall provide funding for the department to conduct training for health care practitioners and other appropriate persons in using the monitoring

program to support the program enhancements.

(14)A pharmacist, pharmacy, or dispensing health care practitioner or his or her agent, before releasing a controlled substance to any person not known to such dispenser, shall require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity to the dispenser. If the person does not have proper identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system will be considered to be proper identification. This subsection does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted. As used in this subsection, the term "proper identification" means an identification that is issued by a state or the Federal Government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

(15)The Agency for Health Care Administration shall continue the promotion of electronic prescribing by health care practitioners, health care facilities, and pharmacies under s. 408.0611.

(16)The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to administer the provisions of this section, which shall include as necessary the reporting, accessing, evaluation, management, development, implementation, operation, and storage of information within the monitoring program's system.

History.—s. 1, ch. 2009-198; s. 41, ch. 2010-151; s. 12, ch. 2010-211; s. 50, ch. 2011-4; s. 23, ch. 2011-141; s. 86, ch. 2012-5.

893.0551Public records exemption for the prescription drug monitoring program.—

(1)For purposes of this section, the term:

(a)"Active investigation" has the same meaning as provided in s. 893.055.

(b)"Dispenser" has the same meaning as provided in s. 893.055.

(c)"Health care practitioner" or "practitioner" has the same meaning as provided in s. 893.055.

(d)"Health care regulatory board" has the same meaning as provided in s. 893.055.

(e)"Law enforcement agency" has the same meaning as provided in s. 893.055.

(f)"Pharmacist" means any person licensed under chapter 465 to practice the profession of pharmacy.

(g)"Pharmacy" has the same meaning as provided in s. 893.055.

(h)"Prescriber" has the same meaning as provided in s. 893.055.

(2)The following information of a patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the

practitioner, a pharmacist, or a pharmacy that is contained in records held by the department under s. 893.055 is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution:

(a)Name.

(b)Address.

(c)Telephone number.

(d)Insurance plan number.

(e)Government-issued identification number.

(f)Provider number.

(g)Drug Enforcement Administration number.

(h)Any other unique identifying information or number.

(3)The department shall disclose such confidential and exempt information to the following entities after using a verification process to ensure the legitimacy of that person's or entity's request for the information:

(a)The Attorney General and his or her designee when working on Medicaid fraud cases involving prescription drugs or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud regarding prescription drugs. The Attorney General or his or her designee may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of prescription drug abuse or prescription drug diversion law as it relates to controlled substances. The Attorney General's Medicaid fraud investigators may not have direct access to the department's database.

(b)The department's relevant health care regulatory boards responsible for the licensure, regulation, or discipline of a practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a specific controlled substances investigation for prescription drugs involving a designated person. The health care regulatory boards may request information from the department but may not have direct access to its database. The health care regulatory boards may provide such information to a law enforcement agency pursuant to ss. 456.066 and 456.073.

(c)A law enforcement agency that has initiated an active investigation involving a specific violation of law regarding prescription drug abuse or diversion of prescribed controlled substances. The law enforcement agency may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of prescription drug abuse or prescription drug diversion law as it relates to controlled substances. A law enforcement agency may request information from the department but may not have direct access to its database.

(d)A health care practitioner who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055.

(e)A pharmacist who certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with ss. 893.04 and 893.055.

(f)A patient or the legal guardian or designated health care surrogate for an incapacitated patient, if applicable, making a request as provided in s. 893.055(7)(c)4.

(g)The patient's pharmacy, prescriber, or dispenser who certifies that the information is necessary to provide medical treatment to his or her current patient in accordance with s. 893.055.

(4)The department shall disclose such confidential and exempt information to the applicable law enforcement agency in accordance with s. 893.055(7)(f). The law enforcement agency may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b).

(5)Any agency or person who obtains such confidential and exempt information pursuant to this section must maintain the confidential and exempt status of that information.

(6)Any person who willfully and knowingly violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(7)This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2014, unless reviewed and saved from repeal through reenactment by the Legislature.

History.—s. 1, ch. 2009-197; s. 13, ch. 2010-211; s. 51, ch. 2011-4.

893.06Distribution of controlled substances; order forms; labeling and packaging requirements.—

(1)Controlled substances in Schedules I and II shall be distributed by a duly licensed manufacturer, distributor, or wholesaler to a duly licensed manufacturer, wholesaler, distributor, practitioner, pharmacy, as defined in chapter 465, hospital, or laboratory only pursuant to an order form. It shall be deemed a compliance with this subsection if the parties to the transaction have complied with federal law respecting the use of order forms.

(2)Possession or control of controlled substances obtained as authorized by this section shall be lawful if in the regular course of business, occupation, profession, employment, or duty.

(3)A person in charge of a hospital or laboratory or in the employ of this state or of any other state, or of any political subdivision thereof, and a master or other proper officer of a ship or aircraft, who obtains controlled substances under the provisions of this section or otherwise, shall not administer, dispense, or otherwise use such controlled substances within this state, except within the scope of her or his employment or official duty, and then only for scientific or medicinal purposes and subject to the provisions of this chapter.

(4)It shall be unlawful to distribute a controlled substance in a commercial container unless such container bears a label showing the name and address of the manufacturer, the quantity, kind, and form of controlled substance contained therein, and the identifying symbol for such substance, as required by federal law. No person except a pharmacist, for the purpose of dispensing a prescription, or a practitioner, for the purpose of dispensing a controlled substance to a patient, shall alter, deface, or remove any labels so affixed.

History.—s. 6, ch. 73-331; s. 1438, ch. 97-102.

893.065Counterfeit-resistant prescription blanks for controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V.—The Department of Health shall develop and adopt by rule the form and content for a counterfeit-resistant prescription blank which must be used by practitioners for the purpose of prescribing a controlled substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V pursuant to s. 456.42. The Department of Health may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances. The prescription blanks may not be transferred.

History.—s. 4, ch. 2007-156; s. 24, ch. 2011-141.

893.07Records.—

(1)Every person who engages in the manufacture, compounding, mixing, cultivating, growing, or by any other process producing or preparing, or in the dispensing, importation, or, as a wholesaler, distribution, of controlled substances shall:

(a)On January 1, 1974, or as soon thereafter as any person first engages in such activity, and every second year thereafter, make a complete and accurate record of all stocks of controlled substances on hand. The inventory may be prepared on the regular physical inventory date which is nearest to, and does not vary by more than 6 months from, the biennial date that would otherwise apply. As additional substances are designated for control under this chapter, they shall be inventoried as provided for in this subsection.

(b)On and after January 1, 1974, maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by him or her, except that this subsection shall not require the maintenance of a perpetual inventory.

Compliance with the provisions of federal law pertaining to the keeping of records of controlled substances shall be deemed a compliance with the requirements of this subsection.

(2)The record of controlled substances received shall in every case show:

(a)The date of receipt.

(b)The name and address of the person from whom received.

(c)The kind and quantity of controlled substances received.

(3)The record of all controlled substances sold, administered, dispensed, or otherwise disposed of shall show:

(a)The date of selling, administering, or dispensing.

(b)The correct name and address of the person to whom or for whose use, or the owner and species of animal for which, sold, administered, or dispensed.

(c)The kind and quantity of controlled substances sold, administered, or dispensed.

(4)Every inventory or record required by this chapter, including prescription records, shall be maintained:

(a)Separately from all other records of the registrant, or

(b)Alternatively, in the case of Schedule III, IV, or V controlled substances, in such form that information required by this chapter is readily retrievable from the ordinary business records of the registrant.

In either case, the records described in this subsection shall be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances. Law enforcement officers are not required to obtain a subpoena, court order, or search warrant in order to obtain access to or copies of such records.

(5)Each person described in subsection (1) shall:

(a)Maintain a record which shall contain a detailed list of controlled substances lost, destroyed, or stolen, if any; the kind and quantity of such controlled substances; and the date of the discovering of such loss, destruction, or theft.

(b)In the event of the discovery of the theft or significant loss of controlled substances, report such theft or significant loss to the sheriff of that county within 24 hours after discovery. A person who fails to report a theft or significant loss of a substance listed in s. 893.03(3), (4), or (5) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. A person who fails to report a theft or significant loss of a substance listed in s. 893.03(2) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

History.—s. 7, ch. 73-331; s. 1439, ch. 97-102; s. 25, ch. 2011-141.

893.08Exceptions.—

(1)The following may be distributed at retail without a prescription, but only by a registered pharmacist:

(a)Any compound, mixture, or preparation described in Schedule V.

(b)Any compound, mixture, or preparation containing any depressant or stimulant substance described in s. 893.03(2)(a) or (c) except any amphetamine drug or sympathomimetic amine drug

or compound designated as a Schedule II controlled substance pursuant to this chapter; in s. 893.03(3)(a); or in Schedule IV, if:

1.The compound, mixture, or preparation contains one or more active medicinal ingredients not having depressant or stimulant effect on the central nervous system, and

2.Such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the controlled substances which do have a depressant or stimulant effect on the central nervous system.

(2)No compound, mixture, or preparation may be dispensed under subsection (1) unless such substance may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold at retail without a prescription.

(3)The exemptions authorized by this section shall be subject to the following conditions:

(a)The compounds, mixtures, and preparations referred to in subsection (1) may be dispensed to persons under age 18 only on prescription. A bound volume must be maintained as a record of sale at retail of excepted compounds, mixtures, and preparations, and the pharmacist must require suitable identification from every unknown purchaser.

(b)Such compounds, mixtures, and preparations shall be sold by the pharmacist in good faith as a medicine and not for the purpose of evading the provisions of this chapter. The pharmacist may, in his or her discretion, withhold sale to any person whom the pharmacist reasonably believes is attempting to purchase excepted compounds, mixtures, or preparations for the purpose of abuse.

(c)The total quantity of controlled substance listed in Schedule V which may be sold to any one purchaser within a given 48-hour period shall not exceed 120 milligrams of codeine, 60 milligrams dihydrocodeine, 30 milligrams of ethyl morphine, or 240 milligrams of opium.

(d)Nothing in this section shall be construed to limit the kind and quantity of any controlled substance that may be prescribed, administered, or dispensed to any person, or for the use of any person or animal, when it is prescribed, administered, or dispensed in compliance with the general provisions of this chapter.

(4)The dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan) shall not be deemed to be included in any schedule by reason of enactment of this chapter.

History.—s. 8, ch. 73-331; s. 1, ch. 77-174; s. 6, ch. 80-354; s. 4, ch. 89-281; s. 2, ch. 93-92; s. 1440, ch. 97-102; s. 105, ch. 97-264; s. 12, ch. 99-186.

893.09Enforcement.—

(1)The Department of Law Enforcement, all state agencies which regulate professions or institutions affected by the provisions of this chapter, and all peace officers of the state shall enforce all provisions of this chapter except those specifically delegated, and shall cooperate with

all agencies charged with the enforcement of the laws of the United States, this state, and all other states relating to controlled substances.

(2)Any agency authorized to enforce this chapter shall have the right to institute an action in its own name to enjoin the violation of any of the provisions of this chapter. Said action for an injunction shall be in addition to any other action, proceeding, or remedy authorized by law.

(3)All law enforcement officers whose duty it is to enforce this chapter shall have authority to administer oaths in connection with their official duties, and any person making a material false statement under oath before such law enforcement officers shall be deemed guilty of perjury and subject to the same punishment as prescribed for perjury.

(4)It shall be unlawful and punishable as provided in chapter 843 for any person to interfere with any such law enforcement officer in the performance of the officer's official duties. It shall also be unlawful for any person falsely to represent himself or herself to be authorized to enforce the drug abuse laws of this state, the United States, or any other state.

(5)No civil or criminal liability shall be imposed by virtue of this chapter upon any person whose duty it is to enforce the provisions of this chapter, by reason of his or her being lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.

History.—s. 9, ch. 73-331; s. 1, ch. 77-174; s. 30, ch. 79-8; s. 1441, ch. 97-102.

893.10Burden of proof; photograph or video recording of evidence.—

(1)It is not necessary for the state to negative any exemption or exception set forth in this chapter in any indictment, information, or other pleading or in any trial, hearing, or other proceeding under this chapter, and the burden of going forward with the evidence with respect to any exemption or exception is upon the person claiming its benefit.

(2)In the prosecution of an offense involving the manufacture of a controlled substance, a photograph or video recording of the manufacturing equipment used in committing the offense, including, but not limited to, grow lights, growing trays, and chemical fertilizers, may be introduced as competent evidence of the existence and use of the equipment and is admissible in the prosecution of the offense to the same extent as if the property were introduced as evidence.

(3)After a law enforcement agency documents the manufacturing equipment by photography or video recording, the manufacturing equipment may be destroyed on site and left in disrepair. The law enforcement agency destroying the equipment is immune from civil liability for the destruction of the equipment. The destruction of the equipment must be recorded by the supervising law enforcement officer in the manner described in s. 893.12(1)(a), and records must be maintained for 24 months.

History.—s. 10, ch. 73-331; s. 1442, ch. 97-102; s. 3, ch. 2008-184; s. 19, ch. 2010-117.

893.101Legislative findings and intent.—

(1)The Legislature finds that the cases of *Scott v. State*, Slip Opinion No. SC94701 (Fla. 2002)

and *Chicone v. State*, 684 So.2d 736 (Fla. 1996), holding that the state must prove that the defendant knew of the illicit nature of a controlled substance found in his or her actual or constructive possession, were contrary to legislative intent.

(2)The Legislature finds that knowledge of the illicit nature of a controlled substance is not an element of any offense under this chapter. Lack of knowledge of the illicit nature of a controlled substance is an affirmative defense to the offenses of this chapter.

(3)In those instances in which a defendant asserts the affirmative defense described in this section, the possession of a controlled substance, whether actual or constructive, shall give rise to a permissive presumption that the possessor knew of the illicit nature of the substance. It is the intent of the Legislature that, in those cases where such an affirmative defense is raised, the jury shall be instructed on the permissive presumption provided in this subsection.

History.—s. 1, ch. 2002-258.

893.105Testing and destruction of seized substances.—

(1)Any controlled substance or listed chemical seized as evidence may be sample tested and weighed by the seizing agency after the seizure. Any such sample and the analysis thereof shall be admissible into evidence in any civil or criminal action for the purpose of proving the nature, composition, and weight of the substance seized. In addition, the seizing agency may photograph or videotape, for use at trial, the controlled substance or listed chemical seized.

(2)Controlled substances or listed chemicals that are not retained for sample testing as provided in subsection (1) may be destroyed pursuant to a court order issued in accordance with s. 893.12.

History.—s. 1, ch. 82-88; s. 3, ch. 91-279.

893.11Suspension, revocation, and reinstatement of business and professional licenses.—For the purposes of s. 120.60(6), any conviction in any court reported to the Comprehensive Case Information System of the Florida Association of Court Clerks and Comptrollers, Inc., for the sale of, or trafficking in, a controlled substance or for conspiracy to sell, or traffic in, a controlled substance constitutes an immediate serious danger to the public health, safety, or welfare, and is grounds for disciplinary action by the licensing state agency. A state agency shall initiate an immediate emergency suspension of an individual professional license issued by the agency, in compliance with the procedures for summary suspensions in s. 120.60(6), upon the agency's findings of the licensee's conviction in any court reported to the Comprehensive Case Information System of the Florida Association of Court Clerks and Comptrollers, Inc., for the sale of, or trafficking in, a controlled substance, or for conspiracy to sell, or traffic in, a controlled substance. Before renewing any professional license, a state agency that issues a professional license must use the Comprehensive Case Information System of the Florida Association of Court Clerks and Comptrollers, Inc., to obtain information relating to any conviction for the sale of, or trafficking in,

a controlled substance or for conspiracy to sell, or traffic in, a controlled substance. The clerk of court shall provide electronic access to each state agency at no cost and also provide certified copies of the judgment upon request to the agency. Upon a showing by any such convicted defendant whose professional license has been suspended or revoked pursuant to this section that his or her civil rights have been restored or upon a showing that the convicted defendant meets the following criteria, the agency head may reinstate or reactivate such license when:

(1)The person has complied with the conditions of paragraphs (a) and (b) which shall be monitored by the Department of Corrections while the person is under any supervisory sanction. If the person fails to comply with provisions of these paragraphs by either failing to maintain treatment or by testing positive for drug use, the department shall notify the licensing agency, which shall revoke the license. The person under supervision may:

(a)Seek evaluation and enrollment in, and once enrolled maintain enrollment in until completion, a drug treatment and rehabilitation program which is approved or regulated by the Department of Children and Family Services. The treatment and rehabilitation program shall be specified by:

1.The court, in the case of court-ordered supervisory sanctions;

2.The Parole Commission, in the case of parole, control release, or conditional release; or

3.The Department of Corrections, in the case of imprisonment or any other supervision required by law.

(b)Submit to periodic urine drug testing pursuant to procedures prescribed by the Department of Corrections. If the person is indigent, the costs shall be paid by the Department of Corrections; or

(2)The person has successfully completed an appropriate program under the Correctional Education Program.

(3)As used in this section, the term “professional license” includes any license, permit, or certificate that authorizes a person to practice his or her profession. However, the term does not include any of the taxes, fees, or permits regulated, controlled, or administered by the Department of Revenue in accordance with s. 213.05.

History.—s. 11, ch. 73-331; s. 1, ch. 77-117; s. 19, ch. 78-95; s. 3, ch. 90-266; s. 126, ch. 91-112; s. 14, ch. 95-325; s. 1443, ch. 97-102; s. 302, ch. 99-8; s. 18, ch. 2012-100.

893.12Contraband; seizure, forfeiture, sale.—

(1)All substances controlled by this chapter and all listed chemicals, which substances or chemicals are handled, delivered, possessed, or distributed contrary to any provisions of this chapter, and all such controlled substances or listed chemicals the lawful possession of which is not established or the title to which cannot be ascertained, are declared to be contraband, are subject to seizure and confiscation by any person whose duty it is to enforce the provisions of the chapter,

and shall be disposed of as follows:

(a)Except as in this section otherwise provided, the court having jurisdiction shall order such controlled substances or listed chemicals forfeited and destroyed. A record of the place where said controlled substances or listed chemicals were seized, of the kinds and quantities of controlled substances or listed chemicals destroyed, and of the time, place, and manner of destruction shall be kept, and a return under oath reporting said destruction shall be made to the court by the officer who destroys them.

(b)Upon written application by the Department of Health, the court by whom the forfeiture of such controlled substances or listed chemicals has been decreed may order the delivery of any of them to said department for distribution or destruction as hereinafter provided.

(c)Upon application by any hospital or laboratory within the state not operated for private gain, the department may, in its discretion, deliver any controlled substances or listed chemicals that have come into its custody by authority of this section to the applicant for medical use. The department may from time to time deliver excess stocks of such controlled substances or listed chemicals to the United States Drug Enforcement Administration or destroy same.

(d)The department shall keep a full and complete record of all controlled substances or listed chemicals received and of all controlled substances or listed chemicals disposed of, showing:

1.The exact kinds, quantities, and forms of such controlled substances or listed chemicals;

2.The persons from whom received and to whom delivered;

3.By whose authority received, delivered, and destroyed; and

4.The dates of the receipt, disposal, or destruction,

which record shall be open to inspection by all persons charged with the enforcement of federal and state drug abuse laws.

(2)(a)Any vessel, vehicle, aircraft, or drug paraphernalia as defined in s. 893.145 which has been or is being used in violation of any provision of this chapter or in, upon, or by means of which any violation of this chapter has taken or is taking place may be seized and forfeited as provided by the Florida Contraband Forfeiture Act.

(b)All real property, including any right, title, leasehold interest, and other interest in the whole of any lot or tract of land and any appurtenances or improvements, which real property is used, or intended to be used, in any manner or part, to commit or to facilitate the commission of, or which real property is acquired with proceeds obtained as a result of, a violation of any provision of this chapter related to a controlled substance described in s. 893.03(1) or (2) may be seized and forfeited as provided by the Florida Contraband Forfeiture Act except that no property shall be forfeited under this paragraph to the extent of an interest of an owner or lienholder by reason of any act or omission established by that owner or lienholder to have been committed or omitted without the knowledge or consent of that owner or lienholder.

(c)All moneys, negotiable instruments, securities, and other things of value furnished or intended to be furnished by any person in exchange for a controlled substance described in s. 893.03(1) or (2) or a listed chemical in violation of any provision of this chapter, all proceeds traceable to such an exchange, and all moneys, negotiable instruments, and securities used or intended to be used to facilitate any violation of any provision of this chapter or which are acquired with proceeds obtained in violation of any provision of this chapter may be seized and forfeited as provided by the Florida Contraband Forfeiture Act, except that no property shall be forfeited under this paragraph to the extent of an interest of an owner or lienholder by reason of any act or omission established by that owner or lienholder to have been committed or omitted without the knowledge or consent of that owner or lienholder.

(d)All books, records, and research, including formulas, microfilm, tapes, and data which are used, or intended for use, or which are acquired with proceeds obtained, in violation of any provision of this chapter related to a controlled substance described in s. 893.03(1) or (2) or a listed chemical may be seized and forfeited as provided by the Florida Contraband Forfeiture Act.

(e)If any of the property described in this subsection:

1.Cannot be located;

2.Has been transferred to, sold to, or deposited with, a third party;

3.Has been placed beyond the jurisdiction of the court;

4.Has been substantially diminished in value by any act or omission of the defendant; or

5.Has been commingled with any property which cannot be divided without difficulty,

the court shall order the forfeiture of any other property of the defendant up to the value of any property subject to forfeiture under this subsection.

(3)Any law enforcement agency is empowered to authorize or designate officers, agents, or other persons to carry out the seizure provisions of this section. It shall be the duty of any officer, agent, or other person so authorized or designated, or authorized by law, whenever she or he shall discover any vessel, vehicle, aircraft, real property or interest in real property, money, negotiable instrument, security, book, record, or research which has been or is being used or intended to be used, or which is acquired with proceeds obtained, in violation of any of the provisions of this chapter, or in, upon, or by means of which any violation of this chapter has taken or is taking place, to seize such vessel, vehicle, aircraft, real property or interest in real property, money, negotiable instrument, security, book, record, or research and place it in the custody of such person as may be authorized or designated for that purpose by the respective law enforcement agency pursuant to these provisions.

(4)The rights of any bona fide holder of a duly recorded mortgage or duly recorded vendor's privilege on the property seized under this chapter shall not be affected by the seizure.

History.—s. 12, ch. 73-331; ss. 10, 11, ch. 74-385; s. 471, ch. 77-147; s. 185, ch. 79-164; s. 4, ch. 80-30; s. 9, ch.

80-68; s. 5, ch. 89-148; s. 4, ch. 91-279; s. 1444, ch. 97-102; s. 1, ch. 98-395; s. 303, ch. 99-8; s. 13, ch. 99-186; s. 21, ch. 2000-320; s. 17, ch. 2004-11.

893.13Prohibited acts; penalties.—

(1)(a)Except as authorized by this chapter and chapter 499, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance. Any person who violates this provision with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.A controlled substance named or described in s. 893.03(5) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(b)Except as provided in this chapter, it is unlawful to sell or deliver in excess of 10 grams of any substance named or described in s. 893.03(1)(a) or (1)(b), or any combination thereof, or any mixture containing any such substance. Any person who violates this paragraph commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c)Except as authorized by this chapter, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising a child care facility as defined in s. 402.302 or a public or private elementary, middle, or secondary school between the hours of 6 a.m. and 12 midnight, or at any time in, on, or within 1,000 feet of real property comprising a state, county, or municipal park, a community center, or a publicly owned recreational facility. For the purposes of this paragraph, the term “community center” means a facility operated by a nonprofit community-based organization for the provision of recreational, social, or educational services to the public. Any person who violates this paragraph with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. The defendant must be sentenced to a minimum term of imprisonment of 3 calendar years unless the offense was committed within 1,000 feet of the real property comprising a child care facility as defined in s. 402.302.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.Any other controlled substance, except as lawfully sold, manufactured, or delivered, must

be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

This paragraph does not apply to a child care facility unless the owner or operator of the facility posts a sign that is not less than 2 square feet in size with a word legend identifying the facility as a licensed child care facility and that is posted on the property of the child care facility in a conspicuous place where the sign is reasonably visible to the public.

(d)Except as authorized by this chapter, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising a public or private college, university, or other postsecondary educational institution. Any person who violates this paragraph with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.Any other controlled substance, except as lawfully sold, manufactured, or delivered, must be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

(e)Except as authorized by this chapter, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance not authorized by law in, on, or within 1,000 feet of a physical place for worship at which a church or religious organization regularly conducts religious services or within 1,000 feet of a convenience business as defined in s. 812.171. Any person who violates this paragraph with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.Any other controlled substance, except as lawfully sold, manufactured, or delivered, must be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

(f)Except as authorized by this chapter, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising a public housing facility at any time. For purposes

of this section, the term “real property comprising a public housing facility” means real property, as defined in s. 421.03(12), of a public corporation created as a housing authority pursuant to part I of chapter 421. Any person who violates this paragraph with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.Any other controlled substance, except as lawfully sold, manufactured, or delivered, must be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

(g)Except as authorized by this chapter, it is unlawful for any person to manufacture methamphetamine or phencyclidine, or possess any listed chemical as defined in s. 893.033 in violation of s. 893.149 and with intent to manufacture methamphetamine or phencyclidine. If any person violates this paragraph and:

1.The commission or attempted commission of the crime occurs in a structure or conveyance where any child under 16 years of age is present, the person commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition, the defendant must be sentenced to a minimum term of imprisonment of 5 calendar years.

2.The commission of the crime causes any child under 16 years of age to suffer great bodily harm, the person commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition, the defendant must be sentenced to a minimum term of imprisonment of 10 calendar years.

(h)Except as authorized by this chapter, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising an assisted living facility, as that term is used in chapter 429. Any person who violates this paragraph with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4. commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2)(a)Except as authorized by this chapter and chapter 499, it is unlawful for any person to purchase, or possess with intent to purchase, a controlled substance. Any person who violates this

provision with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.A controlled substance named or described in s. 893.03(5) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(b)Except as provided in this chapter, it is unlawful to purchase in excess of 10 grams of any substance named or described in s. 893.03(1)(a) or (1)(b), or any combination thereof, or any mixture containing any such substance. Any person who violates this paragraph commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)Any person who delivers, without consideration, not more than 20 grams of cannabis, as defined in this chapter, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. For the purposes of this paragraph, “cannabis” does not include the resin extracted from the plants of the genus *Cannabis* or any compound manufacture, salt, derivative, mixture, or preparation of such resin.

(4)Except as authorized by this chapter, it is unlawful for any person 18 years of age or older to deliver any controlled substance to a person under the age of 18 years, or to use or hire a person under the age of 18 years as an agent or employee in the sale or delivery of such a substance, or to use such person to assist in avoiding detection or apprehension for a violation of this chapter. Any person who violates this provision with respect to:

(a)A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Imposition of sentence may not be suspended or deferred, nor shall the person so convicted be placed on probation.

(5)It is unlawful for any person to bring into this state any controlled substance unless the possession of such controlled substance is authorized by this chapter or unless such person is licensed to do so by the appropriate federal agency. Any person who violates this provision with respect to:

(a)A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b),

or (2)(c)4., commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c)A controlled substance named or described in s. 893.03(5) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(6)(a)It is unlawful for any person to be in actual or constructive possession of a controlled substance unless such controlled substance was lawfully obtained from a practitioner or pursuant to a valid prescription or order of a practitioner while acting in the course of his or her professional practice or to be in actual or constructive possession of a controlled substance except as otherwise authorized by this chapter. Any person who violates this provision commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)If the offense is the possession of not more than 20 grams of cannabis, as defined in this chapter, or 3 grams or less of a controlled substance described in s. 893.03(1)(c)46.-50. and 114.-142., the person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. For the purposes of this subsection, “cannabis” does not include the resin extracted from the plants of the genus *Cannabis*, or any compound manufacture, salt, derivative, mixture, or preparation of such resin, and a controlled substance described in s. 893.03(1)(c)46.-50. and 114.-142. does not include the substance in a powdered form.

(c)Except as provided in this chapter, it is unlawful to possess in excess of 10 grams of any substance named or described in s. 893.03(1)(a) or (1)(b), or any combination thereof, or any mixture containing any such substance. Any person who violates this paragraph commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(d)Notwithstanding any provision to the contrary of the laws of this state relating to arrest, a law enforcement officer may arrest without warrant any person who the officer has probable cause to believe is violating the provisions of this chapter relating to possession of cannabis.

(7)(a)A person may not:

1.Distribute or dispense a controlled substance in violation of this chapter.

2.Refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under this chapter.

3.Refuse entry into any premises for any inspection or refuse to allow any inspection authorized by this chapter.

4.Distribute a controlled substance named or described in s. 893.03(1) or (2) except pursuant to an order form as required by s. 893.06.

5.Keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or

other structure or place which is resorted to by persons using controlled substances in violation of this chapter for the purpose of using these substances, or which is used for keeping or selling them in violation of this chapter.

6.Use to his or her own personal advantage, or reveal, any information obtained in enforcement of this chapter except in a prosecution or administrative hearing for a violation of this chapter.

7.Possess a prescription form which has not been completed and signed by the practitioner whose name appears printed thereon, unless the person is that practitioner, is an agent or employee of that practitioner, is a pharmacist, or is a supplier of prescription forms who is authorized by that practitioner to possess those forms.

8.Withhold information from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person making the request has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days.

9.Acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.

10.Affix any false or forged label to a package or receptacle containing a controlled substance.

11.Furnish false or fraudulent material information in, or omit any material information from, any report or other document required to be kept or filed under this chapter or any record required to be kept by this chapter.

12.Store anhydrous ammonia in a container that is not approved by the United States Department of Transportation to hold anhydrous ammonia or is not constructed in accordance with sound engineering, agricultural, or commercial practices.

13.With the intent to obtain a controlled substance or combination of controlled substances that are not medically necessary for the person or an amount of a controlled substance or substances that is not medically necessary for the person, obtain or attempt to obtain from a practitioner a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. For purposes of this subparagraph, a material fact includes whether the person has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph 8.

(b)A health care practitioner, with the intent to provide a controlled substance or combination of controlled substances that are not medically necessary to his or her patient or an amount of controlled substances that is not medically necessary for his or her patient, may not provide a controlled substance or a prescription for a controlled substance by misrepresentation, fraud,

forgery, deception, subterfuge, or concealment of a material fact. For purposes of this paragraph, a material fact includes whether the patient has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph (a)8.

(c)Any person who violates the provisions of subparagraphs (a)1.-7. commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083; except that, upon a second or subsequent violation, the person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(d)Any person who violates the provisions of subparagraphs (a)8.-12. commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(e)A person or health care practitioner who violates the provisions of subparagraph (a)13. or paragraph (b) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if any controlled substance that is the subject of the offense is listed in Schedule II, Schedule III, or Schedule IV.

(8)(a)Notwithstanding subsection (9), a prescribing practitioner may not:

1.Knowingly assist a patient, other person, or the owner of an animal in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practice of the prescribing practitioner's professional practice;

2.Employ a trick or scheme in the practice of the prescribing practitioner's professional practice to assist a patient, other person, or the owner of an animal in obtaining a controlled substance;

3.Knowingly write a prescription for a controlled substance for a fictitious person; or

4.Write a prescription for a controlled substance for a patient, other person, or an animal if the sole purpose of writing such prescription is to provide a monetary benefit to, or obtain a monetary benefit for, the prescribing practitioner.

(b)If the prescribing practitioner wrote a prescription or multiple prescriptions for a controlled substance for the patient, other person, or animal for which there was no medical necessity, or which was in excess of what was medically necessary to treat the patient, other person, or animal, that fact does not give rise to any presumption that the prescribing practitioner violated subparagraph (a)1., but may be considered with other competent evidence in determining whether the prescribing practitioner knowingly assisted a patient, other person, or the owner of an animal to obtain a controlled substance in violation of subparagraph (a)1.

(c)A person who violates paragraph (a) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(d)Notwithstanding paragraph (c), if a prescribing practitioner has violated paragraph (a) and received $1,000 or more in payment for writing one or more prescriptions or, in the case of a prescription written for a controlled substance described in s. 893.135, has written one or more

prescriptions for a quantity of a controlled substance which, individually or in the aggregate, meets the threshold for the offense of trafficking in a controlled substance under s. 893.15, the violation is reclassified as a felony of the second degree and ranked in level 4 of the Criminal Punishment Code.

(9)The provisions of subsections (1)-(8) are not applicable to the delivery to, or actual or constructive possession for medical or scientific use or purpose only of controlled substances by, persons included in any of the following classes, or the agents or employees of such persons, for use in the usual course of their business or profession or in the performance of their official duties:

(a)Pharmacists.

(b)Practitioners.

(c)Persons who procure controlled substances in good faith and in the course of professional practice only, by or under the supervision of pharmacists or practitioners employed by them, or for the purpose of lawful research, teaching, or testing, and not for resale.

(d)Hospitals that procure controlled substances for lawful administration by practitioners, but only for use by or in the particular hospital.

(e)Officers or employees of state, federal, or local governments acting in their official capacity only, or informers acting under their jurisdiction.

(f)Common carriers.

(g)Manufacturers, wholesalers, and distributors.

(h)Law enforcement officers for bona fide law enforcement purposes in the course of an active criminal investigation.

(10)If a person violates any provision of this chapter and the violation results in a serious injury to a state or local law enforcement officer as defined in s. 943.10, firefighter as defined in s. 633.30, emergency medical technician as defined in s. 401.23, paramedic as defined in s. 401.23, employee of a public utility or an electric utility as defined in s. 366.02, animal control officer as defined in s. 828.27, volunteer firefighter engaged by state or local government, law enforcement officer employed by the Federal Government, or any other local, state, or Federal Government employee injured during the course and scope of his or her employment, the person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the injury sustained results in death or great bodily harm, the person commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—s. 13, ch. 73-331; s. 1, ch. 76-200; s. 1, ch. 77-174; s. 2, ch. 79-1; s. 3, ch. 79-325; s. 5, ch. 80-30; s. 2, ch. 80-70; s. 490, ch. 81-259; s. 2, ch. 82-16; s. 52, ch. 83-215; s. 1, ch. 84-77; s. 5, ch. 85-242; s. 4, ch. 87-243; s. 2, ch. 88-381; s. 4, ch. 89-281; s. 1, ch. 89-524; ss. 1, 6, ch. 90-111; s. 1, ch. 93-59; s. 2, ch. 93-92; s. 1, ch. 93-194; ss. 22, 23, ch. 93-406; s. 2, ch. 96-360; s. 2, ch. 97-1; s. 1, ch. 97-43; s. 1827, ch. 97-102; s. 22, ch. 97-194; s. 106, ch. 97-264; s. 1, ch. 97-269; s. 47, ch. 97-271; s. 1, ch. 98-22; s. 1, ch. 99-154; s. 14, ch. 99-186; s. 3, ch. 2000-320;

s. 11, ch. 2002-78; s. 2, ch. 2002-81; s. 3, ch. 2003-10; s. 1, ch. 2003-95; s. 2, ch. 2005-128; s. 108, ch. 2006-197; s. 2, ch. 2006-306; s. 2, ch. 2008-88; s. 6, ch. 2010-113; ss. 3, 4, ch. 2011-73; s. 2, ch. 2011-90; s. 26, ch. 2011-141; s. 2, ch. 2012-23.

893.135Trafficking; mandatory sentences; suspension or reduction of sentences; conspiracy to engage in trafficking.—

(1)Except as authorized in this chapter or in chapter 499 and notwithstanding the provisions of s. 893.13:

(a)Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, in excess of 25 pounds of cannabis, or 300 or more cannabis plants, commits a felony of the first degree, which felony shall be known as "trafficking in cannabis," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity of cannabis involved:

1.Is in excess of 25 pounds, but less than 2,000 pounds, or is 300 or more cannabis plants, but not more than 2,000 cannabis plants, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $25,000.

2.Is 2,000 pounds or more, but less than 10,000 pounds, or is 2,000 or more cannabis plants, but not more than 10,000 cannabis plants, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $50,000.

3.Is 10,000 pounds or more, or is 10,000 or more cannabis plants, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $200,000.

For the purpose of this paragraph, a plant, including, but not limited to, a seedling or cutting, is a "cannabis plant" if it has some readily observable evidence of root formation, such as root hairs. To determine if a piece or part of a cannabis plant severed from the cannabis plant is itself a cannabis plant, the severed piece or part must have some readily observable evidence of root formation, such as root hairs. Callous tissue is not readily observable evidence of root formation. The viability and sex of a plant and the fact that the plant may or may not be a dead harvested plant are not relevant in determining if the plant is a "cannabis plant" or in the charging of an offense under this paragraph. Upon conviction, the court shall impose the longest term of imprisonment provided for in this paragraph.

(b)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 28 grams or more of cocaine, as described in s. 893.03(2)(a)4., or of any mixture containing cocaine, but less than 150 kilograms of cocaine or any such mixture, commits a felony of the first degree, which felony shall be known as "trafficking in cocaine," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 28 grams or more, but less than 200 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 200 grams or more, but less than 400 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 400 grams or more, but less than 150 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 150 kilograms or more of cocaine, as described in s. 893.03(2)(a)4., commits the first degree felony of trafficking in cocaine. A person who has been convicted of the first degree felony of trafficking in cocaine under this subparagraph shall be punished by life imprisonment and is ineligible for any form of discretionary early release except pardon or executive clemency or conditional medical release under s. 947.149. However, if the court determines that, in addition to committing any act specified in this paragraph:

a.The person intentionally killed an individual or counseled, commanded, induced, procured, or caused the intentional killing of an individual and such killing was the result; or

b.The person's conduct in committing that act led to a natural, though not inevitable, lethal result,

such person commits the capital felony of trafficking in cocaine, punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

3.Any person who knowingly brings into this state 300 kilograms or more of cocaine, as described in s. 893.03(2)(a)4., and who knows that the probable result of such importation would be the death of any person, commits capital importation of cocaine, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(c)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 4 grams or more of any morphine, opium, oxycodone, hydrocodone, hydromorphone, or any salt, derivative, isomer, or salt of an isomer thereof, including heroin, as described in s. 893.03(1)(b), (2)(a), (3)(c)3., or (3)(c)4., or 4 grams or more of any mixture containing any such substance, but less than 30 kilograms of such substance or mixture, commits a felony of the first degree, which felony shall be known as "trafficking in illegal drugs," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 4 grams or more, but less than 14 grams, such person shall be sentenced to a mandatory

minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 14 grams or more, but less than 28 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 28 grams or more, but less than 30 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 25 calendar years and pay a fine of $500,000.

2.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 30 kilograms or more of any morphine, opium, oxycodone, hydrocodone, hydromorphone, or any salt, derivative, isomer, or salt of an isomer thereof, including heroin, as described in s. 893.03(1)(b), (2)(a), (3)(c)3., or (3)(c)4., or 30 kilograms or more of any mixture containing any such substance, commits the first degree felony of trafficking in illegal drugs. A person who has been convicted of the first degree felony of trafficking in illegal drugs under this subparagraph shall be punished by life imprisonment and is ineligible for any form of discretionary early release except pardon or executive clemency or conditional medical release under s. 947.149. However, if the court determines that, in addition to committing any act specified in this paragraph:

a.The person intentionally killed an individual or counseled, commanded, induced, procured, or caused the intentional killing of an individual and such killing was the result; or

b.The person's conduct in committing that act led to a natural, though not inevitable, lethal result,

such person commits the capital felony of trafficking in illegal drugs, punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

3.Any person who knowingly brings into this state 60 kilograms or more of any morphine, opium, oxycodone, hydrocodone, hydromorphone, or any salt, derivative, isomer, or salt of an isomer thereof, including heroin, as described in s. 893.03(1)(b), (2)(a), (3)(c)3., or (3)(c)4., or 60 kilograms or more of any mixture containing any such substance, and who knows that the probable result of such importation would be the death of any person, commits capital importation of illegal drugs, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(d)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 28 grams or more of phencyclidine or of any mixture containing phencyclidine, as described in s. 893.03(2)(b), commits a felony of the first degree, which felony shall be known as "trafficking in phencyclidine,"

punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 28 grams or more, but less than 200 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 200 grams or more, but less than 400 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 400 grams or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly brings into this state 800 grams or more of phencyclidine or of any mixture containing phencyclidine, as described in s. 893.03(2)(b), and who knows that the probable result of such importation would be the death of any person commits capital importation of phencyclidine, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(e)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 200 grams or more of methaqualone or of any mixture containing methaqualone, as described in s. 893.03(1)(d), commits a felony of the first degree, which felony shall be known as “trafficking in methaqualone,” punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 200 grams or more, but less than 5 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 5 kilograms or more, but less than 25 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 25 kilograms or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly brings into this state 50 kilograms or more of methaqualone or of any mixture containing methaqualone, as described in s. 893.03(1)(d), and who knows that the probable result of such importation would be the death of any person commits capital importation of methaqualone, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(f)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 14 grams or more of

amphetamine, as described in s. 893.03(2)(c)2., or methamphetamine, as described in s. 893.03(2)(c)4., or of any mixture containing amphetamine or methamphetamine, or phenylacetone, phenylacetic acid, pseudoephedrine, or ephedrine in conjunction with other chemicals and equipment utilized in the manufacture of amphetamine or methamphetamine, commits a felony of the first degree, which felony shall be known as "trafficking in amphetamine," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 14 grams or more, but less than 28 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 28 grams or more, but less than 200 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 200 grams or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly manufactures or brings into this state 400 grams or more of amphetamine, as described in s. 893.03(2)(c)2., or methamphetamine, as described in s. 893.03(2)(c)4., or of any mixture containing amphetamine or methamphetamine, or phenylacetone, phenylacetic acid, pseudoephedrine, or ephedrine in conjunction with other chemicals and equipment used in the manufacture of amphetamine or methamphetamine, and who knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of amphetamine, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(g)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 4 grams or more of flunitrazepam or any mixture containing flunitrazepam as described in s. 893.03(1)(a) commits a felony of the first degree, which felony shall be known as "trafficking in flunitrazepam," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 4 grams or more but less than 14 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 14 grams or more but less than 28 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 28 grams or more but less than 30 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 25 calendar years and pay a fine of $500,000.

2.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state or who is knowingly in actual or constructive possession of 30 kilograms or more of flunitrazepam or any mixture containing flunitrazepam as described in s. 893.03(1)(a) commits the first degree felony of trafficking in flunitrazepam. A person who has been convicted of the first degree felony of trafficking in flunitrazepam under this subparagraph shall be punished by life imprisonment and is ineligible for any form of discretionary early release except pardon or executive clemency or conditional medical release under s. 947.149. However, if the court determines that, in addition to committing any act specified in this paragraph:

a.The person intentionally killed an individual or counseled, commanded, induced, procured, or caused the intentional killing of an individual and such killing was the result; or

b.The person's conduct in committing that act led to a natural, though not inevitable, lethal result,

such person commits the capital felony of trafficking in flunitrazepam, punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(h)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 1 kilogram or more of gamma-hydroxybutyric acid (GHB), as described in s. 893.03(1)(d), or any mixture containing gamma-hydroxybutyric acid (GHB), commits a felony of the first degree, which felony shall be known as "trafficking in gamma-hydroxybutyric acid (GHB)," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 1 kilogram or more but less than 5 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 5 kilograms or more but less than 10 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 10 kilograms or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly manufactures or brings into this state 150 kilograms or more of gamma-hydroxybutyric acid (GHB), as described in s. 893.03(1)(d), or any mixture containing gamma-hydroxybutyric acid (GHB), and who knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of gamma-hydroxybutyric acid (GHB), a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(i)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 1 kilogram or more of gamma-butyrolactone (GBL), as described in s. 893.03(1)(d), or any mixture containing gamma-butyrolactone (GBL), commits a felony of the first degree, which felony shall be known as "trafficking in gamma-butyrolactone (GBL)," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 1 kilogram or more but less than 5 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 5 kilograms or more but less than 10 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 10 kilograms or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly manufactures or brings into the state 150 kilograms or more of gamma-butyrolactone (GBL), as described in s. 893.03(1)(d), or any mixture containing gamma-butyrolactone (GBL), and who knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of gamma-butyrolactone (GBL), a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(j)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 1 kilogram or more of 1,4-Butanediol as described in s. 893.03(1)(d), or of any mixture containing 1,4-Butanediol, commits a felony of the first degree, which felony shall be known as "trafficking in 1,4-Butanediol," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 1 kilogram or more, but less than 5 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 5 kilograms or more, but less than 10 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 10 kilograms or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $500,000.

2.Any person who knowingly manufactures or brings into this state 150 kilograms or more of 1,4-Butanediol as described in s. 893.03(1)(d), or any mixture containing 1,4-Butanediol, and who

knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of 1,4-Butanediol, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(k)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 10 grams or more of any of the following substances described in s. 893.03(1)(a) or (c):

a.3,4-Methylenedioxymethamphetamine (MDMA);

b.4-Bromo-2,5-dimethoxyamphetamine;

c.4-Bromo-2,5-dimethoxyphenethylamine;

d.2,5-Dimethoxyamphetamine;

e.2,5-Dimethoxy-4-ethylamphetamine (DOET);

f.N-ethylamphetamine;

g.N-Hydroxy-3,4-methylenedioxyamphetamine;

h.5-Methoxy-3,4-methylenedioxyamphetamine;

i.4-methoxyamphetamine;

j.4-methoxymethamphetamine;

k.4-Methyl-2,5-dimethoxyamphetamine;

l.3,4-Methylenedioxy-N-ethylamphetamine;

m.3,4-Methylenedioxyamphetamine;

n.N,N-dimethylamphetamine; or

o.3,4,5-Trimethoxyamphetamine,

individually or in any combination of or any mixture containing any substance listed in sub-subparagraphs a.-o., commits a felony of the first degree, which felony shall be known as “trafficking in Phenethylamines,” punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.If the quantity involved:

a.Is 10 grams or more but less than 200 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 200 grams or more, but less than 400 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 400 grams or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

3.Any person who knowingly manufactures or brings into this state 30 kilograms or more of any of the following substances described in s. 893.03(1)(a) or (c):

a.3,4-Methylenedioxymethamphetamine (MDMA);

b.4-Bromo-2,5-dimethoxyamphetamine;

c.4-Bromo-2,5-dimethoxyphenethylamine;

d.2,5-Dimethoxyamphetamine;

e.2,5-Dimethoxy-4-ethylamphetamine (DOET);

f.N-ethylamphetamine;

g.N-Hydroxy-3,4-methylenedioxyamphetamine;

h.5-Methoxy-3,4-methylenedioxyamphetamine;

i.4-methoxyamphetamine;

j.4-methoxymethamphetamine;

k.4-Methyl-2,5-dimethoxyamphetamine;

l.3,4-Methylenedioxy-N-ethylamphetamine;

m.3,4-Methylenedioxyamphetamine;

n.N,N-dimethylamphetamine; or

o.3,4,5-Trimethoxyamphetamine,

individually or in any combination of or any mixture containing any substance listed in sub-subparagraphs a.-o., and who knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of Phenethylamines, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(l)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 1 gram or more of lysergic acid diethylamide (LSD) as described in s. 893.03(1)(c), or of any mixture containing lysergic acid diethylamide (LSD), commits a felony of the first degree, which felony shall be known as "trafficking in lysergic acid diethylamide (LSD)," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 1 gram or more, but less than 5 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 5 grams or more, but less than 7 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 7 grams or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $500,000.

2.Any person who knowingly manufactures or brings into this state 7 grams or more of lysergic

acid diethylamide (LSD) as described in s. 893.03(1)(c), or any mixture containing lysergic acid diethylamide (LSD), and who knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of lysergic acid diethylamide (LSD), a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(2)A person acts knowingly under subsection (1) if that person intends to sell, purchase, manufacture, deliver, or bring into this state, or to actually or constructively possess, any of the controlled substances listed in subsection (1), regardless of which controlled substance listed in subsection (1) is in fact sold, purchased, manufactured, delivered, or brought into this state, or actually or constructively possessed.

(3)Notwithstanding the provisions of s. 948.01, with respect to any person who is found to have violated this section, adjudication of guilt or imposition of sentence shall not be suspended, deferred, or withheld, nor shall such person be eligible for parole prior to serving the mandatory minimum term of imprisonment prescribed by this section. A person sentenced to a mandatory minimum term of imprisonment under this section is not eligible for any form of discretionary early release, except pardon or executive clemency or conditional medical release under s. 947.149, prior to serving the mandatory minimum term of imprisonment.

(4)The state attorney may move the sentencing court to reduce or suspend the sentence of any person who is convicted of a violation of this section and who provides substantial assistance in the identification, arrest, or conviction of any of that person's accomplices, accessories, coconspirators, or principals or of any other person engaged in trafficking in controlled substances. The arresting agency shall be given an opportunity to be heard in aggravation or mitigation in reference to any such motion. Upon good cause shown, the motion may be filed and heard in camera. The judge hearing the motion may reduce or suspend the sentence if the judge finds that the defendant rendered such substantial assistance.

(5)Any person who agrees, conspires, combines, or confederates with another person to commit any act prohibited by subsection (1) commits a felony of the first degree and is punishable as if he or she had actually committed such prohibited act. Nothing in this subsection shall be construed to prohibit separate convictions and sentences for a violation of this subsection and any violation of subsection (1).

(6)A mixture, as defined in s. 893.02, containing any controlled substance described in this section includes, but is not limited to, a solution or a dosage unit, including but not limited to, a pill or tablet, containing a controlled substance. For the purpose of clarifying legislative intent regarding the weighing of a mixture containing a controlled substance described in this section, the weight of the controlled substance is the total weight of the mixture, including the controlled

substance and any other substance in the mixture. If there is more than one mixture containing the same controlled substance, the weight of the controlled substance is calculated by aggregating the total weight of each mixture.

(7)For the purpose of further clarifying legislative intent, the Legislature finds that the opinion in *Hayes v. State*, 750 So. 2d 1 (Fla. 1999) does not correctly construe legislative intent. The Legislature finds that the opinions in *State v. Hayes*, 720 So. 2d 1095 (Fla. 4th DCA 1998) and *State v. Baxley*, 684 So. 2d 831 (Fla. 5th DCA 1996) correctly construe legislative intent.

History.—s. 1, ch. 79-1; s. 1, ch. 80-70; s. 2, ch. 80-353; s. 491, ch. 81-259; s. 1, ch. 82-2; s. 3, ch. 82-16; s. 53, ch. 83-215; s. 5, ch. 87-243; ss. 1, 4, ch. 89-281; s. 1, ch. 90-112; s. 3, ch. 93-92; s. 24, ch. 93-406; s. 15, ch. 95-184; s. 5, ch. 95-415; s. 54, ch. 96-388; s. 3, ch. 97-1; s. 1828, ch. 97-102; s. 23, ch. 97-194; s. 9, ch. 99-188; s. 4, ch. 2000-320; s. 2, ch. 2001-55; s. 7, ch. 2001-57; ss. 1, 2, 3, ch. 2002-212; s. 4, ch. 2003-10; s. 3, ch. 2005-128; s. 7, ch. 2008-184; s. 5, ch. 2011-73; s. 3, ch. 2011-90.

893.1351Ownership, lease, rental, or possession for trafficking in or manufacturing a controlled substance.—

(1)A person may not own, lease, or rent any place, structure, or part thereof, trailer, or other conveyance with the knowledge that the place, structure, trailer, or conveyance will be used for the purpose of trafficking in a controlled substance, as provided in s. 893.135; for the sale of a controlled substance, as provided in s. 893.13; or for the manufacture of a controlled substance intended for sale or distribution to another. A person who violates this subsection commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2)A person may not knowingly be in actual or constructive possession of any place, structure, or part thereof, trailer, or other conveyance with the knowledge that the place, structure, or part thereof, trailer, or conveyance will be used for the purpose of trafficking in a controlled substance, as provided in s. 893.135; for the sale of a controlled substance, as provided in s. 893.13; or for the manufacture of a controlled substance intended for sale or distribution to another. A person who violates this subsection commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)A person who is in actual or constructive possession of a place, structure, trailer, or conveyance with the knowledge that the place, structure, trailer, or conveyance is being used to manufacture a controlled substance intended for sale or distribution to another and who knew or should have known that a minor is present or resides in the place, structure, trailer, or conveyance commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4)For the purposes of this section, proof of the possession of 25 or more cannabis plants constitutes prima facie evidence that the cannabis is intended for sale or distribution.

History.—s. 1, ch. 91-118; s. 10, ch. 99-188; s. 22, ch. 2000-320; s. 1, ch. 2002-212; s. 14, ch. 2005-128; s. 2, ch.

2008-184.

893.138Local administrative action to abate drug-related, prostitution-related, or stolen-property-related public nuisances and criminal gang activity.—

(1)It is the intent of this section to promote, protect, and improve the health, safety, and welfare of the citizens of the counties and municipalities of this state by authorizing the creation of administrative boards with authority to impose administrative fines and other noncriminal penalties in order to provide an equitable, expeditious, effective, and inexpensive method of enforcing ordinances in counties and municipalities under circumstances when a pending or repeated violation continues to exist.

(2)Any place or premises that has been used:

(a)On more than two occasions within a 6-month period, as the site of a violation of s. 796.07;

(b)On more than two occasions within a 6-month period, as the site of the unlawful sale, delivery, manufacture, or cultivation of any controlled substance;

(c)On one occasion as the site of the unlawful possession of a controlled substance, where such possession constitutes a felony and that has been previously used on more than one occasion as the site of the unlawful sale, delivery, manufacture, or cultivation of any controlled substance;

(d)By a criminal gang for the purpose of conducting criminal gang activity as defined by s. 874.03; or

(e)On more than two occasions within a 6-month period, as the site of a violation of s. 812.019 relating to dealing in stolen property

may be declared to be a public nuisance, and such nuisance may be abated pursuant to the procedures provided in this section.

(3)Any pain-management clinic, as described in s. 458.3265 or s. 459.0137, which has been used on more than two occasions within a 6-month period as the site of a violation of:

(a)Section 784.011, s. 784.021, s. 784.03, or s. 784.045, relating to assault and battery;

(b)Section 810.02, relating to burglary;

(c)Section 812.014, relating to dealing in theft;

(d)Section 812.131, relating to robbery by sudden snatching; or

(e)Section 893.13, relating to the unlawful distribution of controlled substances,

may be declared to be a public nuisance, and such nuisance may be abated pursuant to the procedures provided in this section.

(4)Any county or municipality may, by ordinance, create an administrative board to hear complaints regarding the nuisances described in subsection (2). Any employee, officer, or resident of the county or municipality may bring a complaint before the board after giving not less than 3 days' written notice of such complaint to the owner of the place or premises at his or her last known address. After a hearing in which the board may consider any evidence, including evidence

of the general reputation of the place or premises, and at which the owner of the premises shall have an opportunity to present evidence in his or her defense, the board may declare the place or premises to be a public nuisance as described in subsection (2).

(5)If the board declares a place or premises to be a public nuisance, it may enter an order requiring the owner of such place or premises to adopt such procedure as may be appropriate under the circumstances to abate any such nuisance or it may enter an order immediately prohibiting:

(a)The maintaining of the nuisance;

(b)The operating or maintaining of the place or premises, including the closure of the place or premises or any part thereof; or

(c)The conduct, operation, or maintenance of any business or activity on the premises which is conducive to such nuisance.

(6)An order entered under subsection (5) shall expire after 1 year or at such earlier time as is stated in the order.

(7)An order entered under subsection (5) may be enforced pursuant to the procedures contained in s. 120.69. This subsection does not subject a municipality that creates a board under this section, or the board so created, to any other provision of chapter 120.

(8)The board may bring a complaint under s. 60.05 seeking temporary and permanent injunctive relief against any nuisance described in subsection (2).

(9)This section does not restrict the right of any person to proceed under s. 60.05 against any public nuisance.

(10)As used in this section, the term “controlled substance” includes any substance sold in lieu of a controlled substance in violation of s. 817.563 or any imitation controlled substance defined in s. 817.564.

(11)The provisions of this section may be supplemented by a county or municipal ordinance. The ordinance may include, but is not limited to, provisions that establish additional penalties for public nuisances, including fines not to exceed $250 per day; provide for the payment of reasonable costs, including reasonable attorney fees associated with investigations of and hearings on public nuisances; provide for continuing jurisdiction for a period of 1 year over any place or premises that has been or is declared to be a public nuisance; establish penalties, including fines not to exceed $500 per day for recurring public nuisances; provide for the recording of orders on public nuisances so that notice must be given to subsequent purchasers, successors in interest, or assigns of the real property that is the subject of the order; provide that recorded orders on public nuisances may become liens against the real property that is the subject of the order; and provide for the foreclosure of property subject to a lien and the recovery of all costs, including reasonable attorney fees, associated with the recording of orders and foreclosure. No lien created pursuant to

the provisions of this section may be foreclosed on real property which is a homestead under s. 4, Art. X of the State Constitution. Where a local government seeks to bring an administrative action, based on a stolen property nuisance, against a property owner operating an establishment where multiple tenants, on one site, conduct their own retail business, the property owner shall not be subject to a lien against his or her property or the prohibition of operation provision if the property owner evicts the business declared to be a nuisance within 90 days after notification by registered mail to the property owner of a second stolen property conviction of the tenant. The total fines imposed pursuant to the authority of this section shall not exceed $15,000. Nothing contained within this section prohibits a county or municipality from proceeding against a public nuisance by any other means.

History.—s. 7, ch. 87-243; s. 2, ch. 90-207; s. 1, ch. 91-143; s. 6, ch. 93-227; s. 1, ch. 94-242; s. 42, ch. 96-388; s. 1829, ch. 97-102; s. 1, ch. 97-200; s. 2, ch. 98-395; s. 1, ch. 2000-111; s. 5, ch. 2001-66; s. 24, ch. 2008-238; s. 27, ch. 2011-141; s. 87, ch. 2012-5.

893.145"Drug paraphernalia" defined.—The term "drug paraphernalia" means all equipment, products, and materials of any kind which are used, intended for use, or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, transporting, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of this chapter or s. 877.111. Drug paraphernalia is deemed to be contraband which shall be subject to civil forfeiture. The term includes, but is not limited to:

(1)Kits used, intended for use, or designed for use in the planting, propagating, cultivating, growing, or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived.

(2)Kits used, intended for use, or designed for use in manufacturing, compounding, converting, producing, processing, or preparing controlled substances.

(3)Isomerization devices used, intended for use, or designed for use in increasing the potency of any species of plant which is a controlled substance.

(4)Testing equipment used, intended for use, or designed for use in identifying, or in analyzing the strength, effectiveness, or purity of, controlled substances.

(5)Scales and balances used, intended for use, or designed for use in weighing or measuring controlled substances.

(6)Diluents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose, and lactose, used, intended for use, or designed for use in cutting controlled substances.

(7)Separation gins and sifters used, intended for use, or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, cannabis.

(8)Blenders, bowls, containers, spoons, and mixing devices used, intended for use, or designed for use in compounding controlled substances.

(9)Capsules, balloons, envelopes, and other containers used, intended for use, or designed for use in packaging small quantities of controlled substances.

(10)Containers and other objects used, intended for use, or designed for use in storing, concealing, or transporting controlled substances.

(11)Hypodermic syringes, needles, and other objects used, intended for use, or designed for use in parenterally injecting controlled substances into the human body.

(12)Objects used, intended for use, or designed for use in ingesting, inhaling, or otherwise introducing cannabis, cocaine, hashish, hashish oil, or nitrous oxide into the human body, such as:

(a)Metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes, with or without screens, permanent screens, hashish heads, or punctured metal bowls.

(b)Water pipes.

(c)Carburetion tubes and devices.

(d)Smoking and carburetion masks.

(e)Roach clips: meaning objects used to hold burning material, such as a cannabis cigarette, that has become too small or too short to be held in the hand.

(f)Miniature cocaine spoons, and cocaine vials.

(g)Chamber pipes.

(h)Carburetor pipes.

(i)Electric pipes.

(j)Air-driven pipes.

(k)Chillums.

(l)Bongs.

(m)Ice pipes or chillers.

(n)A cartridge or canister, which means a small metal device used to contain nitrous oxide.

(o)A charger, sometimes referred to as a “cracker,” which means a small metal or plastic device that contains an interior pin that may be used to expel nitrous oxide from a cartridge or container.

(p)A charging bottle, which means a device that may be used to expel nitrous oxide from a cartridge or canister.

(q)A whip-it, which means a device that may be used to expel nitrous oxide.

(r)A tank.

(s)A balloon.

(t)A hose or tube.

(u)A 2-liter-type soda bottle.

(v)Duct tape.

History.—s. 1, ch. 80-30; s. 6, ch. 2000-320; s. 15, ch. 2000-360.

893.146Determination of paraphernalia.—In determining whether an object is drug paraphernalia, a court or other authority or jury shall consider, in addition to all other logically relevant factors, the following:

(1)Statements by an owner or by anyone in control of the object concerning its use.

(2)The proximity of the object, in time and space, to a direct violation of this act.

(3)The proximity of the object to controlled substances.

(4)The existence of any residue of controlled substances on the object.

(5)Direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons who he or she knows, or should reasonably know, intend to use the object to facilitate a violation of this act. The innocence of an owner, or of anyone in control of the object, as to a direct violation of this act shall not prevent a finding that the object is intended for use, or designed for use, as drug paraphernalia.

(6)Instructions, oral or written, provided with the object concerning its use.

(7)Descriptive materials accompanying the object which explain or depict its use.

(8)Any advertising concerning its use.

(9)The manner in which the object is displayed for sale.

(10)Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor of or dealer in tobacco products.

(11)Direct or circumstantial evidence of the ratio of sales of the object or objects to the total sales of the business enterprise.

(12)The existence and scope of legitimate uses for the object in the community.

(13)Expert testimony concerning its use.

History.—s. 2, ch. 80-30; s. 1445, ch. 97-102.

893.147Use, possession, manufacture, delivery, transportation, or advertisement of drug paraphernalia.—

(1)USE OR POSSESSION OF DRUG PARAPHERNALIA.—It is unlawful for any person to use, or to possess with intent to use, drug paraphernalia:

(a)To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of this chapter; or

(b)To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of this chapter.

Any person who violates this subsection is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(2)MANUFACTURE OR DELIVERY OF DRUG PARAPHERNALIA.—It is unlawful for any person to deliver, possess with intent to deliver, or manufacture with intent to deliver drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used:

(a)To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of this act; or

(b)To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of this act.

Any person who violates this subsection is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)DELIVERY OF DRUG PARAPHERNALIA TO A MINOR.—

(a)Any person 18 years of age or over who violates subsection (2) by delivering drug paraphernalia to a person under 18 years of age is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)It is unlawful for any person to sell or otherwise deliver hypodermic syringes, needles, or other objects which may be used, are intended for use, or are designed for use in parenterally injecting substances into the human body to any person under 18 years of age, except that hypodermic syringes, needles, or other such objects may be lawfully dispensed to a person under 18 years of age by a licensed practitioner, parent, or legal guardian or by a pharmacist pursuant to a valid prescription for same. Any person who violates the provisions of this paragraph is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(4)TRANSPORTATION OF DRUG PARAPHERNALIA.—It is unlawful to use, possess with the intent to use, or manufacture with the intent to use drug paraphernalia, knowing or under circumstances in which one reasonably should know that it will be used to transport:

(a)A controlled substance in violation of this chapter; or

(b)Contraband as defined in s. 932.701(2)(a)1.

Any person who violates this subsection commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5)ADVERTISEMENT OF DRUG PARAPHERNALIA.—It is unlawful for any person to place in any newspaper, magazine, handbill, or other publication any advertisement, knowing, or under circumstances where one reasonably should know, that the purpose of the advertisement, in whole or in part, is to promote the sale of objects designed or intended for use as drug paraphernalia. Any person who violates this subsection is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

History.—s. 3, ch. 80-30; s. 1, ch. 81-149; s. 54, ch. 83-215; s. 1, ch. 85-8; s. 223, ch. 91-224; s. 16, ch. 2000-360.

893.149Unlawful possession of listed chemical.—

(1)It is unlawful for any person to knowingly or intentionally:

(a)Possess a listed chemical with the intent to unlawfully manufacture a controlled substance;

(b)Possess or distribute a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to unlawfully manufacture a controlled substance.

(2)Any person who violates this section commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)This section does not apply to a public employee or private contractor authorized to clean up or dispose of hazardous waste or toxic substances resulting from the prohibited activities listed in s. 893.13(1)(g).

(4)Any damages arising out of the unlawful possession of, storage of, or tampering with a listed chemical, as defined in s. 893.033, shall be the sole responsibility of the person or persons unlawfully possessing, storing, or tampering with the listed chemical. In no case shall liability for damages arising out of the unlawful possession of, storage of, or tampering with a listed chemical extend to the lawful owner, installer, maintainer, designer, manufacturer, possessor, or seller of the listed chemical, unless such damages arise out of the acts or omissions of the owner, installer, maintainer, designer, manufacturer, possessor, or seller which constitute negligent misconduct or failure to abide by the laws regarding the possession or storage of a listed chemical.

History.—s. 5, ch. 91-279; s. 3, ch. 2003-15; s. 4, ch. 2005-128.

893.1495Retail sale of ephedrine and related compounds.—

(1)For purposes of this section, the term “ephedrine or related compounds” means ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers.

(2)A person may not knowingly obtain or deliver to an individual in any retail over-the-counter sale any nonprescription compound, mixture, or preparation containing ephedrine or related compounds in excess of the following amounts:

(a)In any single day, any number of packages that contain a total of 3.6 grams of ephedrine or related compounds;

(b)In any single retail, over-the-counter sale, three packages, regardless of weight, containing ephedrine or related compounds; or

(c)In any 30-day period, in any number of retail, over-the-counter sales, a total of 9 grams or more of ephedrine or related compounds.

(3)A person may not knowingly display and offer for retail sale any nonprescription compound, mixture, or preparation containing ephedrine or related compounds other than behind a checkout counter where the public is not permitted or other such location that is not otherwise accessible to the general public.

(4)A person who is the owner or primary operator of a retail outlet where any nonprescription

compound, mixture, or preparation containing ephedrine or related compounds is available for sale may not knowingly allow an employee to engage in the retail sale of such compound, mixture, or preparation unless the employee has completed an employee training program that shall include, at a minimum, basic instruction on state and federal regulations relating to the sale and distribution of such compounds, mixtures, or preparations.

(5)(a)Any person purchasing, receiving, or otherwise acquiring any nonprescription compound, mixture, or preparation containing any detectable quantity of ephedrine or related compounds must:

1.Be at least 18 years of age.

2.Produce a government-issued photo identification showing his or her name, date of birth, address, and photo identification number or an alternative form of identification acceptable under federal regulation 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

3.Sign his or her name on a record of the purchase, either on paper or on an electronic signature capture device.

(b)The Department of Law Enforcement shall approve an electronic recordkeeping system for the purpose of recording and monitoring the real-time purchase of products containing ephedrine or related compounds and for the purpose of monitoring this information in order to prevent or investigate illegal purchases of these products. The approved electronic recordkeeping system shall be provided to a pharmacy or retailer without any additional cost or expense. A pharmacy or retailer may request an exemption from electronic reporting from the Department of Law Enforcement if the pharmacy or retailer lacks the technology to access the electronic recordkeeping system and such pharmacy or retailer maintains a sales volume of less than 72 grams of ephedrine or related compounds in a 30-day period. The electronic recordkeeping system shall record the following:

1.The date and time of the transaction.

2.The name, date of birth, address, and photo identification number of the purchaser, as well as the type of identification and the government of issuance.

3.The number of packages purchased, the total grams per package, and the name of the compound, mixture, or preparation containing ephedrine or related compounds.

4.The signature of the purchaser, or a unique number relating the transaction to a paper signature maintained at the retail premises.

(c)The electronic recordkeeping system shall provide for:

1.Real-time tracking of nonprescription over-the-counter sales under this section.

2.The blocking of nonprescription over-the-counter sales in excess of those allowed by the laws of this state or federal law.

(6)A nonprescription compound, mixture, or preparation containing any quantity of ephedrine

or related compounds may not be sold over the counter unless reported to an electronic recordkeeping system approved by the Department of Law Enforcement. This subsection does not apply if the pharmacy or retailer has received an exemption from the Department of Law Enforcement under paragraph (5)(b).

(7)Prior to completing a transaction, a pharmacy or retailer distributing products containing ephedrine or related compounds to consumers in this state shall submit all required data into an electronic recordkeeping system approved by the Department of Law Enforcement at the point of sale or through an interface with the electronic recordkeeping system, unless granted an exemption by the Department of Law Enforcement pursuant to paragraph (5)(b).

(8)The data submitted to the electronic recordkeeping system must be retained within the system for no less than 2 years following the date of entry.

(9)The requirements of this section relating to the marketing, sale, or distribution of products containing ephedrine or related compounds supersede any local ordinance or regulation passed by a county, municipality, or other local governmental authority.

(10)This section does not apply to:

(a)Licensed manufacturers manufacturing and lawfully distributing products in the channels of commerce.

(b)Wholesalers lawfully distributing products in the channels of commerce.

(c)Health care facilities licensed under chapter 395.

(d)Licensed long-term care facilities.

(e)Government-operated health departments.

(f)Physicians' offices.

(g)Publicly operated prisons, jails, or juvenile correctional facilities or private adult or juvenile correctional facilities under contract with the state.

(h)Public or private educational institutions maintaining health care programs.

(i)Government-operated or industry-operated medical facilities serving employees of the government or industry operating them.

(11)Any individual who violates subsection (2), subsection (3), or subsection (4) commits:

(a)For a first offense, a misdemeanor of the second degree, punishable as provided in s. 775.083.

(b)For a second offense, a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(c)For a third or subsequent offense, a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(12)Information contained within the electronic recordkeeping system shall be disclosed in a manner authorized by state or federal law. Any retailer or entity that collects information on

behalf of a retailer as required by the Combat Methamphetamine Epidemic Act of 2005 and this section may not access or use that information, except for law enforcement purposes pursuant to state or federal law or to facilitate a product recall for public health and safety.

(13)A person who sells any product containing ephedrine or related compounds who in good faith releases information under this section to federal, state, or local law enforcement officers, or any person acting on behalf of such an officer, is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

(14)The Department of Law Enforcement shall contract or enter into a memorandum of understanding, as applicable, with a private third-party administrator to implement the electronic recordkeeping system required by this section.

(15)The Department of Law Enforcement shall adopt rules necessary to implement this section.

History.—s. 5, ch. 2005-128; s. 1, ch. 2010-191.

893.15Rehabilitation.—Any person who violates s. 893.13(6)(a) or (b) relating to possession may, in the discretion of the trial judge, be required to participate in a substance abuse services program approved or regulated by the Department of Children and Family Services pursuant to the provisions of chapter 397, provided the director of such program approves the placement of the defendant in such program. Such required participation shall be imposed in addition to any penalty or probation otherwise prescribed by law. However, the total time of such penalty, probation, and program participation shall not exceed the maximum length of sentence possible for the offense.

History.—s. 15, ch. 73-331; s. 46, ch. 91-110; s. 40, ch. 93-39; s. 3, ch. 94-107; s. 39, ch. 97-194; s. 304, ch. 99-8.

893.165County alcohol and other drug abuse treatment or education trust funds.—

(1)Counties in which there is established or in existence a comprehensive alcohol and other drug abuse treatment or education program which meets the standards for qualification of such programs by the Department of Children and Family Services are authorized to establish a County Alcohol and Other Drug Abuse Trust Fund for the purpose of receiving the assessments collected pursuant to s. 938.23 and disbursing assistance grants on an annual basis to such alcohol and other drug abuse treatment or education program.

(2)Assessments collected by the clerks of court pursuant to s. 938.23 shall be remitted to the board of county commissioners of the county in which the indictment was found or the prosecution commenced for payment into the County Alcohol and Other Drug Abuse Trust Fund. The county commissioners shall require a full report from all clerks of county courts and clerks of circuit courts once each month of the amount of assessments imposed by their courts.

(3)(a)No county shall receive assessments collected pursuant to s. 938.23 in an amount exceeding that county's jurisdictional share as described in subsection (2).

(b)Assessments collected by clerks of circuit courts having more than one county in the

circuit, for any county in the circuit which does not have a County Alcohol and Other Drug Abuse Trust Fund, shall be remitted to the Department of Children and Family Services, in accordance with administrative rules adopted, for deposit into the department's Grants and Donations Trust Fund for distribution pursuant to the guidelines and priorities developed by the department.

(4)No assessments shall be remitted to a county until the board of county commissioners has submitted documentation to the court substantiating the establishment of its County Alcohol and Other Drug Abuse Trust Fund.

(5)If the board of county commissioners chooses to establish a County Alcohol and Other Drug Abuse Trust Fund, the board shall be responsible for the establishment of such fund and its implementation, administration, supervision, and evaluation.

(6)In order to receive assistance grants from the County Alcohol and Other Drug Abuse Trust Fund, county alcohol and other drug abuse prevention, treatment, or education programs shall be designated by the board of county commissioners as the chosen program recipients. Designations shall be made annually, based on success of the programs.

(7)An alcohol and other drug abuse treatment or education program recipient shall, in seeking assistance grants from the County Alcohol and Other Drug Abuse Trust Fund, provide the board of county commissioners with detailed financial information and requests for expenditures.

History.—s. 4, ch. 88-381; s. 3, ch. 93-194; s. 37, ch. 97-271; s. 305, ch. 99-8; s. 5, ch. 2009-47.

893.20Continuing criminal enterprise.—

(1)Any person who commits three or more felonies under this chapter in concert with five or more other persons with respect to whom such person occupies a position of organizer, a supervisory position, or any other position of management and who obtains substantial assets or resources from these acts is guilty of engaging in a continuing criminal enterprise.

(2)A person who commits the offense of engaging in a continuing criminal enterprise is guilty of a life felony, punishable pursuant to the Criminal Punishment Code and by a fine of $500,000.

(3)Notwithstanding the provisions of s. 948.01, with respect to any person who is found to have violated this section, adjudication of guilt or imposition of sentence may not be suspended, deferred, or withheld.

(4)This section does not prohibit separate convictions and sentences for violation of this section and for felony violations of this chapter.

(5)This section must be interpreted in concert with its federal analog, 21 U.S.C. s. 848.

History.—s. 1, ch. 89-145; s. 25, ch. 93-406; s. 24, ch. 97-194.

893.21Drug-related overdoses; medical assistance; immunity from prosecution.—

(1)A person acting in good faith who seeks medical assistance for an individual experiencing a drug-related overdose may not be charged, prosecuted, or penalized pursuant to this chapter for possession of a controlled substance if the evidence for possession of a controlled substance was

obtained as a result of the person's seeking medical assistance.

(2)A person who experiences a drug-related overdose and is in need of medical assistance may not be charged, prosecuted, or penalized pursuant to this chapter for possession of a controlled substance if the evidence for possession of a controlled substance was obtained as a result of the overdose and the need for medical assistance.

(3)Protection in this section from prosecution for possession offenses under this chapter may not be grounds for suppression of evidence in other criminal prosecutions.

History.—s. 2, ch. 2012-36

Title XXXII

REGULATION OF PROFESSIONS AND OCCUPATIONS

CHAPTER 456

HEALTH PROFESSIONS AND OCCUPATIONS: GENERAL PROVISIONS

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45 **6.001Definitions.**—As used in this chapter, the term:

(1)“Board” means any board or commission, or other statutorily created entity to the extent such entity is authorized to exercise regulatory or rulemaking functions, within the department, except that, for ss. 456.003-456.018, 456.022, 456.023, 456.025-456.034, and 456.039-456.082, “board” means only a board, or other statutorily created entity to the extent such entity is authorized to exercise regulatory or rulemaking functions, within the Division of Medical Quality Assurance.

(2)“Consumer member” means a person appointed to serve on a specific board or who has served on a specific board, who is not, and never has been, a member or practitioner of the profession, or of any closely related profession, regulated by such board.

(3)“Department” means the Department of Health.

(4)“Health care practitioner” means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part III or part IV of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

(5)“License” means any permit, registration, certificate, or license, including a provisional license, issued by the department.

(6)“Licensee” means any person or entity issued a permit, registration, certificate, or license, including a provisional license, by the department.

(7)“Profession” means any activity, occupation, profession, or vocation regulated by the department in the Division of Medical Quality Assurance.

History.—s. 33, ch. 97-261; s. 72, ch. 99-397; s. 36, ch. 2000-160; s. 2, ch. 2002-199.

Note.—Former s. 455.501.

456.002Applicability.—This chapter applies only to the regulation by the department of professions.

History.—s. 34, ch. 97-261; s. 37, ch. 2000-160.

Note.—Former s. 455.504.

456.003Legislative intent; requirements.—

(1)It is the intent of the Legislature that persons desiring to engage in any lawful profession regulated by the department shall be entitled to do so as a matter of right if otherwise qualified.

(2)The Legislature further believes that such professions shall be regulated only for the preservation of the health, safety, and welfare of the public under the police powers of the state. Such professions shall be regulated when:

(a)Their unregulated practice can harm or endanger the health, safety, and welfare of the public, and when the potential for such harm is recognizable and clearly outweighs any anticompetitive impact which may result from regulation.

(b)The public is not effectively protected by other means, including, but not limited to, other state statutes, local ordinances, or federal legislation.

(c)Less restrictive means of regulation are not available.

(3)It is further legislative intent that the use of the term “profession” with respect to those activities licensed and regulated by the department shall not be deemed to mean that such activities are not occupations for other purposes in state or federal law.

(4)(a)Neither the department nor any board may create unreasonably restrictive and extraordinary standards that deter qualified persons from entering the various professions. Neither the department nor any board may take any action that tends to create or maintain an economic condition that unreasonably restricts competition, except as specifically provided by law.

(b)Neither the department nor any board may create a regulation that has an unreasonable effect on job creation or job retention in the state or that places unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a profession or occupation to find employment.

(c)The Legislature shall evaluate proposals to increase the regulation of regulated professions or occupations to determine the effect of increased regulation on job creation or retention and employment opportunities.

(5)Policies adopted by the department shall ensure that all expenditures are made in the most cost-effective manner to maximize competition, minimize licensure costs, and maximize public access to meetings conducted for the purpose of professional regulation. The long-range planning function of the department shall be implemented to facilitate effective operations and to eliminate inefficiencies.

(6)Unless expressly and specifically granted in statute, the duties conferred on the boards do not include the enlargement, modification, or contravention of the lawful scope of practice of the profession regulated by the boards. This subsection shall not prohibit the boards, or the department when there is no board, from taking disciplinary action or issuing a declaratory statement.

History.—s. 38, ch. 97-261; s. 135, ch. 99-251; s. 38, ch. 2000-160; s. 57, ch. 2001-277.

Note.—Former s. 455.517.

456.004Department; powers and duties.—The department, for the professions under its jurisdiction, shall:

(1)Adopt rules establishing a procedure for the biennial renewal of licenses; however, the department may issue up to a 4-year license to selected licensees notwithstanding any other provisions of law to the contrary. The rules shall specify the expiration dates of licenses and the process for tracking compliance with continuing education requirements, financial responsibility requirements, and any other conditions of renewal set forth in statute or rule. Fees for such renewal shall not exceed the fee caps for individual professions on an annualized basis as authorized by law.

(2)Appoint the executive director of each board, subject to the approval of the board.

(3)Submit an annual budget to the Legislature at a time and in the manner provided by law.

(4)Develop a training program for persons newly appointed to membership on any board. The program shall familiarize such persons with the substantive and procedural laws and rules and fiscal information relating to the regulation of the appropriate profession and with the structure of the department.

(5)Adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter.

(6)Establish by rules procedures by which the department shall use the expert or technical advice of the appropriate board for the purposes of investigation, inspection, evaluation of applications, other duties of the department, or any other areas the department may deem appropriate.

(7)Require all proceedings of any board or panel thereof and all formal or informal proceedings conducted by the department, an administrative law judge, or a hearing officer with respect to

licensing or discipline to be electronically recorded in a manner sufficient to assure the accurate transcription of all matters so recorded.

(8)Select only those investigators, or consultants who undertake investigations, who meet criteria established with the advice of the respective boards.

(9)Work cooperatively with the Department of Revenue to establish an automated method for periodically disclosing information relating to current licensees to the Department of Revenue, the state's Title IV-D agency. The purpose of this subsection is to promote the public policy of this state relating to child support as established in s. 409.2551. The department shall, when directed by the court or the Department of Revenue pursuant to s. 409.2598, suspend or deny the license of any licensee found not to be in compliance with a support order, a subpoena, an order to show cause, or a written agreement with the Department of Revenue. The department shall issue or reinstate the license without additional charge to the licensee when notified by the court or the Department of Revenue that the licensee has complied with the terms of the support order. The department is not liable for any license denial or suspension resulting from the discharge of its duties under this subsection.

(10)Set an examination fee that includes all costs to develop, purchase, validate, administer, and defend the examination and is an amount certain to cover all administrative costs plus the actual per-applicant cost of the examination.

(11)Work cooperatively with the Agency for Health Care Administration and the judicial system to recover Medicaid overpayments by the Medicaid program. The department shall investigate and prosecute health care practitioners who have not remitted amounts owed to the state for an overpayment from the Medicaid program pursuant to a final order, judgment, or stipulation or settlement.

History.—s. 39, ch. 97-261; s. 118, ch. 98-200; s. 74, ch. 99-397; s. 39, ch. 2000-160; s. 52, ch. 2001-158; s. 5, ch. 2001-277; s. 6, ch. 2008-92; s. 21, ch. 2009-223.

Note.—Former s. 455.521.

456.005Long-range policy planning.—To facilitate efficient and cost-effective regulation, the department and the board, if appropriate, shall develop and implement a long-range policy planning and monitoring process that includes recommendations specific to each profession. The process shall include estimates of revenues, expenditures, cash balances, and performance statistics for each profession. The period covered may not be less than 5 years. The department, with input from the boards and licensees, shall develop and adopt the long-range plan. The department shall monitor compliance with the plan and, with input from the boards and licensees, shall annually update the plans. The department shall provide concise management reports to the boards quarterly. As part of the review process, the department shall evaluate:

(1)Whether the department, including the boards and the various functions performed by the

department, is operating efficiently and effectively and if there is a need for a board or council to assist in cost-effective regulation.

(2)How and why the various professions are regulated.

(3)Whether there is a need to continue regulation, and to what degree.

(4)Whether or not consumer protection is adequate, and how it can be improved.

(5)Whether there is consistency between the various practice acts.

(6)Whether unlicensed activity is adequately enforced.

The plans shall include conclusions and recommendations on these and other issues as appropriate.

History.—s. 40, ch. 97-261; s. 40, ch. 2000-160; s. 61, ch. 2008-6; s. 148, ch. 2010-102.

Note.—Former s. 455.524.

456.006Contacting boards through department.—Each board under the jurisdiction of the department may be contacted through the headquarters of the department in the City of Tallahassee.

History.—s. 41, ch. 97-261; s. 40, ch. 2000-160.

Note.—Former s. 455.527.

456.007Board members.—Notwithstanding any provision of law to the contrary, any person who otherwise meets the requirements of law for board membership and who is connected in any way with any medical college, dental college, or community college may be appointed to any board so long as that connection does not result in a relationship wherein such college represents the person's principal source of income. However, this section shall not apply to the physicians required by s. 458.307(2) to be on the faculty of a medical school in this state or on the full-time staff of a teaching hospital in this state.

History.—s. 2, ch. 84-161; s. 1, ch. 84-271; s. 3, ch. 88-392; s. 42, ch. 97-261; s. 17, ch. 97-264; s. 40, ch. 2000-160.

Note.—Former s. 455.206; s. 455.531.

456.008Accountability and liability of board members.—

(1)Each board member shall be accountable to the Governor for the proper performance of duties as a member of the board. The Governor shall investigate any legally sufficient complaint or unfavorable written report received by the Governor or by the department or a board concerning the actions of the board or its individual members. The Governor may suspend from office any board member for malfeasance, misfeasance, neglect of duty, drunkenness, incompetence, permanent inability to perform his or her official duties, or commission of a felony.

(2)Each board member and each former board member serving on a probable cause panel shall be exempt from civil liability for any act or omission when acting in the member's official capacity, and the department shall defend any such member in any action against any board or member of a board arising from any such act or omission. In addition, the department may defend the member's company or business in any action against the company or business if the department determines that the

actions from which the suit arises are actions taken by the member in the member's official capacity and were not beyond the member's statutory authority. In providing such defense, the department may employ or utilize the legal services of the Department of Legal Affairs or outside counsel retained pursuant to s. 287.059. Fees and costs of providing legal services provided under this subsection shall be paid from a trust fund used by the department to implement this chapter, subject to the provisions of s. 456.025.

History.—s. 45, ch. 97-261; s. 21, ch. 99-7; s. 153, ch. 99-251; s. 41, ch. 2000-160.

Note.—Former s. 455.541.

456.009Legal and investigative services.—

(1)The department shall provide board counsel for boards within the department by contracting with the Department of Legal Affairs, by retaining private counsel pursuant to s. 287.059, or by providing department staff counsel. The primary responsibility of board counsel shall be to represent the interests of the citizens of the state. A board shall provide for the periodic review and evaluation of the services provided by its board counsel. Fees and costs of such counsel shall be paid from a trust fund used by the department to implement this chapter, subject to the provisions of s. 456.025. All contracts for independent counsel shall provide for periodic review and evaluation by the board and the department of services provided.

(2)The department may employ or use the legal services of outside counsel and the investigative services of outside personnel. However, no attorney employed or utilized by the department shall prosecute a matter and provide legal services to the board with respect to the same matter.

(3)Any person retained by the department under contract to review materials, make site visits, or provide expert testimony regarding any complaint or application filed with the department relating to a profession under the jurisdiction of the department shall be considered an agent of the department in determining the state insurance coverage and sovereign immunity protection applicability of ss. 284.31 and 768.28.

History.—s. 60, ch. 97-261; s. 154, ch. 99-251; s. 42, ch. 2000-160.

Note.—Former s. 455.594.

456.011Boards; organization; meetings; compensation and travel expenses.—

(1)Each board within the department shall comply with the provisions of this chapter.

(2)The board shall annually elect from among its number a chairperson and vice chairperson.

(3)The board shall meet at least once annually and may meet as often as is necessary. Meetings shall be conducted through teleconferencing or other technological means, unless disciplinary hearings involving standard of care, sexual misconduct, fraud, impairment, or felony convictions; licensure denial hearings; or controversial rule hearings are being conducted; or unless otherwise approved in advance of the meeting by the director of the Division of Medical Quality Assurance. The chairperson or a quorum of the board shall have the authority to call meetings, except as provided above relating to

in-person meetings. A quorum shall be necessary for the conduct of official business by the board or any committee thereof. Unless otherwise provided by law, 51 percent or more of the appointed members of the board or any committee, when applicable, shall constitute a quorum. The membership of committees of the board, except as otherwise authorized pursuant to this chapter or the applicable practice act, shall be composed of currently appointed members of the board. The vote of a majority of the members of the quorum shall be necessary for any official action by the board or committee. Three consecutive unexcused absences or absences constituting 50 percent or more of the board's meetings within any 12-month period shall cause the board membership of the member in question to become void, and the position shall be considered vacant. The board, or the department when there is no board, shall, by rule, define unexcused absences.

(4)Unless otherwise provided by law, a board member or former board member serving on a probable cause panel shall be compensated $50 for each day in attendance at an official meeting of the board and for each day of participation in any other business involving the board. Each board shall adopt rules defining the phrase "other business involving the board," but the phrase may not routinely be defined to include telephone conference calls that last less than 4 hours. A board member also shall be entitled to reimbursement for expenses pursuant to s. 112.061. Travel out of state shall require the prior approval of the State Surgeon General.

(5)When two or more boards have differences between them, the boards may elect to, or the State Surgeon General may request that the boards, establish a special committee to settle those differences. The special committee shall consist of three members designated by each board, who may be members of the designating board or other experts designated by the board, and of one additional person designated and agreed to by the members of the special committee. In the event the special committee cannot agree on the additional designee, upon request of the special committee, the State Surgeon General may select the designee. The committee shall recommend rules necessary to resolve the differences. If a rule adopted pursuant to this provision is challenged, the participating boards shall share the costs associated with defending the rule or rules. The department shall provide legal representation for any special committee established pursuant to this section.

History.—s. 43, ch. 97-261; s. 43, ch. 2000-160; s. 10, ch. 2001-277; s. 62, ch. 2008-6.

Note.—Former s. 455.534.

456.012Board rules; final agency action; challenges.—

(1)The State Surgeon General shall have standing to challenge any rule or proposed rule of a board under its jurisdiction pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the State Surgeon General, may declare all or part of a rule or proposed rule invalid if it:

(a)Does not protect the public from any significant and discernible harm or damages;

(b)Unreasonably restricts competition or the availability of professional services in the state or in a

significant part of the state; or

(c)Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.

However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in the event that the rule or proposed rule is challenged.

(2)In addition, either the State Surgeon General or the board shall be a substantially interested party for purposes of s. 120.54(7). The board may, as an adversely affected party, initiate and maintain an action pursuant to s. 120.68 challenging the final agency action.

(3)No board created within the department shall have standing to challenge a rule or proposed rule of another board. However, if there is a dispute between boards concerning a rule or proposed rule, the boards may avail themselves of the provisions of s. 456.011(5).

History.—s. 46, ch. 97-261; s. 44, ch. 2000-160; s. 63, ch. 2008-6.

Note.—Former s. 455.544.

456.013Department; general licensing provisions.—

(1)(a)Any person desiring to be licensed in a profession within the jurisdiction of the department shall apply to the department in writing to take the licensure examination. The application shall be made on a form prepared and furnished by the department. The application form must be available on the World Wide Web and the department may accept electronically submitted applications beginning July 1, 2001. The application shall require the social security number of the applicant, except as provided in paragraph (b). The form shall be supplemented as needed to reflect any material change in any circumstance or condition stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department. If an application is submitted electronically, the department may require supplemental materials, including an original signature of the applicant and verification of credentials, to be submitted in a nonelectronic format. An incomplete application shall expire 1 year after initial filing. In order to further the economic development goals of the state, and notwithstanding any law to the contrary, the department may enter into an agreement with the county tax collector for the purpose of appointing the county tax collector as the department's agent to accept applications for licenses and applications for renewals of licenses. The agreement must specify the time within which the tax collector must forward any applications and accompanying application fees to the department.

(b)If an applicant has not been issued a social security number by the Federal Government at the time of application because the applicant is not a citizen or resident of this country, the department may process the application using a unique personal identification number. If such an applicant is otherwise eligible for licensure, the board, or the department when there is no board, may issue a temporary license to the applicant, which shall expire 30 days after issuance unless a social security number is obtained and submitted in writing to the department. Upon receipt of the applicant's social

security number, the department shall issue a new license, which shall expire at the end of the current biennium.

(2)Before the issuance of any license, the department shall charge an initial license fee as determined by the applicable board or, if there is no board, by rule of the department. Upon receipt of the appropriate license fee, the department shall issue a license to any person certified by the appropriate board, or its designee, as having met the licensure requirements imposed by law or rule. The license shall consist of a wallet-size identification card and a wall card measuring 6 1/2 inches by 5 inches. The licensee shall surrender to the department the wallet-size identification card and the wall card if the licensee's license is issued in error or is revoked.

(3)(a)The board, or the department when there is no board, may refuse to issue an initial license to any applicant who is under investigation or prosecution in any jurisdiction for an action that would constitute a violation of this chapter or the professional practice acts administered by the department and the boards, until such time as the investigation or prosecution is complete, and the time period in which the licensure application must be granted or denied shall be tolled until 15 days after the receipt of the final results of the investigation or prosecution.

(b)If an applicant has been convicted of a felony related to the practice or ability to practice any health care profession, the board, or the department when there is no board, may require the applicant to prove that his or her civil rights have been restored.

(c)In considering applications for licensure, the board, or the department when there is no board, may require a personal appearance of the applicant. If the applicant is required to appear, the time period in which a licensure application must be granted or denied shall be tolled until such time as the applicant appears. However, if the applicant fails to appear before the board at either of the next two regularly scheduled board meetings, or fails to appear before the department within 30 days if there is no board, the application for licensure shall be denied.

(4)When any administrative law judge conducts a hearing pursuant to the provisions of chapter 120 with respect to the issuance of a license by the department, the administrative law judge shall submit his or her recommended order to the appropriate board, which shall thereupon issue a final order. The applicant for licensure may appeal the final order of the board in accordance with the provisions of chapter 120.

(5)A privilege against civil liability is hereby granted to any witness for any information furnished by the witness in any proceeding pursuant to this section, unless the witness acted in bad faith or with malice in providing such information.

(6)As a condition of renewal of a license, the Board of Medicine, the Board of Osteopathic Medicine, the Board of Chiropractic Medicine, and the Board of Podiatric Medicine shall each require licensees which they respectively regulate to periodically demonstrate their professional competency by completing at least 40 hours of continuing education every 2 years. The boards may require by rule that up to 1 hour of the required 40 or more hours be in the area of risk management or cost

containment. This provision shall not be construed to limit the number of hours that a licensee may obtain in risk management or cost containment to be credited toward satisfying the 40 or more required hours. This provision shall not be construed to require the boards to impose any requirement on licensees except for the completion of at least 40 hours of continuing education every 2 years. Each of such boards shall determine whether any specific continuing education requirements not otherwise mandated by law shall be mandated and shall approve criteria for, and the content of, any continuing education mandated by such board. Notwithstanding any other provision of law, the board, or the department when there is no board, may approve by rule alternative methods of obtaining continuing education credits in risk management. The alternative methods may include attending a board meeting at which another licensee is disciplined, serving as a volunteer expert witness for the department in a disciplinary case, or serving as a member of a probable cause panel following the expiration of a board member's term. Other boards within the Division of Medical Quality Assurance, or the department if there is no board, may adopt rules granting continuing education hours in risk management for attending a board meeting at which another licensee is disciplined, for serving as a volunteer expert witness for the department in a disciplinary case, or for serving as a member of a probable cause panel following the expiration of a board member's term.

(7)The boards, or the department when there is no board, shall require the completion of a 2-hour course relating to prevention of medical errors as part of the licensure and renewal process. The 2-hour course shall count towards the total number of continuing education hours required for the profession. The course shall be approved by the board or department, as appropriate, and shall include a study of root-cause analysis, error reduction and prevention, and patient safety. In addition, the course approved by the Board of Medicine and the Board of Osteopathic Medicine shall include information relating to the five most misdiagnosed conditions during the previous biennium, as determined by the board. If the course is being offered by a facility licensed pursuant to chapter 395 for its employees, the board may approve up to 1 hour of the 2-hour course to be specifically related to error reduction and prevention methods used in that facility.

(8)The respective boards within the jurisdiction of the department, or the department when there is no board, may adopt rules to provide for the use of approved videocassette courses, not to exceed 5 hours per subject, to fulfill the continuing education requirements of the professions they regulate. Such rules shall provide for prior approval of the board, or the department when there is no board, of the criteria for and content of such courses and shall provide for a videocassette course validation form to be signed by the vendor and the licensee and submitted to the department, along with the license renewal application, for continuing education credit.

(9)Any board that currently requires continuing education for renewal of a license, or the department if there is no board, shall adopt rules to establish the criteria for continuing education courses. The rules may provide that up to a maximum of 25 percent of the required continuing education hours can be fulfilled by the performance of pro bono services to the indigent or to

underserved populations or in areas of critical need within the state where the licensee practices. The board, or the department if there is no board, must require that any pro bono services be approved in advance in order to receive credit for continuing education under this subsection. The standard for determining indigency shall be that recognized by the Federal Poverty Income Guidelines produced by the United States Department of Health and Human Services. The rules may provide for approval by the board, or the department if there is no board, that a part of the continuing education hours can be fulfilled by performing research in critical need areas or for training leading to advanced professional certification. The board, or the department if there is no board, may make rules to define underserved and critical need areas. The department shall adopt rules for administering continuing education requirements adopted by the boards or the department if there is no board.

(10)Notwithstanding any law to the contrary, an elected official who is licensed under a practice act administered by the Division of Medical Quality Assurance may hold employment for compensation with any public agency concurrent with such public service. Such dual service must be disclosed according to any disclosure required by applicable law.

(11)In any instance in which a licensee or applicant to the department is required to be in compliance with a particular provision by, on, or before a certain date, and if that date occurs on a Saturday, Sunday, or a legal holiday, then the licensee or applicant is deemed to be in compliance with the specific date requirement if the required action occurs on the first succeeding day which is not a Saturday, Sunday, or legal holiday.

(12)Pursuant to the federal Personal Responsibility and Work Opportunity Reconciliation Act of 1996, each party is required to provide his or her social security number in accordance with this section. Disclosure of social security numbers obtained through this requirement shall be limited to the purpose of administration of the Title IV-D program for child support enforcement.

History.—s. 44, ch. 92-33; s. 1, ch. 93-27; s. 23, ch. 93-129; s. 27, ch. 95-144; s. 2, ch. 96-309; s. 209, ch. 96-410; s. 1079, ch. 97-103; s. 64, ch. 97-170; s. 51, ch. 97-261; s. 54, ch. 97-278; ss. 7, 237, 262, ch. 98-166; s. 145, ch. 99-251; s. 76, ch. 99-397; s. 45, ch. 2000-160; s. 20, ch. 2000-318; ss. 11, 68, ch. 2001-277; s. 11, ch. 2003-416; s. 1, ch. 2005-62.

Note.—Former s. 455.2141; s. 455.564.

456.0135General background screening provisions.—

(1)An application for initial licensure received on or after January 1, 2013, under chapter 458, chapter 459, chapter 460, chapter 461, chapter 464, or s. 465.022 shall include fingerprints pursuant to procedures established by the department through a vendor approved by the Department of Law Enforcement and fees imposed for the initial screening and retention of fingerprints. Fingerprints must be submitted electronically to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for national processing. Each board, or the department if there is no board, shall screen the results to determine if an applicant meets licensure requirements. For any subsequent renewal of the applicant's

license that requires a national criminal history check, the department shall request the Department of Law Enforcement to forward the retained fingerprints of the applicant to the Federal Bureau of Investigation.

(2)All fingerprints submitted to the Department of Law Enforcement as required under subsection (1) shall be retained by the Department of Law Enforcement as provided under s. 943.05(2)(g) and (h) and (3). The department shall notify the Department of Law Enforcement regarding any person whose fingerprints have been retained but who is no longer licensed.

(3)The costs of fingerprint processing, including the cost for retaining fingerprints, shall be borne by the applicant subject to the background screening.

History.—s. 13, ch. 2012-73.

456.014Public inspection of information required from applicants; exceptions; examination hearing.—

(1)All information required by the department of any applicant shall be a public record and shall be open to public inspection pursuant to s. 119.07, except financial information, medical information, school transcripts, examination questions, answers, papers, grades, and grading keys, which are confidential and exempt from s. 119.07(1) and shall not be discussed with or made accessible to anyone except the program director of an approved program or accredited program as provided in s. 464.019(7), members of the board, the department, and staff thereof, who have a bona fide need to know such information. Any information supplied to the department by any other agency which is exempt from the provisions of chapter 119 or is confidential shall remain exempt or confidential pursuant to applicable law while in the custody of the department or the agency.

(2)The department shall establish by rule the procedure by which an applicant, and the applicant's attorney, may review examination questions and answers. Examination questions and answers are not subject to discovery but may be introduced into evidence and considered only in camera in any administrative proceeding under chapter 120. If an administrative hearing is held, the department shall provide challenged examination questions and answers to the administrative law judge. The examination questions and answers provided at the hearing are confidential and exempt from s. 119.07(1), unless invalidated by the administrative law judge.

(3)Unless an applicant notifies the department at least 5 days prior to an examination hearing of the applicant's inability to attend, or unless an applicant can demonstrate an extreme emergency for failing to attend, the department may require an applicant who fails to attend to pay reasonable attorney's fees, costs, and court costs of the department for the examination hearing.

History.—s. 76, ch. 97-261; s. 46, ch. 2000-160; s. 1, ch. 2010-37.

Note.—Former s. 455.647.

456.015Limited licenses.—

(1)It is the intent of the Legislature that, absent a threat to the health, safety, and welfare of the

public, the use of retired professionals in good standing to serve the indigent, underserved, or critical need populations of this state should be encouraged. To that end, the board, or the department when there is no board, may adopt rules to permit practice by retired professionals as limited licensees under this section.

(2)Any person desiring to obtain a limited license, when permitted by rule, shall submit to the board, or the department when there is no board, an application and fee, not to exceed $300, and an affidavit stating that the applicant has been licensed to practice in any jurisdiction in the United States for at least 10 years in the profession for which the applicant seeks a limited license. The affidavit shall also state that the applicant has retired or intends to retire from the practice of that profession and intends to practice only pursuant to the restrictions of the limited license granted pursuant to this section. If the applicant for a limited license submits a notarized statement from the employer stating that the applicant will not receive monetary compensation for any service involving the practice of her or his profession, the application and all licensure fees shall be waived.

(3)The board, or the department when there is no board, may deny limited licensure to an applicant who has committed, or is under investigation or prosecution for, any act which would constitute the basis for discipline pursuant to the provisions of this chapter or the applicable practice act.

(4)The recipient of a limited license may practice only in the employ of public agencies or institutions or nonprofit agencies or institutions which meet the requirements of s. 501(c)(3) of the Internal Revenue Code, and which provide professional liability coverage for acts or omissions of the limited licensee. A limited licensee may provide services only to the indigent, underserved, or critical need populations within the state. The standard for determining indigency shall be that recognized by the Federal Poverty Income Guidelines produced by the United States Department of Health and Human Services. The board, or the department when there is no board, may adopt rules to define underserved and critical need areas and to ensure implementation of this section.

(5)A board, or the department when there is no board, may provide by rule for supervision of limited licensees to protect the health, safety, and welfare of the public.

(6)Each applicant granted a limited license is subject to all the provisions of this chapter and the respective practice act under which the limited license is issued which are not in conflict with this section.

(7)This section does not apply to chapter 458 or chapter 459.

History.—s. 50, ch. 97-261; s. 22, ch. 99-7; s. 47, ch. 2000-160.

Note.—Former s. 455.561.

456.016Use of professional testing services.—Notwithstanding any other provision of law to the contrary, the department may use a professional testing service to prepare, administer, grade, and evaluate any computerized examination, when that service is available and approved by the board, or

the department if there is no board.

History.—s. 53, ch. 97-261; s. 48, ch. 2000-160.

Note.—Former s. 455.571.

456.01 7Examinations.—

(1)(a)The department shall provide, contract, or approve services for the development, preparation, administration, scoring, score reporting, and evaluation of all examinations, in consultation with the appropriate board. The department shall certify that examinations developed and approved by the department adequately and reliably measure an applicant's ability to practice the profession regulated by the department. After an examination developed or approved by the department has been administered, the board, or the department when there is no board, may reject any question which does not reliably measure the general areas of competency specified in the rules of the board. The department may contract for the preparation, administration, scoring, score reporting, and evaluation of examinations, when such services are available and approved by the board.

(b)For each examination developed by the department or contracted vendor, to the extent not otherwise specified by statute, the board, or the department when there is no board, shall by rule specify the general areas of competency to be covered by each examination, the relative weight to be assigned in grading each area tested, and the score necessary to achieve a passing grade. The department shall assess fees to cover the actual cost for any purchase, development, validation, administration, and defense of required examinations. This subsection does not apply to national examinations approved and administered pursuant to paragraph (c). If a practical examination is deemed to be necessary, the rules shall specify the criteria by which examiners are to be selected, the grading criteria to be used by the examiner, the relative weight to be assigned in grading each criterion, and the score necessary to achieve a passing grade. When a mandatory standardization exercise for a practical examination is required by law, the board, or the department when there is no board, may conduct such exercise. Therefore, board members, or employees of the department when there is no board, may serve as examiners at a practical examination with the consent of the board or department, as appropriate.

(c)The board, or the department when there is no board, shall approve by rule the use of one or more national examinations that the department has certified as meeting requirements of national examinations and generally accepted testing standards pursuant to department rules.

1.Providers of examinations seeking certification shall pay the actual costs incurred by the department in making a determination regarding the certification. The name and number of a candidate may be provided to a national contractor for the limited purpose of preparing the grade tape and information to be returned to the board or department; or, to the extent otherwise specified by rule, the candidate may apply directly to the vendor of the national examination and supply test score information to the department. The department may delegate to the board the duty to provide and

administer the examination. Any national examination approved by a board, or the department when there is no board, prior to October 1, 1997, is deemed certified under this paragraph.

2.Neither the board nor the department may administer a state-developed written examination if a national examination has been certified by the department. The examination may be administered electronically if adequate security measures are used, as determined by rule of the department.

3.The board, or the department when there is no board, may administer a state-developed practical or clinical examination, as required by the applicable practice act, if all costs of development, purchase, validation, administration, review, and defense are paid by the examination candidate prior to the administration of the examination. If a national practical or clinical examination is available and certified by the department pursuant to this section, the board, or the department when there is no board, may administer the national examination.

4.It is the intent of the Legislature to reduce the costs associated with state examinations and to encourage the use of national examinations whenever possible.

(d)Each board, or the department when there is no board, shall adopt rules regarding the security and monitoring of examinations. The department shall implement those rules adopted by the respective boards. In order to maintain the security of examinations, the department may employ the procedures set forth in s. 456.065 to seek fines and injunctive relief against an examinee who violates the provisions of s. 456.018 or the rules adopted pursuant to this paragraph. The department, or any agent thereof, may, for the purposes of investigation, confiscate any written, photographic, or recording material or device in the possession of the examinee at the examination site which the department deems necessary to enforce such provisions or rules. The scores of candidates who have taken state-developed examinations shall be provided to the candidates electronically using a candidate identification number, and the department shall post the aggregate scores on the department's website without identifying the names of the candidates.

(e)If the professional board with jurisdiction over an examination concurs, the department may, for a fee, share with any other state's licensing authority or a national testing entity an examination or examination item bank developed by or for the department unless prohibited by a contract entered into by the department for development or purchase of the examination. The department, with the concurrence of the appropriate board, shall establish guidelines that ensure security of a shared exam and shall require that any other state's licensing authority comply with those guidelines. Those guidelines shall be approved by the appropriate professional board. All fees paid by the user shall be applied to the department's examination and development program for professions regulated by this chapter.

(f)The department may adopt rules necessary to administer this subsection.

(2)For each examination developed by the department or a contracted vendor, the board, or the department when there is no board, shall adopt rules providing for reexamination of any applicants who failed an examination developed by the department or a contracted vendor. If both a written and

a practical examination are given, an applicant shall be required to retake only the portion of the examination on which the applicant failed to achieve a passing grade, if the applicant successfully passes that portion within a reasonable time, as determined by rule of the board, or the department when there is no board, of passing the other portion. Except for national examinations approved and administered pursuant to this section, the department shall provide procedures for applicants who fail an examination developed by the department or a contracted vendor to review their examination questions, answers, papers, grades, and grading key for the questions the candidate answered incorrectly or, if not feasible, the parts of the examination failed. Applicants shall bear the actual cost for the department to provide examination review pursuant to this subsection. An applicant may waive in writing the confidentiality of the applicant's examination grades. Notwithstanding any other provisions, only candidates who fail an examination with a score that is less than 10 percent below the minimum score required to pass the examination shall be entitled to challenge the validity of the examination at hearing.

(3)For each examination developed or administered by the department or a contracted vendor, an accurate record of each applicant's examination questions, answers, papers, grades, and grading key shall be kept for a period of not less than 2 years immediately following the examination, and such record shall thereafter be maintained or destroyed as provided in chapters 119 and 257. This subsection does not apply to national examinations approved and administered pursuant to this section.

(4)Meetings of any member of the department or of any board within the department held for the exclusive purpose of creating or reviewing licensure examination questions or proposed examination questions are exempt from the provisions of s. 286.011 and s. 24(b), Art. I of the State Constitution. Any public records, such as tape recordings, minutes, or notes, generated during or as a result of such meetings are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution. However, these exemptions shall not affect the right of any person to review an examination as provided in subsection (2).

(5)For examinations developed by the department or a contracted vendor, each board, or the department when there is no board, may provide licensure examinations in an applicant's native language. Notwithstanding any other provision of law, applicants for examination or reexamination pursuant to this subsection shall bear the full cost for the department's development, preparation, validation, administration, grading, and evaluation of any examination in a language other than English prior to the examination being administered. Requests for translated examinations must be on file in the board office at least 6 months prior to the scheduled examination. When determining whether it is in the public interest to allow the examination to be translated into a language other than English, the board shall consider the percentage of the population who speak the applicant's native language. Applicants must apply for translation to the applicable board at least 6 months prior to the scheduled examination.

(6)In addition to meeting any other requirements for licensure by examination or by endorsement, and notwithstanding the provisions in paragraph (1)(c), an applicant may be required by a board, or the department when there is no board, to certify competency in state laws and rules relating to the applicable practice act. Beginning October 1, 2001, all laws and rules examinations shall be administered electronically unless the laws and rules examination is administered concurrently with another written examination for that profession or unless the electronic administration would be substantially more expensive.

(7)The department may post examination scores electronically on the Internet in lieu of mailing the scores to each applicant. The electronic posting of the examination scores meets the requirements of chapter 120 if the department also posts along with the examination scores a notification of the rights set forth in chapter 120. The date of receipt for purposes of chapter 120 is the date the examination scores are posted electronically. The department shall also notify the applicant when scores are posted electronically of the availability of postexamination review, if applicable.

History.—s. 46, ch. 92-33; s. 23, ch. 93-129; s. 1, ch. 95-367; s. 304, ch. 96-406; s. 1081, ch. 97-103; s. 54, ch. 97-261; s. 238, ch. 98-166; s. 79, ch. 99-397; s. 49, ch. 2000-160; s. 46, ch. 2000-318; s. 12, ch. 2001-277; s. 2, ch. 2005-62.

Note.—Former s. 455.2173; s. 455.574.

456.018Penalty for theft or reproduction of an examination.—In addition to, or in lieu of, any other discipline imposed pursuant to s. 456.072, the theft of an examination in whole or in part or the act of reproducing or copying any examination administered by the department, whether such examination is reproduced or copied in part or in whole and by any means, constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—s. 55, ch. 97-261; s. 50, ch. 2000-160; s. 27, ch. 2000-318.

Note.—Former s. 455.577.

456.019Restriction on requirement of citizenship.—A person is not disqualified from practicing an occupation or profession regulated by the state solely because she or he is not a United States citizen.

History.—s. 36, ch. 97-261; s. 20, ch. 99-7; s. 51, ch. 2000-160.

Note.—Former s. 455.511.

456.021Qualification of immigrants for examination to practice a licensed profession or occupation.—

(1)It is the declared purpose of this section to encourage the use of foreign-speaking Florida residents duly qualified to become actively qualified in their professions so that all people of this state may receive better services.

(2)Any person who has successfully completed, or is currently enrolled in, an approved course of study created pursuant to chapters 74-105 and 75-177, Laws of Florida, shall be deemed qualified for

examination and reexaminations for a professional or occupational license which shall be administered in the English language unless 15 or more such applicants request that the reexamination be administered in their native language. In the event that such reexamination is administered in a foreign language, the full cost to the board of preparing and administering it shall be borne by the applicants.

(3)Each board within the department shall adopt and implement programs designed to qualify for examination all persons who were resident nationals of the Republic of Cuba and who, on July 1, 1977, were residents of this state.

History.—s. 37, ch. 97-261; s. 51, ch. 2000-160.

Note.—Former s. 455.514.

456.022Foreign-trained professionals; special examination and license provisions.—

(1)When not otherwise provided by law, within its jurisdiction, the department shall by rule provide procedures under which exiled professionals may be examined within each practice act. A person shall be eligible for such examination if the person:

(a)Immigrated to the United States after leaving the person's home country because of political reasons, provided such country is located in the Western Hemisphere and lacks diplomatic relations with the United States;

(b)Applies to the department and submits a fee;

(c)Was a Florida resident immediately preceding the person's application;

(d)Demonstrates to the department, through submission of documentation verified by the applicant's respective professional association in exile, that the applicant was graduated with an appropriate professional or occupational degree from a college or university; however, the department may not require receipt of any documentation from the Republic of Cuba as a condition of eligibility under this section;

(e)Lawfully practiced the profession for at least 3 years;

(f)Prior to 1980, successfully completed an approved course of study pursuant to chapters 74-105 and 75-177, Laws of Florida; and

(g)Presents a certificate demonstrating the successful completion of a continuing education program which offers a course of study that will prepare the applicant for the examination offered under subsection (2). The department shall develop rules for the approval of such programs for its boards.

(2)Upon request of a person who meets the requirements of subsection (1) and submits an examination fee, the department, for its boards, shall provide a written practical examination which tests the person's current ability to practice the profession competently in accordance with the actual practice of the profession. Evidence of meeting the requirements of subsection (1) shall be treated by the department as evidence of the applicant's preparation in the academic and preprofessional fundamentals necessary for successful professional practice, and the applicant shall not be examined

by the department on such fundamentals.

(3)The fees charged for the examinations offered under subsection (2) shall be established by the department, for its boards, by rule and shall be sufficient to develop or to contract for the development of the examination and its administration, grading, and grade reviews.

(4)The department shall examine any applicant who meets the requirements of subsections (1) and (2). Upon passing the examination and the issuance of the license, a licensee is subject to the administrative requirements of this chapter and the respective practice act under which the license is issued. Each applicant so licensed is subject to all provisions of this chapter and the respective practice act under which the license was issued.

(5)Upon a request by an applicant otherwise qualified under this section, the examinations offered under subsection (2) may be given in the applicant's native language, provided that any translation costs are borne by the applicant.

(6)The department, for its boards, shall not issue an initial license to, or renew a license of, any applicant or licensee who is under investigation or prosecution in any jurisdiction for an action which would constitute a violation of this chapter or the professional practice acts administered by the department and the boards until such time as the investigation or prosecution is complete, at which time the provisions of the professional practice acts shall apply.

History.—s. 56, ch. 97-261; s. 52, ch. 2000-160.

Note.—Former s. 455.581.

456.023Exemption for certain out-of-state or foreign professionals; limited practice permitted.—

(1)A professional of any other state or of any territory or other jurisdiction of the United States or of any other nation or foreign jurisdiction is exempt from the requirements of licensure under this chapter and the applicable professional practice act under the agency with regulatory jurisdiction over the profession if that profession is regulated in this state under the agency with regulatory jurisdiction over the profession and if that person:

(a)Holds, if so required in the jurisdiction in which that person practices, an active license to practice that profession.

(b)Engages in the active practice of that profession outside the state.

(c)Is employed or designated in that professional capacity by a sports entity visiting the state for a specific sporting event.

(2)A professional's practice under this section is limited to the members, coaches, and staff of the team for which that professional is employed or designated and to any animals used if the sporting event for which that professional is employed or designated involves animals. A professional practicing under authority of this section shall not have practice privileges in any licensed health care facility or veterinary facility without the approval of that facility.

History.—s. 57, ch. 97-261; s. 53, ch. 2000-160.

Note.—Former s. 455.584.

456.024Members of Armed Forces in good standing with administrative boards or the department; spouses.—

(1)Any member of the Armed Forces of the United States now or hereafter on active duty who, at the time of becoming such a member, was in good standing with any administrative board of the state, or the department when there is no board, and was entitled to practice or engage in his or her profession or vocation in the state shall be kept in good standing by such administrative board, or the department when there is no board, without registering, paying dues or fees, or performing any other act on his or her part to be performed, as long as he or she is a member of the Armed Forces of the United States on active duty and for a period of 6 months after discharge from active duty as a member of the Armed Forces of the United States, provided he or she is not engaged in his or her licensed profession or vocation in the private sector for profit.

(2)The boards listed in s. 20.43, or the department when there is no board, shall adopt rules exempting the spouses of members of the Armed Forces of the United States from licensure renewal provisions, but only in cases of absence from the state because of their spouses' duties with the Armed Forces.

(3)(a)The board, or the department if there is no board, may issue a temporary professional license to the spouse of an active duty member of the Armed Forces of the United States who submits to the department:

1.A completed application upon a form prepared and furnished by the department in accordance with the board's rules;

2.The required application fee;

3.Proof that the applicant is married to a member of the Armed Forces of the United States who is on active duty;

4.Proof that the applicant holds a valid license for the profession issued by another state, the District of Columbia, or a possession or territory of the United States, and is not the subject of any disciplinary proceeding in any jurisdiction in which the applicant holds a license to practice a profession regulated by this chapter;

5.Proof that the applicant's spouse is assigned to a duty station in this state pursuant to the member's official active duty military orders; and

6.Proof that the applicant would otherwise be entitled to full licensure under the appropriate practice act, and is eligible to take the respective licensure examination as required in Florida.

(b)The applicant must also submit to the Department of Law Enforcement a complete set of fingerprints. The Department of Law Enforcement shall conduct a statewide criminal history check and forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check.

(c)Each board, or the department if there is no board, shall review the results of the state and federal criminal history checks according to the level 2 screening standards in s. 435.04 when granting an exemption and when granting or denying the temporary license.

(d)The applicant shall pay the cost of fingerprint processing. If the fingerprints are submitted through an authorized agency or vendor, the agency or vendor shall collect the required processing fees and remit the fees to the Department of Law Enforcement.

(e)The department shall set an application fee, which may not exceed the cost of issuing the license.

(f)A temporary license expires 12 months after the date of issuance and is not renewable.

(g)An applicant for a temporary license under this subsection is subject to the requirements under s. 456.013(3)(a) and (c).

(h)An applicant shall be deemed ineligible for a temporary license pursuant to this section if the applicant:

1.Has been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession;

2.Has had a health care provider license revoked or suspended from another of the United States, the District of Columbia, or a United States territory;

3.Has been reported to the National Practitioner Data Bank, unless the applicant has successfully appealed to have his or her name removed from the data bank; or

4.Has previously failed the Florida examination required to receive a license to practice the profession for which the applicant is seeking a license.

(i)The board, or department if there is no board, may revoke a temporary license upon finding that the individual violated the profession's governing practice act.

(j)An applicant who is issued a temporary professional license to practice as a dentist pursuant to this section must practice under the indirect supervision, as defined in s. 466.003, of a dentist licensed pursuant to chapter 466.

History.—s. 35, ch. 97-261; s. 19, ch. 99-7; s. 73, ch. 99-397; s. 54, ch. 2000-160; s. 1, ch. 2011-95.

Note.—Former s. 455.507.

456.025Fees; receipts; disposition.—

(1)It is the intent of the Legislature that all costs of regulating health care professions and practitioners shall be borne solely by licensees and licensure applicants. It is also the intent of the Legislature that fees should be reasonable and not serve as a barrier to licensure. Moreover, it is the intent of the Legislature that the department operate as efficiently as possible and regularly report to the Legislature additional methods to streamline operational costs. Therefore, the boards in consultation with the department, or the department if there is no board, shall, by rule, set renewal fees which:

(a)Shall be based on revenue projections prepared using generally accepted accounting procedures;

(b)Shall be adequate to cover all expenses relating to that board identified in the department's long-range policy plan, as required by s. 456.005;

(c)Shall be reasonable, fair, and not serve as a barrier to licensure;

(d)Shall be based on potential earnings from working under the scope of the license;

(e)Shall be similar to fees imposed on similar licensure types;

(f)Shall not be more than 10 percent greater than the actual cost to regulate that profession for the previous biennium; and

(g)Shall be subject to challenge pursuant to chapter 120.

(2)The chairpersons of the boards and councils listed in s. 20.43(3)(g) shall meet annually at division headquarters to review the long-range policy plan required by s. 456.005 and current and proposed fee schedules. The chairpersons shall make recommendations for any necessary statutory changes relating to fees and fee caps. Such recommendations shall be compiled by the Department of Health and be included in the annual report to the Legislature required by s. 456.026 as well as be included in the long-range policy plan required by s. 456.005.

(3)Each board within the jurisdiction of the department, or the department when there is no board, shall determine by rule the amount of license fees for the profession it regulates, based upon long-range estimates prepared by the department of the revenue required to implement laws relating to the regulation of professions by the department and the board. Each board, or the department if there is no board, shall ensure that license fees are adequate to cover all anticipated costs and to maintain a reasonable cash balance, as determined by rule of the agency, with advice of the applicable board. If sufficient action is not taken by a board within 1 year after notification by the department that license fees are projected to be inadequate, the department shall set license fees on behalf of the applicable board to cover anticipated costs and to maintain the required cash balance. The department shall include recommended fee cap increases in its annual report to the Legislature. Further, it is the legislative intent that no regulated profession operate with a negative cash balance. The department may provide by rule for advancing sufficient funds to any profession operating with a negative cash balance. The advancement may be for a period not to exceed 2 consecutive years, and the regulated profession must pay interest. Interest shall be calculated at the current rate earned on investments of a trust fund used by the department to implement this chapter. Interest earned shall be allocated to the various funds in accordance with the allocation of investment earnings during the period of the advance.

(4)Each board, or the department if there is no board, may charge a fee not to exceed $25, as determined by rule, for the issuance of a wall certificate pursuant to s. 456.013(2) requested by a licensee who was licensed prior to July 1, 1998, or for the issuance of a duplicate wall certificate requested by any licensee.

(5)Each board, or the department if there is no board, may, by rule, assess and collect a one-time fee from each active status licensee and each inactive status licensee in an amount necessary to eliminate a cash deficit or, if there is not a cash deficit, in an amount sufficient to maintain the financial integrity of the professions as required in this section. Not more than one such assessment may be made in any 4-year period without specific legislative authorization.

(6)If the cash balance of the trust fund at the end of any fiscal year exceeds the total appropriation provided for the regulation of the health care professions in the prior fiscal year, the boards, in consultation with the department, may lower the license renewal fees.

(7)Each board, or the department if there is no board, shall establish, by rule, a fee not to exceed $250 for anyone seeking approval to provide continuing education courses or programs and shall establish by rule a biennial renewal fee not to exceed $250 for the renewal of providership of such courses. The fees collected from continuing education providers shall be used for the purposes of reviewing course provider applications, monitoring the integrity of the courses provided, covering legal expenses incurred as a result of not granting or renewing a providership, and developing and maintaining an electronic continuing education tracking system. The department shall implement an electronic continuing education tracking system for each new biennial renewal cycle for which electronic renewals are implemented after the effective date of this act and shall integrate such system into the licensure and renewal system. All approved continuing education providers shall provide information on course attendance to the department necessary to implement the electronic tracking system. The department shall, by rule, specify the form and procedures by which the information is to be submitted.

(8)All moneys collected by the department from fees or fines or from costs awarded to the agency by a court shall be paid into a trust fund used by the department to implement this chapter. The Legislature shall appropriate funds from this trust fund sufficient to carry out this chapter and the provisions of law with respect to professions regulated by the Division of Medical Quality Assurance within the department and the boards. The department may contract with public and private entities to receive and deposit revenue pursuant to this section. The department shall maintain separate accounts in the trust fund used by the department to implement this chapter for every profession within the department. To the maximum extent possible, the department shall directly charge all expenses to the account of each regulated profession. For the purpose of this subsection, direct charge expenses include, but are not limited to, costs for investigations, examinations, and legal services. For expenses that cannot be charged directly, the department shall provide for the proportionate allocation among the accounts of expenses incurred by the department in the performance of its duties with respect to each regulated profession. The regulation by the department of professions, as defined in this chapter, shall be financed solely from revenue collected by it from fees and other charges and deposited in the Medical Quality Assurance Trust Fund, and all such revenue is hereby appropriated to the department. However, it is legislative intent that each profession shall operate within its

anticipated fees. The department may not expend funds from the account of a profession to pay for the expenses incurred on behalf of another profession, except that the Board of Nursing must pay for any costs incurred in the regulation of certified nursing assistants. The department shall maintain adequate records to support its allocation of agency expenses. The department shall provide any board with reasonable access to these records upon request. On or before October 1 of each year, the department shall provide each board an annual report of revenue and direct and allocated expenses related to the operation of that profession. The board shall use these reports and the department's adopted long-range plan to determine the amount of license fees. A condensed version of this information, with the department's recommendations, shall be included in the annual report to the Legislature prepared under s. 456.026.

(9)The department shall provide a management report of revenues and expenditures, performance measures, and recommendations to each board at least once a quarter.

(10)If a duplicate license is required or requested by the licensee, the board or, if there is no board, the department may charge a fee as determined by rule not to exceed $25 before issuance of the duplicate license.

(11)The department or the appropriate board shall charge a fee not to exceed $25 for the certification of a public record. The fee shall be determined by rule of the department. The department or the appropriate board shall assess a fee for duplicating a public record as provided in s. 119.07(4).

History.—s. 49, ch. 92-33; s. 23, ch. 93-129; s. 58, ch. 97-261; s. 80, ch. 99-397; s. 55, ch. 2000-160; ss. 32, 164, ch. 2000-318; s. 73, ch. 2001-62; s. 6, ch. 2001-277; s. 12, ch. 2003-416; s. 45, ch. 2004-335; s. 149, ch. 2010-102.

Note.—Former s. 455.220; s. 455.587.

456.026Annual report concerning finances, administrative complaints, disciplinary actions, and recommendations.—The department is directed to prepare and submit a report to the President of the Senate and the Speaker of the House of Representatives by November 1 of each year. In addition to finances and any other information the Legislature may require, the report shall include statistics and relevant information, profession by profession, detailing:

(1)The revenues, expenditures, and cash balances for the prior year, and a review of the adequacy of existing fees.

(2)The number of complaints received and investigated.

(3)The number of findings of probable cause made.

(4)The number of findings of no probable cause made.

(5)The number of administrative complaints filed.

(6)The disposition of all administrative complaints.

(7)A description of disciplinary actions taken.

(8)A description of any effort by the department to reduce or otherwise close any investigation or

disciplinary proceeding not before the Division of Administrative Hearings under chapter 120 or otherwise not completed within 1 year after the initial filing of a complaint under this chapter.

(9)The status of the development and implementation of rules providing for disciplinary guidelines pursuant to s. 456.079.

(10)Such recommendations for administrative and statutory changes necessary to facilitate efficient and cost-effective operation of the department and the various boards.

History.—s. 75, ch. 97-261; s. 56, ch. 2000-160; s. 4, ch. 2002-254.

Note.—Former s. 455.644.

456.027Education; accreditation.—Notwithstanding any other provision of law, educational programs and institutions which are required by statute to be accredited, but which were accredited by an agency that has since ceased to perform an accrediting function, shall be recognized until such programs and institutions are accredited by a qualified successor to the original accrediting agency, an accrediting agency recognized by the United States Department of Education, or an accrediting agency recognized by the board, or the department when there is no board.

History.—s. 48, ch. 97-261; s. 57, ch. 2000-160.

Note.—Former s. 455.551.

456.028Consultation with postsecondary education boards prior to adoption of changes to training requirements.—Any state agency or board that has jurisdiction over the regulation of a profession or occupation shall consult with the Commission for Independent Education, the Board of Governors of the State University System, and the State Board of Education prior to adopting any changes to training requirements relating to entry into the profession or occupation. This consultation must allow the educational board to provide advice regarding the impact of the proposed changes in terms of the length of time necessary to complete the training program and the fiscal impact of the changes. The educational board must be consulted only when an institution offering the training program falls under its jurisdiction.

History.—s. 49, ch. 97-261; s. 35, ch. 98-421; s. 57, ch. 2000-160; s. 72, ch. 2004-5; s. 14, ch. 2004-41; s. 54, ch. 2007-217.

Note.—Former s. 455.554.

456.029Education; substituting demonstration of competency for clock-hour requirements.—Any board, or the department when there is no board, that requires student completion of a specific number of clock hours of classroom instruction for initial licensure purposes shall establish the minimal competencies that such students must demonstrate in order to be licensed. The demonstration of such competencies may be substituted for specific classroom clock-hour requirements established in statute or rule which are related to instructional programs for licensure purposes. Student demonstration of the established minimum competencies shall be certified by the educational institution. The provisions

of this section shall not apply to boards for which federal licensure standards are more restrictive or stringent than the standards prescribed in statute.

History.—s. 47, ch. 97-261; s. 57, ch. 2000-160.

Note.—Former s. 455.547.

456.031Requirement for instruction on domestic violence.—

(1)(a)The appropriate board shall require each person licensed or certified under chapter 458, chapter 459, part I of chapter 464, chapter 466, chapter 467, chapter 490, or chapter 491 to complete a 2-hour continuing education course, approved by the board, on domestic violence, as defined in s. 741.28, as part of every third biennial relicensure or recertification. The course shall consist of information on the number of patients in that professional's practice who are likely to be victims of domestic violence and the number who are likely to be perpetrators of domestic violence, screening procedures for determining whether a patient has any history of being either a victim or a perpetrator of domestic violence, and instruction on how to provide such patients with information on, or how to refer such patients to, resources in the local community, such as domestic violence centers and other advocacy groups, that provide legal aid, shelter, victim counseling, batterer counseling, or child protection services.

(b)Each such licensee or certificateholder shall submit confirmation of having completed such course, on a form provided by the board, when submitting fees for every third biennial renewal.

(c)The board may approve additional equivalent courses that may be used to satisfy the requirements of paragraph (a). Each licensing board that requires a licensee to complete an educational course pursuant to this subsection may include the hour required for completion of the course in the total hours of continuing education required by law for such profession unless the continuing education requirements for such profession consist of fewer than 30 hours biennially.

(d)Any person holding two or more licenses subject to the provisions of this subsection shall be permitted to show proof of having taken one board-approved course on domestic violence, for purposes of relicensure or recertification for additional licenses.

(e)Failure to comply with the requirements of this subsection shall constitute grounds for disciplinary action under each respective practice act and under s. 456.072(1)(k). In addition to discipline by the board, the licensee shall be required to complete such course.

(2)Each board may adopt rules to carry out the provisions of this section.

History.—s. 4, ch. 95-187; s. 61, ch. 97-261; s. 58, ch. 2000-160; s. 6, ch. 2000-295; s. 112, ch. 2000-318; s. 1, ch. 2001-176; s. 1, ch. 2001-250; s. 105, ch. 2001-277; s. 1, ch. 2006-251.

Note.—Former s. 455.222; s. 455.597.

456.032Hepatitis B or HIV carriers.—

(1)The department and each appropriate board within the Division of Medical Quality Assurance shall have the authority to establish procedures to handle, counsel, and provide other services to

health care professionals within their respective boards who are infected with hepatitis B or the human immunodeficiency virus.

(2)Any person licensed by the department and any other person employed by a health care facility who contracts a blood-borne infection shall have a rebuttable presumption that the illness was contracted in the course and scope of his or her employment, provided that the person, as soon as practicable, reports to the person's supervisor or the facility's risk manager any significant exposure, as that term is defined in s. 381.004(1)(c), to blood or body fluids. The employer may test the blood or body fluid to determine if it is infected with the same disease contracted by the employee. The employer may rebut the presumption by the preponderance of the evidence. Except as expressly provided in this subsection, there shall be no presumption that a blood-borne infection is a job-related injury or illness.

History.—s. 75, ch. 91-297; s. 76, ch. 94-218; s. 62, ch. 97-261; s. 81, ch. 99-397; s. 59, ch. 2000-160; s. 121, ch. 2012-184.

Note.—Former s. 455.2224; s. 455.601.

456.033Requirement for instruction for certain licensees on HIV and AIDS.—The following requirements apply to each person licensed or certified under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 463; part I of chapter 464; chapter 465; chapter 466; part II, part III, part V, or part X of chapter 468; or chapter 486:

(1)Each person shall be required by the appropriate board to complete no later than upon first renewal a continuing educational course, approved by the board, on human immunodeficiency virus and acquired immune deficiency syndrome as part of biennial relicensure or recertification. The course shall consist of education on the modes of transmission, infection control procedures, clinical management, and prevention of human immunodeficiency virus and acquired immune deficiency syndrome. Such course shall include information on current Florida law on acquired immune deficiency syndrome and its impact on testing, confidentiality of test results, treatment of patients, and any protocols and procedures applicable to human immunodeficiency virus counseling and testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to ss. 381.004 and 384.25.

(2)Each person shall submit confirmation of having completed the course required under subsection (1), on a form as provided by the board, when submitting fees for first renewal.

(3)The board shall have the authority to approve additional equivalent courses that may be used to satisfy the requirements in subsection (1). Each licensing board that requires a licensee to complete an educational course pursuant to this section may count the hours required for completion of the course included in the total continuing educational requirements as required by law.

(4)Any person holding two or more licenses subject to the provisions of this section shall be permitted to show proof of having taken one board-approved course on human immunodeficiency virus

and acquired immune deficiency syndrome, for purposes of relicensure or recertification for additional licenses.

(5)Failure to comply with the above requirements shall constitute grounds for disciplinary action under each respective licensing chapter and s. 456.072(1)(e). In addition to discipline by the board, the licensee shall be required to complete the course.

History.—s. 63, ch. 97-261; s. 4, ch. 98-171; s. 9, ch. 99-331; s. 82, ch. 99-397; s. 60, ch. 2000-160; s. 113, ch. 2000-318; s. 2, ch. 2001-176; s. 2, ch. 2001-250; s. 106, ch. 2001-277; s. 2, ch. 2006-251.

Note.—Former s. 455.604.

456.035Address of record.—

(1)Each licensee of the department is solely responsible for notifying the department in writing of the licensee's current mailing address and place of practice, as defined by rule of the board or the department if there is no board. Electronic notification shall be allowed by the department; however, it shall be the responsibility of the licensee to ensure that the electronic notification was received by the department. A licensee's failure to notify the department of a change of address constitutes a violation of this section, and the licensee may be disciplined by the board or the department if there is no board.

(2)Notwithstanding any other law, service by regular mail to a licensee's last known address of record with the department constitutes adequate and sufficient notice to the licensee for any official communication to the licensee by the board or the department except when other service is required under s. 456.076.

History.—s. 97, ch. 97-261; s. 39, ch. 98-166; s. 62, ch. 2000-160; s. 13, ch. 2001-277.

Note.—Former s. 455.717.

456.036Licenses; active and inactive status; delinquency.—

(1)A licensee may practice a profession only if the licensee has an active status license. A licensee who practices a profession with an inactive status license, a retired status license, or a delinquent license is in violation of this section and s. 456.072, and the board, or the department if there is no board, may impose discipline on the licensee.

(2)Each board, or the department if there is no board, shall permit a licensee to choose, at the time of licensure renewal, an active, inactive, or retired status.

(3)Each board, or the department if there is no board, shall by rule impose a fee for renewal of an active or inactive status license. The renewal fee for an inactive status license may not exceed the fee for an active status license.

(4)Notwithstanding any other provision of law to the contrary, a licensee may change licensure status at any time.

(a)Active status licensees choosing inactive status at the time of license renewal must pay the inactive status renewal fee, and, if applicable, the delinquency fee and the fee to change licensure

status. Active status licensees choosing inactive status at any other time than at the time of license renewal must pay the fee to change licensure status.

(b)An active status licensee or an inactive status licensee who chooses retired status at the time of license renewal must pay the retired status fee, which may not exceed $50 as established by rule of the board or the department if there is no board. An active status licensee or inactive status licensee who chooses retired status at any time other than at the time of license renewal must pay the retired status fee plus a change-of-status fee.

(c)An inactive status licensee may change to active status at any time, if the licensee meets all requirements for active status. Inactive status licensees choosing active status at the time of license renewal must pay the active status renewal fee, any applicable reactivation fees as set by the board, or the department if there is no board, and, if applicable, the delinquency fee and the fee to change licensure status. Inactive status licensees choosing active status at any other time than at the time of license renewal must pay the difference between the inactive status renewal fee and the active status renewal fee, if any exists, any applicable reactivation fees as set by the board, or the department if there is no board, and the fee to change licensure status.

(5)A licensee must apply with a complete application, as defined by rule of the board, or the department if there is no board, to renew an active or inactive status license before the license expires. If a licensee fails to renew before the license expires, the license becomes delinquent in the license cycle following expiration.

(6)A delinquent licensee must affirmatively apply with a complete application, as defined by rule of the board, or the department if there is no board, for active or inactive status during the licensure cycle in which a licensee becomes delinquent. Failure by a delinquent licensee to become active or inactive before the expiration of the current licensure cycle renders the license null without any further action by the board or the department. Any subsequent licensure shall be as a result of applying for and meeting all requirements imposed on an applicant for new licensure.

(7)Each board, or the department if there is no board, shall by rule impose an additional delinquency fee, not to exceed the biennial renewal fee for an active status license, on a delinquent licensee when such licensee applies for active or inactive status.

(8)Each board, or the department if there is no board, shall by rule impose an additional fee, not to exceed the biennial renewal fee for an active status license, for processing a licensee's request to change licensure status at any time other than at the beginning of a licensure cycle.

(9)Each board, or the department if there is no board, may by rule impose reasonable conditions, excluding full reexamination but including part of a national examination or a special purpose examination to assess current competency, necessary to ensure that a licensee who has been on inactive status for more than two consecutive biennial licensure cycles and who applies for active status can practice with the care and skill sufficient to protect the health, safety, and welfare of the public. Reactivation requirements may differ depending on the length of time licensees are inactive.

The costs to meet reactivation requirements shall be borne by licensees requesting reactivation.

(10)Each board, or the department if there is no board, may by rule impose reasonable conditions, including full reexamination to assess current competency, in order to ensure that a licensee who has been on retired status for more than 5 years, or a licensee from another state who has not been in active practice within the past 5 years, and who applies for active status is able to practice with the care and skill sufficient to protect the health, safety, and welfare of the public. Requirements for reactivation of a license may differ depending on the length of time a licensee has been retired.

(11)Before reactivation, an inactive status licensee or a delinquent licensee who was inactive prior to becoming delinquent must meet the same continuing education requirements, if any, imposed on an active status licensee for all biennial licensure periods in which the licensee was inactive or delinquent.

(12)Before the license of a retired status licensee is reactivated, the licensee must meet the same requirements for continuing education, if any, and pay any renewal fees imposed on an active status licensee for all biennial licensure periods during which the licensee was on retired status.

(13)The status or a change in status of a licensee does not alter in any way the right of the board, or of the department if there is no board, to impose discipline or to enforce discipline previously imposed on a licensee for acts or omissions committed by the licensee while holding a license, whether active, inactive, retired, or delinquent.

(14)A person who has been denied renewal of licensure, certification, or registration under s. 456.0635(3) may regain licensure, certification, or registration only by meeting the qualifications and completing the application process for initial licensure as defined by the board, or the department if there is no board. However, a person who was denied renewal of licensure, certification, or registration under s. 24, chapter 2009-223, Laws of Florida, between July 1, 2009, and June 30, 2012, is not required to retake and pass examinations applicable for initial licensure, certification, or registration.

(15)This section does not apply to a business establishment registered, permitted, or licensed by the department to do business.

(16)The board, or the department when there is no board, may adopt rules pursuant to ss. 120.536(1) and 120.54 as necessary to implement this section.

History.—s. 95, ch. 97-261; s. 63, ch. 2000-160; s. 31, ch. 2000-318; s. 3, ch. 2005-62; s. 2, ch. 2012-64.

Note.—Former s. 455.711.

456.037Business establishments; requirements for active status licenses; delinquency; discipline; applicability.—

(1)A business establishment regulated by the Division of Medical Quality Assurance pursuant to this chapter may provide regulated services only if the business establishment has an active status license. A business establishment that provides regulated services without an active status license is in violation

of this section and s. 456.072, and the board, or the department if there is no board, may impose discipline on the business establishment.

(2)A business establishment must apply with a complete application, as defined by rule of the board, or the department if there is no board, to renew an active status license before the license expires. If a business establishment fails to renew before the license expires, the license becomes delinquent, except as otherwise provided in statute, in the license cycle following expiration.

(3)A delinquent business establishment must apply with a complete application, as defined by rule of the board, or the department if there is no board, for active status within 6 months after becoming delinquent. Failure of a delinquent business establishment to renew the license within the 6 months after the expiration date of the license renders the license null without any further action by the board or the department. Any subsequent licensure shall be as a result of applying for and meeting all requirements imposed on a business establishment for new licensure.

(4)The status or a change in status of a business establishment license does not alter in any way the right of the board, or of the department if there is no board, to impose discipline or to enforce discipline previously imposed on a business establishment for acts or omissions committed by the business establishment while holding a license, whether active or null.

(5)This section applies to any business establishment registered, permitted, or licensed by the department to do business. Business establishments include, but are not limited to, dental laboratories, electrology facilities, massage establishments, pharmacies, and pain-management clinics required to be registered under s. 458.3265 or s. 459.0137.

History.—s. 89, ch. 99-397; s. 64, ch. 2000-160; s. 27, ch. 2000-318; s. 102, ch. 2000-349; s. 1, ch. 2010-211.

Note.—Former s. 455.712.

456.038Renewal and cancellation notices.—

(1)At least 90 days before the end of a licensure cycle, the department shall:

(a)Forward a licensure renewal notification to an active or inactive status licensee at the licensee's last known address of record with the department.

(b)Forward a notice of pending cancellation of licensure to a delinquent licensee at the licensee's last known address of record with the department.

(2)Each licensure renewal notification and each notice of pending cancellation of licensure must state conspicuously that a licensee who remains on inactive status for more than two consecutive biennial licensure cycles and who wishes to reactivate the license may be required to demonstrate the competency to resume active practice by sitting for a special purpose examination or by completing other reactivation requirements, as defined by rule of the board or the department if there is no board.

History.—s. 96, ch. 97-261; s. 65, ch. 2000-160; s. 33, ch. 2000-318.

Note.—Former s. 455.714.

456.039Designated health care professionals; information required for licensure.—

(1)Each person who applies for initial licensure as a physician under chapter 458, chapter 459, chapter 460, or chapter 461, except a person applying for registration pursuant to ss. 458.345 and 459.021, must, at the time of application, and each physician who applies for license renewal under chapter 458, chapter 459, chapter 460, or chapter 461, except a person registered pursuant to ss. 458.345 and 459.021, must, in conjunction with the renewal of such license and under procedures adopted by the Department of Health, and in addition to any other information that may be required from the applicant, furnish the following information to the Department of Health:

(a)1.The name of each medical school that the applicant has attended, with the dates of attendance and the date of graduation, and a description of all graduate medical education completed by the applicant, excluding any coursework taken to satisfy medical licensure continuing education requirements.

2.The name of each hospital at which the applicant has privileges.

3.The address at which the applicant will primarily conduct his or her practice.

4.Any certification that the applicant has received from a specialty board that is recognized by the board to which the applicant is applying.

5.The year that the applicant began practicing medicine.

6.Any appointment to the faculty of a medical school which the applicant currently holds and an indication as to whether the applicant has had the responsibility for graduate medical education within the most recent 10 years.

7.A description of any criminal offense of which the applicant has been found guilty, regardless of whether adjudication of guilt was withheld, or to which the applicant has pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony or misdemeanor if committed in this state must be reported. If the applicant indicates that a criminal offense is under appeal and submits a copy of the notice for appeal of that criminal offense, the department must state that the criminal offense is under appeal if the criminal offense is reported in the applicant's profile. If the applicant indicates to the department that a criminal offense is under appeal, the applicant must, upon disposition of the appeal, submit to the department a copy of the final written order of disposition.

8.A description of any final disciplinary action taken within the previous 10 years against the applicant by the agency regulating the profession that the applicant is or has been licensed to practice, whether in this state or in any other jurisdiction, by a specialty board that is recognized by the American Board of Medical Specialties, the American Osteopathic Association, or a similar national organization, or by a licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home. Disciplinary action includes resignation from or nonrenewal of medical staff membership or the restriction of privileges at a licensed hospital, health

maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home taken in lieu of or in settlement of a pending disciplinary case related to competence or character. If the applicant indicates that the disciplinary action is under appeal and submits a copy of the document initiating an appeal of the disciplinary action, the department must state that the disciplinary action is under appeal if the disciplinary action is reported in the applicant's profile.

9.Relevant professional qualifications as defined by the applicable board.

(b)In addition to the information required under paragraph (a), each applicant who seeks licensure under chapter 458, chapter 459, or chapter 461, and who has practiced previously in this state or in another jurisdiction or a foreign country must provide the information required of licensees under those chapters pursuant to s. 456.049. An applicant for licensure under chapter 460 who has practiced previously in this state or in another jurisdiction or a foreign country must provide the same information as is required of licensees under chapter 458, pursuant to s. 456.049.

(2)Before the issuance of the licensure renewal notice required by s. 456.038, the Department of Health shall send a notice to each person licensed under chapter 458, chapter 459, chapter 460, or chapter 461, at the licensee's last known address of record with the department, regarding the requirements for information to be submitted by those practitioners pursuant to this section in conjunction with the renewal of such license and under procedures adopted by the department.

(3)Each person who has submitted information pursuant to subsection (1) must update that information in writing by notifying the Department of Health within 45 days after the occurrence of an event or the attainment of a status that is required to be reported by subsection (1). Failure to comply with the requirements of this subsection to update and submit information constitutes a ground for disciplinary action under each respective licensing chapter and s. 456.072(1)(k). For failure to comply with the requirements of this subsection to update and submit information, the department or board, as appropriate, may:

(a)Refuse to issue a license to any person applying for initial licensure who fails to submit and update the required information.

(b)Issue a citation to any licensee who fails to submit and update the required information and may fine the licensee up to $50 for each day that the licensee is not in compliance with this subsection. The citation must clearly state that the licensee may choose, in lieu of accepting the citation, to follow the procedure under s. 456.073. If the licensee disputes the matter in the citation, the procedures set forth in s. 456.073 must be followed. However, if the licensee does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation becomes a final order and constitutes discipline. Service of a citation may be made by personal service or certified mail, restricted delivery, to the subject at the licensee's last known address.

(4)(a)An applicant for initial licensure must submit a set of fingerprints to the Department of Health in accordance with s. 458.311, s. 458.3115, s. 458.3124, s. 458.313, s. 459.0055, s. 460.406, or s. 461.006.

(b)An applicant for renewed licensure must submit a set of fingerprints for the initial renewal of his or her license after January 1, 2000, to the agency regulating that profession in accordance with procedures established under s. 458.319, s. 459.008, s. 460.407, or s. 461.007.

(c)The Department of Health shall submit the fingerprints provided by an applicant for initial licensure to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check of the applicant. The department shall submit the fingerprints provided by an applicant for a renewed license to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check for the initial renewal of the applicant's license after January 1, 2000; for any subsequent renewal of the applicant's license, the department shall submit the required information for a statewide criminal history check of the applicant.

(5)Each person who is required to submit information pursuant to this section may submit additional information. Such information may include, but is not limited to:

(a)Information regarding publications in peer-reviewed medical literature within the previous 10 years.

(b)Information regarding professional or community service activities or awards.

(c)Languages, other than English, used by the applicant to communicate with patients and identification of any translating service that may be available at the place where the applicant primarily conducts his or her practice.

(d)An indication of whether the person participates in the Medicaid program.

History.—s. 127, ch. 97-237; s. 3, ch. 97-273; ss. 8, 34, ch. 98-166; s. 60, ch. 99-397; s. 66, ch. 2000-160; s. 21, ch. 2000-318; s. 74, ch. 2001-62; s. 13, ch. 2003-416; s. 57, ch. 2010-114.

Note.—Former s. 455.565.

456.0391Advanced registered nurse practitioners; information required for certification.—

(1)(a)Each person who applies for initial certification under s. 464.012 must, at the time of application, and each person certified under s. 464.012 who applies for certification renewal must, in conjunction with the renewal of such certification and under procedures adopted by the Department of Health, and in addition to any other information that may be required from the applicant, furnish the following information to the Department of Health:

1.The name of each school or training program that the applicant has attended, with the months and years of attendance and the month and year of graduation, and a description of all graduate professional education completed by the applicant, excluding any coursework taken to satisfy continuing education requirements.

2.The name of each location at which the applicant practices.

3.The address at which the applicant will primarily conduct his or her practice.

4.Any certification or designation that the applicant has received from a specialty or certification board that is recognized or approved by the regulatory board or department to which the applicant is applying.

5.The year that the applicant received initial certification and began practicing the profession in any jurisdiction and the year that the applicant received initial certification in this state.

6.Any appointment which the applicant currently holds to the faculty of a school related to the profession and an indication as to whether the applicant has had the responsibility for graduate education within the most recent 10 years.

7.A description of any criminal offense of which the applicant has been found guilty, regardless of whether adjudication of guilt was withheld, or to which the applicant has pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony or misdemeanor if committed in this state must be reported. If the applicant indicates that a criminal offense is under appeal and submits a copy of the notice for appeal of that criminal offense, the department must state that the criminal offense is under appeal if the criminal offense is reported in the applicant's profile. If the applicant indicates to the department that a criminal offense is under appeal, the applicant must, within 15 days after the disposition of the appeal, submit to the department a copy of the final written order of disposition.

8.A description of any final disciplinary action taken within the previous 10 years against the applicant by a licensing or regulatory body in any jurisdiction, by a specialty board that is recognized by the board or department, or by a licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home. Disciplinary action includes resignation from or nonrenewal of staff membership or the restriction of privileges at a licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home taken in lieu of or in settlement of a pending disciplinary case related to competence or character. If the applicant indicates that the disciplinary action is under appeal and submits a copy of the document initiating an appeal of the disciplinary action, the department must state that the disciplinary action is under appeal if the disciplinary action is reported in the applicant's profile.

(b)In addition to the information required under paragraph (a), each applicant for initial certification or certification renewal must provide the information required of licensees pursuant to s. 456.049.

(2)The Department of Health shall send a notice to each person certified under s. 464.012 at the certificateholder's last known address of record regarding the requirements for information to be submitted by advanced registered nurse practitioners pursuant to this section in conjunction with the renewal of such certificate.

(3)Each person certified under s. 464.012 who has submitted information pursuant to subsection (1) must update that information in writing by notifying the Department of Health within 45 days after the

occurrence of an event or the attainment of a status that is required to be reported by subsection (1). Failure to comply with the requirements of this subsection to update and submit information constitutes a ground for disciplinary action under chapter 464 and s. 456.072(1)(k). For failure to comply with the requirements of this subsection to update and submit information, the department or board, as appropriate, may:

(a)Refuse to issue a certificate to any person applying for initial certification who fails to submit and update the required information.

(b)Issue a citation to any certificateholder who fails to submit and update the required information and may fine the certificateholder up to $50 for each day that the certificateholder is not in compliance with this subsection. The citation must clearly state that the certificateholder may choose, in lieu of accepting the citation, to follow the procedure under s. 456.073. If the certificateholder disputes the matter in the citation, the procedures set forth in s. 456.073 must be followed. However, if the certificateholder does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation becomes a final order and constitutes discipline. Service of a citation may be made by personal service or certified mail, restricted delivery, to the subject at the certificateholder's last known address.

(4)(a)An applicant for initial certification under s. 464.012 must submit a set of fingerprints to the Department of Health on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the Department of Health for a national criminal history check of the applicant.

(b)An applicant for renewed certification who has not previously submitted a set of fingerprints to the Department of Health for purposes of certification must submit a set of fingerprints to the department as a condition of the initial renewal of his or her certificate after the effective date of this section. The applicant must submit the fingerprints on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the Department of Health for a national criminal history check. For subsequent renewals, the applicant for renewed certification must only submit information necessary to conduct a statewide criminal history check, along with payment in an amount equal to the costs incurred by the Department of Health for a statewide criminal history check.

(c)1.The Department of Health shall submit the fingerprints provided by an applicant for initial certification to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check of the applicant.

2.The department shall submit the fingerprints provided by an applicant for the initial renewal of certification to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check for the initial renewal of the applicant's certificate

after the effective date of this section.

3.For any subsequent renewal of the applicant's certificate, the department shall submit the required information for a statewide criminal history check of the applicant to the Florida Department of Law Enforcement.

(d)Any applicant for initial certification or renewal of certification as an advanced registered nurse practitioner who submits to the Department of Health a set of fingerprints and information required for the criminal history check required under this section shall not be required to provide a subsequent set of fingerprints or other duplicate information required for a criminal history check to the Agency for Health Care Administration, the Department of Juvenile Justice, or the Department of Children and Family Services for employment or licensure with such agency or department, if the applicant has undergone a criminal history check as a condition of initial certification or renewal of certification as an advanced registered nurse practitioner with the Department of Health, notwithstanding any other provision of law to the contrary. In lieu of such duplicate submission, the Agency for Health Care Administration, the Department of Juvenile Justice, and the Department of Children and Family Services shall obtain criminal history information for employment or licensure of persons certified under s. 464.012 by such agency or department from the Department of Health's health care practitioner credentialing system.

(5)Each person who is required to submit information pursuant to this section may submit additional information to the Department of Health. Such information may include, but is not limited to:

(a)Information regarding publications in peer-reviewed professional literature within the previous 10 years.

(b)Information regarding professional or community service activities or awards.

(c)Languages, other than English, used by the applicant to communicate with patients or clients and identification of any translating service that may be available at the place where the applicant primarily conducts his or her practice.

(d)An indication of whether the person participates in the Medicaid program.

History.—s. 152, ch. 2000-318.

456.0392Prescription labeling.—

(1)A prescription written by a practitioner who is authorized under the laws of this state to write prescriptions for drugs that are not listed as controlled substances in chapter 893 but who is not eligible for a federal Drug Enforcement Administration number shall include that practitioner's name and professional license number. The pharmacist or dispensing practitioner must include the practitioner's name on the container of the drug that is dispensed. A pharmacist shall be permitted, upon verification by the prescriber, to document any information required by this section.

(2)A prescription for a drug that is not listed as a controlled substance in chapter 893 which is

written by an advanced registered nurse practitioner certified under s. 464.012 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by a practitioner licensed under chapter 458, chapter 459, or chapter 466.

(3)A prescription for a drug that is not listed as a controlled substance in chapter 893 which is written by a physician assistant licensed under chapter 458 or chapter 459 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by the physician assistant's supervising physician.

History.—s. 1, ch. 2004-8.

456.041Practitioner profile; creation.—

(1)(a)The Department of Health shall compile the information submitted pursuant to s. 456.039 into a practitioner profile of the applicant submitting the information, except that the Department of Health shall develop a format to compile uniformly any information submitted under s. 456.039(4)(b). Beginning July 1, 2001, the Department of Health may compile the information submitted pursuant to s. 456.0391 into a practitioner profile of the applicant submitting the information. The protocol submitted pursuant to s. 464.012(3) must be included in the practitioner profile of the advanced registered nurse practitioner.

(b)Beginning July 1, 2005, the department shall verify the information submitted by the applicant under s. 456.039 concerning disciplinary history and medical malpractice claims at the time of initial licensure and license renewal using the National Practitioner Data Bank. The physician profiles shall reflect the disciplinary action and medical malpractice claims as reported by the National Practitioner Data Bank, and shall include information relating to liability and disciplinary actions obtained as a result of a search of the National Practitioner Data Bank.

(c)Within 30 calendar days after receiving an update of information required for the practitioner's profile, the department shall update the practitioner's profile in accordance with the requirements of subsection (8).

(2)On the profile published under subsection (1), the department shall indicate if the information provided under s. 456.039(1)(a)7. or s. 456.0391(1)(a)7. is or is not corroborated by a criminal history check conducted according to this subsection. The department, or the board having regulatory authority over the practitioner acting on behalf of the department, shall investigate any information received by the department or the board.

(3)The Department of Health shall include in each practitioner's practitioner profile that criminal information that directly relates to the practitioner's ability to competently practice his or her profession. The department must include in each practitioner's practitioner profile the following statement: "The criminal history information, if any exists, may be incomplete; federal criminal history information is not available to the public." The department shall provide in each practitioner profile, for every final disciplinary action taken against the practitioner, an easy-to-read narrative description

that explains the administrative complaint filed against the practitioner and the final disciplinary action imposed on the practitioner. The department shall include a hyperlink to each final order listed in its website report of dispositions of recent disciplinary actions taken against practitioners.

(4)The Department of Health shall include, with respect to a practitioner licensed under chapter 458 or chapter 459, a statement of how the practitioner has elected to comply with the financial responsibility requirements of s. 458.320 or s. 459.0085. The department shall include, with respect to practitioners subject to s. 456.048, a statement of how the practitioner has elected to comply with the financial responsibility requirements of that section. The department shall include, with respect to practitioners licensed under chapter 461, information relating to liability actions which has been reported under s. 456.049 or s. 627.912 within the previous 10 years for any paid claim that exceeds $5,000. The department shall include, with respect to practitioners licensed under chapter 458 or chapter 459, information relating to liability actions which has been reported under ss. 456.049 and 627.912 within the previous 10 years for any paid claim that exceeds $100,000. Such claims information shall be reported in the context of comparing an individual practitioner's claims to the experience of other practitioners within the same specialty, or profession if the practitioner is not a specialist. The department must provide a hyperlink in such practitioner's profile to all such comparison reports. If information relating to a liability action is included in a practitioner's practitioner profile, the profile must also include the following statement: "Settlement of a claim may occur for a variety of reasons that do not necessarily reflect negatively on the professional competence or conduct of the practitioner. A payment in settlement of a medical malpractice action or claim should not be construed as creating a presumption that medical malpractice has occurred."

(5)The Department of Health shall include the date of a hospital or ambulatory surgical center disciplinary action taken by a licensed hospital or an ambulatory surgical center, in accordance with the requirements of s. 395.0193, in the practitioner profile. The department shall state whether the action related to professional competence and whether it related to the delivery of services to a patient.

(6)The Department of Health shall provide in each practitioner profile for every physician or advanced registered nurse practitioner terminated for cause from participating in the Medicaid program, pursuant to s. 409.913, or sanctioned by the Medicaid program a statement that the practitioner has been terminated from participating in the Florida Medicaid program or sanctioned by the Medicaid program.

(7)The Department of Health may include in the practitioner's practitioner profile any other information that is a public record of any governmental entity and that relates to a practitioner's ability to competently practice his or her profession.

(8)Upon the completion of a practitioner profile under this section, the Department of Health shall furnish the practitioner who is the subject of the profile a copy of it for review and verification. The practitioner has a period of 30 days in which to review and verify the contents of the profile and to

correct any factual inaccuracies in it. The Department of Health shall make the profile available to the public at the end of the 30-day period regardless of whether the practitioner has provided verification of the profile content. A practitioner shall be subject to a fine of up to $100 per day for failure to verify the profile contents and to correct any factual errors in his or her profile within the 30-day period. The department shall make the profiles available to the public through the World Wide Web and other commonly used means of distribution. The department must include the following statement, in boldface type, in each profile that has not been reviewed by the practitioner to which it applies: "The practitioner has not verified the information contained in this profile."

(9)The Department of Health must provide in each profile an easy-to-read explanation of any disciplinary action taken and the reason the sanction or sanctions were imposed.

(10)The Department of Health may provide one link in each profile to a practitioner's professional website if the practitioner requests that such a link be included in his or her profile.

(11)Making a practitioner profile available to the public under this section does not constitute agency action for which a hearing under s. 120.57 may be sought.

History.—s. 128, ch. 97-237; s. 4, ch. 97-273; s. 35, ch. 98-166; s. 77, ch. 99-397; s. 111, ch. 2000-153; s. 67, ch. 2000-160; ss. 22, 153, ch. 2000-318; s. 14, ch. 2003-416; s. 7, ch. 2005-62; s. 1, ch. 2005-266; s. 3, ch. 2006-251; s. 22, ch. 2009-223; s. 103, ch. 2010-5.

Note.—Former s. 455.5651.

456.042Practitioner profiles; update.—A practitioner must submit updates of required information within 15 days after the final activity that renders such information a fact. The Department of Health shall update each practitioner's practitioner profile periodically. An updated profile is subject to the same requirements as an original profile.

History.—s. 129, ch. 97-237; s. 5, ch. 97-273; s. 68, ch. 2000-160; s. 15, ch. 2003-416.

Note.—Former s. 455.5652.

456.043Practitioner profiles; data storage.—Effective upon this act becoming a law, the Department of Health must develop or contract for a computer system to accommodate the new data collection and storage requirements under this act pending the development and operation of a computer system by the Department of Health for handling the collection, input, revision, and update of data submitted by physicians as a part of their initial licensure or renewal to be compiled into individual practitioner profiles. The Department of Health must incorporate any data required by this act into the computer system used in conjunction with the regulation of health care professions under its jurisdiction. The Department of Health is authorized to contract with and negotiate any interagency agreement necessary to develop and implement the practitioner profiles. The Department of Health shall have access to any information or record maintained by the Agency for Health Care Administration, including any information or record that is otherwise confidential and exempt from the provisions of chapter 119 and s. 24(a), Art. I of the State Constitution, so that the Department of

Health may corroborate any information that practitioners are required to report under s. 456.039 or s. 456.0391.

History.—s. 130, ch. 97-237; s. 6, ch. 97-273; s. 112, ch. 2000-153; s. 69, ch. 2000-160; ss. 23, 154, ch. 2000-318.

Note.—Former s. 455.5653.

456.044Practitioner profiles; rules; workshops.—Effective upon this act becoming a law, the Department of Health shall adopt rules for the form of a practitioner profile that the agency is required to prepare. The Department of Health, pursuant to chapter 120, must hold public workshops for purposes of rule development to implement this section. An agency to which information is to be submitted under this act may adopt by rule a form for the submission of the information required under s. 456.039 or s. 456.0391.

History.—s. 131, ch. 97-237; s. 7, ch. 97-273; s. 113, ch. 2000-153; s. 70, ch. 2000-160; ss. 24, 155, ch. 2000-318.

Note.—Former s. 455.5654.

456.045Practitioner profiles; maintenance of superseded information.—Information in superseded practitioner profiles must be maintained by the Department of Health, in accordance with general law and the rules of the Department of State.

History.—s. 132, ch. 97-237; s. 8, ch. 97-273; s. 71, ch. 2000-160.

Note.—Former s. 455.5655.

456.046Practitioner profiles; confidentiality.—Any patient name or other information that identifies a patient which is in a record obtained by the Department of Health or its agent for the purpose of compiling a practitioner profile pursuant to s. 456.041 is confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution. Other data received by the department or its agent as a result of its duty to compile and promulgate practitioner profiles are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the profile into which the data are incorporated or with respect to which the data are submitted is made public pursuant to the requirements of s. 456.041. Any information or record that the Department of Health obtains from the Agency for Health Care Administration or any other governmental entity for the purpose of compiling a practitioner profile or substantiating other information or records submitted for that purpose which is otherwise exempt from public disclosure shall remain exempt as otherwise provided by law.

History.—s. 1, ch. 97-175; s. 71, ch. 2000-160; s. 1, ch. 2002-198.

Note.—Former s. 455.5656.

456.048Financial responsibility requirements for certain health care practitioners.—

(1)As a prerequisite for licensure or license renewal, the Board of Acupuncture, the Board of Chiropractic Medicine, the Board of Podiatric Medicine, and the Board of Dentistry shall, by rule,

require that all health care practitioners licensed under the respective board, and the Board of Medicine and the Board of Osteopathic Medicine shall, by rule, require that all anesthesiologist assistants licensed pursuant to s. 458.3475 or s. 459.023, and the Board of Nursing shall, by rule, require that advanced registered nurse practitioners certified under s. 464.012, and the department shall, by rule, require that midwives maintain medical malpractice insurance or provide proof of financial responsibility in an amount and in a manner determined by the board or department to be sufficient to cover claims arising out of the rendering of or failure to render professional care and services in this state.

(2)The board or department may grant exemptions upon application by practitioners meeting any of the following criteria:

(a)Any person licensed under chapter 457, s. 458.3475, s. 459.023, chapter 460, chapter 461, s. 464.012, chapter 466, or chapter 467 who practices exclusively as an officer, employee, or agent of the Federal Government or of the state or its agencies or its subdivisions. For the purposes of this subsection, an agent of the state, its agencies, or its subdivisions is a person who is eligible for coverage under any self-insurance or insurance program authorized by the provisions of s. 768.28(16) or who is a volunteer under s. 110.501(1).

(b)Any person whose license or certification has become inactive under chapter 457, s. 458.3475, s. 459.023, chapter 460, chapter 461, part I of chapter 464, chapter 466, or chapter 467 and who is not practicing in this state. Any person applying for reactivation of a license must show either that such licensee maintained tail insurance coverage which provided liability coverage for incidents that occurred on or after October 1, 1993, or the initial date of licensure in this state, whichever is later, and incidents that occurred before the date on which the license became inactive; or such licensee must submit an affidavit stating that such licensee has no unsatisfied medical malpractice judgments or settlements at the time of application for reactivation.

(c)Any person holding a limited license pursuant to s. 456.015, and practicing under the scope of such limited license.

(d)Any person licensed or certified under chapter 457, s. 458.3475, s. 459.023, chapter 460, chapter 461, s. 464.012, chapter 466, or chapter 467 who practices only in conjunction with his or her teaching duties at an accredited school or in its main teaching hospitals. Such person may engage in the practice of medicine to the extent that such practice is incidental to and a necessary part of duties in connection with the teaching position in the school.

(e)Any person holding an active license or certification under chapter 457, s. 458.3475, s. 459.023, chapter 460, chapter 461, s. 464.012, chapter 466, or chapter 467 who is not practicing in this state. If such person initiates or resumes practice in this state, he or she must notify the department of such activity.

(f)Any person who can demonstrate to the board or department that he or she has no malpractice exposure in the state.

(3)Notwithstanding the provisions of this section, the financial responsibility requirements of ss. 458.320 and 459.0085 shall continue to apply to practitioners licensed under those chapters, except for anesthesiologist assistants licensed pursuant to s. 458.3475 or s. 459.023 who must meet the requirements of this section.

History.—s. 1, ch. 93-41; s. 193, ch. 97-103; s. 90, ch. 97-261; s. 266, ch. 98-166; s. 88, ch. 99-397; s. 73, ch. 2000-160; s. 116, ch. 2000-318; s. 73, ch. 2004-5; s. 1, ch. 2004-303.

Note.—Former s. 455.2456; s. 455.694.

456.049Health care practitioners; reports on professional liability claims and actions.—Any practitioner of medicine licensed pursuant to the provisions of chapter 458, practitioner of osteopathic medicine licensed pursuant to the provisions of chapter 459, podiatric physician licensed pursuant to the provisions of chapter 461, or dentist licensed pursuant to the provisions of chapter 466 shall report to the Office of Insurance Regulation any claim or action for damages for personal injury alleged to have been caused by error, omission, or negligence in the performance of such licensee's professional services or based on a claimed performance of professional services without consent pursuant to s. 627.912.

History.—s. 13, ch. 88-1; s. 7, ch. 91-140; s. 309, ch. 96-406; s. 91, ch. 97-261; s. 193, ch. 98-166; s. 74, ch. 2000-160; s. 16, ch. 2003-416.

Note.—Former s. 455.247; s. 455.697.

456.051Reports of professional liability actions; bankruptcies; Department of Health's responsibility to provide.—

(1)The report of a claim or action for damages for personal injury which is required to be provided to the Department of Health under s. 456.049 or s. 627.912 is public information except for the name of the claimant or injured person, which remains confidential as provided in s. 627.912(2)(e). The Department of Health shall, upon request, make such report available to any person. The department shall make such report available as a part of the practitioner's profile within 30 calendar days after receipt.

(2)Any information in the possession of the Department of Health which relates to a bankruptcy proceeding by a practitioner of medicine licensed under chapter 458, a practitioner of osteopathic medicine licensed under chapter 459, a podiatric physician licensed under chapter 461, or a dentist licensed under chapter 466 is public information. The Department of Health shall, upon request, make such information available to any person. The department shall make such report available as a part of the practitioner's profile within 30 calendar days after receipt.

History.—s. 146, ch. 97-237; s. 22, ch. 97-273; ss. 38, 194, ch. 98-166; s. 75, ch. 2000-160; s. 17, ch. 2003-416; s. 74, ch. 2004-5.

Note.—Former s. 455.698.

456.052Disclosure of financial interest by production.—

(1)A health care provider shall not refer a patient to an entity in which such provider is an investor unless, prior to the referral, the provider furnishes the patient with a written disclosure form, informing the patient of:

(a)The existence of the investment interest.

(b)The name and address of each applicable entity in which the referring health care provider is an investor.

(c)The patient's right to obtain the items or services for which the patient has been referred at the location or from the provider or supplier of the patient's choice, including the entity in which the referring provider is an investor.

(d)The names and addresses of at least two alternative sources of such items or services available to the patient.

(2)The physician or health care provider shall post a copy of the disclosure forms in a conspicuous public place in his or her office.

(3)A violation of this section shall constitute a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. In addition to any other penalties or remedies provided, a violation of this section shall be grounds for disciplinary action by the respective board.

History.—s. 1, ch. 86-31; s. 84, ch. 91-224; s. 13, ch. 92-178; s. 92, ch. 97-261; s. 76, ch. 2000-160.

Note.—Former s. 455.25; s. 455.701.

456.053Financial arrangements between referring health care providers and providers of health care services.—

(1)SHORT TITLE.—This section may be cited as the "Patient Self-Referral Act of 1992."

(2)LEGISLATIVE INTENT.—It is recognized by the Legislature that the referral of a patient by a health care provider to a provider of health care services in which the referring health care provider has an investment interest represents a potential conflict of interest. The Legislature finds these referral practices may limit or eliminate competitive alternatives in the health care services market, may result in overutilization of health care services, may increase costs to the health care system, and may adversely affect the quality of health care. The Legislature also recognizes, however, that it may be appropriate for providers to own entities providing health care services, and to refer patients to such entities, as long as certain safeguards are present in the arrangement. It is the intent of the Legislature to provide guidance to health care providers regarding prohibited patient referrals between health care providers and entities providing health care services and to protect the people of Florida from unnecessary and costly health care expenditures.

(3)DEFINITIONS.—For the purpose of this section, the word, phrase, or term:

(a)"Board" means any of the following boards relating to the respective professions: the Board of Medicine as created in s. 458.307; the Board of Osteopathic Medicine as created in s. 459.004; the

Board of Chiropractic Medicine as created in s. 460.404; the Board of Podiatric Medicine as created in s. 461.004; the Board of Optometry as created in s. 463.003; the Board of Pharmacy as created in s. 465.004; and the Board of Dentistry as created in s. 466.004.

(b)“Comprehensive rehabilitation services” means services that are provided by health care professionals licensed under part I or part III of chapter 468 or chapter 486 to provide speech, occupational, or physical therapy services on an outpatient or ambulatory basis.

(c)“Designated health services” means, for purposes of this section, clinical laboratory services, physical therapy services, comprehensive rehabilitative services, diagnostic-imaging services, and radiation therapy services.

(d)“Diagnostic imaging services” means magnetic resonance imaging, nuclear medicine, angiography, arteriography, computed tomography, positron emission tomography, digital vascular imaging, bronchography, lymphangiography, splenography, ultrasound, EEG, EKG, nerve conduction studies, and evoked potentials.

(e)“Direct supervision” means supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.

(f)“Entity” means any individual, partnership, firm, corporation, or other business entity.

(g)“Fair market value” means value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes, not taking into account its intended use, and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

(h)“Group practice” means a group of two or more health care providers legally organized as a partnership, professional corporation, or similar association:

1.In which each health care provider who is a member of the group provides substantially the full range of services which the health care provider routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel;

2.For which substantially all of the services of the health care providers who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group; and

3.In which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined by members of the group.

(i)“Health care provider” means any physician licensed under chapter 458, chapter 459, chapter 460, or chapter 461, or any health care provider licensed under chapter 463 or chapter 466.

(j)“Immediate family member” means a health care provider’s spouse, child, child’s spouse,

grandchild, grandchild's spouse, parent, parent-in-law, or sibling.

(k)"Investment interest" means an equity or debt security issued by an entity, including, without limitation, shares of stock in a corporation, units or other interests in a partnership, bonds, debentures, notes, or other equity interests or debt instruments. The following investment interests shall be excepted from this definition:

1.An investment interest in an entity that is the sole provider of designated health services in a rural area;

2.An investment interest in notes, bonds, debentures, or other debt instruments issued by an entity which provides designated health services, as an integral part of a plan by such entity to acquire such investor's equity investment interest in the entity, provided that the interest rate is consistent with fair market value, and that the maturity date of the notes, bonds, debentures, or other debt instruments issued by the entity to the investor is not later than October 1, 1996.

3.An investment interest in real property resulting in a landlord-tenant relationship between the health care provider and the entity in which the equity interest is held, unless the rent is determined, in whole or in part, by the business volume or profitability of the tenant or exceeds fair market value; or

4.An investment interest in an entity which owns or leases and operates a hospital licensed under chapter 395 or a nursing home facility licensed under chapter 400.

(l)"Investor" means a person or entity owning a legal or beneficial ownership or investment interest, directly or indirectly, including, without limitation, through an immediate family member, trust, or another entity related to the investor within the meaning of 42 C.F.R. s. 413.17, in an entity.

(m)"Outside referral for diagnostic imaging services" means a referral of a patient to a group practice or sole provider for diagnostic imaging services by a physician who is not a member of the group practice or of the sole provider's practice and who does not have an investment interest in the group practice or sole provider's practice, for which the group practice or sole provider billed for both the technical and the professional fee for the patient, and the patient did not become a patient of the group practice or sole provider's practice.

(n)"Patient of a group practice" or "patient of a sole provider" means a patient who receives a physical examination, evaluation, diagnosis, and development of a treatment plan if medically necessary by a physician who is a member of the group practice or the sole provider's practice.

(o)"Referral" means any referral of a patient by a health care provider for health care services, including, without limitation:

1.The forwarding of a patient by a health care provider to another health care provider or to an entity which provides or supplies designated health services or any other health care item or service; or

2.The request or establishment of a plan of care by a health care provider, which includes the provision of designated health services or other health care item or service.

3.The following orders, recommendations, or plans of care shall not constitute a referral by a health care provider:

a.By a radiologist for diagnostic-imaging services.

b.By a physician specializing in the provision of radiation therapy services for such services.

c.By a medical oncologist for drugs and solutions to be prepared and administered intravenously to such oncologist's patient, as well as for the supplies and equipment used in connection therewith to treat such patient for cancer and the complications thereof.

d.By a cardiologist for cardiac catheterization services.

e.By a pathologist for diagnostic clinical laboratory tests and pathological examination services, if furnished by or under the supervision of such pathologist pursuant to a consultation requested by another physician.

f.By a health care provider who is the sole provider or member of a group practice for designated health services or other health care items or services that are prescribed or provided solely for such referring health care provider's or group practice's own patients, and that are provided or performed by or under the direct supervision of such referring health care provider or group practice; provided, however, that effective July 1, 1999, a physician licensed pursuant to chapter 458, chapter 459, chapter 460, or chapter 461 may refer a patient to a sole provider or group practice for diagnostic imaging services, excluding radiation therapy services, for which the sole provider or group practice billed both the technical and the professional fee for or on behalf of the patient, if the referring physician has no investment interest in the practice. The diagnostic imaging service referred to a group practice or sole provider must be a diagnostic imaging service normally provided within the scope of practice to the patients of the group practice or sole provider. The group practice or sole provider may accept no more than 15 percent of their patients receiving diagnostic imaging services from outside referrals, excluding radiation therapy services.

g.By a health care provider for services provided by an ambulatory surgical center licensed under chapter 395.

h.By a urologist for lithotripsy services.

i.By a dentist for dental services performed by an employee of or health care provider who is an independent contractor with the dentist or group practice of which the dentist is a member.

j.By a physician for infusion therapy services to a patient of that physician or a member of that physician's group practice.

k.By a nephrologist for renal dialysis services and supplies, except laboratory services.

l.By a health care provider whose principal professional practice consists of treating patients in their private residences for services to be rendered in such private residences, except for services rendered by a home health agency licensed under chapter 400. For purposes of this sub-subparagraph, the term "private residences" includes patients' private homes, independent living centers, and assisted living facilities, but does not include skilled nursing facilities.

m.By a health care provider for sleep-related testing.

(p)“Present in the office suite” means that the physician is actually physically present; provided, however, that the health care provider is considered physically present during brief unexpected absences as well as during routine absences of a short duration if the absences occur during time periods in which the health care provider is otherwise scheduled and ordinarily expected to be present and the absences do not conflict with any other requirement in the Medicare program for a particular level of health care provider supervision.

(q)“Rural area” means a county with a population density of no greater than 100 persons per square mile, as defined by the United States Census.

(r)“Sole provider” means one health care provider licensed under chapter 458, chapter 459, chapter 460, or chapter 461, who maintains a separate medical office and a medical practice separate from any other health care provider and who bills for his or her services separately from the services provided by any other health care provider. A sole provider shall not share overhead expenses or professional income with any other person or group practice.

(4)REQUIREMENTS FOR ACCEPTING OUTSIDE REFERRALS FOR DIAGNOSTIC IMAGING.—

(a)A group practice or sole provider accepting outside referrals for diagnostic imaging services is required to comply with the following conditions:

1.Diagnostic imaging services must be provided exclusively by a group practice physician or by a full-time or part-time employee of the group practice or of the sole provider’s practice.

2.All equity in the group practice or sole provider’s practice accepting outside referrals for diagnostic imaging must be held by the physicians comprising the group practice or the sole provider’s practice, each of whom must provide at least 75 percent of his or her professional services to the group. Alternatively, the group must be incorporated under chapter 617 and must be exempt under the provisions of s. 501(c)(3) of the Internal Revenue Code and be part of a foundation in existence prior to January 1, 1999, that is created for the purpose of patient care, medical education, and research.

3.A group practice or sole provider may not enter into, extend or renew any contract with a practice management company that provides any financial incentives, directly or indirectly, based on an increase in outside referrals for diagnostic imaging services from any group or sole provider managed by the same practice management company.

4.The group practice or sole provider accepting outside referrals for diagnostic imaging services must bill for both the professional and technical component of the service on behalf of the patient, and no portion of the payment, or any type of consideration, either directly or indirectly, may be shared with the referring physician.

5.Group practices or sole providers that have a Medicaid provider agreement with the Agency for Health Care Administration must furnish diagnostic imaging services to their Medicaid patients and may not refer a Medicaid recipient to a hospital for outpatient diagnostic imaging services unless the physician furnishes the hospital with documentation demonstrating the medical necessity for such a

referral. If necessary, the Agency for Health Care Administration may apply for a federal waiver to implement this subparagraph.

6.All group practices and sole providers accepting outside referrals for diagnostic imaging shall report annually to the Agency for Health Care Administration providing the number of outside referrals accepted for diagnostic imaging services and the total number of all patients receiving diagnostic imaging services.

(b)If a group practice or sole provider accepts an outside referral for diagnostic imaging services in violation of this subsection or if a group practice or sole provider accepts outside referrals for diagnostic imaging services in excess of the percentage limitation established in subparagraph (a)2., the group practice or the sole provider shall be subject to the penalties in subsection (5).

(c)Each managing physician member of a group practice and each sole provider who accepts outside referrals for diagnostic imaging services shall submit an annual attestation signed under oath to the Agency for Health Care Administration which shall include the annual report required under subparagraph (a)6. and which shall further confirm that each group practice or sole provider is in compliance with the percentage limitations for accepting outside referrals and the requirements for accepting outside referrals listed in paragraph (a). The agency may verify the report submitted by group practices and sole providers.

(5)PROHIBITED REFERRALS AND CLAIMS FOR PAYMENT.—Except as provided in this section:

(a)A health care provider may not refer a patient for the provision of designated health services to an entity in which the health care provider is an investor or has an investment interest.

(b)A health care provider may not refer a patient for the provision of any other health care item or service to an entity in which the health care provider is an investor unless:

1.The provider's investment interest is in registered securities purchased on a national exchange or over-the-counter market and issued by a publicly held corporation:

a.Whose shares are traded on a national exchange or on the over-the-counter market; and

b.Whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million; or

2.With respect to an entity other than a publicly held corporation described in subparagraph 1., and a referring provider's investment interest in such entity, each of the following requirements are met:

a.No more than 50 percent of the value of the investment interests are held by investors who are in a position to make referrals to the entity.

b.The terms under which an investment interest is offered to an investor who is in a position to make referrals to the entity are no different from the terms offered to investors who are not in a position to make such referrals.

c.The terms under which an investment interest is offered to an investor who is in a position to make referrals to the entity are not related to the previous or expected volume of referrals from that

investor to the entity.

d.There is no requirement that an investor make referrals or be in a position to make referrals to the entity as a condition for becoming or remaining an investor.

3.With respect to either such entity or publicly held corporation:

a.The entity or corporation does not loan funds to or guarantee a loan for an investor who is in a position to make referrals to the entity or corporation if the investor uses any part of such loan to obtain the investment interest.

b.The amount distributed to an investor representing a return on the investment interest is directly proportional to the amount of the capital investment, including the fair market value of any preoperational services rendered, invested in the entity or corporation by that investor.

4.Each board and, in the case of hospitals, the Agency for Health Care Administration, shall encourage the use by licensees of the declaratory statement procedure to determine the applicability of this section or any rule adopted pursuant to this section as it applies solely to the licensee. Boards shall submit to the Agency for Health Care Administration the name of any entity in which a provider investment interest has been approved pursuant to this section, and the Agency for Health Care Administration shall adopt rules providing for periodic quality assurance and utilization review of such entities.

(c)No claim for payment may be presented by an entity to any individual, third-party payor, or other entity for a service furnished pursuant to a referral prohibited under this section.

(d)If an entity collects any amount that was billed in violation of this section, the entity shall refund such amount on a timely basis to the payor or individual, whichever is applicable.

(e)Any person that presents or causes to be presented a bill or a claim for service that such person knows or should know is for a service for which payment may not be made under paragraph (c), or for which a refund has not been made under paragraph (d), shall be subject to a civil penalty of not more than $15,000 for each such service to be imposed and collected by the appropriate board.

(f)Any health care provider or other entity that enters into an arrangement or scheme, such as a cross-referral arrangement, which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil penalty of not more than $100,000 for each such circumvention arrangement or scheme to be imposed and collected by the appropriate board.

(g)A violation of this section by a health care provider shall constitute grounds for disciplinary action to be taken by the applicable board pursuant to s. 458.331(2), s. 459.015(2), s. 460.413(2), s. 461.013(2), s. 463.016(2), or s. 466.028(2). Any hospital licensed under chapter 395 found in violation of this section shall be subject to the rules adopted by the Agency for Health Care Administration pursuant to s. 395.0185(2).

(h)Any hospital licensed under chapter 395 that discriminates against or otherwise penalizes a

health care provider for compliance with this act.

(i)The provision of paragraph (a) shall not apply to referrals to the offices of radiation therapy centers managed by an entity or subsidiary or general partner thereof, which performed radiation therapy services at those same offices prior to April 1, 1991, and shall not apply also to referrals for radiation therapy to be performed at no more than one additional office of any entity qualifying for the foregoing exception which, prior to February 1, 1992, had a binding purchase contract on and a nonrefundable deposit paid for a linear accelerator to be used at the additional office. The physical site of the radiation treatment centers affected by this provision may be relocated as a result of the following factors: acts of God; fire; strike; accident; war; eminent domain actions by any governmental body; or refusal by the lessor to renew a lease. A relocation for the foregoing reasons is limited to relocation of an existing facility to a replacement location within the county of the existing facility upon written notification to the Office of Licensure and Certification.

(j)A health care provider who meets the requirements of paragraphs (b) and (i) must disclose his or her investment interest to his or her patients as provided in s. 456.052.

History.—s. 7, ch. 92-178; s. 89, ch. 94-218; s. 60, ch. 95-144; s. 35, ch. 95-146; s. 8, ch. 96-296; s. 1083, ch. 97-103; s. 78, ch. 97-261; s. 70, ch. 97-264; s. 263, ch. 98-166; s. 62, ch. 98-171; s. 1, ch. 99-356; s. 10, ch. 2000-159; s. 77, ch. 2000-160; s. 14, ch. 2002-389; s. 23, ch. 2009-223.

Note.—Former s. 455.236; s. 455.654.

456.054Kickbacks prohibited.—

(1)As used in this section, the term "kickback" means a remuneration or payment, by or on behalf of a provider of health care services or items, to any person as an incentive or inducement to refer patients for past or future services or items, when the payment is not tax deductible as an ordinary and necessary expense.

(2)It is unlawful for any health care provider or any provider of health care services to offer, pay, solicit, or receive a kickback, directly or indirectly, overtly or covertly, in cash or in kind, for referring or soliciting patients.

(3)Violations of this section shall be considered patient brokering and shall be punishable as provided in s. 817.505.

History.—s. 8, ch. 92-178; s. 2, ch. 96-152; s. 79, ch. 97-261; s. 8, ch. 99-204; s. 78, ch. 2000-160; s. 6, ch. 2006-305.

Note.—Former s. 455.237; s. 455.657.

456.055Chiropractic and podiatric health care; denial of payment; limitation.—A chiropractic physician licensed under chapter 460 or a podiatric physician licensed under chapter 461 shall not be denied payment for treatment rendered solely on the basis that the chiropractic physician or podiatric physician is not a member of a particular preferred provider organization or exclusive provider organization which is composed only of physicians licensed under the same chapter.

History.—s. 43, ch. 85-167; s. 87, ch. 97-261; ss. 191, 264, ch. 98-166; s. 78, ch. 2000-160.

Note.—Former s. 455.244; s. 455.684.

456.056Treatment of Medicare beneficiaries; refusal, emergencies, consulting physicians.—

(1)Effective as of January 1, 1993, as used in this section, the term:

(a)"Physician" means a physician licensed under chapter 458, an osteopathic physician licensed under chapter 459, a chiropractic physician licensed under chapter 460, a podiatric physician licensed under chapter 461, or an optometrist licensed under chapter 463.

(b)"Beneficiary" means a beneficiary of health insurance under Title XVIII of the federal Social Security Act.

(c)"Consulting physician" means any physician to whom a primary physician refers a Medicare beneficiary for treatment.

(2)A physician may refuse to treat a beneficiary. However, nothing contained in this section shall be construed to limit a physician's obligation under state or federal law to treat a patient for an emergency medical condition, regardless of the patient's ability to pay.

(3)If treatment is provided to a beneficiary for an emergency medical condition as defined in [1]s. 395.0142(2)(c), the physician must accept Medicare assignment provided that the requirement to accept Medicare assignment for an emergency medical condition shall not apply to treatment rendered after the patient is stabilized, or the treatment is unrelated to the original emergency medical condition. For the purpose of this subsection "stabilized" is defined to mean with respect to an emergency medical condition, that no material deterioration of the condition is likely within reasonable medical probability.

(4)If treatment provided to a beneficiary is not for such emergency medical condition, and the primary physician accepts assignment, all consulting physicians must accept assignment unless the patient agrees in writing, before receiving the treatment, that the physician need not accept assignment.

(5)Any attempt by a primary physician or a consulting physician to collect from a Medicare beneficiary any amount of charges for medical services in excess of those authorized under this section, other than the unmet deductible and the 20 percent of charges that Medicare does not pay, shall be deemed null, void, and of no merit.

History.—s. 1, ch. 92-118; s. 160, ch. 92-149; s. 89, ch. 97-261; ss. 192, 265, ch. 98-166; s. 78, ch. 2000-160.

[1]**Note.**—"Emergency medical condition" is no longer defined in s. 395.0142, which was amended and transferred to s. 395.1041 by s. 24, ch. 92-289.

Note.—Former s. 455.2455; s. 455.691.

456.057Ownership and control of patient records; report or copies of records to be furnished.—

(1)As used in this section, the term "records owner" means any health care practitioner who generates a medical record after making a physical or mental examination of, or administering

treatment or dispensing legend drugs to, any person; any health care practitioner to whom records are transferred by a previous records owner; or any health care practitioner's employer, including, but not limited to, group practices and staff-model health maintenance organizations, provided the employment contract or agreement between the employer and the health care practitioner designates the employer as the records owner.

(2)As used in this section, the terms "records owner," "health care practitioner," and "health care practitioner's employer" do not include any of the following persons or entities; furthermore, the following persons or entities are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of this section to maintain those documents required by the part or chapter under which they are licensed or regulated:

(a)Certified nursing assistants regulated under part II of chapter 464.

(b)Pharmacists and pharmacies licensed under chapter 465.

(c)Dental hygienists licensed under s. 466.023.

(d)Nursing home administrators licensed under part II of chapter 468.

(e)Respiratory therapists regulated under part V of chapter 468.

(f)Athletic trainers licensed under part XIII of chapter 468.

(g)Electrologists licensed under chapter 478.

(h)Clinical laboratory personnel licensed under part III of chapter 483.

(i)Medical physicists licensed under part IV of chapter 483.

(j)Opticians and optical establishments licensed or permitted under part I of chapter 484.

(k)Persons or entities practicing under s. 627.736(7).

(3)As used in this section, the term "records custodian" means any person or entity that:

(a)Maintains documents that are authorized in subsection (2); or

(b)Obtains medical records from a records owner.

(4)Any health care practitioner's employer who is a records owner and any records custodian shall maintain records or documents as provided under the confidentiality and disclosure requirements of this section.

(5)This section does not apply to facilities licensed under chapter 395.

(6)Any health care practitioner licensed by the department or a board within the department who makes a physical or mental examination of, or administers treatment or dispenses legend drugs to, any person shall, upon request of such person or the person's legal representative, furnish, in a timely manner, without delays for legal review, copies of all reports and records relating to such examination or treatment, including X rays and insurance information. However, when a patient's psychiatric, chapter 490 psychological, or chapter 491 psychotherapeutic records are requested by the patient or the patient's legal representative, the health care practitioner may provide a report of examination and treatment in lieu of copies of records. Upon a patient's written request, complete copies of the patient's psychiatric records shall be provided directly to a subsequent treating psychiatrist. The

furnishing of such report or copies shall not be conditioned upon payment of a fee for services rendered.

(7)(a)Except as otherwise provided in this section and in s. 440.13(4)(c), such records may not be furnished to, and the medical condition of a patient may not be discussed with, any person other than the patient or the patient's legal representative or other health care practitioners and providers involved in the care or treatment of the patient, except upon written authorization of the patient. However, such records may be furnished without written authorization under the following circumstances:

1.To any person, firm, or corporation that has procured or furnished such examination or treatment with the patient's consent.

2.When compulsory physical examination is made pursuant to Rule 1.360, Florida Rules of Civil Procedure, in which case copies of the medical records shall be furnished to both the defendant and the plaintiff.

3.In any civil or criminal action, unless otherwise prohibited by law, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or the patient's legal representative by the party seeking such records.

4.For statistical and scientific research, provided the information is abstracted in such a way as to protect the identity of the patient or provided written permission is received from the patient or the patient's legal representative.

5.To a regional poison control center for purposes of treating a poison episode under evaluation, case management of poison cases, or compliance with data collection and reporting requirements of s. 395.1027 and the professional organization that certifies poison control centers in accordance with federal law.

(b)Absent a specific written release or authorization permitting utilization of patient information for solicitation or marketing the sale of goods or services, any use of that information for those purposes is prohibited.

(8)Except in a medical negligence action or administrative proceeding when a health care practitioner or provider is or reasonably expects to be named as a defendant, information disclosed to a health care practitioner by a patient in the course of the care and treatment of such patient is confidential and may be disclosed only to other health care practitioners and providers involved in the care or treatment of the patient, or if permitted by written authorization from the patient or compelled by subpoena at a deposition, evidentiary hearing, or trial for which proper notice has been given.

(9)(a)1.The department may obtain patient records pursuant to a subpoena without written authorization from the patient if the department and the probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has excessively or inappropriately prescribed any controlled substance specified in chapter 893 in violation of this chapter

or any professional practice act or that a health care practitioner has practiced his or her profession below that level of care, skill, and treatment required as defined by this chapter or any professional practice act and also find that appropriate, reasonable attempts were made to obtain a patient release. Notwithstanding the foregoing, the department need not attempt to obtain a patient release when investigating an offense involving the inappropriate prescribing, overprescribing, or diversion of controlled substances and the offense involves a pain-management clinic. The department may obtain patient records without patient authorization or subpoena from any pain-management clinic required to be licensed if the department has probable cause to believe that a violation of any provision of s. 458.3265 or s. 459.0137 is occurring or has occurred and reasonably believes that obtaining such authorization is not feasible due to the volume of the dispensing and prescribing activity involving controlled substances and that obtaining patient authorization or the issuance of a subpoena would jeopardize the investigation.

2.The department may obtain patient records and insurance information pursuant to a subpoena without written authorization from the patient if the department and the probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has provided inadequate medical care based on termination of insurance and also find that appropriate, reasonable attempts were made to obtain a patient release.

3.The department may obtain patient records, billing records, insurance information, provider contracts, and all attachments thereto pursuant to a subpoena without written authorization from the patient if the department and probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has submitted a claim, statement, or bill using a billing code that would result in payment greater in amount than would be paid using a billing code that accurately describes the services performed, requested payment for services that were not performed by that health care practitioner, used information derived from a written report of an automobile accident generated pursuant to chapter 316 to solicit or obtain patients personally or through an agent regardless of whether the information is derived directly from the report or a summary of that report or from another person, solicited patients fraudulently, received a kickback as defined in s. 456.054, violated the patient brokering provisions of s. 817.505, or presented or caused to be presented a false or fraudulent insurance claim within the meaning of s. 817.234(1)(a), and also find that, within the meaning of s. 817.234(1)(a), patient authorization cannot be obtained because the patient cannot be located or is deceased, incapacitated, or suspected of being a participant in the fraud or scheme, and if the subpoena is issued for specific and relevant records.

4.Notwithstanding subparagraphs 1.-3., when the department investigates a professional liability claim or undertakes action pursuant to s. 456.049 or s. 627.912, the department may obtain patient records pursuant to a subpoena without written authorization from the patient if the patient refuses to cooperate or if the department attempts to obtain a patient release and the failure to obtain the patient records would be detrimental to the investigation.

(b)Patient records, billing records, insurance information, provider contracts, and all attachments thereto obtained by the department pursuant to this subsection shall be used solely for the purpose of the department and the appropriate regulatory board in disciplinary proceedings. This section does not limit the assertion of the psychotherapist-patient privilege under s. 90.503 in regard to records of treatment for mental or nervous disorders by a medical practitioner licensed pursuant to chapter 458 or chapter 459 who has primarily diagnosed and treated mental and nervous disorders for a period of not less than 3 years, inclusive of psychiatric residency. However, the health care practitioner shall release records of treatment for medical conditions even if the health care practitioner has also treated the patient for mental or nervous disorders. If the department has found reasonable cause under this section and the psychotherapist-patient privilege is asserted, the department may petition the circuit court for an in camera review of the records by expert medical practitioners appointed by the court to determine if the records or any part thereof are protected under the psychotherapist-patient privilege.

(10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

(b)Notwithstanding paragraph (a), all patient records obtained by the department and any other documents maintained by the department which relate to a current or former Medicaid recipient shall be provided to the Medicaid Fraud Control Unit in the Department of Legal Affairs, upon request.

(11)All records owners shall develop and implement policies, standards, and procedures to protect the confidentiality and security of the medical record. Employees of records owners shall be trained in these policies, standards, and procedures.

(12)Records owners are responsible for maintaining a record of all disclosures of information contained in the medical record to a third party, including the purpose of the disclosure request. The record of disclosure may be maintained in the medical record. The third party to whom information is disclosed is prohibited from further disclosing any information in the medical record without the expressed written consent of the patient or the patient's legal representative.

(13)Notwithstanding the provisions of s. 456.058, records owners shall place an advertisement in the local newspaper or notify patients, in writing, when they are terminating practice, retiring, or relocating, and no longer available to patients, and offer patients the opportunity to obtain a copy of their medical record.

(14)Notwithstanding the provisions of s. 456.058, records owners shall notify the appropriate board office when they are terminating practice, retiring, or relocating, and no longer available to patients, specifying who the new records owner is and where medical records can be found.

(15)Whenever a records owner has turned records over to a new records owner, the new records owner shall be responsible for providing a copy of the complete medical record, upon written request, of the patient or the patient's legal representative.

(16)Licensees in violation of the provisions of this section shall be disciplined by the appropriate licensing authority.

(17)The Attorney General is authorized to enforce the provisions of this section for records owners not otherwise licensed by the state, through injunctive relief and fines not to exceed $5,000 per violation.

(18)A health care practitioner or records owner furnishing copies of reports or records or making the reports or records available for digital scanning pursuant to this section shall charge no more than the actual cost of copying, including reasonable staff time, or the amount specified in administrative rule by the appropriate board, or the department when there is no board.

(19)Nothing in this section shall be construed to limit health care practitioner consultations, as necessary.

(20)A records owner shall release to a health care practitioner who, as an employee of the records owner, previously provided treatment to a patient, those records that the health care practitioner actually created or generated when the health care practitioner treated the patient. Records released pursuant to this subsection shall be released only upon written request of the health care practitioner and shall be limited to the notes, plans of care, and orders and summaries that were actually generated by the health care practitioner requesting the record.

(21)The board, or department when there is no board, may temporarily or permanently appoint a person or entity as a custodian of medical records in the event of the death of a practitioner, the mental or physical incapacitation of the practitioner, or the abandonment of medical records by a practitioner. The custodian appointed shall comply with all provisions of this section, including the release of patient records.

History.—s. 1, ch. 79-302; s. 1, ch. 82-22; s. 1, ch. 83-108; s. 81, ch. 83-218; ss. 14, 119, ch. 83-329; s. 2, ch. 84-15; s. 41, ch. 85-175; s. 4, ch. 87-333; s. 9, ch. 88-1; s. 2, ch. 88-208; s. 14, ch. 88-219; s. 6, ch. 88-277; s. 10, ch. 88-392; s. 2, ch. 89-85; s. 14, ch. 89-124; s. 28, ch. 89-289; s. 1, ch. 90-263; s. 11, ch. 91-137; s. 6, ch. 91-140; s. 12, ch. 91-176; s. 4, ch. 91-269; s. 62, ch. 92-33; s. 32, ch. 92-149; s. 23, ch. 93-129; s. 315, ch. 94-119; ss. 90, 91, ch. 94-218; s. 308, ch. 96-406; s. 1084, ch. 97-103; s. 82, ch. 97-261; s. 6, ch. 98-166; s. 12, ch. 99-349; s. 86, ch. 99-397; s. 79, ch. 2000-160; s. 9, ch. 2000-163; s. 114, ch. 2000-318; s. 9, ch. 2001-222; ss. 69, 140, ch. 2001-277; s. 18, ch. 2003-416; s. 4, ch. 2005-256; s. 1, ch. 2006-271; s. 2, ch. 2010-211.

Note.—Former s. 455.241; s. 455.667.

456.0575Duty to notify patients.—Every licensed health care practitioner shall inform each patient, or an individual identified pursuant to s. 765.401(1), in person about adverse incidents that result in serious harm to the patient. Notification of outcomes of care that result in harm to the

patient under this section shall not constitute an acknowledgment of admission of liability, nor can such notifications be introduced as evidence.

History.—s. 8, ch. 2003-416.

456.058Disposition of records of deceased practitioners or practitioners relocating or terminating practice.—Each board created under the provisions of chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 463, part I of chapter 464, chapter 465, chapter 466, part I of chapter 484, chapter 486, chapter 490, or chapter 491, and the department under the provisions of chapter 462, shall provide by rule for the disposition, under that chapter, of the medical records or records of a psychological nature of practitioners which are in existence at the time the practitioner dies, terminates practice, or relocates and is no longer available to patients and which records pertain to the practitioner's patients. The rules shall provide that the records be retained for at least 2 years after the practitioner's death, termination of practice, or relocation. In the case of the death of the practitioner, the rules shall provide for the disposition of such records by the estate of the practitioner.

History.—s. 85, ch. 97-261; s. 80, ch. 2000-160; s. 115, ch. 2000-318.

Note.—Former s. 455.677.

456.059Communications confidential; exceptions.—Communications between a patient and a psychiatrist, as defined in s. 394.455, shall be held confidential and shall not be disclosed except upon the request of the patient or the patient's legal representative. Provision of psychiatric records and reports shall be governed by s. 456.057. Notwithstanding any other provision of this section or s. 90.503, where:

(1)A patient is engaged in a treatment relationship with a psychiatrist;

(2)Such patient has made an actual threat to physically harm an identifiable victim or victims; and

(3)The treating psychiatrist makes a clinical judgment that the patient has the apparent capability to commit such an act and that it is more likely than not that in the near future the patient will carry out that threat,

the psychiatrist may disclose patient communications to the extent necessary to warn any potential victim or to communicate the threat to a law enforcement agency. No civil or criminal action shall be instituted, and there shall be no liability on account of disclosure of otherwise confidential communications by a psychiatrist in disclosing a threat pursuant to this section.

History.—s. 10, ch. 88-1; s. 33, ch. 92-149; s. 43, ch. 96-169; s. 83, ch. 97-261; s. 81, ch. 2000-160.

Note.—Former s. 455.2415; s. 455.671.

456.061Practitioner disclosure of confidential information; immunity from civil or criminal liability.—

(1)A practitioner regulated through the Division of Medical Quality Assurance of the department

shall not be civilly or criminally liable for the disclosure of otherwise confidential information to a sexual partner or a needle-sharing partner under the following circumstances:

(a)If a patient of the practitioner who has tested positive for human immunodeficiency virus discloses to the practitioner the identity of a sexual partner or a needle-sharing partner;

(b)The practitioner recommends the patient notify the sexual partner or the needle-sharing partner of the positive test and refrain from engaging in sexual or drug activity in a manner likely to transmit the virus and the patient refuses, and the practitioner informs the patient of his or her intent to inform the sexual partner or needle-sharing partner; and

(c)If pursuant to a perceived civil duty or the ethical guidelines of the profession, the practitioner reasonably and in good faith advises the sexual partner or the needle-sharing partner of the patient of the positive test and facts concerning the transmission of the virus.

However, any notification of a sexual partner or a needle-sharing partner pursuant to this section shall be done in accordance with protocols developed pursuant to rule of the Department of Health.

(2)Notwithstanding the foregoing, a practitioner regulated through the Division of Medical Quality Assurance of the department shall not be civilly or criminally liable for failure to disclose information relating to a positive test result for human immunodeficiency virus of a patient to a sexual partner or a needle-sharing partner.

History.—s. 43, ch. 88-380; s. 12, ch. 89-350; s. 191, ch. 97-103; s. 84, ch. 97-261; s. 220, ch. 99-8; s. 82, ch. 2000-160.

Note.—Former s. 455.2416; s. 455.674.

456.062Advertisement by a health care practitioner of free or discounted services; required statement.—In any advertisement for a free, discounted fee, or reduced fee service, examination, or treatment by a health care practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, chapter 466, chapter 467, chapter 478, chapter 483, part I of chapter 484, chapter 486, chapter 490, or chapter 491, the following statement shall appear in capital letters clearly distinguishable from the rest of the text: THE PATIENT AND ANY OTHER PERSON RESPONSIBLE FOR PAYMENT HAS A RIGHT TO REFUSE TO PAY, CANCEL PAYMENT, OR BE REIMBURSED FOR PAYMENT FOR ANY OTHER SERVICE, EXAMINATION, OR TREATMENT THAT IS PERFORMED AS A RESULT OF AND WITHIN 72 HOURS OF RESPONDING TO THE ADVERTISEMENT FOR THE FREE, DISCOUNTED FEE, OR REDUCED FEE SERVICE, EXAMINATION, OR TREATMENT. However, the required statement shall not be necessary as an accompaniment to an advertisement of a licensed health care practitioner defined by this section if the advertisement appears in a classified directory the primary purpose of which is to provide products and services at free, reduced, or discounted prices to consumers and in which the statement prominently appears in at least one place.

History.—s. 81, ch. 97-261; s. 85, ch. 99-397; s. 82, ch. 2000-160; s. 1, ch. 2006-215.

Note.—Former s. 455.664.

456.063Sexual misconduct; disqualification for license, certificate, or registration.—

(1)Sexual misconduct in the practice of a health care profession means violation of the professional relationship through which the health care practitioner uses such relationship to engage or attempt to engage the patient or client, or an immediate family member, guardian, or representative of the patient or client in, or to induce or attempt to induce such person to engage in, verbal or physical sexual activity outside the scope of the professional practice of such health care profession. Sexual misconduct in the practice of a health care profession is prohibited.

(2)Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to any examination and refuse to issue a license, certificate, or registration to any applicant if the candidate or applicant has:

(a)Had any license, certificate, or registration to practice any profession or occupation revoked or surrendered based on a violation of sexual misconduct in the practice of that profession under the laws of any other state or any territory or possession of the United States and has not had that license, certificate, or registration reinstated by the licensing authority of the jurisdiction that revoked the license, certificate, or registration; or

(b)Committed any act in any other state or any territory or possession of the United States which if committed in this state would constitute sexual misconduct.

For purposes of this subsection, a licensing authority's acceptance of a candidate's relinquishment of a license which is offered in response to or in anticipation of the filing of administrative charges against the candidate's license constitutes the surrender of the license.

(3)Licensed health care practitioners shall report allegations of sexual misconduct to the department, regardless of the practice setting in which the alleged sexual misconduct occurred.

History.—s. 1, ch. 95-183; s. 52, ch. 97-261; s. 78, ch. 99-397; s. 82, ch. 2000-160; s. 25, ch. 2000-318; s. 70, ch. 2001-277.

Note.—Former s. 455.2142; s. 455.567.

456.0635Health care fraud; disqualification for license, certificate, or registration.—

(1)Health care fraud in the practice of a health care profession is prohibited.

(2)Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to any examination and refuse to issue a license, certificate, or registration to any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:

(a)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the candidate or applicant has successfully completed a drug court program for that felony and provides proof that the plea has been withdrawn or the charges have been dismissed. Any such conviction or plea shall exclude the applicant or

candidate from licensure, examination, certification, or registration unless the sentence and any subsequent period of probation for such conviction or plea ended:

1.For felonies of the first or second degree, more than 15 years before the date of application.

2.For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3.For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application;

(b)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application;

(c)Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the candidate or applicant has been in good standing with the Florida Medicaid program for the most recent 5 years;

(d)Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the candidate or applicant has been in good standing with a state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application; or

(e)Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

This subsection does not apply to candidates or applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2009, which was recognized by a board or, if there is no board, recognized by the department, and who applied for licensure after July 1, 2012.

(3)The department shall refuse to renew a license, certificate, or registration of any applicant if the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:

(a)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the applicant is currently enrolled in a drug court program that allows the withdrawal of the plea for that felony upon successful completion of that program. Any such conviction or plea excludes the applicant from licensure renewal unless the sentence and any subsequent period of probation for such conviction or plea ended:

1.For felonies of the first or second degree, more than 15 years before the date of application.

2.For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3.For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of

application.

(b)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396 since July 1, 2009, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application.

(c)Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.

(d)Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application.

(e)Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(4)Licensed health care practitioners shall report allegations of health care fraud to the department, regardless of the practice setting in which the alleged health care fraud occurred.

(5)The acceptance by a licensing authority of a licensee's relinquishment of a license which is offered in response to or anticipation of the filing of administrative charges alleging health care fraud or similar charges constitutes the permanent revocation of the license.

History.—s. 24, ch. 2009-223; s. 1, ch. 2012-64.

456.065Unlicensed practice of a health care profession; intent; cease and desist notice; penalties; enforcement; citations; fees; allocation and disposition of moneys collected.—

(1)It is the intent of the Legislature that vigorous enforcement of licensure regulation for all health care professions is a state priority in order to protect Florida residents and visitors from the potentially serious and dangerous consequences of receiving medical and health care services from unlicensed persons whose professional education and training and other relevant qualifications have not been approved through the issuance of a license by the appropriate regulatory board or the department when there is no board. The unlicensed practice of a health care profession or the performance or delivery of medical or health care services to patients in this state without a valid, active license to practice that profession, regardless of the means of the performance or delivery of such services, is strictly prohibited.

(2)The penalties for unlicensed practice of a health care profession shall include the following:

(a)When the department has probable cause to believe that any person not licensed by the department, or the appropriate regulatory board within the department, has violated any provision of this chapter or any statute that relates to the practice of a profession regulated by the department, or any rule adopted pursuant thereto, the department may issue and deliver to such person a notice to cease and desist from such violation. In addition, the department may issue and deliver a notice to

cease and desist to any person who aids and abets the unlicensed practice of a profession by employing such unlicensed person. The issuance of a notice to cease and desist shall not constitute agency action for which a hearing under ss. 120.569 and 120.57 may be sought. For the purpose of enforcing a cease and desist order, the department may file a proceeding in the name of the state seeking issuance of an injunction or a writ of mandamus against any person who violates any provisions of such order.

(b)In addition to the remedies under paragraph (a), the department may impose by citation an administrative penalty not to exceed $5,000 per incident. The citation shall be issued to the subject and shall contain the subject's name and any other information the department determines to be necessary to identify the subject, a brief factual statement, the sections of the law allegedly violated, and the penalty imposed. If the subject does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation shall become a final order of the department. The department may adopt rules to implement this section. The penalty shall be a fine of not less than $500 nor more than $5,000 as established by rule of the department. Each day that the unlicensed practice continues after issuance of a notice to cease and desist constitutes a separate violation. The department shall be entitled to recover the costs of investigation and prosecution in addition to the fine levied pursuant to the citation. Service of a citation may be made by personal service or by mail to the subject at the subject's last known address or place of practice. If the department is required to seek enforcement of the cease and desist or agency order, it shall be entitled to collect its attorney's fees and costs.

(c)In addition to or in lieu of any other administrative remedy, the department may seek the imposition of a civil penalty through the circuit court for any violation for which the department may issue a notice to cease and desist. The civil penalty shall be no less than $500 and no more than $5,000 for each offense. The court may also award to the prevailing party court costs and reasonable attorney fees and, in the event the department prevails, may also award reasonable costs of investigation and prosecution.

(d)In addition to the administrative and civil remedies under paragraphs (b) and (c) and in addition to the criminal violations and penalties listed in the individual health care practice acts:

1.It is a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, to practice, attempt to practice, or offer to practice a health care profession without an active, valid Florida license to practice that profession. Practicing without an active, valid license also includes practicing on a suspended, revoked, or void license, but does not include practicing, attempting to practice, or offering to practice with an inactive or delinquent license for a period of up to 12 months which is addressed in subparagraph 3. Applying for employment for a position that requires a license without notifying the employer that the person does not currently possess a valid, active license to practice that profession shall be deemed to be an attempt or offer to practice that health care profession without a license. Holding oneself out, regardless of the means of communication, as able to practice a health care profession or as able to provide services that require a health care license shall

be deemed to be an attempt or offer to practice such profession without a license. The minimum penalty for violating this subparagraph shall be a fine of $1,000 and a minimum mandatory period of incarceration of 1 year.

2.It is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, to practice a health care profession without an active, valid Florida license to practice that profession when such practice results in serious bodily injury. For purposes of this section, “serious bodily injury” means death; brain or spinal damage; disfigurement; fracture or dislocation of bones or joints; limitation of neurological, physical, or sensory function; or any condition that required subsequent surgical repair. The minimum penalty for violating this subparagraph shall be a fine of $1,000 and a minimum mandatory period of incarceration of 1 year.

3.It is a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, to practice, attempt to practice, or offer to practice a health care profession with an inactive or delinquent license for any period of time up to 12 months. However, practicing, attempting to practice, or offering to practice a health care profession when that person’s license has been inactive or delinquent for a period of time of 12 months or more shall be a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. The minimum penalty for violating this subparagraph shall be a term of imprisonment of 30 days and a fine of $500.

(3)Because all enforcement costs should be covered by professions regulated by the department, the department shall impose, upon initial licensure and each licensure renewal, a special fee of $5 per licensee to fund efforts to combat unlicensed activity. Such fee shall be in addition to all other fees collected from each licensee. The department shall make direct charges to the Medical Quality Assurance Trust Fund by profession. The department shall seek board advice regarding enforcement methods and strategies. The department shall directly credit the Medical Quality Assurance Trust Fund, by profession, with the revenues received from the department’s efforts to enforce licensure provisions. The department shall include all financial and statistical data resulting from unlicensed activity enforcement as a separate category in the quarterly management report provided for in s. 456.025. For an unlicensed activity account, a balance which remains at the end of a renewal cycle may, with concurrence of the applicable board and the department, be transferred to the operating fund account of that profession. The department shall also use these funds to inform and educate consumers generally on the importance of using licensed health care practitioners.

(4)The provisions of this section apply only to health care professional practice acts administered by the department.

(5)Nothing herein shall be construed to limit or restrict the sale, use, or recommendation of the use of a dietary supplement, as defined by the Food, Drug, and Cosmetic Act, 21 U.S.C. s. 321, so long as the person selling, using, or recommending the dietary supplement does so in compliance with federal and state law.

History.—s. 73, ch. 97-261; s. 84, ch. 2000-160; s. 35, ch. 2000-318; s. 54, ch. 2001-277.

Note.—Former s. 455.637.

456.066Prosecution of criminal violations.—The department or the appropriate board shall report any criminal violation of any statute relating to the practice of a profession regulated by the department or appropriate board to the proper prosecuting authority for prompt prosecution.

History.—s. 72, ch. 97-261; s. 85, ch. 2000-160.

Note.—Former s. 455.634.

456.067Penalty for giving false information.—In addition to, or in lieu of, any other discipline imposed pursuant to s. 456.072, the act of knowingly giving false information in the course of applying for or obtaining a license from the department, or any board thereunder, with intent to mislead a public servant in the performance of his or her official duties, or the act of attempting to obtain or obtaining a license from the department, or any board thereunder, to practice a profession by knowingly misleading statements or knowing misrepresentations constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—s. 71, ch. 97-261; s. 24, ch. 99-7; s. 86, ch. 2000-160; s. 27, ch. 2000-318.

Note.—Former s. 455.631.

456.068Toll-free telephone number for reporting of complaints.—The Agency for Health Care Administration shall establish a toll-free telephone number for public reporting of complaints relating to medical treatment or services provided by health care professionals.

History.—s. 148, ch. 97-237; s. 24, ch. 97-273; s. 87, ch. 2000-160.

Note.—Former s. 455.699.

456.069Authority to inspect.—In addition to the authority specified in s. 465.017, duly authorized agents and employees of the department shall have the power to inspect in a lawful manner at all reasonable hours:

(1)Any pharmacy; or

(2)Any establishment at which the services of a licensee authorized to prescribe controlled substances specified in chapter 893 are offered,

for the purpose of determining if any of the provisions of this chapter or any practice act of a profession or any rule adopted thereunder is being violated; or for the purpose of securing such other evidence as may be needed for prosecution.

History.—s. 86, ch. 97-261; s. 88, ch. 2000-160.

Note.—Former s. 455.681.

456.071Power to administer oaths, take depositions, and issue subpoenas.—For the purpose of any investigation or proceeding conducted by the department, the department shall have the power to administer oaths, take depositions, make inspections when authorized by statute, issue subpoenas

which shall be supported by affidavit, serve subpoenas and other process, and compel the attendance of witnesses and the production of books, papers, documents, and other evidence. The department shall exercise this power on its own initiative or whenever requested by a board or the probable cause panel of any board. Challenges to, and enforcement of, the subpoenas and orders shall be handled as provided in s. 120.569.

History.—s. 65, ch. 97-261; s. 89, ch. 2000-160.

Note.—Former s. 455.611.

456.072Grounds for discipline; penalties; enforcement.—

(1)The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(a)Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession.

(b)Intentionally violating any rule adopted by the board or the department, as appropriate.

(c)Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

(d)Using a Class III or a Class IV laser device or product, as defined by federal regulations, without having complied with the rules adopted under s. 501.122(2) governing the registration of the devices.

(e)Failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome.

(f)Having a license or the authority to practice any regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law. The licensing authority's acceptance of a relinquishment of licensure, stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as action against the license.

(g)Having been found liable in a civil proceeding for knowingly filing a false report or complaint with the department against another licensee.

(h)Attempting to obtain, obtaining, or renewing a license to practice a profession by bribery, by fraudulent misrepresentation, or through an error of the department or the board.

(i)Except as provided in s. 465.016, failing to report to the department any person who the licensee knows is in violation of this chapter, the chapter regulating the alleged violator, or the rules of the department or the board.

(j)Aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice a profession contrary to this chapter, the chapter regulating the profession, or the rules of the department or the board.

(k)Failing to perform any statutory or legal obligation placed upon a licensee. For purposes of this section, failing to repay a student loan issued or guaranteed by the state or the Federal Government in accordance with the terms of the loan or failing to comply with service scholarship obligations shall be considered a failure to perform a statutory or legal obligation, and the minimum disciplinary action imposed shall be a suspension of the license until new payment terms are agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount. Fines collected shall be deposited into the Medical Quality Assurance Trust Fund.

(l)Making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing another person to do so. Such reports or records shall include only those that are signed in the capacity of a licensee.

(m)Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or scheme in or related to the practice of a profession.

(n)Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party.

(o)Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform.

(p)Delegating or contracting for the performance of professional responsibilities by a person when the licensee delegating or contracting for performance of the responsibilities knows, or has reason to know, the person is not qualified by training, experience, and authorization when required to perform them.

(q)Violating a lawful order of the department or the board, or failing to comply with a lawfully issued subpoena of the department.

(r)Improperly interfering with an investigation or inspection authorized by statute, or with any disciplinary proceeding.

(s)Failing to comply with the educational course requirements for domestic violence.

(t)Failing to identify through written notice, which may include the wearing of a name tag, or orally to a patient the type of license under which the practitioner is practicing. Any advertisement for health care services naming the practitioner must identify the type of license the practitioner holds. This paragraph does not apply to a practitioner while the practitioner is providing services in a facility licensed under chapter 394, chapter 395, chapter 400, or chapter 429. Each board, or the department where there is no board, is authorized by rule to determine how its practitioners may comply with this disclosure requirement.

(u)Failing to comply with the requirements of ss. 381.026 and 381.0261 to provide patients with information about their patient rights and how to file a patient complaint.

(v)Engaging or attempting to engage in sexual misconduct as defined and prohibited in s. 456.063(1).

(w)Failing to comply with the requirements for profiling and credentialing, including, but not limited to, failing to provide initial information, failing to timely provide updated information, or making misleading, untrue, deceptive, or fraudulent representations on a profile, credentialing, or initial or renewal licensure application.

(x)Failing to report to the board, or the department if there is no board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction. Convictions, findings, adjudications, and pleas entered into prior to the enactment of this paragraph must be reported in writing to the board, or department if there is no board, on or before October 1, 1999.

(y)Using information about people involved in motor vehicle accidents which has been derived from accident reports made by law enforcement officers or persons involved in accidents under s. 316.066, or using information published in a newspaper or other news publication or through a radio or television broadcast that has used information gained from such reports, for the purposes of commercial or any other solicitation whatsoever of the people involved in the accidents.

(z)Being unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. In enforcing this paragraph, the department shall have, upon a finding of the State Surgeon General or the State Surgeon General's designee that probable cause exists to believe that the licensee is unable to practice because of the reasons stated in this paragraph, the authority to issue an order to compel a licensee to submit to a mental or physical examination by physicians designated by the department. If the licensee refuses to comply with the order, the department's order directing the examination may be enforced by filing a petition for enforcement in the circuit court where the licensee resides or does business. The department shall be entitled to the summary procedure provided in s. 51.011. A licensee or certificateholder affected under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate that he or she can resume the competent practice of his or her profession with reasonable skill and safety to patients.

(aa)Testing positive for any drug, as defined in s. 112.0455, on any confirmed preemployment or employer-ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using the drug.

(bb)Performing or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition. For the purposes of this paragraph, performing or attempting to perform health care services includes the preparation of the patient.

(cc)Leaving a foreign body in a patient, such as a sponge, clamp, forceps, surgical needle, or other

paraphernalia commonly used in surgical, examination, or other diagnostic procedures. For the purposes of this paragraph, it shall be legally presumed that retention of a foreign body is not in the best interest of the patient and is not within the standard of care of the profession, regardless of the intent of the professional.

(dd)Violating any provision of this chapter, the applicable practice act, or any rules adopted pursuant thereto.

(ee)With respect to making a personal injury protection claim as required by s. 627.736, intentionally submitting a claim, statement, or bill that has been "upcoded" as defined in s. 627.732.

(ff)With respect to making a personal injury protection claim as required by s. 627.736, intentionally submitting a claim, statement, or bill for payment of services that were not rendered.

(gg)Engaging in a pattern of practice when prescribing medicinal drugs or controlled substances which demonstrates a lack of reasonable skill or safety to patients, a violation of any provision of this chapter, a violation of the applicable practice act, or a violation of any rules adopted under this chapter or the applicable practice act of the prescribing practitioner. Notwithstanding s. 456.073(13), the department may initiate an investigation and establish such a pattern from billing records, data, or any other information obtained by the department.

(hh)Being terminated from a treatment program for impaired practitioners, which is overseen by an impaired practitioner consultant as described in s. 456.076, for failure to comply, without good cause, with the terms of the monitoring or treatment contract entered into by the licensee, or for not successfully completing any drug treatment or alcohol treatment program.

(ii)Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518, or 42 U.S.C. ss. 1320a-7b, relating to the Medicaid program.

(jj)Failing to remit the sum owed to the state for an overpayment from the Medicaid program pursuant to a final order, judgment, or stipulation or settlement.

(kk)Being terminated from the state Medicaid program pursuant to s. 409.913, any other state Medicaid program, or the federal Medicare program, unless eligibility to participate in the program from which the practitioner was terminated has been restored.

(ll)Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(mm)Failure to comply with controlled substance prescribing requirements of s. 456.44.

(nn)Violating any of the provisions of s. 790.338.

(2)When the board, or the department when there is no board, finds any person guilty of the grounds set forth in subsection (1) or of any grounds set forth in the applicable practice act, including conduct constituting a substantial violation of subsection (1) or a violation of the applicable practice act which occurred prior to obtaining a license, it may enter an order imposing one or more of the following penalties:

(a)Refusal to certify, or to certify with restrictions, an application for a license.

(b)Suspension or permanent revocation of a license.

(c)Restriction of practice or license, including, but not limited to, restricting the licensee from practicing in certain settings, restricting the licensee to work only under designated conditions or in certain settings, restricting the licensee from performing or providing designated clinical and administrative services, restricting the licensee from practicing more than a designated number of hours, or any other restriction found to be necessary for the protection of the public health, safety, and welfare.

(d)Imposition of an administrative fine not to exceed $10,000 for each count or separate offense. If the violation is for fraud or making a false or fraudulent representation, the board, or the department if there is no board, must impose a fine of $10,000 per count or offense.

(e)Issuance of a reprimand or letter of concern.

(f)Placement of the licensee on probation for a period of time and subject to such conditions as the board, or the department when there is no board, may specify. Those conditions may include, but are not limited to, requiring the licensee to undergo treatment, attend continuing education courses, submit to be reexamined, work under the supervision of another licensee, or satisfy any terms which are reasonably tailored to the violations found.

(g)Corrective action.

(h)Imposition of an administrative fine in accordance with s. 381.0261 for violations regarding patient rights.

(i)Refund of fees billed and collected from the patient or a third party on behalf of the patient.

(j)Requirement that the practitioner undergo remedial education.

In determining what action is appropriate, the board, or department when there is no board, must first consider what sanctions are necessary to protect the public or to compensate the patient. Only after those sanctions have been imposed may the disciplining authority consider and include in the order requirements designed to rehabilitate the practitioner. All costs associated with compliance with orders issued under this subsection are the obligation of the practitioner.

(3)(a)Notwithstanding subsection (2), if the ground for disciplinary action is the first-time failure of the licensee to satisfy continuing education requirements established by the board, or by the department if there is no board, the board or department, as applicable, shall issue a citation in accordance with s. 456.077 and assess a fine, as determined by the board or department by rule. In addition, for each hour of continuing education not completed or completed late, the board or department, as applicable, may require the licensee to take 1 additional hour of continuing education for each hour not completed or completed late.

(b)Notwithstanding subsection (2), if the ground for disciplinary action is the first-time violation of a practice act for unprofessional conduct, as used in ss. 464.018(1)(h), 467.203(1)(f), 468.365(1)(f), and 478.52(1)(f), and no actual harm to the patient occurred, the board or department, as applicable, shall

issue a citation in accordance with s. 456.077 and assess a penalty as determined by rule of the board or department.

(4)In addition to any other discipline imposed through final order, or citation, entered on or after July 1, 2001, under this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is no board, shall assess costs related to the investigation and prosecution of the case. The costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. In any case where the board or the department imposes a fine or assessment and the fine or assessment is not paid within a reasonable time, the reasonable time to be prescribed in the rules of the board, or the department when there is no board, or in the order assessing the fines or costs, the department or the Department of Legal Affairs may contract for the collection of, or bring a civil action to recover, the fine or assessment.

(5)In addition to, or in lieu of, any other remedy or criminal prosecution, the department may file a proceeding in the name of the state seeking issuance of an injunction or a writ of mandamus against any person who violates any of the provisions of this chapter, or any provision of law with respect to professions regulated by the department, or any board therein, or the rules adopted pursuant thereto.

(6)If the board, or the department when there is no board, determines that revocation of a license is the appropriate penalty, the revocation shall be permanent. However, the board may establish by rule requirements for reapplication by applicants whose licenses have been permanently revoked. The requirements may include, but are not limited to, satisfying current requirements for an initial license.

(7)Notwithstanding subsection (2), upon a finding that a physician has prescribed or dispensed a controlled substance, or caused a controlled substance to be prescribed or dispensed, in a manner that violates the standard of practice set forth in s. 458.331(1)(q) or (t), s. 459.015(1)(t) or (x), s. 461.013(1)(o) or (s), or s. 466.028(1)(p) or (x), the physician shall be suspended for a period of not less than 6 months and pay a fine of not less than $10,000 per count. Repeated violations shall result in increased penalties.

(8)The purpose of this section is to facilitate uniform discipline for those actions made punishable under this section and, to this end, a reference to this section constitutes a general reference under the doctrine of incorporation by reference.

History.—s. 69, ch. 97-261; s. 84, ch. 99-397; s. 90, ch. 2000-160; s. 26, ch. 2000-318; s. 71, ch. 2001-277; s. 2, ch. 2002-254; s. 6, ch. 2003-411; s. 19, ch. 2003-416; s. 10, ch. 2004-344; s. 1, ch. 2005-240; s. 2, ch. 2006-207; s. 111, ch. 2007-5; s. 64, ch. 2008-6; s. 25, ch. 2009-223; s. 3, ch. 2011-112; s. 1, ch. 2011-141.

Note.—Former s. 455.624.

456.0721Practitioners in default on student loan or scholarship obligations; investigation; report.—The Department of Health shall obtain from the United States Department of Health and Human Services information necessary to investigate and prosecute health care practitioners for failing to repay a student loan or comply with scholarship service obligations pursuant to s. 456.072(1)(k). The department shall obtain from the United States Department of Health and Human Services a list of default health care practitioners each month, along with the information necessary to investigate a complaint in accordance with s. 456.073. The department may obtain evidence to support the investigation and prosecution from any financial institution or educational institution involved in providing the loan or education to the practitioner. The department shall report to the Legislature as part of the annual report required by s. 456.026, the number of practitioners in default, along with the results of the department's investigations and prosecutions, and the amount of fines collected from practitioners prosecuted for violating s. 456.072(1)(k).

History.—s. 3, ch. 2002-254.

456.073Disciplinary proceedings.—Disciplinary proceedings for each board shall be within the jurisdiction of the department.

(1)The department, for the boards under its jurisdiction, shall cause to be investigated any complaint that is filed before it if the complaint is in writing, signed by the complainant, and legally sufficient. A complaint filed by a state prisoner against a health care practitioner employed by or otherwise providing health care services within a facility of the Department of Corrections is not legally sufficient unless there is a showing that the prisoner complainant has exhausted all available administrative remedies within the state correctional system before filing the complaint. However, if the Department of Health determines after a preliminary inquiry of a state prisoner's complaint that the practitioner may present a serious threat to the health and safety of any individual who is not a state prisoner, the Department of Health may determine legal sufficiency and proceed with discipline. The Department of Health shall be notified within 15 days after the Department of Corrections disciplines or allows a health care practitioner to resign for an offense related to the practice of his or her profession. A complaint is legally sufficient if it contains ultimate facts that show that a violation of this chapter, of any of the practice acts relating to the professions regulated by the department, or of any rule adopted by the department or a regulatory board in the department has occurred. In order to determine legal sufficiency, the department may require supporting information or documentation. The department may investigate, and the department or the appropriate board may take appropriate final action on, a complaint even though the original complainant withdraws it or otherwise indicates a desire not to cause the complaint to be investigated or prosecuted to completion. The department may investigate an anonymous complaint if the complaint is in writing and is legally sufficient, if the alleged violation of law or rules is substantial, and if the department has reason to believe, after preliminary inquiry, that the violations alleged in the complaint are true. The department may

investigate a complaint made by a confidential informant if the complaint is legally sufficient, if the alleged violation of law or rule is substantial, and if the department has reason to believe, after preliminary inquiry, that the allegations of the complainant are true. The department may initiate an investigation if it has reasonable cause to believe that a licensee or a group of licensees has violated a Florida statute, a rule of the department, or a rule of a board. Notwithstanding subsection (13), the department may investigate information filed pursuant to s. 456.041(4) relating to liability actions with respect to practitioners licensed under chapter 458 or chapter 459 which have been reported under s. 456.049 or s. 627.912 within the previous 6 years for any paid claim that exceeds $50,000. Except as provided in ss. 458.331(9), 459.015(9), 460.413(5), and 461.013(6), when an investigation of any subject is undertaken, the department shall promptly furnish to the subject or the subject's attorney a copy of the complaint or document that resulted in the initiation of the investigation. The subject may submit a written response to the information contained in such complaint or document within 20 days after service to the subject of the complaint or document. The subject's written response shall be considered by the probable cause panel. The right to respond does not prohibit the issuance of a summary emergency order if necessary to protect the public. However, if the State Surgeon General, or the State Surgeon General's designee, and the chair of the respective board or the chair of its probable cause panel agree in writing that such notification would be detrimental to the investigation, the department may withhold notification. The department may conduct an investigation without notification to any subject if the act under investigation is a criminal offense.

(2)The department shall allocate sufficient and adequately trained staff to expeditiously and thoroughly determine legal sufficiency and investigate all legally sufficient complaints. For purposes of this section, it is the intent of the Legislature that the term "expeditiously" means that the department complete the report of its initial investigative findings and recommendations concerning the existence of probable cause within 6 months after its receipt of the complaint. The failure of the department, for disciplinary cases under its jurisdiction, to comply with the time limits of this section while investigating a complaint against a licensee constitutes harmless error in any subsequent disciplinary action unless a court finds that either the fairness of the proceeding or the correctness of the action may have been impaired by a material error in procedure or a failure to follow prescribed procedure. When its investigation is complete and legally sufficient, the department shall prepare and submit to the probable cause panel of the appropriate regulatory board the investigative report of the department. The report shall contain the investigative findings and the recommendations of the department concerning the existence of probable cause. The department shall not recommend a letter of guidance in lieu of finding probable cause if the subject has already been issued a letter of guidance for a related offense. At any time after legal sufficiency is found, the department may dismiss any case, or any part thereof, if the department determines that there is insufficient evidence to support the prosecution of allegations contained therein. The department shall provide a detailed report to the appropriate probable cause panel prior to dismissal of any case or part thereof, and to the subject of

the complaint after dismissal of any case or part thereof, under this section. For cases dismissed prior to a finding of probable cause, such report is confidential and exempt from s. 119.07(1). The probable cause panel shall have access, upon request, to the investigative files pertaining to a case prior to dismissal of such case. If the department dismisses a case, the probable cause panel may retain independent legal counsel, employ investigators, and continue the investigation and prosecution of the case as it deems necessary.

(3)As an alternative to the provisions of subsections (1) and (2), when a complaint is received, the department may provide a licensee with a notice of noncompliance for an initial offense of a minor violation. Each board, or the department if there is no board, shall establish by rule those minor violations under this provision which do not endanger the public health, safety, and welfare and which do not demonstrate a serious inability to practice the profession. Failure of a licensee to take action in correcting the violation within 15 days after notice may result in the institution of regular disciplinary proceedings.

(4)The determination as to whether probable cause exists shall be made by majority vote of a probable cause panel of the board, or by the department, as appropriate. Each regulatory board shall provide by rule that the determination of probable cause shall be made by a panel of its members or by the department. Each board may provide by rule for multiple probable cause panels composed of at least two members. Each board may provide by rule that one or more members of the panel or panels may be a former board member. The length of term or repetition of service of any such former board member on a probable cause panel may vary according to the direction of the board when authorized by board rule. Any probable cause panel must include one of the board's former or present consumer members, if one is available, is willing to serve, and is authorized to do so by the board chair. Any probable cause panel must include a present board member. Any probable cause panel must include a former or present professional board member. However, any former professional board member serving on the probable cause panel must hold an active valid license for that profession. All proceedings of the panel are exempt from s. 286.011 until 10 days after probable cause has been found to exist by the panel or until the subject of the investigation waives his or her privilege of confidentiality. The probable cause panel may make a reasonable request, and upon such request the department shall provide such additional investigative information as is necessary to the determination of probable cause. A request for additional investigative information shall be made within 15 days from the date of receipt by the probable cause panel of the investigative report of the department or the agency. The probable cause panel or the department, as may be appropriate, shall make its determination of probable cause within 30 days after receipt by it of the final investigative report of the department. The State Surgeon General may grant extensions of the 15-day and the 30-day time limits. In lieu of a finding of probable cause, the probable cause panel, or the department if there is no board, may issue a letter of guidance to the subject. If, within the 30-day time limit, as may be extended, the probable cause panel does not make a determination regarding the existence of probable cause or does not issue

a letter of guidance in lieu of a finding of probable cause, the department must make a determination regarding the existence of probable cause within 10 days after the expiration of the time limit. If the probable cause panel finds that probable cause exists, it shall direct the department to file a formal complaint against the licensee. The department shall follow the directions of the probable cause panel regarding the filing of a formal complaint. If directed to do so, the department shall file a formal complaint against the subject of the investigation and prosecute that complaint pursuant to chapter 120. However, the department may decide not to prosecute the complaint if it finds that probable cause has been improvidently found by the panel. In such cases, the department shall refer the matter to the board. The board may then file a formal complaint and prosecute the complaint pursuant to chapter 120. The department shall also refer to the board any investigation or disciplinary proceeding not before the Division of Administrative Hearings pursuant to chapter 120 or otherwise completed by the department within 1 year after the filing of a complaint. The department, for disciplinary cases under its jurisdiction, must establish a uniform reporting system to quarterly refer to each board the status of any investigation or disciplinary proceeding that is not before the Division of Administrative Hearings or otherwise completed by the department within 1 year after the filing of the complaint. Annually, the department, in consultation with the applicable probable cause panel, must establish a plan to expedite or otherwise close any investigation or disciplinary proceeding that is not before the Division of Administrative Hearings or otherwise completed by the department within 1 year after the filing of the complaint. A probable cause panel or a board may retain independent legal counsel, employ investigators, and continue the investigation as it deems necessary; all costs thereof shall be paid from a trust fund used by the department to implement this chapter. All proceedings of the probable cause panel are exempt from s. 120.525.

(5)A formal hearing before an administrative law judge from the Division of Administrative Hearings shall be held pursuant to chapter 120 if there are any disputed issues of material fact. The determination of whether or not a licensee has violated the laws and rules regulating the profession, including a determination of the reasonable standard of care, is a conclusion of law to be determined by the board, or department when there is no board, and is not a finding of fact to be determined by an administrative law judge. The administrative law judge shall issue a recommended order pursuant to chapter 120. Notwithstanding s. 120.569(2), the department shall notify the division within 45 days after receipt of a petition or request for a formal hearing.

(6)The appropriate board, with those members of the panel, if any, who reviewed the investigation pursuant to subsection (4) being excused, or the department when there is no board, shall determine and issue the final order in each disciplinary case. Such order shall constitute final agency action. Any consent order or agreed-upon settlement shall be subject to the approval of the department.

(7)The department shall have standing to seek judicial review of any final order of the board, pursuant to s. 120.68.

(8)Any proceeding for the purpose of summary suspension of a license, or for the restriction of the

license, of a licensee pursuant to s. 120.60(6) shall be conducted by the State Surgeon General or his or her designee, as appropriate, who shall issue the final summary order.

(9)(a)The department shall periodically notify the person who filed the complaint, as well as the patient or the patient's legal representative, of the status of the investigation, indicating whether probable cause has been found and the status of any civil action or administrative proceeding or appeal.

(b)In any disciplinary case for which probable cause has been found, the department shall provide to the person who filed the complaint a copy of the administrative complaint and:

1.A written explanation of how an administrative complaint is resolved by the disciplinary process.

2.A written explanation of how and when the person may participate in the disciplinary process.

3.A written notice of any hearing before the Division of Administrative Hearings or the regulatory board at which final agency action may be taken.

(c)In any disciplinary case for which probable cause is not found, the department shall so inform the person who filed the complaint and notify that person that he or she may, within 60 days, provide any additional information to the department which may be relevant to the decision. To facilitate the provision of additional information, the person who filed the complaint may receive, upon request, a copy of the department's expert report that supported the recommendation for closure, if such a report was relied upon by the department. In no way does this require the department to procure an expert opinion or report if none was used. Additionally, the identity of the expert shall remain confidential. In any administrative proceeding under s. 120.57, the person who filed the disciplinary complaint shall have the right to present oral or written communication relating to the alleged disciplinary violations or to the appropriate penalty.

(10)The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) until 10 days after probable cause has been found to exist by the probable cause panel or by the department, or until the regulated professional or subject of the investigation waives his or her privilege of confidentiality, whichever occurs first. Upon completion of the investigation and a recommendation by the department to find probable cause, and pursuant to a written request by the subject or the subject's attorney, the department shall provide the subject an opportunity to inspect the investigative file or, at the subject's expense, forward to the subject a copy of the investigative file. Notwithstanding s. 456.057, the subject may inspect or receive a copy of any expert witness report or patient record connected with the investigation if the subject agrees in writing to maintain the confidentiality of any information received under this subsection until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to s. 456.057. The subject may file a written response to the information contained in the investigative file. Such response must be filed within 20 days of mailing by the department, unless an extension of time has been granted by the department. This subsection does not prohibit the department from providing such information to any law enforcement agency or to any other regulatory agency.

(11)A privilege against civil liability is hereby granted to any complainant or any witness with regard to information furnished with respect to any investigation or proceeding pursuant to this section, unless the complainant or witness acted in bad faith or with malice in providing such information.

(12)(a)No person who reports in any capacity, whether or not required by law, information to the department with regard to the incompetence, impairment, or unprofessional conduct of any health care provider licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, or chapter 466 shall be held liable in any civil action for reporting against such health care provider if such person acts without intentional fraud or malice.

(b)No facility licensed under chapter 395, health maintenance organization certificated under part I of chapter 641, physician licensed under chapter 458, or osteopathic physician licensed under chapter 459 shall discharge, threaten to discharge, intimidate, or coerce any employee or staff member by reason of such employee's or staff member's report to the department about a physician licensed under chapter 458, chapter 459, chapter 460, chapter 461, or chapter 466 who may be guilty of incompetence, impairment, or unprofessional conduct so long as such report is given without intentional fraud or malice.

(c)In any civil suit brought outside the protections of paragraphs (a) and (b) in which intentional fraud or malice is alleged, the person alleging intentional fraud or malice shall be liable for all court costs and for the other party's reasonable attorney's fees if intentional fraud or malice is not proved.

(13)Notwithstanding any provision of law to the contrary, an administrative complaint against a licensee shall be filed within 6 years after the time of the incident or occurrence giving rise to the complaint against the licensee. If such incident or occurrence involved criminal actions, diversion of controlled substances, sexual misconduct, or impairment by the licensee, this subsection does not apply to bar initiation of an investigation or filing of an administrative complaint beyond the 6-year timeframe. In those cases covered by this subsection in which it can be shown that fraud, concealment, or intentional misrepresentation of fact prevented the discovery of the violation of law, the period of limitations is extended forward, but in no event to exceed 12 years after the time of the incident or occurrence.

History.—s. 68, ch. 97-261; s. 23, ch. 99-7; s. 114, ch. 2000-153; s. 91, ch. 2000-160; ss. 14, 72, ch. 2001-277; s. 5, ch. 2002-254; s. 1, ch. 2003-27; s. 20, ch. 2003-416; s. 65, ch. 2008-6.

Note.—Former s. 455.621.

456.074Certain health care practitioners; immediate suspension of license.—

(1)The department shall issue an emergency order suspending the license of any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, chapter 466, or chapter 484 who pleads guilty to, is convicted or found guilty of, or who enters a plea of nolo contendere to, regardless of adjudication, to:

(a)A felony under chapter 409, chapter 817, or chapter 893 or under 21 U.S.C. ss. 801-970 or under 42 U.S.C. ss. 1395-1396; or

(b)A misdemeanor or felony under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518 or 42 U.S.C. ss. 1320a-7b, relating to the Medicaid program.

(2)If the board has previously found any physician or osteopathic physician in violation of the provisions of s. 458.331(1)(t) or s. 459.015(1)(x), in regard to her or his treatment of three or more patients, and the probable cause panel of the board finds probable cause of an additional violation of that section, then the State Surgeon General shall review the matter to determine if an emergency suspension or restriction order is warranted. Nothing in this section shall be construed so as to limit the authority of the State Surgeon General to issue an emergency order.

(3)The department may issue an emergency order suspending or restricting the license of any health care practitioner as defined in s. 456.001(4) who tests positive for any drug on any government or private sector preemployment or employer-ordered confirmed drug test, as defined in s. 112.0455, when the practitioner does not have a lawful prescription and legitimate medical reason for using such drug. The practitioner shall be given 48 hours from the time of notification to the practitioner of the confirmed test result to produce a lawful prescription for the drug before an emergency order is issued.

(4)Upon receipt of information that a Florida-licensed health care practitioner has defaulted on a student loan issued or guaranteed by the state or the Federal Government, the department shall notify the licensee by certified mail that he or she shall be subject to immediate suspension of license unless, within 45 days after the date of mailing, the licensee provides proof that new payment terms have been agreed upon by all parties to the loan. The department shall issue an emergency order suspending the license of any licensee who, after 45 days following the date of mailing from the department, has failed to provide such proof. Production of such proof shall not prohibit the department from proceeding with disciplinary action against the licensee pursuant to s. 456.073.

History.—s. 88, ch. 97-261; s. 25, ch. 99-7; s. 87, ch. 99-397; s. 92, ch. 2000-160; s. 73, ch. 2001-277; s. 1, ch. 2002-254; s. 66, ch. 2008-6; s. 26, ch. 2009-223.

Note.—Former s. 455.687.

456.075Criminal proceedings against licensees; appearances by department representatives.—In any criminal proceeding against a person licensed by the department to practice a health care profession in this state, a representative of the department may voluntarily appear and furnish pertinent information, make recommendations regarding specific conditions of probation, or provide any other assistance necessary to promote justice or protect the public. The court may order a representative of the department to appear in any criminal proceeding if the crime charged is substantially related to the qualifications, functions, or duties of a health care professional licensed by the department.

History.—s. 1, ch. 2002-81.

456.076Treatment programs for impaired practitioners.—

(1)For professions that do not have impaired practitioner programs provided for in their practice acts, the department shall, by rule, designate approved impaired practitioner programs under this section. The department may adopt rules setting forth appropriate criteria for approval of treatment providers. The rules may specify the manner in which the consultant, retained as set forth in subsection (2), works with the department in intervention, requirements for evaluating and treating a professional, requirements for continued care of impaired professionals by approved treatment providers, continued monitoring by the consultant of the care provided by approved treatment providers regarding the professionals under their care, and requirements related to the consultant's expulsion of professionals from the program.

(2)The department shall retain one or more impaired practitioner consultants. The consultant shall be a licensee under the jurisdiction of the Division of Medical Quality Assurance within the department who must be a practitioner or recovered practitioner licensed under chapter 458, chapter 459, or part I of chapter 464, or an entity employing a medical director who must be a practitioner or recovered practitioner licensed under chapter 458, chapter 459, or part I of chapter 464. The consultant shall assist the probable cause panel and department in carrying out the responsibilities of this section. This shall include working with department investigators to determine whether a practitioner is, in fact, impaired. The consultant may contract for services to be provided, for appropriate compensation, if requested by the school, for students enrolled in schools for licensure as allopathic physicians or physician assistants under chapter 458, osteopathic physicians or physician assistants under chapter 459, nurses under chapter 464, or pharmacists under chapter 465 who are alleged to be impaired as a result of the misuse or abuse of alcohol or drugs, or both, or due to a mental or physical condition. The department is not responsible under any circumstances for paying the costs of care provided by approved treatment providers, and the department is not responsible for paying the costs of consultants' services provided for students. A medical school accredited by the Liaison Committee on Medical Education of the Commission on Osteopathic College Accreditation, or other school providing for the education of students enrolled in preparation for licensure as allopathic physicians under chapter 458 or osteopathic physicians under chapter 459, which is governed by accreditation standards requiring notice and the provision of due process procedures to students, is not liable in any civil action for referring a student to the consultant retained by the department or for disciplinary actions that adversely affect the status of a student when the disciplinary actions are instituted in reasonable reliance on the recommendations, reports, or conclusions provided by such consultant, if the school, in referring the student or taking disciplinary action, adheres to the due process procedures adopted by the applicable accreditation entities and if the school committed no intentional fraud in carrying out the provisions of this section.

(3)(a)Whenever the department receives a written or oral legally sufficient complaint alleging that a licensee under the jurisdiction of the Division of Medical Quality Assurance within the department is impaired as a result of the misuse or abuse of alcohol or drugs, or both, or due to a mental or physical condition which could affect the licensee's ability to practice with skill and safety, and no complaint against the licensee other than impairment exists, the reporting of such information shall not constitute grounds for discipline pursuant to s. 456.072 or the corresponding grounds for discipline within the applicable practice act if the probable cause panel of the appropriate board, or the department when there is no board, finds:

1.The licensee has acknowledged the impairment problem.

2.The licensee has voluntarily enrolled in an appropriate, approved treatment program.

3.The licensee has voluntarily withdrawn from practice or limited the scope of practice as required by the consultant, in each case, until such time as the panel, or the department when there is no board, is satisfied the licensee has successfully completed an approved treatment program.

4.The licensee has executed releases for medical records, authorizing the release of all records of evaluations, diagnoses, and treatment of the licensee, including records of treatment for emotional or mental conditions, to the consultant. The consultant shall make no copies or reports of records that do not regard the issue of the licensee's impairment and his or her participation in a treatment program.

(b)If, however, the department has not received a legally sufficient complaint and the licensee agrees to withdraw from practice until such time as the consultant determines the licensee has satisfactorily completed an approved treatment program or evaluation, the probable cause panel, or the department when there is no board, shall not become involved in the licensee's case.

(c)Inquiries related to impairment treatment programs designed to provide information to the licensee and others and which do not indicate that the licensee presents a danger to the public shall not constitute a complaint within the meaning of s. 456.073 and shall be exempt from the provisions of this subsection.

(d)Whenever the department receives a legally sufficient complaint alleging that a licensee is impaired as described in paragraph (a) and no complaint against the licensee other than impairment exists, the department shall forward all information in its possession regarding the impaired licensee to the consultant. For the purposes of this section, a suspension from hospital staff privileges due to the impairment does not constitute a complaint.

(e)The probable cause panel, or the department when there is no board, shall work directly with the consultant, and all information concerning a practitioner obtained from the consultant by the panel, or the department when there is no board, shall remain confidential and exempt from the provisions of s. 119.07(1), subject to the provisions of subsections (5) and (6).

(f)A finding of probable cause shall not be made as long as the panel, or the department when there is no board, is satisfied, based upon information it receives from the consultant and the department, that the licensee is progressing satisfactorily in an approved impaired practitioner

program and no other complaint against the licensee exists.

(4)In any disciplinary action for a violation other than impairment in which a licensee establishes the violation for which the licensee is being prosecuted was due to or connected with impairment and further establishes the licensee is satisfactorily progressing through or has successfully completed an approved treatment program pursuant to this section, such information may be considered by the board, or the department when there is no board, as a mitigating factor in determining the appropriate penalty. This subsection does not limit mitigating factors the board may consider.

(5)(a)An approved treatment provider shall, upon request, disclose to the consultant all information in its possession regarding the issue of a licensee's impairment and participation in the treatment program. All information obtained by the consultant and department pursuant to this section is confidential and exempt from the provisions of s. 119.07(1), subject to the provisions of this subsection and subsection (6). Failure to provide such information to the consultant is grounds for withdrawal of approval of such program or provider.

(b)If in the opinion of the consultant, after consultation with the treatment provider, an impaired licensee has not progressed satisfactorily in a treatment program, all information regarding the issue of a licensee's impairment and participation in a treatment program in the consultant's possession shall be disclosed to the department. Such disclosure shall constitute a complaint pursuant to the general provisions of s. 456.073. Whenever the consultant concludes that impairment affects a licensee's practice and constitutes an immediate, serious danger to the public health, safety, or welfare, that conclusion shall be communicated to the State Surgeon General.

(6)A consultant, licensee, or approved treatment provider who makes a disclosure pursuant to this section is not subject to civil liability for such disclosure or its consequences. The provisions of s. 766.101 apply to any officer, employee, or agent of the department or the board and to any officer, employee, or agent of any entity with which the department has contracted pursuant to this section.

(7)(a)A consultant retained pursuant to subsection (2), a consultant's officers and employees, and those acting at the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to perform such intervention shall be considered agents of the department for purposes of s. 768.28 while acting within the scope of the consultant's duties under the contract with the department if the contract complies with the requirements of this section. The contract must require that:

1.The consultant indemnify the state for any liabilities incurred up to the limits set out in chapter 768.

2.The consultant establish a quality assurance program to monitor services delivered under the contract.

3.The consultant's quality assurance program, treatment, and monitoring records be evaluated quarterly.

4.The consultant's quality assurance program be subject to review and approval by the

department.

5.The consultant operate under policies and procedures approved by the department.

6.The consultant provide to the department for approval a policy and procedure manual that comports with all statutes, rules, and contract provisions approved by the department.

7.The department be entitled to review the records relating to the consultant's performance under the contract for the purpose of management audits, financial audits, or program evaluation.

8.All performance measures and standards be subject to verification and approval by the department.

9.The department be entitled to terminate the contract with the consultant for noncompliance with the contract.

(b)In accordance with s. 284.385, the Department of Financial Services shall defend any claim, suit, action, or proceeding against the consultant, the consultant's officers or employees, or those acting at the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to perform such intervention which is brought as a result of any act or omission by any of the consultant's officers and employees and those acting under the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to perform such intervention when such act or omission arises out of and in the scope of the consultant's duties under its contract with the department.

(c)If the consultant retained pursuant to subsection (2) is retained by any other state agency, and if the contract between such state agency and the consultant complies with the requirements of this section, the consultant, the consultant's officers and employees, and those acting under the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to perform such intervention shall be considered agents of the state for the purposes of this section while acting within the scope of and pursuant to guidelines established in the contract between such state agency and the consultant.

History.—s. 38, ch. 92-149; s. 1, ch. 95-139; s. 310, ch. 96-406; s. 1085, ch. 97-103; s. 3, ch. 97-209; s. 94, ch. 97-261; s. 2, ch. 98-130; s. 94, ch. 2000-160; ss. 29, 117, ch. 2000-318; s. 67, ch. 2008-6; s. 1, ch. 2008-63.

Note.—Former s. 455.261; s. 455.707.

456.077Authority to issue citations.—

(1)Notwithstanding s. 456.073, the board, or the department if there is no board, shall adopt rules to permit the issuance of citations. The citation shall be issued to the subject and shall contain the subject's name and address, the subject's license number if applicable, a brief factual statement, the sections of the law allegedly violated, and the penalty imposed. The citation must clearly state that the subject may choose, in lieu of accepting the citation, to follow the procedure under s. 456.073. If the subject disputes the matter in the citation, the procedures set forth in s. 456.073 must be

followed. However, if the subject does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation becomes a public final order and does not constitute discipline for a first offense, but does constitute discipline for a second or subsequent offense. The penalty shall be a fine or other conditions as established by rule.

(2)The board, or the department if there is no board, shall adopt rules designating violations for which a citation may be issued. Such rules shall designate as citation violations those violations for which there is no substantial threat to the public health, safety, and welfare or no violation of standard of care involving injury to a patient. Violations for which a citation may be issued shall include violations of continuing education requirements; failure to timely pay required fees and fines; failure to comply with the requirements of ss. 381.026 and 381.0261 regarding the dissemination of information regarding patient rights; failure to comply with advertising requirements; failure to timely update practitioner profile and credentialing files; failure to display signs, licenses, and permits; failure to have required reference books available; and all other violations that do not pose a direct and serious threat to the health and safety of the patient or involve a violation of standard of care that has resulted in injury to a patient.

(3)The department shall be entitled to recover the costs of investigation, in addition to any penalty provided according to board or department rule, as part of the penalty levied pursuant to the citation.

(4)A citation must be issued within 6 months after the filing of the complaint that is the basis for the citation.

(5)Service of a citation may be made by personal service or certified mail, restricted delivery, to the subject at the subject's last known address.

(6)A board has 6 months in which to enact rules designating violations and penalties appropriate for citation offenses. Failure to enact such rules gives the department exclusive authority to adopt rules as required for implementing this section. A board has continuous authority to amend its rules adopted pursuant to this section.

History.—s. 67, ch. 97-261; s. 95, ch. 2000-160; s. 74, ch. 2001-277; s. 21, ch. 2003-416.

Note.—Former s. 455.617.

456.078Mediation.—

(1)Notwithstanding the provisions of s. 456.073, the board, or the department when there is no board, shall adopt rules to designate which violations of the applicable professional practice act are appropriate for mediation. The board, or the department when there is no board, shall designate as mediation offenses those complaints where harm caused by the licensee:

(a)Is economic in nature except any act or omission involving intentional misconduct;

(b)Can be remedied by the licensee;

(c)Is not a standard of care violation involving any type of injury to a patient; or

(d)Does not result in an adverse incident.

(2)For the purposes of this section, an “adverse incident” means an event that results in:

(a)The death of a patient;

(b)Brain or spinal damage to a patient;

(c)The performance of a surgical procedure on the wrong patient;

(d)The performance of a wrong-site surgical procedure;

(e)The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient’s diagnosis or medical condition;

(f)The surgical repair of damage to a patient resulting from a planned surgical procedure, which damage is not a recognized specific risk as disclosed to the patient and documented through the informed-consent process;

(g)The performance of a procedure to remove unplanned foreign objects remaining from a surgical procedure; or

(h)The performance of any other surgical procedure that breached the standard of care.

(3)After the department determines a complaint is legally sufficient and the alleged violations are defined as mediation offenses, the department or any agent of the department may conduct informal mediation to resolve the complaint. If the complainant and the subject of the complaint agree to a resolution of a complaint within 14 days after contact by the mediator, the mediator shall notify the department of the terms of the resolution. The department or board shall take no further action unless the complainant and the subject each fail to record with the department an acknowledgment of satisfaction of the terms of mediation within 60 days of the mediator’s notification to the department. A successful mediation shall not constitute discipline. In the event the complainant and subject fail to reach settlement terms or to record the required acknowledgment, the department shall process the complaint according to the provisions of s. 456.073.

(4)Conduct or statements made during mediation are inadmissible in any proceeding pursuant to s. 456.073. Further, any information relating to the mediation of a case shall be subject to the confidentiality provisions of s. 456.073.

(5)No licensee shall go through the mediation process more than three times without approval of the department. The department may consider the subject and dates of the earlier complaints in rendering its decision. Such decision shall not be considered a final agency action for purposes of chapter 120.

(6)Any board created on or after January 1, 1995, shall have 6 months to adopt rules designating which violations are appropriate for mediation, after which time the department shall have exclusive authority to adopt rules pursuant to this section. A board shall have continuing authority to amend its rules adopted pursuant to this section.

History.—s. 66, ch. 97-261; s. 96, ch. 2000-160; s. 22, ch. 2003-416.

Note.—Former s. 455.614.

456.079Disciplinary guidelines.—

(1)Each board, or the department if there is no board, shall adopt by rule and periodically review the disciplinary guidelines applicable to each ground for disciplinary action which may be imposed by the board, or the department if there is no board, pursuant to this chapter, the respective practice acts, and any rule of the board or department.

(2)The disciplinary guidelines shall specify a meaningful range of designated penalties based upon the severity and repetition of specific offenses, it being the legislative intent that minor violations be distinguished from those which endanger the public health, safety, or welfare; that such guidelines provide reasonable and meaningful notice to the public of likely penalties which may be imposed for proscribed conduct; and that such penalties be consistently applied by the board.

(3)A specific finding in the final order of mitigating or aggravating circumstances shall allow the board to impose a penalty other than that provided for in such guidelines. If applicable, the board, or the department if there is no board, shall adopt by rule disciplinary guidelines to designate possible mitigating and aggravating circumstances and the variation and range of penalties permitted for such circumstances.

(4)The department must review such disciplinary guidelines for compliance with the legislative intent as set forth herein to determine whether the guidelines establish a meaningful range of penalties and may also challenge such rules pursuant to s. 120.56.

(5)The administrative law judge, in recommending penalties in any recommended order, must follow the penalty guidelines established by the board or department and must state in writing the mitigating or aggravating circumstances upon which the recommended penalty is based.

History.—s. 70, ch. 97-261; s. 97, ch. 2000-160; s. 16, ch. 2001-277.

Note.—Former s. 455.627.

456.081Publication of information.—The department and the boards shall have the authority to advise licensees periodically, through the publication of a newsletter on the department's website, about information that the department or the board determines is of interest to the industry. The department and the boards shall maintain a website which contains copies of the newsletter; information relating to adverse incident reports without identifying the patient, practitioner, or facility in which the adverse incident occurred until 10 days after probable cause is found, at which time the name of the practitioner and facility shall become public as part of the investigative file; information about error prevention and safety strategies; and information concerning best practices. Unless otherwise prohibited by law, the department and the boards shall publish on the website a summary of final orders entered after July 1, 2001, resulting in disciplinary action, and any other information the department or the board determines is of interest to the public. In order to provide useful and timely information at minimal cost, the department and boards may consult with, and include information provided by, professional associations and national organizations.

History.—s. 44, ch. 97-261; s. 98, ch. 2000-160; ss. 15, 75, ch. 2001-277.

Note.—Former s. 455.537.

456.082Disclosure of confidential information.—

(1)No officer, employee, or person under contract with the department, or any board therein, or any subject of an investigation shall convey knowledge or information to any person who is not lawfully entitled to such knowledge or information about any public meeting or public record, which at the time such knowledge or information is conveyed is exempt from the provisions of s. 119.01, s. 119.07(1), or s. 286.011.

(2)Any person who willfully violates any provision of this section is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, and may be subject to discipline pursuant to s. 456.072, and, if applicable, shall be removed from office, employment, or the contractual relationship.

(3)Any person injured as a result of a willful violation of this section shall have a civil cause of action for treble damages, reasonable attorney fees, and costs.

History.—s. 77, ch. 97-261; s. 37, ch. 98-166; s. 7, ch. 99-356; s. 188, ch. 99-397; s. 99, ch. 2000-160; s. 27, ch. 2000-318.

Note.—Former s. 455.651.

456.36Health care professionals; exemption from disqualification from employment or contracting.—Any other provision of law to the contrary notwithstanding, only the appropriate regulatory board, or the department when there is no board, may grant an exemption from disqualification from employment or contracting as provided in s. 435.07 to a person under the licensing jurisdiction of that board or the department, as applicable.

History.—s. 34, ch. 2000-318.

456.38Practitioner registry for disasters and emergencies.—The Department of Health may include on its forms for the licensure or certification of health care practitioners, as defined in s. 456.001, who could assist the department in the event of a disaster a question asking if the practitioner would be available to provide health care services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disaster. The names of practitioners who answer affirmatively shall be maintained by the department as a health care practitioner registry for disasters and emergencies.

History.—s. 20, ch. 2000-140.

456.41Complementary or alternative health care treatments.—

(1)LEGISLATIVE INTENT.—It is the intent of the Legislature that citizens be able to make informed choices for any type of health care they deem to be an effective option for treating human disease,

pain, injury, deformity, or other physical or mental condition. It is the intent of the Legislature that citizens be able to choose from all health care options, including the prevailing or conventional treatment methods as well as other treatments designed to complement or substitute for the prevailing or conventional treatment methods. It is the intent of the Legislature that health care practitioners be able to offer complementary or alternative health care treatments with the same requirements, provisions, and liabilities as those associated with the prevailing or conventional treatment methods.

(2)DEFINITIONS.—As used in this section, the term:

(a)"Complementary or alternative health care treatment" means any treatment that is designed to provide patients with an effective option to the prevailing or conventional treatment methods associated with the services provided by a health care practitioner. Such a treatment may be provided in addition to or in place of other treatment options.

(b)"Health care practitioner" means any health care practitioner as defined in s. 456.001(4).

(3)COMMUNICATION OF TREATMENT ALTERNATIVES.—A health care practitioner who offers to provide a patient with a complementary or alternative health care treatment must inform the patient of the nature of the treatment and must explain the benefits and risks associated with the treatment to the extent necessary for the patient to make an informed and prudent decision regarding such treatment option. In compliance with this subsection:

(a)The health care practitioner must inform the patient of the practitioner's education, experience, and credentials in relation to the complementary or alternative health care treatment option.

(b)The health care practitioner may, in his or her discretion, communicate the information orally or in written form directly to the patient or to the patient's legal representative.

(c)The health care practitioner may, in his or her discretion and without restriction, recommend any mode of treatment that is, in his or her judgment, in the best interests of the patient, including complementary or alternative health care treatments, in accordance with the provisions of his or her license.

(4)RECORDS.—Every health care practitioner providing a patient with a complementary or alternative health care treatment must indicate in the patient's care record the method by which the requirements of subsection (3) were met.

(5)EFFECT.—This section does not modify or change the scope of practice of any licensees of the department, nor does it alter in any way the provisions of the individual practice acts for those licensees, which require licensees to practice within their respective standards of care and which prohibit fraud and exploitation of patients.

History.—s. 1, ch. 2001-116.

456.42Written prescriptions for medicinal drugs.—

(1)A written prescription for a medicinal drug issued by a health care practitioner licensed by law

to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be dated; and must be signed by the prescribing practitioner on the day when issued. However, a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must be dated and signed by the prescribing practitioner only on the day issued, which signature may be in an electronic format as defined in s. 668.003(4).

(2)A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats, must be dated with the abbreviated month written out on the face of the prescription, and must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department or electronically prescribed as that term is used in s. 408.0611. As a condition of being an approved vendor, a prescription pad vendor must submit a monthly report to the department which, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may, by rule, require the reporting of additional information.

History.—s. 1, ch. 2003-41; s. 2, ch. 2006-271; s. 2, ch. 2009-202; s. 2, ch. 2011-141.

456.43Electronic prescribing for medicinal drugs.—

(1)Electronic prescribing shall not interfere with a patient's freedom to choose a pharmacy.

(2)Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, advertising, instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be triggered or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.

(a)The term "prescribing decision" means a prescribing practitioner's decision to prescribe a certain pharmaceutical.

(b)The term "point of care" means the time that a prescribing practitioner or his or her agent is in the act of prescribing a certain pharmaceutical.

(3)Electronic prescribing software may show information regarding a payor's formulary as long as nothing is designed to preclude or make more difficult the act of a prescribing practitioner or patient selecting any particular pharmacy or pharmaceutical.

History.—s. 3, ch. 2006-271.

456.44Controlled substance prescribing.—

(1)DEFINITIONS.—

(a)“Addiction medicine specialist” means a board-certified psychiatrist with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine, an addiction medicine physician certified or eligible for certification by the American Society of Addiction Medicine, or an osteopathic physician who holds a certificate of added qualification in Addiction Medicine through the American Osteopathic Association.

(b)“Adverse incident” means any incident set forth in s. 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

(c)“Board-certified pain management physician” means a physician who possesses board certification in pain medicine by the American Board of Pain Medicine, board certification by the American Board of Interventional Pain Physicians, or board certification or subcertification in pain management or pain medicine by a specialty board recognized by the American Association of Physician Specialists or the American Board of Medical Specialties or an osteopathic physician who holds a certificate in Pain Management by the American Osteopathic Association.

(d)“Board eligible” means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

(e)“Chronic nonmalignant pain” means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

(f)“Mental health addiction facility” means a facility licensed under chapter 394 or chapter 397.

(2)REGISTRATION.—Effective January 1, 2012, a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

(a)Designate himself or herself as a controlled substance prescribing practitioner on the physician’s practitioner profile.

(b)Comply with the requirements of this section and applicable board rules.

(3)STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(a)A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient’s risk of aberrant drug-related behavior, which may include patient drug

testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(b)Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c)The physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The physician shall use a written controlled substance agreement between the physician and the patient outlining the patient's responsibilities, including, but not limited to:

1.Number and frequency of controlled substance prescriptions and refills.

2.Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.

3.An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.

(d)The patient shall be seen by the physician at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.

(e)The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist.

(f)A physician registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section,

the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1.The complete medical history and a physical examination, including history of drug abuse or dependence.

2.Diagnostic, therapeutic, and laboratory results.

3.Evaluations and consultations.

4.Treatment objectives.

5.Discussion of risks and benefits.

6.Treatments.

7.Medications, including date, type, dosage, and quantity prescribed.

8.Instructions and agreements.

9.Periodic reviews.

10.Results of any drug testing.

11.A photocopy of the patient's government-issued photo identification.

12.If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.

13.The physician's full name presented in a legible manner.

(g)Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

This subsection does not apply to a board-eligible or board-certified anesthesiologist, physiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties or the

American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a physician who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

History.—s. 3, ch. 2011-141; s. 31, ch. 2012-160.

456.50Repeated medical malpractice.—

(1)For purposes of s. 26, Art. X of the State Constitution and ss. 458.331(1)(t), (4), and (5) and 459.015(1)(x), (4), and (5):

(a)"Board" means the Board of Medicine, in the case of a physician licensed pursuant to chapter 458, or the Board of Osteopathic Medicine, in the case of an osteopathic physician licensed pursuant to chapter 459.

(b)"Final administrative agency decision" means a final order of the licensing board following a hearing as provided in s. 120.57(1) or (2) or s. 120.574 finding that the licensee has violated s. 458.331(1)(t) or s. 459.015(1)(x).

(c)"Found to have committed" means the malpractice has been found in a final judgment of a court of law, final administrative agency decision, or decision of binding arbitration.

(d)"Incident" means the wrongful act or occurrence from which the medical malpractice arises, regardless of the number of claimants or findings. For purposes of this section:

1.A single act of medical malpractice, regardless of the number of claimants, shall count as only one incident.

2.Multiple findings of medical malpractice arising from the same wrongful act or series of wrongful acts associated with the treatment of the same patient shall count as only one incident.

(e)"Level of care, skill, and treatment recognized in general law related to health care licensure" means the standard of care specified in s. 766.102.

(f)"Medical doctor" means a physician licensed pursuant to chapter 458 or chapter 459.

(g)"Medical malpractice" means the failure to practice medicine in accordance with the level of care, skill, and treatment recognized in general law related to health care licensure. Only for the purpose of finding repeated medical malpractice pursuant to this section, any similar wrongful act, neglect, or default committed in another state or country which, if committed in this state, would have been considered medical malpractice as defined in this paragraph, shall be considered medical malpractice if the standard of care and burden of proof applied in the other state or country equaled or exceeded that used in this state.

(h)"Repeated medical malpractice" means three or more incidents of medical malpractice found to have been committed by a medical doctor. Only an incident occurring on or after November 2, 2004, shall be considered an incident for purposes of finding repeated medical malpractice under this section.

(2)For purposes of implementing s. 26, Art. X of the State Constitution, the board shall not license or continue to license a medical doctor found to have committed repeated medical malpractice, the finding of which was based upon clear and convincing evidence. In order to rely on an incident of medical malpractice to determine whether a license must be denied or revoked under this section, if the facts supporting the finding of the incident of medical malpractice were determined on a standard less stringent than clear and convincing evidence, the board shall review the record of the case and determine whether the finding would be supported under a standard of clear and convincing evidence. Section 456.073 applies. The board may verify on a biennial basis an out-of-state licensee's medical malpractice history using federal, state, or other databases. The board may require licensees and applicants for licensure to provide a copy of the record of the trial of any medical malpractice judgment, which may be required to be in an electronic format, involving an incident that occurred on or after November 2, 2004. For purposes of implementing s. 26, Art. X of the State Constitution, the 90-day requirement for granting or denying a complete allopathic or osteopathic licensure application in s. 120.60(1) is extended to 180 days.

History.—s. 2, ch. 2005-266

2012 Florida Statutes

Chapter 499

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499.001 Florida Drug and Cosmetic Act; short title.—Sections 499.001-499.081 may be cited as the "Florida Drug and Cosmetic Act."

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 1, ch. 86-133; ss. 1, 52, ch. 92-69.

499.002Purpose, administration, and enforcement of and exemption from this part.—

(1)This part is intended to:

(a)Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.

(b)Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.

(c)Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.

(2)The department shall administer and enforce this part to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.

(3)For the purpose of any investigation or proceeding conducted by the department under this part, the department may administer oaths, take depositions, issue and serve subpoenas, and compel the attendance of witnesses and the production of books, papers, documents, or other evidence. The department shall exercise this power on its own initiative. Challenges to, and enforcement of, the subpoenas and orders shall be handled as provided in s. 120.569.

(4)Each state attorney, county attorney, or municipal attorney to whom the department or its designated agent reports any violation of this part shall cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law.

(5)This part does not require the department to report, for the institution of proceedings under this part, minor violations of this part when it believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

(6)Common carriers engaged in interstate commerce are not subject to this part if they are engaged in the usual course of business as common carriers.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 2, 3, ch. 86-133; s. 2, ch. 87-50; ss. 2, 4, 6, 48, 49, 50, 52, ch. 92-69; s. 240, ch. 96-410; s. 236, ch. 99-8; s. 1, ch. 2008-207.

Note.—Subsection (2) former s. 499.004; subsection (3) former s. 499.0053; subsection (4) former s. 499.07; subsection (5) former s. 499.071; subsection (6) former s. 499.081.

499.003Definitions of terms used in this part.—As used in this part, the term:

(1)"Advertisement" means any representation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.

(2)"Affiliated group" means an affiliated group as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group. The affiliated group must disclose the names of all its members to the department.

(3)"Affiliated party" means:

(a)A director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant;

(b)A person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant;

(c)A person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or

(d)The five largest natural shareholders that own at least 5 percent of the permittee or applicant.

(4)"Applicant" means a person applying for a permit or certification under this part.

(5)"Authenticate" means to affirmatively verify upon receipt of a prescription drug that each transaction listed on the pedigree paper has occurred.

(a)A wholesale distributor is not required to open a sealed, medical convenience kit to authenticate a pedigree paper for a prescription drug contained within the kit.

(b)Authentication of a prescription drug included in a sealed, medical convenience kit shall be limited to verifying the transaction and pedigree information received.

(6)"Certificate of free sale" means a document prepared by the department which certifies a drug, device, or cosmetic, that is registered with the department, as one that can be legally sold in the state.

(7)"Chain pharmacy warehouse" means a wholesale distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intracompany transfers of such drugs to a member of its affiliated group.

(8)"Closed pharmacy" means a pharmacy that is licensed under chapter 465 and purchases prescription drugs for use by a limited patient population and not for wholesale distribution or sale to the public. The term does not include retail pharmacies.

(9)"Color" includes black, white, and intermediate grays.

(10)"Color additive" means, with the exception of any material that has been or hereafter is exempt under the federal act, a material that:

(a)Is a dye pigment, or other substance, made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or

(b)When added or applied to a drug or cosmetic or to the human body, or any part thereof, is capable alone, or through reaction with other substances, of imparting color thereto.

(11)"Compressed medical gas" means any liquefied or vaporized gas that is a prescription drug, whether it is alone or in combination with other gases.

(12)"Contraband prescription drug" means any adulterated drug, as defined in s. 499.006, any counterfeit drug, as defined in this section, and also means any prescription drug for which a pedigree paper does not exist, or for which the pedigree paper in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter.

(13)"Cosmetic" means an article, with the exception of soap, that is:

(a)Intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or

(b)Intended for use as a component of any such article.

(14)"Counterfeit drug," "counterfeit device," or "counterfeit cosmetic" means a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint,

or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor.

(15)"Department" means the Department of Business and Professional Regulation.

(16)"Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including its components, parts, or accessories, which is:

(a)Recognized in the current edition of the United States Pharmacopoeia and National Formulary, or any supplement thereof,

(b)Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or

(c)Intended to affect the structure or any function of the body of humans or other animals,

and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(17)"Distribute" or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.

(18)"Drop shipment" means the sale of a prescription drug from a manufacturer to a wholesale distributor, where the wholesale distributor takes title to, but not possession of, the prescription drug, and the manufacturer of the prescription drug ships the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003.

(19)"Drug" means an article that is:

(a)Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b)Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c)Intended to affect the structure or any function of the body of humans or other animals; or

(d)Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients, but does not include devices or their nondrug components, parts, or accessories. For purposes of this paragraph, an "active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.

(20)"Establishment" means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the

buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

(21)"Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

(22)"Freight forwarder" means a person who receives prescription drugs which are owned by another person and designated by that person for export, and exports those prescription drugs.

(23)"Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(g)1.c.

(24)"Health care facility" means a health care facility licensed under chapter 395.

(25)"Hospice" means a corporation licensed under part IV of chapter 400.

(26)"Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395.

(27)"Immediate container" does not include package liners.

(28)"Label" means a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic. A requirement made by or under authority of this part or rules adopted under this part that any word, statement, or other information appear on the label is not complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such drug, device, or cosmetic or is easily legible through the outside container or wrapper.

(29)"Labeling" means all labels and other written, printed, or graphic matters:

(a)Upon a drug, device, or cosmetic, or any of its containers or wrappers; or

(b)Accompanying or related to such drug, device, or cosmetic.

(30)"Manufacture" means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic.

(31)"Manufacturer" means:

(a)A person who prepares, derives, manufactures, or produces a drug, device, or cosmetic;

(b)The holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA), provided such application has become effective or is otherwise approved consistent with s. 499.023;

(c)A private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged;

(d)A person registered under the federal act as a manufacturer of a prescription drug, who is described in paragraph (a), paragraph (b), or paragraph (c), who has entered into a written agreement with another prescription drug manufacturer that authorizes either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug consistent with the federal act and its implementing regulations;

(e)A member of an affiliated group that includes, but is not limited to, persons described in paragraph (a), paragraph (b), paragraph (c), or paragraph (d), which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of the affiliated group. As used in this paragraph, the term "affiliated group" means an affiliated group as defined in s. 1504 of the Internal Revenue Code of 1986, as amended. The

manufacturer must disclose the names of all of its affiliated group members to the department; or

(f)A person permitted as a third party logistics provider, only while providing warehousing, distribution, or other logistics services on behalf of a person described in paragraph (a), paragraph (b), paragraph (c), paragraph (d), or paragraph (e).

The term does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(32)"Medical convenience kit" means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2).

(33)"New drug" means:

(a)Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of that drug; or

(b)Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under certain conditions, has been recognized for use under such conditions, but which drug has not, other than in those investigations, been used to a material extent or for a material time under such conditions.

(34)"Normal distribution chain" means a wholesale distribution of a prescription drug in which the wholesale distributor or its wholly owned subsidiary purchases and receives the specific unit of the prescription drug directly from the manufacturer and distributes the prescription drug directly, or through up to two intracompany transfers, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003. For purposes of this subsection, the term "intracompany" means any transaction or transfer between any parent, division, or subsidiary wholly owned by a corporate entity.

(35)"Nursing home" means a facility licensed under part II of chapter 400.

(36)"Official compendium" means the current edition of the official United States Pharmacopoeia and National Formulary, or any supplement thereto.

(37)"Pedigree paper" means a document in written or electronic form approved by the department which contains information required by s. 499.01212 regarding the sale and distribution of any given prescription drug.

(38)"Permittee" means any person holding a permit issued pursuant to s. 499.012.

(39)"Person" means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within this state, and any representative, agent, or agency of any of the foregoing, or any other group or combination of the foregoing.

(40)"Pharmacist" means a person licensed under chapter 465.

(41)"Pharmacy" means an entity licensed under chapter 465.

(42)"Prepackaged drug product" means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing in the establishment in which the prepackaging occurred.

(43)"Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act

or s. 465.003(8), s. 499.007(13), or subsection (11), subsection (46), or subsection (53), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

(44)"Prescription drug label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug prior to its dispensing to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.

(45)"Prescription label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug dispensed pursuant to a prescription of a practitioner authorized by law to prescribe.

(46)"Prescription medical oxygen" means oxygen USP which is a drug that can only be sold on the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.

(47)"Primary wholesale distributor" means any wholesale distributor that:

(a)Purchased 90 percent or more of the total dollar volume of its purchases of prescription drugs directly from manufacturers in the previous year; and

(b)1.Directly purchased prescription drugs from not fewer than 50 different prescription drug manufacturers in the previous year; or

2.Has, or the affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member has, not fewer than 250 employees.

(c)For purposes of this subsection, "directly from manufacturers" means:

1.Purchases made by the wholesale distributor directly from the manufacturer of prescription drugs; and

2.Transfers from a member of an affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member, if:

a.The affiliated group purchases 90 percent or more of the total dollar volume of its purchases of prescription drugs from the manufacturer in the previous year; and

b.The wholesale distributor discloses to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group agrees in writing to provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.

(48)"Proprietary drug," or "OTC drug," means a patent or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be purchased without a prescription.

(49)"Repackage" includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

(50)"Repackager" means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(51)"Retail pharmacy" means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

(52)"Secondary wholesale distributor" means a wholesale distributor that is not a primary wholesale distributor.

(53)"Veterinary prescription drug" means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

(54)"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a)Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1.The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2.The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3.The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4.The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a.The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.

b.The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c.In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

d.The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e.The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph d.

f.In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

(b)Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

1.The sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2.The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. For purposes of this subparagraph, the term "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

3.The transfer of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

4.The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier.

5.The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

6.The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

7.The transfer of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that transfers prescription drugs pursuant to this subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

(c)The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

(d)The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this paragraph, the term "blood" means whole blood collected from a single donor and processed for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

(e)The lawful dispensing of a prescription drug in accordance with chapter 465.

(f)The sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

(55)"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions.

History.—s. 34, ch. 82-225; s. 105, ch. 83-218; s. 1, ch. 83-265; s. 1, ch. 84-115; s. 1, ch. 87-57; s. 3, ch. 88-159; ss. 3, 15, 52, ch. 92-69; s. 584, ch. 97-103; s. 31, ch. 98-151; s. 235, ch. 99-8; ss. 124, 172, ch. 99-397; s. 34, ch. 2000-242; s. 10, ch. 2000-326; s. 38, ch. 2002-400; ss. 3, 13, 14, 25, ch. 2003-155; s. 1, ch. 2004-328; ss. 1, 2, ch. 2005-248; ss. 1, 3, ch. 2006-310; s. 122, ch. 2007-5; s. 20, ch. 2007-6; s. 104, ch. 2008-6; s. 2, ch. 2008-207; s. 60, ch. 2009-21; s. 1, ch. 2009-221; s. 22, ch. 2010-161; s. 2, ch. 2012-37; s. 33, ch. 2012-61; s. 3, ch. 2012-143; s. 122, ch. 2012-184.
Note.—Subsection (24) former s. 499.029(3)(f); subsection (25) former s. 499.029(3)(h); subsection (26) former s. 499.029(3)(i); subsection (34) former s. 499.029(3)(j); subsection (37) former s. 499.0661(1); subsection (39) former s. 499.029(3)(l); subsection (40) former s. 499.029(3)(m); subsection (46) intro., paragraphs (a), (b) former s. 499.012(1)(d); paragraph (46)(c) former s. 499.012(1)(e); subsection (50) former s. 499.012(1)(c); subsection (51) former s. 499.012(1)(f); subsection (53) former s. 499.012(1)(a); subsection (54) former s. 499.012(1)(b).

499.005Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(1)The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(2)The adulteration or misbranding of any drug, device, or cosmetic.

(3)The receipt of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery of such drug, device, or cosmetic, for pay or otherwise.

(4)The sale, distribution, purchase, trade, holding, or offering of any drug, device, or cosmetic in violation of this part.

(5)The dissemination of any false or misleading advertisement of a drug, device, or cosmetic.

(6)The refusal or constructive refusal:

(a)To allow the department to enter or inspect an establishment in which drugs, devices, or cosmetics are manufactured, processed, repackaged, sold, brokered, or held;

(b)To allow inspection of any record of that establishment;

(c)To allow the department to enter and inspect any vehicle that is being used to transport drugs, devices, or cosmetics; or

(d)To allow the department to take samples of any drug, device, or cosmetic.

(7)The purchase or sale of prescription drugs for wholesale distribution in exchange for currency, as defined in s. 560.103.

(8)Committing any act that causes a drug, device, or cosmetic to be a counterfeit drug, device, or cosmetic; or selling, dispensing, or holding for sale a counterfeit drug, device, or cosmetic.

(9)The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a drug, device, or cosmetic, or the doing of any other act with respect to a drug, device, or cosmetic, if the act is done while the drug, device, or cosmetic is held for sale and the act results in the drug, device, or cosmetic being misbranded.

(10)Forging; counterfeiting; simulating; falsely representing any drug, device, or cosmetic; or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part.

(11)The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.

(12)The possession of any drug in violation of this part.

(13)The sale, delivery, holding, or offering for sale of any self-testing kits designed to tell persons their status concerning human immunodeficiency virus or acquired immune deficiency syndrome or related disorders or conditions. This prohibition shall not apply to home access HIV test kits approved for distribution and sale by the United States Food and Drug Administration.

(14)The purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.

(15)The sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

(16)The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.

(17)The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.

(18)Failure to maintain records as required by this part and rules adopted under this part.

(19)Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this part.

(20)The importation of a prescription drug except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.

(21)The wholesale distribution of any prescription drug that was:

(a)Purchased by a public or private hospital or other health care entity; or

(b)Donated or supplied at a reduced price to a charitable organization,

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(g)1.c.

(22)Failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by this part for that activity.

(23)Obtaining or attempting to obtain a prescription drug or device by fraud, deceit, misrepresentation or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug or device.

(24)The distribution of a prescription device to the patient or ultimate consumer without a prescription or order from a practitioner licensed by law to use or prescribe the device.

(25)Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.

(26)Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.

(27)Distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(28)Failure to acquire or deliver a pedigree paper as required under this part.

(29)The receipt of a prescription drug pursuant to a wholesale distribution without having previously received or simultaneously receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor as required under this part.

History.—s. 34, ch. 82-225; s. 106, ch. 83-218; s. 1, ch. 83-265; s. 24, ch. 88-380; ss. 5, 52, ch. 92-69; s. 3, ch. 95-308; s. 585, ch. 97-103; s. 29, ch. 98-151; s. 37, ch. 99-397; s. 35, ch. 2000-242; s. 17, ch. 2001-63; s. 32, ch. 2001-89; s. 4, ch. 2003-155; s. 4, ch. 2006-310; s. 21, ch. 2007-6; s. 48, ch. 2008-177; s. 3, ch. 2008-207; s. 3, ch. 2012-37.

499.0051Criminal acts.—

(1)FAILURE TO MAINTAIN OR DELIVER PEDIGREE PAPERS.—

(a)A person, other than a manufacturer, engaged in the wholesale distribution of prescription drugs who fails to deliver to another person complete and accurate pedigree papers concerning a prescription drug or contraband prescription drug prior to, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)A person engaged in the wholesale distribution of prescription drugs who fails to acquire complete and accurate pedigree papers concerning a prescription drug or contraband prescription drug prior to, or simultaneous with, the receipt of the prescription drug or contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c)Any person who knowingly destroys, alters, conceals, or fails to maintain complete and accurate pedigree papers concerning any prescription drug or contraband prescription drug in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2)FAILURE TO AUTHENTICATE PEDIGREE PAPERS.—Effective July 1, 2006:

(a)A person engaged in the wholesale distribution of prescription drugs who is in possession of pedigree papers concerning prescription drugs or contraband prescription drugs and who fails to authenticate the matters contained in the pedigree papers and who nevertheless attempts to further distribute prescription drugs or contraband prescription drugs commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)A person in possession of pedigree papers concerning prescription drugs or contraband prescription drugs who falsely swears or certifies that he or she has authenticated the matters contained in the pedigree papers commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)KNOWING FORGERY OF PEDIGREE PAPERS.—A person who knowingly forges, counterfeits, or falsely creates any pedigree paper; who falsely represents any factual matter contained on any pedigree paper; or who knowingly omits to record material information required to be recorded in a pedigree paper, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4)KNOWING PURCHASE OR RECEIPT OF PRESCRIPTION DRUG FROM UNAUTHORIZED PERSON.—A person who knowingly purchases or receives from a person not authorized to distribute prescription drugs under this chapter a prescription drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5)KNOWING SALE OR TRANSFER OF PRESCRIPTION DRUG TO UNAUTHORIZED PERSON.—A person who knowingly sells or transfers to a person not authorized to purchase or possess prescription drugs, under the law of the jurisdiction in which the person receives the drug, a prescription drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6)KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO SELL, CONTRABAND PRESCRIPTION DRUGS.—A person who is knowingly in actual or

constructive possession of any amount of contraband prescription drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband prescription drugs, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(7)KNOWING TRAFFICKING IN CONTRABAND PRESCRIPTION DRUGS.—A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs valued at $25,000 or more commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(a)Upon conviction, each defendant shall be ordered to pay a mandatory fine according to the following schedule:

1.If the value of contraband prescription drugs involved is $25,000 or more, but less than $100,000, the defendant shall pay a mandatory fine of $25,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $75,000.

2.If the value of contraband prescription drugs involved is $100,000 or more, but less than $250,000, the defendant shall pay a mandatory fine of $100,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $300,000.

3.If the value of contraband prescription drugs involved is $250,000 or more, the defendant shall pay a mandatory fine of $200,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $600,000.

(b)As used in this subsection, the term "value" means the market value of the property at the time and place of the offense or, if such cannot be satisfactorily ascertained, the cost of replacement of the property within a reasonable time after the offense. Amounts of value of separate contraband prescription drugs involved in distinct transactions for the distribution of the contraband prescription drugs committed pursuant to one scheme or course of conduct, whether involving the same person or several persons, may be aggregated in determining the punishment of the offense.

(8)KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION DRUG LABELS.—A person who knowingly forges, counterfeits, or falsely creates any prescription label or prescription drug label, or who falsely represents any factual matter contained on any prescription label or prescription drug label, commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(9)KNOWING SALE OR PURCHASE OF CONTRABAND PRESCRIPTION DRUGS RESULTING IN GREAT BODILY HARM.—A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, and whose acts in violation of this subsection result in great bodily harm to a person, commits a felony of the first degree, as provided in s. 775.082, s. 775.083, or s. 775.084.

(10)KNOWING SALE OR PURCHASE OF CONTRABAND PRESCRIPTION DRUGS RESULTING IN DEATH.—A person who knowingly manufactures, sells, purchases, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, and whose acts in violation of this subsection result in the death of a person, commits a felony of the first degree, punishable by a term of years not exceeding life, as provided in s. 775.082, s. 775.083, or s. 775.084.

(11)VIOLATIONS OF S. 499.005 RELATED TO DEVICES AND COSMETICS; DISSEMINATION OF FALSE ADVERTISEMENT.—

(a)Any person who violates any of the provisions of s. 499.005 with respect to a device or cosmetic commits a misdemeanor of the second degree, punishable as

provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083 or as otherwise provided in this part, except that any person who violates s. 499.005(8) or (10) with respect to a device or cosmetic commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part.

(b)A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, wholesaler, or seller of the article to which a false advertisement relates, is not liable under this subsection by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, wholesaler, seller, or advertising agency that asked him or her to disseminate such advertisement.

(12)ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as otherwise provided in this part:

(a)The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(b)The adulteration or misbranding of any drug intended for further distribution.

(c)The receipt of any drug that is adulterated or misbranded, and the delivery or proffered delivery of such drug, for pay or otherwise.

(d)The dissemination of any false or misleading advertisement of a drug.

(e)The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.

(f)The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.

(g)Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.

(h)The failure to maintain records related to a drug as required by this part and rules adopted under this part, except for pedigree papers, invoices, or shipping documents related to prescription drugs.

(i)The possession of any drug in violation of this part, except if the violation relates to a deficiency in pedigree papers.

(13)REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(a)The refusal or constructive refusal to allow:

1.The department to enter or inspect an establishment in which drugs are manufactured, processed, repackaged, sold, brokered, or held;

2.Inspection of any record of that establishment;

3.The department to enter and inspect any vehicle that is being used to transport drugs; or

4.The department to take samples of any drug.

(b)The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.

(c)Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this part related to a drug.

(d)The failure to receive, maintain, or provide invoices and shipping documents, other than pedigree papers, if applicable, related to the distribution of a prescription drug.

(e)The importation of a prescription drug for wholesale distribution, except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.

(f)The wholesale distribution of a prescription drug that was:

1.Purchased by a public or private hospital or other health care entity; or

2.Donated or supplied at a reduced price to a charitable organization.

(g)The failure to obtain a permit as a prescription drug wholesale distributor when a permit is required by this part for that activity.

(h)Knowingly possessing any adulterated or misbranded prescription drug outside of a designated quarantine area.

(i)The purchase or sale of a prescription drug for wholesale distribution in exchange for currency, as defined in s. 560.103.

(14)OTHER VIOLATIONS.—Any person who violates any of the following provisions commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(a)Knowingly manufacturing, repackaging, selling, delivering, or holding or offering for sale any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(b)Knowingly adulterating a drug that is intended for further distribution.

(c)Knowingly receiving a drug that is adulterated and delivering or proffering delivery of such drug for pay or otherwise.

(d)Committing any act that causes a drug to be a counterfeit drug, or selling, dispensing, or knowingly holding for sale a counterfeit drug.

(e)Forging, counterfeiting, simulating, or falsely representing any drug, or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part.

(f)Knowingly obtaining or attempting to obtain a prescription drug for wholesale distribution by fraud, deceit, misrepresentation, or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug.

(g)Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.

(h)Knowingly distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(15)FALSE ADVERTISEMENT.—A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, repackager, wholesale distributor, or seller of the article to which a false advertisement relates, is not liable under subsection (12), subsection (13), or subsection (14) by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, repackager, wholesale distributor, seller, or advertising agency that asked him or her to disseminate such advertisement.

(16)FALSE REPORT.—Any person who submits a report required by s. 499.0121(14) knowing that such report contains a false statement commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(17)CONTROLLED SUBSTANCE DISTRIBUTION.—Any person who engages in the wholesale distribution of prescription drugs and who knowingly distributes controlled substances in violation of s. 499.0121(14) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition to any other fine that may be imposed, a person convicted of such a violation may be sentenced to pay a fine that does not exceed three times the gross monetary value gained from such violation, plus court costs and the reasonable costs of investigation and prosecution.

History.—s. 34, ch. 82-225; s. 118, ch. 83-218; s. 1, ch. 83-265; ss. 47, 52, ch. 92-69; s. 595, ch. 97-103; s. 40, ch. 99-397; ss. 5, 6, 7, 8, 27, 28, ch. 2003-155; s. 16, ch. 2007-6; s. 49, ch. 2008-177; s. 4, ch. 2008-207; s. 16, ch. 2011-141.

Note.—Subsection (7) former s. 499.0052; subsection (9) former s. 499.00535; subsection (10) former s. 499.00545; subsection (11) former s. 499.069; subsections (12)-(15) former s. 499.0691.

499.0054Advertising and labeling of drugs, devices, and cosmetics; exemptions.—

(1)It is a violation of the Florida Drug and Cosmetic Act to perform or cause the performance of any of the following acts:

(a)The dissemination of any false advertisement of any drug, device, or cosmetic. An advertisement is false if it is false or misleading in any way.

(b)The distribution in commerce of any drug, device, or cosmetic, if its labeling or advertising is in violation of this part.

(c)The manufacturing, repackaging, packaging, selling, delivery, holding, or offering for sale of any drug, device, or cosmetic for which the advertising or labeling is false or misleading.

(d)The advertising of any drug, device, or cosmetic that is adulterated or misbranded.

(e)The receiving in commerce of any drug, device, or cosmetic that is falsely advertised or labeled or the delivering or proffering for delivery of any such drug, device, or cosmetic.

(f)The advertising or labeling of any product containing ephedrine, a salt of ephedrine, an isomer of ephedrine, or a salt of an isomer of ephedrine, for the indication of stimulation, mental alertness, weight loss, appetite control, energy, or other indications not approved by the pertinent United States Food and Drug Administration Over-the-Counter Final or Tentative Final Monograph or approved new drug application under the federal act. In determining compliance with this requirement, the department may consider the following factors:

1.The packaging of the product.

2.The name and labeling of the product.

3.The manner of distribution, advertising, and promotion of the product, including verbal representations at the point of sale.

4.The duration, scope, and significance of abuse of the particular product.

(g)The advertising of any drug or device represented to have any effect in any of the following conditions, disorders, diseases, or processes:

1.Blood disorders.

2.Bone or joint diseases.

3.Kidney diseases or disorders.

4.Cancer.

5.Diabetes.

6.Gall bladder diseases or disorders.

7.Heart and vascular diseases.

8.High blood pressure.
9.Diseases or disorders of the ear or auditory apparatus, including hearing loss or deafness.
10.Mental disease or mental retardation.
11.Paralysis.
12.Prostate gland disorders.
13.Conditions of the scalp affecting hair loss.
14.Baldness.
15.Endocrine disorders.
16.Sexual impotence.
17.Tumors.
18.Venereal diseases.
19.Varicose ulcers.
20.Breast enlargement.
21.Purifying blood.
22.Metabolic disorders.
23.Immune system disorders or conditions affecting the immune system.
24.Extension of life expectancy.
25.Stress and tension.
26.Brain stimulation or performance.
27.The body's natural defense mechanisms.
28.Blood flow.
29.Depression.
30.Human immunodeficiency virus or acquired immune deficiency syndrome or related disorders or conditions.
(h)The representation or suggestion in labeling or advertising that an article is approved under this part, when such is not the case.
(2)In determining whether an advertisement is false or misleading, the department shall review the representations made or suggested by statement, word, design, device, sound, or any combination thereof within the advertisement and the extent to which the advertisement fails to reveal material facts with respect to consequences that can result from the use of the drug, device, or cosmetic to which the advertisement relates under the conditions of use prescribed in the labeling or advertisement.
(3)(a)An advertisement that is not prohibited under paragraph (1)(a) is not prohibited under paragraph (1)(g) if it is disseminated:
1.To the public solely to advertise the product for those indications that are safe and effective indications and the product is safe and effective for self-medication, as established by the United States Food and Drug Administration; or
2.Only to members of the medical, dental, pharmaceutical, or veterinary professions or appears only in the scientific periodicals of these professions.
(b)Compliance with this part and the rules adopted under this part creates no legal presumption that a drug or device is safe or effective.
History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 1, 2, 4, ch. 86-271; s. 5, ch. 88-172; s. 25, ch. 88-380; ss. 7, 8, 9, 52, ch. 92-69; ss. 2, 3, ch. 95-415; s. 36, ch. 2000-242; s. 5, ch. 2008-207.
Note.—Subsection (2) former s. 499.0055; subsection (3) former s. 499.0057.
499.006Adulterated drug or device.—A drug or device is adulterated:
(1)If it consists in whole or in part of any filthy, putrid, or decomposed substance;
(2)If it has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health;
(3)If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated

or administered in conformity with, current good manufacturing practices to assure that the drug meets the requirements of this part and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess;

(4)If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health;

(5)If it is a drug and it bears or contains, for the purpose of coloring only, a color additive that is unsafe within the meaning of the federal act; or, if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, and it is unsafe within the meaning of the federal act;

(6)If it purports to be, or is represented as, a drug the name of which is recognized in the official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. The determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in such compendium, or, when such tests or methods of assay are absent or inadequate, in accordance with those tests or methods of assay prescribed under authority of the federal act. A drug defined in the official compendium is not adulterated under this subsection merely because it differs from the standard of strength, quality, or purity set forth for that drug in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label;

(7)If it is not subject to subsection (6) and its strength differs from, or its purity or quality falls below the standard of, that which it purports or is represented to possess;

(8)If it is a drug:

(a)With which any substance has been mixed or packed so as to reduce the quality or strength of the drug; or

(b)For which any substance has been substituted wholly or in part;

(9)If it is a drug or device for which the expiration date has passed;

(10)If it is a prescription drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of this part or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so; or

(11)If it is a prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian to a limited prescription drug veterinary wholesale distributor.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 10, 52, ch. 92-69; s. 9, ch. 2003-155; s. 1, ch. 2006-92; s. 6, ch. 2008-207.

499.007Misbranded drug or device.—A drug or device is misbranded:

(1)If its labeling is in any way false or misleading.

(2)If in package form, it does not bear a label containing:

(a)The name and place of business of the manufacturer, repackager, or distributor of the finished dosage form of the drug. For the purpose of this paragraph, the finished dosage form of a prescription drug is that form of the drug which is, or is intended to be, dispensed or administered to the patient and requires no further manufacturing or processing other than packaging, reconstitution, and labeling; and

(b)An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. However, under this section, reasonable variations are permitted, and the department shall establish by rule exemptions for small packages.

(3)If it is an active pharmaceutical ingredient in bulk form and does not bear a label containing:

(a)The name and place of business of the manufacturer, repackager, or distributor; and

(b)An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

(4)If any word, statement, or other information required by or under this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices in the labeling, and in such terms, as to render the word, statement, or other information likely to be read and understood under customary conditions of purchase and use.

(5)If it is a drug and is not designated solely by a name recognized in an official compendium and its label does not bear:

(a)The common or usual name of the drug, if any; and

(b)In case it is fabricated from two or more ingredients, the common or usual name and quantity of each active ingredient.

(6)If its labeling does not bear:

(a)Adequate directions for use; and

(b)Adequate warnings against use in those pathological conditions in which its use may be dangerous to health or against use by children if its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

(7)If it purports to be a drug the name of which is recognized in the official compendium and it is not packaged and labeled as prescribed therein. However, the method of packaging may be modified with the consent of the department.

(8)If it has been found by the department to be a drug liable to deterioration and it is not packaged in such form and manner, and its label bears a statement of such precautions, as the department by rule requires as necessary to protect the public health. Such rule may not be established for any drug recognized in an official compendium until the department has informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and that body has failed within a reasonable time to prescribe such requirements.

(9)If it is:

(a)A drug and its container or finished dosage form is so made, formed, or filled as to be misleading;

(b)An imitation of another drug; or

(c)Offered for sale under the name of another drug.

(10)If it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug.

(11)If it is, purports to be, or is represented as a drug composed wholly or partly of insulin and it is not from a batch with respect to which a certificate has been issued pursuant to s. 506 of the federal act, which certificate is in effect with respect to the drug.

(12)If it is, purports to be, or is represented as a drug composed wholly or partly of any kind of antibiotic requiring certification under the federal act and it is not from a batch with respect to which a certificate has been issued pursuant to s. 507 of the federal act, which certificate is in effect with respect to the drug. However, this subsection does not apply to any drug or class of drugs exempted by regulations adopted under s. 507(c) or (d) of the federal act.

(13)If it is a drug intended for use by humans which is a habit-forming drug or which, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or

which is limited by an effective application under s. 505 of the federal act to use under the professional supervision of a practitioner licensed by law to prescribe such drug, if it is not dispensed only:

(a)Upon the written prescription of a practitioner licensed by law to prescribe such drug;

(b)Upon an oral prescription of such practitioner, which is reduced promptly to writing and filled by the pharmacist; or

(c)By refilling any such written or oral prescription, if such refilling is authorized by the prescriber in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(14)If it is a drug that is subject to paragraph (13)(a), and if, at any time before it is dispensed, its label does not bear the statement:

(a)"Caution: Federal Law Prohibits Dispensing Without Prescription";

(b)"Rx Only";

(c)The prescription symbol followed by the word "Only"; or

(d)"Caution: State Law Prohibits Dispensing Without Prescription."

(15)If it is a drug that is not subject to paragraph (13)(a), if at any time before it is dispensed its label bears the statement of caution required in subsection (14).

(16)If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only and its packaging and labeling are not in conformity with the packaging and labeling requirements that apply to such color additive and are prescribed under the federal act.

(17)A drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to prescribe such drug is exempt from the requirements of this section, except subsections (1), (9), (11), and (12) and the packaging requirements of subsections (7) and (8), if the drug bears a label that contains the name and address of the dispenser or seller, the prescription number and the date the prescription was written or filled, the name of the prescriber and the name of the patient, and the directions for use and cautionary statements. This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to any drug dispensed in violation of subsection (13). The department may, by rule, exempt drugs subject to s. 499.062 from subsection (13) if compliance with that subsection is not necessary to protect the public health, safety, and welfare.

History.—s. 34, ch. 82-225; s. 107, ch. 83-218; s. 1, ch. 83-265; s. 2, ch. 84-115; ss. 11, 52, ch. 92-69; s. 586, ch. 97-103; s. 38, ch. 99-397; s. 10, ch. 2003-155; s. 84, ch. 2004-5; s. 7, ch. 2008-207.

499.008Adulterated cosmetics.—A cosmetic is adulterated:

(1)If it bears or contains any poisonous or deleterious substance that is injurious to users under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual; however, this subsection does not apply to coal-tar hair dye:

(a)The label of which bears the following legend conspicuously displayed thereon: "Caution: This product contains ingredients which may cause skin irritation on certain individuals, and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness"; and

(b)The labeling of which bears adequate directions for such preliminary testing.

(2)If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(3)If it has been produced, prepared, packed, or held under conditions whereby it could have become contaminated with filth or whereby it could have been rendered injurious to health.
(4)If it is not a hair dye and it is, or it bears or contains, a color additive that is unsafe within the meaning of the federal act.
(5)For the purposes of subsections (1) and (4), the term "hair dye" does not include eyelash dyes or eyebrow dyes.
History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 12, 52, ch. 92-69; s. 8, ch. 2008-207.
499.009Misbranded cosmetics.—A cosmetic is misbranded:
(1)If its labeling is false or misleading in any particular.
(2)If in package form, it does not bear a label containing:
(a)The name and place of business of the manufacturer, packer, or distributor;
(b)An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; however, under this paragraph reasonable variations are permitted, and the department shall establish by rule exemptions for small packages; and
(c)A declaration of ingredients in descending order of predominance, or as otherwise required by federal law.
(3)If any word, statement, or other information required by or under authority of this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices in the labeling, and in such terms, as to render the word, statement, or other information likely to be read and understood by an individual under customary conditions of purchase and use.
(4)If its container is so made, formed, or filled as to be misleading.
(5)If it is a color additive, its packaging and labeling are not in conformity with the packaging and labeling requirements applicable to that color additive prescribed under the federal act. This subsection does not apply to packages of color additives that, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes.
History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 13, 52, ch. 92-69; s. 9, ch. 2008-207.
499.01Permits.—
(1)Prior to operating, a permit is required for each person and establishment that intends to operate as:
(a)A prescription drug manufacturer;
(b)A prescription drug repackager;
(c)A nonresident prescription drug manufacturer;
(d)A prescription drug wholesale distributor;
(e)An out-of-state prescription drug wholesale distributor;
(f)A retail pharmacy drug wholesale distributor;
(g)A restricted prescription drug distributor;
(h)A complimentary drug distributor;
(i)A freight forwarder;
(j)A veterinary prescription drug retail establishment;
(k)A veterinary prescription drug wholesale distributor;
(l)A limited prescription drug veterinary wholesale distributor;
(m)A medical oxygen retail establishment;
(n)A compressed medical gas wholesale distributor;
(o)A compressed medical gas manufacturer;
(p)An over-the-counter drug manufacturer;
(q)A device manufacturer;

(r)A cosmetic manufacturer;
(s)A third party logistics provider; or
(t)A health care clinic establishment.
(2)The following permits are established:
(a)Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.
1.A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, which apply to a wholesale distributor.
2.A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.
3.A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(54)(d) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.
(b)Prescription drug repackager permit.—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.
1.A person that operates an establishment permitted as a prescription drug repackager may engage in wholesale distribution of prescription drugs repackaged at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.
2.A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.
(c)Nonresident prescription drug manufacturer permit.—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a wholesale distributor under this part, except s. 499.01212.
1.A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(31)(e).
2.Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any product wholesaled into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.
(d)Prescription drug wholesale distributor permit.—A prescription drug wholesale distributor is a wholesale distributor that may engage in the wholesale distribution of prescription drugs. A prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the

bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later. The department may adopt rules for issuing a prescription drug wholesale distributor-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(e)Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later. The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

(f)Retail pharmacy drug wholesale distributor permit.—A retail pharmacy drug wholesale distributor is a retail pharmacy engaged in wholesale distribution of prescription drugs within this state under the following conditions:

1.The pharmacy must obtain a retail pharmacy drug wholesale distributor permit pursuant to this part and the rules adopted under this part.

2.The wholesale distribution activity does not exceed 30 percent of the total annual purchases of prescription drugs. If the wholesale distribution activity exceeds the 30-percent maximum, the pharmacy must obtain a prescription drug wholesale distributor permit.

3.The transfer of prescription drugs that appear in any schedule contained in chapter 893 is subject to chapter 893 and the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

4.The transfer is between a retail pharmacy and another retail pharmacy, or a Modified Class II institutional pharmacy, or a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs.

5.All records of sales of prescription drugs subject to this section must be maintained separate and distinct from other records and comply with the recordkeeping requirements of this part.

(g)Restricted prescription drug distributor permit.—

1.A restricted prescription drug distributor permit is required for:

a.Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(54)(a).

b.Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c.A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(54)(d) to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I)Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II)Blood-collection containers approved under s. 505 of the federal act;

(III)Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV)Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V)To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2.Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212 if the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b.

3.A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4.The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

(h)Complimentary drug distributor permit.—A complimentary drug distributor permit is required for any person that engages in the distribution of a complimentary drug, subject to the requirements of s. 499.028.

(i)Freight forwarder permit.—A freight forwarder permit is required for any person that engages in the distribution of a prescription drug as a freight forwarder unless the person is a common carrier. The storage, handling, and recordkeeping of such distributions must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212. A freight forwarder must provide the source of the prescription drugs with a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.

(j)Veterinary prescription drug retail establishment permit.—A veterinary prescription drug retail establishment permit is required for any person that sells veterinary prescription drugs to the public but does not include a pharmacy licensed under chapter 465.

1.The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2.Veterinary prescription drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3.An order may not be valid for more than 1 year.

4.A veterinary prescription drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5.A veterinary prescription drug retail establishment must sell a veterinary prescription drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary prescription drug.

6.A veterinary prescription drug retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

7.Prescription drugs sold by a veterinary prescription drug retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

(k)Veterinary prescription drug wholesale distributor permit.—A veterinary prescription drug wholesale distributor permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesale distributor that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a limited prescription drug veterinary wholesale distributor in lieu of the veterinary prescription drug wholesale distributor permit. A veterinary prescription drug wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212.

(l)Limited prescription drug veterinary wholesale distributor permit.—Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale distributor, or out-of-state prescription drug wholesale distributor, a limited prescription drug veterinary wholesale distributor permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act under the following conditions:

1.The person is engaged in the business of wholesaling prescription and veterinary prescription drugs to persons:

a.Licensed as veterinarians practicing on a full-time basis;

b.Regularly and lawfully engaged in instruction in veterinary medicine;

c.Regularly and lawfully engaged in law enforcement activities;

d.For use in research not involving clinical use; or

e.For use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing.

2.No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3.The person does not distribute in any jurisdiction prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4.A limited prescription drug veterinary wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

5.A limited prescription drug veterinary wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6.A limited prescription drug veterinary wholesale distributor must comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, except that a limited prescription drug veterinary wholesale distributor is not required to provide a pedigree paper as required by s. 499.01212 upon the wholesale distribution of a prescription drug to a veterinarian.

7.A limited prescription drug veterinary wholesale distributor may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8.A limited prescription drug veterinary wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesale distributor in this state if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.

(m)Medical oxygen retail establishment permit.—A medical oxygen retail establishment permit is required for any person that sells medical oxygen to patients only. The sale must be based on an order from a practitioner authorized by law to prescribe. The term does not include a pharmacy licensed under chapter 465.

1.A medical oxygen retail establishment may not possess, purchase, sell, or trade any prescription drug other than medical oxygen.

2.A medical oxygen retail establishment may refill medical oxygen for an individual patient based on an order from a practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills medical oxygen must comply with all appropriate state and federal good manufacturing practices.

3.A medical oxygen retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

4.Prescription medical oxygen sold by a medical oxygen retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

(n)Compressed medical gas wholesale distributor permit.—A compressed medical gas wholesale distributor is a wholesale distributor that is limited to the wholesale distribution of compressed medical gases to other than the consumer or patient. The compressed medical gas must be in the original sealed container that was purchased by that wholesale distributor. A compressed medical gas wholesale distributor may not possess or engage in the wholesale distribution of any prescription drug other than compressed medical gases. The department shall adopt rules that govern the wholesale distribution of prescription medical oxygen for emergency use. With respect to the emergency use of prescription medical oxygen, those rules may not be inconsistent with rules and regulations of federal agencies unless the Legislature specifically directs otherwise.

(o)Compressed medical gas manufacturer permit.—A compressed medical gas manufacturer permit is required for any person that engages in the manufacture of compressed medical gases or repackages compressed medical gases from one container to another.

1.A compressed medical gas manufacturer may not manufacture or possess any prescription drug other than compressed medical gases.

2.A compressed medical gas manufacturer may engage in wholesale distribution of compressed medical gases manufactured at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.

3.A compressed medical gas manufacturer must comply with all appropriate state and federal good manufacturing practices.

(p)Over-the-counter drug manufacturer permit.—An over-the-counter drug manufacturer permit is required for any person that engages in the manufacture or repackaging of an over-the-counter drug.

1.An over-the-counter drug manufacturer may not possess or purchase prescription drugs.

2.A pharmacy is exempt from obtaining an over-the-counter drug manufacturer permit if it is operating in compliance with pharmacy practice standards as defined in chapter 465 and the rules adopted under that chapter.

3.An over-the-counter drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(q)Device manufacturer permit.—

1.A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if:

a.The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient; or

b.The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8).

2.A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

3.The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of medical devices for human use.

(r)Cosmetic manufacturer permit.—A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph.

(s)Third party logistics provider permit.—A third party logistics provider permit is required for any person that contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer or wholesale distributor, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. Each third party logistics provider permittee shall comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, with the exception of those wholesale distributions described in s. 499.01212(3)(a), and other rules that the department requires.

(t)Health care clinic establishment permit.—Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1.An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2.The health care clinic establishment must employ a qualifying practitioner at each establishment.

3.In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4.The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.

5.A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6.This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license.

(3)A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited

quantities intended for research and development and not for resale or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subsection and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; if available, the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The department shall define the term "limited quantities" by rule, and may include the allowable number of transactions within a given period of time and the amount of prescription drugs distributed into the state for purposes of this exemption. The failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(4)(a)A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1.Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2.Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

(b)A permit issued under this part is not required to distribute limited quantities of a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing. The department shall define "limited quantities" by rule and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.

1.Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2.All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3.Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

4.The immediate package or container of any active pharmaceutical ingredient distributed into the state that is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: "Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale."

(c)An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for such transactions.

(d)Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file:

1.A record of the FDA establishment registration number, if any;

2.The resident state prescription drug wholesale distribution license, permit, or registration number; and

3.A copy of the most recent resident state or FDA inspection report, for all distributors and establishments [1]from whom they purchase or receive prescription drugs under this subsection.

(e)All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs within or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f)A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity, potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g)The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(h)This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(5)A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(54)(a)3., if:

(a)The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;

(b)The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;

(c)The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and

(d)The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.

The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection.

History.—s. 34, ch. 82-225; s. 108, ch. 83-218; s. 1, ch. 83-265; ss. 14, 15, 18, 19, 52, ch. 92-69; ss. 30, 31, 34, 35, ch. 98-151; ss. 37, 40, ch. 2000-242; s. 20, ch. 2001-53; s. 138, ch. 2001-277; ss. 11, 12, 13, 14, 18, 19, ch. 2003-155; s. 85, ch. 2004-5; ss. 2, 3, ch. 2004-328; ss. 2, 3, ch. 2006-92; ss. 22, 25, ch. 2007-6; ss. 10, 11, ch. 2008-207; s. 2, ch. 2009-221; ss. 23, 39, ch. 2010-161; s. 4, ch. 2012-37; s. 34, ch. 2012-61; s. 11, ch. 2012-143.

[1]Note.—The word "from" was inserted by the editors.

Note.—Subsection (2) intro. former s. 499.012(2) intro.; paragraph (2)(c) former s. 499.012(2)(e); paragraph (2)(d) former s. 499.012(2)(a); paragraph (2)(e) former s. 499.012(2)(c); paragraph (2)(f) former s. 499.012(2)(d); paragraph (2)(g) former s. 499.014; paragraph (2)(i) former s. 499.012(2)(f); paragraph (2)(k) former s. 499.012(2)(g); paragraph (2)(l) former s. 499.012(2)(h); paragraph (2)(n) former s. 499.012(2)(b); paragraph (2)(o) former s. 499.013(2)(c); paragraph (2)(p) former s. 499.013(2)(b); paragraph (2)(q) former s. 499.013(2)(d); paragraph (2)(r) former s. 499.013(2)(e).

499.012Permit application requirements.—

(1)(a)A permit issued pursuant to this part may be issued only to a natural person who is at least 18 years of age or to an applicant that is not a natural person if each person who, directly or indirectly, manages, controls, or oversees the operation of that applicant is at least 18 years of age.

(b)An establishment that is a place of residence may not receive a permit and may not operate under this part.

(c)A person that applies for or renews a permit to manufacture or distribute prescription drugs may not use a name identical to the name used by any other establishment or licensed person authorized to purchase prescription drugs in this state, except that a restricted drug distributor permit issued to a health care entity will be issued in the name in which the institutional pharmacy permit is issued and a retail pharmacy drug wholesale distributor will be issued a permit in the name of its retail pharmacy permit.

(d)A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesale distributor, limited prescription drug veterinary wholesale distributor, or retail pharmacy drug wholesale distributor may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art

pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy drug wholesale distributor permit to the address of a community pharmacy licensed under chapter 465 which does not meet the definition of a closed pharmacy in s. 499.003.

(e)A county or municipality may not issue an occupational license for any licensing period beginning on or after October 1, 2003, for any establishment that requires a permit pursuant to this part, unless the establishment exhibits a current permit issued by the department for the establishment. Upon presentation of the requisite permit issued by the department, an occupational license may be issued by the municipality or county in which application is made. The department shall furnish to local agencies responsible for issuing occupational licenses a current list of all establishments licensed pursuant to this part.

(2)Notwithstanding subsection (6), a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed; however, a new permit for a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

(3)A written application for a permit or to renew a permit must be filed with the department on forms furnished by the department. The department shall establish, by rule, the form and content of the application to obtain or renew a permit. The applicant must submit to the department with the application a statement that swears or affirms that the information is true and correct.

(4)(a)Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor, an application for a permit must include:

1.The name, full business address, and telephone number of the applicant;

2.All trade or business names used by the applicant;

3.The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs;

4.The type of ownership or operation, such as a partnership, corporation, or sole proprietorship; and

5.The names of the owner and the operator of the establishment, including:

a.If an individual, the name of the individual;

b.If a partnership, the name of each partner and the name of the partnership;

c.If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

d.If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

e.If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company, and the name of the state in which the limited liability company was organized; and

f.Any other relevant information that the department requires.

(b)Upon approval of the application by the department and payment of the required fee, the department shall issue a permit to the applicant, if the applicant meets the requirements of this part and rules adopted under this part.

(c)Any change in information required under paragraph (a) must be submitted to the department before the change occurs.

(d)The department shall consider, at a minimum, the following factors in reviewing the qualifications of persons to be permitted under this part:

1.The applicant's having been found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a violation of a law that directly relates to a drug, device, or cosmetic. A plea of nolo contendere constitutes a finding of guilt for purposes of this subparagraph.

2.The applicant's having been disciplined by a regulatory agency in any state for any offense that would constitute a violation of this part.

3.Any felony conviction of the applicant under a federal, state, or local law;

4.The applicant's past experience in manufacturing or distributing drugs, devices, or cosmetics;

5.The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distributing drugs, devices, or cosmetics;

6.Suspension or revocation by a federal, state, or local government of any permit currently or previously held by the applicant for the manufacture or distribution of any drugs, devices, or cosmetics;

7.Compliance with permitting requirements under any previously granted permits;

8.Compliance with requirements to maintain or make available to the state permitting authority or to federal, state, or local law enforcement officials those records required under this section; and

9.Any other factors or qualifications the department considers relevant to and consistent with the public health and safety.

(5)Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:

(a)The department shall adopt rules for the biennial renewal of permits.

(b)The department shall renew a permit upon receipt of the renewal application and renewal fee if the applicant meets the requirements established under this part and the rules adopted under this part.

(c)A permit, unless sooner suspended or revoked, automatically expires 2 years after the last day of the anniversary month in which the permit was originally issued. A permit issued under this part may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees. If a renewal application and fee are submitted and postmarked after the expiration date of the permit, the permit may be renewed only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, not later than 60 days after the expiration date.

(d)Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this part has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department.

(6)A permit issued by the department is nontransferable. Each permit is valid only for the person or governmental unit to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily; nor is a permit valid for any establishment other than the establishment for which it was originally issued.

(a)A person permitted under this part must notify the department before making a change of address. The department shall set a change of location fee not to exceed $100.

(b)1.An application for a new permit is required when a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or when a lessee agrees to undertake or provide services to the extent that legal liability for operation of the establishment will rest with the lessee. The application for the new permit must be made before the date of the sale, transfer, assignment, or lease.

2.A permittee that is authorized to distribute prescription drugs may transfer such drugs to the new owner or lessee under subparagraph 1. only after the new owner or lessee has been approved for a permit to distribute prescription drugs.

(c)If an establishment permitted under this part closes, the owner must notify the department in writing before the effective date of closure and must:

1.Return the permit to the department;

2.If the permittee is authorized to distribute prescription drugs, indicate the disposition of such drugs, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to records that are required to be maintained under this part. Transfer of ownership of prescription drugs may be made only to persons authorized to possess prescription drugs under this part.

The department may revoke the permit of any person that fails to comply with the requirements of this subsection.

(7)A permit must be posted in a conspicuous place on the licensed premises.

(8)An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor submitted to the department must include:

(a)The name, full business address, and telephone number of the applicant.

(b)All trade or business names used by the applicant.

(c)The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs.

(d)The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

(e)The names of the owner and the operator of the establishment, including:

1.If an individual, the name of the individual.

2.If a partnership, the name of each partner and the name of the partnership.

3.If a corporation:

a.The name, address, and title of each corporate officer and director.

b.The name and address of the corporation, resident agent of the corporation, the resident agent's address, and the corporation's state of incorporation.

c.The name and address of each shareholder of the corporation that owns 5 percent or more of the outstanding stock of the corporation.

4.If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

5.If a limited liability company:

a.The name and address of each member.

b.The name and address of each manager.

c.The name and address of the limited liability company, the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(f)If applicable, the name and address of each member of the affiliated group of which the applicant is a member.

(g)1.For an application for a new permit, the estimated annual dollar volume of prescription drug sales of the applicant, the estimated annual percentage of the applicant's total company sales that are prescription drugs, the applicant's estimated annual total dollar volume of purchases of prescription drugs, and the applicant's estimated annual total dollar volume of prescription drug purchases directly from manufacturers.

2.For an application to renew a permit, the total dollar volume of prescription drug sales in the previous year, the total dollar volume of prescription drug sales made in the previous 6 months, the percentage of total company sales that were prescription drugs in the previous year, the total dollar volume of purchases of prescription drugs in the previous year, and the total dollar volume of prescription drug purchases directly from manufacturers in the previous year.

Such portions of the information required pursuant to this paragraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

(h)The tax year of the applicant.

(i)A copy of the deed for the property on which applicant's establishment is located, if the establishment is owned by the applicant, or a copy of the applicant's lease for the property on which applicant's establishment is located that has an original term of not less than 1 calendar year, if the establishment is not owned by the applicant.

(j)A list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or possess prescription drugs.

(k)The name of the manager of the establishment that is applying for the permit or to renew the permit, the next four highest ranking employees responsible for prescription drug wholesale operations for the establishment, and the name of all affiliated parties for the establishment, together with the personal information statement and fingerprints required pursuant to subsection (9) for each of such persons.

(l)The name of each of the applicant's designated representatives as required by subsection (16), together with the personal information statement and fingerprints required pursuant to subsection (9) for each such person.

(m)For an applicant that is a secondary wholesale distributor, each of the following:

1.A personal background information statement containing the background information and fingerprints required pursuant to subsection (9) for each person named in the applicant's response to paragraphs (k) and (l) and for each affiliated party of the applicant.

2.If any of the five largest shareholders of the corporation seeking the permit is a corporation, the name, address, and title of each corporate officer and director of each such corporation; the name and address of such corporation; the name of such corporation's resident agent, such corporation's resident agent's address, and such corporation's state of its incorporation; and the name and address of each shareholder of such corporation that owns 5 percent or more of the stock of such corporation.

3.The name and address of all financial institutions in which the applicant has an account which is used to pay for the operation of the establishment or to pay for drugs purchased for the establishment, together with the names of all persons that are authorized signatories on such accounts. The portions of the information required

pursuant to this subparagraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

4.The sources of all funds and the amounts of such funds used to purchase or finance purchases of prescription drugs or to finance the premises on which the establishment is to be located.

5.If any of the funds identified in subparagraph 4. were borrowed, copies of all promissory notes or loans used to obtain such funds.

(n)Any other relevant information that the department requires, including, but not limited to, any information related to whether the applicant satisfies the definition of a primary wholesale distributor or a secondary wholesale distributor.

(o)Documentation of the credentialing policies and procedures required by s. 499.0121(15).

(9)(a)Each person required by subsection (8) to provide a personal information statement and fingerprints shall provide the following information to the department on forms prescribed by the department:

1.The person's places of residence for the past 7 years.

2.The person's date and place of birth.

3.The person's occupations, positions of employment, and offices held during the past 7 years.

4.The principal business and address of any business, corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on.

5.Whether the person has been, during the past 7 years, the subject of any proceeding for the revocation of any license and, if so, the nature of the proceeding and the disposition of the proceeding.

6.Whether, during the past 7 years, the person has been enjoined, temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning any such event.

7.A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past 7 years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party.

8.A description of any felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony in this state must be reported. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the department a copy of the final written order of disposition.

9.A photograph of the person taken in the previous 30 days.

10.A set of fingerprints for the person on a form and under procedures specified by the department, together with payment of an amount equal to the costs incurred by the department for the criminal record check of the person.

11.The name, address, occupation, and date and place of birth for each member of the person's immediate family who is 18 years of age or older. As used in this subparagraph, the term "member of the person's immediate family" includes the person's spouse, children, parents, siblings, the spouses of the person's children, and the spouses of the person's siblings.

12.Any other relevant information that the department requires.

(b)The information required pursuant to paragraph (a) shall be provided under oath.

(c)The department shall submit the fingerprints provided by a person for initial licensure to the Department of Law Enforcement for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person. The department shall submit the fingerprints provided by a person as a part of a renewal application to the Department of Law Enforcement for a statewide criminal record check, and for forwarding to the Federal Bureau of Investigation for a national criminal record check, for the initial renewal of a permit after January 1, 2004; for any subsequent renewal of a permit, the department shall submit the required information for a statewide and national criminal record check of the person. Any person who as a part of an initial permit application or initial permit renewal after January 1, 2004, submits to the department a set of fingerprints required for the criminal record check required in this paragraph shall not be required to provide a subsequent set of fingerprints for a criminal record check to the department, if the person has undergone a criminal record check as a condition of the issuance of an initial permit or the initial renewal of a permit of an applicant after January 1, 2004.

(10)The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor if:

(a)The applicant has not met the requirements for the permit.

(b)The management, officers, or directors of the applicant or any affiliated party are found by the department to be incompetent or untrustworthy.

(c)The applicant is so lacking in experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health.

(d)The applicant is so lacking in experience in managing a wholesale distributor as to jeopardize the reasonable promise of successful operation of the wholesale distributor.

(e)The applicant is lacking in experience in the distribution of prescription drugs.

(f)The applicant's past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.

(g)The applicant is affiliated directly or indirectly through ownership, control, or other business relations, with any person or persons whose business operations are or have been detrimental to the public health.

(h)The applicant, or any affiliated party, has been found guilty of or has pleaded guilty or nolo contendere to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country, regardless of whether adjudication of guilt was withheld.

(i)The applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period.

(j)The applicant has furnished false or fraudulent information or material in any application made in this state or any other state in connection with obtaining a permit or license to manufacture or distribute drugs, devices, or cosmetics.

(k)That a federal, state, or local government permit currently or previously held by the applicant, or any affiliated party, for the manufacture or distribution of any drugs, devices, or cosmetics has been disciplined, suspended, or revoked and has not been reinstated.

(l)The applicant does not possess the financial or physical resources to operate in compliance with the permit being sought, this chapter, and the rules adopted under this chapter.

(m)The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund.

(n)The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, any federal or state drug law, or any felony where the underlying facts related to drugs, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld, other than through the ownership of stock in a publicly traded company or a mutual fund.

(o)The applicant for renewal of a permit under s. 499.01(2)(d) or (e) has not actively engaged in the wholesale distribution of prescription drugs, as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by not fewer than 12 wholesale distributions in the previous year and not fewer than three wholesale distributions in the previous 6 months.

(p)Information obtained in response to s. 499.01(2)(d) or (e) demonstrates it would not be in the best interest of the public health, safety, and welfare to issue a permit.

(q)The applicant does not possess the financial standing and business experience for the successful operation of the applicant.

(r)The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under this part, similar federal laws, similar laws in other states, or the rules adopted under such laws.

(11)Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor permit to the applicant.

(12)For a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:

(a)The department shall adopt rules for the annual renewal of permits. At least 90 days before the expiration of a permit, the department shall forward a permit renewal notification and renewal application to the prescription drug wholesale distributor or out-of-state prescription drug wholesale distributor at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire and that the establishment may not operate unless the permit for the establishment is renewed timely.

(b)A permit, unless sooner suspended or revoked, automatically expires 1 year after the last day of the anniversary month in which the permit was originally issued. A permit may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees. If a renewal application and fee are submitted and postmarked after 45 days prior to the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee. A permittee that has submitted a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal application.

(c)Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this section has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit; pay the applicable application fee, initial permit fee, and all applicable penalties; and be issued a new permit by the department.

(13)A person that engages in wholesale distribution of prescription drugs in this state must have a wholesale distributor's permit issued by the department, except as noted in this section. Each establishment must be separately permitted except as noted in this subsection.

(a)A separate establishment permit is not required when a permitted prescription drug wholesale distributor consigns a prescription drug to a pharmacy that is permitted under chapter 465 and located in this state, provided that:

1.The consignor wholesale distributor notifies the department in writing of the contract to consign prescription drugs to a pharmacy along with the identity and location of each consignee pharmacy;

2.The pharmacy maintains its permit under chapter 465;

3.The consignor wholesale distributor, which has no legal authority to dispense prescription drugs, complies with all wholesale distribution requirements of ss. 499.0121 and 499.01212 with respect to the consigned drugs and maintains records documenting the transfer of title or other completion of the wholesale distribution of the consigned prescription drugs;

4.The distribution of the prescription drug is otherwise lawful under this chapter and other applicable law;

5.Open packages containing prescription drugs within a pharmacy are the responsibility of the pharmacy, regardless of how the drugs are titled; and

6.The pharmacy dispenses the consigned prescription drug in accordance with the limitations of its permit under chapter 465 or returns the consigned prescription drug to the consignor wholesale distributor. In addition, a person who holds title to prescription drugs may transfer the drugs to a person permitted or licensed to handle the reverse distribution or destruction of drugs. Any other distribution by and means of the consigned prescription drug by any person, not limited to the consignor wholesale distributor or consignee pharmacy, to any other person is prohibited.

(b)A wholesale distributor's permit is not required for the one-time transfer of title of a pharmacy's lawfully acquired prescription drug inventory by a pharmacy with a valid permit issued under chapter 465 to a consignor prescription drug wholesale distributor, permitted under this chapter, in accordance with a written consignment agreement between the pharmacy and that wholesale distributor if the permitted pharmacy and the permitted prescription drug wholesale distributor comply with all of the provisions of paragraph (a) and the prescription drugs continue to be within the permitted pharmacy's inventory for dispensing in accordance with the limitations of the pharmacy permit under chapter 465. A consignor drug wholesale distributor may not use the pharmacy as a wholesale distributor through which it distributes the prescription drugs to other pharmacies. Nothing in this section is intended to prevent a wholesale distributor from obtaining this inventory in the event of nonpayment by the pharmacy.

(c)A separate establishment permit is not required when a permitted prescription drug wholesale distributor operates temporary transit storage facilities for the sole purpose of storage, for up to 16 hours, of a delivery of prescription drugs when the wholesale distributor was temporarily unable to complete the delivery to the recipient.

(d)The department shall require information from each wholesale distributor as part of the permit and renewal of such permit, as required under this section.

(14)Personnel employed in wholesale distribution must have appropriate education and experience to enable them to perform their duties in compliance with state permitting requirements.

(15)The name of a permittee or establishment on a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit may not include any indicia of attainment of any educational degree, any indicia that

the permittee or establishment possesses a professional license, or any name or abbreviation that the department determines is likely to cause confusion or mistake or that the department determines is deceptive, including that of any other entity authorized to purchase prescription drugs.

(16)(a)Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor must designate in writing to the department at least one natural person to serve as the designated representative of the wholesale distributor. Such person must have an active certification as a designated representative from the department.

(b)To be certified as a designated representative, a natural person must:

1.Submit an application on a form furnished by the department and pay the appropriate fees;

2.Be at least 18 years of age;

3.Have not less than 2 years of verifiable full-time work experience in a pharmacy licensed in this state or another state, where the person's responsibilities included, but were not limited to, recordkeeping for prescription drugs, or have not less than 2 years of verifiable full-time managerial experience with a prescription drug wholesale distributor licensed in this state or in another state;

4.Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs. This requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year; and

5.Provide the department with a personal information statement and fingerprints pursuant to subsection (9).

(c)The department may deny an application for certification as a designated representative or may suspend or revoke a certification of a designated representative pursuant to s. 499.067.

(d)A designated representative:

1.Must be actively involved in and aware of the actual daily operation of the wholesale distributor.

2.Must be employed full time in a managerial position by the wholesale distributor.

3.Must be physically present at the establishment during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence.

4.May serve as a designated representative for only one wholesale distributor at any one time.

(e)A wholesale distributor must notify the department when a designated representative leaves the employ of the wholesale distributor. Such notice must be provided to the department within 10 business days after the last day of designated representative's employment with the wholesale distributor.

(f)A wholesale distributor may not operate under a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.

History.—s. 34, ch. 82-225; s. 108, ch. 83-218; s. 1, ch. 83-265; ss. 14, 15, 52, ch. 92-69; s. 187, ch. 97-264; ss. 30, 31, ch. 98-151; s. 172, ch. 99-397; s. 37, ch. 2000-242; s. 20, ch. 2001-53; s. 138, ch. 2001-277; s. 38, ch. 2002-400; ss. 11,

12, 13, 14, ch. 2003-155; s. 85, ch. 2004-5; s. 3, ch. 2004-328; s. 2, ch. 2005-248; ss. 2, 3, ch. 2006-92; s. 22, ch. 2007-6; ss. 2, 10, 11, 28, ch. 2008-207; s. 61, ch. 2009-21; s. 17, ch. 2011-141; s. 67, ch. 2012-5.
Note.—Subsections (1)-(7) former s. 499.01(2)-(8).

499.01201Agency for Health Care Administration review and use of statute and rule violation or compliance data.—Notwithstanding any other provisions of law to the contrary, the Agency for Health Care Administration may not:

(1)Review or use any violation or alleged violation of s. 499.0121(6) or s. 499.01212, or any rules adopted under those sections, as a ground for denying or withholding any payment of a Medicaid reimbursement to a pharmacy licensed under chapter 465; or

(2)Review or use compliance with s. 499.0121(6) or s. 499.01212, or any rules adopted under those sections, as the subject of any audit of Medicaid-related records held by a pharmacy licensed under chapter 465.
History.—s. 4, ch. 2005-248; s. 12, ch. 2008-207.

499.0121Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(1)ESTABLISHMENTS.—An establishment at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed must:

(a)Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(b)Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c)Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(d)Be maintained in a clean and orderly condition; and

(e)Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2)SECURITY.—

(a)An establishment that is used for wholesale drug distribution must be secure from unauthorized entry.

1.Access from outside the premises must be kept to a minimum and be well-controlled.

2.The outside perimeter of the premises must be well-lighted.

3.Entry into areas where prescription drugs are held must be limited to authorized personnel.

(b)An establishment that is used for wholesale drug distribution must be equipped with:

1.An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers and establishments that only handle medical oxygen; and

2.A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c)Any vehicle that contains prescription drugs must be secure from unauthorized access to the prescription drugs in the vehicle.

(3)STORAGE.—All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the official compendium.

(a)If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(b)Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs must be used to document proper storage of prescription drugs.

(c)The recordkeeping requirements in subsection (6) must be followed for all stored prescription drugs.

(4)EXAMINATION OF MATERIALS AND RECORDS.—

(a)Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b)Each outgoing shipment must be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have expired or been damaged in storage or held under improper conditions.

(c)The recordkeeping requirements in subsection (6) must be followed for all incoming and outgoing prescription drugs.

(d)Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. This includes authenticating each transaction listed on a pedigree paper, as defined in s. 499.003(37).

(5)RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.—

(a)1.Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs.

2.Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined.

(b)Any prescription drugs of which the immediate or sealed outer containers or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.

(c)If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling, as a result of storage or shipping.

(d)The recordkeeping requirements in subsection (6) must be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(6)RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(a)Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:

1.The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2.The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs;

3.The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of;

4.The dates of receipt and distribution or other disposition of the drugs; and

5.Any financial documentation supporting the transaction.

(b)Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials for a period of 2 years following disposition of the drugs or 3 years after the creation of the records, whichever period is longer.

(c)Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and must be readily available.

(d)Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain records that include the name and principal address of the seller or transferor of the product, the address of the location from which the product was shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person who purchased the product.

(e)When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part.

(7)PRESCRIPTION DRUG PURCHASE LIST.—Each wholesale distributor, except for a manufacturer, shall annually provide the department with a written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list. Such portions of the information required pursuant to this subsection which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

(8)WRITTEN POLICIES AND PROCEDURES.—Wholesale distributors must establish, maintain, and adhere to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale distributors must include in their written policies and procedures:

(a)A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

(b)A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:

1.Any action initiated at the request of the Food and Drug Administration or any other federal, state, or local law enforcement or other government agency, including the department.

2.Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market; or

3.Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(c)A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, state, or national emergency, occurs.

(d)A procedure to ensure that any outdated prescription drugs are segregated from other drugs and returned to the manufacturer or repackager or destroyed. This procedure must provide for written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for 2 years after disposition of the outdated drugs.

(9)RESPONSIBLE PERSONS.—Wholesale distributors must establish and maintain lists of officers, directors, managers, designated representatives, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(10)COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.—A wholesale distributor must operate in compliance with applicable federal, state, and local laws and regulations.

(a)A wholesale distributor must allow the department and authorized federal, state, and local officials to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b)A wholesale distributor that deals in controlled substances must register with the Drug Enforcement Administration and must comply with all applicable state, local, and federal laws. A wholesale distributor that distributes any substance controlled under chapter 893 must notify the department when registering with the Drug Enforcement Administration pursuant to that chapter and must provide the department with its DEA number.

(11)SALVAGING AND REPROCESSING.—A wholesale distributor is subject to any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

(12)SHIPPING AND TRANSPORTATION.—The person responsible for shipment and transportation of a prescription drug in a wholesale distribution may use a common carrier; its own vehicle or employee acting within the scope of employment if authorized under s. 499.03 for the possession of prescription drugs in this state; or, in the case of a prescription drug intended for domestic distribution, an independent contractor who must be the agent of the authorized seller or recipient responsible for shipping and transportation as set forth in a written contract between the parties. A person selling a prescription drug for export must obtain documentation, such as a validated airway bill, bill of lading, or other appropriate documentation that the prescription drug was exported. A person responsible for shipping or transporting prescription drugs is not required to maintain documentation from a common carrier that the designated recipient received the prescription drugs; however, the person must obtain such documentation from the common carrier and make it available to the department upon request of the department.

(13)DUE DILIGENCE OF SUPPLIERS.—Prior to purchasing any prescription drugs from another wholesale distributor, a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a prescription drug repackager must:

(a)Enter an agreement with the selling wholesale distributor by which the selling wholesale distributor will indemnify the purchasing wholesale distributor for any loss caused to the purchasing wholesale distributor related to the purchase of drugs from the selling wholesale distributor which are determined to be counterfeit or to have been distributed in violation of any federal or state law governing the distribution of drugs.

(b)Determine that the selling wholesale distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department under s. 499.012(8)(g) or $500,000; however the coverage need not exceed $2 million.

(c)Obtain information from the selling wholesale distributor, including the length of time the selling wholesale distributor has been licensed in this state, a copy of the selling wholesale distributor's licenses or permits, and background information concerning the ownership of the selling wholesale distributor, including the experience of the wholesale distributor in the wholesale distribution of prescription drugs.

(d)Verify that the selling wholesale distributor's Florida permit is valid.

(e)Inspect the selling wholesale distributor's licensed establishment to document that it has a policies and procedures manual relating to the distribution of drugs, the appropriate temperature controlled environment for drugs requiring temperature control, an alarm system, appropriate access restrictions, and procedures to ensure that records related to the wholesale distribution of prescription drugs are maintained as required by law:

1.Before purchasing any drug from the wholesale distributor, and at least once each subsequent year; or

2.Before purchasing any drug from the wholesale distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale distributors in the state in which the establishment is located.

(14)DISTRIBUTION REPORTING.—Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by the 20th of the next month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug Enforcement Administration. Submission of electronic data must be made in a secured Internet environment that allows for manual or automated transmission. Upon successful transmission, an acknowledgment page must be displayed to confirm receipt. The report must contain the following information:

(a)The federal Drug Enforcement Administration registration number of the wholesale distributing location.
(b)The federal Drug Enforcement Administration registration number of the entity to which the drugs are distributed or from which the drugs are received.
(c)The transaction code that indicates the type of transaction.
(d)The National Drug Code identifier of the product and the quantity distributed or received.
(e)The Drug Enforcement Administration Form 222 number or Controlled Substance Ordering System Identifier on all Schedule II transactions.
(f)The date of the transaction.

The department must share the reported data with the Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity's clinical needs. The Department of Law Enforcement shall investigate purchases at levels that are inconsistent with the purchasing entity's clinical needs to determine whether violations of chapter 893 have occurred.

(15)DUE DILIGENCE OF PURCHASERS.—
(a)Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor must establish and maintain policies and procedures to credential physicians licensed under chapter 458, chapter 459, chapter 461, or chapter 466 and pharmacies that purchase or otherwise receive from the wholesale distributor controlled substances listed in Schedule II or Schedule III as provided in s. 893.03. The prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, or retail pharmacy drug wholesale distributor shall maintain records of such credentialing and make the records available to the department upon request. Such credentialing must, at a minimum, include:
1.A determination of the clinical nature of the receiving entity, including any specialty practice area.
2.A review of the receiving entity's history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor.
3.A determination that the receiving entity's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs.
(b)A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the distributor's policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.

(c)A wholesale distributor may not distribute controlled substances to an entity if any criminal history record check for any person associated with that entity shows that the person has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.

(d)The department shall assess national data from the Automation of Reports and Consolidated Orders System of the federal Drug Enforcement Administration, excluding Florida data, and identify the national average of grams of hydrocodone, morphine, oxycodone, and methadone distributed per pharmacy registrant per month in the most recent year for which data is available. The department shall report the average for each of these drugs to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2011. The department shall assess the data reported pursuant to subsection (14) and identify the statewide average of grams of each benzodiazepine distributed per community pharmacy per month. The department shall report the average for each benzodiazepine to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2011.

History.—s. 16, ch. 92-69; s. 32, ch. 98-151; ss. 38, 40, ch. 2000-242; ss. 15, 16, 18, ch. 2003-155; s. 86, ch. 2004-5; s. 4, ch. 2004-328; s. 10, ch. 2004-387; s. 3, ch. 2005-248; s. 5, ch. 2006-310; s. 17, ch. 2007-6; s. 13, ch. 2008-207; s. 62, ch. 2009-21; s. 3, ch. 2009-221; s. 40, ch. 2010-161; s. 18, ch. 2011-141.

Note.—Paragraph (6)(d) former s. 499.013(4).

499.01211Drug Wholesale Distributor Advisory Council.—

(1)There is created the Drug Wholesale Distributor Advisory Council within the department. The council shall meet at least once each calendar quarter. Staff for the council shall be provided by the department. The council shall consist of 11 members who shall serve without compensation. The council shall elect a chairperson and a vice chairperson annually.

(2)The Secretary of Business and Professional Regulation or his or her designee and the Secretary of Health Care Administration or her or his designee shall be members of the council. The Secretary of Business and Professional Regulation shall appoint nine additional members to the council who shall be appointed to a term of 4 years each, as follows:

(a)Three different persons each of whom is employed by a different prescription drug wholesale distributor licensed under this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003(47).

(b)One person employed by a prescription drug wholesale distributor licensed under this part which is a secondary wholesale distributor, as defined in s. 499.003(52).

(c)One person employed by a retail pharmacy chain located in this state.

(d)One person who is a member of the Board of Pharmacy and is a pharmacist licensed under chapter 465.

(e)One person who is a physician licensed pursuant to chapter 458 or chapter 459.

(f)One person who is an employee of a hospital licensed pursuant to chapter 395 and is a pharmacist licensed pursuant to chapter 465.

(g)One person who is an employee of a pharmaceutical manufacturer.

(3)The council shall review this part and the rules adopted to administer this part annually, provide input to the department regarding all proposed rules to administer this part, make recommendations to the department to improve the protection of the prescription drugs and public health, make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs, and make recommendations to

minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.
History.—s. 17, ch. 2003-155; s. 23, ch. 2007-6; s. 105, ch. 2008-6; s. 14, ch. 2008-207; s. 41, ch. 2010-161; s. 4, ch. 2012-143.

499.01212Pedigree paper.—

(1)APPLICATION.—Each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.

(2)FORMAT.—A pedigree paper must contain the following information:

(a)For the wholesale distribution of a prescription drug within the normal distribution chain:

1.The following statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."

2.The manufacturer's national drug code identifier and the name and address of the wholesale distributor and the purchaser of the prescription drug.

3.The name of the prescription drug as it appears on the label.

4.The quantity, dosage form, and strength of the prescription drug.

The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers, the date of the shipment from the manufacturer to the wholesale distributor, the lot numbers of such drugs, and the invoice numbers from the manufacturer.

(b)For all other wholesale distributions of prescription drugs:

1.The quantity, dosage form, and strength of the prescription drugs.

2.The lot numbers of the prescription drugs.

3.The name and address of each owner of the prescription drug and his or her signature.

4.Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.

5.An invoice number, a shipping document number, or another number uniquely identifying the transaction.

6.A certification that the recipient wholesale distributor has authenticated the pedigree papers.

7.The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.

8.The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.

When an affiliated group member obtains title to a prescription drug before distributing the prescription drug as the manufacturer under s. 499.003(31)(e), information regarding the distribution between those affiliated group members may be omitted from a pedigree paper required under this paragraph for subsequent distributions of that prescription drug.

(3)EXCEPTIONS.—A pedigree paper is not required for:

(a)The wholesale distribution of a prescription drug by the manufacturer or by a third party logistics provider performing a wholesale distribution of a prescription drug for a manufacturer.

(b)The wholesale distribution of a prescription drug by a freight forwarder within the authority of a freight forwarder permit.

(c)The wholesale distribution of a prescription drug by a limited prescription drug veterinary wholesale distributor to a veterinarian.

(d)The wholesale distribution of a compressed medical gas.
(e)The wholesale distribution of a veterinary prescription drug.
(f)A drop shipment, provided:
1.The wholesale distributor delivers to the recipient of the prescription drug, within 14 days after the shipment notification from the manufacturer, an invoice and the following sworn statement: "This wholesale distributor purchased the specific unit of the prescription drug listed on the invoice directly from the manufacturer, and the specific unit of prescription drug was shipped by the manufacturer directly to a person authorized by law to administer or dispense the legend drug, as defined in s. 465.003, Florida Statutes, or a member of an affiliated group, with the exception of a repackager." The invoice must contain a unique cross-reference to the shipping document sent by the manufacturer to the recipient of the prescription drug.
2.The manufacturer of the prescription drug shipped directly to the recipient provides and the recipient of the prescription drug acquires, within 14 days after receipt of the prescription drug, a shipping document from the manufacturer that contains, at a minimum:
a.The name and address of the manufacturer, including the point of origin of the shipment, and the names and addresses of the wholesale distributor and the purchaser.
b.The name of the prescription drug as it appears on the label.
c.The quantity, dosage form, and strength of the prescription drug.
d.The date of the shipment from the manufacturer.
3.The wholesale distributor maintains and makes available to the department, upon request, the lot number of such drug if not contained in the shipping document acquired by the recipient.
4.The wholesale distributor that takes title to, but not possession of, the prescription drug is not a member of the affiliated group that receives the prescription drug directly from the manufacturer.

Failure of the manufacturer to provide, the recipient to acquire, or the wholesale distributor to deliver the documentation required under this paragraph shall constitute failure to acquire or deliver a pedigree paper under ss. 499.005(28) and 499.0051. Forgery by the manufacturer, the recipient, or the wholesale distributor of the documentation required to be acquired or delivered under this paragraph shall constitute forgery of a pedigree paper under s. 499.0051.

(g)The wholesale distribution of a prescription drug by a warehouse within an affiliated group to a warehouse or retail pharmacy within its affiliated group, provided:
1.Any affiliated group member that purchases or receives a prescription drug from outside the affiliated group must receive a pedigree paper if the prescription drug is distributed in or into this state and a pedigree paper is required under this section and must authenticate the documentation as required in s. 499.0121(4), regardless of whether the affiliated group member is directly subject to regulation under this part; and
2.The affiliated group makes available, within 48 hours, to the department on request to one or more of its members all records related to the purchase or acquisition of prescription drugs by members of the affiliated group, regardless of the location where the records are stored, if the prescription drugs were distributed in or into this state.
(h)The repackaging of prescription drugs by a repackager solely for distribution to its affiliated group members for the exclusive distribution to and among retail pharmacies that are members of the affiliated group to which the repackager is a member.

1.The repackager must:

a.For all repackaged prescription drugs distributed in or into this state, state in writing under oath with each distribution of a repackaged prescription drug to an affiliated group member warehouse or repackager: "All repackaged prescription drugs are purchased by the affiliated group directly from the manufacturer or from a prescription drug wholesale distributor that purchased the prescription drugs directly from the manufacturer."

b.Purchase all prescription drugs it repackages:

(I)Directly from the manufacturer; or

(II)From a prescription drug wholesale distributor that purchased the prescription drugs directly from the manufacturer.

c.Maintain records in accordance with this section to document that it purchased the prescription drugs directly from the manufacturer or that its prescription drug wholesale supplier purchased the prescription drugs directly from the manufacturer.

2.All members of the affiliated group must provide, within 48 hours, to agents of the department on request to one or more of its members records of purchases by all members of the affiliated group of prescription drugs that have been repackaged, regardless of the location at which the records are stored or at which the repackager is located.

(i)The wholesale distribution of prescription drugs within a medical convenience kit if:

1.The medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a medical device manufacturer;

2.The medical convenience kit manufacturer purchased the prescription drug directly from the manufacturer or from a wholesaler that purchased the prescription drug directly from the manufacturer;

3.The medical convenience kit manufacturer complies with federal law for the distribution of the prescription drugs within the kit; and

4.The drugs contained in the medical kit are:

a.Intravenous solutions intended for the replenishment of fluids and electrolytes;

b.Products intended to maintain the equilibrium of water and minerals in the body;

c.Products intended for irrigation or reconstitution;

d.Anesthetics; or

e.Anticoagulants.

This exemption does not apply to a convenience kit containing any controlled substance that appears in a schedule contained in or subject to chapter 893 or the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

History.—s. 15, ch. 2008-207; s. 4, ch. 2009-221; s. 24, ch. 2010-161.

499.015Registration of drugs, devices, and cosmetics; issuance of certificates of free sale.—

(1)(a)Except for those persons exempted from the definition of manufacturer in s. 499.003(31), any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in this state must register such drug, device, or cosmetic biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug, device, or cosmetic at the time of registration.

(b)The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(2)The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs, devices, and cosmetics packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs, devices, and cosmetics, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug, device, or cosmetic product. This approval or denial must include written notification to the manufacturer.

(3)Except for those persons exempted from the definition of manufacturer in s. 499.003(31), a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug, device, or cosmetic product to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4)Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs, devices, or cosmetics covered by this part until he or she complies with the requirements of this section.

(5)A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6)The department may issue a certificate of free sale for any product that is required to be registered under this part.

(7)A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8)Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a)The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b)The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9)However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.01 and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:

(a)For Class II devices, a copy of the premarket notification letter (510K);

(b)For Class III devices, a Federal Drug Administration premarket approval number;

(c)For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a Federal Drug Administration registration number; or

(d)For a manufacturer of medical devices whose devices are exempt from premarket approval by the Federal Drug Administration, a Federal Drug Administration registration number.

History.—s. 34, ch. 82-225; s. 110, ch. 83-218; s. 1, ch. 83-265; s. 3, ch. 84-115; ss. 20, 52, ch. 92-69; s. 587, ch. 97-103; s. 36, ch. 98-151; s. 1, ch. 99-165; s. 41, ch. 2000-242; s. 12, ch. 2000-326; s. 18, ch. 2001-63; s. 33, ch. 2001-89; s. 88, ch. 2004-5; s. 18, ch. 2008-207; s. 63, ch. 2009-21.

499.023New drugs; sale, manufacture, repackaging, distribution.—A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 26, 52, ch. 92-69.

499.024Drug product classification.—The department shall adopt rules to classify drug products intended for use by humans which the United States Food and Drug Administration has not classified in the federal act or the Code of Federal Regulations.

(1)Drug products must be classified as proprietary, prescription, or investigational drugs.

(2)If a product is distributed without required labeling, it is misbranded while held for sale.

(3)Any product that falls under the definition of drug in s. 499.003(19) may be classified under the authority of this section. This section does not subject portable emergency oxygen inhalators to classification; however, this section does not exempt any person from ss. 499.01 and 499.015.

(4)Any product classified under the authority of this section reverts to the federal classification, if different, upon the federal regulation or act becoming effective.

(5)The department may by rule reclassify drugs subject to this part when such classification action is necessary to protect the public health.

(6)The department may adopt rules that exempt from any labeling or packaging requirements of this part drugs classified under this section if those requirements are not necessary to protect the public health.

History.—s. 9, ch. 88-159; s. 1, ch. 89-296; ss. 27, 52, ch. 92-69; s. 589, ch. 97-103; s. 42, ch. 2000-242; s. 13, ch. 2000-326; s. 61, ch. 2006-1; s. 106, ch. 2008-6; s. 19, ch. 2008-207; s. 5, ch. 2012-143.

499.025Drug products in finished, solid, oral dosage form; identification requirements.—

(1)A drug product in finished, solid, oral dosage form for which a prescription is required by federal or state law may not be manufactured or distributed within this state unless it is clearly and prominently marked or imprinted with an individual symbol, number, company name, words, letters, marking, or national drug code, or any combination thereof, that identifies the drug product and the manufacturer or distributor of the drug product which has the ability to respond to requests for information regarding the drug product.

(2)A manufacturer or distributor must make available to the department on request descriptive material that identifies each current imprint used by the manufacturer.

(3)The department, upon application by a manufacturer, may exempt a particular drug product from the requirements of subsection (1) on the ground that imprinting is not feasible because of the size, texture, or other unique characteristic of the drug product.

(4)This section does not apply to drug products compounded by a pharmacist licensed under chapter 465 in a pharmacy operating under a permit issued by the Board of Pharmacy.

(5)The department shall adopt rules for implementing this section.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 22, ch. 86-256; ss. 28, 52, ch. 92-69; s. 18, ch. 2000-326.

499.028Drug samples or complimentary drugs; starter packs; permits to distribute.—

(1)As used in this section, the term:

(a)"Drug sample," or "complimentary drug," means a human prescription drug that is labeled "sample," "not to be sold," "complimentary," or other words to that effect, that is provided as a courtesy, that is not intended to be sold, and that is intended to promote the sale of the drug.

(b)"Starter packs," also known as "stock samples," "trade packages," "initial dose packs," or "starter stocks," means human prescription drugs that are generally distributed without charge by manufacturers or distributors to pharmacies to be placed in stock and sold at retail. Although starter packs are generally given without charge to the pharmacy, they are not intended to be a free sample to the consumer nor are they labeled as such. Starter packs are subject to regulation as prescription drugs under the Florida Drug and Cosmetic Act in the same manner as stock shipments of prescription drugs. Starter packs are not drug samples.

(2)A person may not sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. An officer or executive of a drug manufacturer or distributor is not subject to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade of a drug sample in violation of this subsection by other employees of the manufacturer or distributor.

(3)Except as provided in this section, a representative of a drug manufacturer or distributor may not distribute any drug sample.

(a)The manufacturer or distributor of a human prescription drug may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. Such a distribution of drug samples may only be made:

1.In response to a written request for drug samples made on a form that meets the requirements of paragraph (b); and

2.Under a system that requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and to return the receipt to the manufacturer or distributor.

(b)A written request for a drug sample that is required by this section must contain:

1.The name, address, professional designation, and signature of the practitioner who makes the request;

2.The name, strength, and dosage form of the drug sample requested and the quantity requested;

3.The name of the manufacturer of the drug sample requested; and

4.The date of the request.

(c)Each drug manufacturer or distributor that makes distributions by mail or common carrier under this paragraph must maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and must maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this paragraph must be made available by the drug manufacturer or distributor to the department for its review and inspection.

(d)The manufacturer or distributor of a drug subject to paragraph (1)(a) may, by means other than mail or common carrier, distribute drug samples only if the

manufacturer or distributor makes the distributions in accordance with paragraph (e) and carries out the activities described in subsections (4)-(9).

(e)Drug samples may only be distributed:

1.To a practitioner authorized by law to prescribe such drugs if the practitioner makes a written request for the drug samples; or

2.At the written request of such a practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. The written request for drug samples must be made on a form that contains the practitioner's name, address, and professional designation, the name, strength, and dosage form of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or distributor of the drug sample, the date of the request, and the signature of the practitioner that makes the request.

(4)A drug manufacturer or distributor must store drug samples under the conditions described on their labels that will maintain the stability, integrity, and effectiveness of the drug samples and will assure that the drug samples remain free of contamination, deterioration, and adulteration.

(5)A drug manufacturer or distributor must conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor. A drug manufacturer or distributor must maintain lists of the names and addresses of each of its representatives who distribute drug samples and of the sites where drug samples are stored. A drug manufacturer or distributor must maintain for at least 3 years records of all drug samples distributed, destroyed, or returned to the manufacturer or distributor, of all inventories maintained under this subsection, of all thefts or significant losses of drug samples, and of all requests made under [1]subparagraph 1. for drug samples. The drug manufacturer or distributor must make available to the department upon request any record or list maintained under this subsection. The department shall provide to the Department of Business and Professional Regulation the names of those practitioners who have received an excessive or inappropriate quantity of such drugs.

(6)A drug manufacturer or distributor must notify the department of any significant loss of drug samples and any known theft of drug samples.

(7)A drug manufacturer or distributor must report to the department any conviction of itself or of its assigns, agents, employees, or representatives for a violation of s. 503(c)(1) of the federal act or of this part because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(8)Drug manufacturers or distributors must provide to the department the name and telephone number of the individual responsible for responding to a request for information regarding drug samples.

(9)All out-of-date drug samples must be returned to the manufacturer or distributor of that drug sample.

(10)A manufacturer or distributor may not directly or through its agents, employees, or independent contractors, hold, distribute, or otherwise dispose of any complimentary drugs or drug samples in this state without first obtaining a complimentary drug distributor permit pursuant to this section.

(11)(a)Application for a permit by a manufacturer or distributor to hold, distribute, or otherwise dispose of drugs pursuant to this section must be made on a form prescribed by the department and must be accompanied by an application fee in an amount not exceeding $250 per year, as is determined by the department.

(b)A permit issued under this section expires 2 years after the date of issuance, unless sooner suspended or revoked.

(c)A permit is renewable biennially upon the filing of an application for renewal and the payment of a renewal fee of not more than $250 per year, as determined by the

department, if the applicant meets the requirements established by this section and the rules adopted under this section.

(12)The department may suspend or revoke a permit issued under this section, after giving notice and an opportunity to be heard pursuant to chapter 120, when:

(a)Such permit was obtained by misrepresentation or fraud or through a mistake of the department.

(b)The holder of the permit has distributed or disposed of any prescription drug, directly or through its agents, employees, or independent contractors, to any person not authorized to possess such drug.

(c)The holder of the permit, or its agents, employees, or independent contractors, has distributed or possessed any prescription drug except in the usual course of its business.

(d)The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription drug that is misbranded or adulterated under this part.

(e)The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription drug without written request, when a written request is required by this section.

(f)The holder of the permit has in its employ, or uses as agent or independent contractor for the purpose of distributing or disposing of drugs, any person who has:

1.Violated the requirements of this section or any rule adopted under this section.

2.Been convicted in any of the courts of this state, the United States, or any other state of a felony or any other crime involving moral turpitude or involving those drugs named or described in chapter 893.

(13)The department may, pursuant to chapter 120, impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of this section or rules adopted under this section. Each day such violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine. All amounts collected under this section shall be deposited into the Professional Regulation Trust Fund. In determining the amount of fine to be levied for a violation, the following factors must be considered:

(a)The severity of the violation.

(b)Any actions taken by the permittee to correct the violation or to remedy complaints.

(c)Any previous violations.

(14)Chapter 893 applies to all drug samples that are controlled substances.

(15)A person may not possess a prescription drug sample unless:

(a)The drug sample was prescribed to her or him as evidenced by the label required in s. 465.0276(5).

(b)She or he is the employee of a complimentary drug distributor that holds a permit issued under this part.

(c)She or he is a person to whom prescription drug samples may be distributed pursuant to this section.

(d)He or she is an officer or employee of a federal, state, or local government acting within the scope of his or her employment.

History.—s. 34, ch. 82-225; s. 114, ch. 83-218; s. 1, ch. 83-265; s. 8, ch. 84-115; s. 23, ch. 86-256; ss. 29, 52, ch. 92-69; s. 198, ch. 94-218; s. 23, ch. 97-98; s. 590, ch. 97-103; s. 39, ch. 99-397; s. 20, ch. 2008-207; s. 12, ch. 2012-143.

[1]Note.—Subsection (5) does not contain subparagraphs.

499.029Cancer Drug Donation Program.—

(1)This section may be cited as the "Cancer Drug Donation Program Act."

(2)There is created a Cancer Drug Donation Program within the department for the purpose of authorizing and facilitating the donation of cancer drugs and supplies to eligible patients.

(3)As used in this section:

(a)"Cancer drug" means a prescription drug that has been approved under s. 505 of the federal Food, Drug, and Cosmetic Act and is used to treat cancer or its side effects or is used to treat the side effects of a prescription drug used to treat cancer or its side effects. "Cancer drug" does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

(b)"Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.

(c)"Donor" means a patient or patient representative who donates cancer drugs or supplies needed to administer cancer drugs that have been maintained within a closed drug delivery system; health care facilities, nursing homes, hospices, or hospitals with closed drug delivery systems; or pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies, in accordance with this section. "Donor" includes a physician licensed under chapter 458 or chapter 459 who receives cancer drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

(d)"Eligible patient" means a person who the department determines is eligible to receive cancer drugs from the program.

(e)"Participant facility" means a class II hospital pharmacy that has elected to participate in the program and that accepts donated cancer drugs and supplies under the rules adopted by the department for the program.

(f)"Prescribing practitioner" means a physician licensed under chapter 458 or chapter 459 or any other medical professional with authority under state law to prescribe cancer medication.

(g)"Program" means the Cancer Drug Donation Program created by this section.

(h)"Supplies" means any supplies used in the administration of a cancer drug.

(4)Any donor may donate cancer drugs or supplies to a participant facility that elects to participate in the program and meets criteria established by the department for such participation. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program. Cancer drugs billed to and paid for by Medicaid in long-term care facilities that are eligible for return to stock under federal Medicaid regulations shall be credited to Medicaid and are not eligible for donation under the program. A participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital.

(5)The cancer drugs or supplies donated to the program may be prescribed only by a prescribing practitioner for use by an eligible patient and may be dispensed only by a pharmacist.

(6)(a)A cancer drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container, or in a tamper-evident unit-dose packaging, except that a cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened with tamper-resistant packaging intact.

(b)A cancer drug may not be accepted or dispensed under the program if the drug bears an expiration date that is less than 6 months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled as determined in paragraph (c).

(c)Prior to being dispensed to an eligible patient, the cancer drug or supplies donated under the program shall be inspected by a pharmacist to determine that the drug and supplies do not appear to have been tampered with or mislabeled.

(d)A dispenser of donated cancer drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated cancer drugs or supplies dispensed to any patient under the program, and a public or private third-party payor is not required to provide reimbursement to a dispenser for donated cancer drugs or supplies dispensed to any patient under the program.

(7)(a)A donation of cancer drugs or supplies shall be made only at a participant facility. A participant facility may decline to accept a donation. A participant facility that accepts donated cancer drugs or supplies under the program shall comply with all applicable provisions of state and federal law relating to the storage and dispensing of the donated cancer drugs or supplies.

(b)A participant facility that voluntarily takes part in the program may charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies under the program. The fee shall be established in rules adopted by the department.

(8)The department, upon the recommendation of the Board of Pharmacy, shall adopt rules to carry out the provisions of this section. Initial rules under this section shall be adopted no later than 90 days after the effective date of this act. The rules shall include, but not be limited to:

(a)Eligibility criteria, including a method to determine priority of eligible patients under the program.

(b)Standards and procedures for participant facilities that accept, store, distribute, or dispense donated cancer drugs or supplies.

(c)Necessary forms for administration of the program, including, but not limited to, forms for use by entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program.

(d)The maximum handling fee that may be charged by a participant facility that accepts and distributes or dispenses donated cancer drugs or supplies.

(e)Categories of cancer drugs and supplies that the program will accept for dispensing; however, the department may exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.

(f)Maintenance and distribution of the participant facility registry established in subsection (10).

(9)A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, by any other prescription drug program funded in whole or in part by the Federal Government, or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted, or a certain cancer drug or supply is not covered by the prescription drug program, is ineligible to participate in the program created under this section.

(10)The department shall establish and maintain a participant facility registry for the program. The participant facility registry shall include the participant facility's name, address, and telephone number. The department shall make the participant facility registry available on the department's website to any donor wishing to donate cancer drugs or supplies to the program. The department's website shall also contain links to cancer drug manufacturers that offer drug assistance programs or free medication.

(11)Any donor of cancer drugs or supplies, or any participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies under the program and the rules adopted under this section shall

be immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(12)A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

(13)If any conflict exists between the provisions in this section and the provisions in this chapter or chapter 465, the provisions in this section shall control the operation of the Cancer Drug Donation Program.

History.—s. 1, ch. 2006-310; s. 122, ch. 2007-5; ss. 2, 21, ch. 2008-207.

499.03Possession of certain drugs without prescriptions unlawful; exemptions and exceptions.—

(1)A person may not possess, or possess with intent to sell, dispense, or deliver, any habit-forming, toxic, harmful, or new drug subject to s. 499.003(33), or prescription drug as defined in s. 499.003(43), unless the possession of the drug has been obtained by a valid prescription of a practitioner licensed by law to prescribe the drug. However, this section does not apply to the delivery of such drugs to persons included in any of the classes named in this subsection, or to the agents or employees of such persons, for use in the usual course of their businesses or practices or in the performance of their official duties, as the case may be; nor does this section apply to the possession of such drugs by those persons or their agents or employees for such use:

(a)A licensed pharmacist or any person under the licensed pharmacist's supervision while acting within the scope of the licensed pharmacist's practice;

(b)A licensed practitioner authorized by law to prescribe prescription drugs or any person under the licensed practitioner's supervision while acting within the scope of the licensed practitioner's practice;

(c)A qualified person who uses prescription drugs for lawful research, teaching, or testing, and not for resale;

(d)A licensed hospital or other institution that procures such drugs for lawful administration or dispensing by practitioners;

(e)An officer or employee of a federal, state, or local government; or

(f)A person that holds a valid permit issued by the department pursuant to this part which authorizes that person to possess prescription drugs.

(2)The possession of a drug under subsection (1) by any person not exempted under this section, which drug is not properly labeled to indicate that possession is by a valid prescription of a practitioner licensed by law to prescribe such drug, is prima facie evidence that such possession is unlawful.

(3)Violation of subsection (1) is a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083, except that possession with the intent to sell, dispense, or deliver is a third degree felony, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4)The department may adopt rules regarding persons engaged in lawful teaching, research, or testing who possess prescription drugs and may issue letters of exemption to facilitate the lawful possession of prescription drugs under this section.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 5, ch. 84-115; s. 75, ch. 87-243; ss. 30, 52, ch. 92-69; s. 37, ch. 98-151; s. 43, ch. 2000-242; s. 14, ch. 2000-326; s. 19, ch. 2001-63; s. 89, ch. 2004-5; s. 22, ch. 2008-207; s. 42, ch. 2010-161.

499.032Phenylalanine; prescription required.—Phenylalanine restricted formula is declared to be a prescription drug and may be dispensed only upon the prescription of a practitioner authorized by law to prescribe prescription drugs.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 31, 52, ch. 92-69; s. 23, ch. 2008-207.

499.033Ephedrine; prescription required.—Ephedrine is declared to be a prescription drug.

(1)Except as provided in subsection (2), any product that contains any quantity of ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine may be dispensed only upon the prescription of a duly licensed practitioner authorized by the laws of the state to prescribe prescription drugs.

(2)A product containing ephedrine described in paragraphs (a)-(e) is exempt from subsection (1) if it may lawfully be sold over the counter without a prescription under the federal act; is labeled and marketed in a manner consistent with the pertinent United States Food and Drug Administration Over-the-Counter Tentative Final or Final Monograph; and is manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse, when considered in the context with: the package sizes and the manner of packaging of the drug product; the name and labeling of the product; the manner of distribution, advertising, and promotion of the product; the duration, scope, health significance, and societal cost of abuse of the particular product; the need to provide medically important ephedrine-containing therapies to the public for United States Food and Drug Administration approved indications on an unrestricted, over-the-counter basis; and other facts as may be relevant to and consistent with public health and safety.

(a)Solid oral dosage forms that combine active ingredients in the following ranges for each dosage unit:

1.Theophylline (100-130mg), ephedrine (12.5-24mg).

2.Theophylline (60-100mg), ephedrine (12.5-24mg), guaifenesin (200-400mg).

3.Ephedrine (12.5-25mg), guaifenesin (200-400mg).

4.Phenobarbital (not greater than 8mg) in combination with the ingredients of subparagraph 1. or subparagraph 2.

(b)Liquid oral dosage forms that combine active ingredients in the following ranges for each (5ml) dose:

1.Theophylline (not greater than 45mg), ephedrine (not greater than 36mg), guaifenesin (not greater than 100mg), phenobarbital (not greater than 12mg).

2.Phenylephrine (not greater than 5mg), ephedrine (not greater than 5mg), chlorpheniramine (not greater than 2mg), dextromethorphan (not greater than 10mg), ammonium chloride (not greater than 40mg), ipecac fluid extract (not greater than 0.005ml).

(c)Anorectal preparations containing less than 5 percent ephedrine.

(d)Nasal decongestant compounds, mixtures, or preparations containing 0.5 percent or less ephedrine.

(e)Any drug product containing ephedrine that is marketed pursuant to an approved new drug application or legal equivalent under the federal act.

(3)The department may implement this section by rule.

History.—s. 7, ch. 94-309; s. 1, ch. 95-415; s. 61, ch. 2003-1; s. 24, ch. 2008-207.

499.035Dimethyl sulfoxide (DMSO); labeling and advertising.—

(1)Dimethyl sulfoxide (DMSO) not approved for drug use must be clearly marked in at least 12-point boldfaced type: "May be unsafe. Not approved for human use."

(2)All advertisements for the sale of dimethyl sulfoxide (DMSO) not approved for drug use must contain, within the advertisement and in bold lettering, the following statement: "Warning. May be unsafe. Not approved for human use."

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 1, ch. 83-265; ss. 32, 52, ch. 92-69; ss. 1, 5, 8, ch. 94-309.

499.039Sale, distribution, or transfer of harmful chemical substances; penalties; authority for enforcement.—It is unlawful for a person to sell, deliver, or give to a

person under the age of 18 years any compound, liquid, or chemical containing toluol, hexane, trichloroethylene, acetone, toluene, ethyl acetate, methyl ethyl ketone, trichloroethane, isopropanol, methyl isobutyl ketone, ethylene glycol monomethyl ether acetate, cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites (butyl nitrite), or any similar substance for the purpose of inducing by breathing, inhaling, or ingesting a condition of intoxication or which is intended to distort or disturb the auditory, visual, or other physical or mental processes.

(1)On the first violation of this section, the department may issue a warning according to s. 499.002(5), if the violation has not caused temporary or permanent physical or mental injury to the user.

(2)If any violation of this section has caused temporary or permanent physical or mental injury to the user, the department may, pursuant to chapter 120, impose fines according to s. 499.066 and may report any violation to the appropriate state attorney for prosecution.

(3)The department shall adopt rules to implement this section.

History.—s. 12, ch. 86-133; s. 1, ch. 89-296; ss. 33, 52, ch. 92-69; s. 239, ch. 99-8; s. 25, ch. 2008-207.

499.04Fee authority.—The department may collect fees for all drug, device, and cosmetic applications, permits, product registrations, and free-sale certificates. The total amount of fees collected from all permits, applications, product registrations, and free-sale certificates must be adequate to fund the expenses incurred by the department in carrying out this part. The department shall, by rule, establish a schedule of fees that are within the ranges provided in this section and shall adjust those fees from time to time based on the costs associated with administering this part. The fees are payable to the department to be deposited into the Professional Regulation Trust Fund for the sole purpose of carrying out this part.

History.—s. 34, ch. 82-225; s. 115, ch. 83-218; s. 1, ch. 83-265; ss. 34, 52, ch. 92-69; s. 15, ch. 2000-326; s. 26, ch. 2008-207; s. 13, ch. 2012-143.

499.041Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—

(1)The department shall assess applicants requiring a manufacturing permit an annual fee within the ranges established in this section for the specific type of manufacturer.

(a)The fee for a prescription drug manufacturer permit may not be less than $500 or more than $750 annually.

(b)The fee for a device manufacturer permit may not be less than $500 or more than $600 annually.

(c)The fee for a cosmetic manufacturer permit may not be less than $250 or more than $400 annually.

(d)The fee for an over-the-counter drug manufacturer permit may not be less than $300 or more than $400 annually.

(e)The fee for a compressed medical gas manufacturer permit may not be less than $400 or more than $500 annually.

(f)The fee for a prescription drug repackager permit may not be less than $500 or more than $750 annually.

(g)A manufacturer may not be required to pay more than one fee per establishment to obtain an additional manufacturing permit, but each manufacturer must pay the highest fee applicable to his or her operation in each establishment.

(2)The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

(a)The fee for a prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.

(b)The fee for a compressed medical gas wholesale distributor permit may not be less than $200 or more than $300 annually.
(c)The fee for an out-of-state prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.
(d)The fee for a nonresident prescription drug manufacturer permit may not be less than $300 or more than $500 annually.
(e)The fee for a retail pharmacy drug wholesale distributor permit may not be less than $35 or more than $50 annually.
(f)The fee for a freight forwarder permit may not be less than $200 or more than $300 annually.
(g)The fee for a veterinary prescription drug wholesale distributor permit may not be less than $300 or more than $500 annually.
(h)The fee for a limited prescription drug veterinary wholesale distributor permit may not be less than $300 or more than $500 annually.
(i)The fee for a third party logistics provider permit may not be less than $200 or more than $300 annually.
(3)The department shall assess an applicant that is required to have a retail establishment permit an annual fee within the ranges established in this section for the specific type of retail establishment.
(a)The fee for a veterinary prescription drug retail establishment permit may not be less than $200 or more than $300 annually.
(b)The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.
(c)The fee for a health care clinic establishment permit may not be less than $125 or more than $250 annually.
(4)The department shall assess an applicant that is required to have a restricted prescription drug distributor permit an annual fee of not less than $200 or more than $300.
(5)In addition to the fee charged for a permit required by this part, the department shall assess applicants an initial application fee of $150 for each new permit issued by the department which requires an onsite inspection.
(6)A person that is required to register drugs, devices, or cosmetic products under s. 499.015 shall pay an annual product registration fee of not less than $5 or more than $15 for each separate and distinct product in package form. The registration fee is in addition to the fee charged for a free-sale certificate.
(7)The department shall assess an applicant that requests a free-sale certificate a fee of $25. A fee of $2 will be charged for each signature copy of a free-sale certificate that is obtained at the same time the free-sale certificate is issued.
(8)The department shall assess an out-of-state prescription drug wholesale distributor applicant or permittee an onsite inspection fee of not less than $1,000 or more than $3,000 annually, to be based on the actual cost of the inspection if an onsite inspection is performed by agents of the department.
(9)The department shall assess each person applying for certification as a designated representative a fee of $150, plus the cost of processing the criminal history record check.
(10)The department shall assess other fees as provided in this part.
History.—s. 34, ch. 82-225; s. 116, ch. 83-218; s. 1, ch. 83-265; ss. 10, 14, ch. 88-159; s. 4, ch. 89-296; ss. 35, 52, ch. 92-69; s. 591, ch. 97-103; s. 16, ch. 2000-326; s. 20, ch. 2003-155; s. 5, ch. 2004-328; s. 5, ch. 2006-92; s. 27, ch. 2008-207.
499.05Rules.—
(1)The department shall adopt rules to implement and enforce this part with respect to:

(a)The definition of terms used in this part, and used in the rules adopted under this part, when the use of the term is not its usual and ordinary meaning.
(b)Labeling requirements for drugs, devices, and cosmetics.
(c)The establishment of fees authorized in this part.
(d)The identification of permits that require an initial application and onsite inspection or other prerequisites for permitting which demonstrate that the establishment and person are in compliance with the requirements of this part.
(e)The application processes and forms for product registration.
(f)Procedures for requesting and issuing certificates of free sale.
(g)Inspections and investigations conducted under s. 499.051, and the identification of information claimed to be a trade secret and exempt from the public records law as provided in s. 499.051(7).
(h)The establishment of a range of penalties, as provided in s. 499.066; requirements for notifying persons of the potential impact of a violation of this part; and a process for the uncontested settlement of alleged violations.
(i)Additional conditions that qualify as an emergency medical reason under s. 499.003(54)(b)2.
(j)Procedures and forms relating to the pedigree paper requirement of s. 499.01212.
(k)The protection of the public health, safety, and welfare regarding good manufacturing practices that manufacturers and repackagers must follow to ensure the safety of the products.
(l)Information required from each retail establishment pursuant to s. 499.012(3), including requirements for prescriptions or orders.
(m)The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(54)(a)-(d).
(n)Alternatives to compliance with s. 499.01212 for a prescription drug in the inventory of a permitted prescription drug wholesale distributor as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.
(o)Wholesale distributor reporting requirements of s. 499.0121(14).
(p)Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).
(2)With respect to products in interstate commerce, those rules must not be inconsistent with rules and regulations of federal agencies unless specifically otherwise directed by the Legislature.
(3)The department shall adopt rules regulating recordkeeping for and the storage, handling, and distribution of medical devices and over-the-counter drugs to protect the public from adulterated products.
History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 6, ch. 84-115; s. 88, ch. 85-81; s. 4, ch. 86-133; ss. 17, 18, 36, ch. 92-69; ss. 2, 5, 8, ch. 94-309; ss. 31, 34, 38, ch. 98-151; s. 172, ch. 99-397; ss. 39, 44, ch. 2000-242; s. 20, ch. 2001-63; s. 32, ch. 2001-89; ss. 13, 14, 18, ch. 2003-155; ss. 87, 90, ch. 2004-5; s. 28, ch. 2008-207; s. 43, ch. 2010-161; s. 19, ch. 2011-141.
Note.—Paragraph (1)(k) former s. 499.013(3); paragraph (1)(l) former s. 499.0122(2)(b); paragraph (1)(m) former s. 499.012(12).
499.051Inspections and investigations.—
(1)The agents of the department and of the Department of Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this part during business hours for the purpose of enforcing this part, chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.

(2)In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this part and rules adopted under this part regarding any drug, device, or cosmetic product.

(3)Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this part and rules adopted under this part constitutes permission for any entry or inspection of the premises in order to verify compliance with this part and rules; to discover, investigate, and determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations.

(4)Any application for a permit made pursuant to s. 499.012 and rules adopted under that section constitutes permission for agents of the department and the Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy any financial document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with this part and the rules adopted by the department to administer this part, in order to discover, investigate, and determine the existence of compliance, or to elicit, receive, respond to, and resolve complaints and violations.

(5)The authority to inspect under this section includes the authority to access, review, and copy any and all financial documents related to the activity of manufacturing, repackaging, or distributing prescription drugs.

(6)The authority to inspect under this section includes the authority to secure:

(a)Samples or specimens of any drug, device, or cosmetic; or

(b)Such other evidence as is needed for any action to enforce this part and the rules adopted under this part.

(7)The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation and the enforcement action are completed. However, trade secret information contained therein as defined by s. 812.081(1)(c) shall remain confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution, as long as the information is retained by the department. This subsection does not prohibit the department from using such information for regulatory or enforcement proceedings under this chapter or from providing such information to any law enforcement agency or any other regulatory agency. However, the receiving agency shall keep such records confidential and exempt as provided in this subsection. In addition, this subsection is not intended to prevent compliance with the provisions of s. 499.01212, and the pedigree papers required in that section shall not be deemed a trade secret.

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 1, ch. 83-265; s. 5, ch. 86-133; s. 11, ch. 88-159; ss. 37, 52, ch. 92-69; s. 199, ch. 94-218; ss. 3, 5, 8, ch. 94-309; s. 7, ch. 95-366; s. 332, ch. 96-406; s. 240, ch. 99-8; s. 62, ch. 2003-1; s. 21, ch. 2003-155; s. 26, ch. 2007-6; s. 29, ch. 2008-207.

499.052Records of interstate shipment.—For the purpose of enforcing this part, carriers engaged in interstate commerce and persons receiving drugs, devices, or cosmetics in interstate commerce must, upon the request, in the manner set out below, by an officer or employee duly designated by the department, permit the officer or employee to have access to and to copy all records showing the movement in interstate commerce of any drug, device, or cosmetic, and the quantity, shipper, and consignee thereof.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 38, 52, ch. 92-69; s. 30, ch. 2008-207.

499.055Reports and dissemination of information by department.—

(1)The department may cause to be published from time to time reports summarizing all judgments, decrees, and court orders that have been rendered under ss. 499.001-499.79, including the nature of any charges and the dispositions of the charges.

(2)The department may also cause to be disseminated such information regarding drugs, devices, and cosmetics as considered necessary in the interest of public health and the protection of consumers against fraud.

(3)This section does not prohibit the department from collecting, reporting, and illustrating the results of its investigations.

(4)The department shall publish on the department's website and update at least monthly:

(a)A list of the prescription drug wholesale distributors, out-of-state prescription drug wholesale distributors, and retail pharmacy drug wholesale distributors against whom the department has initiated enforcement action pursuant to this part to suspend or revoke a permit, seek an injunction, or otherwise file an administrative complaint and the permit number of each such wholesale distributor.

(b)A list of the prescription drug wholesale distributors, out-of-state prescription drug wholesale distributors, and retail pharmacy drug wholesale distributors to which the department has issued a permit, including the date on which each permit will expire.

(c)A list of the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor permits that have been returned to the department, were suspended, were revoked, have expired, or were not renewed in the previous year.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 6, ch. 86-133; ss. 39, 52, ch. 92-69; s. 22, ch. 2003-155; s. 31, ch. 2008-207.

499.057Expenses and salaries.—Except as otherwise provided in the General Appropriations Act, all expenses and salaries shall be paid out of the Professional Regulation Trust Fund.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 40, 52, ch. 92-69; s. 564, ch. 2003-261; s. 14, ch. 2012-143.

499.06Embargoing, detaining, or destroying article or processing equipment which is in violation of law or rule.—

(1)When a duly authorized agent of the department finds, or has probable cause to believe, that any drug, device, or cosmetic is in violation of any provision of this part or any rule adopted under this part so as to be dangerous, unwholesome, or fraudulent within the meaning of this part, she or he may issue and enforce a stop-sale, stop-use, removal, or hold order, which order gives notice that such article or processing equipment is, or is suspected of being, in violation and has been detained or embargoed, and which order warns all persons not to remove, use, or dispose of such article or processing equipment by sale or otherwise until permission for removal, use, or disposal is given by such agent or the court. It is unlawful for any person to remove, use, or dispose of such detained or embargoed article or processing equipment by sale or otherwise without such permission; and such act is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2)When an article or processing equipment detained or embargoed under subsection (1) has been found by such agent to be in violation of law or rule, she or he shall, within 90 days after the issuance of such notice, petition the circuit court, in the jurisdiction of which the article or processing equipment is detained or embargoed, for an order for condemnation of such article or processing equipment. When such agent has found that an article or processing equipment so detained or

embargoed is not in violation, she or he shall rescind the stop-sale, stop-use, removal, or hold order.

(3)If the court finds that the detained or embargoed article or processing equipment is in violation, such article or processing equipment shall, after entry of the court order, be destroyed or made sanitary at the expense of the claimant thereof, under the supervision of such agent; and all court costs, fees, and storage and other proper expenses shall be taxed against the claimant of such article or processing equipment or her or his agent. However, when the violation can be corrected by proper labeling of the article or sanitizing of the processing equipment, and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article be so labeled or processed or such processing equipment be so sanitized, has been executed, the court may by order direct that such article or processing equipment be delivered to the claimant thereof for such labeling, processing, or sanitizing, under the supervision of an agent of the department. The expense of such supervision shall be paid by the claimant. Such bond shall be returned to the claimant of the article or processing equipment upon representation to the court by the department that the article or processing equipment is no longer in violation of this part and that the expenses of such supervision have been paid.

(4)When the department or any of its authorized agents finds in any room, building, vehicle of transportation, or other structure any perishable articles that are unsound or contain any filthy, decomposed, or putrid substances, or which may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the department, or its authorized agent, shall forthwith condemn or destroy such articles or in any other manner render such articles unsalable.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 41, 52, ch. 92-69; s. 592, ch. 97-103; s. 32, ch. 2008-207.

499.062Seizure and condemnation of drugs, devices, or cosmetics.—

(1)Any article of any drug, device, or cosmetic that is adulterated or misbranded under this part is subject to seizure and condemnation by the department or by its duly authorized agents designated for that purpose in regard to drugs, devices, or cosmetics.

(2)Whenever a duly authorized officer or employee of the department finds cause, or has probable cause to believe that cause exists, for the seizure of any drug, device, or cosmetic, as set out in this part, he or she shall affix to the article a tag, stamp, or other appropriate marking, giving notice that the article is, or is suspected of being, subject to seizure under this part and that the article has been detained and seized by the department. Such officer or employee shall also warn all persons not to remove or dispose of the article, by sale or otherwise, until permission is given by the department or the court. Any person who violates this subsection is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(a)When any article detained or seized under this subsection has been found by the department to be subject to seizure and condemnation, the department shall petition the court for an order of condemnation or sale, as the court directs. The proceeds of the sale of drugs, devices, and cosmetics, less the legal costs and charges, shall be deposited into the Professional Regulation Trust Fund.

(b)If the department finds that any article seized under this subsection was not subject to seizure, the department or the designated officer or employee shall remove the tag or marking.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 42, 43, 44, 52, ch. 92-69; s. 593, ch. 97-103; s. 33, ch. 2008-207; s. 15, ch. 2012-143.

Note.—Subsection (2) intro. former s. 499.063; paragraphs (2)(a), (b) former s. 499.064.

499.065Inspections; imminent danger.—

(1)Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, and retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part as often as necessary to ensure compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities at any reasonable time.

(2)To protect the public from prescription drugs that are adulterated or otherwise unfit for human or animal consumption, the department may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those drugs. The department may immediately seize and remove any prescription drugs if the Secretary of Business and Professional Regulation or his or her designee determines that the prescription drugs represent a threat to the public health. The owner of any property seized under this section may, within 10 days after the seizure, apply to a court of competent jurisdiction for whatever relief is appropriate. At any time after 10 days, the department may destroy the drugs as contraband.

(3)The department may determine that a prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, or retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part is an imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public's health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

(4)For purposes of this section, a refusal to allow entry to the department for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.

History.—s. 23, ch. 2003-155; s. 6, ch. 2004-328; s. 6, ch. 2006-92; s. 107, ch. 2008-6; s. 34, ch. 2008-207; s. 6, ch. 2012-143.

499.066Penalties; remedies.—In addition to other penalties and other enforcement provisions:

(1)The department may institute such suits or other legal proceedings as are required to enforce any provision of this part. If it appears that a person has violated any provision of this part for which criminal prosecution is provided, the department may provide the appropriate state attorney or other prosecuting agency having jurisdiction with respect to such prosecution with the relevant information in the department's possession.

(2)If any person engaged in any activity covered by this part violates any provision of this part, any rule adopted under this part, or a cease and desist order as provided by this part, the department may obtain an injunction in the circuit court of the county in which the violation occurred or in which the person resides or has its principal place of business, and may apply in that court for such temporary and permanent orders as the department considers necessary to restrain the person from engaging in any such activities until the person complies with this part, the rules adopted under this part, and the orders of the department authorized by this part or

to mandate compliance with this part, the rules adopted under this part, and any order or permit issued by the department under this part.

(3)The department may impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of any provision of this part or rules adopted under this part. Each day a violation continues constitutes a separate violation, and each separate violation is subject to a separate fine. All amounts collected pursuant to this section shall be deposited into the Professional Regulation Trust Fund and are appropriated for the use of the department in administering this part. In determining the amount of the fine to be levied for a violation, the department shall consider:

(a)The severity of the violation;

(b)Any actions taken by the person to correct the violation or to remedy complaints; and

(c)Any previous violations.

(4)The department shall deposit any rewards, fines, or collections that are due the department and which derive from joint enforcement activities with other state and federal agencies which relate to this part, chapter 893, or the federal act, into the Professional Regulation Trust Fund. The proceeds of those rewards, fines, and collections are appropriated for the use of the department in administering this part.

(5)The department may issue an emergency order immediately suspending or revoking a permit if it determines that any condition in the establishment presents a danger to the public health, safety, and welfare.

(6)The department may issue an emergency order to immediately remove from commerce and public access any drug, device, or cosmetic, if the department determines that the drug, device, or cosmetic presents a clear and present danger to the public health, safety, and welfare.

(7)Resignation or termination of an affiliated party does not affect the department's jurisdiction or discretion to proceed with action to suspend or revoke a permit or to impose other penalties or enforcement actions authorized by law.

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 117, ch. 83-218; s. 1, ch. 83-265; s. 7, ch. 86-133; s. 3, ch. 86-271; ss. 45, 52, ch. 92-69; ss. 4, 5, 8, ch. 94-309; s. 24, ch. 2003-155; s. 35, ch. 2008-207; s. 16, ch. 2012-143.

499.0661Cease and desist orders; removal of certain persons.—

(1)CEASE AND DESIST ORDERS.—

(a)In addition to any authority otherwise provided in this chapter, the department may issue and serve a complaint stating charges upon any permittee or upon any affiliated party, whenever the department has reasonable cause to believe that the person or individual named therein is engaging in or has engaged in conduct that is:

1.An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this part, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2.A violation of any provision of this part;

3.A violation of any rule of the department;

4.A violation of any order of the department; or

5.A breach of any written agreement with the department.

(b)The complaint must contain a statement of facts and notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57.

(c)If a hearing is not requested within the time allowed by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges are proven, the department may enter an order directing the permittee or the affiliated party named in the complaint to cease and desist from engaging in the conduct complained of and take corrective action to remedy the effects of past improper conduct and assure future compliance.

(d)A contested or default cease and desist order is effective when reduced to writing and served upon the permittee or affiliated party named therein. An uncontested cease and desist order is effective as agreed.

(e)Whenever the department finds that conduct described in paragraph (a) is likely to cause an immediate threat to the public health, it may issue an emergency cease and desist order requiring the permittee or any affiliated party to immediately cease and desist from engaging in the conduct complained of and to take corrective and remedial action. The emergency order is effective immediately upon service of a copy of the order upon the permittee or affiliated party named therein and remains effective for 90 days. If the department begins nonemergency cease and desist proceedings under this subsection, the emergency order remains effective until the conclusion of the proceedings under ss. 120.569 and 120.57.

(2)REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—

(a)The department may issue and serve a complaint stating charges upon any affiliated party and upon the permittee involved whenever the department has reason to believe that an affiliated party is engaging in or has engaged in conduct that constitutes:

1.An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this part, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2.A willful violation of this part; however, if the violation constitutes a misdemeanor, a complaint may not be served as provided in this section until the affiliated party is notified in writing of the matter of the violation and has been afforded a reasonable period of time, as set forth in the notice, to correct the violation and has failed to do so;

3.A violation of any other law involving fraud or moral turpitude which constitutes a felony;

4.A willful violation of any rule of the department;

5.A willful violation of any order of the department; or

6.A material misrepresentation of fact, made knowingly and willfully or made with reckless disregard for the truth of the matter.

(b)The complaint must contain a statement of facts and notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57.

(c)If a hearing is not requested within the time allotted by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges in the complaint are proven true, the department may enter an order removing the affiliated party or restricting or prohibiting participation by the person in the affairs of that permittee or of any other permittee.

(d)A contested or default order of removal, restriction, or prohibition is effective when reduced to writing and served on the permittee and the affiliated party. An uncontested order of removal, restriction, or prohibition is effective as agreed.

(e)1.The chief executive officer, designated representative, or the person holding the equivalent office, of a permittee shall promptly notify the department if she or he has actual knowledge that any affiliated party is charged with a felony in a state or federal court.

2.Whenever any affiliated party is charged with a felony in a state or federal court or with the equivalent of a felony in the courts of any foreign country with which the United States maintains diplomatic relations, and the charge alleges violation of any law involving prescription drugs, pharmaceuticals, fraud, theft, or moral turpitude, the department may enter an emergency order suspending the affiliated party or restricting or prohibiting participation by the affiliated party in the affairs of the particular permittee or of any other permittee upon service of the order upon the

permittee and the affiliated party charged. The order must contain notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57, where the affiliated party may request a postsuspension hearing to show that continued service to or participation in the affairs of the permittee does not pose a threat to the public health or the interests of the permittee and does not threaten to impair public confidence in the permittee. In accordance with applicable departmental rules, the department shall notify the affiliated party whether the order suspending or prohibiting the person from participation in the affairs of a permittee will be rescinded or otherwise modified. The emergency order remains in effect, unless otherwise modified by the department, until the criminal charge is disposed of. The acquittal of the person charged, or the final, unappealed dismissal of all charges against the person, dissolves the emergency order but does not prohibit the department from instituting proceedings under paragraph (a). If the person charged is convicted or pleads guilty or nolo contendere, whether or not an adjudication of guilt is entered by the court, the emergency order shall become final.

(f)Any affiliated party removed pursuant to this section is not eligible for reemployment by the permittee or to be an affiliated party of any permittee except upon the written consent of the department. Any affiliated party who is removed, restricted, or prohibited from participating in the affairs of a permittee pursuant to this section may petition the department for modification or termination of the removal, restriction, or prohibition.

History.—s. 25, ch. 2003-155; ss. 2, 36, ch. 2008-207.

499.067Denial, suspension, or revocation of permit, certification, or registration.—

(1)(a)The department may deny, suspend, or revoke a permit if it finds that there has been a substantial failure to comply with this part or chapter 465, chapter 501, or chapter 893, the rules adopted under this part or those chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics.

(b)The department may deny an application for a permit or certification, or suspend or revoke a permit or certification, if the department finds that:

1.The applicant is not of good moral character or that it would be a danger or not in the best interest of the public health, safety, and welfare if the applicant were issued a permit or certification.

2.The applicant has not met the requirements for the permit or certification.

3.The applicant is not eligible for a permit or certification for any of the reasons enumerated in s. 499.012.

4.The applicant, permittee, or person certified under s. 499.012(16) demonstrates any of the conditions enumerated in s. 499.012.

5.The applicant, permittee, or person certified under s. 499.012(16) has committed any violation of ss. 499.005-499.0054.

(2)The department may deny, suspend, or revoke any registration required by the provisions of this part for the violation of any provision of this part or of any rules adopted under this part.

(3)The department may revoke or suspend a permit:

(a)If the permit was obtained by misrepresentation or fraud or through a mistake of the department;

(b)If the permit was procured, or attempted to be procured, for any other person by making or causing to be made any false representation; or

(c)If the permittee has violated any provision of this part or rules adopted under this part.

(4)If any permit issued under this part is revoked or suspended, the owner, manager, operator, or proprietor of the establishment shall cease to operate as the permit authorized, from the effective date of the suspension or revocation until the

person is again registered with the department and possesses the required permit. If a permit is revoked or suspended, the owner, manager, or proprietor shall remove all signs and symbols that identify the operation as premises permitted as a drug wholesaling establishment; drug, device, or cosmetic manufacturing establishment; or retail establishment. The department shall determine the length of time for which the permit is to be suspended. If a permit is revoked, the person that owns or operates the establishment may not apply for any permit under this part for a period of 1 year after the date of the revocation. A revocation of a permit may be permanent if the department considers that to be in the best interest of the public health.

(5)The department may deny, suspend, or revoke a permit issued under this part which authorizes the permittee to purchase prescription drugs if any owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, or any federal or state drug law, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld.

(6)The department shall deny, suspend, or revoke the permit of any person or establishment if the assignment, sale, transfer, or lease of an establishment permitted under this part will avoid an administrative penalty, civil action, or criminal prosecution.

(7)Notwithstanding s. 120.60(5), if a permittee fails to comply with s. 499.012(6), the department may revoke the permit of the permittee and shall provide notice of the intended agency action by posting a notice at the department's headquarters and by mailing a copy of the notice of intended agency action by certified mail to the most recent mailing address on record with the department and, if the permittee is not a natural person, to the permittee's registered agent on file with the Department of State.

(8)The department may deny, suspend, or revoke a permit if it finds the permittee has not complied with the credentialing requirements of s. 499.0121(15).

(9)The department may deny, suspend, or revoke a permit if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(14).

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 8, ch. 86-133; ss. 12, 14, ch. 88-159; s. 4, ch. 89-296; ss. 46, 52, ch. 92-69; s. 44, ch. 95-144; s. 594, ch. 97-103; s. 17, ch. 2000-326; s. 26, ch. 2003-155; s. 37, ch. 2008-207; s. 20, ch. 2011-141.

PART II

ETHER

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499.601Legislative intent; construction.—

(1)The Legislature finds that the unregulated possession of bulk quantities of ether poses a substantial risk to the health, safety, and welfare of the citizens of this state, and it is the intent of the Legislature that this part be liberally construed to provide all protection necessary for the citizens of this state.

(2)The provisions of this part are cumulative and shall not be construed as repealing or affecting any powers, duties, or authority of the department under any other law of this state; except that, with respect to the regulation of ether as herein provided, in instances in which the provisions of this part may conflict with any other such law, the provisions of this part shall control.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 241, ch. 99-8; s. 7, ch. 2012-143; s. 123, ch. 2012-184.

499.61Definitions.—As used in this part:

(1)"Dealer" means any person, firm, corporation, or other entity selling, brokering, or transferring ether to anyone other than a licensed ether manufacturer, distributor, or dealer.

(2)"Department" means the Department of Business and Professional Regulation.

(3)"Distributor" means any person, firm, corporation, or other entity distributing, selling, marketing, transferring, or otherwise supplying ether to retailers, dealers, or any other entity in the primary channel of trade, but does not include retailers.

(4)"Ether" means diethyl ether in any form.

(5)"Manufacturer" means any person, firm, corporation, or other entity preparing, deriving, producing, synthesizing, or otherwise making ether in any form or repacking, relabeling, or manipulating ether.

(6)"Purchaser" means any person, firm, corporation, or other entity who purchases ether in quantities of 2.5 gallons, or equivalent by weight, or more for any purpose whatsoever, but does not include a dealer, distributor, or manufacturer.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 242, ch. 99-8; s. 8, ch. 2012-143; s. 124, ch. 2012-184.

499.62License or permit required of manufacturer, distributor, dealer, or purchaser of ether.—

(1)It shall be unlawful for any person to engage in the business of manufacturing, distributing, or dealing in ether in this state, except when done in conformity with the provisions of this part. No person shall be required to obtain more than one license under this part to handle ether, but each person shall pay the highest fee applicable to her or his operation in each location.

(2)Any person who manufactures, distributes, or deals in ether in this state must possess a current valid license issued by the department, except that a manufacturer, distributor, or dealer who also purchases ether in this state shall not be required to obtain an additional permit as a purchaser of ether.

(3)Any person who manufactures, distributes, or deals in ether at or from more than one location must possess a current valid license for each location.

(4)Any person who purchases ether in this state must possess a current valid permit issued by the department, except that no permit shall be required of any

person who purchases ether in quantities of less than 2.5 gallons, or equivalent by weight.

(5)Annual fees for licenses and permits shall be specified by rule of the department, but shall not exceed the following amounts:

(a)Manufacturer's license.....$700

(b)Distributor's license.....$700

(c)Dealer's license.....$350

(d)Purchaser's permit.....$150

(6)Licenses and permits issued by the department shall be valid beginning on October 1 of the year for which they are issued and shall expire on the following September 30.

(7)A licensed or permitted facility shall renew its license or permit prior to its expiration date. If a renewal application and fee are not filed by the expiration date of any year, the permit may be reinstated only upon payment of a delinquent fee of $50, plus the required renewal fee, within 30 days after the date of expiration. If any person who is subject to the requirements of this part fails to comply with the renewal, the department shall have the authority to seize all ether products and dispose of them as of November 1 of the year the license or permit expires. Any funds collected from the disposal shall be placed in the Professional Regulation Trust Fund.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 596, ch. 97-103; s. 17, ch. 2012-143.

499.63Forms for applications for licenses and permits.—

(1)The forms for applications for ether licenses and permits shall be prescribed by the department.

(2)Each application for a license or permit required by the provisions of this part shall be filed in writing with the department. Each application shall require, as a minimum, the full name, date of birth, place of birth, social security number, physical description of the applicant, residence address and telephone number, and business address and telephone number of the applicant. Each application must be accompanied by an accurate and current photograph of the applicant and a complete set of fingerprints of the applicant taken by an authorized law enforcement officer; however, a set of fingerprints shall not be required if the applicant has possessed a valid Florida license or permit under this part during the prior license or permit year and such Florida license or permit has not lapsed or been suspended or revoked. If fingerprints are required, the set of fingerprints shall be submitted by the department to the Department of Law Enforcement for state processing and to the Federal Bureau of Investigation for federal processing. If the application does not require a set of fingerprints, the department shall submit the name and other identifying data to the Department of Law Enforcement for processing. Each application shall be in such form as to provide that the data and other information set forth therein shall be sworn to by the applicant or, if the applicant is a corporation, by all officers of the corporation. The officers applying on behalf of a corporation shall provide all the data and other information required by this subsection and subsection (3), and shall meet all other requirements, which are required of a natural person.

(3)The department may require an applicant to furnish such other information or data not required by this section if the information or data is deemed necessary by the department.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.64Issuance of licenses and permits; prohibitions.—

(1)Each license and permit issued by the department shall set forth, as a minimum, the full name, date of birth, and physical description of the licensee or

permittee and shall have permanently affixed an accurate and current photograph of the licensee or permittee. A license or permit issued to a corporation shall set forth the full name, date of birth, and physical description of the chief executive officer and/or resident agent residing in this state and shall have permanently affixed an accurate and current photograph of the chief executive officer and/or resident agent residing in this state. Each license and permit shall also contain a license or permit number.

(2)The department may, in its discretion, include other data or information in the license or permit when deemed appropriate.

(3)No license or permit shall be issued, renewed, or allowed to remain in effect for any natural person, or for any corporation which has any corporate officer:

(a)Under 18 years of age.

(b)Who has been convicted of a felony under the prescription drug or controlled substance laws of this state or any other state or federal jurisdiction, regardless of whether he or she has been pardoned or had his or her civil rights restored.

(c)Who has been convicted of any felony other than a felony under the prescription drug or controlled substance laws of this state or any other state or federal jurisdiction and has not been pardoned or had his or her civil rights restored.

(d)Who has been adjudicated mentally incompetent and has not had his or her civil rights restored.

(4)It is unlawful for any person to knowingly withhold information or present to the department any false, fictitious, or misrepresented application, identification, document, information, or data intended or likely to deceive the department for the purpose of obtaining a license or permit.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 597, ch. 97-103.

499.65Possession of ether without license or permit prohibited; confiscation and disposal; exceptions.—

(1)It is unlawful for any person to possess 2.5 gallons, or equivalent by weight, or more of ether unless she or he is the holder of a current valid license or permit as provided by this part.

(2)Whenever the department has reason to believe that any person is or has been violating the provisions of this part or any rules adopted pursuant thereto, the department may, without further process of law, confiscate and dispose of the ether in question. The department is authorized to seize and dispose of any abandoned ether.

(3)The department is authorized to enter into contracts with private business entities for the purpose of confiscation and disposal of ether as authorized in subsection (2).

(4)The provisions of subsection (1) shall not apply to:

(a)Any common carrier transporting ether into this state or within the boundaries of this state by air, highway, railroad, or water;

(b)Any contract or private carrier transporting ether on highways into this state or within the boundaries of this state by motor vehicle when such contract or private carrier is engaged in such transport pursuant to certificate or permit, by whatever name, issued to them by any federal or state officer, agency, bureau, commission, or department;

(c)Pharmacists, for use in the usual course of their professional practice or in the performance of their official duties;

(d)Medical practitioners, for use in the usual course of their professional practice or in the performance of their official duties;

(e)Persons who procure ether for disposition by or under the supervision of pharmacists or medical practitioners employed by them or for the purpose of lawful research, teaching, or testing, and not for resale;

(f)Hospitals and other institutions which procure ether for lawful administration by practitioners;

(g)Officers or employees of federal, state, or local governments carrying out their official duties; and

(h)Law enforcement agencies of this state or any of its political subdivisions, and the employees thereof, so long as said agencies and employees are acting within the scope of their respective official capacities and in the performance of their duties.

(5)The department may adopt rules regarding persons engaged in lawful teaching, research, or testing who possess ether and may issue letters of exemption to facilitate the lawful possession of ether under this section.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 598, ch. 97-103; s. 39, ch. 98-151.

499.66Maintenance of records and sales of ether by manufacturers, distributors, and dealers; inspections.—

(1)It is unlawful for any manufacturer, distributor, or dealer to sell, distribute, or otherwise transfer ether to any person except a person presenting a current valid license or permit as provided by this part.

(2)Each sale or transfer of ether shall be evidenced by an invoice, receipt, sales ticket, or sales slip which shall bear the name, address, and license or permit number of the manufacturer, distributor, or dealer and the purchaser or transferee, the date of sale or transfer, and the quantity sold or transferred. All original invoices, receipts, sales tickets, and sales slips shall be retained by the manufacturer, distributor, or dealer, and a copy thereof provided to the purchaser or transferee.

(3)Each manufacturer, distributor, and dealer shall keep an accurate and current written account of all inventories, sales, and transfers of ether. Such records shall be maintained by the manufacturer, distributor, or dealer for a period of 5 years.

(4)Records and inventories as required by subsections (2) and (3) shall be made immediately accessible to, and subject to examination and copying by, the department and any law enforcement officer of this state without any requirement of probable cause or search warrant.

(5)It is unlawful for any person to knowingly withhold information or to make any false or fictitious entry or misrepresentation upon any invoice, receipt, sales ticket, or sales slip for the sale, distribution, or transfer of ether or upon any account of inventories of ether.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 40, ch. 98-151.

499.67Maintenance of records by purchasers; inspections.—

(1)It is unlawful for any person to purchase, receive, store, or use ether without maintaining an accurate and current written inventory of all ether purchased, received, stored, and used.

(2)Such records shall include, but not be limited to, invoices, receipts, sales tickets, and sales slips; locations, quantities, and dates of use; the names of any persons using the ether; and the names and license or permit numbers of all persons making such records. Such records shall be maintained by permittees for a period of 5 years.

(3)Such records shall be made accessible to, and subject to examination and copying by, the department and any law enforcement officer of this state without any requirement of probable cause or search warrant.

(4)It is unlawful for any person to knowingly withhold information or make any false or fictitious entry or misrepresentation upon any such records for the purchase, receipt, storage, or use of ether.

(5)It is unlawful for any person to refuse entry or inspection by the department of factories, warehouses, or establishments in which ether is manufactured, processed,

repackaged, or held; to refuse entry by the department into any vehicle being used to transport ether; or to refuse the taking of samples by the department.
History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 41, ch. 98-151.

499.68Reports of thefts, illegal use, or illegal possession.—

(1)Any sheriff, police department, or law enforcement officer of this state shall give immediate notice to the department of any theft, illegal use, or illegal possession of ether involving any person and shall forward a copy of his or her final written report to the department.

(2)Any licensee or permittee who incurs a loss, an unexplained shortage, or a theft of ether, or who has knowledge of a loss, an unexplained shortage, or a theft of ether, shall, within 12 hours after the discovery thereof, report such loss, theft, or unexplained shortage to the county sheriff or police chief of the jurisdiction in which the loss, theft, or unexplained shortage occurred. Such loss, theft, or unexplained shortage must also be reported to the department by the close of the next business day following the discovery thereof.

(3)Any law enforcement agency which investigates the causes and circumstances of any loss, theft, or unexplained shortage of ether shall forward a copy of its final written report to the department. The department shall retain all such reports in the respective files of the affected licensees and permittees.
History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 599, ch. 97-103.

499.69Possession in or near residential housing prohibited; legal entitlement to possession of premises not a defense.—

(1)Notwithstanding the possession of a current valid license or permit as provided in this part, it is unlawful for any person to possess 2.5 gallons, or equivalent by weight, or more of ether in, or within 500 feet of, any residential housing structure.

(2)A defendant's legal entitlement to possession of the property where the violation occurred shall not be a defense to a prosecution for a violation of subsection (1).
History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.701Adoption of rules by the department.—

(1)The department shall adopt and enforce rules necessary to the administration of its authority under this part. The rules must be such as are reasonably necessary for the protection of the health, welfare, and safety of the public and persons manufacturing, distributing, dealing, and possessing ether, and must provide for application forms and procedures, recordkeeping requirements, and security. The rules must be in substantial conformity with generally accepted standards of safety concerning such subject matter.

(2)The department may adopt rules regarding recordkeeping and security for methyl ethyl ketone (MEK) or butyl acetate as needed. These products and records are open to inspection in the same manner as are ether products and records.
History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 45, ch. 2000-242.

499.71Procedure for cease and desist orders.—

(1)Whenever the department has reason to believe that any person is or has been violating any provision of this part or any rules adopted pursuant thereto, it shall proceed to determine the matter.

(2)If the department determines that any provision of this part or any rules adopted pursuant thereto have been violated, it shall issue to the person charged with such violation an order requiring such person to cease and desist from such violation or imposing an administrative fine, or both.
History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.72Administrative fines.—

(1)If any person violates any provision of this part or any rule adopted pursuant thereto, or violates a cease and desist order issued by the department, the

department may impose an administrative fine, not to exceed $5,000 for each violation per day, or may suspend or revoke the license or permit issued to such person, or both. Each day such violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine. The department shall allow the licensee or permittee a reasonable period, not to exceed 30 days, within which to pay to the department the amount of the fine so imposed. If the licensee or permittee fails to pay the fine in its entirety to the department at its office in Tallahassee within the period so allowed, the licenses or permits of such person shall stand revoked upon expiration of such period.

(2)All such fines, monetary penalties, and costs received by the department in connection with this part shall be deposited in the Professional Regulation Trust Fund.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 18, ch. 2012-143.

499.73Suspension or revocation of license or permit.—

(1)The violation of any provision of this part, any rule adopted pursuant thereto, or any cease and desist order issued by the department by a licensee or permittee as provided in this part shall be cause for revocation or suspension of all licenses or permits held by such licensee or permittee after the department has determined the licensee or permittee to be guilty of such violation.

(2)If the department finds the licensee or permittee to be guilty of such violation, it shall enter its order suspending or revoking the license or permit of the person charged. An order of suspension shall state the period of time of such suspension, which period shall not be in excess of 1 year from the date of such order. An order of revocation may be entered for a period not exceeding 5 years; such order shall effect the revocation of all licenses or permits then held by the person charged, and during such period no license or permit shall be issued to said person. If, during the period between the beginning of proceedings and the entry of an order of suspension or revocation by the department, a new license or permit has been issued to the person charged, any order of suspension or revocation shall operate effectively with respect to the new license or permit held by such person.

(3)Any person or office of a corporation whose permit or license has been suspended or revoked shall not be issued a new permit or license under any other name or company name until the expiration of the suspension or revocation in which she or he has been involved.

(4)The provisions of this section are cumulative and shall not affect the administrative fine and injunction provisions of ss. 499.72 and 499.76.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 600, ch. 97-103.

499.74Conduct of hearings; review of orders of the department.—

(1)All hearings shall be conducted in accordance with the provisions of chapter 120.

(2)All review of orders of the department shall be in accordance with the provisions of chapter 120.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.75Penalties.—

(1)Any person who knowingly manufactures, distributes, or deals in ether without possessing a valid current license as required by s. 499.62(2) is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2)Any person who knowingly purchases 2.5 gallons, or equivalent by weight, or more of ether without possessing a valid current permit as required by s. 499.62(4) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)Any person who knowingly withholds information or presents to the department any false, fictitious, or misrepresented application, identification, document,

information, statement, or data intended or likely to deceive the department for the purpose of obtaining a license or permit as prohibited by s. 499.64(4) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(4)Any person who knowingly possesses 2.5 gallons, or equivalent by weight, or more of ether and is not the holder of a valid current license or permit as prohibited by s. 499.65(1) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5)Any person who knowingly sells or otherwise transfers 2.5 gallons, or equivalent by weight, or more of ether to any person who is not the holder of a valid current license or permit as prohibited by s. 499.66(1) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6)Any person who knowingly withholds information or makes any false or fictitious entry or misrepresentation upon any invoice, receipt, sales ticket, sales slip, or account of inventories as prohibited by s. 499.66(5) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(7)Any licensee who knowingly fails to maintain written accounts of inventories or records of sales or transfers as required by s. 499.66(3) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(8)Any permittee who knowingly fails to maintain written inventories and records as required by s. 499.67 is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(9)Any licensee or permittee who fails to report the loss, unexplained shortage, or theft of ether as required by s. 499.68(2) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(10)Any person who knowingly possesses 2.5 gallons, or equivalent by weight, or more of ether in, or within 500 feet of, any residential housing structure as prohibited by s. 499.69(1) is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—ss. 10, 11, ch. 86-133; s. 121, ch. 91-224; s. 4, ch. 91-429.

499.76Injunctive relief.—In addition to the penalties and other enforcement provisions of this part, in the event any person engaged in any of the activities covered by this part violates any provision of this part, any rule adopted pursuant thereto, or any cease and desist order as provided by this part, the department is authorized to resort to proceedings for injunction in the circuit court of the county in which the violation occurred or in which the person resides or has his or her principal place of business and may therein apply for such temporary and permanent orders as the department may deem necessary to restrain such person from engaging in any such activities until such person complies with the provisions of this part, the rules adopted pursuant thereto, and the orders of the department as authorized by this part.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 601, ch. 97-103.

499.77Exceptions.—Nothing contained in this part shall apply to the regular military and naval forces of the United States, or to the duly organized military forces of any state or territory thereof, provided that they are acting within their respective official capacities and in the performance of their duties.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.78County and municipal ordinances.—Nothing contained in this part shall affect any existing ordinance, rule, or regulation pertaining to ether in any county or municipality in this state, which ordinance, rule, or regulation is more restrictive than the provisions of this part and the rules adopted pursuant thereto; nor shall the provisions of this part limit the power of any county or municipality to make ordinances, rules, or regulations pertaining to ether which may be more restrictive than the provisions of this part and the rules adopted pursuant thereto.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.79Deposit of fees.—All fees collected for licenses and permits required by this part shall be deposited in the Professional Regulation Trust Fund, and all moneys collected under this part and deposited in the trust fund shall be used by the department in the administration of this part. The Department of Business and Professional Regulation shall maintain a separate account in the Professional Regulation Trust Fund for the Drugs, Devices, and Cosmetics program.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 45, ch. 95-144; s. 19, ch. 2012-143.

The 2012 Florida Statutes

CHAPTER 120

ADMINISTRATIVE PROCEDURE ACT

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120.50Exception to application of chapter.—This chapter shall not apply to:

(1)The Legislature.

(2)The courts.

History.—s. 1, ch. 74-310; s. 3, ch. 77-468; s. 1, ch. 78-162.

120.51Short title.—This chapter may be known and cited as the "Administrative Procedure Act."

History.—s. 1, ch. 74-310.

[1] **120.515Declaration of policy.**—This chapter provides uniform procedures for the exercise of specified authority. This chapter does not limit or impinge upon the assignment of executive power under Article IV of the State Constitution or the legal authority of an appointing authority to direct and supervise those appointees serving at the pleasure of the appointing authority. For purposes of this chapter, adherence to the direction and supervision of an appointing authority does not constitute delegation or transfer of statutory authority assigned to the appointee.

History.—s. 7, ch. 2012-116.

[1]**Note.**—Section 3, ch. 2012-116, provides that "[t]he Legislature intends that the amendments made by this act to ss. 20.02, 20.03, and 20.05, Florida Statutes, which apply to the organizational structure of the executive branch, and the creation of s. 120.515, Florida Statutes, which applies to administrative procedure, are to clarify that the placement of an executive department under the direct administration of an officer or board appointed by and serving at the pleasure of the Governor does not implicitly limit or restrict the Governor's prerogative, legal authority, and constitutional responsibility to direct and supervise the execution of the law and the exercise of lawful discretion."

120.52Definitions.—As used in this act:

(1)"Agency" means the following officers or governmental entities if acting pursuant to powers other

than those derived from the constitution:

(a)The Governor; each state officer and state department, and each departmental unit described in s. 20.04; the Board of Governors of the State University System; the Commission on Ethics; the Fish and Wildlife Conservation Commission; a regional water supply authority; a regional planning agency; a multicounty special district, but only when a majority of its governing board is comprised of nonelected persons; educational units; and each entity described in chapters 163, 373, 380, and 582 and s. 186.504.

(b)Each officer and governmental entity in the state having statewide jurisdiction or jurisdiction in more than one county.

(c)Each officer and governmental entity in the state having jurisdiction in one county or less than one county, to the extent they are expressly made subject to this act by general or special law or existing judicial decisions.

This definition does not include any municipality or legal entity created solely by a municipality; any legal entity or agency created in whole or in part pursuant to part II of chapter 361; any metropolitan planning organization created pursuant to s. 339.175; any separate legal or administrative entity created pursuant to s. 339.175 of which a metropolitan planning organization is a member; an expressway authority pursuant to chapter 348 or any transportation authority under chapter 343 or chapter 349; or any legal or administrative entity created by an interlocal agreement pursuant to s. 163.01(7), unless any party to such agreement is otherwise an agency as defined in this subsection.

(2)“Agency action” means the whole or part of a rule or order, or the equivalent, or the denial of a petition to adopt a rule or issue an order. The term also includes any denial of a request made under s. 120.54(7).

(3)“Agency head” means the person or collegial body in a department or other governmental unit statutorily responsible for final agency action. An agency head appointed by and serving at the pleasure of an appointing authority remains subject to the direction and supervision of the appointing authority, but actions taken by the agency head as authorized by statute are official acts.

(4)“Committee” means the Administrative Procedures Committee.

(5)“Division” means the Division of Administrative Hearings. Any document filed with the division by a party represented by an attorney shall be filed by electronic means through the division’s website. Any document filed with the division by a party not represented by an attorney shall, whenever possible, be filed by electronic means through the division’s website.

(6)“Educational unit” means a local school district, a community college district, the Florida School for the Deaf and the Blind, or a state university when the university is acting pursuant to statutory authority derived from the Legislature.

(7)“Final order” means a written final decision which results from a proceeding under s. 120.56, s.

120.565, s. 120.569, s. 120.57, s. 120.573, or s. 120.574 which is not a rule, and which is not excepted from the definition of a rule, and which has been filed with the agency clerk, and includes final agency actions which are affirmative, negative, injunctive, or declaratory in form. A final order includes all materials explicitly adopted in it. The clerk shall indicate the date of filing on the order.

(8)"Invalid exercise of delegated legislative authority" means action that goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:

(a)The agency has materially failed to follow the applicable rulemaking procedures or requirements set forth in this chapter;

(b)The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1.;

(c)The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1.;

(d)The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;

(e)The rule is arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational; or

(f)The rule imposes regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.

A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the enabling statute.

(9)"Law implemented" means the language of the enabling statute being carried out or interpreted by an agency through rulemaking.

(10)"License" means a franchise, permit, certification, registration, charter, or similar form of authorization required by law, but it does not include a license required primarily for revenue purposes when issuance of the license is merely a ministerial act.

(11)"Licensing" means the agency process respecting the issuance, denial, renewal, revocation,

suspension, annulment, withdrawal, or amendment of a license or imposition of terms for the exercise of a license.

(12)“Official reporter” means the publication in which an agency publishes final orders, the index to final orders, and the list of final orders which are listed rather than published.

(13)“Party” means:

(a)Specifically named persons whose substantial interests are being determined in the proceeding.

(b)Any other person who, as a matter of constitutional right, provision of statute, or provision of agency regulation, is entitled to participate in whole or in part in the proceeding, or whose substantial interests will be affected by proposed agency action, and who makes an appearance as a party.

(c)Any other person, including an agency staff member, allowed by the agency to intervene or participate in the proceeding as a party. An agency may by rule authorize limited forms of participation in agency proceedings for persons who are not eligible to become parties.

(d)Any county representative, agency, department, or unit funded and authorized by state statute or county ordinance to represent the interests of the consumers of a county, when the proceeding involves the substantial interests of a significant number of residents of the county and the board of county commissioners has, by resolution, authorized the representative, agency, department, or unit to represent the class of interested persons. The authorizing resolution shall apply to a specific proceeding and to appeals and ancillary proceedings thereto, and it shall not be required to state the names of the persons whose interests are to be represented.

The term “party” does not include a member government of a regional water supply authority or a governmental or quasi-judicial board or commission established by local ordinance or special or general law where the governing membership of such board or commission is shared with, in whole or in part, or appointed by a member government of a regional water supply authority in proceedings under s. 120.569, s. 120.57, or s. 120.68, to the extent that an interlocal agreement under ss. 163.01 and 373.713 exists in which the member government has agreed that its substantial interests are not affected by the proceedings or that it is to be bound by alternative dispute resolution in lieu of participating in the proceedings. This exclusion applies only to those particular types of disputes or controversies, if any, identified in an interlocal agreement.

(14)“Person” means any person described in s. 1.01, any unit of government in or outside the state, and any agency described in subsection (1).

(15)“Recommended order” means the official recommendation of an administrative law judge assigned by the division or of any other duly authorized presiding officer, other than an agency head or member of an agency head, for the final disposition of a proceeding under ss. 120.569 and 120.57.

(16)“Rule” means each agency statement of general applicability that implements, interprets, or

prescribes law or policy or describes the procedure or practice requirements of an agency and includes any form which imposes any requirement or solicits any information not specifically required by statute or by an existing rule. The term also includes the amendment or repeal of a rule. The term does not include:

(a)Internal management memoranda which do not affect either the private interests of any person or any plan or procedure important to the public and which have no application outside the agency issuing the memorandum.

(b)Legal memoranda or opinions issued to an agency by the Attorney General or agency legal opinions prior to their use in connection with an agency action.

(c)The preparation or modification of:

1.Agency budgets.

2.Statements, memoranda, or instructions to state agencies issued by the Chief Financial Officer or Comptroller as chief fiscal officer of the state and relating or pertaining to claims for payment submitted by state agencies to the Chief Financial Officer or Comptroller.

3.Contractual provisions reached as a result of collective bargaining.

4.Memoranda issued by the Executive Office of the Governor relating to information resources management.

(17)“Rulemaking authority” means statutory language that explicitly authorizes or requires an agency to adopt, develop, establish, or otherwise create any statement coming within the definition of the term “rule.”

(18)“Small city” means any municipality that has an unincarcerated population of 10,000 or less according to the most recent decennial census.

(19)“Small county” means any county that has an unincarcerated population of 75,000 or less according to the most recent decennial census.

(20)“Unadopted rule” means an agency statement that meets the definition of the term “rule,” but that has not been adopted pursuant to the requirements of s. 120.54.

(21)“Variance” means a decision by an agency to grant a modification to all or part of the literal requirements of an agency rule to a person who is subject to the rule. Any variance shall conform to the standards for variances outlined in this chapter and in the uniform rules adopted pursuant to s. 120.54(5).

(22)“Waiver” means a decision by an agency not to apply all or part of a rule to a person who is subject to the rule. Any waiver shall conform to the standards for waivers outlined in this chapter and in the uniform rules adopted pursuant to s. 120.54(5).

History.—s. 1, ch. 74-310; s. 1, ch. 75-191; s. 1, ch. 76-131; s. 1, ch. 77-174; s. 12, ch. 77-290; s. 2, ch. 77-453; s. 1, ch. 78-28; s. 1, ch. 78-425; s. 1, ch. 79-20; s. 55, ch. 79-40; s. 1, ch. 79-299; s. 2, ch. 81-119; s. 1, ch. 81-180; s. 7, ch. 82-180; s. 1, ch. 83-78; s. 2, ch. 83-273; s. 10, ch. 84-170; s. 15, ch. 85-80; s. 1, ch. 85-168; s. 2, ch. 87-385; s. 1, ch. 88-367; s. 1, ch. 89-147; s. 1, ch. 91-46; s. 9, ch. 92-166; s. 50, ch. 92-279; s. 55, ch. 92-326; s. 3, ch. 96-159; s. 1, ch. 97-176; s. 2, ch. 97-286; s. 1, ch. 98-

402; s. 64, ch. 99-245; s. 2, ch. 99-379; s. 895, ch. 2002-387; s. 1, ch. 2003-94; s. 138, ch. 2003-261; s. 7, ch. 2003-286; s. 3, ch. 2007-196; s. 13, ch. 2007-217; s. 2, ch. 2008-104; s. 1, ch. 2009-85; s. 1, ch. 2009-187; s. 10, ch. 2010-5; s. 2, ch. 2010-205; s. 7, ch. 2011-208; s. 8, ch. 2012-116.

120.525Meetings, hearings, and workshops.—

(1)Except in the case of emergency meetings, each agency shall give notice of public meetings, hearings, and workshops by publication in the Florida Administrative Weekly and on the agency's website not less than 7 days before the event. The notice shall include a statement of the general subject matter to be considered.

(2)An agenda shall be prepared by the agency in time to ensure that a copy of the agenda may be received at least 7 days before the event by any person in the state who requests a copy and who pays the reasonable cost of the copy. The agenda, along with any meeting materials available in electronic form excluding confidential and exempt information, shall be published on the agency's website. The agenda shall contain the items to be considered in order of presentation. After the agenda has been made available, a change shall be made only for good cause, as determined by the person designated to preside, and stated in the record. Notification of such change shall be at the earliest practicable time.

(3)If an agency finds that an immediate danger to the public health, safety, or welfare requires immediate action, the agency may hold an emergency public meeting and give notice of such meeting by any procedure that is fair under the circumstances and necessary to protect the public interest, if:

(a)The procedure provides at least the procedural protection given by other statutes, the State Constitution, or the United States Constitution.

(b)The agency takes only that action necessary to protect the public interest under the emergency procedure.

(c)The agency publishes in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances. The agency findings of immediate danger, necessity, and procedural fairness shall be judicially reviewable.

History.—s. 4, ch. 96-159; s. 3, ch. 2009-187.

120.53Maintenance of orders; indexing; listing; organizational information.—

(1)(a)Each agency shall maintain:

1.All agency final orders.

2.a.A current hierarchical subject-matter index, identifying for the public any rule or order as specified in this subparagraph.

b.In lieu of the requirement for making available for public inspection and copying a hierarchical subject-matter index of its orders, an agency may maintain and make available for public use an electronic database

of its orders that allows users to research and retrieve the full texts of agency orders by devising an ad hoc indexing system employing any logical search terms in common usage which are composed by the user and which are contained in the orders of the agency or by descriptive information about the order which may not be specifically contained in the order.

c.The agency orders that must be indexed, unless excluded under paragraph (c) or paragraph (d), include:

(I)Each final agency order resulting from a proceeding under s. 120.57 or s. 120.573.

(II)Each final agency order rendered pursuant to s. 120.57(4) which contains a statement of agency policy that may be the basis of future agency decisions or that may otherwise contain a statement of precedential value.

(III)Each declaratory statement issued by an agency.

(IV)Each final order resulting from a proceeding under s. 120.56 or s. 120.574.

3.A list of all final orders rendered pursuant to s. 120.57(4) which have been excluded from the indexing requirement of this section, with the approval of the Department of State, because they do not contain statements of agency policy or statements of precedential value. The list must include the name of the parties to the proceeding and the number assigned to the final order.

4.All final orders listed pursuant to subparagraph 3.

(b)An agency final order that must be indexed or listed pursuant to paragraph (a) must be indexed or listed within 120 days after the order is rendered. Each final order that must be indexed or listed pursuant to paragraph (a) must have attached a copy of the complete text of any materials incorporated by reference; however, if the quantity of the materials incorporated makes attachment of the complete text of the materials impractical, the order may contain a statement of the location of such materials and the manner in which the public may inspect or obtain copies of the materials incorporated by reference. The Department of State shall establish by rule procedures for indexing final orders, and procedures of agencies for indexing orders must be approved by the department.

(c)Each agency must receive approval in writing from the Department of State for:

1.The specific types and categories of agency final orders that may be excluded from the indexing and public inspection requirements, as determined by the department pursuant to paragraph (d).

2.The method for maintaining indexes, lists, and final orders that must be indexed or listed and made available to the public.

3.The method by which the public may inspect or obtain copies of indexes, lists, and final orders.

4.A sequential numbering system which numbers all final orders required to be indexed or listed pursuant to paragraph (a), in the order rendered.

5.Proposed rules for implementing the requirements of this section for indexing and making final orders

available for public inspection.

(d)In determining which final orders may be excluded from the indexing and public inspection requirements, the Department of State may consider all factors specified by an agency, including precedential value, legal significance, and purpose. Only agency final orders that are of limited or no precedential value, that are of limited or no legal significance, or that are ministerial in nature may be excluded.

(e)Each agency shall specify the specific types or categories of agency final orders that are excluded from the indexing and public inspection requirements.

(f)Each agency shall specify the location or locations where agency indexes, lists, and final orders that are required to be indexed or listed are maintained and shall specify the method or procedure by which the public may inspect or obtain copies of indexes, lists, and final orders.

(g)Each agency shall specify all systems in use by the agency to search and locate agency final orders that are required to be indexed or listed, including, but not limited to, any automated system. An agency shall make the search capabilities employed by the agency available to the public subject to reasonable terms and conditions, including a reasonable charge, as provided by s. 119.07. The agency shall specify how assistance and information pertaining to final orders may be obtained.

(h)Each agency shall specify the numbering system used to identify agency final orders.

(2)(a)An agency may comply with subparagraphs (1)(a)1. and 2. by designating an official reporter to publish and index by subject matter each agency order that must be indexed and made available to the public, or by electronically transmitting to the division a copy of such orders for posting on the division's website. An agency is in compliance with subparagraph (1)(a)3. if it publishes in its designated reporter a list of each agency final order that must be listed and preserves each listed order and makes it available for public inspection and copying.

(b)An agency may publish its official reporter or may contract with a publishing firm to publish its official reporter; however, if an agency contracts with a publishing firm to publish its reporter, the agency is responsible for the quality, timeliness, and usefulness of the reporter. The Department of State may publish an official reporter for an agency or may contract with a publishing firm to publish the reporter for the agency; however, if the department contracts for publication of the reporter, the department is responsible for the quality, timeliness, and usefulness of the reporter. A reporter that is designated by an agency as its official reporter and approved by the Department of State constitutes the official compilation of the administrative final orders for that agency.

(c)A reporter that is published by the Department of State may be made available by annual subscription, and each agency that designates an official reporter published by the department may be charged a space rate payable to the department. The subscription rate and the space rate must be equitably apportioned to cover the costs of publishing the reporter.

(d)An agency that designates an official reporter need not publish the full text of an agency final order that is rendered pursuant to s. 120.57(4) and that must be indexed pursuant to paragraph (1)(a), if the final order is preserved by the agency and made available for public inspection and copying and the official reporter indexes the final order and includes a synopsis of the order. A synopsis must include the names of the parties to the order; any rule, statute, or constitutional provision pertinent to the order; a summary of the facts, if included in the order, which are pertinent to the final disposition; and a summary of the final disposition.

(3)Agency orders that must be indexed or listed are documents of continuing legal value and must be permanently preserved and made available to the public. Each agency to which this chapter applies shall provide, under the direction of the Department of State, for the preservation of orders as required by this chapter and for maintaining an index to those orders.

(4)Each agency must provide any person who makes a request with a written description of its organization and the general course of its operations.

History.—s. 1, ch. 74-310; s. 2, ch. 75-191; s. 2, ch. 76-131; s. 2, ch. 79-299; s. 1, ch. 81-296; s. 2, ch. 81-309; s. 8, ch. 83-92; s. 34, ch. 83-217; s. 3, ch. 83-273; s. 1, ch. 84-203; s. 77, ch. 85-180; s. 2, ch. 87-100; s. 2, ch. 88-384; s. 44, ch. 90-136; s. 35, ch. 90-302; s. 2, ch. 91-30; s. 79, ch. 91-45; s. 1, ch. 91-191; s. 1, ch. 92-166; s. 143, ch. 92-279; s. 55, ch. 92-326; s. 757, ch. 95-147; s. 5, ch. 96-159; s. 2, ch. 96-423; s. 2, ch. 97-176; s. 3, ch. 2008-104.

120.533Coordination of indexing by Department of State.—The Department of State shall:

(1)Administer the coordination of the indexing, management, preservation, and availability of agency orders that must be indexed or listed pursuant to s. 120.53(1).

(2)Provide, by rule, guidelines for the indexing of agency orders. More than one system for indexing may be approved by the Department of State, including systems or methods in use, or proposed for use, by an agency. More than one system may be approved for use by a single agency as best serves the needs of that agency and the public.

(3)Provide, by rule, for storage and retrieval systems to be maintained by agencies for indexing, and making available, agency orders by subject matter. The Department of State may approve more than one system, including systems in use, or proposed for use, by an agency. Storage and retrieval systems that may be used by an agency include, without limitation, a designated reporter or reporters, a microfilming system, an automated system, or any other system considered appropriate by the Department of State.

(4)Determine which final orders must be indexed for each agency.

(5)Require each agency to report to the department concerning which types or categories of agency orders establish precedent for each agency.

History.—s. 9, ch. 91-30; s. 1, ch. 91-191; s. 7, ch. 96-159.

120.536Rulemaking authority; repeal; challenge.—

(1)A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the enabling statute.

(2)Unless otherwise expressly provided by law:

(a)The repeal of one or more provisions of law implemented by a rule that on its face implements only the provision or provisions repealed and no other provision of law nullifies the rule. Whenever notice of the nullification of a rule under this subsection is received from the committee or otherwise, the Department of State shall remove the rule from the Florida Administrative Code as of the effective date of the law effecting the nullification and update the historical notes for the code to show the rule repealed by operation of law.

(b)The repeal of one or more provisions of law implemented by a rule that on its face implements the provision or provisions repealed and one or more other provisions of law nullifies the rule or applicable portion of the rule to the extent that it implements the repealed law. The agency having authority to repeal or amend the rule shall, within 180 days after the effective date of the repealing law, publish a notice of rule development identifying all portions of rules affected by the repealing law, and if no notice is timely published the operation of each rule implementing a repealed provision of law shall be suspended until such notice is published.

(c)The repeal of one or more provisions of law that, other than as provided in paragraph (a) or paragraph (b), causes a rule or portion of a rule to be of uncertain enforceability requires the Department of State to treat the rule as provided by s. 120.555. A rule shall be considered to be of uncertain enforceability under this paragraph if the division notifies the Department of State that a rule or a portion of the rule has been invalidated in a division proceeding based upon a repeal of law, or the committee gives written notification to the Department of State and the agency having power to amend or repeal the rule that a law has been repealed creating doubt about whether the rule is still in full force and effect.

(3)The Administrative Procedures Committee or any substantially affected person may petition an agency to repeal any rule, or portion thereof, because it exceeds the rulemaking authority permitted by this section. Not later than 30 days after the date of filing the petition if the agency is headed by an individual, or not later than 45 days if the agency is headed by a collegial body, the agency shall initiate rulemaking proceedings

to repeal the rule, or portion thereof, or deny the petition, giving a written statement of its reasons for the denial.

(4)Nothing in this section shall be construed to change the legal status of a rule that has otherwise been judicially or administratively determined to be invalid.

History.—s. 9, ch. 96-159; s. 3, ch. 99-379; s. 15, ch. 2000-151; s. 15, ch. 2005-2; s. 4, ch. 2008-104; s. 1, ch. 2012-31.

120.54Rulemaking.—

(1)GENERAL PROVISIONS APPLICABLE TO ALL RULES OTHER THAN EMERGENCY RULES.—

(a)Rulemaking is not a matter of agency discretion. Each agency statement defined as a rule by s. 120.52 shall be adopted by the rulemaking procedure provided by this section as soon as feasible and practicable.

1.Rulemaking shall be presumed feasible unless the agency proves that:

a.The agency has not had sufficient time to acquire the knowledge and experience reasonably necessary to address a statement by rulemaking; or

b.Related matters are not sufficiently resolved to enable the agency to address a statement by rulemaking.

2.Rulemaking shall be presumed practicable to the extent necessary to provide fair notice to affected persons of relevant agency procedures and applicable principles, criteria, or standards for agency decisions unless the agency proves that:

a.Detail or precision in the establishment of principles, criteria, or standards for agency decisions is not reasonable under the circumstances; or

b.The particular questions addressed are of such a narrow scope that more specific resolution of the matter is impractical outside of an adjudication to determine the substantial interests of a party based on individual circumstances.

(b)Whenever an act of the Legislature is enacted which requires implementation of the act by rules of an agency within the executive branch of state government, such rules shall be drafted and formally proposed as provided in this section within 180 days after the effective date of the act, unless the act provides otherwise.

(c)No statutory provision shall be delayed in its implementation pending an agency's adoption of implementing rules unless there is an express statutory provision prohibiting its application until the adoption of implementing rules.

(d)In adopting rules, all agencies must, among the alternative approaches to any regulatory objective and to the extent allowed by law, choose the alternative that does not impose regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.

(e)No agency has inherent rulemaking authority, nor has any agency authority to establish penalties for violation of a rule unless the Legislature, when establishing a penalty, specifically provides that the penalty

applies to rules.

(f)An agency may adopt rules authorized by law and necessary to the proper implementation of a statute prior to the effective date of the statute, but the rules may not be effective until the statute upon which they are based is effective. An agency may not adopt retroactive rules, including retroactive rules intended to clarify existing law, unless that power is expressly authorized by statute.

(g)Each rule adopted shall contain only one subject.

(h)In rulemaking proceedings, the agency may recognize any material which may be judicially noticed, and it may provide that materials so recognized be incorporated into the record of the proceeding. Before the record of any proceeding is completed, all parties shall be provided a list of these materials and given a reasonable opportunity to examine them and offer written comments or written rebuttal.

(i)1.A rule may incorporate material by reference but only as the material exists on the date the rule is adopted. For purposes of the rule, changes in the material are not effective unless the rule is amended to incorporate the changes.

2.An agency rule that incorporates by specific reference another rule of that agency automatically incorporates subsequent amendments to the referenced rule unless a contrary intent is clearly indicated in the referencing rule. A notice of amendments to a rule that has been incorporated by specific reference in other rules of that agency must explain the effect of those amendments on the referencing rules.

3.In rules adopted after December 31, 2010, material may not be incorporated by reference unless:

a.The material has been submitted in the prescribed electronic format to the Department of State and the full text of the material can be made available for free public access through an electronic hyperlink from the rule making the reference in the Florida Administrative Code; or

b.The agency has determined that posting the material on the Internet for purposes of public examination and inspection would constitute a violation of federal copyright law, in which case a statement to that effect, along with the address of locations at the Department of State and the agency at which the material is available for public inspection and examination, must be included in the notice required by subparagraph (3)(a)1.

4.A rule may not be amended by reference only. Amendments must set out the amended rule in full in the same manner as required by the State Constitution for laws.

5.Notwithstanding any contrary provision in this section, when an adopted rule of the Department of Environmental Protection or a water management district is incorporated by reference in the other agency's rule to implement a provision of part IV of chapter 373, subsequent amendments to the rule are not effective as to the incorporating rule unless the agency incorporating by reference notifies the committee and the Department of State of its intent to adopt the subsequent amendment, publishes notice of such intent in the Florida Administrative Weekly, and files with the Department of State a copy of the amended rule

incorporated by reference. Changes in the rule incorporated by reference are effective as to the other agency 20 days after the date of the published notice and filing with the Department of State. The Department of State shall amend the history note of the incorporating rule to show the effective date of such change. Any substantially affected person may, within 14 days after the date of publication of the notice of intent in the Florida Administrative Weekly, file an objection to rulemaking with the agency. The objection shall specify the portions of the rule incorporated by reference to which the person objects and the reasons for the objection. The agency shall not have the authority under this subparagraph to adopt those portions of the rule specified in such objection. The agency shall publish notice of the objection and of its action in response in the next available issue of the Florida Administrative Weekly.

6.The Department of State may adopt by rule requirements for incorporating materials pursuant to this paragraph.

(j)A rule published in the Florida Administrative Code must be indexed by the Department of State within 90 days after the rule is filed. The Department of State shall by rule establish procedures for indexing rules.

(k)An agency head may delegate the authority to initiate rule development under subsection (2); however, rulemaking responsibilities of an agency head under subparagraph (3)(a)1., subparagraph (3)(e)1., or subparagraph (3)(e)6. may not be delegated or transferred.

(2)RULE DEVELOPMENT; WORKSHOPS; NEGOTIATED RULEMAKING.—

(a)Except when the intended action is the repeal of a rule, agencies shall provide notice of the development of proposed rules by publication of a notice of rule development in the Florida Administrative Weekly before providing notice of a proposed rule as required by paragraph (3)(a). The notice of rule development shall indicate the subject area to be addressed by rule development, provide a short, plain explanation of the purpose and effect of the proposed rule, cite the specific legal authority for the proposed rule, and include the preliminary text of the proposed rules, if available, or a statement of how a person may promptly obtain, without cost, a copy of any preliminary draft, if available.

(b)All rules should be drafted in readable language. The language is readable if:

1.It avoids the use of obscure words and unnecessarily long or complicated constructions; and

2.It avoids the use of unnecessary technical or specialized language that is understood only by members of particular trades or professions.

(c)An agency may hold public workshops for purposes of rule development. An agency must hold public workshops, including workshops in various regions of the state or the agency's service area, for purposes of rule development if requested in writing by any affected person, unless the agency head explains in writing why a workshop is unnecessary. The explanation is not final agency action subject to review pursuant to ss. 120.569 and 120.57. The failure to provide the explanation when required may be a material error in procedure pursuant to s. 120.56(1)(c). When a workshop or public hearing is held, the agency must ensure

that the persons responsible for preparing the proposed rule are available to explain the agency's proposal and to respond to questions or comments regarding the rule being developed. The workshop may be facilitated or mediated by a neutral third person, or the agency may employ other types of dispute resolution alternatives for the workshop that are appropriate for rule development. Notice of a rule development workshop shall be by publication in the Florida Administrative Weekly not less than 14 days prior to the date on which the workshop is scheduled to be held and shall indicate the subject area which will be addressed; the agency contact person; and the place, date, and time of the workshop.

(d)1.An agency may use negotiated rulemaking in developing and adopting rules. The agency should consider the use of negotiated rulemaking when complex rules are being drafted or strong opposition to the rules is anticipated. The agency should consider, but is not limited to considering, whether a balanced committee of interested persons who will negotiate in good faith can be assembled, whether the agency is willing to support the work of the negotiating committee, and whether the agency can use the group consensus as the basis for its proposed rule. Negotiated rulemaking uses a committee of designated representatives to draft a mutually acceptable proposed rule.

2.An agency that chooses to use the negotiated rulemaking process described in this paragraph shall publish in the Florida Administrative Weekly a notice of negotiated rulemaking that includes a listing of the representative groups that will be invited to participate in the negotiated rulemaking process. Any person who believes that his or her interest is not adequately represented may apply to participate within 30 days after publication of the notice. All meetings of the negotiating committee shall be noticed and open to the public pursuant to the provisions of this chapter. The negotiating committee shall be chaired by a neutral facilitator or mediator.

3.The agency's decision to use negotiated rulemaking, its selection of the representative groups, and approval or denial of an application to participate in the negotiated rulemaking process are not agency action. Nothing in this subparagraph is intended to affect the rights of an affected person to challenge a proposed rule developed under this paragraph in accordance with s. 120.56(2).

(3)ADOPTION PROCEDURES.—

(a)*Notices.*—

1.Prior to the adoption, amendment, or repeal of any rule other than an emergency rule, an agency, upon approval of the agency head, shall give notice of its intended action, setting forth a short, plain explanation of the purpose and effect of the proposed action; the full text of the proposed rule or amendment and a summary thereof; a reference to the grant of rulemaking authority pursuant to which the rule is adopted; and a reference to the section or subsection of the Florida Statutes or the Laws of Florida being implemented or interpreted. The notice must include a summary of the agency's statement of the estimated regulatory costs, if one has been prepared, based on the factors set forth in s. 120.541(2); a statement that

any person who wishes to provide the agency with information regarding the statement of estimated regulatory costs, or to provide a proposal for a lower cost regulatory alternative as provided by s. 120.541(1), must do so in writing within 21 days after publication of the notice; and a statement as to whether, based on the statement of the estimated regulatory costs or other information expressly relied upon and described by the agency if no statement of regulatory costs is required, the proposed rule is expected to require legislative ratification pursuant to s. 120.541(3). The notice must state the procedure for requesting a public hearing on the proposed rule. Except when the intended action is the repeal of a rule, the notice must include a reference both to the date on which and to the place where the notice of rule development that is required by subsection (2) appeared.

2.The notice shall be published in the Florida Administrative Weekly not less than 28 days prior to the intended action. The proposed rule shall be available for inspection and copying by the public at the time of the publication of notice.

3.The notice shall be mailed to all persons named in the proposed rule and to all persons who, at least 14 days prior to such mailing, have made requests of the agency for advance notice of its proceedings. The agency shall also give such notice as is prescribed by rule to those particular classes of persons to whom the intended action is directed.

4.The adopting agency shall file with the committee, at least 21 days prior to the proposed adoption date, a copy of each rule it proposes to adopt; a copy of any material incorporated by reference in the rule; a detailed written statement of the facts and circumstances justifying the proposed rule; a copy of any statement of estimated regulatory costs that has been prepared pursuant to s. 120.541; a statement of the extent to which the proposed rule relates to federal standards or rules on the same subject; and the notice required by subparagraph 1.

(b)*Special matters to be considered in rule adoption.*—

1.Statement of estimated regulatory costs.—Before the adoption, amendment, or repeal of any rule other than an emergency rule, an agency is encouraged to prepare a statement of estimated regulatory costs of the proposed rule, as provided by s. 120.541. However, an agency must prepare a statement of estimated regulatory costs of the proposed rule, as provided by s. 120.541, if:

a.The proposed rule will have an adverse impact on small business; or

b.The proposed rule is likely to directly or indirectly increase regulatory costs in excess of $200,000 in the aggregate in this state within 1 year after the implementation of the rule.

2.Small businesses, small counties, and small cities.—

a.Each agency, before the adoption, amendment, or repeal of a rule, shall consider the impact of the rule on small businesses as defined by s. 288.703 and the impact of the rule on small counties or small cities as defined by s. 120.52. Whenever practicable, an agency shall tier its rules to reduce disproportionate

impacts on small businesses, small counties, or small cities to avoid regulating small businesses, small counties, or small cities that do not contribute significantly to the problem the rule is designed to address. An agency may define “small business” to include businesses employing more than 200 persons, may define “small county” to include those with populations of more than 75,000, and may define “small city” to include those with populations of more than 10,000, if it finds that such a definition is necessary to adapt a rule to the needs and problems of small businesses, small counties, or small cities. The agency shall consider each of the following methods for reducing the impact of the proposed rule on small businesses, small counties, and small cities, or any combination of these entities:

(I)Establishing less stringent compliance or reporting requirements in the rule.

(II)Establishing less stringent schedules or deadlines in the rule for compliance or reporting requirements.

(III)Consolidating or simplifying the rule’s compliance or reporting requirements.

(IV)Establishing performance standards or best management practices to replace design or operational standards in the rule.

(V)Exempting small businesses, small counties, or small cities from any or all requirements of the rule.

b.(I)If the agency determines that the proposed action will affect small businesses as defined by the agency as provided in sub-subparagraph a., the agency shall send written notice of the rule to the rules ombudsman in the Executive Office of the Governor at least 28 days before the intended action.

(II)Each agency shall adopt those regulatory alternatives offered by the rules ombudsman in the Executive Office of the Governor and provided to the agency no later than 21 days after the [1]council’s receipt of the written notice of the rule which it finds are feasible and consistent with the stated objectives of the proposed rule and which would reduce the impact on small businesses. When regulatory alternatives are offered by the rules ombudsman in the Executive Office of the Governor, the 90-day period for filing the rule in subparagraph (e)2. is extended for a period of 21 days.

(III)If an agency does not adopt all alternatives offered pursuant to this sub-subparagraph, it shall, before rule adoption or amendment and pursuant to subparagraph (d)1., file a detailed written statement with the committee explaining the reasons for failure to adopt such alternatives. Within 3 working days after the filing of such notice, the agency shall send a copy of such notice to the rules ombudsman in the Executive Office of the Governor.

(c)*Hearings.*—

1.If the intended action concerns any rule other than one relating exclusively to procedure or practice, the agency shall, on the request of any affected person received within 21 days after the date of publication of the notice of intended agency action, give affected persons an opportunity to present evidence and argument on all issues under consideration. The agency may schedule a public hearing on the rule and, if requested by any affected person, shall schedule a public hearing on the rule. When a public hearing is held,

the agency must ensure that staff are available to explain the agency's proposal and to respond to questions or comments regarding the rule. If the agency head is a board or other collegial body created under s. 20.165(4) or s. 20.43(3)(g), and one or more requested public hearings is scheduled, the board or other collegial body shall conduct at least one of the public hearings itself and may not delegate this responsibility without the consent of those persons requesting the public hearing. Any material pertinent to the issues under consideration submitted to the agency within 21 days after the date of publication of the notice or submitted to the agency between the date of publication of the notice and the end of the final public hearing shall be considered by the agency and made a part of the record of the rulemaking proceeding.

2.Rulemaking proceedings shall be governed solely by the provisions of this section unless a person timely asserts that the person's substantial interests will be affected in the proceeding and affirmatively demonstrates to the agency that the proceeding does not provide adequate opportunity to protect those interests. If the agency determines that the rulemaking proceeding is not adequate to protect the person's interests, it shall suspend the rulemaking proceeding and convene a separate proceeding under the provisions of ss. 120.569 and 120.57. Similarly situated persons may be requested to join and participate in the separate proceeding. Upon conclusion of the separate proceeding, the rulemaking proceeding shall be resumed.

(d)*Modification or withdrawal of proposed rules.*—

1.After the final public hearing on the proposed rule, or after the time for requesting a hearing has expired, if the rule has not been changed from the rule as previously filed with the committee, or contains only technical changes, the adopting agency shall file a notice to that effect with the committee at least 7 days prior to filing the rule for adoption. Any change, other than a technical change that does not affect the substance of the rule, must be supported by the record of public hearings held on the rule, must be in response to written material submitted to the agency within 21 days after the date of publication of the notice of intended agency action or submitted to the agency between the date of publication of the notice and the end of the final public hearing, or must be in response to a proposed objection by the committee. In addition, when any change is made in a proposed rule, other than a technical change, the adopting agency shall provide a copy of a notice of change by certified mail or actual delivery to any person who requests it in writing no later than 21 days after the notice required in paragraph (a). The agency shall file the notice of change with the committee, along with the reasons for the change, and provide the notice of change to persons requesting it, at least 21 days prior to filing the rule for adoption. The notice of change shall be published in the Florida Administrative Weekly at least 21 days prior to filing the rule for adoption. This subparagraph does not apply to emergency rules adopted pursuant to subsection (4).

2.After the notice required by paragraph (a) and prior to adoption, the agency may withdraw the rule in whole or in part.

3.After adoption and before the rule becomes effective, a rule may be modified or withdrawn only in the

following circumstances:

a.When the committee objects to the rule;

b.When a final order, which is not subject to further appeal, is entered in a rule challenge brought pursuant to s. 120.56 after the date of adoption but before the rule becomes effective pursuant to subparagraph (e)6.;

c.If the rule requires ratification, when more than 90 days have passed since the rule was filed for adoption without the Legislature ratifying the rule, in which case the rule may be withdrawn but may not be modified; or

d.When the committee notifies the agency that an objection to the rule is being considered, in which case the rule may be modified to extend the effective date by not more than 60 days.

4.The agency shall give notice of its decision to withdraw or modify a rule in the first available issue of the publication in which the original notice of rulemaking was published, shall notify those persons described in subparagraph (a)3. in accordance with the requirements of that subparagraph, and shall notify the Department of State if the rule is required to be filed with the Department of State.

5.After a rule has become effective, it may be repealed or amended only through the rulemaking procedures specified in this chapter.

(e)*Filing for final adoption; effective date.*—

1.If the adopting agency is required to publish its rules in the Florida Administrative Code, the agency, upon approval of the agency head, shall file with the Department of State three certified copies of the rule it proposes to adopt; one copy of any material incorporated by reference in the rule, certified by the agency; a summary of the rule; a summary of any hearings held on the rule; and a detailed written statement of the facts and circumstances justifying the rule. Agencies not required to publish their rules in the Florida Administrative Code shall file one certified copy of the proposed rule, and the other material required by this subparagraph, in the office of the agency head, and such rules shall be open to the public.

2.A rule may not be filed for adoption less than 28 days or more than 90 days after the notice required by paragraph (a), until 21 days after the notice of change required by paragraph (d), until 14 days after the final public hearing, until 21 days after a statement of estimated regulatory costs required under s. 120.541 has been provided to all persons who submitted a lower cost regulatory alternative and made available to the public, or until the administrative law judge has rendered a decision under s. 120.56(2), whichever applies. When a required notice of change is published prior to the expiration of the time to file the rule for adoption, the period during which a rule must be filed for adoption is extended to 45 days after the date of publication. If notice of a public hearing is published prior to the expiration of the time to file the rule for adoption, the period during which a rule must be filed for adoption is extended to 45 days after adjournment of the final hearing on the rule, 21 days after receipt of all material authorized to be submitted at the hearing, or 21 days

after receipt of the transcript, if one is made, whichever is latest. The term “public hearing” includes any public meeting held by any agency at which the rule is considered. If a petition for an administrative determination under s. 120.56(2) is filed, the period during which a rule must be filed for adoption is extended to 60 days after the administrative law judge files the final order with the clerk or until 60 days after subsequent judicial review is complete.

3.At the time a rule is filed, the agency shall certify that the time limitations prescribed by this paragraph have been complied with, that all statutory rulemaking requirements have been met, and that there is no administrative determination pending on the rule.

4.At the time a rule is filed, the committee shall certify whether the agency has responded in writing to all material and timely written comments or written inquiries made on behalf of the committee. The department shall reject any rule that is not filed within the prescribed time limits; that does not comply with all statutory rulemaking requirements and rules of the department; upon which an agency has not responded in writing to all material and timely written inquiries or written comments; upon which an administrative determination is pending; or which does not include a statement of estimated regulatory costs, if required.

5.If a rule has not been adopted within the time limits imposed by this paragraph or has not been adopted in compliance with all statutory rulemaking requirements, the agency proposing the rule shall withdraw the rule and give notice of its action in the next available issue of the Florida Administrative Weekly.

6.The proposed rule shall be adopted on being filed with the Department of State and become effective 20 days after being filed, on a later date specified in the notice required by subparagraph (a)1., on a date required by statute, or upon ratification by the Legislature pursuant to s. 120.541(3). Rules not required to be filed with the Department of State shall become effective when adopted by the agency head, on a later date specified by rule or statute, or upon ratification by the Legislature pursuant to s. 120.541(3). If the committee notifies an agency that an objection to a rule is being considered, the agency may postpone the adoption of the rule to accommodate review of the rule by the committee. When an agency postpones adoption of a rule to accommodate review by the committee, the 90-day period for filing the rule is tolled until the committee notifies the agency that it has completed its review of the rule.

For the purposes of this paragraph, the term “administrative determination” does not include subsequent judicial review.

(4)EMERGENCY RULES.—

(a)If an agency finds that an immediate danger to the public health, safety, or welfare requires emergency action, the agency may adopt any rule necessitated by the immediate danger. The agency may adopt a rule by any procedure which is fair under the circumstances if:

1.The procedure provides at least the procedural protection given by other statutes, the State

Constitution, or the United States Constitution.

2.The agency takes only that action necessary to protect the public interest under the emergency procedure.

3.The agency publishes in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances. In any event, notice of emergency rules, other than those of educational units or units of government with jurisdiction in only one or a part of one county, including the full text of the rules, shall be published in the first available issue of the Florida Administrative Weekly and provided to the committee along with any material incorporated by reference in the rules. The agency's findings of immediate danger, necessity, and procedural fairness shall be judicially reviewable.

(b)Rules pertaining to the public health, safety, or welfare shall include rules pertaining to perishable agricultural commodities or rules pertaining to the interpretation and implementation of the requirements of chapters 97-102 and chapter 105 of the Election Code.

(c)An emergency rule adopted under this subsection shall not be effective for a period longer than 90 days and shall not be renewable, except when the agency has initiated rulemaking to adopt rules addressing the subject of the emergency rule and either:

1.A challenge to the proposed rules has been filed and remains pending; or

2.The proposed rules are awaiting ratification by the Legislature pursuant to s. 120.541(3).

Nothing in this paragraph prohibits the agency from adopting a rule or rules identical to the emergency rule through the rulemaking procedures specified in subsection (3).

(d)Subject to applicable constitutional and statutory provisions, an emergency rule becomes effective immediately on filing, or on a date less than 20 days thereafter if specified in the rule, if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

(5)UNIFORM RULES.—

(a)1.By July 1, 1997, the Administration Commission shall adopt one or more sets of uniform rules of procedure which shall be reviewed by the committee and filed with the Department of State. Agencies must comply with the uniform rules by July 1, 1998. The uniform rules shall establish procedures that comply with the requirements of this chapter. On filing with the department, the uniform rules shall be the rules of procedure for each agency subject to this chapter unless the Administration Commission grants an exception to the agency under this subsection.

2.An agency may seek exceptions to the uniform rules of procedure by filing a petition with the Administration Commission. The Administration Commission shall approve exceptions to the extent necessary to implement other statutes, to the extent necessary to conform to any requirement imposed as a condition

precedent to receipt of federal funds or to permit persons in this state to receive tax benefits under federal law, or as required for the most efficient operation of the agency as determined by the Administration Commission. The reasons for the exceptions shall be published in the Florida Administrative Weekly.

3.Agency rules that provide exceptions to the uniform rules shall not be filed with the department unless the Administration Commission has approved the exceptions. Each agency that adopts rules that provide exceptions to the uniform rules shall publish a separate chapter in the Florida Administrative Code that delineates clearly the provisions of the agency's rules that provide exceptions to the uniform rules and specifies each alternative chosen from among those authorized by the uniform rules. Each chapter shall be organized in the same manner as the uniform rules.

(b)The uniform rules of procedure adopted by the commission pursuant to this subsection shall include, but are not limited to:

1.Uniform rules for the scheduling of public meetings, hearings, and workshops.

2.Uniform rules for use by each state agency that provide procedures for conducting public meetings, hearings, and workshops, and for taking evidence, testimony, and argument at such public meetings, hearings, and workshops, in person and by means of communications media technology. The rules shall provide that all evidence, testimony, and argument presented shall be afforded equal consideration, regardless of the method of communication. If a public meeting, hearing, or workshop is to be conducted by means of communications media technology, or if attendance may be provided by such means, the notice shall so state. The notice for public meetings, hearings, and workshops utilizing communications media technology shall state how persons interested in attending may do so and shall name locations, if any, where communications media technology facilities will be available. Nothing in this paragraph shall be construed to diminish the right to inspect public records under chapter 119. Limiting points of access to public meetings, hearings, and workshops subject to the provisions of s. 286.011 to places not normally open to the public shall be presumed to violate the right of access of the public, and any official action taken under such circumstances is void and of no effect. Other laws relating to public meetings, hearings, and workshops, including penal and remedial provisions, shall apply to public meetings, hearings, and workshops conducted by means of communications media technology, and shall be liberally construed in their application to such public meetings, hearings, and workshops. As used in this subparagraph, "communications media technology" means the electronic transmission of printed matter, audio, full-motion video, freeze-frame video, compressed video, and digital video by any method available.

3.Uniform rules of procedure for the filing of notice of protests and formal written protests. The Administration Commission may prescribe the form and substantive provisions of a required bond.

4.Uniform rules of procedure for the filing of petitions for administrative hearings pursuant to s. 120.569 or s. 120.57. Such rules shall require the petition to include:

a.The identification of the petitioner, including the petitioner's e-mail address, if any, for the

transmittal of subsequent documents by electronic means.

b.A statement of when and how the petitioner received notice of the agency's action or proposed action.

c.An explanation of how the petitioner's substantial interests are or will be affected by the action or proposed action.

d.A statement of all material facts disputed by the petitioner or a statement that there are no disputed facts.

e.A statement of the ultimate facts alleged, including a statement of the specific facts the petitioner contends warrant reversal or modification of the agency's proposed action.

f.A statement of the specific rules or statutes that the petitioner contends require reversal or modification of the agency's proposed action, including an explanation of how the alleged facts relate to the specific rules or statutes.

g.A statement of the relief sought by the petitioner, stating precisely the action petitioner wishes the agency to take with respect to the proposed action.

5.Uniform rules for the filing of request for administrative hearing by a respondent in agency enforcement and disciplinary actions. Such rules shall require a request to include:

a.The name, address, e-mail address, and telephone number of the party making the request and the name, address, and telephone number of the party's counsel or qualified representative upon whom service of pleadings and other papers shall be made;

b.A statement that the respondent is requesting an administrative hearing and disputes the material facts alleged by the petitioner, in which case the respondent shall identify those material facts that are in dispute, or that the respondent is requesting an administrative hearing and does not dispute the material facts alleged by the petitioner; and

c.A reference by file number to the administrative complaint that the party has received from the agency and the date on which the agency pleading was received.

The agency may provide an election-of-rights form for the respondent's use in requesting a hearing, so long as any form provided by the agency calls for the information in sub-subparagraphs a. through c. and does not impose any additional requirements on a respondent in order to request a hearing, unless such requirements are specifically authorized by law.

6.Uniform rules of procedure for the filing and prompt disposition of petitions for declaratory statements. The rules shall also describe the contents of the notices that must be published in the Florida Administrative Weekly under s. 120.565, including any applicable time limit for the filing of petitions to intervene or petitions for administrative hearing by persons whose substantial interests may be affected.

7.Provision of a method by which each agency head shall provide a description of the agency's organization and general course of its operations. The rules shall require that the statement concerning the

agency's organization and operations be published on the agency's website.

8.Uniform rules establishing procedures for granting or denying petitions for variances and waivers pursuant to s. 120.542.

(6)ADOPTION OF FEDERAL STANDARDS.—Notwithstanding any contrary provision of this section, in the pursuance of state implementation, operation, or enforcement of federal programs, an agency is empowered to adopt rules substantively identical to regulations adopted pursuant to federal law, in accordance with the following procedures:

(a)The agency shall publish notice of intent to adopt a rule pursuant to this subsection in the Florida Administrative Weekly at least 21 days prior to filing the rule with the Department of State. The agency shall provide a copy of the notice of intent to adopt a rule to the committee at least 21 days prior to the date of filing with the Department of State. Prior to filing the rule with the Department of State, the agency shall consider any written comments received within 14 days after the date of publication of the notice of intent to adopt a rule. The rule shall be adopted upon filing with the Department of State. Substantive changes from the rules as noticed shall require republishing of notice as required in this subsection.

(b)Any rule adopted pursuant to this subsection shall become effective upon the date designated by the agency in the notice of intent to adopt a rule; however, no such rule shall become effective earlier than the effective date of the substantively identical federal regulation.

(c)Any substantially affected person may, within 14 days after the date of publication of the notice of intent to adopt a rule, file an objection to rulemaking with the agency. The objection shall specify the portions of the proposed rule to which the person objects and the specific reasons for the objection. The agency shall not proceed pursuant to this subsection to adopt those portions of the proposed rule specified in an objection, unless the agency deems the objection to be frivolous, but may proceed pursuant to subsection (3). An objection to a proposed rule, which rule in no material respect differs from the requirements of the federal regulation upon which it is based, is deemed to be frivolous.

(d)Whenever any federal regulation adopted as an agency rule pursuant to this subsection is declared invalid or is withdrawn, revoked, repealed, remanded, or suspended, the agency shall, within 60 days thereafter, publish a notice of repeal of the substantively identical agency rule in the Florida Administrative Weekly. Such repeal is effective upon publication of the notice. Whenever any federal regulation adopted as an agency rule pursuant to this subsection is substantially amended, the agency may adopt the amended regulation as a rule. If the amended regulation is not adopted as a rule within 180 days after the effective date of the amended regulation, the original rule is deemed repealed and the agency shall publish a notice of repeal of the original agency rule in the next available Florida Administrative Weekly.

(e)Whenever all or part of any rule proposed for adoption by the agency is substantively identical to a regulation adopted pursuant to federal law, such rule shall be written in a manner so that the rule specifically

references the regulation whenever possible.

(7)PETITION TO INITIATE RULEMAKING.—

(a)Any person regulated by an agency or having substantial interest in an agency rule may petition an agency to adopt, amend, or repeal a rule or to provide the minimum public information required by this chapter. The petition shall specify the proposed rule and action requested. Not later than 30 calendar days following the date of filing a petition, the agency shall initiate rulemaking proceedings under this chapter, otherwise comply with the requested action, or deny the petition with a written statement of its reasons for the denial.

(b)If the petition filed under this subsection is directed to an unadopted rule, the agency shall, not later than 30 days following the date of filing a petition, initiate rulemaking, or provide notice in the Florida Administrative Weekly that the agency will hold a public hearing on the petition within 30 days after publication of the notice. The purpose of the public hearing is to consider the comments of the public directed to the agency rule which has not been adopted by the rulemaking procedures or requirements of this chapter, its scope and application, and to consider whether the public interest is served adequately by the application of the rule on a case-by-case basis, as contrasted with its adoption by the rulemaking procedures or requirements set forth in this chapter.

(c)Within 30 days following the public hearing provided for by paragraph (b), if the agency does not initiate rulemaking or otherwise comply with the requested action, the agency shall publish in the Florida Administrative Weekly a statement of its reasons for not initiating rulemaking or otherwise complying with the requested action, and of any changes it will make in the scope or application of the unadopted rule. The agency shall file the statement with the committee. The committee shall forward a copy of the statement to the substantive committee with primary oversight jurisdiction of the agency in each house of the Legislature. The committee or the committee with primary oversight jurisdiction may hold a hearing directed to the statement of the agency. The committee holding the hearing may recommend to the Legislature the introduction of legislation making the rule a statutory standard or limiting or otherwise modifying the authority of the agency.

(8)RULEMAKING RECORD.—In all rulemaking proceedings the agency shall compile a rulemaking record. The record shall include, if applicable, copies of:

(a)All notices given for the proposed rule.

(b)Any statement of estimated regulatory costs for the rule.

(c)A written summary of hearings on the proposed rule.

(d)The written comments and responses to written comments as required by this section and s. 120.541.

(e)All notices and findings made under subsection (4).

(f)All materials filed by the agency with the committee under subsection (3).

(g)All materials filed with the Department of State under subsection (3).

(h)All written inquiries from standing committees of the Legislature concerning the rule.

Each state agency shall retain the record of rulemaking as long as the rule is in effect. When a rule is no longer in effect, the record may be destroyed pursuant to the records-retention schedule developed under s. 257.36(6).

History.—s. 1, ch. 74-310; s. 3, ch. 75-191; s. 3, ch. 76-131; ss. 1, 2, ch. 76-276; s. 1, ch. 77-174; s. 13, ch. 77-290; s. 3, ch. 77-453; s. 2, ch. 78-28; s. 2, ch. 78-425; s. 7, ch. 79-3; s. 3, ch. 79-299; s. 69, ch. 79-400; s. 5, ch. 80-391; s. 1, ch. 81-309; s. 2, ch. 83-351; s. 1, ch. 84-173; s. 2, ch. 84-203; s. 7, ch. 85-104; s. 1, ch. 86-30; s. 3, ch. 87-385; s. 36, ch. 90-302; ss. 2, 4, 7, ch. 92-166; s. 63, ch. 93-187; s. 758, ch. 95-147; s. 6, ch. 95-295; s. 10, ch. 96-159; s. 6, ch. 96-320; s. 9, ch. 96-370; s. 3, ch. 97-176; s. 3, ch. 98-200; s. 4, ch. 99-379; s. 9, ch. 2001-75; s. 2, ch. 2003-94; s. 50, ch. 2005-278; s. 3, ch. 2006-82; ss. 5, 6, ch. 2008-104; s. 7, ch. 2008-149; s. 4, ch. 2009-187; ss. 1, 5, ch. 2010-279; HJR 9-A, 2010 Special Session A; s. 49, ch. 2011-142; s. 8, ch. 2011-208; s. 1, ch. 2011-225; s. 2, ch. 2012-27; s. 1, ch. 2012-63.

[1]**Note.**—The word "council's" refers to the Small Business Regulatory Advisory Council. Section 5, ch. 2012-27, repealed s. 288.7001, which created the council, and other provisions in ch. 2012-27 reassigned the council's duties to the rules ombudsman in the Executive Office of the Governor.

1**20.54**1**Statement of estimated regulatory costs.**—

(1)(a)Within 21 days after publication of the notice required under s. 120.54(3)(a), a substantially affected person may submit to an agency a good faith written proposal for a lower cost regulatory alternative to a proposed rule which substantially accomplishes the objectives of the law being implemented. The proposal may include the alternative of not adopting any rule if the proposal explains how the lower costs and objectives of the law will be achieved by not adopting any rule. If such a proposal is submitted, the 90-day period for filing the rule is extended 21 days. Upon the submission of the lower cost regulatory alternative, the agency shall prepare a statement of estimated regulatory costs as provided in subsection (2), or shall revise its prior statement of estimated regulatory costs, and either adopt the alternative or provide a statement of the reasons for rejecting the alternative in favor of the proposed rule.

(b)If a proposed rule will have an adverse impact on small business or if the proposed rule is likely to directly or indirectly increase regulatory costs in excess of $200,000 in the aggregate within 1 year after the implementation of the rule, the agency shall prepare a statement of estimated regulatory costs as required by s. 120.54(3)(b).

(c)The agency shall revise a statement of estimated regulatory costs if any change to the rule made under s. 120.54(3)(d) increases the regulatory costs of the rule.

(d)At least 21 days before filing the rule for adoption, an agency that is required to revise a statement of estimated regulatory costs shall provide the statement to the person who submitted the lower cost regulatory alternative and to the committee and shall provide notice on the agency's website that it is available to the

public.

(e)Notwithstanding s. 120.56(1)(c), the failure of the agency to prepare a statement of estimated regulatory costs or to respond to a written lower cost regulatory alternative as provided in this subsection is a material failure to follow the applicable rulemaking procedures or requirements set forth in this chapter.

(f)An agency's failure to prepare a statement of estimated regulatory costs or to respond to a written lower cost regulatory alternative may not be raised in a proceeding challenging the validity of a rule pursuant to s. 120.52(8)(a) unless:

1.Raised in a petition filed no later than 1 year after the effective date of the rule; and

2.Raised by a person whose substantial interests are affected by the rule's regulatory costs.

(g)A rule that is challenged pursuant to s. 120.52(8)(f) may not be declared invalid unless:

1.The issue is raised in an administrative proceeding within 1 year after the effective date of the rule;

2.The challenge is to the agency's rejection of a lower cost regulatory alternative offered under paragraph (a) or s. 120.54(3)(b)2.b.; and

3.The substantial interests of the person challenging the rule are materially affected by the rejection.

(2)A statement of estimated regulatory costs shall include:

(a)An economic analysis showing whether the rule directly or indirectly:

1.Is likely to have an adverse impact on economic growth, private sector job creation or employment, or private sector investment in excess of $1 million in the aggregate within 5 years after the implementation of the rule;

2.Is likely to have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of $1 million in the aggregate within 5 years after the implementation of the rule; or

3.Is likely to increase regulatory costs, including any transactional costs, in excess of $1 million in the aggregate within 5 years after the implementation of the rule.

(b)A good faith estimate of the number of individuals and entities likely to be required to comply with the rule, together with a general description of the types of individuals likely to be affected by the rule.

(c)A good faith estimate of the cost to the agency, and to any other state and local government entities, of implementing and enforcing the proposed rule, and any anticipated effect on state or local revenues.

(d)A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including local government entities, required to comply with the requirements of the rule. As used in this section, "transactional costs" are direct costs that are readily ascertainable based upon standard business practices, and include filing fees, the cost of obtaining a license, the cost of equipment required to be installed or used or procedures required to be employed in complying with the rule, additional operating costs

incurred, the cost of monitoring and reporting, and any other costs necessary to comply with the rule.

(e)An analysis of the impact on small businesses as defined by s. 288.703, and an analysis of the impact on small counties and small cities as defined in s. 120.52. The impact analysis for small businesses must include the basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses.

(f)Any additional information that the agency determines may be useful.

(g)In the statement or revised statement, whichever applies, a description of any regulatory alternatives submitted under paragraph (1)(a) and a statement adopting the alternative or a statement of the reasons for rejecting the alternative in favor of the proposed rule.

(3)If the adverse impact or regulatory costs of the rule exceed any of the criteria established in paragraph (2)(a), the rule shall be submitted to the President of the Senate and Speaker of the House of Representatives no later than 30 days prior to the next regular legislative session, and the rule may not take effect until it is ratified by the Legislature.

[1] (4)This section does not apply to the adoption of emergency rules pursuant to s. 120.54(4) or the adoption of federal standards pursuant to s. 120.54(6).

History.—s. 11, ch. 96-159; s. 4, ch. 97-176; ss. 2, 5, ch. 2010-279; HJR 9-A, 2010 Special Session A; s. 1, ch. 2011-222; s. 2, ch. 2011-225.

[1]**Note.**—As amended by s. 2, ch. 2011-225. For a description of multiple acts in the same session affecting a statutory provision, *see* preface to the *Florida Statutes*, "Statutory Construction." Subsection (4) was also amended by s. 1, ch. 2011-222, and that version reads:

Subsection (4) (3) does not apply to the adoption of:

Federal (a) standards pursuant to s. 120.54(6).

Triennial (b) updates of and amendments to the Florida Building Code which are expressly authorized by s. 553.73.

Triennial (c) updates of and amendments to the Florida Fire Prevention Code which are expressly authorized by s. 633.0215.

120.542Variances and waivers.—

(1)Strict application of uniformly applicable rule requirements can lead to unreasonable, unfair, and unintended results in particular instances. The Legislature finds that it is appropriate in such cases to adopt a procedure for agencies to provide relief to persons subject to regulation. A public employee is not a person subject to regulation under this section for the purpose of petitioning for a variance or waiver to a rule that affects that public employee in his or her capacity as a public employee. Agencies are authorized to grant variances and waivers to requirements of their rules consistent with this section and with rules adopted under the authority of this section. An agency may limit the duration of any grant of a variance or waiver or otherwise impose conditions on the grant only to the extent necessary for the purpose of the underlying statute to be achieved. This section does not authorize agencies to grant variances or waivers to statutes or to

rules required by the Federal Government for the agency's implementation or retention of any federally approved or delegated program, except as allowed by the program or when the variance or waiver is also approved by the appropriate agency of the Federal Government. This section is supplemental to, and does not abrogate, the variance and waiver provisions in any other statute.

(2)Variances and waivers shall be granted when the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person and when application of a rule would create a substantial hardship or would violate principles of fairness. For purposes of this section, "substantial hardship" means a demonstrated economic, technological, legal, or other type of hardship to the person requesting the variance or waiver. For purposes of this section, "principles of fairness" are violated when the literal application of a rule affects a particular person in a manner significantly different from the way it affects other similarly situated persons who are subject to the rule.

(3)The Governor and Cabinet, sitting as the Administration Commission, shall adopt uniform rules of procedure pursuant to the requirements of s. 120.54(5) establishing procedures for granting or denying petitions for variances and waivers. The uniform rules shall include procedures for the granting, denying, or revoking of emergency and temporary variances and waivers. Such provisions may provide for expedited timeframes, waiver of or limited public notice, and limitations on comments on the petition in the case of such temporary or emergency variances and waivers.

(4)Agencies shall advise persons of the remedies available through this section and shall provide copies of this section, the uniform rules on variances and waivers, and, if requested, the underlying statute, to persons who inquire about the possibility of relief from rule requirements.

(5)A person who is subject to regulation by an agency rule may file a petition with that agency, with a copy to the committee, requesting a variance or waiver from the agency's rule. In addition to any requirements mandated by the uniform rules, each petition shall specify:

(a)The rule from which a variance or waiver is requested.

(b)The type of action requested.

(c)The specific facts that would justify a waiver or variance for the petitioner.

(d)The reason why the variance or the waiver requested would serve the purposes of the underlying statute.

(6)Within 15 days after receipt of a petition for variance or waiver, an agency shall provide notice of the petition to the Department of State, which shall publish notice of the petition in the first available issue of the Florida Administrative Weekly. The notice shall contain the name of the petitioner, the date the petition was filed, the rule number and nature of the rule from which variance or waiver is sought, and an explanation of how a copy of the petition can be obtained. The uniform rules shall provide a means for interested persons to provide comments on the petition.

(7)Except for requests for emergency variances or waivers, within 30 days after receipt of a petition for a variance or waiver, an agency shall review the petition and request submittal of all additional information that the agency is permitted by this section to require. Within 30 days after receipt of such additional information, the agency shall review it and may request only that information needed to clarify the additional information or to answer new questions raised by or directly related to the additional information. If the petitioner asserts that any request for additional information is not authorized by law or by rule of the affected agency, the agency shall proceed, at the petitioner's written request, to process the petition.

(8)An agency shall grant or deny a petition for variance or waiver within 90 days after receipt of the original petition, the last item of timely requested additional material, or the petitioner's written request to finish processing the petition. A petition not granted or denied within 90 days after receipt of a completed petition is deemed approved. A copy of the order granting or denying the petition shall be filed with the committee and shall contain a statement of the relevant facts and reasons supporting the agency's action. The agency shall provide notice of the disposition of the petition to the Department of State, which shall publish the notice in the next available issue of the Florida Administrative Weekly. The notice shall contain the name of the petitioner, the date the petition was filed, the rule number and nature of the rule from which the waiver or variance is sought, a reference to the place and date of publication of the notice of the petition, the date of the order denying or approving the variance or waiver, the general basis for the agency decision, and an explanation of how a copy of the order can be obtained. The agency's decision to grant or deny the petition shall be supported by competent substantial evidence and is subject to ss. 120.569 and 120.57. Any proceeding pursuant to ss. 120.569 and 120.57 in regard to a variance or waiver shall be limited to the agency action on the request for the variance or waiver, except that a proceeding in regard to a variance or waiver may be consolidated with any other proceeding authorized by this chapter.

(9)Each agency shall maintain a record of the type and disposition of each petition, including temporary or emergency variances and waivers, filed pursuant to this section.

History.—s. 12, ch. 96-159; s. 5, ch. 97-176; s. 37, ch. 2010-102.

120.545Committee review of agency rules.—

(1)As a legislative check on legislatively created authority, the committee shall examine each proposed rule, except for those proposed rules exempted by s. 120.81(1)(e) and (2), and its accompanying material, and each emergency rule, and may examine any existing rule, for the purpose of determining whether:

(a)The rule is an invalid exercise of delegated legislative authority.

(b)The statutory authority for the rule has been repealed.

(c)The rule reiterates or paraphrases statutory material.

(d)The rule is in proper form.

(e)The notice given prior to its adoption was sufficient to give adequate notice of the purpose and effect

of the rule.

(f)The rule is consistent with expressed legislative intent pertaining to the specific provisions of law which the rule implements.

(g)The rule is necessary to accomplish the apparent or expressed objectives of the specific provision of law which the rule implements.

(h)The rule is a reasonable implementation of the law as it affects the convenience of the general public or persons particularly affected by the rule.

(i)The rule could be made less complex or more easily comprehensible to the general public.

(j)The rule's statement of estimated regulatory costs complies with the requirements of s. 120.541 and whether the rule does not impose regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.

(k)The rule will require additional appropriations.

(l)If the rule is an emergency rule, there exists an emergency justifying the adoption of such rule, the agency is within its statutory authority, and the rule was adopted in compliance with the requirements and limitations of s. 120.54(4).

(2)The committee may request from an agency such information as is reasonably necessary for examination of a rule as required by subsection (1). The committee shall consult with legislative standing committees having jurisdiction over the subject areas. If the committee objects to a rule, the committee shall, within 5 days after the objection, certify that fact to the agency whose rule has been examined and include with the certification a statement detailing its objections with particularity. The committee shall notify the Speaker of the House of Representatives and the President of the Senate of any objection to an agency rule concurrent with certification of that fact to the agency. Such notice shall include a copy of the rule and the statement detailing the committee's objections to the rule.

(3)Within 30 days after receipt of the objection, if the agency is headed by an individual, or within 45 days after receipt of the objection, if the agency is headed by a collegial body, the agency shall:

(a)If the rule is not yet in effect:

1.File notice pursuant to s. 120.54(3)(d) of only such modifications as are necessary to address the committee's objection;

2.File notice pursuant to s. 120.54(3)(d) of withdrawal of the rule; or

3.Notify the committee in writing that it refuses to modify or withdraw the rule.

(b)If the rule is in effect:

1.File notice pursuant to s. 120.54(3)(a), without prior notice of rule development, to amend the rule to address the committee's objection;

2.File notice pursuant to s. 120.54(3)(a) to repeal the rule; or

3.Notify the committee in writing that the agency refuses to amend or repeal the rule.

(c)If the objection is to the statement of estimated regulatory costs:

1.Prepare a corrected statement of estimated regulatory costs, give notice of the availability of the corrected statement in the first available issue of the Florida Administrative Weekly, and file a copy of the corrected statement with the committee; or

2.Notify the committee that it refuses to prepare a corrected statement of estimated regulatory costs.

(4)Failure of the agency to respond to a committee objection to a rule that is not yet in effect within the time prescribed in subsection (3) constitutes withdrawal of the rule in its entirety. In this event, the committee shall notify the Department of State that the agency, by its failure to respond to a committee objection, has elected to withdraw the rule. Upon receipt of the committee's notice, the Department of State shall publish a notice to that effect in the next available issue of the Florida Administrative Weekly. Upon publication of the notice, the rule shall be stricken from the files of the Department of State and the files of the agency.

(5)Failure of the agency to respond to a committee objection to a rule that is in effect within the time prescribed in subsection (3) constitutes a refusal to amend or repeal the rule.

(6)Failure of the agency to respond to a committee objection to a statement of estimated regulatory costs within the time prescribed in subsection (3) constitutes a refusal to prepare a corrected statement of estimated regulatory costs.

(7)If the committee objects to a rule and the agency refuses to modify, amend, withdraw, or repeal the rule, the committee shall file with the Department of State a notice of the objection, detailing with particularity the committee's objection to the rule. The Department of State shall publish this notice in the Florida Administrative Weekly. If the rule is published in the Florida Administrative Code, a reference to the committee's objection and to the issue of the Florida Administrative Weekly in which the full text thereof appears shall be recorded in a history note.

(8)(a)If the committee objects to a rule, or portion of a rule, and the agency fails to initiate administrative action to modify, amend, withdraw, or repeal the rule consistent with the objection within 60 days after the objection, or thereafter fails to proceed in good faith to complete such action, the committee may submit to the President of the Senate and the Speaker of the House of Representatives a recommendation that legislation be introduced to address the committee's objection.

(b)1.If the committee votes to recommend the introduction of legislation to address the committee's objection, the committee shall, within 5 days after this determination, certify that fact to the agency whose rule or proposed rule has been examined. The committee may request that the agency temporarily suspend the rule or suspend the adoption of the proposed rule, pending consideration of proposed legislation during the next regular session of the Legislature.

2.Within 30 days after receipt of the certification, if the agency is headed by an individual, or within 45 days after receipt of the certification, if the agency is headed by a collegial body, the agency shall:

a.Temporarily suspend the rule or suspend the adoption of the proposed rule; or

b.Notify the committee in writing that the agency refuses to temporarily suspend the rule or suspend the adoption of the proposed rule.

3.If the agency elects to temporarily suspend the rule or suspend the adoption of the proposed rule, the agency shall give notice of the suspension in the Florida Administrative Weekly. The rule or the rule adoption process shall be suspended upon publication of the notice. An agency may not base any agency action on a suspended rule or suspended proposed rule, or portion of such rule, prior to expiration of the suspension. A suspended rule or suspended proposed rule, or portion of such rule, continues to be subject to administrative determination and judicial review as provided by law.

4.Failure of an agency to respond to committee certification within the time prescribed by subparagraph 2. constitutes a refusal to suspend the rule or to suspend the adoption of the proposed rule.

(c)The committee shall prepare proposed legislation to address the committee's objection in accordance with the rules of the Senate and the House of Representatives for prefiling and introduction in the next regular session of the Legislature. The proposed legislation shall be presented to the President of the Senate and the Speaker of the House of Representatives with the committee recommendation.

(d)If proposed legislation addressing the committee's objection fails to become law, any temporary agency suspension shall expire.

History.—s. 4, ch. 76-131; s. 1, ch. 77-174; s. 6, ch. 80-391; s. 3, ch. 81-309; s. 4, ch. 87-385; s. 8, ch. 92-166; s. 20, ch. 95-280; s. 14, ch. 96-159; s. 16, ch. 2000-151; s. 18, ch. 2008-4; s. 7, ch. 2008-104.

120.55Publication.—

(1)The Department of State shall:

(a)1.Through a continuous revision and publication system, compile and publish electronically, on an Internet website managed by the department, the "Florida Administrative Code." The Florida Administrative Code shall contain all rules adopted by each agency, citing the grant of rulemaking authority and the specific law implemented pursuant to which each rule was adopted, all history notes as authorized in s. 120.545(7), complete indexes to all rules contained in the code, and any other material required or authorized by law or deemed useful by the department. The electronic code shall display each rule chapter currently in effect in browse mode and allow full text search of the code and each rule chapter. The department may contract with a publishing firm for a printed publication; however, the department shall retain responsibility for the code as provided in this section. The electronic publication shall be the official compilation of the administrative rules of this state. The Department of State shall retain the copyright over the Florida Administrative Code.

2.Rules general in form but applicable to only one school district, community college district, or county,

or a part thereof, or state university rules relating to internal personnel or business and finance shall not be published in the Florida Administrative Code. Exclusion from publication in the Florida Administrative Code shall not affect the validity or effectiveness of such rules.

3.At the beginning of the section of the code dealing with an agency that files copies of its rules with the department, the department shall publish the address and telephone number of the executive offices of each agency, the manner by which the agency indexes its rules, a listing of all rules of that agency excluded from publication in the code, and a statement as to where those rules may be inspected.

4.Forms shall not be published in the Florida Administrative Code; but any form which an agency uses in its dealings with the public, along with any accompanying instructions, shall be filed with the committee before it is used. Any form or instruction which meets the definition of "rule" provided in s. 120.52 shall be incorporated by reference into the appropriate rule. The reference shall specifically state that the form is being incorporated by reference and shall include the number, title, and effective date of the form and an explanation of how the form may be obtained. Each form created by an agency which is incorporated by reference in a rule notice of which is given under s. 120.54(3)(a) after December 31, 2007, must clearly display the number, title, and effective date of the form and the number of the rule in which the form is incorporated.

5.The department shall allow adopted rules and material incorporated by reference to be filed in electronic form as prescribed by department rule. When a rule is filed for adoption with incorporated material in electronic form, the department's publication of the Florida Administrative Code on its Internet website must contain a hyperlink from the incorporating reference in the rule directly to that material. The department may not allow hyperlinks from rules in the Florida Administrative Code to any material other than that filed with and maintained by the department, but may allow hyperlinks to incorporated material maintained by the department from the adopting agency's website or other sites.

(b)Electronically publish on an Internet website managed by the department a continuous revision and publication entitled the "Florida Administrative Register," which shall serve as the official publication and must contain:

1.All notices required by s. 120.54(3)(a), showing the text of all rules proposed for consideration.

2.All notices of public meetings, hearings, and workshops conducted in accordance with s. 120.525, including a statement of the manner in which a copy of the agenda may be obtained.

3.A notice of each request for authorization to amend or repeal an existing uniform rule or for the adoption of new uniform rules.

4.Notice of petitions for declaratory statements or administrative determinations.

5.A summary of each objection to any rule filed by the Administrative Procedures Committee.

6.Any other material required or authorized by law or deemed useful by the department.

The department may contract with a publishing firm for a printed publication of the Florida Administrative Register and make copies available on an annual subscription basis.

(c)Prescribe by rule the style and form required for rules, notices, and other materials submitted for filing.

(d)Charge each agency using the Florida Administrative Register a space rate to cover the costs related to the Florida Administrative Register and the Florida Administrative Code.

(e)Maintain a permanent record of all notices published in the Florida Administrative Register.

(2)The Florida Administrative Register Internet website must allow users to:

(a)Search for notices by type, publication date, rule number, word, subject, and agency.

(b)Search a database that makes available all notices published on the website for a period of at least 5 years.

(c)Subscribe to an automated e-mail notification of selected notices to be sent out before or concurrently with publication of the electronic Florida Administrative Register. Such notification must include in the text of the e-mail a summary of the content of each notice.

(d)View agency forms and other materials submitted to the department in electronic form and incorporated by reference in proposed rules.

(e)Comment on proposed rules.

(3)Publication of material required by paragraph (1)(b) on the Florida Administrative Register Internet website does not preclude publication of such material on an agency's website or by other means.

(4)Each agency shall provide copies of its rules upon request, with citations to the grant of rulemaking authority and the specific law implemented for each rule.

(5)Any publication of a proposed rule promulgated by an agency, whether published in the Florida Administrative Register or elsewhere, shall include, along with the rule, the name of the person or persons originating such rule, the name of the agency head who approved the rule, and the date upon which the rule was approved.

(6)Access to the Florida Administrative Register Internet website and its contents, including the e-mail notification service, shall be free for the public.

(7)(a)All fees and moneys collected by the Department of State under this chapter shall be deposited in the Records Management Trust Fund for the purpose of paying for costs incurred by the department in carrying out this chapter.

(b)The unencumbered balance in the Records Management Trust Fund for fees collected pursuant to this chapter may not exceed $300,000 at the beginning of each fiscal year, and any excess shall be transferred to the General Revenue Fund.

History.—s. 1, ch. 74-310; s. 1, ch. 75-107; s. 4, ch. 75-191; s. 5, ch. 76-131; s. 1, ch. 77-174; s. 4, ch. 77-453; s. 3, ch. 78-

425; s. 4, ch. 79-299; s. 7, ch. 80-391; s. 4, ch. 81-309; s. 1, ch. 82-19; s. 1, ch. 82-47; s. 3, ch. 83-351; s. 3, ch. 84-203; s. 17, ch. 87-224; s. 1, ch. 87-322; s. 20, ch. 91-45; s. 15, ch. 96-159; s. 896, ch. 2002-387; s. 5, ch. 2004-235; s. 14, ch. 2004-335; s. 4, ch. 2006-82; ss. 8, 9, ch. 2008-104; ss. 11, 12, ch. 2010-5; s. 2, ch. 2012-63.

120.555Summary removal of published rules no longer in force and effect.—When, as part of the continuous revision system authorized in s. 120.55(1)(a)1. or as otherwise provided by law, the Department of State is in doubt whether a rule published in the official version of the Florida Administrative Code is still in full force and effect, the procedure in this section shall be employed.

(1)The Department of State shall submit to the head of the agency with authority to repeal or amend the rule, if any, or if no such agency can be identified, to the Governor, a written request for a statement as to whether the rule is still in full force and effect. A copy of the request shall be promptly delivered to the committee and to the Attorney General. The Department of State shall publish a notice of the request together with a copy of the request in the Florida Administrative Weekly next available after delivery of the request to the head of the agency or the Governor.

(2)No later than 90 days after the date the notice required in subsection (1) is published, the agency or the Governor, notified pursuant to subsection (1), shall file a written response with the Department of State stating whether the rule is in full force and effect and under the jurisdiction of an agency with full authority to amend or repeal the rule. Failure to respond timely under this subsection constitutes an acknowledgment by the agency or the Governor that the rule is no longer in effect and is subject to summary repeal under this section.

(3)The Department of State shall publish a notice of the agency's or Governor's timely response or the acknowledgment determined under subsection (2) in the Florida Administrative Weekly next available after receipt of the response or the expiration of the response period, whichever occurs first.

(4)If the response states that the rule is no longer in effect, or if no response is filed timely with the Department of State, the notice required in subsection (3) shall also give notice of the following:

(a)Based on the agency's or Governor's written response or the acknowledgment determined under subsection (2), the rule will be repealed summarily pursuant to this section and removed from the Florida Administrative Code.

(b)Any objection to the summary repeal under this section must be filed as a petition challenging a proposed rule under s. 120.56 and must be filed no later than 21 days after the date the notice is published in the Florida Administrative Weekly.

(c)For purposes only of challenging a summary repeal under this section, the agency with current authority to repeal the rule under s. 120.54 shall be named as the respondent in the petition and shall be the proper party in interest. In such circumstances, the Department of State shall not be named as a party in a petition filed under paragraph (b) and this paragraph.

(d)If no agency currently has authority to repeal the rule under s. 120.54, the Department of State shall be named as the respondent in a petition filed under paragraph (b) and this paragraph. The Attorney General shall represent the Department of State in all proceedings under this paragraph.

(5)Upon the expiration of the 21-day period to file an objection to a notice of summary repeal published pursuant to subsection (4), if no timely objection is filed, or, if a timely objection is filed, on the date a decision finding the rule is no longer in effect becomes final, the Department of State shall update the Florida Administrative Code to remove the rule and shall provide historical notes identifying the manner in which the rule ceased to have effect, including the summary repeal pursuant to this section.

History.—s. 2, ch. 2012-31.

120.56Challenges to rules.—

(1)GENERAL PROCEDURES FOR CHALLENGING THE VALIDITY OF A RULE OR A PROPOSED RULE.—

(a)Any person substantially affected by a rule or a proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority.

(b)The petition seeking an administrative determination must state with particularity the provisions alleged to be invalid with sufficient explanation of the facts or grounds for the alleged invalidity and facts sufficient to show that the person challenging a rule is substantially affected by it, or that the person challenging a proposed rule would be substantially affected by it.

(c)The petition shall be filed by electronic means with the division which shall, immediately upon filing, forward by electronic means copies to the agency whose rule is challenged, the Department of State, and the committee. Within 10 days after receiving the petition, the division director shall, if the petition complies with the requirements of paragraph (b), assign an administrative law judge who shall conduct a hearing within 30 days thereafter, unless the petition is withdrawn or a continuance is granted by agreement of the parties or for good cause shown. Evidence of good cause includes, but is not limited to, written notice of an agency's decision to modify or withdraw the proposed rule or a written notice from the chair of the committee stating that the committee will consider an objection to the rule at its next scheduled meeting. The failure of an agency to follow the applicable rulemaking procedures or requirements set forth in this chapter shall be presumed to be material; however, the agency may rebut this presumption by showing that the substantial interests of the petitioner and the fairness of the proceedings have not been impaired.

(d)Within 30 days after the hearing, the administrative law judge shall render a decision and state the reasons therefor in writing. The division shall forthwith transmit by electronic means copies of the administrative law judge's decision to the agency, the Department of State, and the committee.

(e)Hearings held under this section shall be de novo in nature. The standard of proof shall be the preponderance of the evidence. Hearings shall be conducted in the same manner as provided by ss. 120.569

and 120.57, except that the administrative law judge's order shall be final agency action. The petitioner and the agency whose rule is challenged shall be adverse parties. Other substantially affected persons may join the proceedings as intervenors on appropriate terms which shall not unduly delay the proceedings. Failure to proceed under this section shall not constitute failure to exhaust administrative remedies.

(2)CHALLENGING PROPOSED RULES; SPECIAL PROVISIONS.—

(a)A substantially affected person may seek an administrative determination of the invalidity of a proposed rule by filing a petition seeking such a determination with the division within 21 days after the date of publication of the notice required by s. 120.54(3)(a); within 10 days after the final public hearing is held on the proposed rule as provided by s. 120.54(3)(e)2.; within 20 days after the statement of estimated regulatory costs or revised statement of estimated regulatory costs, if applicable, has been prepared and made available as provided in s. 120.541(1)(d); or within 20 days after the date of publication of the notice required by s. 120.54(3)(d). The petition must state with particularity the objections to the proposed rule and the reasons that the proposed rule is an invalid exercise of delegated legislative authority. The petitioner has the burden of going forward. The agency then has the burden to prove by a preponderance of the evidence that the proposed rule is not an invalid exercise of delegated legislative authority as to the objections raised. A person who is substantially affected by a change in the proposed rule may seek a determination of the validity of such change. A person who is not substantially affected by the proposed rule as initially noticed, but who is substantially affected by the rule as a result of a change, may challenge any provision of the rule and is not limited to challenging the change to the proposed rule.

(b)The administrative law judge may declare the proposed rule wholly or partly invalid. Unless the decision of the administrative law judge is reversed on appeal, the proposed rule or provision of a proposed rule declared invalid shall not be adopted. After a petition for administrative determination has been filed, the agency may proceed with all other steps in the rulemaking process, including the holding of a factfinding hearing. In the event part of a proposed rule is declared invalid, the adopting agency may, in its sole discretion, withdraw the proposed rule in its entirety. The agency whose proposed rule has been declared invalid in whole or part shall give notice of the decision in the first available issue of the Florida Administrative Weekly.

(c)When any substantially affected person seeks determination of the invalidity of a proposed rule pursuant to this section, the proposed rule is not presumed to be valid or invalid.

(3)CHALLENGING EXISTING RULES; SPECIAL PROVISIONS.—

(a)A substantially affected person may seek an administrative determination of the invalidity of an existing rule at any time during the existence of the rule. The petitioner has a burden of proving by a preponderance of the evidence that the existing rule is an invalid exercise of delegated legislative authority as to the objections raised.

(b)The administrative law judge may declare all or part of a rule invalid. The rule or part thereof declared invalid shall become void when the time for filing an appeal expires. The agency whose rule has been declared invalid in whole or part shall give notice of the decision in the Florida Administrative Weekly in the first available issue after the rule has become void.

(4)CHALLENGING AGENCY STATEMENTS DEFINED AS RULES; SPECIAL PROVISIONS.—

(a)Any person substantially affected by an agency statement may seek an administrative determination that the statement violates s. 120.54(1)(a). The petition shall include the text of the statement or a description of the statement and shall state with particularity facts sufficient to show that the statement constitutes a rule under s. 120.52 and that the agency has not adopted the statement by the rulemaking procedure provided by s. 120.54.

(b)The administrative law judge may extend the hearing date beyond 30 days after assignment of the case for good cause. Upon notification to the administrative law judge provided before the final hearing that the agency has published a notice of rulemaking under s. 120.54(3), such notice shall automatically operate as a stay of proceedings pending adoption of the statement as a rule. The administrative law judge may vacate the stay for good cause shown. A stay of proceedings pending rulemaking shall remain in effect so long as the agency is proceeding expeditiously and in good faith to adopt the statement as a rule. If a hearing is held and the petitioner proves the allegations of the petition, the agency shall have the burden of proving that rulemaking is not feasible or not practicable under s. 120.54(1)(a).

(c)The administrative law judge may determine whether all or part of a statement violates s. 120.54(1)(a). The decision of the administrative law judge shall constitute a final order. The division shall transmit a copy of the final order to the Department of State and the committee. The Department of State shall publish notice of the final order in the first available issue of the Florida Administrative Weekly.

(d)If an administrative law judge enters a final order that all or part of an agency statement violates s. 120.54(1)(a), the agency must immediately discontinue all reliance upon the statement or any substantially similar statement as a basis for agency action.

(e)If proposed rules addressing the challenged statement are determined to be an invalid exercise of delegated legislative authority as defined in s. 120.52(8)(b)-(f), the agency must immediately discontinue reliance on the statement and any substantially similar statement until rules addressing the subject are properly adopted, and the administrative law judge shall enter a final order to that effect.

(f)All proceedings to determine a violation of s. 120.54(1)(a) shall be brought pursuant to this subsection. A proceeding pursuant to this subsection may be consolidated with a proceeding under subsection (3) or under any other section of this chapter. This paragraph does not prevent a party whose substantial interests have been determined by an agency action from bringing a proceeding pursuant to s. 120.57(1)(e).

(5)CHALLENGING EMERGENCY RULES; SPECIAL PROVISIONS.—Challenges to the validity of an emergency

rule shall be subject to the following time schedules in lieu of those established by paragraphs (1)(c) and (d). Within 7 days after receiving the petition, the division director shall, if the petition complies with paragraph (1)(b), assign an administrative law judge, who shall conduct a hearing within 14 days, unless the petition is withdrawn. The administrative law judge shall render a decision within 14 days after the hearing.

History.—s. 1, ch. 74-310; s. 5, ch. 75-191; s. 6, ch. 76-131; s. 1, ch. 77-174; s. 4, ch. 78-425; s. 759, ch. 95-147; s. 16, ch. 96-159; s. 6, ch. 97-176; s. 5, ch. 99-379; s. 3, ch. 2003-94; s. 5, ch. 2006-82; ss. 10, 11, ch. 2008-104; ss. 3, 5, ch. 2010-279; HJR 9-A, 2010 Special Session A; s. 10, ch. 2011-208; s. 3, ch. 2011-225.

120.565Declaratory statement by agencies.—

(1)Any substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a statutory provision, or of any rule or order of the agency, as it applies to the petitioner's particular set of circumstances.

(2)The petition seeking a declaratory statement shall state with particularity the petitioner's set of circumstances and shall specify the statutory provision, rule, or order that the petitioner believes may apply to the set of circumstances.

(3)The agency shall give notice of the filing of each petition in the next available issue of the Florida Administrative Weekly and transmit copies of each petition to the committee. The agency shall issue a declaratory statement or deny the petition within 90 days after the filing of the petition. The declaratory statement or denial of the petition shall be noticed in the next available issue of the Florida Administrative Weekly. Agency disposition of petitions shall be final agency action.

History.—s. 6, ch. 75-191; s. 7, ch. 76-131; s. 5, ch. 78-425; s. 5, ch. 79-299; s. 760, ch. 95-147; s. 17, ch. 96-159.

120.569Decisions which affect substantial interests.—

(1)The provisions of this section apply in all proceedings in which the substantial interests of a party are determined by an agency, unless the parties are proceeding under s. 120.573 or s. 120.574. Unless waived by all parties, s. 120.57(1) applies whenever the proceeding involves a disputed issue of material fact. Unless otherwise agreed, s. 120.57(2) applies in all other cases. If a disputed issue of material fact arises during a proceeding under s. 120.57(2), then, unless waived by all parties, the proceeding under s. 120.57(2) shall be terminated and a proceeding under s. 120.57(1) shall be conducted. Parties shall be notified of any order, including a final order. Unless waived, a copy of the order shall be delivered or mailed to each party or the party's attorney of record at the address of record. Each notice shall inform the recipient of any administrative hearing or judicial review that is available under this section, s. 120.57, or s. 120.68; shall indicate the procedure which must be followed to obtain the hearing or judicial review; and shall state the time limits which apply.

(2)(a)Except for any proceeding conducted as prescribed in s. 120.56, a petition or request for a hearing

under this section shall be filed with the agency. If the agency requests an administrative law judge from the division, it shall so notify the division by electronic means through the division's website within 15 days after receipt of the petition or request. A request for a hearing shall be granted or denied within 15 days after receipt. On the request of any agency, the division shall assign an administrative law judge with due regard to the expertise required for the particular matter. The referring agency shall take no further action with respect to a proceeding under s. 120.57(1), except as a party litigant, as long as the division has jurisdiction over the proceeding under s. 120.57(1). Any party may request the disqualification of the administrative law judge by filing an affidavit with the division prior to the taking of evidence at a hearing, stating the grounds with particularity.

(b)All parties shall be afforded an opportunity for a hearing after reasonable notice of not less than 14 days; however, the 14-day notice requirement may be waived with the consent of all parties. The notice shall include:

1.A statement of the time, place, and nature of the hearing.

2.A statement of the legal authority and jurisdiction under which the hearing is to be held.

(c)Unless otherwise provided by law, a petition or request for hearing shall include those items required by the uniform rules adopted pursuant to s. 120.54(5)(b). Upon the receipt of a petition or request for hearing, the agency shall carefully review the petition to determine if it contains all of the required information. A petition shall be dismissed if it is not in substantial compliance with these requirements or it has been untimely filed. Dismissal of a petition shall, at least once, be without prejudice to petitioner's filing a timely amended petition curing the defect, unless it conclusively appears from the face of the petition that the defect cannot be cured. The agency shall promptly give written notice to all parties of the action taken on the petition, shall state with particularity its reasons if the petition is not granted, and shall state the deadline for filing an amended petition if applicable. This paragraph does not eliminate the availability of equitable tolling as a defense to the untimely filing of a petition.

(d)The agency may refer a petition to the division for the assignment of an administrative law judge only if the petition is in substantial compliance with the requirements of paragraph (c).

(e)All pleadings, motions, or other papers filed in the proceeding must be signed by the party, the party's attorney, or the party's qualified representative. The signature constitutes a certificate that the person has read the pleading, motion, or other paper and that, based upon reasonable inquiry, it is not interposed for any improper purposes, such as to harass or to cause unnecessary delay, or for frivolous purpose or needless increase in the cost of litigation. If a pleading, motion, or other paper is signed in violation of these requirements, the presiding officer shall impose upon the person who signed it, the represented party, or both, an appropriate sanction, which may include an order to pay the other party or parties the amount of reasonable expenses incurred because of the filing of the pleading, motion, or other paper, including a

reasonable attorney's fee.

(f)The presiding officer has the power to swear witnesses and take their testimony under oath, to issue subpoenas, and to effect discovery on the written request of any party by any means available to the courts and in the manner provided in the Florida Rules of Civil Procedure, including the imposition of sanctions, except contempt. However, no presiding officer has the authority to issue any subpoena or order directing discovery to any member or employee of the Legislature when the subpoena or order commands the production of documents or materials or compels testimony relating to the legislative duties of the member or employee. Any subpoena or order directing discovery directed to a member or an employee of the Legislature shall show on its face that the testimony sought does not relate to legislative duties.

(g)Irrelevant, immaterial, or unduly repetitious evidence shall be excluded, but all other evidence of a type commonly relied upon by reasonably prudent persons in the conduct of their affairs shall be admissible, whether or not such evidence would be admissible in a trial in the courts of Florida. Any part of the evidence may be received in written form, and all testimony of parties and witnesses shall be made under oath.

(h)Documentary evidence may be received in the form of a copy or excerpt. Upon request, parties shall be given an opportunity to compare the copy with the original, if available.

(i)When official recognition is requested, the parties shall be notified and given an opportunity to examine and contest the material.

(j)A party shall be permitted to conduct cross-examination when testimony is taken or documents are made a part of the record.

(k)1.Any person subject to a subpoena may, before compliance and on timely petition, request the presiding officer having jurisdiction of the dispute to invalidate the subpoena on the ground that it was not lawfully issued, is unreasonably broad in scope, or requires the production of irrelevant material.

2.A party may seek enforcement of a subpoena, order directing discovery, or order imposing sanctions issued under the authority of this chapter by filing a petition for enforcement in the circuit court of the judicial circuit in which the person failing to comply with the subpoena or order resides. A failure to comply with an order of the court shall result in a finding of contempt of court. However, no person shall be in contempt while a subpoena is being challenged under subparagraph 1. The court may award to the prevailing party all or part of the costs and attorney's fees incurred in obtaining the court order whenever the court determines that such an award should be granted under the Florida Rules of Civil Procedure.

3.Any public employee subpoenaed to appear at an agency proceeding shall be entitled to per diem and travel expenses at the same rate as that provided for state employees under s. 112.061 if travel away from such public employee's headquarters is required. All other witnesses appearing pursuant to a subpoena shall be paid such fees and mileage for their attendance as is provided in civil actions in circuit courts of this state. In the case of a public employee, such expenses shall be processed and paid in the manner provided for

agency employee travel expense reimbursement, and in the case of a witness who is not a public employee, payment of such fees and expenses shall accompany the subpoena.

(l)Unless the time period is waived or extended with the consent of all parties, the final order in a proceeding which affects substantial interests must be in writing and include findings of fact, if any, and conclusions of law separately stated, and it must be rendered within 90 days:

1.After the hearing is concluded, if conducted by the agency;

2.After a recommended order is submitted to the agency and mailed to all parties, if the hearing is conducted by an administrative law judge; or

3.After the agency has received the written and oral material it has authorized to be submitted, if there has been no hearing.

(m)Findings of fact, if set forth in a manner which is no more than mere tracking of the statutory language, must be accompanied by a concise and explicit statement of the underlying facts of record which support the findings.

(n)If an agency head finds that an immediate danger to the public health, safety, or welfare requires an immediate final order, it shall recite with particularity the facts underlying such finding in the final order, which shall be appealable or enjoinable from the date rendered.

(o)On the request of any party, the administrative law judge shall enter an initial scheduling order to facilitate the just, speedy, and inexpensive determination of the proceeding. The initial scheduling order shall establish a discovery period, including a deadline by which all discovery shall be completed, and the date by which the parties shall identify expert witnesses and their opinions. The initial scheduling order also may require the parties to meet and file a joint report by a date certain.

(p)For any proceeding arising under chapter 373, chapter 378, or chapter 403, if a nonapplicant petitions as a third party to challenge an agency's issuance of a license, permit, or conceptual approval, the order of presentation in the proceeding is for the permit applicant to present a prima facie case demonstrating entitlement to the license, permit, or conceptual approval, followed by the agency. This demonstration may be made by entering into evidence the application and relevant material submitted to the agency in support of the application, and the agency's staff report or notice of intent to approve the permit, license, or conceptual approval. Subsequent to the presentation of the applicant's prima facie case and any direct evidence submitted by the agency, the petitioner initiating the action challenging the issuance of the license, permit, or conceptual approval has the burden of ultimate persuasion and has the burden of going forward to prove the case in opposition to the license, permit, or conceptual approval through the presentation of competent and substantial evidence. The permit applicant and agency may on rebuttal present any evidence relevant to demonstrating that the application meets the conditions for issuance. Notwithstanding subsection (1), this paragraph applies to proceedings under s. 120.574.

History.—s. 18, ch. 96-159; s. 7, ch. 97-176; s. 4, ch. 98-200; s. 4, ch. 2003-94; s. 6, ch. 2006-82; s. 14, ch. 2008-104; s. 11, ch. 2011-208; s. 10, ch. 2011-225.

120.57Additional procedures for particular cases.—

(1)ADDITIONAL PROCEDURES APPLICABLE TO HEARINGS INVOLVING DISPUTED ISSUES OF MATERIAL FACT.—

(a)Except as provided in ss. 120.80 and 120.81, an administrative law judge assigned by the division shall conduct all hearings under this subsection, except for hearings before agency heads or a member thereof. If the administrative law judge assigned to a hearing becomes unavailable, the division shall assign another administrative law judge who shall use any existing record and receive any additional evidence or argument, if any, which the new administrative law judge finds necessary.

(b)All parties shall have an opportunity to respond, to present evidence and argument on all issues involved, to conduct cross-examination and submit rebuttal evidence, to submit proposed findings of facts and orders, to file exceptions to the presiding officer's recommended order, and to be represented by counsel or other qualified representative. When appropriate, the general public may be given an opportunity to present oral or written communications. If the agency proposes to consider such material, then all parties shall be given an opportunity to cross-examine or challenge or rebut the material.

(c)Hearsay evidence may be used for the purpose of supplementing or explaining other evidence, but it shall not be sufficient in itself to support a finding unless it would be admissible over objection in civil actions.

(d)Notwithstanding s. 120.569(2)(g), similar fact evidence of other violations, wrongs, or acts is admissible when relevant to prove a material fact in issue, such as proof of motive, opportunity, intent, preparation, plan, knowledge, identity, or absence of mistake or accident, but it is inadmissible when the evidence is relevant solely to prove bad character or propensity. When the state in an administrative proceeding intends to offer evidence of other acts or offenses under this paragraph, the state shall furnish to the party whose substantial interests are being determined and whose other acts or offenses will be the subject of such evidence, no fewer than 10 days before commencement of the proceeding, a written statement of the acts or offenses it intends to offer, describing them and the evidence the state intends to offer with particularity. Notice is not required for evidence of acts or offenses which is used for impeachment or on rebuttal.

(e)1.An agency or an administrative law judge may not base agency action that determines the substantial interests of a party on an unadopted rule. The administrative law judge shall determine whether an agency statement constitutes an unadopted rule. This subparagraph does not preclude application of adopted rules and applicable provisions of law to the facts.

2.Notwithstanding subparagraph 1., if an agency demonstrates that the statute being implemented directs it to adopt rules, that the agency has not had time to adopt those rules because the requirement was

so recently enacted, and that the agency has initiated rulemaking and is proceeding expeditiously and in good faith to adopt the required rules, then the agency's action may be based upon those unadopted rules, subject to de novo review by the administrative law judge. The agency action shall not be presumed valid or invalid. The agency must demonstrate that the unadopted rule:

a.Is within the powers, functions, and duties delegated by the Legislature or, if the agency is operating pursuant to authority derived from the State Constitution, is within that authority;

b.Does not enlarge, modify, or contravene the specific provisions of law implemented;

c.Is not vague, establishes adequate standards for agency decisions, or does not vest unbridled discretion in the agency;

d.Is not arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational;

e.Is not being applied to the substantially affected party without due notice; and

f.Does not impose excessive regulatory costs on the regulated person, county, or city.

3.The recommended and final orders in any proceeding shall be governed by the provisions of paragraphs (k) and (l), except that the administrative law judge's determination regarding an unadopted rule under subparagraph 1. or subparagraph 2. shall not be rejected by the agency unless the agency first determines from a review of the complete record, and states with particularity in the order, that such determination is clearly erroneous or does not comply with essential requirements of law. In any proceeding for review under s. 120.68, if the court finds that the agency's rejection of the determination regarding the unadopted rule does not comport with the provisions of this subparagraph, the agency action shall be set aside and the court shall award to the prevailing party the reasonable costs and a reasonable attorney's fee for the initial proceeding and the proceeding for review.

(f)The record in a case governed by this subsection shall consist only of:

1.All notices, pleadings, motions, and intermediate rulings.

2.Evidence admitted.

3.Those matters officially recognized.

4.Proffers of proof and objections and rulings thereon.

5.Proposed findings and exceptions.

6.Any decision, opinion, order, or report by the presiding officer.

7.All staff memoranda or data submitted to the presiding officer during the hearing or prior to its disposition, after notice of the submission to all parties, except communications by advisory staff as permitted under s. 120.66(1), if such communications are public records.

8.All matters placed on the record after an ex parte communication.

9.The official transcript.

(g)The agency shall accurately and completely preserve all testimony in the proceeding, and, on the request of any party, it shall make a full or partial transcript available at no more than actual cost.

(h)Any party to a proceeding in which an administrative law judge of the Division of Administrative Hearings has final order authority may move for a summary final order when there is no genuine issue as to any material fact. A summary final order shall be rendered if the administrative law judge determines from the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, that no genuine issue as to any material fact exists and that the moving party is entitled as a matter of law to the entry of a final order. A summary final order shall consist of findings of fact, if any, conclusions of law, a disposition or penalty, if applicable, and any other information required by law to be contained in the final order.

(i)When, in any proceeding conducted pursuant to this subsection, a dispute of material fact no longer exists, any party may move the administrative law judge to relinquish jurisdiction to the agency. An order relinquishing jurisdiction shall be rendered if the administrative law judge determines from the pleadings, depositions, answers to interrogatories, and admissions on file, together with supporting and opposing affidavits, if any, that no genuine issue as to any material fact exists. If the administrative law judge enters an order relinquishing jurisdiction, the agency may promptly conduct a proceeding pursuant to subsection (2), if appropriate, but the parties may not raise any issues of disputed fact that could have been raised before the administrative law judge. An order entered by an administrative law judge relinquishing jurisdiction to the agency based upon a determination that no genuine dispute of material fact exists, need not contain findings of fact, conclusions of law, or a recommended disposition or penalty.

(j)Findings of fact shall be based upon a preponderance of the evidence, except in penal or licensure disciplinary proceedings or except as otherwise provided by statute, and shall be based exclusively on the evidence of record and on matters officially recognized.

(k)The presiding officer shall complete and submit to the agency and all parties a recommended order consisting of findings of fact, conclusions of law, and recommended disposition or penalty, if applicable, and any other information required by law to be contained in the final order. All proceedings conducted under this subsection shall be de novo. The agency shall allow each party 15 days in which to submit written exceptions to the recommended order. The final order shall include an explicit ruling on each exception, but an agency need not rule on an exception that does not clearly identify the disputed portion of the recommended order by page number or paragraph, that does not identify the legal basis for the exception, or that does not include appropriate and specific citations to the record.

(l)The agency may adopt the recommended order as the final order of the agency. The agency in its final order may reject or modify the conclusions of law over which it has substantive jurisdiction and interpretation of administrative rules over which it has substantive jurisdiction. When rejecting or modifying such conclusion

of law or interpretation of administrative rule, the agency must state with particularity its reasons for rejecting or modifying such conclusion of law or interpretation of administrative rule and must make a finding that its substituted conclusion of law or interpretation of administrative rule is as or more reasonable than that which was rejected or modified. Rejection or modification of conclusions of law may not form the basis for rejection or modification of findings of fact. The agency may not reject or modify the findings of fact unless the agency first determines from a review of the entire record, and states with particularity in the order, that the findings of fact were not based upon competent substantial evidence or that the proceedings on which the findings were based did not comply with essential requirements of law. The agency may accept the recommended penalty in a recommended order, but may not reduce or increase it without a review of the complete record and without stating with particularity its reasons therefor in the order, by citing to the record in justifying the action.

(m)If a recommended order is submitted to an agency, the agency shall provide a copy of its final order and any exceptions to the division within 15 days after the order is filed with the agency clerk.

(n)Notwithstanding any law to the contrary, when statutes or rules impose conflicting time requirements for the scheduling of expedited hearings or issuance of recommended or final orders, the director of the division shall have the authority to set the proceedings for the orderly operation of this chapter.

(2)ADDITIONAL PROCEDURES APPLICABLE TO HEARINGS NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT.—In any case to which subsection (1) does not apply:

(a)The agency shall:

1.Give reasonable notice to affected persons of the action of the agency, whether proposed or already taken, or of its decision to refuse action, together with a summary of the factual, legal, and policy grounds therefor.

2.Give parties or their counsel the option, at a convenient time and place, to present to the agency or hearing officer written or oral evidence in opposition to the action of the agency or to its refusal to act, or a written statement challenging the grounds upon which the agency has chosen to justify its action or inaction.

3.If the objections of the parties are overruled, provide a written explanation within 7 days.

(b)The record shall only consist of:

1.The notice and summary of grounds.

2.Evidence received.

3.All written statements submitted.

4.Any decision overruling objections.

5.All matters placed on the record after an ex parte communication.

6.The official transcript.

7.Any decision, opinion, order, or report by the presiding officer.

(3)ADDITIONAL PROCEDURES APPLICABLE TO PROTESTS TO CONTRACT SOLICITATION OR AWARD.—Agencies subject to this chapter shall use the uniform rules of procedure, which provide procedures for the resolution of protests arising from the contract solicitation or award process. Such rules shall at least provide that:

(a)The agency shall provide notice of a decision or intended decision concerning a solicitation, contract award, or exceptional purchase by electronic posting. This notice shall contain the following statement: "Failure to file a protest within the time prescribed in section 120.57(3), Florida Statutes, or failure to post the bond or other security required by law within the time allowed for filing a bond shall constitute a waiver of proceedings under chapter 120, Florida Statutes."

(b)Any person who is adversely affected by the agency decision or intended decision shall file with the agency a notice of protest in writing within 72 hours after the posting of the notice of decision or intended decision. With respect to a protest of the terms, conditions, and specifications contained in a solicitation, including any provisions governing the methods for ranking bids, proposals, or replies, awarding contracts, reserving rights of further negotiation, or modifying or amending any contract, the notice of protest shall be filed in writing within 72 hours after the posting of the solicitation. The formal written protest shall be filed within 10 days after the date the notice of protest is filed. Failure to file a notice of protest or failure to file a formal written protest shall constitute a waiver of proceedings under this chapter. The formal written protest shall state with particularity the facts and law upon which the protest is based. Saturdays, Sundays, and state holidays shall be excluded in the computation of the 72-hour time periods provided by this paragraph.

(c)Upon receipt of the formal written protest that has been timely filed, the agency shall stop the solicitation or contract award process until the subject of the protest is resolved by final agency action, unless the agency head sets forth in writing particular facts and circumstances which require the continuance of the solicitation or contract award process without delay in order to avoid an immediate and serious danger to the public health, safety, or welfare.

(d)1.The agency shall provide an opportunity to resolve the protest by mutual agreement between the parties within 7 days, excluding Saturdays, Sundays, and state holidays, after receipt of a formal written protest.

2.If the subject of a protest is not resolved by mutual agreement within 7 days, excluding Saturdays, Sundays, and state holidays, after receipt of the formal written protest, and if there is no disputed issue of material fact, an informal proceeding shall be conducted pursuant to subsection (2) and applicable agency rules before a person whose qualifications have been prescribed by rules of the agency.

3.If the subject of a protest is not resolved by mutual agreement within 7 days, excluding Saturdays, Sundays, and state holidays, after receipt of the formal written protest, and if there is a disputed issue of material fact, the agency shall refer the protest to the division by electronic means through the division's

website for proceedings under subsection (1).

(e)Upon receipt of a formal written protest referred pursuant to this subsection, the director of the division shall expedite the hearing and assign an administrative law judge who shall commence a hearing within 30 days after the receipt of the formal written protest by the division and enter a recommended order within 30 days after the hearing or within 30 days after receipt of the hearing transcript by the administrative law judge, whichever is later. Each party shall be allowed 10 days in which to submit written exceptions to the recommended order. A final order shall be entered by the agency within 30 days of the entry of a recommended order. The provisions of this paragraph may be waived upon stipulation by all parties.

(f)In a protest to an invitation to bid or request for proposals procurement, no submissions made after the bid or proposal opening which amend or supplement the bid or proposal shall be considered. In a protest to an invitation to negotiate procurement, no submissions made after the agency announces its intent to award a contract, reject all replies, or withdraw the solicitation which amend or supplement the reply shall be considered. Unless otherwise provided by statute, the burden of proof shall rest with the party protesting the proposed agency action. In a competitive-procurement protest, other than a rejection of all bids, proposals, or replies, the administrative law judge shall conduct a de novo proceeding to determine whether the agency's proposed action is contrary to the agency's governing statutes, the agency's rules or policies, or the solicitation specifications. The standard of proof for such proceedings shall be whether the proposed agency action was clearly erroneous, contrary to competition, arbitrary, or capricious. In any bid-protest proceeding contesting an intended agency action to reject all bids, proposals, or replies, the standard of review by an administrative law judge shall be whether the agency's intended action is illegal, arbitrary, dishonest, or fraudulent.

(g)For purposes of this subsection, the definitions in s. 287.012 apply.

(4)INFORMAL DISPOSITION.—Unless precluded by law, informal disposition may be made of any proceeding by stipulation, agreed settlement, or consent order.

(5)APPLICABILITY.—This section does not apply to agency investigations preliminary to agency action.

History.—s. 1, ch. 74-310; s. 7, ch. 75-191; s. 8, ch. 76-131; s. 1, ch. 77-174; s. 5, ch. 77-453; ss. 6, 11, ch. 78-95; s. 6, ch. 78-425; s. 8, ch. 79-7; s. 7, ch. 80-95; s. 4, ch. 80-289; s. 57, ch. 81-259; s. 2, ch. 83-78; s. 9, ch. 83-216; s. 2, ch. 84-173; s. 4, ch. 84-203; ss. 1, 2, ch. 86-108; s. 44, ch. 87-6; ss. 1, 2, ch. 87-54; s. 5, ch. 87-385; s. 1, ch. 90-283; s. 4, ch. 91-30; s. 1, ch. 91-191; s. 22, ch. 92-315; s. 7, ch. 94-218; s. 1420, ch. 95-147; s. 1, ch. 95-328; s. 19, ch. 96-159; s. 1, ch. 96-423; s. 8, ch. 97-176; s. 5, ch. 98-200; s. 3, ch. 98-279; s. 47, ch. 99-2; s. 6, ch. 99-379; s. 2, ch. 2002-207; s. 5, ch. 2003-94; s. 7, ch. 2006-82; s. 12, ch. 2008-104; s. 12, ch. 2011-208.

120.573Mediation of disputes.—Each announcement of an agency action that affects substantial interests shall advise whether mediation of the administrative dispute for the type of agency action announced is available and that choosing mediation does not affect the right to an administrative hearing. If

the agency and all parties to the administrative action agree to mediation, in writing, within 10 days after the time period stated in the announcement for election of an administrative remedy under ss. 120.569 and 120.57, the time limitations imposed by ss. 120.569 and 120.57 shall be tolled to allow the agency and parties to mediate the administrative dispute. The mediation shall be concluded within 60 days of such agreement unless otherwise agreed by the parties. The mediation agreement shall include provisions for mediator selection, the allocation of costs and fees associated with mediation, and the mediating parties' understanding regarding the confidentiality of discussions and documents introduced during mediation. If mediation results in settlement of the administrative dispute, the agency shall enter a final order incorporating the agreement of the parties. If mediation terminates without settlement of the dispute, the agency shall notify the parties in writing that the administrative hearing processes under ss. 120.569 and 120.57 are resumed.

History.—s. 20, ch. 96-159; s. 9, ch. 97-176.

120.574Summary hearing.—

(1)(a)Within 5 business days following the division's receipt of a petition or request for hearing, the division shall issue and serve on all original parties an initial order that assigns the case to a specific administrative law judge and provides general information regarding practice and procedure before the division. The initial order shall also contain a statement advising the addressees that a summary hearing is available upon the agreement of all parties under subsection (2) and briefly describing the expedited time sequences, limited discovery, and final order provisions of the summary procedure.

(b)Within 15 days after service of the initial order, any party may file with the division a motion for summary hearing in accordance with subsection (2). If all original parties agree, in writing, to the summary proceeding, the proceeding shall be conducted within 30 days of the agreement, in accordance with the provisions of subsection (2).

(c)Intervenors in the proceeding shall be governed by the decision of the original parties regarding whether the case will proceed in accordance with the summary hearing process and shall not have standing to challenge that decision.

(d)If a motion for summary hearing is not filed within 15 days after service of the division's initial order, the matter shall proceed in accordance with ss. 120.569 and 120.57.

(2)In any case to which this subsection is applicable, the following procedures apply:

(a)Motions shall be limited to the following:

1.A motion in opposition to the petition.

2.A motion requesting discovery beyond the informal exchange of documents and witness lists described in paragraph (b). Upon a showing of necessity, additional discovery may be permitted in the discretion of the administrative law judge, but only if it can be completed not later than 5 days prior to the final hearing.

3.A motion for continuance of the final hearing date.

4.A motion requesting a prehearing conference, or the administrative law judge may require a prehearing conference, for the purpose of identifying: the legal and factual issues to be considered at the final hearing; the names and addresses of witnesses who may be called to testify at the final hearing; documentary evidence that will be offered at the final hearing; the range of penalties that may be imposed upon final hearing; and any other matter that the administrative law judge determines would expedite resolution of the proceeding. The prehearing conference may be held by telephone conference call.

5.During or after any preliminary hearing or conference, any party or the administrative law judge may suggest that the case is no longer appropriate for summary disposition. Following any argument requested by the parties, the administrative law judge may enter an order referring the case back to the formal adjudicatory process described in s. 120.57(1), in which event the parties shall proceed accordingly.

(b)Not later than 5 days prior to the final hearing, the parties shall furnish to each other copies of documentary evidence and lists of witnesses who may testify at the final hearing.

(c)All parties shall have an opportunity to respond, to present evidence and argument on all issues involved, to conduct cross-examination and submit rebuttal evidence, and to be represented by counsel or other qualified representative.

(d)The record in a case governed by this subsection shall consist only of:

1.All notices, pleadings, motions, and intermediate rulings.

2.Evidence received.

3.A statement of matters officially recognized.

4.Proffers of proof and objections and rulings thereon.

5.Matters placed on the record after an ex parte communication.

6.The written decision of the administrative law judge presiding at the final hearing.

7.The official transcript of the final hearing.

(e)The agency shall accurately and completely preserve all testimony in the proceeding and, upon request by any party, shall make a full or partial transcript available at no more than actual cost.

(f)The decision of the administrative law judge shall be rendered within 30 days after the conclusion of the final hearing or the filing of the transcript thereof, whichever is later. The administrative law judge's decision, which shall be final agency action subject to judicial review under s. 120.68, shall include the following:

1.Findings of fact based exclusively on the evidence of record and matters officially recognized.

2.Conclusions of law.

3.Imposition of a fine or penalty, if applicable.

4.Any other information required by law or rule to be contained in a final order.

History.—s. 21, ch. 96-159; s. 10, ch. 97-176; s. 11, ch. 2000-158; s. 10, ch. 2000-336.

120.595Attorney's fees.—

(1)CHALLENGES TO AGENCY ACTION PURSUANT TO SECTION 120.57(1).—

(a)The provisions of this subsection are supplemental to, and do not abrogate, other provisions allowing the award of fees or costs in administrative proceedings.

(b)The final order in a proceeding pursuant to s. 120.57(1) shall award reasonable costs and a reasonable attorney's fee to the prevailing party only where the nonprevailing adverse party has been determined by the administrative law judge to have participated in the proceeding for an improper purpose.

(c)In proceedings pursuant to s. 120.57(1), and upon motion, the administrative law judge shall determine whether any party participated in the proceeding for an improper purpose as defined by this subsection. In making such determination, the administrative law judge shall consider whether the nonprevailing adverse party has participated in two or more other such proceedings involving the same prevailing party and the same project as an adverse party and in which such two or more proceedings the nonprevailing adverse party did not establish either the factual or legal merits of its position, and shall consider whether the factual or legal position asserted in the instant proceeding would have been cognizable in the previous proceedings. In such event, it shall be rebuttably presumed that the nonprevailing adverse party participated in the pending proceeding for an improper purpose.

(d)In any proceeding in which the administrative law judge determines that a party participated in the proceeding for an improper purpose, the recommended order shall so designate and shall determine the award of costs and attorney's fees.

(e)For the purpose of this subsection:

1."Improper purpose" means participation in a proceeding pursuant to s. 120.57(1) primarily to harass or to cause unnecessary delay or for frivolous purpose or to needlessly increase the cost of litigation, licensing, or securing the approval of an activity.

2."Costs" has the same meaning as the costs allowed in civil actions in this state as provided in chapter 57.

3."Nonprevailing adverse party" means a party that has failed to have substantially changed the outcome of the proposed or final agency action which is the subject of a proceeding. In the event that a proceeding results in any substantial modification or condition intended to resolve the matters raised in a party's petition, it shall be determined that the party having raised the issue addressed is not a nonprevailing adverse party. The recommended order shall state whether the change is substantial for purposes of this subsection. In no event shall the term "nonprevailing party" or "prevailing party" be deemed to include any party that has intervened in a previously existing proceeding to support the position of an agency.

(2)CHALLENGES TO PROPOSED AGENCY RULES PURSUANT TO SECTION 120.56(2).—If the appellate court or

administrative law judge declares a proposed rule or portion of a proposed rule invalid pursuant to s. 120.56(2), a judgment or order shall be rendered against the agency for reasonable costs and reasonable attorney's fees, unless the agency demonstrates that its actions were substantially justified or special circumstances exist which would make the award unjust. An agency's actions are "substantially justified" if there was a reasonable basis in law and fact at the time the actions were taken by the agency. If the agency prevails in the proceedings, the appellate court or administrative law judge shall award reasonable costs and reasonable attorney's fees against a party if the appellate court or administrative law judge determines that a party participated in the proceedings for an improper purpose as defined by paragraph (1)(e). No award of attorney's fees as provided by this subsection shall exceed $50,000.

(3)CHALLENGES TO EXISTING AGENCY RULES PURSUANT TO SECTION 120.56(3) AND (5).—If the appellate court or administrative law judge declares a rule or portion of a rule invalid pursuant to s. 120.56(3) or (5), a judgment or order shall be rendered against the agency for reasonable costs and reasonable attorney's fees, unless the agency demonstrates that its actions were substantially justified or special circumstances exist which would make the award unjust. An agency's actions are "substantially justified" if there was a reasonable basis in law and fact at the time the actions were taken by the agency. If the agency prevails in the proceedings, the appellate court or administrative law judge shall award reasonable costs and reasonable attorney's fees against a party if the appellate court or administrative law judge determines that a party participated in the proceedings for an improper purpose as defined by paragraph (1)(e). No award of attorney's fees as provided by this subsection shall exceed $50,000.

(4)CHALLENGES TO AGENCY ACTION PURSUANT TO SECTION 120.56(4).—

(a)If the appellate court or administrative law judge determines that all or part of an agency statement violates s. 120.54(1)(a), or that the agency must immediately discontinue reliance on the statement and any substantially similar statement pursuant to s. 120.56(4)(e), a judgment or order shall be entered against the agency for reasonable costs and reasonable attorney's fees, unless the agency demonstrates that the statement is required by the Federal Government to implement or retain a delegated or approved program or to meet a condition to receipt of federal funds.

(b)Upon notification to the administrative law judge provided before the final hearing that the agency has published a notice of rulemaking under s. 120.54(3)(a), such notice shall automatically operate as a stay of proceedings pending rulemaking. The administrative law judge may vacate the stay for good cause shown. A stay of proceedings under this paragraph remains in effect so long as the agency is proceeding expeditiously and in good faith to adopt the statement as a rule. The administrative law judge shall award reasonable costs and reasonable attorney's fees accrued by the petitioner prior to the date the notice was published, unless the agency proves to the administrative law judge that it did not know and should not have known that the statement was an unadopted rule. Attorneys' fees and costs under this paragraph and paragraph (a) shall be

awarded only upon a finding that the agency received notice that the statement may constitute an unadopted rule at least 30 days before a petition under s. 120.56(4) was filed and that the agency failed to publish the required notice of rulemaking pursuant to s. 120.54(3) that addresses the statement within that 30-day period. Notice to the agency may be satisfied by its receipt of a copy of the s. 120.56(4) petition, a notice or other paper containing substantially the same information, or a petition filed pursuant to s. 120.54(7). An award of attorney's fees as provided by this paragraph may not exceed $50,000.

(c)Notwithstanding the provisions of chapter 284, an award shall be paid from the budget entity of the secretary, executive director, or equivalent administrative officer of the agency, and the agency shall not be entitled to payment of an award or reimbursement for payment of an award under any provision of law.

(d)If the agency prevails in the proceedings, the appellate court or administrative law judge shall award reasonable costs and attorney's fees against a party if the appellate court or administrative law judge determines that the party participated in the proceedings for an improper purpose as defined in paragraph (1)(e) or that the party or the party's attorney knew or should have known that a claim was not supported by the material facts necessary to establish the claim or would not be supported by the application of then-existing law to those material facts.

(5)APPEALS.—When there is an appeal, the court in its discretion may award reasonable attorney's fees and reasonable costs to the prevailing party if the court finds that the appeal was frivolous, meritless, or an abuse of the appellate process, or that the agency action which precipitated the appeal was a gross abuse of the agency's discretion. Upon review of agency action that precipitates an appeal, if the court finds that the agency improperly rejected or modified findings of fact in a recommended order, the court shall award reasonable attorney's fees and reasonable costs to a prevailing appellant for the administrative proceeding and the appellate proceeding.

(6)OTHER SECTIONS NOT AFFECTED.—Other provisions, including ss. 57.105 and 57.111, authorize the award of attorney's fees and costs in administrative proceedings. Nothing in this section shall affect the availability of attorney's fees and costs as provided in those sections.

History.—s. 25, ch. 96-159; s. 11, ch. 97-176; s. 48, ch. 99-2; s. 6, ch. 2003-94; s. 13, ch. 2008-104.

120.60Licensing.—

(1)Upon receipt of a license application, an agency shall examine the application and, within 30 days after such receipt, notify the applicant of any apparent errors or omissions and request any additional information the agency is permitted by law to require. An agency may not deny a license for failure to correct an error or omission or to supply additional information unless the agency timely notified the applicant within this 30-day period. The agency may establish by rule the time period for submitting any additional information requested by the agency. For good cause shown, the agency shall grant a request for an extension of time for submitting the additional information. If the applicant believes the agency's request for additional

information is not authorized by law or rule, the agency, at the applicant's request, shall proceed to process the application. An application is complete upon receipt of all requested information and correction of any error or omission for which the applicant was timely notified or when the time for such notification has expired. An application for a license must be approved or denied within 90 days after receipt of a completed application unless a shorter period of time for agency action is provided by law. The 90-day time period is tolled by the initiation of a proceeding under ss. 120.569 and 120.57. Any application for a license which is not approved or denied within the 90-day or shorter time period, within 15 days after conclusion of a public hearing held on the application, or within 45 days after a recommended order is submitted to the agency and the parties, whichever action and timeframe is latest and applicable, is considered approved unless the recommended order recommends that the agency deny the license. Subject to the satisfactory completion of an examination if required as a prerequisite to licensure, any license that is considered approved shall be issued and may include such reasonable conditions as are authorized by law. Any applicant for licensure seeking to claim licensure by default under this subsection shall notify the agency clerk of the licensing agency, in writing, of the intent to rely upon the default license provision of this subsection, and may not take any action based upon the default license until after receipt of such notice by the agency clerk.

(2)If an applicant seeks a license for an activity that is exempt from licensure, the agency shall notify the applicant and return any tendered application fee within 30 days after receipt of the original application.

(3)Each applicant shall be given written notice, personally or by mail, that the agency intends to grant or deny, or has granted or denied, the application for license. The notice must state with particularity the grounds or basis for the issuance or denial of the license, except when issuance is a ministerial act. Unless waived, a copy of the notice shall be delivered or mailed to each party's attorney of record and to each person who has made a written request for notice of agency action. Each notice must inform the recipient of the basis for the agency decision, inform the recipient of any administrative hearing pursuant to ss. 120.569 and 120.57 or judicial review pursuant to s. 120.68 which may be available, indicate the procedure that must be followed, and state the applicable time limits. The issuing agency shall certify the date the notice was mailed or delivered, and the notice and the certification must be filed with the agency clerk.

(4)When a licensee has made timely and sufficient application for the renewal of a license which does not automatically expire by statute, the existing license shall not expire until the application for renewal has been finally acted upon by the agency or, in case the application is denied or the terms of the license are limited, until the last day for seeking review of the agency order or a later date fixed by order of the reviewing court.

1 (5)No revocation, suspension, annulment, or withdrawal of any license is lawful unless, prior to the entry of a final order, the agency has served, by personal service or certified mail, an administrative complaint which affords reasonable notice to the licensee of facts or conduct which warrant the intended action and

unless the licensee has been given an adequate opportunity to request a proceeding pursuant to ss. 120.569 and 120.57. When personal service cannot be made and the certified mail notice is returned undelivered, the agency shall cause a short, plain notice to the licensee to be published once each week for 4 consecutive weeks in a newspaper published in the county of the licensee's last known address as it appears on the records of the agency. If no newspaper is published in that county, the notice may be published in a newspaper of general circulation in that county.

(6)If the agency finds that immediate serious danger to the public health, safety, or welfare requires emergency suspension, restriction, or limitation of a license, the agency may take such action by any procedure that is fair under the circumstances if:

(a)The procedure provides at least the same procedural protection as is given by other statutes, the State Constitution, or the United States Constitution;

(b)The agency takes only that action necessary to protect the public interest under the emergency procedure; and

(c)The agency states in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances. The agency's findings of immediate danger, necessity, and procedural fairness are judicially reviewable. Summary suspension, restriction, or limitation may be ordered, but a suspension or revocation proceeding pursuant to ss. 120.569 and 120.57 shall also be promptly instituted and acted upon.

(7)No agency shall include as a condition of approval of any license any provision that is based upon a statement, policy, or guideline of another agency unless the statement, policy, or guideline is within the jurisdiction of the other agency. The other agency shall identify for the licensing agency the specific legal authority for each such statement, policy, or guideline. The licensing agency must provide the licensee with an opportunity to challenge the condition as invalid. If the licensing agency bases a condition of approval or denial of the license upon the statement, policy, or guideline of the other agency, any party to an administrative proceeding that arises from the approval with conditions or denial of the license may require the other agency to join as a party in determining the validity of the condition.

History.—s. 1, ch. 74-310; s. 10, ch. 76-131; s. 1, ch. 77-174; ss. 6, 9, ch. 77-453; s. 57, ch. 78-95; s. 8, ch. 78-425; s. 1, ch. 79-142; s. 6, ch. 79-299; s. 2, ch. 81-180; s. 6, ch. 84-203; s. 2, ch. 84-265; s. 1, ch. 85-82; s. 14, ch. 90-51; s. 762, ch. 95-147; s. 26, ch. 96-159; s. 326, ch. 96-410; s. 12, ch. 97-176; s. 7, ch. 2003-94; ss. 4, 5, ch. 2010-279; HJR 9-A, 2010 Special Session A; s. 10, ch. 2012-212.

[1]**Note.**—Section 21, ch. 2012-212, provides that "[e]xcept as otherwise expressly provided in this act, this act shall take effect July 1, 2012, and shall apply to legal notices that must be published on or after that date."

120.62Agency investigations.—

(1)Every person who responds to a request or demand by any agency or representative thereof for written data or an oral statement shall be entitled to a transcript or recording of his or her oral statement at no more than cost.

(2)Any person compelled to appear, or who appears voluntarily, before any presiding officer or agency in an investigation or in any agency proceeding has the right, at his or her own expense, to be accompanied, represented, and advised by counsel or by other qualified representatives.

History.—s. 1, ch. 74-310; s. 763, ch. 95-147; s. 28, ch. 96-159.

120.63Exemption from act.—

(1)Upon application of any agency, the Administration Commission may exempt any process or proceeding governed by this act from one or more requirements of this act:

(a)When the agency head has certified that the requirement would conflict with any provision of federal law or rules with which the agency must comply;

(b)In order to permit persons in the state to receive tax benefits or federal funds under any federal law; or

(c)When the commission has found that conformity with the requirements of the part or parts of this act for which exemption is sought would be so inconvenient or impractical as to defeat the purpose of the agency proceeding involved or the purpose of this act and would not be in the public interest in light of the nature of the intended action and the enabling act or other laws affecting the agency.

(2)The commission may not exempt an agency from any requirement of this act pursuant to this section until it establishes alternative procedures to achieve the agency's purpose which shall be consistent, insofar as possible, with the intent and purpose of the act.

(a)Prior to the granting of any exemption authorized by this section, the commission shall hold a public hearing after notice given as provided in s. 120.525. Upon the conclusion of the hearing, the commission, through the Executive Office of the Governor, shall issue an order specifically granting or denying the exemption and specifying any processes or proceedings exempted and the extent of the exemption; transmit to the committee and to the Department of State a copy of the petition, a certified copy of the order granting or denying the petition, and a copy of any alternative procedures prescribed; and give notice of the petition and the commission's response in the Florida Administrative Weekly.

(b)An exemption and any alternative procedure prescribed shall terminate 90 days following adjournment sine die of the then-current or next regular legislative session after issuance of the exemption order, or upon the effective date of any subsequent legislation incorporating the exemption or any partial exemption related thereto, whichever is earlier. The exemption granted by the commission shall be renewable upon the same or

similar facts not more than once. Such renewal shall terminate as would an original exemption.

History.—s. 1, ch. 74-310; s. 11, ch. 76-131; s. 1, ch. 77-53; s. 8, ch. 77-453; s. 87, ch. 79-190; s. 7, ch. 79-299; s. 70, ch. 79-400; s. 58, ch. 81-259; s. 29, ch. 96-159.

120.65Administrative law judges.—

(1)The Division of Administrative Hearings within the Department of Management Services shall be headed by a director who shall be appointed by the Administration Commission and confirmed by the Senate. The director, who shall also serve as the chief administrative law judge, and any deputy chief administrative law judge must possess the same minimum qualifications as the administrative law judges employed by the division. The Deputy Chief Judge of Compensation Claims must possess the minimum qualifications established in s. 440.45(2) and shall report to the director. The division shall be a separate budget entity, and the director shall be its agency head for all purposes. The Department of Management Services shall provide administrative support and service to the division to the extent requested by the director. The division shall not be subject to control, supervision, or direction by the Department of Management Services in any manner, including, but not limited to, personnel, purchasing, transactions involving real or personal property, and budgetary matters.

(2)The director has the right to appeal actions by the Executive Office of the Governor that affect amendments to the division's approved operating budget or any personnel actions pursuant to chapter 216 to the Administration Commission, which shall decide such issue by majority vote. The appropriations committees may advise the Administration Commission on the issue. If the President of the Senate and the Speaker of the House of Representatives object in writing to the effects of the appeal, the appeal may be affirmed by the affirmative vote of two-thirds of the commission members present.

(3)Each state agency as defined in chapter 216 and each political subdivision shall make its facilities available, at a time convenient to the provider, for use by the division in conducting proceedings pursuant to this chapter.

(4)The division shall employ administrative law judges to conduct hearings required by this chapter or other law. Any person employed by the division as an administrative law judge must have been a member of The Florida Bar in good standing for the preceding 5 years.

(5)If the division cannot furnish a division administrative law judge promptly in response to an agency request, the director shall designate in writing a qualified full-time employee of an agency other than the requesting agency to conduct the hearing. The director shall have the discretion to designate such a hearing officer who is located in that part of the state where the parties and witnesses reside.

(6)By rule, the division may establish:

(a)Further qualifications for administrative law judges and shall establish procedures by which candidates will be considered for employment or contract.

(b)The manner in which public notice will be given of vacancies in the staff of administrative law judges.

(c)Procedures for the assignment of administrative law judges.

(7)The division is authorized to provide administrative law judges on a contract basis to any governmental entity to conduct any hearing not covered by this section.

(8)The division shall have the authority to adopt reasonable rules to carry out the provisions of this act.

(9)Rules promulgated by the division may authorize any reasonable sanctions except contempt for violation of the rules of the division or failure to comply with a reasonable order issued by an administrative law judge, which is not under judicial review.

(10)Not later than February 1 of each year, the division shall issue a written report to the Administrative Procedures Committee and the Administration Commission, including at least the following information:

(a)A summary of the extent and effect of agencies' utilization of administrative law judges, court reporters, and other personnel in proceedings under this chapter.

(b)Recommendations for change or improvement in the Administrative Procedure Act or any agency's practice or policy with respect thereto.

(c)Recommendations as to those types of cases or disputes which should be conducted under the summary hearing process described in s. 120.574.

(d)A report regarding each agency's compliance with the filing requirement in s. 120.57(1)(m).

(11)The division shall be reimbursed for administrative law judge services and travel expenses by the following entities: water management districts, regional planning councils, school districts, community colleges, the Division of Florida Colleges, state universities, the Board of Governors of the State University System, the State Board of Education, the Florida School for the Deaf and the Blind, and the Commission for Independent Education. These entities shall contract with the division to establish a contract rate for services and provisions for reimbursement of administrative law judge travel expenses and video teleconferencing expenses attributable to hearings conducted on behalf of these entities. The contract rate must be based on a total-cost-recovery methodology.

History.—s. 1, ch. 74-310; s. 9, ch. 75-191; s. 14, ch. 76-131; s. 9, ch. 78-425; s. 46, ch. 79-190; s. 1, ch. 86-297; s. 46, ch. 87-6; s. 25, ch. 87-101; s. 54, ch. 88-1; s. 30, ch. 88-277; s. 51, ch. 92-279; s. 23, ch. 92-315; s. 55, ch. 92-326; s. 764, ch. 95-147; s. 31, ch. 96-159; s. 13, ch. 97-176; s. 38, ch. 2000-371; s. 4, ch. 2001-91; s. 1, ch. 2004-247; s. 8, ch. 2006-82; s. 14, ch. 2007-217; s. 8, ch. 2009-228.

120.651Designation of two administrative law judges to preside over actions involving department or boards.—The Division of Administrative Hearings shall designate at least two administrative law judges who shall specifically preside over actions involving the Department of Health or boards within the Department of Health. Each designated administrative law judge must be a member of The Florida Bar in good standing and must have legal, managerial, or clinical experience in issues related to health care or have attained board certification in health care law from The Florida Bar.

History.—s. 32, ch. 2003-416.

120.655Withholding funds to pay for administrative law judge services to school boards.—If a district school board fails to make a timely payment for the services provided by an administrative law judge of the Division of Administrative Hearings as provided annually in the General Appropriations Act, the Commissioner of Education shall withhold, from any general revenue funds the district is eligible to receive, an amount sufficient to pay for the administrative law judge's services. The commissioner shall transfer the amount withheld to the Division of Administrative Hearings in payment of such services.

History.—s. 1, ch. 92-121; s. 32, ch. 96-159.

120.66Ex parte communications.—

(1)In any proceeding under ss. 120.569 and 120.57, no ex parte communication relative to the merits, threat, or offer of reward shall be made to the agency head, after the agency head has received a recommended order, or to the presiding officer by:

(a)An agency head or member of the agency or any other public employee or official engaged in prosecution or advocacy in connection with the matter under consideration or a factually related matter.

(b)A party to the proceeding, the party's authorized representative or counsel, or any person who, directly or indirectly, would have a substantial interest in the proposed agency action.

Nothing in this subsection shall apply to advisory staff members who do not testify on behalf of the agency in the proceeding or to any rulemaking proceedings under s. 120.54.

(2)A presiding officer, including an agency head or designee, who is involved in the decisional process and who receives an ex parte communication in violation of subsection (1) shall place on the record of the pending matter all written communications received, all written responses to such communications, and a memorandum stating the substance of all oral communications received and all oral responses made, and shall also advise all parties that such matters have been placed on the record. Any party desiring to rebut the ex parte communication shall be allowed to do so, if such party requests the opportunity for rebuttal within 10 days after notice of such communication. The presiding officer may, if necessary to eliminate the effect of an ex parte communication, withdraw from the proceeding, in which case the entity that appointed the presiding officer shall assign a successor.

(3)Any person who makes an ex parte communication prohibited by subsection (1), and any presiding officer, including an agency head or designee, who fails to place in the record any such communication, is in violation of this act and may be assessed a civil penalty not to exceed $500 or be subjected to other disciplinary action.

History.—s. 1, ch. 74-310; s. 10, ch. 75-191; s. 12, ch. 76-131; s. 1, ch. 77-174; s. 10, ch. 78-425; s. 765, ch. 95-147; s. 33, ch. 96-159; s. 14, ch. 97-176.

120.665Disqualification of agency personnel.—

(1)Notwithstanding the provisions of s. 112.3143, any individual serving alone or with others as an agency head may be disqualified from serving in an agency proceeding for bias, prejudice, or interest when any party to the agency proceeding shows just cause by a suggestion filed within a reasonable period of time prior to the agency proceeding. If the disqualified individual was appointed, the appointing power may appoint a substitute to serve in the matter from which the individual is disqualified. If the individual is an elected official, the Governor may appoint a substitute to serve in the matter from which the individual is disqualified. However, if a quorum remains after the individual is disqualified, it shall not be necessary to appoint a substitute.

(2)Any agency action taken by a duly appointed substitute for a disqualified individual shall be as conclusive and effective as if agency action had been taken by the agency as it was constituted prior to any substitution.

History.—s. 1, ch. 74-310; s. 12, ch. 78-425; s. 2, ch. 83-329; s. 767, ch. 95-147; s. 34, ch. 96-159.

Note.—Former s. 120.71.

120.68Judicial review.—

(1)A party who is adversely affected by final agency action is entitled to judicial review. A preliminary, procedural, or intermediate order of the agency or of an administrative law judge of the Division of Administrative Hearings is immediately reviewable if review of the final agency decision would not provide an adequate remedy.

(2)(a)Judicial review shall be sought in the appellate district where the agency maintains its headquarters or where a party resides or as otherwise provided by law. All proceedings shall be instituted by filing a notice of appeal or petition for review in accordance with the Florida Rules of Appellate Procedure within 30 days after the rendition of the order being appealed. If the appeal is of an order rendered in a proceeding initiated under s. 120.56, the agency whose rule is being challenged shall transmit a copy of the notice of appeal to the committee.

(b)When proceedings under this chapter are consolidated for final hearing and the parties to the consolidated proceeding seek review of final or interlocutory orders in more than one district court of appeal, the courts of appeal are authorized to transfer and consolidate the review proceedings. The court may transfer such appellate proceedings on its own motion, upon motion of a party to one of the appellate proceedings, or by stipulation of the parties to the appellate proceedings. In determining whether to transfer a proceeding, the court may consider such factors as the interrelationship of the parties and the proceedings, the desirability of avoiding inconsistent results in related matters, judicial economy, and the burden on the parties of reproducing the record for use in multiple appellate courts.

(3)The filing of the petition does not itself stay enforcement of the agency decision, but if the agency decision has the effect of suspending or revoking a license, supersedeas shall be granted as a matter of right upon such conditions as are reasonable, unless the court, upon petition of the agency, determines that a supersedeas would constitute a probable danger to the health, safety, or welfare of the state. The agency also may grant a stay upon appropriate terms, but, whether or not the action has the effect of suspending or revoking a license, a petition to the agency for a stay is not a prerequisite to a petition to the court for supersedeas. In any event the court shall specify the conditions, if any, upon which the stay or supersedeas is granted.

(4)Judicial review of any agency action shall be confined to the record transmitted and any additions made thereto in accordance with paragraph (7)(a).

(5)The record for judicial review shall be compiled in accordance with the Florida Rules of Appellate Procedure.

(6)(a)The reviewing court's decision may be mandatory, prohibitory, or declaratory in form, and it shall provide whatever relief is appropriate irrespective of the original form of the petition. The court may:

1.Order agency action required by law; order agency exercise of discretion when required by law; set aside agency action; remand the case for further agency proceedings; or decide the rights, privileges, obligations, requirements, or procedures at issue between the parties; and

2.Order such ancillary relief as the court finds necessary to redress the effects of official action wrongfully taken or withheld.

(b)If the court sets aside agency action or remands the case to the agency for further proceedings, it may make such interlocutory order as the court finds necessary to preserve the interests of any party and the public pending further proceedings or agency action.

(7)The court shall remand a case to the agency for further proceedings consistent with the court's decision or set aside agency action, as appropriate, when it finds that:

(a)There has been no hearing prior to agency action and the reviewing court finds that the validity of the action depends upon disputed facts;

(b)The agency's action depends on any finding of fact that is not supported by competent, substantial evidence in the record of a hearing conducted pursuant to ss. 120.569 and 120.57; however, the court shall not substitute its judgment for that of the agency as to the weight of the evidence on any disputed finding of fact;

(c)The fairness of the proceedings or the correctness of the action may have been impaired by a material error in procedure or a failure to follow prescribed procedure;

(d)The agency has erroneously interpreted a provision of law and a correct interpretation compels a particular action; or

(e)The agency's exercise of discretion was:

1.Outside the range of discretion delegated to the agency by law;

2.Inconsistent with agency rule;

3.Inconsistent with officially stated agency policy or a prior agency practice, if deviation therefrom is not explained by the agency; or

4.Otherwise in violation of a constitutional or statutory provision;

but the court shall not substitute its judgment for that of the agency on an issue of discretion.

(8)Unless the court finds a ground for setting aside, modifying, remanding, or ordering agency action or ancillary relief under a specified provision of this section, it shall affirm the agency's action.

(9)No petition challenging an agency rule as an invalid exercise of delegated legislative authority shall be instituted pursuant to this section, except to review an order entered pursuant to a proceeding under s. 120.56 or an agency's findings of immediate danger, necessity, and procedural fairness prerequisite to the adoption of an emergency rule pursuant to s. 120.54(4), unless the sole issue presented by the petition is the constitutionality of a rule and there are no disputed issues of fact.

(10)If an administrative law judge's final order depends on any fact found by the administrative law judge, the court shall not substitute its judgment for that of the administrative law judge as to the weight of the evidence on any disputed finding of fact. The court shall, however, set aside the final order of the administrative law judge or remand the case to the administrative law judge, if it finds that the final order depends on any finding of fact that is not supported by competent substantial evidence in the record of the proceeding.

History.—s. 1, ch. 74-310; s. 13, ch. 76-131; s. 38, ch. 77-104; s. 1, ch. 77-174; s. 11, ch. 78-425; s. 4, ch. 84-173; s. 7, ch. 87-385; s. 36, ch. 90-302; s. 6, ch. 91-30; s. 1, ch. 91-191; s. 10, ch. 92-166; s. 35, ch. 96-159; s. 15, ch. 97-176; s. 8, ch. 2003-94.

120.69Enforcement of agency action.—

(1)Except as otherwise provided by statute:

(a)Any agency may seek enforcement of an action by filing a petition for enforcement, as provided in this section, in the circuit court where the subject matter of the enforcement is located.

(b)A petition for enforcement of any agency action may be filed by any substantially interested person who is a resident of the state. However, no such action may be commenced:

1.Prior to 60 days after the petitioner has given notice of the violation of the agency action to the head of the agency concerned, the Attorney General, and any alleged violator of the agency action.

2.If an agency has filed, and is diligently prosecuting, a petition for enforcement.

(c)A petition for enforcement filed by a nongovernmental person shall be in the name of the State of Florida on the relation of the petitioner, and the doctrines of res judicata and collateral estoppel shall apply.

(d)In an action brought under paragraph (b), the agency whose action is sought to be enforced, if not a

party, may intervene as a matter of right.

(2)A petition for enforcement may request declaratory relief; temporary or permanent equitable relief; any fine, forfeiture, penalty, or other remedy provided by statute; any combination of the foregoing; or, in the absence of any other specific statutory authority, a fine not to exceed $1,000.

(3)After the court has rendered judgment on a petition for enforcement, no other petition shall be filed or adjudicated against the same agency action, on the basis of the same transaction or occurrence, unless expressly authorized on remand. The doctrines of res judicata and collateral estoppel shall apply, and the court shall make such orders as are necessary to avoid multiplicity of actions.

(4)In all enforcement proceedings:

(a)If enforcement depends on any facts other than those appearing in the record, the court may ascertain such facts under procedures set forth in s. 120.68(7)(a).

(b)If one or more petitions for enforcement and a petition for review involving the same agency action are pending at the same time, the court considering the review petition may order all such actions transferred to and consolidated in one court. Each party shall be under an affirmative duty to notify the court when it becomes aware of multiple proceedings.

(c)Should any party willfully fail to comply with an order of the court, the court shall punish that party in accordance with the law applicable to contempt committed by a person in the trial of any other action.

(5)In any enforcement proceeding the respondent may assert as a defense the invalidity of any relevant statute, the inapplicability of the administrative determination to respondent, compliance by the respondent, the inappropriateness of the remedy sought by the agency, or any combination of the foregoing. In addition, if the petition for enforcement is filed during the time within which the respondent could petition for judicial review of the agency action, the respondent may assert the invalidity of the agency action.

(6)Notwithstanding any other provision of this section, upon receipt of evidence that an alleged violation of an agency's action presents an imminent and substantial threat to the public health, safety, or welfare, the agency may bring suit for immediate temporary relief in an appropriate circuit court, and the granting of such temporary relief shall not have res judicata or collateral estoppel effect as to further relief sought under a petition for enforcement relating to the same violation.

(7)In any final order on a petition for enforcement the court may award to the prevailing party all or part of the costs of litigation and reasonable attorney's fees and expert witness fees, whenever the court determines that such an award is appropriate.

History.—s. 1, ch. 74-310; s. 766, ch. 95-147; s. 36, ch. 96-159.

120.695Notice of noncompliance.—

(1)It is the policy of the state that the purpose of regulation is to protect the public by attaining compliance with the policies established by the Legislature. Fines and other penalties may be provided in

order to assure compliance; however, the collection of fines and the imposition of penalties are intended to be secondary to the primary goal of attaining compliance with an agency's rules. It is the intent of the Legislature that an agency charged with enforcing rules shall issue a notice of noncompliance as its first response to a minor violation of a rule in any instance in which it is reasonable to assume that the violator was unaware of the rule or unclear as to how to comply with it.

(2)(a)Each agency shall issue a notice of noncompliance as a first response to a minor violation of a rule. A "notice of noncompliance" is a notification by the agency charged with enforcing the rule issued to the person or business subject to the rule. A notice of noncompliance may not be accompanied with a fine or other disciplinary penalty. It must identify the specific rule that is being violated, provide information on how to comply with the rule, and specify a reasonable time for the violator to comply with the rule. A rule is agency action that regulates a business, occupation, or profession, or regulates a person operating a business, occupation, or profession, and that, if not complied with, may result in a disciplinary penalty.

(b)Each agency shall review all of its rules and designate those for which a violation would be a minor violation and for which a notice of noncompliance must be the first enforcement action taken against a person or business subject to regulation. A violation of a rule is a minor violation if it does not result in economic or physical harm to a person or adversely affect the public health, safety, or welfare or create a significant threat of such harm. If an agency under the direction of a cabinet officer mails to each licensee a notice of the designated rules at the time of licensure and at least annually thereafter, the provisions of paragraph (a) may be exercised at the discretion of the agency. Such notice shall include a subject-matter index of the rules and information on how the rules may be obtained.

(c)The agency's review and designation must be completed by December 1, 1995; each agency under the direction of the Governor shall make a report to the Governor, and each agency under the joint direction of the Governor and Cabinet shall report to the Governor and Cabinet by January 1, 1996, on which of its rules have been designated as rules the violation of which would be a minor violation.

(d)The Governor or the Governor and Cabinet, as appropriate pursuant to paragraph (c), may evaluate the review and designation effects of each agency and may apply a different designation than that applied by the agency.

(e)This section does not apply to the regulation of law enforcement personnel or teachers.

(f)Designation pursuant to this section is not subject to challenge under this chapter.

History.—s. 1, ch. 95-402.

120.72Legislative intent; references to chapter 120 or portions thereof.—Unless expressly provided otherwise, a reference in any section of the Florida Statutes to chapter 120 or to any section or sections or portion of a section of chapter 120 includes, and shall be understood as including, all subsequent amendments to chapter 120 or to the referenced section or sections or portions of a section.

History.—s. 3, ch. 74-310; s. 1, ch. 76-207; s. 1, ch. 77-174; s. 57, ch. 78-95; s. 13, ch. 78-425; s. 38, ch. 96-159.

120.73Circuit court proceedings; declaratory judgments.—Nothing in this chapter shall be construed to repeal any provision of the Florida Statutes which grants the right to a proceeding in the circuit court in lieu of an administrative hearing or to divest the circuit courts of jurisdiction to render declaratory judgments under the provisions of chapter 86.

History.—s. 11, ch. 75-191; s. 14, ch. 78-425.

120.74Agency review, revision, and report.—

(1)Each agency shall review and revise its rules as often as necessary to ensure that its rules are correct and comply with statutory requirements. Additionally, each agency shall perform a formal review of its rules every 2 years. In the review, each agency must:

(a)Identify and correct deficiencies in its rules;

(b)Clarify and simplify its rules;

(c)Delete obsolete or unnecessary rules;

(d)Delete rules that are redundant of statutes;

(e)Seek to improve efficiency, reduce paperwork, or decrease costs to government and the private sector;

(f)Contact agencies that have concurrent or overlapping jurisdiction to determine whether their rules can be coordinated to promote efficiency, reduce paperwork, or decrease costs to government and the private sector; and

(g)Determine whether the rules should be continued without change or should be amended or repealed to reduce the impact on small business while meeting the stated objectives of the proposed rule.

(2)Beginning October 1, 1997, and by October 1 of every other year thereafter, the head of each agency shall file a report with the President of the Senate, the Speaker of the House of Representatives, and the committee, with a copy to each appropriate standing committee of the Legislature, which certifies that the agency has complied with the requirements of this section. The report must specify any changes made to its rules as a result of the review and, when appropriate, recommend statutory changes that will promote efficiency, reduce paperwork, or decrease costs to government and the private sector. The report must specifically address the economic impact of the rules on small business. The report must identify the types of cases or disputes in which the agency is involved which should be conducted under the summary hearing process described in s. 120.574.

(3)Beginning in 2012, and no later than July 1 of each year, each agency shall file with the President of the Senate, the Speaker of the House of Representatives, and the committee a regulatory plan identifying and describing each rule the agency proposes to adopt for the 12-month period beginning on the July 1 reporting

date and ending on the subsequent June 30, excluding emergency rules.

(4)For the year 2011, the certification required in subsection (2) may omit any information included in the reports provided under s. 120.745. Reporting under subsections (1) and (2) shall be suspended for the year 2013, but required reporting under those subsections shall resume in 2015 and biennially thereafter.

History.—s. 46, ch. 96-399; s. 16, ch. 97-176; s. 9, ch. 2006-82; s. 15, ch. 2008-104; s. 8, ch. 2008-149; s. 4, ch. 2011-225.

120.745Legislative review of agency rules in effect on or before November 16, 2010.—

(1)DEFINITIONS.—The following definitions apply exclusively to this section:

(a)"Agency" has the same meaning and application as provided in s. 120.52(1), but for the purposes of this section excludes each officer and governmental entity in the state with jurisdiction in one county or less than one county.

(b)"Compliance economic review" means a good faith economic analysis that includes and presents the following information pertaining to a particular rule:

1.A justification for the rule summarizing the benefits of the rule; and

2.A statement of estimated regulatory costs as described in s. 120.541(2); however:

a.The applicable period for the economic analysis shall be 5 years beginning on July 1, 2011;

b.For the analysis required in s. 120.541(2)(a)3., the estimated regulatory costs over the 5-year period shall be used instead of the likely increase in regulatory costs after implementation; and

c.An explanation of the methodology used to conduct the analysis must be provided. A technical methodology need not be used to develop the statement of estimated regulatory costs, if the agency uses routine regulatory communications or its Internet website to reasonably survey regulated entities, political subdivisions, and local governments and makes good faith estimates of regulatory costs in conformity with recommendations from the Office of Fiscal Accountability and Regulatory Reform ("OFARR"), or from one or more legislative offices if requested by the agency and such request is approved by the President of the Senate and the Speaker of the House of Representatives.

(c)"Data collection rules" means those rules requiring the submission of data to the agency from external sources, including, but not limited to, local governments, service providers, clients, licensees, regulated entities, other constituents, and market participants.

(d)"Revenue rules" means those rules fixing amounts or providing for the collection of money.

(e)"Rule" has the same general meaning and application as provided in s. 120.52(16), but for purposes of this section may include only those rules for which publication in the Florida Administrative Code is required pursuant to s. 120.55(1). As used in this section, the term "rule" means each entire statement and all subparts published under a complete title, chapter, and decimal rule number in the Florida Administrative Code in compliance with Florida Administrative Code Rule 1B-30.001.

(2)ENHANCED BIENNIAL REVIEW.—By December 1, 2011, each agency shall complete an enhanced biennial

review of the agency's existing rules, which shall include, but is not limited to:

(a)Conduct of the review and submission of the report required by s. 120.74 and an explanation of how the agency has accomplished the requirements of s. 120.74(1). This paragraph extends the October 1 deadline provided in s. 120.74(2) for the year 2011.

(b)Review of each rule to determine whether the rule has been reviewed by OFARR pursuant to the Governor's Executive Order 2011-01.

(c)Review of each rule to determine whether the rule is a revenue rule, to identify the statute or statutes authorizing the collection of any revenue, to identify the fund or account into which revenue collections are deposited, and, for each revenue rule, to determine whether the rule authorizes, imposes, or implements:

1.Registration, license, or inspection fees.

2.Transportation service tolls for road, bridge, rail, air, waterway, or port access.

3.Fees for a specific service or purpose not included in subparagraph 1. or subparagraph 2.

4.Fines, penalties, costs, or attorney fees.

5.Any tax.

6.Any other amounts collected that are not covered under subparagraphs 1.-5.

(d)Review of each rule to determine whether the rule is a data collection rule, providing the following information for each rule determined to be a data collection rule:

1.The statute or statutes authorizing the collection of such data.

2.The purposes for which the agency uses the data and any purpose for which the data is used by others.

3.The policies supporting the reporting and retention of the data.

4.Whether and to what extent the data is exempt from public inspection under chapter 119.

(e)Identification of each entire rule the agency plans to repeal and, if so, the estimated timetable for repeal.

(f)Identification of each entire rule or subpart of a rule the agency plans to amend to substantially reduce the economic impact and the estimated timetable for amendment.

(g)Identification of each rule for which the agency will be required to prepare a compliance economic review, to include each entire rule that:

1.The agency does not plan to repeal on or before December 31, 2012;

2.Was effective on or before November 16, 2010; and

3.Probably will have any of the economic impacts described in s. 120.541(2)(a), for 5 years beginning on July 1, 2011, excluding in such estimation any part or subpart identified for amendment under paragraph (f).

(h)Listing of all rules identified for compliance economic review in paragraph (g), divided into two approximately equal groups, identified as "Group 1" and "Group 2." Such division shall be made at the

agency's discretion.

(i)Written certification of the agency head to the committee verifying the completion of the report for all rules of the agency, including each separate part or subsection. The duty to certify completion of the report is the responsibility solely of the agency head as defined in s. 120.52(3) and may not be delegated to any other person. If the defined agency head is a collegial body, the written certification must be prepared by the chair or equivalent presiding officer of that body.

(3)PUBLICATION OF REPORT.—No later than December 1, 2011, each agency shall publish, in the manner provided in subsection (7), a report of the entire enhanced biennial review pursuant to subsection (2), including the results of the review; a complete list of all rules the agency has placed in Group 1 or Group 2; the name, physical address, fax number, and e-mail address for the person the agency has designated to receive all inquiries, public comments, and objections pertaining to the report; and the certification of the agency head pursuant to paragraph (2)(i). The report of results shall summarize certain information required in subsection (2) in a table consisting of the following columns:

(a)Column 1: Agency name.

(b)Column 2: F.A.C. rule number, with subcolumns including:

1.Column 2a: F.A.C. title and any subtitle or chapter designation; and

2.Column 2b: F.A.C. number, excluding title and subtitle or chapter designation.

(c)Column 3: OFARR reviewed rule under Executive Order 2011-01. Entries should be "Y" or "N."

(d)Column 4: Revenue rule/fund or account with subcolumns including:

1.Column 4a: Licensure fees.

2.Column 4b: Transportation tolls.

3.Column 4c: Other fees.

4.Column 4d: Fines.

5.Column 4e: Tax.

6.Column 4f: Other revenue.

Entries should be "N" or the identification of the fund or account where receipts are deposited and provide notes indicating the statutory authority for revenue collection.

(e)Column 5: Data collection rule. Entries should be "Y" or "N." If "Y," provide notes supplying the information required in paragraph (2)(d).

(f)Column 6: Repeal. Entries should be "Y" or "N" for the entire rule. If "Y," provide notes estimating the timetable for repeal.

(g)Column 7: Amend. Entries should be "Y" or "N," based on the response required in paragraph (2)(f), and provide notes identifying each specific subpart that will be amended and estimating the timetable for amendment.

(h)Column 8: Effective on or before 11/16/2010. Entries should be “Y” or “N.”

(i)Column 9: Section 120.541(2)(a) impacts. Entries should be “NA” if Column 8 is “N” or, if Column 6 is “Y,” “NP” for not probable, based on the response required in subparagraph (2)(g)3., or “1” or “2,” reflecting the group number assigned by the division required in paragraph (2)(h).

(4)PUBLIC COMMENT ON ENHANCED BIENNIAL REVIEW AND REPORT; OBJECTIONS.—Public input on reports required in subsection (3) may be provided by stating an objection to the information required in paragraphs (2)(b), (c), (d), and (g) and identifying the entire rule or any subpart to which the objection relates, and shall be submitted in writing or electronically to the person designated in the report.

(a)An objection under this subsection to a report that an entire rule or any subpart probably will not have, for 5 years beginning on July 1, 2011, any of the economic impacts described in s. 120.541(2)(a), must include allegations of fact upon which the objection is based, stating the precise information upon which a contrary evaluation of probable impact may be made. Allegations of fact related to other objections may be included.

(b)Objections may be submitted by any interested person no later than June 1, 2012.

(c)The agency shall determine whether to sustain an objection based upon the information provided with the objection and whether any further review of information available to the agency is necessary to correct its report.

(d)No later than 20 days after the date an objection is submitted, the agency shall publish its determination of the objection in the manner provided in subsection (7).

(e)The agency’s determination with respect to an objection is final but not a final agency action subject to further proceedings, hearing, or judicial review.

(f)If the agency sustains an objection, it shall amend its report within 10 days after the determination. The amended report shall indicate that a change has been made, the date of the last change, and identify the amended portions. The agency shall publish notice of the amendment in the manner provided in subsection (7).

(g)On or before July 1, 2012, the agency shall deliver a written certification of the agency head or designee to the committee verifying the completion of determinations of all objections under this subsection and of any report amendments required under paragraph (f). The certification shall be published as an addendum to the report required in subsection (3). Notice of the certification shall be published in the manner provided in subsection (7).

(5)COMPLIANCE ECONOMIC REVIEW OF RULES AND REQUIRED REPORT.—Each agency shall perform a compliance economic review and report for all rules, including separate reviews of subparts, listed under Group 1 “Group 1 rules” or Group 2 “Group 2 rules” pursuant to subparagraph (2)(g)3. Group 1 rules shall be reviewed and reported on in 2012, and Group 2 rules shall be reviewed and reported on in 2013.

(a)No later than May 1, each agency shall:

1.Complete a compliance economic review for each entire rule or subpart in the appropriate group.

2.File the written certification of the agency head with the committee verifying the completion of each compliance economic review required for the respective year. The certification shall be dated and published as an addendum to the report required in subsection (3). The duty to certify completion of the required compliance economic reviews is the responsibility solely of the agency head as defined in s. 120.52(3) and may not be delegated to any other person. If the defined agency head is a collegial body, the written certification must be prepared by the chair or equivalent presiding officer of that body.

3.Publish a copy of the compliance economic review, directions on how and when interested parties may submit lower cost regulatory alternatives to the agency, and the date the notice is published in the manner provided in subsection (7).

4.Publish notice of the publications required in subparagraphs 2. and 3. in the manner provided in subsection (7).

5.Submit each compliance economic review to the rules ombudsman in the Executive Office of the Governor for [1]the ombudsman's review.

(b)Any agency rule, including subparts, reviewed pursuant to Executive Order 2011-01 are exempt from the compliance economic review if the review found that the rule:

1.Does not unnecessarily restrict entry into a profession or occupation;

2.Does not adversely affect the availability of professional or occupational services to the public;

3.Does not unreasonably affect job creation or job retention;

4.Does not place unreasonable restrictions on individuals attempting to find employment;

5.Does not impose burdensome costs on businesses; or

6.Is justifiable when the overall cost-effectiveness and economic impact of the regulation, including indirect costs to consumers, is considered.

(c)No later than August 1, the rules ombudsman in the Executive Office of the Governor may submit lower cost regulatory alternatives to any rule to the agency that adopted the rule. No later than June 15, other interested parties may submit lower cost regulatory alternatives to any rule.

(d)No later than December 1, each agency shall publish a final report of the agency's review under this subsection in the manner provided in subsection (7). For each rule the report shall include:

1.The text of the rule.

2.The compliance economic review for the rule.

3.All lower regulatory cost alternatives received by the agency.

4.The agency's written explanation for rejecting submitted lower regulatory cost alternatives.

5.The agency's justification to repeal or amend the rule or to retain the rule without amendment.

6.The written certification of the agency head to the committee verifying the completion of the reviews and reporting required under this subsection for that year. The certification shall be dated and published as an addendum to the report required in subsection (3). The duty to certify completion of the report is the responsibility solely of the agency head as defined in s. 120.52(3) and may not be delegated to any other person. If the defined agency head is a collegial body, the written certification must be prepared by the chair or equivalent presiding officer of that body.

(e)Notice of publication of the final report and certification shall be published in the manner provided in subsection (7).

(f)By December 1, each agency shall begin proceedings under s. 120.54(3) to amend or repeal those rules so designated in the report under this subsection. Proceedings to repeal rules are exempt from the requirements for the preparation, consideration, or use of a statement of estimated regulatory costs under s. 120.54 and the provisions of s. 120.541.

(6)LEGISLATIVE CONSIDERATION.—With respect to a rule identified for retention without amendment in the report required in subsection (5), the Legislature may consider specific legislation nullifying the rule or altering the statutory authority for the rule.

(7)MANNER OF PUBLICATION OF NOTICES, DETERMINATIONS, AND REPORTS.—Agencies shall publish notices, determinations, and reports required under this section exclusively in the following manner:

(a)The agency shall publish each notice, determination, and complete report on its Internet website. If the agency does not have an Internet website, the information shall be published on the committee's Internet website using www.japc.state.fl.us/[agency name]/ in place of the address of the agency's Internet website. The following URL formats shall be used:

1.Reports required under subsection (3), including any reports amended as a result of a determination under subsection (4):

[Address of agency's Internet website]/2011_Rule_review/
[Florida Administrative Code (F.A.C.) title and subtitle (if applicable) designation for the rules included].

(Example: http://www.dos.state.fl.us/2011_Rule_review/1S).

2.The lists of Group 1 rules and Group 2 rules, required under subsection (3):

[Address of agency's Internet website]/2011_Rule_review/
Economic_Review/Schedule.

(Example: http://www.dos.state.fl.us/2011_Rule_review/
Economic_Review/Schedule).

3.Determinations under subsection (4):

[Address of agency's Internet website]/2011_Rule_review/
Objection_Determination/[F.A.C. Rule number].

(Example: http://www.dos.state.fl.us/2011_Rule_review/Objection_Determination/1S-1.001).

4.Completed compliance economic reviews reported under subsection (5):

[Address of agency's Internet website]/2011_Rule_review/Economic_Review/[F.A.C. Rule number].

(Example: http://www.dos.state.fl.us/2011_Rule_review/Economic_Review/1S-1.001).

5.Final reports under paragraph (5)(d), with the appropriate year:

[Address of agency's Internet website]/2011_Rule_review/Economic_Review/[YYYY_Final_Report].

(Example: http://www.dos.state.fl.us/2011_Rule_review/Economic_Review/2012_Final_Report).

(b)1.Each notice shall be published using the following URL format:

[Address of agency's Internet website]/2011_Rule_review/Notices.

(Example: http://www.dos.state.fl.us/2011_Rule_review/Notices).

2.Once each week a copy of all notices published in the previous week on the Internet under this paragraph shall be delivered to the Department of State, for publication in the next available issue of the Florida Administrative Weekly, and a copy shall be delivered by electronic mail to the committee.

3.Each notice shall identify the publication for which notice is being given and include:

a.The name of the agency.

b.The name, physical address, fax number, and e-mail address for the person designated to receive all inquiries, public comments, and objections pertaining to the publication identified in the notice.

c.The particular Internet address through which the publication may be accessed.

d.The date the notice and publication is first published on the agency's Internet website.

(c)Publication pursuant to this section is deemed to be complete as of the date the notice, determination, or report is posted on the agency's Internet website.

(8)FAILURE TO FILE CERTIFICATION OF COMPLETION.—If an agency fails to timely file any written certification required in paragraph (2)(i), paragraph (4)(g), subparagraph (5)(a)2., or subparagraph (5)(d)6., the entire rulemaking authority delegated to the agency by the Legislature under any statute or law shall be suspended automatically as of the due date of the required certification and shall remain suspended until the date that the agency files the required certification with the committee.

(a)During the period of any suspension under this subsection, the agency has no authority to engage in rulemaking under s. 120.54.

(b)A suspension under this subsection does not authorize an agency to promulgate any statement defined as a rule under s. 120.52(16).

(c)A suspension under this subsection shall toll the time requirements under s. 120.54 for any rulemaking proceeding the agency initiated before the date of suspension, which time requirements shall resume on the date the agency files the written certification with the committee and publishes notice of the required certification in the manner provided in subsection (7).

(d)Failure to timely file a written certification required under paragraph (2)(i) tolls the time for public response, which period shall not begin until the date the agency files the written certification with the committee and publishes notice of the required certification in the manner provided in subsection (7). The period for public response shall be extended by the number of days equivalent to the period of suspension under this subsection.

(e)Failure to timely file a written certification required under subparagraph (5)(a)2. shall toll the deadline for submission of lower cost regulatory alternatives for any rule or subpart for which a compliance economic review has not been timely published. The period of tolling shall be the number of days after May 1 until the date of the certification as published.

(9)EXEMPTION FROM ENHANCED BIENNIAL REVIEW AND COMPLIANCE ECONOMIC REVIEW.—

(a)An agency is exempt from subsections (1)-(8) if it has cooperated or cooperates with OFARR in a review of the agency's rules in a manner consistent with Executive Order 2011-01, or any alternative review directed by OFARR; if the agency or OFARR identifies each data collection rule and each revenue rule; and if the information developed thereby becomes publicly available on the Internet by December 1, 2011. Each such agency is exempt from the biennial review required in s. 120.74(2) for the year 2011.

(b)For each rule reviewed under this subsection, OFARR may identify whether the rule imposes a significant regulatory cost or economic impact and shall schedule and obtain or direct a reasonable economic estimate of such cost and impact for each rule so identified. A report on each such estimate shall be published on the Internet by December 31, 2013. On or before October 1, 2013, the agency head shall certify in writing to the committee that the agency has completed each economic estimate required under this paragraph, and thereupon the agency is exempt from the biennial review required in s. 120.74(2) for the year 2013.

(c)The exemption under this paragraph does not apply unless the agency head certifies in writing to the committee, on or before October 1, 2011, that the agency has chosen such exemption and has cooperated with OFARR in undertaking the review required in paragraph (a).

(10)REPEAL.—This section is repealed July 1, 2014.

History.—s. 5, ch. 2011-225; s. 10, ch. 2012-5; s. 3, ch. 2012-27.

[1]**Note.**—The words "the ombudsman's" were substituted by the editors for the word "its."

120.7455Legislative survey of regulatory impacts.—

(1)From July 1, 2011, until July 1, 2014, the Legislature may establish and maintain an Internet-based public survey of regulatory impact soliciting information from the public regarding the kind and degree of regulation affecting private activities in the state. The input may include, but need not be limited to:

(a)The registered business name or other name of each reporting person.

(b)The number and identity of agencies licensing, inspecting, registering, permitting, or otherwise regulating lawful activities of the reporting person.

(c)The types, numbers, and nature of licenses, permits, and registrations required for various lawful activities of the reporting person.

(d)The identity of local, state, and federal agencies, and other entities acting under color of law which regulate the lawful activities of the reporting person or otherwise exercise power to enforce laws applicable to such activities.

(e)The identification and nature of each ordinance, law, or administrative rule or regulation deemed unreasonably burdensome by the reporting person.

(2)The President of the Senate and the Speaker of the House of Representatives may certify in writing to the chair of the committee and to the Attorney General the establishment and identity of any Internet-based public survey established under this section.

(3)Any person reporting or otherwise providing information solicited by the Legislature in conformity with this section is immune from any enforcement action or prosecution that:

(a)Is instituted on account of, or in reliance upon, the fact of reporting or nonreporting of information in response to the Legislature's solicitation of information pursuant to this section; or

(b)Uses information provided in response to the Legislature's solicitation of information pursuant to this section.

(4)Any alleged violator against whom an enforcement action is brought may object to any proposed penalty in excess of the minimum provided by law or rule on the basis that the action is in retaliation for the violator providing or withholding any information in response to the Legislature's solicitation of information pursuant to this section. If the presiding judge determines that the enforcement action was motivated in whole or in part by retaliation, any penalty imposed is limited to the minimum penalties provided by law for each separate violation adjudicated.

History.—s. 6, ch. 2011-225.

120.80Exceptions and special requirements; agencies.—

(1)DIVISION OF ADMINISTRATIVE HEARINGS.—

(a)*Division as a party.*—Notwithstanding s. 120.57(1)(a), a hearing in which the division is a party may not be conducted by an administrative law judge assigned by the division. An attorney assigned by the Administration Commission shall be the hearing officer.

(b)*Workers' compensation.*—Notwithstanding s. 120.52(1), a judge of compensation claims, in adjudicating matters under chapter 440, is not an agency or part of an agency for purposes of this chapter.

(2)DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES.—

(a)Marketing orders under chapter 527, chapter 573, or chapter 601 are not rules.

(b)Notwithstanding s. 120.57(1)(a), hearings held by the Department of Agriculture and Consumer Services pursuant to chapter 601 need not be conducted by an administrative law judge assigned by the division.

(3)OFFICE OF FINANCIAL REGULATION.—

(a)Notwithstanding s. 120.60(1), in proceedings for the issuance, denial, renewal, or amendment of a license or approval of a merger pursuant to title XXXVIII:

1.a.The Office of Financial Regulation of the Financial Services Commission shall have published in the Florida Administrative Weekly notice of the application within 21 days after receipt.

b.Within 21 days after publication of notice, any person may request a hearing. Failure to request a hearing within 21 days after notice constitutes a waiver of any right to a hearing. The Office of Financial Regulation or an applicant may request a hearing at any time prior to the issuance of a final order. Hearings shall be conducted pursuant to ss. 120.569 and 120.57, except that the Financial Services Commission shall by rule provide for participation by the general public.

2.Should a hearing be requested as provided by sub-subparagraph 1.b., the applicant or licensee shall publish at its own cost a notice of the hearing in a newspaper of general circulation in the area affected by the application. The Financial Services Commission may by rule specify the format and size of the notice.

3.Notwithstanding s. 120.60(1), and except as provided in subparagraph 4., every application for license for a new bank, new trust company, new credit union, or new savings and loan association shall be approved or denied within 180 days after receipt of the original application or receipt of the timely requested additional information or correction of errors or omissions. Any application for such a license or for acquisition of such control which is not approved or denied within the 180-day period or within 30 days after conclusion of a public hearing on the application, whichever is later, shall be deemed approved subject to the satisfactory completion of conditions required by statute as a prerequisite to license and approval of insurance of accounts for a new bank, a new savings and loan association, or a new credit union by the appropriate insurer.

4.In the case of every application for license to establish a new bank, trust company, or capital stock savings association in which a foreign national proposes to own or control 10 percent or more of any class of voting securities, and in the case of every application by a foreign national for approval to acquire control of a bank, trust company, or capital stock savings association, the Office of Financial Regulation shall request that a public hearing be conducted pursuant to ss. 120.569 and 120.57. Notice of such hearing shall be published by

the applicant as provided in subparagraph 2. The failure of any such foreign national to appear personally at the hearing shall be grounds for denial of the application. Notwithstanding the provisions of s. 120.60(1) and subparagraph 3., every application involving a foreign national shall be approved or denied within 1 year after receipt of the original application or any timely requested additional information or the correction of any errors or omissions, or within 30 days after the conclusion of the public hearing on the application, whichever is later.

(b)In any application for a license or merger pursuant to title XXXVIII which is referred by the agency to the division for hearing, the administrative law judge shall complete and submit to the agency and to all parties a written report consisting of findings of fact and rulings on evidentiary matters. The agency shall allow each party at least 10 days in which to submit written exceptions to the report.

(4)DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION.—

(a)*Business regulation.*—The Division of Pari-mutuel Wagering is exempt from the hearing and notice requirements of ss. 120.569 and 120.57(1)(a), but only for stewards, judges, and boards of judges when the hearing is to be held for the purpose of the imposition of fines or suspensions as provided by rules of the Division of Pari-mutuel Wagering, but not for revocations, and only upon violations of subparagraphs 1.-6. The Division of Pari-mutuel Wagering shall adopt rules establishing alternative procedures, including a hearing upon reasonable notice, for the following violations:

1.Horse riding, harness riding, greyhound interference, and jai alai game actions in violation of chapter 550.

2.Application and usage of drugs and medication to horses, greyhounds, and jai alai players in violation of chapter 550.

3.Maintaining or possessing any device which could be used for the injection or other infusion of a prohibited drug to horses, greyhounds, and jai alai players in violation of chapter 550.

4.Suspensions under reciprocity agreements between the Division of Pari-mutuel Wagering and regulatory agencies of other states.

5.Assault or other crimes of violence on premises licensed for pari-mutuel wagering.

6.Prearranging the outcome of any race or game.

(b)*Professional regulation.*—Notwithstanding s. 120.57(1)(a), formal hearings may not be conducted by the Secretary of Business and Professional Regulation or a board or member of a board within the Department of Business and Professional Regulation for matters relating to the regulation of professions, as defined by chapter 455.

(5)FLORIDA LAND AND WATER ADJUDICATORY COMMISSION.—Notwithstanding the provisions of s. 120.57(1)(a), when the Florida Land and Water Adjudicatory Commission receives a notice of appeal pursuant to s. 380.07, the commission shall notify the division within 60 days after receipt of the notice of appeal if the

commission elects to request the assignment of an administrative law judge.

(6)DEPARTMENT OF LAW ENFORCEMENT.—Law enforcement policies and procedures of the Department of Law Enforcement which relate to the following are not rules as defined by this chapter:

(a)The collection, management, and dissemination of active criminal intelligence information and active criminal investigative information; management of criminal investigations; and management of undercover investigations and the selection, assignment, and fictitious identity of undercover personnel.

(b)The recruitment, management, identity, and remuneration of confidential informants or sources.

(c)Surveillance techniques, the selection of surveillance personnel, and electronic surveillance, including court-ordered and consensual interceptions of communication conducted pursuant to chapter 934.

(d)The safety and release of hostages.

(e)The provision of security and protection to public figures.

(f)The protection of witnesses.

(7)DEPARTMENT OF CHILDREN AND FAMILY SERVICES.—Notwithstanding s. 120.57(1)(a), hearings conducted within the Department of Children and Family Services in the execution of those social and economic programs administered by the former Division of Family Services of the former Department of Health and Rehabilitative Services prior to the reorganization effected by chapter 75-48, Laws of Florida, need not be conducted by an administrative law judge assigned by the division.

(8)DEPARTMENT OF HIGHWAY SAFETY AND MOTOR VEHICLES.—

(a)*Drivers' licenses.*—

1.Notwithstanding s. 120.57(1)(a), hearings regarding drivers' licensing pursuant to chapter 322 need not be conducted by an administrative law judge assigned by the division.

2.Notwithstanding s. 120.60(5), cancellation, suspension, or revocation of a driver's license shall be by personal delivery to the licensee or by first-class mail as provided in s. 322.251.

(b)*Wrecker operators.*—Notwithstanding s. 120.57(1)(a), hearings held by the Division of the Florida Highway Patrol of the Department of Highway Safety and Motor Vehicles to deny, suspend, or remove a wrecker operator from participating in the wrecker rotation system established by s. 321.051 need not be conducted by an administrative law judge assigned by the division. These hearings shall be held by a hearing officer appointed by the director of the Division of the Florida Highway Patrol.

(9)OFFICE OF INSURANCE REGULATION.—Notwithstanding s. 120.60(1), every application for a certificate of authority as required by s. 624.401 shall be approved or denied within 180 days after receipt of the original application. Any application for a certificate of authority which is not approved or denied within the 180-day period, or within 30 days after conclusion of a public hearing held on the application, shall be deemed approved, subject to the satisfactory completion of conditions required by statute as a prerequisite to licensure.

(10)DEPARTMENT OF ECONOMIC OPPORTUNITY.—

(a)Notwithstanding s. 120.54, the rulemaking provisions of this chapter do not apply to reemployment assistance appeals referees.

(b)Notwithstanding s. 120.54(5), the uniform rules of procedure do not apply to appeal proceedings conducted under chapter 443 by the Reemployment Assistance Appeals Commission, special deputies, or reemployment assistance appeals referees.

(c)Notwithstanding s. 120.57(1)(a), hearings under chapter 443 may not be conducted by an administrative law judge assigned by the division, but instead shall be conducted by the Reemployment Assistance Appeals Commission in reemployment assistance appeals, reemployment assistance appeals referees, and the Department of Economic Opportunity or its special deputies under s. 443.141.

(11)NATIONAL GUARD.—Notwithstanding s. 120.52(16), the enlistment, organization, administration, equipment, maintenance, training, and discipline of the militia, National Guard, organized militia, and unorganized militia, as provided by s. 2, Art. X of the State Constitution, are not rules as defined by this chapter.

(12)PUBLIC EMPLOYEES RELATIONS COMMISSION.—

(a)Notwithstanding s. 120.57(1)(a), hearings within the jurisdiction of the Public Employees Relations Commission need not be conducted by an administrative law judge assigned by the division.

(b)Section 120.60 does not apply to certification of employee organizations pursuant to s. 447.307.

(13)FLORIDA PUBLIC SERVICE COMMISSION.—

(a)Agency statements that relate to cost-recovery clauses, factors, or mechanisms implemented pursuant to chapter 366, relating to public utilities, are exempt from the provisions of s. 120.54(1)(a).

(b)Notwithstanding ss. 120.569 and 120.57, a hearing on an objection to proposed action of the Florida Public Service Commission may only address the issues in dispute. Issues in the proposed action which are not in dispute are deemed stipulated.

(c)The Florida Public Service Commission is exempt from the time limitations in s. 120.60(1) when issuing a license.

(d)Notwithstanding the provisions of this chapter, in implementing the Telecommunications Act of 1996, Pub. L. No. 104-104, the Public Service Commission is authorized to employ procedures consistent with that act.

(e)Notwithstanding the provisions of this chapter, s. 350.128, or s. 364.381, appellate jurisdiction for Public Service Commission decisions that implement the Telecommunications Act of 1996, Pub. L. No. 104-104, shall be consistent with the provisions of that act.

(f)Notwithstanding any provision of this chapter, all public utilities and companies regulated by the Public Service Commission shall be entitled to proceed under the interim rate provisions of chapter 364 or the

procedures for interim rates contained in chapter 74-195, Laws of Florida, or as otherwise provided by law.

(14)DEPARTMENT OF REVENUE.—

(a)*Assessments.*—An assessment of tax, penalty, or interest by the Department of Revenue is not a final order as defined by this chapter. Assessments by the Department of Revenue shall be deemed final as provided in the statutes and rules governing the assessment and collection of taxes.

(b)*Taxpayer contest proceedings.*—

1.In any administrative proceeding brought pursuant to this chapter as authorized by s. 72.011(1), the taxpayer shall be designated the "petitioner" and the Department of Revenue shall be designated the "respondent," except that for actions contesting an assessment or denial of refund under chapter 207, the Department of Highway Safety and Motor Vehicles shall be designated the "respondent," and for actions contesting an assessment or denial of refund under chapters 210, 550, 561, 562, 563, 564, and 565, the Department of Business and Professional Regulation shall be designated the "respondent."

2.In any such administrative proceeding, the applicable department's burden of proof, except as otherwise specifically provided by general law, shall be limited to a showing that an assessment has been made against the taxpayer and the factual and legal grounds upon which the applicable department made the assessment.

3.a.Prior to filing a petition under this chapter, the taxpayer shall pay to the applicable department the amount of taxes, penalties, and accrued interest assessed by that department which are not being contested by the taxpayer. Failure to pay the uncontested amount shall result in the dismissal of the action and imposition of an additional penalty of 25 percent of the amount taxed.

b.The requirements of s. 72.011(2) and (3)(a) are jurisdictional for any action under this chapter to contest an assessment or denial of refund by the Department of Revenue, the Department of Highway Safety and Motor Vehicles, or the Department of Business and Professional Regulation.

4.Except as provided in s. 220.719, further collection and enforcement of the contested amount of an assessment for nonpayment or underpayment of any tax, interest, or penalty shall be stayed beginning on the date a petition is filed. Upon entry of a final order, an agency may resume collection and enforcement action.

5.The prevailing party, in a proceeding under ss. 120.569 and 120.57 authorized by s. 72.011(1), may recover all legal costs incurred in such proceeding, including reasonable attorney's fees, if the losing party fails to raise a justiciable issue of law or fact in its petition or response.

6.Upon review pursuant to s. 120.68 of final agency action concerning an assessment of tax, penalty, or interest with respect to a tax imposed under chapter 212, or the denial of a refund of any tax imposed under chapter 212, if the court finds that the Department of Revenue improperly rejected or modified a conclusion of law, the court may award reasonable attorney's fees and reasonable costs of the appeal to the prevailing appellant.

(c)*Proceedings to establish paternity or paternity and child support; orders to appear for genetic testing; proceedings for administrative support orders.*—In proceedings to establish paternity or paternity and child support pursuant to s. 409.256 and proceedings for the establishment of administrative support orders pursuant to s. 409.2563, final orders in cases referred by the Department of Revenue to the Division of Administrative Hearings shall be entered by the division's administrative law judge and transmitted to the Department of Revenue for filing and rendering. The Department of Revenue has the right to seek judicial review under s. 120.68 of a final order entered by an administrative law judge. The Department of Revenue or the person ordered to appear for genetic testing may seek immediate judicial review under s. 120.68 of an order issued by an administrative law judge pursuant to s. 409.256(5)(b). Final orders that adjudicate paternity or paternity and child support pursuant to s. 409.256 and administrative support orders rendered pursuant to s. 409.2563 may be enforced pursuant to s. 120.69 or, alternatively, by any method prescribed by law for the enforcement of judicial support orders, except contempt. Hearings held by the Division of Administrative Hearings pursuant to ss. 409.256, 409.2563, and 409.25635 shall be held in the judicial circuit where the person receiving services under Title IV-D resides or, if the person receiving services under Title IV-D does not reside in this state, in the judicial circuit where the respondent resides. If the department and the respondent agree, the hearing may be held in another location. If ordered by the administrative law judge, the hearing may be conducted telephonically or by videoconference.

(15)DEPARTMENT OF HEALTH.—Notwithstanding s. 120.57(1)(a), formal hearings may not be conducted by the State Surgeon General, the Secretary of Health Care Administration, or a board or member of a board within the Department of Health or the Agency for Health Care Administration for matters relating to the regulation of professions, as defined by chapter 456. Notwithstanding s. 120.57(1)(a), hearings conducted within the Department of Health in execution of the Special Supplemental Nutrition Program for Women, Infants, and Children; Child Care Food Program; Children's Medical Services Program; the Brain and Spinal Cord Injury Program; and the exemption from disqualification reviews for certified nurse assistants program need not be conducted by an administrative law judge assigned by the division. The Department of Health may contract with the Department of Children and Family Services for a hearing officer in these matters.

(16)FLORIDA BUILDING COMMISSION.—

(a)Notwithstanding the provisions of s. 120.542, the Florida Building Commission may not accept a petition for waiver or variance and may not grant any waiver or variance from the requirements of the Florida Building Code.

(b)The Florida Building Commission shall adopt within the Florida Building Code criteria and procedures for alternative means of compliance with the code or local amendments thereto, for enforcement by local governments, local enforcement districts, or other entities authorized by law to enforce the Florida Building Code. Appeals from the denial of the use of alternative means shall be heard by the local board, if one exists,

and may be appealed to the Florida Building Commission.

(c)Notwithstanding ss. 120.565, 120.569, and 120.57, the Florida Building Commission and hearing officer panels appointed by the commission in accordance with s. 553.775(3)(c)1. may conduct proceedings to review decisions of local building code officials in accordance with s. 553.775(3)(c).

(d)Section 120.541(3) does not apply to the adoption of amendments and the triennial update to the Florida Building Code expressly authorized by s. 553.73.

(17)STATE FIRE MARSHAL.—Section 120.541(3) does not apply to the adoption of amendments and the triennial update to the Florida Fire Prevention Code expressly authorized by s. 633.0215.

(18)DEPARTMENT OF TRANSPORTATION.—Sections 120.54(3)(b) and 120.541 do not apply to the adjustment of tolls pursuant to s. 338.165(3).

History.—s. 41, ch. 96-159; s. 13, ch. 98-166; s. 10, ch. 99-8; s. 4, ch. 99-397; s. 1, ch. 2000-141; s. 17, ch. 2000-151; s. 2, ch. 2000-160; s. 11, ch. 2000-304; s. 4, ch. 2000-305; ss. 2, 11, ch. 2000-312; s. 4, ch. 2000-355; s. 3, ch. 2000-367; s. 18, ch. 2001-158; s. 2, ch. 2001-279; s. 8, ch. 2002-173; s. 1, ch. 2002-239; s. 3, ch. 2003-36; s. 139, ch. 2003-261; s. 1, ch. 2004-52; s. 7, ch. 2004-334; ss. 12, 13, ch. 2005-39; s. 1, ch. 2005-96; s. 13, ch. 2005-147; s. 1, ch. 2005-209; s. 5, ch. 2006-45; s. 9, ch. 2008-6; s. 16, ch. 2008-104; s. 5, ch. 2009-187; s. 1, ch. 2011-64; s. 50, ch. 2011-142; s. 8, ch. 2011-225; s. 43, ch. 2012-30.

120.81Exceptions and special requirements; general areas.—

(1)EDUCATIONAL UNITS.—

(a)Notwithstanding s. 120.536(1) and the flush left provisions of s. 120.52(8), district school boards may adopt rules to implement their general powers under s. 1001.41.

(b)The preparation or modification of curricula by an educational unit is not a rule as defined by this chapter.

(c)Notwithstanding s. 120.52(16), any tests, test scoring criteria, or testing procedures relating to student assessment which are developed or administered by the Department of Education pursuant to s. 1003.43, s. 1003.438, s. 1008.22, or s. 1008.25, or any other statewide educational tests required by law, are not rules.

(d)Notwithstanding any other provision of this chapter, educational units shall not be required to include the full text of the rule or rule amendment in notices relating to rules and need not publish these or other notices in the Florida Administrative Weekly, but notice shall be made:

1.By publication in a newspaper of general circulation in the affected area;

2.By mail to all persons who have made requests of the educational unit for advance notice of its proceedings and to organizations representing persons affected by the proposed rule; and

3.By posting in appropriate places so that those particular classes of persons to whom the intended action is directed may be duly notified.

(e)Educational units, other than the Florida School for the Deaf and the Blind, shall not be required to

make filings with the committee of the documents required to be filed by s. 120.54 or s. 120.55(1)(a)4.

(f)Notwithstanding s. 120.57(1)(a), hearings which involve student disciplinary suspensions or expulsions may be conducted by educational units.

(g)Sections 120.569 and 120.57 do not apply to any proceeding in which the substantial interests of a student are determined by a state university or a community college.

(h)Notwithstanding ss. 120.569 and 120.57, in a hearing involving a student disciplinary suspension or expulsion conducted by an educational unit, the 14-day notice of hearing requirement may be waived by the agency head or the hearing officer without the consent of parties.

(i)For purposes of s. 120.68, a district school board whose decision is reviewed under the provisions of s. 1012.33 and whose final action is modified by a superior administrative decision shall be a party entitled to judicial review of the final action.

(j)Notwithstanding s. 120.525(2), the agenda for a special meeting of a district school board under authority of s. 1001.372(1) shall be prepared upon the calling of the meeting, but not less than 48 hours prior to the meeting.

(k)Students are not persons subject to regulation for the purposes of petitioning for a variance or waiver to rules of educational units under s. 120.542.

(l)Sections 120.54(3)(b) and 120.541 do not apply to the adoption of rules pursuant to s. 1012.22, s. 1012.27, s. 1012.335, s. 1012.34, or s. 1012.795.

(2)LOCAL UNITS OF GOVERNMENT.—

(a)Local units of government with jurisdiction in only one county or part thereof shall not be required to make filings with the committee of the documents required to be filed by s. 120.54.

(b)Notwithstanding any other provision of this chapter, units of government with jurisdiction in only one county or part thereof need not publish required notices in the Florida Administrative Weekly, but shall publish these notices in the manner required by their enabling acts for notice of rulemaking or notice of meeting. Notices relating to rules are not required to include the full text of the rule or rule amendment.

(3)PRISONERS AND PAROLEES.—

(a)Notwithstanding s. 120.52(13), prisoners, as defined by s. 944.02, shall not be considered parties in any proceedings other than those under s. 120.54(3)(c) or (7), and may not seek judicial review under s. 120.68 of any other agency action. Prisoners are not eligible to seek an administrative determination of an agency statement under s. 120.56(4). Parolees shall not be considered parties for purposes of agency action or judicial review when the proceedings relate to the rescission or revocation of parole.

(b)Notwithstanding s. 120.54(3)(c), prisoners, as defined by s. 944.02, may be limited by the Department of Corrections to an opportunity to present evidence and argument on issues under consideration by submission of written statements concerning intended action on any department rule.

(c)Notwithstanding ss. 120.569 and 120.57, in a preliminary hearing for revocation of parole, no less than 7 days' notice of hearing shall be given.

(4)REGULATION OF PROFESSIONS.—Notwithstanding s. 120.569(2)(g), in a proceeding against a licensed professional or in a proceeding for licensure of an applicant for professional licensure which involves allegations of sexual misconduct:

(a)The testimony of the victim of the sexual misconduct need not be corroborated.

(b)Specific instances of prior consensual sexual activity between the victim of the sexual misconduct and any person other than the offender is inadmissible, unless:

1.It is first established to the administrative law judge in a proceeding in camera that the victim of the sexual misconduct is mistaken as to the identity of the perpetrator of the sexual misconduct; or

2.If consent by the victim of the sexual misconduct is at issue and it is first established to the administrative law judge in a proceeding in camera that such evidence tends to establish a pattern of conduct or behavior on the part of such victim which is so similar to the conduct or behavior in the case that it is relevant to the issue of consent.

(c)Reputation evidence relating to the prior sexual conduct of a victim of sexual misconduct is inadmissible.

(5)HUNTING AND FISHING REGULATION.—Agency action which has the effect of altering established hunting or fishing seasons, or altering established annual harvest limits for saltwater fishing if the procedure for altering such harvest limits is set out by rule of the Fish and Wildlife Conservation Commission, is not a rule as defined by this chapter, provided such action is adequately noticed in the area affected through publishing in a newspaper of general circulation or through notice by broadcasting by electronic media.

(6)RISK IMPACT STATEMENT.—The Department of Environmental Protection shall prepare a risk impact statement for any rule that is proposed for approval by the Environmental Regulation Commission and that establishes or changes standards or criteria based on impacts to or effects upon human health. The Department of Agriculture and Consumer Services shall prepare a risk impact statement for any rule that is proposed for adoption that establishes standards or criteria based on impacts to or effects upon human health.

(a)This subsection does not apply to rules adopted pursuant to federally delegated or mandated programs where such rules are identical or substantially identical to the federal regulations or laws being adopted or implemented by the Department of Environmental Protection or Department of Agriculture and Consumer Services, as applicable. However, the Department of Environmental Protection and the Department of Agriculture and Consumer Services shall identify any risk analysis information available to them from the Federal Government that has formed the basis of such a rule.

(b)This subsection does not apply to emergency rules adopted pursuant to this chapter.

(c)The Department of Environmental Protection and the Department of Agriculture and Consumer Services shall prepare and publish notice of the availability of a clear and concise risk impact statement for all applicable rules. The risk impact statement must explain the risk to the public health addressed by the rule and shall identify and summarize the source of the scientific information used in evaluating that risk.

(d)Nothing in this subsection shall be construed to create a new cause of action or basis for challenging a rule nor diminish any existing cause of action or basis for challenging a rule.

History.—s. 42, ch. 96-159; s. 17, ch. 97-176; s. 49, ch. 99-2; s. 65, ch. 99-245; s. 7, ch. 99-379; s. 28, ch. 99-398; s. 4, ch. 2000-214; s. 897, ch. 2002-387; s. 17, ch. 2008-104; s. 4, ch. 2010-78; s. 9, ch. 2011-225.

CHAPTER 64B16-25
ORGANIZATION AND PURPOSE

64B16-25.130 Executive Director (Repealed)
64B16-25.170 Probable Cause Panel
64B16-25.340 Meetings and Workshops

64B16-25.130 Executive Director.

Rulemaking Authority 465.005 FS. Law Implemented 48.111(2), 456.004, 456.009 FS. History–New 10-17-79, Formerly 21S-8.04, 21S-8.004, Amended 7-30-91, Formerly 21S-25.130, 61F10-25.130, 59X-25.130, Amended 10-29-97, 11-2-03, Repealed 3-28-12.

64B16-25.170 Probable Cause Panel.

(1) The determination as to whether probable cause exists to believe that a violation of Chapter 456, Part II, 465, 499, or 893, F.S., or of the rules promulgated thereunder, has occurred shall be made by the probable cause panel. The panel shall meet as necessary.

(2) The probable cause panel shall be composed of two (2) persons, either current or former board members appointed by the chairman of the Board. One appointee must be a current board member. The panel must include a former or current board member who is a licensed pharmacist. An appointee may be a former board member.

Rulemaking Authority 465.005 FS. Law Implemented 456.073 FS. History–New 10-17-79, Formerly 21S-8.08, 21S-8.008, 21S-25.170, 61F10-25.170, 59X-25.170, Amended 11-24-09.

64B16-25.340 Meetings and Workshops.

The following are considered to be official meetings of the Board:

(1) Board Meetings.

(2) Examination Committee Meetings.

(3) Tripartite Continuing Education Committee Meeting.

(4) Meetings of committees set out in the official minutes of the Board where statutory authority is given by the practice act.

(5) Meetings of a Board member with Department staff or contractors of the Department at the Department's or Board's request. Any participation or meeting of members noticed or unnoticed will be on file in the Board office.

(6) Where a Board member has been requested by the State Surgeon General to participate in a meeting.

(7) Probable Cause Panel meetings.

(8) All activity of Board members, if authorized by the Board, when grading, proctoring or reviewing examinations given by the Department.

(9) All participation in Board authorized meetings with professional associations of which the Board is a member or invitee. This would include all meetings of the National Association of Boards of Pharmacy of which the Board is a member as well as Board authorized participation in meetings of national or professional associations or organizations involved in educating, regulating and reviewing the profession over which the Board has statutory authority.

(10) Any and all other activities which are Board approved and which are necessary for Board members to attend in order to further protect the public health, safety and welfare, through the regulation of which the Board has statutory authority.

Rulemaking Authority 456.011(4) FS. Law Implemented 456.011(4) FS. History–New 9-30-81, Amended 11-13-81, 12-31-81, Formerly 21S-10.05, 21S-10.005, Amended 7-30-91, Formerly 21S-25.340, 61F10-25.340, 59X-25.340, Amended 2-18-08.

CHAPTER 64B16-26
PHARMACISTS LICENSURE

64B16-26.100 Pharmacists Newly Licensed (Repealed)
64B16-26.101 Fees and License Renewal Application
64B16-26.1001 Examination and Application Fees
64B16-26.1002 Initial License Fees
64B16-26.1003 Active License Renewal Fees
64B16-26.1004 Inactive License Election; Renewal; Fees
64B16-26.1005 Retired License Election; Renewal; Fees.
64B16-26.1012 Approved Continuing Education Provider Renewal Fee
64B16-26.102 Inactive License Renewal (Repealed)
64B16-26.1021 Delinquent License Reversion; Reinstatement; Fees
64B16-26.1022 Permit Fees
64B16-26.103 Continuing Education Credits; Renewal
64B16-26.1031 Influenza Immunization Certification Program
64B16-26.1032 Influenza Immunization Administration Certification Application
64B16-26.104 Exemptions for Members of the Armed Forces; Spouses
64B16-26.105 Consultant Pharmacists Initial Registration Fee and Renewal Fee (Repealed)
64B16-26.106 Nuclear Pharmacists Initial Registration Fee and Renewal Fee (Repealed)
64B16-26.107 Inactive Nuclear Pharmacist License Renewal (Repealed)
64B16-26.200 Examination Requirements
64B16-26.201 Reexamination (Repealed)
64B16-26.202 Examination Review Procedure (Repealed)
64B16-26.203 Licensure by Examination; Application
64B16-26.2031 Licensure by Examination; Foreign Pharmacy Graduates
64B16-26.2032 Pharmacy Intern Registration Internship Requirements (U.S. Pharmacy Students/Graduates)
64B16-26.2033 Pharmacy Intern Registration and Internship Requirements (Foreign Pharmacy Graduates)
64B16-26.2035 Examination Fees (Repealed)
64B16-26.204 Licensure by Endorsement
64B16-26.205 Requirements for Foreign Pharmacy Graduates to Be Admitted to the Pharmacist Licensure Examination (Repealed)
64B16-26.300 Consultant Pharmacist Licensure
64B16-26.301 Subject Matter for Consultant Pharmacist Training Program
64B16-26.302 Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education
64B16-26.303 Nuclear Pharmacist Licensure
64B16-26.304 Subject Matter for Nuclear Pharmacist License Renewal Continuing Education Programs
64B16-26.320 Subject Matter for Continuing Education to Order and Evaluate Laboratory Tests
64B16-26.350 Requirements for Pharmacy Technician Registration
64B16-26.351 Standards for Approval of Registered Pharmacy Technician Training Programs
64B16-26.355 Subject Matter for Registered Pharmacy Technician Continuing Education
64B16-26.400 Pharmacy Interns; Registration; Employment
64B16-26.401 Requirements for an Internship Program Sufficient to Qualify an Applicant for Licensure by Examination (Repealed)
64B16-26.600 Tripartite Continuing Education Committee
64B16-26.601 Standards for Approval of Courses and Providers
64B16-26.6012 Guidelines for Board Ordered Disciplinary Continuing Education Courses
64B16-26.603 Continuing Education Records Requirements
64B16-26.602 Recommendation by the Tripartite Continuing Education Committee (Repealed)
64B16-26.606 Number of Required Hours (Repealed)

64B16-26.100 Pharmacists Newly Licensed.

Rulemaking Authority 456.013(2), 465.005 FS. Law Implemented 456.013(2), 465.008 FS. History–New 3-19-79, Formerly 21S-6.04, Amended 1-7-87, 12-29-88, 10-16-90, Formerly 21S-6.004, Amended 1-10-93, Formerly 21S-26.100, 61F10-26.100, 59X-26.100, Amended 4-17-01, Repealed 3-10-05.

64B16-26.101 Fees and License Renewal Application.

Rulemaking Authority 465.005 FS. Law Implemented 456.036, 456.064, 465.008 FS. History–New 3-19-79, Formerly 21S-6.05, Amended 1-7-87, 4-21-87, 12-29-88, Formerly 21S-6.005, Amended 7-31-91, 1-10-93, Formerly 21S-26.101, 61F10-26.101, Amended 3-10-96, Formerly 59X-26.101, Amended 12-31-97, 12-3-00, 3-18-01, 10-15-01, Repealed 3-10-05.

64B16-26.1001 Examination and Application Fees.

(1) The non-refundable examination fee for licensure by examination shall be $100, payable to the Board. Examination fees for the National Practice Examination and jurisprudence examination are payable to the examination vendor.

(2) The non-refundable application fee licensure by endorsement shall be $100, payable to the Board.

(3) The non-refundable application fee for a continuing education provider seeking approved provider status shall be $150, payable to the Board.

(4) The non-refundable application fee for the Influenza Immunization Certification shall be $55, payable to the Board.

(5) The non-refundable application fee for registered pharmacy technicians shall be $50, payable to the Board.

Rulemaking Authority 465.005, 465.009 FS. Law Implemented 456.025(7), 465.007, 465.0075, 465.009, 465.014 FS. History–New 1-11-05, Amended 10-30-07, 11-15-09, 7-7-10.

64B16-26.1002 Initial License Fees.

(1) The initial license fee for a pharmacist license shall be $190 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(2) The initial license fee for a consultant pharmacist license shall be $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(3) The initial license fee for a nuclear pharmacist license shall be $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(4) The initial registration fee for a registered pharmacy technician shall be $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

Rulemaking Authority 465.005, 465.0125, 465.0126 FS. Law Implemented 456.013(2), 456.065(3), 465.0125, 465.0126, 465.014 FS. History–New 1-11-05, Amended 11-24-09.

64B16-26.1003 Active License Renewal Fees.

(1) The biennial license renewal fee for an active pharmacist license shall be $200 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(2) The biennial license renewal fee for a consultant pharmacist active license shall be $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(3) The biennial license renewal fee for a nuclear pharmacist active license shall be $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(4) The biennial registration renewal fee for a registered pharmacy technician shall be $50 plus $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

Rulemaking Authority 456.036, 465.005, 465.008, 465.0125, 465.0126 FS. Law Implemented 456.036, 456.065(3), 465.008, 465.0125, 465.0126, 465.014 FS. History–New 1-11-05, Amended 2-24-10, 2-1-12.

64B16-26.1004 Inactive License Election; Renewal; Fees.

(1) A pharmacist licensee may elect:

(a) At the time of license renewal to place the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $245 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $245 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status, submits the reactivation fee of $70, and the current active renewal fee set forth in Rule 64B16-26.1001, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status and submits the reactivation fee of $70, a change of status fee of $25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(2) A consultant pharmacist licensee may elect:

(a) At the time of license renewal to place the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the consultant pharmacist license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status consultant pharmacist license to active status, provided the consultant pharmacist licensee meets the continuing education requirements of subsection 64B16-26.103(2), F.A.C., for each biennium the license was on inactive status and by submitting a reactivation fee of $25, and the active consultant pharmacist renewal fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status, and submits the reactivation fee of $25, a change of status fee of $25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(3) A nuclear pharmacist licensee may elect:

(a) At the time of license renewal to place the nuclear pharmacist license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the nuclear pharmacist license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status license to active status, provided the nuclear pharmacist meets the continuing education requirements of Rule 64B16-26.304, F.A.C., for each biennium the license was on inactive status, and by submitting a reactivation fee of $50, and the active nuclear license renewal fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the nuclear pharmacist licensee meets the continuing education requirements of Rule 64B16-26.304, F.A.C., for each biennium the license was on inactive status and by submitting a reactivation fee of $50, a change of status fee of $25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(4) A registered pharmacy technician may elect:

(a) At the time of renewal to place the registered pharmacy technician registration on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of renewal, if the registered pharmacy technician registration is inactive, to continue the registration on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of renewal to change the inactive status registration to active status, provided the registered pharmacy technician meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the registration was on inactive status, and by submitting a reactivation fee of $50, and the active registration fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than renewal to change the inactive status registration to active status, provided the registered pharmacy technician meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the registration was on inactive status and by submitting a reactivation fee of $50, a change of status fee of $25 and the difference between the inactive

status renewal fee and the active status renewal fee, if any exists.

Rulemaking Authority 456.036, 465.005, 465.012, 465.0125, 465.0126 FS. Law Implemented 456.036, 456.065(3), 465.012, 465.0125, 465.0126 FS. History–New 1-11-05, Amended 10-30-07, 10-27-09.

64B16-26.1005 Retired License Election; Renewal; Fees.

(1) A licensee may elect to place his or her license on retired status.

(a) At the time of license renewal, to place the license on retired status, the licensee must submit a written request with the board for retired status and submit the retired status fee of $50.00 pursuant to Section 456.036(4)(b), F.S., and the current unlicensed activity fee.

(b) At a time other than license renewal, to place the license on retired status, the licensee must submit a written request to the Board for the retired status plus submit the retired status fee of $50.00 pursuant to Section 456.036(4)(b), F.S., plus a change of status fee of $25.00, plus the current unlicensed activity fee.

(c) Before the license of a retired status licensee is reactivated, the licensee must meet the continuing education requirements in Rule 64B16-26.103, F.A.C., and pay any renewal fees imposed on an active status licensee for all biennial licensure periods, plus the current unlicensed activity fee during which the licensee was on retired status.

(2) Any pharmacist applying for an active status license who has been on retired status for 5 years or more, or if licensed elsewhere, has not been active during the past 5 years, shall as a condition of licensure, demonstrate that he or she is able to practice with the care and skill sufficient to protect the health, safety, and welfare of the public by:

(a) If inactive for less than 5 years, the licensee must pass a jurisprudence examination;

(b) If inactive for 5 or more years, in addition to paragraph (a), the licensee must pass the NAPLEX.

Rulemaking Authority 456.036(15) FS. Law Implemented 456.013, 456.036(4)(b) FS. History–New 11-29-06, Amended 12-22-09.

64B16-26.1012 Approved Continuing Education Provider Renewal Fee.

The biennial fee to renew as an approved continuing education provider shall be $150.

Rulemaking Authority 456.013(9), 465.005 FS. Law Implemented 456.013(9), 465.009, 465.012 FS. History–New 1-11-05.

64B16-26.1021 Delinquent License Reversion; Reinstatement; Fees.

(1) An active or inactive license that is not renewed by midnight of the expiration date of the license shall automatically revert to delinquent status.

(2) A pharmacist may request that a delinquent license be reinstated to active or inactive status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status, and by submitting a reactivation fee of $100 plus the current fee for an active status or inactive status license set forth in Rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(3) A consultant pharmacist may request that a delinquent consultant pharmacist license be reinstated to an active or inactive status by submitting a delinquent fee of $100 plus the current fee for an active or inactive status consultant pharmacist license set forth in Rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(4) A nuclear pharmacist may request that a delinquent nuclear pharmacist license be reinstated to an active or inactive license status by submitting a delinquent fee of $100 plus the current fee for an active or inactive nuclear pharmacist license set forth in Rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(5) A registered pharmacy technician may request that a delinquent registered pharmacy technician registration be reinstated to an active or inactive status provided the registered pharmacy technician meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the registration was on inactive status, and by submitting a reactivation fee of $25 plus the current fee for an active or inactive status registered pharmacy technician registration set forth in Rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(6) A license in delinquent status that is not renewed prior to midnight of the expiration date of the current licensure cycle shall be rendered null without any further action by the Department. Any subsequent license shall be the result of applying for and meeting all requirements imposed on an applicant for new licensure.

Rulemaking Authority 456.036, 465.005, 465.012 FS. Law Implemented 456.036, 465.012 FS. History–New 1-11-05, Amended 10-27-09.

64B16-26.102 Inactive License Renewal.

Rulemaking Authority 465.005 FS. Law Implemented 465.008, 465.012 FS. History–New 3-19-79, Formerly 21S-6.06, Amended 1-7-87, 12-29-88, Formerly 21S-6.006, Amended 7-31-91, 1-10-93, Formerly 21S-26.102, 61F10-26.102, Amended 3-10-96, Formerly 59X-26.102, Amended 3-18-01, Repealed 3-10-05.

64B16-26.1022 Permit Fees.

(1) The initial permit fee for a pharmacy, as provided by Section 465.022(8)(a), F.S., shall be $250.

(2) The biennial permit renewal fee for a pharmacy, as provided by Section 465.022(8)(b), F.S., shall be $250.

(3) The change of location fee for a pharmacy, as provided by Section 465.022(8)(d), F.S., shall be $100.

(4) The delinquent fee for a pharmacy permit, as provided by Section 465.022(8)(c), F.S., shall be $100.

Rulemaking Authority 465.005, 465.022(8) FS. Law Implemented 465.022(8) FS. History–New 1-11-05.

64B16-26.103 Continuing Education Credits; Renewal.

(1) Prior to biennal renewal of pharmacist licensure, a licensee shall complete no less than 30 hours of approved courses of continued professional pharmaceutical education within the 24 month period prior to the expiration date of the license. The following conditions shall apply.

(a) Upon a licensee's first renewal of licensure, the licensee must document the completion of one (1) hour of board approved continuing education which includes the topics of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome; the modes of transmission, including transmission from a healthcare worker to a patient and the patient to the healthcare worker; infection control procedures, including universal precautions; epidemiology of the disease; related infections including tuberculosis (TB); clinical management; prevention; and current Florida law on AIDS and its impact on testing, confidentiality of test results, and treatment of patients. In order to meet this requirement, licensees must demonstrate that the course includes information on the State of Florida law on HIV/AIDS and its impact on testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to Sections 381.004 and 384.25, F.S. Any HIV/AIDS continuing education course taken during the second or subsequent renewal of licensure may be applied to satisfy the general continuing education hours requirement.

(b) The initial renewal of a pharmacist license will not require completion of courses of continued professional pharmaceutical education hours if the license was issued less than 12 months prior to the expiration date of the license. If the initial renewal occurs 12 months or more after the initial licensure, then 15 hours of continued professional pharmaceutical education hours shall be completed prior to the renewal of the license but no earlier than the date of initial licensure

(c) Prior to renewal a licensee must complete, within the 24 month period prior to the expiration date of the license, a two-hour continuing education course approved in advance by the Board on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. Hours obtained pursuant to this section may be applied by the licensee to the requirements of subsection (1).

(d) Five hours of continuing education in the subject area of risk management may be obtained by attending one full day or eight (8) hours of a board meeting at which disciplinary hearings are conducted by the Board of Pharmacy in compliance with the following:

1. The licensee must sign in with the Executive Director or designee of the Board before the meeting day begins;

2. The licensee must remain in continuous attendance;

3. The licensee cannot receive continuing education credit for attendance at a board meeting if required to appear before the board; and

4. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(e) A member of the Board of Pharmacy may obtain five (5) hours of continuing education in the subject area of risk management for attendance at one Board meeting at which disciplinary hearings are conducted. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(f) Up to five hours per biennium of continuing education credit may be fulfilled by the performance of volunteer services to the indigent as provided in Section 456.013(9), F.S., or to underserved populations, or in areas of critical need within the state where the licensee practices. In order to receive credit, the licensee must make application to and receive approval in advance from the Board. Application shall be made on form DH-MQA 1170 (Rev. 02/09), Individual Request for Continuing Education for Volunteers, which is hereby incorporated by reference. The form can be obtained from the Board of Pharmacy, 4052 Bald Cypress Way, Bin

#C04, Tallahassee, Florida 32399-3254. One hour credit shall be given for each two hours volunteered in the 24 months prior to the expiration date of the license. In the application for approval, the licensee shall disclose the type, nature and extent of services to be rendered, the facility where the services will be rendered, the number of patients expected to be serviced, and a statement indicating that the patients to be served are indigent. If the licensee intends to provide services in underserved or critical need areas, the application shall provide a brief explanation as to those facts. A licensee who is completing community service as a condition of discipline imposed by the board cannot use such service to complete continuing education requirements.

(g) Continuing education credit shall be granted for completion of post professional degree programs provided by accredited colleges or schools of pharmacy. Credit shall be awarded at the rate of 5 hours of continuing education credit per semester hour completed within the 24 months prior to the expiration date of the license.

(h) Continuing education may consist of post-graduate studies, institutes, seminars, lectures, conferences, workshops, correspondence courses, or other educational opportunities which advance the practice of the profession of pharmacy if approved by the Board. A course shall be approved prior to completion and will be evaluated by the Tripartite Committee using the standards found in Rule 64B16-26.601, F.A.C. Individuals must submit requests for course approval at least 45 days in advance of the program or course by completing the approved application form DOH/MQA/PH 112, (Rev. 6/12), entitled Individual Requests for Continuing Education Credit, which is incorporated by reference, and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-01636 and the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or from the website located at http://www.doh.state.fl.us/mqa/pharmacy. Individuals seeking course approval must attach to the application a detailed program outline, overview or syllabus which describes the educational content, objectives and faculty qualifications.

(i) Any volunteer expert witness who is providing expert witness opinions for cases being reviewed by the Department of Health pursuant to Chapter 465, F.S., shall receive five (5) hours of credit in the area of risk management for each case reviewed in the 24 months prior to the expiration date of the license, up to a maximum of ten (10) hours per biennium.

(j) The presenter of a live seminar, a live video teleconference or through an interactive computer-based application shall receive 1 credit for each course credit hour presented, however presenter will not receive additional credit for multiple same course presentations.

(k) All programs approved by the ACPE for continuing education for pharmacists are deemed approved by the Board for general continuing education hours for pharmacists. Any course necessary to meet the continuing education requirement for HIV/AIDS, medication errors, or consultant pharmacist license renewal shall be Board approved.

(l) General continuing education earned by a non-resident pharmacist in another state that is not ACPE approved, but is approved by the board of pharmacy in the state of residence can be applied to meet the requirements of license renewal in subsection (1) above.

(m) At least ten (10) of the required 30 hours must be obtained either at a live seminar, a live video teleconference, or through an interactive computer-based application.

(2) Prior to renewal a consultant pharmacist shall complete no less than 24 hours of Board approved continuing education in the course work specified in Rule 64B16-26.302, F.A.C., within the 24 month period prior to the expiration date of the consultant license. The hours earned to satisfy this requirement cannot be used to apply toward the 30 hours required in subsection (1) above. However, if consultant recertification hours are earned and not used to meet the requirements of this paragraph, they may be applied by the licensee to the 30 hours required in subsection (1).

(a) If the initial renewal of a consultant pharmacist license occurs less than 12 months after the initial licensure, then completion of consultant courses of continuing education hours will not be required.

(b) If the initial renewal of a consultant pharmacist license occurs 12 months or more after the initial licensure, then 12 hours of consultant continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(3) Prior to renewal a nuclear pharmacist shall complete no less than 24 hours of Board approved continuing education in the course work specified in Rule 64B16-26.304, F.A.C., within the 24 month period prior to the expiration date of the nuclear pharmacist license. The hours earned to satisfy this requirement cannot be used to apply toward the 30 hours required in subsection (1) above. However, if nuclear pharmacist license renewal hours are earned and not used to meet the requirements of this paragraph, they may be applied by the licensee to the 30 hours required in subsection (1).

(a) If the initial renewal of a nuclear pharmacist license occurs less than 12 months after the initial licensure, then completion of

courses of nuclear pharmacy continuing education hours will not be required.

(b) If the initial renewal of a nuclear pharmacist license occurs 12 months or more after the initial licensure, then 12 hours of nuclear pharmacy continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(c) All programs approved by the ACPE for continuing education for nuclear pharmacists are deemed approved by the Board for general continuing education hours for nuclear pharmacists.

(4) Prior to renewal a registered phamacy technician shall complete no less than twenty (20) hours of Board approved continuing education in the course work specified in Rule 64B16-26.355, F.A.C., within the 24 month period prior to the expiration date of the phamacy technician registration.

(a) Upon a pharmacy technician's first renewal, registrtant must document the completion of one (1) hour of board approved continuing education which includes the topics of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome; the modes of transmission, including transmission from a healthcare worker to a patient and the patient to the healthcare worker; infection control procedures, including universal precautions; epidemiology of the disease; related infections including tuberculosis (TB); clinical management; prevention; and current Florida law on AIDS and its impact on testing, confidentiality of test results, and treatment of patients. In order to meet this requirement, licensees must demonstrate that the course includes information on the State of Florida law on HIV/AIDS and its impact on testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to Sections 381.004 and 384.25, F.S. Any HIV/AIDS continuing education course taken during the second or subsequent renewal of registration may be applied to satisfy the general continuing education hours requirement.

(b) If the initial renewal of a pharmacy technician registration occurs less than 12 months after the initial licensure, then completion of courses of a pharmacy technician registration education hours will not be required.

(c) If the initial renewal of a pharmacy techician registration occurs 12 months or more after the initial licensure, then 12 hours of registered phamacy technician continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(d) All programs approved by the ACPE for continuing education for pharmacy technicians are deemed approved by the Board for general continuing education hours for registered pharmacy technicians. Any course necessary to meet the continuing education requirement for HIV/AIDS license renewal shall be Board approved.

(e) Prior to renewal a licensee must complete, within the 24 month period prior to the expiration date of the license, a two-hour continuing education course approved in advance by the Board on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. Hours obtained pursuant to this section may be applied by the licensee to the requirements of subsection (1).

(f) Five hours of continuing education in the subject area of risk management may be obtained by attending one full day or eight (8) hours of a board meeting at which disciplinary hearings are conducted by the Board of Pharmacy in compliance with the following:

1. The registratrant must sign in with the Executive Director or designee of the Board before the meeting day begins;

2. The registrant must remain in continuous attendance;

3. The registrant cannot receive continuing education credit for attendance at a board meeting if required to appear before the board; and

4. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(g) At least four (4) of the required 20 hours must be obtained either at a live seminar, a live video teleconference, or through an interactive computer-based application.

Rulemaking Authority 456.033, 465.009 FS. Law Implemented 456.013(7), (9), 456.033, 465.009 FS. History–New 3-19-79, Formerly 21S-6.07, Amended 1-7-87, Formerly 21S-6.007, Amended 7-31-91, 10-14-91, Formerly 21S-26.103, 61F10-26.103, Amended 7-1-97, Formerly 59X-26.103, Amended 7-11-00, 10-15-01, 1-2-02, 1-12-03, 4-12-05, 5-26-09, 5-27-10, 9-20-12.

64B16-26.1031 Influenza Immunization Certification Program.

(1) All applications for immunization certification programs shall be made on board approved form DH-MQA 1234, "Immunization Certification Program Application", effective 04/10, which is hereby incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850) 488-0595, or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy.

(2) The Board shall approve for initial certification of pharmacist administration of influenza immunizations, programs of study not less than 20 hours that include coursework covering all of the following;

(a) Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

(b) Immunization Schedules;

(c) Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry through enrollment application DH Form 1997 (effective 10/07) herein incorporated by reference and may be obtained from the Board office by writing to the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or by telephoning 1(877)888-7468;

(d) Vaccine storage and handling;

(e) Bio-Hazardous waste disposal and sterile techniques;

(f) Entering, negotiating and performing pursuant to physician oversight protocols;

(g) Community immunization resources and programs;

(h) Identifying, managing and responding to adverse incidents including but not limited to potential allergic reactions associated with vaccine administration;

(i) Procedures and policies for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS);

(j) Reimbursement procedures and vaccine coverage by federal, state and local governmental jurisdictions and private third party payors;

(k) Administration techniques;

(l) The current influenza immunization guidelines and recommendations of the United States Department of Health Centers for Disease Control and Prevention published in the Morbidity Weekly Report (MMWR) December 1, 2006, Vol. 55 No. RR-15 and updated MMWR July 13, 2007, Vol. 56, No. RR-6;

(m) Review of Section 465.189, F.S.; and

(n) Cardiopulmonary Resuscitation (CPR) training.

Successful completion of the certification program must include a successful demonstration of competency in the administration technique and a cognitive examination.

Rulemaking Authority 465.005 FS. Law Implemented 465.189 FS. History–New 3-20-08, Amended 8-30-10.

64B16-26.1032 Influenza Immunization Administration Certification Application.

All applications for immunization certification shall be made on board approved form DH-MQA 1125, "Immunization Administration Certification Application," effective February 2010, which is hereby incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850) 488-0595, or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy. The application must be accompanied with a non-refundable application fee as set forth in Rule 64B16-26.1001, F.A.C.

Rulemaking Authority 465.005 FS. Law Implemented 465.189 FS. History–New 9-21-10.

64B16-26.104 Exemptions for Members of the Armed Forces; Spouses.

(1) Any pharmacist or registered pharmacy technician on active duty with the Armed Forces of the United States who at the time of becoming a member of the Armed Forces of the United States was in good standing with the Board and was entitled to practice the profession of pharmacy or registered as a pharmacy technician in Florida shall be exempt from all license renewal provisions so long as the licensee is on active duty with the Armed Forces and for a period of six months after discharge so long as the licensee is not engaged in the practice of pharmacy in the private sector for profit.

(2) A pharmacist or registered pharmacy technician who is a spouse of a member of the Armed Forces of the United States and who was caused to be absent from the State of Florida because of the spouse's duties with the Armed Forces shall be exempt from all license renewal provisions.

Rulemaking Authority 465.005 FS. Law Implemented 456.024 FS. History–New 3-19-79, Amended 4-30-85, Formerly 21S-6.09, 21S-6.009, Amended 7-31-91, Formerly 21S-26.104, 61F10-26.104, 59X-26.104, Amended 1-11-05, 10-27-09.

64B16-26.105 Consultant Pharmacists Initial Registration Fee and Renewal Fee.

Rulemaking Authority 465.005, 465.008, 465.0125 FS. Law Implemented 456.036, 465.0125 FS. History–New 10-26-83, Amended 2-21-84, Formerly 21S-6.10, 21S-6.010, 21S-26.105, 61F10-26.105, Amended 3-28-95, Formerly 59X-26.105, Repealed 3-10-05.

64B16-26.106 Nuclear Pharmacists Initial Registration Fee and Renewal Fee

Rulemaking Authority 465.005, 465.0126 FS. Law Implemented 456.036, 465.0126 FS. History–New 12-29-88, Formerly 21S-6.011, 21S-26.106, 61F10-26.106, Amended 6-26-95, 3-11-96, Formerly 59X-26.106, Repealed 3-10-05.

64B16-26.107 Inactive Nuclear Pharmacist License Renewal.

Rulemaking Authority 465.005, 465.008, 465.012, 465.022(8) FS. Law Implemented 465.008, 465.012, 465.022(8) FS. History–New 6-26-95, Formerly 59X-26.107, Repealed 3-10-05.

64B16-26.200 Examination Requirements.

The examination provided in Section 465.007, F.S., shall be as follows:

(1) Part A – North American Pharmacist Licensure Examination (NAPLEX).

(2) Part B – Multistate Pharmacy Jurisprudence Examination – Florida Version.

Rulemaking Authority 456.017, 465.005 FS. Law Implemented 456.017 FS. History–New 10-17-79, Amended 2-8-81, 6-22-82, 8-16-84, 4-30-85, Formerly 21S-12.01, Amended 5-6-86, Formerly 21S-12.001, Amended 1-10-93, Formerly 21S-26.200, 61F10-26.200, Amended 7-1-97, Formerly 59X-26.200, Amended 3-22-99, 1-11-05.

64B16-26.201 Reexamination.

Rulemaking Authority 456.017, 465.005 FS. Law Implemented 456.017 FS. History–New 10-17-79, Amended 2-8-81, 11-27-84, 4-30-85, Formerly 21S-12.02, Amended 5-6-86, Formerly 21S-12.002, 21S-26.201, 61F10-26.201, 59X-26.201, Repealed 3-10-05.

64B16-26.202 Examination Review Procedure.

Rulemaking Authority 456.017(2) FS. Law Implemented 456.017(2) FS. History–New 10-17-79, Amended 12-27-82, Formerly 21S-12.03, Amended 12-24-89, Formerly 21S-12.003, 21S-26.202, 61F10-26.202, 59X-26.202, Repealed 3-10-05.

64B16-26.203 Licensure by Examination; Application.

Applicants who are at least 18 years of age and a recipient of a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Office of Education may apply to take the licensure examination.

(1) All applications for licensure by examination must be made on board approved form DOH/MQA/101, Pharmacist Examination Application for U.S. and Puerto Rico Graduates and Instructions, (Rev 9/09), which is hereby incorporated by reference, and which can be obtained from the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850)488-0595 to request an application or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy. The application must be accompanied with a non-refundable examination fee and an initial license fee as set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(2) The applicant must submit proof of having met the following requirements:

(a) Completion of an internship program provided by either an accredited school or college of pharmacy or a state board of pharmacy or jointly by both provided that the program meets requirements of Rule 64B16-26.2032, F.A.C.

(b) Completion of a board approved course not less than 2 hours on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. For those applicants who apply within one year following receipt of their pharmacy degree, completed academic course work on medication errors will be accepted by the Board as an educational course under this section, provided such course work is no less than 2 contact hours and that it covers the study of root-cause analysis, error reduction and prevention, and patient safety, as evidenced by a letter attesting to subject matter covered from the Dean of the University.

(3) An applicant must reapply if all requirements for licensure are not met within one year of the receipt of the application.

(4) Passing examination scores may be used upon reapplication only if the examination was completed within 3 years of the reapplication.

Rulemaking Authority 456.033, 465.005 FS. Law Implemented 456.013(1), (7), 456.025(3), 456.033, 465.007, 465.022 FS. History–New 10-17-79, Formerly 21S-12.04, 21S-12.004, Amended 7-31-91, 10-14-91, Formerly 21S-26.203, 61F10-26.203, Amended 7-1-97, Formerly 59X-26.203, Amended 8-17-99, 10-15-01, 1-2-02, 1-12-03, 1-11-05, 2-18-08, 5-26-09, 5-11-10.

64B16-26.2031 Licensure by Examination; Foreign Pharmacy Graduates.

In order for a foreign pharmacy graduate to be admitted to the professional licensure examination, the applicant must be a graduate of a four year undergraduate pharmacy program at a school or college outside the United States and have completed an internship program approved by the Board.

(1) All applications for licensure by examination must be made on form DH-MQA 103 (Rev. 09/09), Pharmacist Examination Application For Foreign Graduates and Instructions, which is hereby incorporated by reference. Contact the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595 to request an application or download the application from the Board's website at http://www.doh.state.fl.us/mqa/pharmacy. The application must be accompanied with a non-refundable examination fee and an initial license fee set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(a) For applications received at the Board of Pharmacy on or before June 30, 2009, the applicant must:

1. Successfully pass the foreign pharmacy graduate equivalency examination which is given by the Foreign Pharmacy Graduate Equivalency Commission with a minimum score of 75%.

2. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language (TOEFL), which is administered by the Educational Testing Service, Inc., with a score of at least 500 for the pencil and paper test or 173 for the computer version and by passing the Test of Spoken English (TSE) with a score of 45 on the recalibrated TSE; or

3. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language Internet-based test (TOEFL ibt) with scores of: Listening – 18; Reading – 21; Speaking – 26; and Writing – 24.

(b) For applications received at the Board of Pharmacy on or after July 1, 2009, the applicant must:

1. Successfully pass the foreign pharmacy graduate equivalency examination which is given by the Foreign Pharmacy Graduate Equivalency Commission with a minimum score of 75%;

2. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language (TOEFL), which is administered by the Educational Testing Service, Inc., with a score of at least 550 for the pencil and paper test or 213 for the computer version and by passing the Test of Spoken English (TSE) with a score of 50 on the recalibrated TSE; or

3. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language Internet-based test (TOEFL ibt) with scores of: Listening – 18; Reading – 21; Speaking – 26; and Writing – 24.

(2) Complete 2080 hours of supervised work activity, of which a minimum of 500 hours must be completed within the State of Florida. Such experience must be equivalent to that required in the internship program as set forth in Rule 64B16-26.2032, F.A.C. The work experience program including both the preceptor and the permittee must be approved by the Board of Pharmacy. The work experience shall be documented on form DH-MQA 1153 (Rev. 01/10), Foreign Graduate Intern Work Activity Manual, which is hereby incorporated by reference. Contact the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850)488-0595 to request a manual or download the manual from the Board's website at http://www.doh.state.fl.us/mqa/pharmacy. Further, no program of supervised work activity shall be approved for any applicant until said applicant has obtained the specified passing scores on the Foreign Pharmacy Graduate Equivalency Examination.

(3) Completion of a Board approved course not less than 2 hours on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. For applicants who apply within one year following receipt of their pharmacy degree, completed academic course work on medication errors will be accepted by the Board as an educational course under this section, provided such course work is no less than 2 contact hours and that it covers the study of root-cause analysis, error reduction and prevention, and patient safety as evidence by a letter attesting to subject matter covered from the Dean of the University.

Rulemaking Authority 465.005, 465.007 FS. Law Implemented 465.007 FS. History–New 1-11-05, Amended 8-8-07, 6-10-09, 5-27-10.

64B16-26.2032 Pharmacy Intern Registration Internship Requirements (U.S. Pharmacy Students/Graduates).

A U.S. pharmacy student or graduate is required to be registered with the Department of Health as an intern before being employed as an intern in a pharmacy in Florida.

(1) All applications for registration must be made on form DH-MQA 104, Pharmacy Intern Application for U.S. Pharmacy Students/Graduates and Instructions, (Rev. 09/09), which is hereby incorporated by reference. Contact the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595 to request an application or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy.

(2) An applicant for pharmacy intern registration must submit proof of:

(a) Enrollment in an intern program at a college or school of pharmacy accredited by the Accreditation Council of Pharmaceutical Education (ACPE); or

(b) Graduation from a college or school of pharmacy accredited by the ACPE.

(3) Upon the receipt of proof satisfactory to the Board that the intern applicant meets the requirement of either paragraph (2)(a) or (2)(b), unless there exists good cause for the Board's refusal to certify an applicant as set forth in Section 465.013, F.S., the Board shall certify the applicant to the Department for registration as an intern.

(4) No intern shall perform any acts relating to the filing, compounding, or dispensing of medicinal drugs unless it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy in this state.

(5) All internship experience for the purpose of qualifying for the examination pursuant to Section 465.007(1)(c), F.S., shall be obtained in a community pharmacy, institutional pharmacy or any Florida Board of Pharmacy approved pharmacy practice, which includes significant aspects of the practice of pharmacy as defined in Section 465.003(13), F.S.

(6) An internship program at college or school of pharmacy accredited by the ACPE shall assure that community or institutional pharmacies utilized for the obtaining of internship experience meet the following minimum requirements:

(a) The pharmacy shall hold a current license or permit issued by the state in which they are operating and shall have available all necessary equipment for professional services, necessary reference works, in addition to the official standards and current professional journals.

(b) The pharmacy shall be operated at all times under the supervision of a pharmacist and shall be willing to train persons desiring to obtain professional experience.

(c) The pharmacy shall establish to the program's satisfaction that the pharmacy fills, compounds and dispenses a sufficient number, kind and variety of prescriptions during the course of a year so as to afford to an intern a broad experience in the filling, compounding and dispensing of prescription drugs.

(d) The pharmacy shall have a clear record as to observance of federal, state and municipal laws and ordinances covering any phase of activity in which it is engaged.

(7) The program shall assure that all preceptors meet the following requirements:

(a) The pharmacist shall willingly accept the responsibility for professional guidance and training of the intern and be able to devote time to preceptor training sessions and to instruction of the intern.

(b) The pharmacist shall hold current licensure in the state in which pharmacy is practiced.

(c) The pharmacist shall be ineligible to serve as a preceptor during any period in which the pharmacist's license to practice pharmacy is revoked, suspended, on probation, or subject to payment of an unpaid fine levied by lawful Board order, or during any period in which the pharmacist's license is the subject of ongoing disciplinary proceedings.

(d) The pharmacist shall agree to assist the school or college of pharmacy in the achievement of the educational objectives set forth and to provide a professional environment for the training of the intern.

(e) Evidence shall be provided of the pharmacist's desire to continue broadening professional education and of an active involvement in a patient-oriented practice.

(8) In the event a program meets all the requirements set forth in subsection (6) of this rule, except for prior approval by the Florida Board of Pharmacy, any applicant submitting it for the purpose of qualifying for licensure by examination must show in addition to successful completion of the internship:

(a) Approval of the program by a state board of pharmacy; and

(b) Sufficient hours to total 2080 hours; or

(c) Licensure in another state and work performed as a pharmacist for a sufficient number of hours to total 2080 hours when combined with the internship hours.

(9) All internship hours may be obtained prior to the applicant's graduation.

(10) Proof of completion of an internship program shall consist of a certification that the applicant has completed the program. If additional hours are required to total 2080 hours, satisfactory proof of the additional hours shall be constituted by the program's certification of completion of the additional hours.

(11) Hours worked in excess of 50 hours per week prior to the applicant's graduation or in excess of 60 hours per week after an applicant's graduation, will not be credited toward meeting the required internship hours.

(12) The Board approves all internships that are required to obtain the doctor of pharmacy degree from institutions which are accredited as provided by Section 465.007(1)(b)1., F.S. Applicants graduating after January 1, 2001 with the doctor of pharmacy degree from such institutions shall be deemed to have met the requirements of this section with documentation of graduation.

(13) The Board may conduct periodic review of programs to assure compliance with these rules.

(14) Proof of current licensure in another state and work as a pharmacist for up to 2080 hours may substitute for all or part of the internship requirement.

(15) Governmental and private radiopharmacy internship programs shall not apply to the pharmacy internship required under subsection (5) of this rule.

Rulemaking Authority 465.005 FS. Law Implemented 465.003(12), 465.007, 465.0075, 465.013 FS. History–New 4-1-07, Amended 7-7-10, 10-7-12.

64B16-26.2033 Pharmacy Intern Registration and Internship Requirements (Foreign Pharmacy Graduates).

A foreign pharmacy graduate is required to be registered with the Department of Health as an intern before being employed as an intern in a pharmacy in Florida.

(1) All applicants for intern registration must be made on form DH-MQA 102, "Pharmacy Intern Application for Foreign Graduates and Instructions," effective September 2009, which is incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850) 488-0595 to request a form or download the form from the board's website at http://www.doh.state.fl.us/mqa/pharmacy.

(2) An applicant for foreign pharmacy graduate intern registration in Florida must submit proof of:

(a) Eligibility by the Foreign Pharmacy Graduate Equivalency Committee to sit for the Foreign Pharmacy Graduate Equivalency Examination, or

(b) A passing score on the Foreign Pharmacy Graduate Equivalency Examination to be considered a graduate of an accredited college or school of pharmacy.

(3) Upon the receipt of proof satisfactory to the Board that the intern applicant meets the requirements of either paragraph (a) or (b) of subsection (1), and submitted a completed application as required in subsection (2) unless there exists good cause for the Board's refusal to certify an applicant as set forth in Section 465.013, F.S., the Board shall certify the applicant to the Department for registration as an intern.

(4) No intern shall perform any acts relating to the filling, compounding, or dispensing of medicinal drugs unless it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy in this state.

(5) All internship experience for the purpose of qualifying for the examination pursuant to Section 465.007(1)(c), F.S., shall be obtained in a community pharmacy, institutional pharmacy or any Florida Board of Pharmacy approved pharmacy practice, which includes significant aspects of the practice of pharmacy as defined in Section 465.003(13), F.S.

(6) An internship program at an accredited college or school of pharmacy shall assure that community or institutional pharmacies utilized for the obtaining of internship experience meet the following minimum requirements:

(a) The pharmacy shall hold a current license or permit issued by the state in which they are operating and shall have available all necessary equipment for professional services, necessary reference works, in addition to the official standards and current professional journals.

(b) The pharmacy shall be operated at all times under the supervision of a pharmacist and shall be willing to train persons desiring to obtain professional experience.

(c) The pharmacy shall establish to the program's satisfaction that the pharmacy fills, compounds and dispenses a sufficient number, kind and variety of prescriptions during the course of a year so as to afford to an intern a broad experience in the filling, compounding and dispensing of prescription drugs.

(d) The pharmacy shall have a clear record as to observance of federal, state and municipal laws and ordinances covering any phase of activity in which it is engaged.

(e) No pharmacist may be responsible for the supervision of more than one intern at any one time.

(7) The program shall assure that all preceptors meet the following requirements:

(a) The pharmacist shall willingly accept the responsibility for professional guidance and training of the intern and be able to devote time to preceptor training sessions and to instruction of the intern.

(b) The pharmacist shall hold current licensure in the state in which pharmacy is practiced.

(c) The pharmacist shall be ineligible to serve as a preceptor during any period in which the pharmacist's license to practice pharmacy is revoked, suspended, on probation, or subject to payment of an unpaid fine levied by lawful Board order, or during any period in which the pharmacist's license is the subject of ongoing disciplinary proceedings.

(d) The pharmacist shall agree to assist the school or college of pharmacy in the achievement of the educational objectives set forth and to provide a professional environment for the training of the intern.

(e) Evidence shall be provided of the pharmacist's desire to continue broadening professional education and of an active involvement in a patient-oriented practice.

(8) In the event a program meets all the requirements set forth in subsection (2) of this rule, except for prior approval by the Florida Board of Pharmacy, any applicant submitting it for the purpose of qualifying for licensure by examination must show in addition to successful completion of the internship:

(a) Approval of the program by a state board of pharmacy; and

(b) Sufficient hours to total 1580 hours; or

(c) Licensure in another state and work performed as a pharmacist for a sufficient number of hours to total 1580 hours when combined with the internship hours.

(9) All internship hours may be obtained prior to the applicant's graduation.

(10) Proof of completion of an internship program shall consist of a certification that the applicant has completed the program. If additional hours are required to total 2080 hours, satisfactory proof of the additional hours shall be constituted by the program's certification of completion of the additional hours.

(11) Hours worked in excess of 50 hours per week prior to the applicant's graduation or in excess of 60 hours per week after an applicant's graduation, will not be credited toward meeting the required internship hours.

(12) The Board approves all internships that are required to obtain the doctor of pharmacy degree from institutions which are accredited as provided by Section 465.007(1)(b)1., F.S. Applicants graduating after January 1, 2001 with the doctor of pharmacy degree from such institutions shall be deemed to have met the requirements of this section with documentation of graduation.

(13) The Board may conduct periodic review of programs to assure compliance with these rules.

(14) Proof of current licensure in another state and work as a pharmacist for up to 1580 hours may substitute for all or part of the internship hours requirement.

(15) Governmental and private radiopharmacy internship programs shall not apply to the pharmacy internship required under subsection (1) of this rule.

(16) All foreign pharmacy graduates must complete 500 hours of supervised work activity within the state of Florida as provided by Section 465.007(1)(b)2., F.S. The supervised work activity program experience shall be documented on form DH-MQA 1153, "Foreign Graduate Registered Intern Work Activity Manual," effective 01/10. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850)488-0595 to request a form or download the form from the board's website at http://www.doh.state.fl.us/mqa/pharmacy. Further, this 500 hours of work activity program shall not be recognized for any applicant until said applicant has obtained the passing score on the Foreign Pharmacy Graduate Equivalency Exam as provided in Section 465.007, F.S.

Rulemaking Authority 465.005 FS. Law Implemented 456.013(1), 465.002, 465.007, 465.0075, 465.013 FS. History–New 5-27-10.

64B16-26.2035 Examination Fees.

Rulemaking Authority 465.005 FS. Law Implemented 465.007 FS. History–New 9-19-94, Amended 3-10-96, Formerly 59X-26.2035, Amended 3-22-99, 10-30-00, Repealed 3-10-05

64B16-26.204 Licensure by Endorsement.

An applicant for licensure by endorsement must be at least 18 years of age and a recipient of a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Office of Education.

(1) All applications for licensure by endorsement shall be made on board approved form DOH/MQA100 effective June 2010. Pharmacist Licensure by Endorsement Application and Instructions (U.S. and territories), which is hereby incorporated by reference, can be obtained from the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595 to request a form or download the form from the board's website at http://www.doh.state.fl.us/mqa/pharmacy. The application must be accompanied with a non-refundable application fee and initial licensure fee as set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(2) The applicant must submit satisfactory proof that one of the following requirements has been met:

(a) Two (2) years of active practice, as defined in Section 465.0075(1)(c), F.S., within the immediately preceding five (5) years. If the applicant meets the requirements of this section, proof of completion of 30 hours of Florida Board of Pharmacy, ACPE, or other state board of pharmacy approved continuing education obtained in the two calendar years immediately preceding application, must also be submitted.

(b) Successful completion of an internship meeting the requirements of Section 465.007(1)(c), F.S., within the immediately preceding two (2) years.

(3) Completion of a Board approved course not less than 2 hours on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. For applicants who apply within one year following receipt of their pharmacy degree, completed academic course work on medication errors will be accepted by the Board as an educational course under this section, provided such course work is no less than 2 contact hours and that it covers the study of root-cause analysis, error reduction and prevention, and patient safety as evidenced by a letter attesting to subject matter covered from an official of the university where the course was taken.

(4) Applicants qualifying under the education requirements of Section 465.007(1)(b)2., F.S., (foreign graduates), must complete the requirements of Rule 64B16-26.2031, F.A.C., prior to certification for the examination required in subsection (6) of this rule.

(5) All requirements for licensure by endorsement must be met within one (1) year of the receipt of the application. Applicants failing to meet this requirement must reapply.

(6) Applicants applying under the provisions of Section 465.0075, F.S., must have obtained a passing score on the licensure examination as described in subsection 64B16-26.200(1), F.A.C.

(7) Applicants applying under the provisions of Section 465.0075, F.S., shall cause the National Association of Boards of Pharmacy, or other similar organization to issue a Transfer of Pharmaceutical Licensure certificate showing examination date, examination results, states of licensure, disciplinary actions, and licensure status.

(8) Applicants deemed qualified for licensure by endorsement shall be required to complete the Multistate Pharmacy Jurisprudence Examination – Florida Version. Passing scores on this examination may be used upon reapplication only if the examination was completed within three (3) years of the reapplication.

Rulemaking Authority 465.005, 465.0075 FS. Law Implemented 456.013(1), 465.007, 465.0075, 465.022 FS. History–New 11-8-01, Amended 1-11-05, 2-18-08, 5-26-09, 10-10-10.

64B16-26.205 Requirements for Foreign Pharmacy Graduates to Be Admitted to the Pharmacist Licensure Examination.

Rulemaking Authority 465.005, 465.007 FS. Law Implemented 465.007 FS. History–New 4-18-84, Formerly 21S-12.06, Amended 9-17-87, Formerly 21S-12.006, Amended 7-31-91, 1-10-93, 4-8-93, Formerly 21S-26.205, 61F10-26.205, Amended 3-10-96, Formerly 59X-26.205, Amended 8-17-99, Repealed 3-10-05.

64B16-26.300 Consultant Pharmacist Licensure.

(1) No person shall serve as consultant pharmacist as defined in Section 465.003(3), F.S., unless that person holds a license as a consultant pharmacist.

(2) Application for consultant pharmacist licensure shall be made on form DOH-MQA 1109, 02/09, Consultant Pharmacist Application and Information, which is hereby incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595 to request an application or download the application from the board's website at www.doh.state.fl.us/mqa/pharmacy. The application shall be accompanied by a non-refundable application fee.

(3) In order to be licensed as a consultant pharmacist, a person must meet the following requirements:

(a) Hold a license as a pharmacist which is active and in good standing,

(b) Successfully complete a consultant pharmacist course of no fewer than twelve (12) hours, sponsored by an accredited college of pharmacy located within the State of Florida, and approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and subject matter set forth in Rule 64B16-26.301, F.A.C. The course shall be instructionally designed to include a cognitive test on which the applicant must score a passing grade for certification of successful completion of the course.

(c) Successfully complete a period of assessment and evaluation under the supervision of a preceptor within one (1) year of completion of the course set forth in paragraph (b) above. This period of assessment and evaluation shall be completed over no more than three (3) consecutive months and shall include at least 40 hours of training in the following practice areas, 60% of which shall occur on-site at an institution that holds a pharmacy permit. The training shall include:

Minimum Skills Required	Percent of Time	Hours
Minimum of 40 Hours in Maximum of Three Months		
1. Regimen review, documentation and communication. a. Demonstrate ability to carry out process and understand documentation functions. b. Understand and perform drug regimen review. Communicate findings to appropriate individuals or groups. c. The applicant is responsible for learning other skills needed to perform in his/her type of facility where he/she is or will be the consultant Pharmacist of Record.	60%	24
2. Facility review. Demonstrate areas that should be evaluated, documentation, and reporting procedures.	20%	8
3. Committee and Reports. Review quarterly Quality of Care Committee minutes and preparation and delivery of pharmacist quarterly report.	5%	2
4. Policy and Procedures. Preparation, review, updating Policy and Methods.	5%	2
5. Principles of formulary management. Demonstrate ability to manage formulary.	5%	2
6. Professional Relationships. Knowledge and interaction of facility administration and professional staff.	5%	2

(4) In order to act as a preceptor, a person shall:

(a) Be a consultant pharmacist of record at an institutional pharmacy which is required to have a consultant pharmacist under

the provisions of Chapter 465, F.S., and these rules.

(b) Have a minimum of one (1) year of experience as a consultant pharmacist of record.

(c) Maintain all pharmacist licenses in good standing with the Board.

(d) Not act as a preceptor to more than two (2) applicants at the same time.

(5) Upon completion of the requirements set forth above, the applicant's preceptor shall confirm that the applicant's assessment and evaluation have met the requirements and that the applicant has successfully completed all required assignments under the preceptor's guidance and supervision.

(6) After licensure a consultant pharmacist's license shall be renewed biennially upon payment of the fee set forth in Rule 64B16-26.1003, F.A.C., and upon completing twenty-four (24) hours of board approved continuing education based upon the provisions of Rule 64B16-26.302, F.A.C.

(7) The number of hours earned in recertification programs by a consultant pharmacist, if applied to the twenty-four (24) hours required for consultant pharmacist license renewal, may not be used toward the thirty (30) hours of continued professional pharmaceutical education credits as set forth in Rule 64B16-26.103, F.A.C.

(8) An applicant who applies for a consultant pharmacist license after the effective date of this rule shall be required to complete the assessment and evaluation required in paragraph (3)(c) prior to being licensed as a consultant pharmacist.

Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0125 FS. History–New 5-19-72, Revised 4-19-74, Repromulgated 12-18-74, Amended 10-17-79, 4-8-80, 7-29-81, 7-1-83, 4-10-84, 4-30-85, Formerly 21S-1.26, 21S-1.026, Amended 7-31-91, 10-14-91, Formerly 21S-26.300, 61F10-26.300, Amended 9-19-94, 3-28-95, 3-10-96, Formerly 59X-26.300, Amended 5-22-01, 5-5-05, 11-29-06, 3-29-10.

64B16-26.301 Subject Matter for Consultant Pharmacist Training Program.

(1) Jurisprudence.

(a) Laws and regulations, state and federal, pertaining to institutional pharmacy and health care facilities.

(b) Laws and regulations, state and federal, pertaining to the safe and controlled storage of alcohol and other related substances, and relating to fire and health-hazard control.

(2) Policy and Procedures.

(a) Written procedures for outlining the medication system in effect.

1. Traditional systems.

2. Unit-dose systems.

a. Centralized.

b. Decentralized.

c. Automated medication systems.

3. Routine and emergency use of drugs.

4. After hours procedure for medication dispensing.

5. Managing drug shortages.

(b) Record keeping and reports.

1. Controlled substance control and record-of-usage.

2. Alcohol inventory and record-of-usage.

3. Patient drug use control and records.

a. Recalls.

b. Medication use evaluation.

c. Medication errors.

4. Drug charges, methods, accountability, and reports.

5. Statistical reports of usage, volume, etc.

(3) Administrative Responsibilities.

(a) Fiscal Control.

1. Perpetual and traditional inventory systems.

2. Application of EDP techniques.

(b) Personnel Management, orientation and training.

(c) Intra-professional relations pertaining to medication use.

(d) Inter-professional relations with other members of the institutional health care team.

1. Pharmacy & Therapeutic Committee.

a. Rational drug therapy; review of medication use and prescribing.

b. Formulary development – evaluation, appraisal, selection, procurement, storage, distribution, medication safety, criteria for use development and safety.

c. Automatic stop orders on potent and dangerous drugs.

d. Controls on storage and use of investigational drugs.

2. In-service education of nurses and other health-related personnel.

3. Infectious Disease Committee.

(4) Professional Responsibilities.

(a) Drug information retrieval and methods of dispersal.

(b) Development of pharmacy practice.

(c) Development of an IV Admixture service.

(d) Procedures to enhance medication safety.

1. Availability of equipment, technique, etc., to prepare special dosage forms for pediatric and geriatric patients.

2. Preparation of sterile dosage forms.

3. Proper writing, transcribing and initiating and/or transferring patient medication orders; development of physician's chart order copy system.

4. Safety of patient self-medication and control of drugs at bedside.

5. Reporting and trending adverse drug reactions.

6. Screening for potential drug interactions.

7. Development and maintenance of up-to-date emergency kits.

(e) Maintain drug quality and safe storage.

1. Procedures for eliminating out-dated drugs.

2. Requirements for safe and appropriate storage conditions.

(f) Maintain drug identity.

1. Procedures for labeling, transferring of bulk medications, etc.

2. Manufacturing and packaging procedures.

3. Pre-packaging control and supervision.

(5) The Institutional Environment.

(a) The institution's pharmacy function and purpose.

(b) Interdepartmental relationships important to the institutional pharmacy.

(c) Understanding of scope of service and in-patient care mission of the institution.

(d) Special training with respect to the operation of nursing homes and Extended Care Facilities (ECF)/pharmacy relationship and special procurement procedures.

(6) Nuclear pharmacy.

(a) Procurement.

(b) Compounding.

(c) Quality control procedures.

(d) Dispensing.

(e) Distribution.

(f) Basic radiation protection and practices.

(g) Consultation and education to the nuclear medicine community; including patients, pharmacists, other health professionals, and the general public.

(h) Research and development of new formulations.

(i) Record keeping.

(j) Reporting adverse drug reactions and medication errors.

(k) Screening for potential drug interaction.

Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0125 FS. History–New 5-19-72, Amended 12-18-74, 10-17-79, Formerly 21S-

1.27, 21S-1.027, Amended 7-31-91, Formerly 21S-26.301, 61F10-26.301, 59X-26.301, Amended 5-5-05.

64B16-26.302 Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education.
A Consultant Pharmacist License Renewal Continuing Education Program must contain at least three (3) hours of training in any of the subjects specified below. Duplicate courses are not acceptable.

(1) Drug Therapy – Disease State. Patient Drug Therapy – management and monitoring.

(a) Drug, Disease State Information – In-depth disclosure of the drug or therapeutic class of drugs or disease state including pharmacology, side effects and interaction.

(b) New Therapeutic Modalities: Expansion of current drug therapy or treatment.

(c) Patient Assessment: Assessment techniques by consultant pharmacist to determine the need and effectiveness of indicated drug therapy along with identification and assessment of side effects on patient's well-being.

(d) Pertinent Laboratory Tests.

(e) Therapeutic Dosing.

(2) Administrative Responsibilities.

(a) Update on Administrative Responsibilities.

1. Legal requirements including statutes, rules and regulation (Federal and State).
2. The Joint Commission on the Accreditation of Healthcare Organizations.
3. Personnel requirements.
4. Health Insurance Portability and Accountability.

(b) Focus on Consultant Pharmacist Practice Issues/Concerns.

1. How to get things accomplished in complex organizations.
2. Key contacts to be effective as a consultant pharmacist.
3. Considerations and preparation for site inspections.

(3) Consultant Pharmacist Facility Responsibilities. This segment details the requirements in one of the facility types for which a consultant pharmacist is required. Only one practice setting may be included in each program.

(a) Pharmacist-Medication Responsibilities – Assessment mechanism for delivery system, review procedures and monitoring processes.

(b) Pharmacist-Patient Responsibilities – Patient assessment, laboratory test monitoring and therapeutic dosing.

(c) Committee Responsibilities – Make-up and responsibilities for various facility committees.

(d) Reporting requirements.

Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0125 FS. History–New 10-14-91, Formerly 21S-26.302, 61F10-26.302, 59X-26.302, Amended 5-5-05, 7-21-09.

64B16-26.303 Nuclear Pharmacist Licensure.

(1) A pharmacist licensed to practice pharmacy in this state who performs a radiopharmaceutical service shall, prior to engaging in such specialized practice, be actively licensed as a nuclear pharmacist.

(2) A pharmacist seeking licensure as a nuclear pharmacist in this state shall submit to the Board of Pharmacy a course outline from an accredited college of pharmacy or other program recognized by the Florida Department of Health and the Florida Board of Pharmacy (a program comparable to those offered by accredited colleges of pharmacy for the training of nuclear pharmacists), and a certificate of training which provides a minimum of 200 clock hours of formal didactic training, which includes:

(a) Radiation physics and instrumentation (85 hours).

(b) Radiation protection (45 hours).

(c) Mathematics pertaining to the use and measurement of radioactivity (20 hours).

(d) Radiation biology (20 hours).

(e) Radiopharmaceutical chemistry (30 hours).

(3) Such academic training programs will be submitted to the Board of Pharmacy for approval by an accredited educational institution which operates under the auspices of or in conjunction with an accredited college of pharmacy.

(4) The minimum on-the-job training which shall be included in a radiopharmacy internship is 500 hours of training and experience in the handling of unsealed radioactive material under the supervision of a licensed nuclear pharmacist. The training and

experience shall include but shall not be limited to the following:

(a) Ordering, receiving and unpackaging in a safe manner, radioactive material, including the performance of related radiation surveys.

(b) Calibrating dose calibrators, scintillation detectors, and radiation monitoring equipment.

(c) Calculating, preparing and verifying patient doses, including the proper use of radiation shields.

(d) Following appropriate internal control procedures to prevent mislabeling.

(e) Learning emergency procedures to safely handle and contain spilled materials, including related decontamination procedures and surveys.

(f) Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(g) Clinical practice concepts.

(5) If the didactic and experiential training required in this section have not been completed within the last seven (7) years, the applicant must have been engaged in the lawful practice of nuclear pharmacy in another jurisdiction at least 1080 hours during the last seven (7) years.

Rulemaking Authority 465.005, 465.0126 FS. Law Implemented 465.0126 FS. History–New 1-18-05.

64B16-26.304 Subject Matter for Nuclear Pharmacist License Renewal Continuing Education Programs.

(1) A licensee completing the continuing education requirement for nuclear pharmacist license renewal pursuant to Rule 64B16-26.103, F.A.C., shall complete twenty-four (24) additional hours per biennium of coursework each two year period by or through a Committee approved provider, instructionally designed to provide in-depth treatment of nuclear pharmacy practice with suggested subject matter set out in subsection (2) of this rule.

(2) Content of nuclear pharmacist continuing education program.

(a) Application of radiopharmaceutical theory in a practice or a research setting with respect to the drug products and their clinical application. Provision of drug and radiopharmaceutical information as it pertains to optimal handling and use of these products in a clinical setting.

(b) Effective communication skills in a multi-disciplinary environment with patients, nuclear medicine physicians, nuclear medicine technologists, radiation safety personnel and other nuclear pharmacists. The multi-faceted regulatory environment requires such skills in the preparation and maintenance of a radioactive by-product materials license, the identification and reporting of adverse reactions and misadministration, instances of poor product performance, environmental and personnel radiation safety.

(c) Application of the most rigorous and up-to-date principles of radiation safety and quality assurance in order to assure regulatory compendia, and operational standards for drug and radiopharmaceutical products and equipment. Record-keeping and other documentation activities essential to procurement, storage, compounding, handling and use, distribution and disposal should be emphasized.

(d) Management of a nuclear pharmacy unit in accordance with regulatory and administrative agencies' requirements.

(e) Advances in drug, radiopharmaceutical or related technology (including, but not limited to: monoclonal antibodies, magnetic resonance imaging, computed tomography, positron-emission tomography, radioplaque and other contact enhancement agents, radioimmunoassay) with emphasis on paragraphs (a)-(d) above for such new agents.

Rulemaking Authority 465.005, 465.0126 FS. Law Implemented 465.0126 FS. History–New 1-18-05.

64B16-26.320 Subject Matter for Continuing Education to Order and Evaluate Laboratory Tests.

(1) Consultant pharmacists and pharmacists holding the Doctor of Pharmacy degree that wish to order and evaluate laboratory tests under the provisions of Section 465.0125, F.S., shall successfully complete the requirements of a continuing education course set forth herein prior to such practice. Successful completion of the course will certify the pharmacist for this practice for two (2) years from date of completion.

(2) Providers of courses seeking approval under this section shall meet the procedures and standards provided for in Rule 64B16-26.601, F.A.C. Courses approved under this section shall be at least three (3) hours in duration for initial certification and at least one (1) hour for recertification, and shall cover the following subjects:

(a) Requirements for monitoring laboratory values,

(b) Interpretation of laboratory values,

(c) Use of laboratory data to monitor and improve drug therapy,

(d) Legal aspects, restrictions, and requirements for obtaining laboratory studies,

(e) Use of laboratory data and therapeutic outcomes,

(f) Documentation of interventions, and

(g) Laboratory studies as an element of complete patient care.

(3) A consultant pharmacist may apply the three (3) hour initial certification course and the one (1) hour recertification course toward the continuing education requirement for renewal of a consultant pharmacist license under Rule 64B16-26.300, F.A.C., or may apply such continuing education hours toward the continuing education requirement for renewal of a pharmacist license under Rule 64B16-26.103, F.A.C., but may not use the same continuing education hours to satisfy both requirements. A Doctor of Pharmacy who is not a consultant pharmacist may apply the three (3) hour initial certification course and the one (1) hour recertification course toward the continuing education requirement for renewal of a pharmacist license under Rule 64B16-26.103, F.A.C.

Rulemaking Authority 465.009, 465.0125(3) FS. Law Implemented 465.009, 465.0125(2) FS. History–New 2-23-98, Amended 6-15-98, 1-12-03, 3-10-05.

64B16-26.350 Requirements for Pharmacy Technician Registration.

Applicants who are at least 17 years of age may apply to become a registered pharmacy technician.

(1) All applicants for registration must be made on form DH-MQA PH1183, "Pharmacy Technician Registration Application and Instructions" effective September 2009, which is incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850) 488-0595 to request an application or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy. The application must be accompanied with a non-refundable application fee and an initial registration fee set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(2) Prior to January 1, 2011, a registered pharmacy technician must submit proof of having met one of the following requirements:

(a) Completed a Board approved training course as outlined in Rule 64B16-26.351, F.A.C; or

(b) Worked as a registered pharmacy technician for a minimum of 1500 hours under the supervision of a pharmacist; or

(c) Received certification as a pharmacy technician by a certification program accredited by the National Commission for Certifying Agencies.

(3) Applicants applying for registration after January 1, 2011 must submit proof of completion of a Board approved training course as outlined in Rule 64B16-26.351, F.A.C.

Rulemaking Authority 465.014 FS. Law Implemented 465.014 FS. History–New 8-5-10.

64B16-26.351 Standards for Approval of Registered Pharmacy Technician Training Programs.

(1) The following programs are approved Registered Pharmacy Technician Training programs:

(a) Pharmacy technician training programs accredited, on or before January 1, 2011 by the American Society of Health-System Pharmacists,

(b) Pharmacy technician training programs at institutions accredited, on or before January 1, 2011 by the Southern Association of Colleges and Schools,

(c) Pharmacy technician training programs approved on or before January 1, 2011 by the Florida Commission for Independent Education,

(d) Pharmacy technician training programs provided by a branch of the federal armed services on or before January 1, 2011.

(e) Pharmacy technician training programs at institutions accredited on or before January 1, 2011 by the Council on Occupational Education.

(2) All programs not listed in paragraphs (1)(a) through (e) and which are not employer based programs, must:

(a) Meet the requirements of and be licensed by the Commission for Independent Education pursuant to Chapter 1005, F.S., or the equivalent licensing authority of another state or be within the public school system of the State of Florida; and:

(b) Offer a course of study that includes classroom study and clinical instruction that includes the following:

1. Introduction to pharmacy and health care systems:

a. Confidentiality,

b. Patient rights and Health Insurance Portability and Accountability Act (HIPAA),

2. Pharmacy law:

a. Federal law,

b. Florida State law,

c. Florida State rules,

d. Pharmacy technician Florida rules and law,

3. Pharmaceutical – medical terminology, abbreviations, and symbols:

a. Medication safety and error prevention,

b. Prescriptions and medication orders,

4. Records management and inventory control:

a. Pharmaceutical supplies,

b. Medication labeling,

c. Medication packaging and storage,

d. Controlled substances,

e. Adjudication and billing,

5. Interpersonal relations, communications, and ethics:

a. Diversity of communications,

b. Empathetic communications,

c. Ethics governing pharmacy practice,

d. Patient and caregiver communication,

6. Pharmaceutical calculations.

(c) Apply directly to the Board of Pharmacy on approved form DH-MQA 1239 "Board of Pharmacy Application for Registered Pharmacy Technician Training Programs," effective December 2010, https://www.flrules.org/gateway/reference.asp?NO=Ref-00717, which is hereby incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850) 488-0595, or download the application from the board's website at http//:www.doh.state.fl.us/mqa/pharmacy and provide the following information:

1. Sample transcript and diploma;

2. Copy of curriculum, catalog or other course descriptions; and

3. Faculty credentials.

(d) Use materials and methods that demonstrate that:

1. Learning experiences and teaching methods convey the content stated above.

2. Time allocated for each participant shall be sufficient to meet the objectives of each activity.

3. Principles of adult education are utilized in determining teaching strategies and learning activities.

(e) Demonstrate that the faculty is qualified to teach the subject-matter by complying with the following:

1. The program shall provide evidence of academic preparation or experience in the subject matter by submitting a job description, resume or curriculum vitae which describes the faculty member's work experience and level of academic preparation.

2. When the subject matter of an offering includes pharmacy technician practice, a licensed pharmacist or registered pharmacy technician with expertise in the content area must be involved in the planning and instruction.

3. Pharmacy technician faculty supervising learning experiences in a clinical area in this State shall be licensed or registered.

(3) All other training programs must be employer based. Any pharmacy technician training program sponsored by a Florida permitted pharmacy or affiliated group of pharmacies under common ownership, must contain a minimum of 160 hours of training, that extends over a period not to exceed 6 months; is provided solely to employees of said pharmacy or affiliated group; and has been approved by the Board. An application for approval of a Registered Pharmacy Technician Training Program shall be made on Board of Pharmacy approved form DH-MQA 1239 "Board of Pharmacy Application for Registered Pharmacy Technician Training Programs," effective December 2010. The applicant must attach to the application copy of curriculum, catalog or other course description. All employer based programs must:

(a) Offer a course of study that includes a classroom study and clinical instruction that includes the following:

1. Introduction to pharmacy and health care systems:

a. Confidentiality,

b. Patient rights and Health Insurance Portability and Accountability Act (HIPAA).

2. Pharmacy law:

a. Federal law,

b. Florida State law,

c. Florida State rules,

d. Pharmacy technician Florida rules and law.

3. Pharmaceutical-medical terminology, abbreviations, and symbols:

a. Medication safety and error prevention,

b. Prescriptions and medication orders.

4. Records management and inventory control:

a. Pharmaceutical supplies,

b. Medication labeling,

c. Medication packaging and storage,

d. Controlled substances,

e. Adjudication and billing.

5. Interpersonal relations, communications, and ethics:

a. Diversity of communications,

b. Empathetic communications,

c. Ethics governing pharmacy practice,

d. Patient and caregiver communication.

6. Pharmaceutical calculations.

(b) Use materials and methods that demonstrate that:

1. Learning experiences and teaching methods convey the content stated above.

2. Time allocated for each participant shall be sufficient to meet the objectives of each activity.

3. Principles of adult education are utilized in determining teaching strategies and learning activities.

(c) Demonstrate that the faculty is qualified to teach the subject matter by complying with the following:

1. The program shall provide evidence of academic preparation or experience in the subject matter by submitting a job description, resume or curriculum vitae which describes the faculty member's work experience and level of academic preparation.

2. When the subject matter of an offering includes pharmacy technician practice, a licensed pharmacist or registered pharmacy technician with expertise in the content area must be involved in the planning and instruction.

3. Pharmacy technician faculty supervising learning experiences in a clinical area in this State shall be licensed or registered.

4. When an offering includes clinical practice training in Florida, a Florida licensed pharmacist competent in the practice area shall provide supervision.

(d) Give participants an opportunity to evaluate learning experiences, instructional methods, facilities and resources used for the offering. To ensure participants will be given an opportunity to evaluate the program, the applicant must submit a sample evaluation to be reviewed by the Board.

(e) Ensure that self-directed learning experiences, including but not limited to home study, computer programs, internet or web-based courses evaluate participant knowledge at the completion of the learning experience. The evaluation must include a minimum of 100 questions. The participant must achieve a minimum score of 70% on the evaluation to receive the certificate of completion. The evaluation must be graded by the provider.

(f) Designate a person to assume responsibility for registered pharmacy technician training program. If the contact person is not a licensed pharmacist or registered pharmacy technician, provision should be made for insuring licensed pharmacist or registered pharmacy technician input in overall program planning and evaluation.

(g) Establish written policies and procedures for implementation of the registered pharmacy technician training program.

(h) Maintain a system of record-keeping which provides for storage of program information.

(i) Maintain program records for a period not less than three years during which time the records must be available for inspection by the board or department.

(j) Furnish each participant with an authenticated individual Certificate of Completion.

Rulemaking Authority 465.014 FS. Law Implemented 465.014 FS. History–New 6-23-10, Amended 11-17-11.

64B16-26.355 Subject Matter for Registered Pharmacy Technician Continuing Education.

A Registered Pharmacy Technician Continuing Education Program must contain subject matter specifically designed to meet the objectives and the stated level and learning needs of the participants. The content shall be planned in logical order and reflect input from experts in the subject matter. Appropriate subject matter for continuing education offering shall reflect the professional educational needs for the learner in order to meet the health care needs of the consumer and consist of content from one or more of the following:

(1) Pharmacy technician practice areas and special health care problems.

(2) Biological, physical, behavioral and social sciences.

(3) Legal aspects of health care.

(4) Management/administration of health care personnel and patient care.

(5) Teaching/learning process of health care personnel and patients.

(6) Subjects which are taken at an accredited educational institution as verified by an official transcript, that meet any one of the criteria in Rule 64B16-26.351, F.A.C., and are advanced beyond that completed for original registration shall be approved for continuing education under this rule.

Rulemaking Authority 465.005, 465.014 FS. Law Implemented 465.014 FS. History–New 10-10-10.

64B16-26.400 Pharmacy Interns; Registration; Employment.

(1) A pharmacy intern is required to be registered with the Department of Health as an intern before being employed as an intern in a pharmacy in Florida.

(2) An applicant for pharmacy intern registration must submit proof of:

(a) Enrollment in an intern program at an accredited college or school of pharmacy or;

(b) Graduation from an accredited college or school of pharmacy and not yet licensed in the state. For purposes of this rule only, any individual who has been accepted by the Foreign Pharmacy Graduate Examination Commission to sit for the Foreign Pharmacy Graduate Equivalency Examination shall be considered a graduate of an accredited college or school of pharmacy. The internship experience allowed under this provision shall not count toward the 500-hours internship required subsequent to passage of the Foreign Pharmacy Graduate Equivalency Examination as mandated in Section 465.007(1)(b)2., F.S., and as defined in Rule 64B16-26.203, F.A.C.

(3) Upon the receipt of proof satisfactory to the Board that the intern applicant meets the requirements of either paragraph (a) or (b) of subsection (2), and unless there exists good cause for the Board's refusal to certify an applicant as set forth in Section 465.013, F.S., the Board shall certify the applicant to the Department for registration as an intern.

(4) No intern shall perform any acts relating to the filling, compounding, or dispensing of medicinal drugs unless it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy in this state.

Rulemaking Authority 465.005 FS. Law Implemented 465.013 FS. History–Amended 8-20-63, 5-19-72, 8-18-73, Repromulgated 12-18-74, Amended 11-10-80, 4-30-85, Formerly 21S-1.21, Amended 10-20-88, Formerly 21S-1.021, Amended 7-31-91, 1-10-93, Formerly 21S-26.400, 61F10-26.400, 59X-26.400, Amended 3-10-05.

64B16-26.401 Requirements for an Internship Program Sufficient to Qualify an Applicant for Licensure by Examination.

Rulemaking Authority 465.005 FS. Law Implemented 465.007 FS. History–New 8-20-83, Amended 5-19-72, 8-18-73, 12-18-74, 11-10-80, 10-25-84, Formerly 21S-1.22, 21S-1.022, Amended 7-31-91, Formerly 21S-26.401, Amended 12-27-93, Formerly 61F10-26.401, 59X-26.401, Amended 4-19-01, Repealed 3-10-05.

64B16-26.600 Tripartite Continuing Education Committee.

(1) The Tripartite Continuing Education Committee will be composed of equal representation from the Board of Pharmacy, each College or School of Pharmacy in the State, and practicing pharmacists within the State. The members of the Committee shall be selected by the Board of Pharmacy and shall serve for a period of two years. The chairman of the committee shall be selected by the Chair of the Board.

(2) The Tripartite Continuing Education Committee shall perform the following duties pursuant to Rule 64B16-26.601, F.A.C.:

(a) Review continuing education providers and make recommendations to the Board;

(b) Approve continuing education course or program for approved providers or individuals that are non-approved providers for the following:

1. General;
2. Initial Consultant Pharmacist Certification;
3. Consultant Recertification;
4. Nuclear Recertification;
5. Medication Errors;
6. HIV/AIDS;
7. Laboratory Tests;
8. Laws and Rules;
9. Quality Related Events.

(3) The Tripartite Continuing Education Committee shall perform auditing and monitoring activities pursuant to Rule 64B16-26.601, F.A.C. The Tripartite Committee shall perform an audit on each approved continuing education provider 90 days prior to the end of the biennium. The approved provider shall submit the following information for one program of the provider's choosing and one program selected by the Board:

(a) Title, date and location of the program;

(b) Program Number;

(c) Any Co-sponsors;

(d) Total number of pharmacists attending;

(e) Rosters of attendees with appropriate license numbers;

(f) Brochures of program announcement;

(g) CV's of each speaker;

(h) Handouts, Copy of CE Credit statement, educational materials distributed as part of the program; and

(i) Summary report of program evaluations.

(4) The Committee shall hold meetings as may be convened at the call of the Chairman of the Committee.

Rulemaking Authority 465.005, 465.009(5) FS. Law Implemented 465.009 FS. History–New 10-18-79, Amended 7-29-81, Formerly 21S-13.01, 21S-13.001, 21S-26.600, 61F10-26.600, 59X-26.600, Amended 10-15-01, 3-10-05, 6-11-09.

64B16-26.601 Standards for Approval of Courses and Providers.

(1) Each proposal for program or course approval submitted by a qualified provider must contain a detailed outline of the content of said program or course on forms which will be provided by the Board of Pharmacy upon request, and must build upon Standards of Practice and a basic course or courses offered in the curricula of accredited colleges or schools of pharmacy. Continuing education may consist of post-baccalaureate degree programs offered by accredited colleges or schools of pharmacy, post-graduate studies, institutes, seminars, lectures, conferences, workshops, correspondence courses, or other such committee-approved educational methods.

(2) All offerings must meet the following standards:

(a) Education Content Development.

1. Continuing education offerings shall involve advance planning that includes a statement of measurable educational goals and behavioral objectives.

2. Continuing education offerings shall be designed to reflect the educational needs of the pharmacist and build on the standards for practice and courses in the curricula of accredited colleges or schools of pharmacy.

3. Each continuing education offering shall be designed to explore one subject or a group of closely related subjects or

standards.

(b) Methods of Delivery.

1. The method of delivery of a course shall be determined by giving appropriate consideration to such factors as educational content, objectives, and composition of the audience.

2. The method of delivery must encourage active participation and involvement on the part of the pharmacist.

(c) Program Faculty Qualifications.

1. The program faculty for a particular continuing education offering shall be competent in the subject matter and qualified by experience.

2. An appropriate number of program faculty for each activity shall be utilized.

3. There shall be adequate personnel to assist with administrative matters and personnel with competencies outside content areas in cases where the method of delivery requires technical or other special expertise.

(d) Facilities.

1. The facilities to be utilized shall be appropriate and adequate to the content, method of delivery, size of the audience and promote the attainment of the objectives of the offering.

(e) Evaluation. The provider must make provision for evaluation of the participants' attainment of the stated learner objectives through in-process activities that provide a measurable demonstration of the learner's achievement(s).

2. The provider must develop and employ an evaluation mechanism for the purpose of allowing the participant to assess his/her achievement of personal objectives.

3. The provider shall develop and employ an evaluation mechanism that will assess the effectiveness of the learning experiences, instructional methods, facilities, and resources used for the offering.

(f) Contact Hour Criteria. The number of contact hours or Continuing Education Units shall be determined by the provider in advance of the offering subject to approval by the committee and awarded upon the successful completion of the entire planned education experience.

(g) Record Keeping.

1. Records of individual offerings shall be maintained by the provider for inspection by the Board. The records shall be adequate to serve the needs of the participants and to permit the Board to monitor for adherence to the standards for continuing education offerings as outlined in the rules.

2. An individual certificate of attendance specifying title of offering, provider number, date of offering, and number of contact hours earned shall be furnished to each participant by the provider.

3. Records shall be maintained by the provider for a minimum of three (3) years.

(3) Providers seeking board approval shall meet each of the standards outlined herein:

(a) All continuing education offerings conducted by the provider shall meet the standards for continuing education offerings as outlined in these rules.

(b) There shall be a visible, continuous, and identifiable authority charged with administration of continuing education programs. The person or persons in whom the administrative function is vested shall be qualified by virtue of background and experience and approval by the committee.

(4) All programs approved by the Accreditation Council on Pharmacy Education (ACPE) for continuing education for pharmacists may be deemed approved by this Board for general continuing education hours for pharmacists.

(5) Entities or individuals who wish to become approved providers of continuing education must submit an initial approval fee of $150 and provide information to demonstrate compliance with the requirements of this rule. A provider seeking to renew approved provider status shall pay a renewal fee of $150.

(6) Entities or individuals applying for approval of an individual program shall submit a fee of $50 and provide information to demonstrate compliance with this rule.

Rulemaking Authority 465.005, 465.009 FS. Law Implemented 456.025(7), 465.009 FS. History–New 10-17-79, Amended 7-29-81, Formerly 21S-13.02, 21S-13.002, Amended 1-10-93, Formerly 21S-26.601, 61F10-26.601, 59X-26.601, Amended 1-29-03.

64B16-26.6012 Guidelines for Board Ordered Disciplinary Continuing Education Courses.

Any continuing education course being taken as part of a disciplinary order, unless otherwise ordered by the Board, may be conducted by any method, including live, correspondence, or distant education.

(1) Laws and Rules courses shall be at least twelve (12) hours in length. The program shall include review and analysis of the laws regulating the profession of pharmacy in the State of Florida with discussion of recent changes to Florida Statutes and Board of Pharmacy rules. The remainder of the continuing education program shall be derived from the following areas:

(a) Federal laws related to:

1. Handling, management, and dispensing of controlled substances;
2. Protected patient information; and
3. Medicare.

(b) Chapters 456, 499 and 893, F.S;

(c) Florida Medicaid program;

(d) Nursing home and Assisted Living Facility regulations;

(e) Prescriber laws and regulations;

(f) Pharmacy ethics;

(g) The Joint Commission (TJC) standards;

(h) Food and Drug Administration policies and procedures;

(i) Implementation of disaster and emergency preparedness plans by Florida pharmacists and pharmacy services providers; and

(j) Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH) guidelines and requirements for pharmacy employers.

(2) Quality Related Event (QRE) courses shall be at least eight (8) hours in length.

(a) Course material shall include:

1. Pharmacy error detection;
2. Pharmacy error prevention; and
3. Case studies of pharmacists who have made dosing calculation, checking/interpreting prescriptions, or dispensing errors.

(b) Course material shall include the following specific subject areas:

1. Common error types and causes;
2. Root cause analysis;
3. Process mapping and management;
4. System analysis;
5. Failure mode and effects analysis;
6. Human factors, cognitive and personality impacts;
7. Practice management and effective delegation tools;
8. Stress management;
9. Effective communication;
10. Continuous Quality Improvement (CQI) rules;
11. CQI implementation tools;
12. Individual self assessment, planning, and goal setting. The individual self assessment shall include a requirement that the pharmacist prepare a written report, in essay form, summarizing the impact of the course, what the pharmacist learned, and the changes that the pharmacist will implement in practice as a result of the course.

Rulemaking Authority 456.072(2) 465.005, 465.016(4) FS. Law Implemented 456.072(2), 465.016(4) FS. History–New 7-21-09.

64B16-26.602 Recommendation by the Tripartite Continuing Education Committee.

Rulemaking Authority 465.005 FS. Law Implemented 465.009 FS. History–New 10-17-79, Amended 7-29-81, Formerly 21S-13.03, 21S-13.003, 21S-26.602, Amended 7-18-94, Formerly 61F10-26.602, 59X-26.602, Repealed 8-16-01

64B16-26.603 Continuing Education Records Requirements.

Each pharmacist shall retain documentation of participation in continuing education programs required for license renewal for not less than two years after the license is renewed for audit purposes if and when such audit is undertaken by the Department of Health and the Board of Pharmacy. Such documentation shall consist of statements of credit for lecture attendance, certification forms from instructors, or course completion slips from correspondence courses.

Rulemaking Authority 465.005 FS. Law Implemented 465.009 FS. History–New 10-17-79, Formerly 21S-13.04, Amended 5-10-89, Formerly 21S-13.004, 21S-26.603, 61F10-26.603, 59X-26.603, Amended 1-11-05.

64B16-26.606 Number of Required Hours.

Rulemaking Authority 465.005 FS. Law Implemented 465.009 FS. History–New 10-17-79, Formerly 21S-13.07, 21S-13.007, Amended 7-31-91, Formerly 21S-26.606, 61F10-26.606, 59X-26.606, Amended 2-23-98, 1-12-03, Repealed 3-10-05.

CHAPTER 64B16-27
PHARMACY PRACTICE

64B16-27.100 Display of Current License; Pharmacist, Registered Pharmacy Technician Intern Identification
64B16-27.1001 Practice of Pharmacy
64B16-27.1003 Transmission of Prescription Orders
64B16-27.101 Counterfeit Drugs
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64B16-27.100 Display of Current License; Pharmacist, Registered, Intern, and Registered Pharmacy Technician Identification.

(1) The current license of each pharmacist engaged in the practice of the profession of pharmacy as defined by Section 465.003(13), F.S., in any pharmacy shall be displayed, when applicable, in a conspicuous place in or near the prescription department, and in such manner that said license can be easily read by patrons of said establishment. Pharmacists employed in secondary practice sites shall present a valid wallet license as evidence of licensure upon request.

(2) No pharmacist shall display, cause to be displayed or allow to be displayed, their license in any pharmacy where said pharmacist is not engaged in the practice of the profession as defined in Section 465.003(13), F.S.

(3) A pharmacist and registered pharmacy intern must be clearly identified by a means such as an identification badge or monogrammed smock showing their name and if they are a pharmacist or a registered pharmacy intern.

(4) The current registration of each registered pharmacy technician shall be displayed, when applicable, in a conspicuous place in or near the prescription department, and in such a manner that can be easily read by patrons of said establishment. Registered

pharmacy technicians employed in a secondary practice site shall present a valid wallet registration as evidence of registration upon request.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.06, 21S-1.006, Amended 7-30-91, Formerly 21S-27.100, 61F10-27.100, Amended 1-30-96, Formerly 59X-27.100, Amended 11-18-07, 1-1-10.

64B16-27.1001 Practice of Pharmacy.

Those functions within the definition of the practice of the profession of pharmacy, as defined by Section 465.003(13), F.S., are specifically reserved to a pharmacist or a duly registered pharmacy intern in this state acting under the direct and immediate personal supervision of a pharmacist. The following subjects come solely within the purview of the pharmacist.

(1) A pharmacist or registered pharmacy intern must:

(a) Supervise and be responsible for the controlled substance inventory.

(b) Receive verbal prescriptions from a practitioner.

(c) Interpret and identify prescription contents.

(d) Engage in consultation with a practitioner regarding interpretation of the prescription and date in patient profile.

(e) Engage in professional communication with practitioners, nurses or other health professionals.

(f) Advise or consult with a patient, both as to the prescription and the patient profile record.

(2) When parenteral and bulk solutions of all sizes are prepared, regardless of the route of administration, the pharmacist must:

(a) Interpret and identify all incoming orders.

(b) Mix all extemporaneous compounding or be physically present and give direction to the registered pharmacy technician for reconstitution, for addition of additives, or for bulk compounding of the parenteral solution.

(c) Physically examine, certify to the accuracy of the final preparation, thereby assuming responsibility for the final preparation.

(d) Systemize all records and documentation of processing in such a manner that professional responsibility can be easily traced to a pharmacist.

(3) Only a pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.

(4) The pharmacist, as an integral aspect of dispensing, shall be directly and immediately available to the patient or the patient's agent for consultation and shall not dispense to a third party. No prescription shall be deemed to be properly dispensed unless the pharmacist is personally available.

(5) The pharmacist performing in this state any of the acts defined as "the practice of the profession of pharmacy" in Section 465.003(13), F.S., shall be actively licensed as a pharmacist in this state, regardless of whether the practice occurs in a permitted location (facility) or other location.

(6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:

(a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.

(b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.

(c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.

(7) The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one pharmacist and one registered pharmacy technician. In every pharmacy, the

pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in the licensee's employ or under the licensee's supervision.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(11)(b), (13), 465.014, 465.026 FS. History–New 11-18-07, Amended 1-1-10.

64B16-27.1003 Transmission of Prescription Orders.

Prescriptions may be transmitted from prescriber to dispenser in written form or by any means of communication. Prescriptions may be transmitted by facsimile systems as provided in Section 465.035, F.S., and federal law. Any direct transmission of prescriptions, including verbal, facsimile, telephonic or electronic data transmission, shall only be with the approval of the patient or patient's agent. The pharmacist receiving any such transmitted prescription shall not participate in any system that the pharmacist knows or should have reason to know restricts the patient's choice of pharmacy. The pharmacist shall take such measures necessary to ensure the validity of all prescriptions received.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History–New 11-18-07.

64B16-27.101 Counterfeit Drugs.

No pharmacist or pharmacy employee or proprietor shall knowingly purchase, sell, possess or distribute drugs which are commonly called counterfeit, or which are misbranded, or improperly labeled as described by the Florida Drug and Cosmetic Law.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.15, 21S-1.015, Amended 7-30-91, Formerly 21S-27.101, 61F10-27.101, 59X-27.101.

64B16-27.103 Oral Prescriptions and Copies.

(1) Only a pharmacist or registered pharmacy intern acting under the supervision of a pharmacist may, in the State of Florida, accept an oral prescription of any nature.

(2) Only a pharmacist or registered pharmacy intern acting under the supervision of a pharmacist may, in the State of Florida, prepare a copy of a prescription or read a prescription to any person for purposes of providing reference concerning treatment of the person or animal for whom the prescription was written, and when said copy is given a notation shall be made upon the prescription that a copy has been given, the date given, and to whom given.

Rulemaking Authority 465.005, 465.0155, 465.014, 465.022 FS. Law Implemented 465.003(13), 465.014, 465.022, 893.07(1)(b) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.18, 21S-1.018, 21S-27.103, 61F10-27.103, Amended 9-19-94, Formerly 59X-27.103, Amended 10-15-01, 11-18-07.

64B16-27.104 Conduct Governing Pharmacists and Pharmacy Permittees.

(1) A pharmacist or pharmacy shall be permitted to advertise medicinal drugs other than those controlled substances specified in Chapter 893, F.S., and patent and proprietary preparations so long as such advertising is not false, misleading or deceptive.

(2) No pharmacist, employer or employee of a pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Florida Board of Pharmacy, from which to solicit, accept or dispense prescriptions.

(3) No pharmacist or pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with any physician or other practitioner or nursing home or extended care facility for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement of any kind, whereby in any way a patient's free choice of a pharmacist or pharmacy is or may be limited.

(4) No pharmacist, employer or employee of a pharmacy may knowingly place in stock of any pharmacy any part of any prescription compounded for, or dispensed to, any customer of any pharmacy and returned by said customer, unless otherwise permitted by Rule 64B16-28.118, F.A.C.

(5) Pursuant to Section 465.018, F.S., a permit for a community pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department and following such other rules as relate to the practice of the profession of pharmacy. The Board shall not register a prescription department manager as the manager of more than one pharmacy. The Board shall grant an exception to this requirement upon application by the permittee and the prescription department manager showing circumstances such as proximity of

permits and limited pharmacist workload that would allow the manager to carry out all duties and responsibilities required of a prescription department manager.

Rulemaking Authority 465.005, 465.0155, 465.018, 465.022 FS. Law Implemented 465.018, 465.022, 465.024 FS. History–New 10-20-81, Formerly 21S-1.20, 21S-1.020, Amended 7-30-91, Formerly 21S-27.104, 61F10-27.104, 59X-27.104, Amended 11-18-07.

64B16-27.1042 Rebates Prohibited; Violations Defined.

As provided in Section 465.185(1), F.S., acts which will be considered as falling within the range of activities which would justify discipline against a pharmacist or permittee as provided in Section 465.016(1)(e) or Section 465.023(1)(c), F.S., shall include:

(1) Offering or providing cash, or goods, or entertainment (including, money, food or decorations) to a health care facility (as defined in Section 408.032(7), F.S.) or its representative in exchange for favorable consideration in obtaining or maintaining the business of the facility;

(2) Offering or providing supplies or equipment to a health care facility (as defined in Section 408.032(7), F.S.) at no charge or below market value when these items are not integral elements of the medication distribution system;

(3) Paying rent to a health care facility (as defined in Section 408.032(7), F.S.) for space that is not used or is unusable or paying a rental rate for space that is significantly greater than the usual and customary rental rate for similar space;

(4) Offering or providing computers, FAX machines, or other electronic devices to a health care facility (as defined in Section 408.032(7), F.S.) when that equipment is not an integral element in providing pharmacy or consultant services;

(5) Offering or providing a health care facility (as defined in Section 408.032(7), F.S.) consultant pharmacist services, or providing patient medical record systems, or any personnel services outside the practice of pharmacy, at no charge, below market value, or below cost in exchange for obtaining or maintaining the business of the facility.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.185, 465.0155 FS. History–New 3-9-94, Formerly 61F10-27.1042, 59X-27.1042.

64B16-27.105 Transfer of Prescriptions.

(1) A pharmacist or registered pharmacy intern acting under the direct personal supervision of a Florida registered pharmacist may transfer a valid prescription which is on file in another pharmacy in this state or any other state if such transfer is consistent with the conditions set forth in Section 465.026, F.S. Prior to dispensing, the pharmacist or pharmacy where the prescription is on file shall be notified verbally, or by any electronic means that the former prescription must be voided.

(2) In processing a transferred prescription pursuant to Section 465.026, F.S., the pharmacist has the option of substituting a generically equivalent product if such substitution is consistent with the provisions of Section 465.025, F.S.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.026 FS. History–New 1-3-79, Formerly 21S-1.33, 21S-1.033, Amended 7-30-91, Formerly 21S-27.105, 61F10-27.105, Amended 9-19-94, Formerly 59X-27.105, Amended 6-15-98.

64B16-27.120 Ordering and Evaluation of Laboratory Tests.

Those consultant pharmacists and pharmacists holding the Doctor of Pharmacy degree that meet the continuing education requirements of Rule 64B16-26.320, F.A.C., may order and evaluate laboratory tests to the extent allowed by the provisions of Section 465.0125, F.S. Evidence of such training and authorization to perform these tasks shall be furnished to the board, the patient, or the patient's physician upon request.

Rulemaking Authority 465.0125(3) FS. Law Implemented 465.0125(2) FS. History–New 2-23-98.

64B16-27.200 Purpose and Effect.

The purpose of this rule chapter is to set forth pursuant to the requirements of Section 465.186, F.S., the medicinal drug products which may be ordered and dispensed by pharmacists to the public and to set forth the terms and conditions under which such ordering and dispensing by the pharmacist may take place. The list of drugs set forth below and the conditions under which said drugs may be ordered and dispensed have been determined pursuant to a joint committee of medical, osteopathic and pharmacy professionals as created by Section 465.186, F.S.

Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Formerly 21S-18.001, 21S-27.200, 61F10-27.200, 59X-

27.200.

64B16-27.210 General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products.

Pursuant to the authority of the Formulary Committee in Section 465.186, F.S., a pharmacist may order the medicinal drug products listed in Rule 64B16-27.220, F.A.C., subject to the following terms and limitations:

(1) Injectable products shall not be ordered by the pharmacist.

(2) No oral medicinal drugs shall be ordered by a pharmacist for a pregnant patient or nursing mother.

(3) In any case of dispensing hereunder, the amount or quantity of drug dispensed shall not exceed a 34-day supply or standard course of treatment unless subject to the specific limitations in this rule. Patients shall be advised that they should seek the advice of an appropriate health care provider if their present condition, symptom, or complaint does not improve upon the completion of the drug regimen.

(4) The directions for use of all prescribed medicinal drugs shall not exceed the manufacturer's recommended dosage.

(5) The pharmacist may only perform the acts of ordering and dispensing in a pharmacy which has been issued a permit by the Board of Pharmacy.

(6) The pharmacist shall create a prescription when ordering and dispensing medicinal drug products which shall be maintained in the prescription files of the pharmacy. The pharmacist shall place the trade or generic name and the quantity dispensed on the prescription label, in addition to all other label requirements.

(7) The pharmacist shall maintain patient profiles, separate from the prescription order, for all patients for whom the pharmacist orders and dispenses medicinal drug products and shall initial and date each profile entry. Such profiles shall be maintained at the pharmacy wherein the ordering and dispensing originated for a period of two (2) years.

(8) In the patient profiles, the pharmacist shall record as a minimum the following information if a medicinal drug product is ordered and dispensed.

(a) Patient's chief complaint or condition in the patient's own words.

(b) A statement regarding the patient's medical history.

(c) A statement regarding the patient's current complaint which may include, onset, duration and frequency of the problem.

(d) The medicinal drug product ordered and dispensed.

(e) The pharmacist ordering and dispensing the medicinal drug product shall initial the profile.

(f) The prescription number shall be recorded in the patient's profile.

(9) A medicinal drug product may be ordered, and dispensed only by the pharmacist so ordering.

(10) Only legend medicinal drugs may be prescribed by a pharmacist. Over-the-counter drugs are exempt from the requirements of this rule and shall be recommended as over-the-counter products.

(11) Pharmacy interns and technicians may not be involved in the ordering of the medicinal drugs permitted in this rule.

Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Formerly 21S-18.002, 21S-27.210, 61F10-27.210, 59X-27.210, Amended 11-18-07.

64B16-27.211 Prescription Refills.

No prescription may be filled or refilled in excess of one (1) year from the date of the original prescription was written. No prescription for a controlled substance listed in Schedule II may be refilled. No prescription for a controlled substance listed in Schedules III, IV, or V may be filled or refilled more than five (5) times within a period of six (6) months after the date on which the prescription was written.

Rulemaking Authority 465.005, 465.016(1), 465.022(1)(a), 893.04 FS. Law Implemented 465.022 FS. History–New 11-18-07.

64B16-27.220 Medicinal Drugs Which May Be Ordered by Pharmacists.

A Pharmacist may order and dispense from the following formulary, within their professional judgment, subject to the stated conditions.

(1) Oral analgesics for mild to moderate pain. The pharmacist may order these drugs for minor pain and menstrual cramps for patients with no history of peptic ulcer disease. The prescription shall be limited to a six (6) day supply for one treatment. If appropriate, the prescription shall be labeled to be taken with food or milk.

(a) Magnesium salicylate/phenyltoloxamine citrate.

(b) Acetylsalicylic acid (Zero order release, long acting tablets).

(c) Choline salicylate and magnesium salicylate.

(d) Naproxen sodium.

(e) Naproxen.

(f) Ibuprofen.

(2) Urinary analgesics. Phenazopyridine, not exceeding a two (2) day supply. The prescriptions shall be labeled about the tendency to discolor urine. If appropriate, the prescription shall be labeled to be taken after meals.

(3) Otic analgesics. Antipyrine 5.4%, benzocaine 1.4%, glycerin, if clinical signs or symptions of tympanic membrane perforation do not exist. The product shall be labeled for use in the ear only.

(4) Anti-nausea preparations.

(a) Meclizine up to 25 mg., except for a patient currently using a central nervous system (CNS) depressant. The prescription shall be labeled to advise the patient of drowsiness and to caution against concomitant use with alcohol or other depressants.

(b) Scopolamine not exceeding 1.5 mg. per dermal patch. Patient shall be warned to seek appropriate medical attention if eye pain, redness or decreased vision develops.

(5) Antihistamines and decongestants. The following, including their salts, either as a single ingredient product or in combination, including nasal decongestants, may be ordered for a patient above 6 years of age.

(a) Antihistamines. The pharmacist shall warn the patient that an antihistamine should not be used by patients with bronchial asthma or other lower respiratory symptoms, glaucoma, cardiovascular disorders, hypertension, prostate conditions and urinary retention. An antihistamine shall be labeled to advise the patient of drowsiness and caution against the concomitant use with alcohol or other depressants.

1. Diphenhydramine.
2. Carbinoxamine.
3. Pyrilamine.
4. Dexchlorpheniramine.
5. Brompheniramine.

(b) Decongestants. The pharmacist shall not order an oral decongestant for use by a patient with coronary artery disease, angina, hyperthyroidism, diabetes, glaucoma, prostate conditions, hypertension, or a patient currently using a monoamine oxidase inhibitor.

1. Phenylephrine.
2. Azatadine.

(6) Topical antifungal/antibacterials. The pharmacist shall warn the patient that any of the products should not be used near deep or puncture wounds and contact with eyes or mucous membranes should be avoided. Iodochlorhydroxyquin preparations shall be labeled with staining potential.

(a) Iodochlorhydroxyquin with 0.5% Hydrocortisone (not exceeding 20 grams).

(b) Haloprogin 1%.

(c) Clotrimazole topical cream and lotion.

(d) Erythromycin topical.

(7) Topical anti-inflammatory. The pharmacist shall warn the patient that hydrocortisone should not be used on bacterial infections, viral infections, fungal infections, or by patients with impaired circulation. The prescription shall be labeled to advise the patient to avoid contact with eyes, mucous membranes or broken skin. Preparations containing hydrocortisone not exceeding 2.5%.

(8) Otic antifungal/antibacterial. Acetic acid 2% in aluminum acetate solution which shall be labeled for use in ears only.

(9) Keratolytics. Salicylic acid 16.7% and lactic acid 16.7% in flexible collodion, to be applied to warts, except for patients under two (2) years of age, and those with diabetes or impaired circulation. Prescriptions shall be labeled to avoid contact with normal skin, eyes and mucous membranes.

(10) Vitamins with fluoride. (This does not include vitamins with folic acid in excess of 0.9 mg.)

(11) Medicinal drug shampoos containing Lindane. The pharmacist shall:

(a) Limit the order to the treatment of head lice only;

(b) Order no more than four (4) ounces per person; and

(c) Provide the patient with the appropriate instructions and precautions for use.

(12) Ophthalmics. Naphazoline 0.1% ophthalmic solution.

(13) Histamine H2 antagonists. The pharrmacist shall advise the patient to seek medical attention if symptom persist longer than 14 days while using the medication or if stools darken or contain blood.

(a) Cimetidine.

(b) Famotidine.

(c) Ranitidine HC1.

(14) Acne products. Benzoyl Peroxide. The prescription shall be labeled to advise the patient to avoid use on the eye, eyelid, or mucous membranes.

(15) Topical Antiviral.

(a) Acyclovir ointment may be ordered for the treatment of herpes simplex infections of the lips.

(b) Penciclovir.

Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Amended 10-7-90, Formerly 21S-18.003, Amended 7-30-91, Formerly 21S-27.220, 61F10-27.220, Amended 3-12-97, Formerly 59X-27.220, Amended 6-15-98, 11-30-99, 11-18-07.

64B16-27.230 Fluoride Containing Products That May Be Ordered by Pharmacists.

Oral medicinal drug products containing fluoride may be ordered by pharmacists for their patients who do not have fluoride supplement in their drinking water, pursuant to the following limitations:

(1) The fluoride content of drinking water does not exceed 0.5 ppm.

(2) Once a fluoride treatment has been initiated with one specific fluoride medicinal drug product it should not be interchanged with a product of a different manufacturer for the course of the treatment.

(3) If the fluoride content is less than 0.5 ppm then the following dosage schedule for oral usage shall be followed.

(a)1. For ages 0-6 months.

a. Less than 0.3 ppm in water – no supplementation,

b. 0.3-0.6 ppm in water – no supplementation,

c. 0.6 ppm in water – no supplementation,

2. For ages 6 months – 3 years,

a. Less than 0.3 ppm in water – supplement with 0.25 mg. F/day,

b. 0.3-0.6 ppm in water – no supplementation,

c. 0.6 ppm in water – no supplementation.

3. For ages 3-6 years.

a. Less than 0.3 ppm in water – supplement with 0.5 mg. F/day,

b. 0.3-0.6 ppm in water – supplement with 0.25 mg. F/day,

c. 0.6 ppm in water – no supplementation.

4. For ages 6-16 years.

a. Less than 0.3 ppm in water – supplement with 1.00 mg. F/day,

b. 0.3-0.6 ppm in water – supplement with 0.5 mg. F/day,

c. 0.6 ppm in water – no supplementation.

(b) No more than 264 mg. of sodium fluoride may be dispensed at any one time to a patient.

(c) Notwithstanding the provisions of subsection 64B16-27.210(3), F.A.C., a pharmacist may continue a course of therapy with fluoride products until appropriate referral to another health care practitioner is indicated or in no event shall the course of therapy be more than one (1) year.

Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Formerly 21S-18.004, 21S-27.230, 61F10-27.230, 59X-27.230, Amended 6-15-98.

64B16-27.300 Standards of Practice - Continuous Quality Improvement Program.

(1) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) "Quality-Related Event" means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber's prescription order, including, but not limited to:

1. Incorrect drug;
2. Incorrect drug strength;
3. Incorrect dosage form;
4. Incorrect patient; or
5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:

1. Over-utilization or under-utilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions; or
7. Clinical abuse/misuse.

(3)(a) Each pharmacy shall establish a Continuous Quality Improvement Program which program shall be described in the pharmacy's policy and procedure manual and, at a minimum shall contain:

1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, registered pharmacy interns, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager or the consultant pharmacist of record;
2. Provisions for the prescription department manager or the consultant pharmacist of record to ensure that the committee conducts a review of Quality Related Events at least every three months.
3. A planned process to record, measure, assess, and improve the quality of patient care; and
4. The procedure for reviewing Quality Related Events.

(b) As a component of its Continuous Quality Improvement Program, each pharmacy shall assure that, following a Quality-Related Event, all reasonably necessary steps have been taken to remedy any problem for the patient.

(c) At a minimum, the review shall consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

(4) Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. The Quality-Related Event shall be initially documented by the pharmacist to whom it is described, and it shall be recorded on the same day of its having been described to the pharmacist. Documentation of a Quality-Related Event shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacists shall maintain such records at least until the event has been considered by the committee and incorporated in the summary required in subsection (5) below.

(5) Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the provisions of Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The summarization document shall analyze remedial measures undertaken following a Quality-Related Event. No patient name or employee name shall be included in this summarization. The summarization shall be maintained for two years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

Rulemaking Authority 465.0155 FS. Law Implemented 465.0155 FS. History–New 7-15-99, Amended 1-2-02, 6-16-03, 11-18-07, 1-1-10.

64B16-27.400 Practice of Pharmacy.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(11)(b), (13), 465.014, 465.026 FS. History–New 2-14-77, Formerly 21S-4.01, 21S-4.001, Amended 7-30-91, Formerly 21S-27.400, 61F10-27.400, Amended 1-30-96, 10-1-96, Formerly 59X-27.400, Amended 4-13-00, Repealed 10-5-09.

64B16-27.410 Registered Pharmacy Technician, to Pharmacist Ratio.

(1) Registered pharmacy technicians may assist a pharmacist in performing professional services within a pharmacy environment provided that no pharmacist shall supervise more than one registered pharmacy technician unless otherwise permitted by the Florida Board of Pharmacy. A pharmacist's supervision of a registered pharmacy technician in a working environment

requires that a registered pharmacy technician be under the direct personal supervision of a pharmacist.

(2) The prescription department manager or consultant pharmacist of record is required to submit a written request and receive approval prior to the pharmacy's allowing a pharmacist to supervise more than one registered pharmacy technician as permitted by law. Such requests shall be reviewed and pre-approved by Board staff according to the guidelines adopted herein, and submitted to the Board for ratification.

(3) The request to practice with a ratio greater than 1:1 shall include a brief description of the workflow needs that justify the ratio request. The brief description of workflow needs shall include the operating hours of the pharmacy, number of pharmacists, registered interns, and registered pharmacy technicians employed.

(4) A pharmacy that employs pharmacy technicians shall meet the following conditions:

(a) Establish written job descriptions, task protocols, and policies and procedures that pertain to duties performed by the registered pharmacy technician and provide this information to the Board upon request;

(b) Establish that each registered pharmacy technician is knowledgeable in the established job descriptions, task protocols, and policy and procedures in the pharmacy setting in which the technician is to perform his or her duties;

(c) Ensure that the duties assigned to any registered pharmacy technician do not exceed the established job descriptions, task protocols, and policy and procedures, nor involve any of the prohibited tasks in Rule 64B16-27.420, F.A.C.; or

(d) Ensure that each registered pharmacy technician receives employer-based or on-the-job training in order for the registered pharmacy technician to assume his or her responsibilities and maintain documentation of the training.

(5) The pharmacy shall maintain a policy and procedure manual with regard to registered pharmacy technicians which shall include the following:

(a) Supervision by a pharmacist;

(b) Minimum qualifications as established by law;

(c) Documentation of in-service education and/or on-going training and demonstration of competency, specific to practice site and job function;

(d) General duties and responsibilities of registered pharmacy technicians;

(e) Retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;

(f) All functions related to prescription processing;

(g) All functions related to prescription legend drug and controlled substance ordering and inventory control, including procedures for documentation and recordkeeping;

(h) rescription refill and renewal authorization;

(i) Registered pharmacy technician functions related to automated pharmacy systems; and

(j) Continuous quality improvement program.

Rulemaking Authority 465.005 FS. Law Implemented 465.014, 893.07(1)(b) FS. History–New 2-14-77, Amended 3-31-81, Formerly 21S-4.02, Amended 8-31-87, Formerly 21S-4.002, Amended 9-9-92, Formerly 21S-27.410, 61F10-27.410, Amended 1-30-96, Formerly 59X-27.410, Amended 2-23-98, 10-15-01, 1-1-10.

64B16-27.420 Registered Pharmacy Technician Responsibilities.

(1) Registered pharmacy technicians may assist the pharmacist in performing the following tasks:

(a) Retrieval of prescription files, patient files and profiles and other such records pertaining to the practice of pharmacy;

(b) Data Entry;

(c) Label preparation;

(d) The counting, weighing, measuring, pouring and mixing of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system;

(e) Initiate communication to a prescribing practitioner or their medical staffs (or agents) regarding patient prescription refill authorization requests. For the purposes of this section "prescription refill" means the dispensing of medications pursuant to a prescriber's authorization provided on the original prescription;

(f) Initiate communication to confirm the patient's name, medication, strength, quantity, directions and date of last refill;

(g) Initiate communication to a prescribing practitioner or their medical staff (or agents) to obtain clarification on missing or illegible dates, prescriber name, brand/generic preference, quantity, DEA registration number or license numbers; and

(h) May accept authorization for a prescription renewal. For the purposes of this section, "prescription renewal" means the dispensing of medications pursuant to a practitioner's authorization to fill an existing prescription that has no refill remaining.

(2) Registered Pharmacy technicians shall not:

(a) Receive new verbal prescriptions or any change in the medication, strength or directions;

(b) Interpret a prescription or medication order for therapeutic acceptability and appropriateness;

(c) Conduct a final verification of dosage and directions;

(d) Engage in prospective drug review;

(e) Provide patient counseling;

(f) Monitor prescription usage; and

(g) Override clinical alerts without first notifying the pharmacist.

(3) Nuclear pharmacy permits allow the registered pharmacy technician to receive diagnostic orders only. The pharmacist must receive therapy or blood product procedure orders.

(4)(a) All registered pharmacy technicians shall identify themselves as registered pharmacy technicians by wearing a type of identification badge that is clearly visible which specifically identifies the employee by name and by status as a "registered pharmacy technician"; and

(b) All registered pharmacy technicians shall state their names and verbally identify themselves as registered pharmacy technicians in the context of telephone or other forms of communication.

Rulemaking Authority 465.005, 465.014 FS. Law Implemented 465.014 FS. History–New 8-31-87, Formerly 21S-4.0025, Amended 7-30-91, Formerly 21S-27.420, 61F10-27.420, 59X-27.420, Amended 2-23-98, 1-1-10, 8-26-12.

64B16-27.430 Responsibilities of the Pharmacist.

The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one (1) pharmacist and one (1) registered pharmacy technician. In every pharmacy, the licensed pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in his employ and under his supervision.

Rulemaking Authority 465.005 FS. Law Implemented 465.014 FS. History–New 2-14-77, Formerly 21S-4.03, Amended 9-1-87, Formerly 21S-4.003, 21S-27.430, 61F10-27.430, 59X-27.430, Amended 1-1-10.

64B16-27.440 Policies and Procedures.

Any pharmacy utilizing registered pharmacy technicians shall be required to have written policies and procedures regarding the number of positions and their utilization, including the specific scope of responsibilities of technicians, available for inspection by the Florida Board of Pharmacy or its authorized agents and representatives.

Rulemaking Authority 465.005 FS. Law Implemented 465.014 FS. History–New 2-14-77, Formerly 21S-4.04, 21S-4.004, Amended 9-9-92, Formerly 21S-27.440, 61F10-27.440, 59X-27.440, Amended 1-1-10.

64B16-27.500 Negative Drug Formulary.

The negative drug formulary is composed of medicinal drugs which have been specifically determined by the Board of Pharmacy and the Board of Medicine to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, could produce adverse clinical effects, or could otherwise pose a threat to the health and safety of patients receiving such prescription medications. Except where certain dosage forms are included on the negative drug formulary as a class, all medicinal drugs are listed by their official United States Pharmacopoeia Non-Proprietary (generic) name. The generic name of a drug shall be applicable to and include all brand-name equivalents of such drug for which a prescriber may write a prescription. Substitution by a dispensing pharmacist on a prescription written for any brand name equivalent of a generic named drug product listed on the negative formulary or for a drug within the class of certain dosage forms as listed, is strictly prohibited. In cases where the prescription is written for a drug listed on the negative drug formulary but a brand name equivalent is not specified by the prescriber, the drug dispensed must be one obtained from a manufacturer or distributor holding an approved new drug application or abbreviated new drug application issued by the Food and Drug Administration, United States Department of Health and Welfare permitting that manufacturer or distributor to market those medicinal drugs or when the former is non-applicable, those manufacturers or distributors supplying such medicinal drugs must show compliance with other applicable Federal Food and Drug Administration marketing requirements. The following are included on the negative drug formulary:

(1) Digitoxin.
(2) Conjugated Estrogen.
(3) Dicumarol.
(4) Chlorpromazine (Solid Oral Dosage Forms).
(5) Theophylline (Controlled Release).
(6) Pancrelipase (Oral Dosage Forms).

Rulemaking Authority 465.005, 465.025(6) FS., Ch. 2001-146, Laws of Florida. Law Implemented 465.025(6) FS., Ch. 2001-146, Laws of Florida. History–New 12-14-76, Amended 3-17-77, 7-2-79, 4-9-81, 9-14-82, 9-26-84, Formerly 21S-5.01, Amended 3-30-89, 7-1-90, Formerly 21S-5.001, Amended 12-25-90, 10-1-92, Formerly 21S-27.500, Amended 2-21-94, Formerly 61F10-27.500, 59X-27.500, Amended 12-4-01, 3-18-10.

64B16-27.510 Identification of Manufacturer.

Each formulary of generic and brand name drug products established by each community pharmacy pursuant to the provisions of Section 465.025, F.S., shall include the name of the manufacturer of the generic drug listed in said formulary.

Rulemaking Authority 465.005 FS. Law Implemented 465.025 FS. History–New 3-16-77, Formerly 21S-5.02, 21S-5.002, 21S-27.510, 61F10-27.510, 59X-27.510.

64B16-27.520 Positive Drug Formulary.

A positive formulary of generic and brand name drug products is required of each community pharmacy pursuant to subsection 465.025(5), F.S. Those medicinal drugs on the positive formulary shall be obtained from manufacturers or distributors holding an approved new drug application or abbreviated new drug application issued by the Food and Drug Administration, U.S. Department of Health, Education and Welfare permitting that manufacturer or distributor to market those medicinal drugs or when the former is non-applicable, those manufacturers or distributors supplying those medicinal drugs must show compliance with other applicable Federal Food and Drug Administration marketing requirements.

Rulemaking Authority 465.005 FS. Law Implemented 465.025(6) FS. History–New 12-7-77, Formerly 21S-5.03, 21S-5.003, 21S-27.520, 61F10-27.520, 59X-27.520.

64B16-27.530 Duty of Pharmacist to Inform Regarding Drug Substitution.
Prior to the delivery of the prescription, a pharmacist must inform the person presenting a prescription of any substitution of a generic drug product for a brand name drug product, of any retail price difference between the two, and of the person's right to refuse the substitution. This information must be communicated at a meaningful time such as to allow the person to make an informed choice as to whether to exercise the option to refuse substitution without undue inconvenience to the presenter of the prescription or to the consumer of the drug. This information shall be communicated to the person presenting the prescription in a manner determined to be appropriate by the pharmacist using professional discretion and judgment.

Rulemaking Authority 465.005 FS. Law Implemented 465.025(3)(a) FS. History–New 11-10-80, Formerly 21S-5.04, 21S-5.004, 21S-27.530, 61F10-27.530, 59X-27.530, Amended 11-18-07.

64B16-27.615 Possession and Disposition of Sample Medicinal Drugs.
(1) Pharmacies may not be in possession of sample medicinal drugs except:
(a) Pharmacies may possess the sample medicinal drugs that are listed within Rule 64B16-27.220, F.A.C., Medicinal Drugs That May be Ordered by Pharmacists.
(b) Institutional pharmacies may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.
(c) Those community pharmacies that are pharmacies of health care entities, as defined by Sections 499.003(3) and (14), F.S., may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.
(2) Sample packages of medicinal drugs that are found to be unsuitable for dispensing by reason of physical condition or failure to meet requirements of state or federal law shall be returned to the company of origin in accordance with the requirements of Chapter 499, F.S.

Rulemaking Authority 465.005, 465.022, 499.028 FS. Law Implemented 465.018, 465.019, 465.022, 465.186, 499.028 FS. History–New 11-4-93, Formerly 61F10-27.615, 59X-27.615, Amended 11-18-07.

64B16-27.620 Disposition of Complimentary or Sample Medicinal Drugs Which Are Unsuitable for Dispensing.

Rulemaking Authority 465.005, 465.022, 499.028 FS. Law Implemented 465.022 FS. History–New 12-26-79, Formerly 21S-15.03, 21S-15.003, 21S-27.620, Amended 11-4-93, Formerly 61F10-27.620, 59X-27.620, Repealed 10-5-09.

64B16-27.700 Definition of Compounding.
"Compounding" is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent; and shall specifically include the professional act of preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S. The term also includes the preparation of nuclear pharmaceuticals and diagnostic kits incident to use of such nuclear pharmaceuticals. The term "commercially available products," as used in this section, means any medicinal product as defined by Sections 465.003(7) and (8), F.S., that are legally distributed in the State of Florida by a drug manufacturer or wholesaler.
(1) Compounding includes:
(a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.
(b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.
(c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.
(2) The preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding and is not within the practice of the profession of pharmacy. Except that the supply of patient specific compounded prescriptions to another pharmacy under the provisions of Section 465.0265, F.S., and Rule 64B16-28.450, F.A.C., is authorized.

(3) Office use compounding, "Office use" means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy. A pharmacist may dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with this section provided:

(a) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration date of the drug;

(b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;

(c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

Rulemaking Authority 465.005 FS. Law Implemented 465.003(12), 465.0155, 465.0265 FS. History–New 10-1-92, Formerly 21S-27.700, 61F10-27.700, 59X-27.700, Amended 11-2-03, 10-7-08.

64B16-27.797 Standards of Practice for Compounding Sterile Preparations (CSPs).

The purpose of this section is to assure positive patient outcomes through the provision of standards for 1) pharmaceutical care; 2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies, pursuant to or in anticipation of a prescription drug order, and 3) product quality and characteristics. These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office).

(1) Definitions:

(a) "Anteroom" means an area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas. The Anteroom area is to be maintained within ISO Class 8 level of particulate contamination.

(b) "Antineoplastic" means a pharmaceutical agent that has the intent of causing cell death targeted to cancer cells, metastatic cells, or other cells involved in a severe inflammatory or autoimmune response.

(c) "Beyond-use-date" means the date after which a compounded preparation should not be used and is determined from the date the preparation was compounded.

(d) "Biological safety cabinet" means a containment unit suitable for the preparation of low, moderate, and high risk agents where there is a need for protection of the product, personnel, and environment.

(e) "Bulk Compounding" means the compounding of CSPs in increments of twenty-five (25) or more doses from a single source.

(f) "Buffer area" (Clean room) is an area where the activities of CSP take place; it shall not contain sinks or drains. In High-Risk compounding this must be a separate room. The Buffer area is to be maintained within ISO Class 7 level of particulate contamination.

(g) "Class 100 environment" means an atmospheric environment which contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air. A class 100 environment is equivalent to ISO Class 5 level of particulate contamination.

(h) "Compounding Aseptic Isolator" (CAI) – is a form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process. Air exchange into the isolator from the surrounding environment should not occur unless it is first passed through a microbially retentive filter (HEPA minimum 0.2 microns).

(i) "High-Risk Level CSPs" – are products compounded under any of the following conditions are either non-sterile or at high risk to become non-sterile with infectious microorganisms.

1. Non-sterile ingredients, including manufactured products for routes of administration other than sterile parenteral administration are incorporated or a non-sterile device is employed before terminal sterilization.

2. Sterile contents of commercially manufactured products, CSP that lack effective antimicrobial preservatives, sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs are exposed to air quality worse than ISO Class 5 for more than one (1) hour.

3. Before sterilization, non-sterile procedures such as weighing and mixing are conducted in air quality worse than ISO Class 7, compounding personnel are improperly garbed and gloved, or water-containing preparations are stored for more than 6 hours.

4. For properly stored sterilized high-risk preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and exposed for not more than 24 hours at controlled room temperature, and for not more than 3 days at a cold temperature (2-8 degrees Celsius) and for not more than 45 days in solid frozen state at -20 degrees celsius or colder.

5. Examples of high-risk compounding include: (1) dissolving non-sterile bulk drug and nutrient powders to make solutions, which will be terminally sterilized; (2) exposing the sterile ingredients and components used to prepare and package CSPs to room air quality worse than ISO Class 5 for more than one (1) hour; (3) measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed; (4) assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

6. All high risk category products must be rendered sterile by heat sterilization, gas sterilization, or filtration sterilization in order to become a CSP.

7. Quality assurance practices for high-risk level CSPs include all those for low-risk level CSPs. In addition, each person authorized to compound high-risk level CSPs demonstrates competency by completing a media-filled test that represents high-level compounding semiannually.

(j) Immediate Use CSPs:

1. Requires only simple aseptic measuring and transfer manipulations are performed with not more than three (3) sterile non-hazardous drug or diagnostic radiopharmaceutical drug preparations, including an infusion or dilution solution.

2. The preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour.

3. At no point during preparation and prior to administration are critical surfaces and ingredients of the CSP directly exposed to contact contamination such as human touch, cosmetic flakes or particulates, blood, human body substances (excretions and secretions, e.g., nasal or oral) and non-sterile inanimate sources.

4. Administration begins not later than one (1) hour following the start of preparing the CSP.

5. When the CSP is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the CSP container shall bear a label listing patient identification information (name, identification numbers), and the names and amounts of all active ingredients, and the name or identifiable initials of the person who prepared the CSP, and one (1) hour beyond-use time and date.

6. If administration has not begun within one (1) hour following the start of preparing the CSP, the CSP is promptly and safely discarded. Immediate use CSPs shall not be stored for later use.

(k) ISO Class 5 guidelines are met when particulate contamination is measured at "not more than 3,520 particles 0.5 micron size or larger per cubic meter of air for any lamiar airflow workbench (LAWF), BSC, or CAI. (Also referred to as a "Class 100 environment.")

(l) ISO Class 7 guidelines are met when particulate contamination is measured at "not more than 352,000 particles 0.5 micron size or larger per cubic meter of air for any buffer area (room)."

(m) ISO Class 8 guidelines are met when particulate contamination is measured at "not more than 3,520,000 particles 0.5 micron size or larger per cubic meter of air for any anteroom (area)."

(n) Low-Risk Level CSPs compounded under all of the following are at a low risk of contamination:

1. The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 (class 100) or better air quality using only sterile ingredients, products, components, and devices.

2. The compounding involves only transfer, measuring, and mixing manipulations using no more than three commercially manufactured sterile products and entries into one container (e.g., bag, vial) of sterile product to make the CSP.

3. Manipulations are limited to aseptically opening ampoules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers for storage and dispensing. The contents of ampoules shall be passed through a sterile filter to remove any particles.

4. For low-risk preparation, in the absence of passing a sterility test or a documented validated process, the storage periods cannot exceed the following time periods; before administration, the CSPs are properly stored and exposed for not more than 48

hours at controlled room temperature, and for not more than 14 days at a cold temperature (2-8 degrees celsius) and for 45 days in solid frozen state at -20 degrees celsius or colder.

5. Quality Assurance practices include, but are not limited to, the following: (1) routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality; (2) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments; (3) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded; (4) Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and accuracy and thoroughness of labeling.

6. All compounding personnel are required to demonstrate competency by completing a media-filled test that represents low-level compounding annually. A media-filled test is a commercially available sterile fluid culture media that shall be able to promote exponential colonization of bacteria that are both likely to be transmitted to CSP from the compounding personnel and environment. Media filled vials are incubated at 25-35 degrees celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days.

(o) Medium-Risk Level CSPs – When CSPs are compounded aseptically under Low-Risk Conditions, and one or more of the following conditions exist, such CSPs are at a medium risk of contamination:

1. CSPs containing more than three (3) commercial sterile drug products and those requiring complex manipulations and/or preparation methods.

2. Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.

3. The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing.

4. For Medium-risk preparation, in the absence of passing a sterility test or a documented validated process, the storage periods cannot exceed the following time periods; before administration, the CSPs are properly stored and exposed for not more than 30 hours at controlled room temperature, and for not more than 9 days at a cold temperature and for 45 days in solid frozen state at -20 degrees celsius or colder.

5. These include compounding of total parenteral nutrition (TPN) using either manual or automated devices during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.

6. Filling of reservoirs of injection and infusion devices with more than three (3) sterile drug products and evacuation of air from those reservoirs before the filled devices are dispensed.

7. Transfer of volumes from multiple ampules or vials into one or more final sterile containers.

8. Quality assurance practices for medium-risk level CSPs include all those for low-risk level CSPs.

9. Demonstrates competency by completing a media-filled test that represents medium-level compounding annually.

(p) Parenteral means a sterile preparation of drugs for injection through one or more layers of the skin.

(q) Risk level of the sterile preparation means the level assigned to a sterile product by a pharmacist that represents the probability that the sterile product will be contaminated with microbial organisms, spores, endotoxins, foreign chemicals or other physical matter.

(r) Sterile preparation means any dosage form devoid of viable microorganisms, including but not limited to, parenterals, injectables, ophthalmics, and aqueous inhalant solutions for respiratory treatments.

(2) Compounded sterile preparations include, but are not limited, to the following:

(a) Total Parenteral Nutrition (TPN) solutions;

(b) Parenteral analgesic drugs;

(c) Parenteral antibiotics;

(d) Parenteral antineoplastic agents;

(e) Parenteral electrolytes;

(f) Parenteral vitamins;

(g) Irrigating fluids;

(h) Ophthalmic preparations; and

(i) Aqueous inhalant solutions for respiratory treatments.

(3) Sterile preparations shall not include commercially manufactured products that do not require compounding prior to dispensing.

(4) Policy & Procedure Manual. A policy and procedure manual shall be prepared and maintained for the compounding, dispensing, and delivery of sterile preparation prescriptions. The policy and procedure manual shall be available for inspection by the Department and include at a minimum:

(a) Use of single dose and multiple dose containers not to exceed United States Pharmacopeia 797 guidelines.

(b) Verification of compounding accuracy and sterility.

(c) Personnel training and evaluation in aseptic manipulation skills.

(d) Environmental quality and control:

1. Air particle monitoring for hoods (or Barrier Isolator), clean room and buffer area (or anteroom) when applicable;
2. Unidirectional airflow (pressure differential monitoring);
3. Cleaning and disinfecting the sterile compounding areas;
4. Personnel cleansing and garbing;
5. Environmental monitoring (air and surfaces).

(e) Personnel monitoring and validation.

(f) Finished product checks and tests.

(g) Method to identify and verify ingredients used in compounding.

(h) Labeling requirements for bulk compounded products:

1. Contents;
2. Beyond-Use-Date; and
3. Storage requirements.

(i) Packing, storage, and transportation conditions.

(5) Physical Requirements.

(a) The pharmacy shall have a designated area with entry restricted to designated personnel for preparing parenteral products. This area shall have a specified ante area and buffer area; in high risk compounding, this shall be separate rooms. This area shall be structurally isolated from other areas with restricted entry or access, and must be designed to avoid unnecessary traffic and interference with unidirectional airflow. It shall be used only for the preparation of these sterile preparations. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The pharmacy compounding parenteral and sterile preparation shall have the following:

1. Appropriate environmental control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; furthermore, these devices must be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air;
2. Appropriate disposal containers for used needles, syringes, and if applicable, for antineoplastic waste from the preparation of chemotherapy agents;
3. Appropriate environmental control including approved biohazard cabinetry when antineoplastic drug products are prepared;
4. Appropriate temperature and transport containers;
5. Infusion devices and equipment, if appropriate.

(c) The pharmacy shall maintain and use supplies adequate to preserve an environment suitable for the aseptic preparation of sterile preparations, such as:

1. Gloves, masks, shoe covers, head and facial hair covers, and non-shedding gowns;
2. Needles and syringes of various standard sizes;
3. Disinfectant cleaning agents;
4. Clean towels;
5. Hand washing materials with bactericidal properties;
6. Vacuum containers and various transfer sets;
7. "Spill kits" for antineoplastic agent spills.

(d) The pharmacy should have current reference material in hard copy or readily available on line:

1. USP Pharmacist Pharmacopeia (optional) or Handbook of Injectable Drugs by American Society of Hospital Pharmacists; or other nationally recognized standard reference; and

2. "Practice Guidelines for Personnel Dealing with Cytotoxic Drugs," or other nationally recognized standard cytotoxic reference if applicable.

(e) Barrier isolator is exempt from all physical requirements subject to manufacturer guidelines for proper placement.

(6) Antineoplastic Drugs. The following requirements are necessary for those pharmacies that prepare antineoplastic drugs to ensure the protection of the personnel involved:

(a) All antineoplastic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet placed in negative pressure room unless using barrier isolators. Other preparations shall not be compounded in this cabinet.

(b) Protective apparel shall be worn by personnel compounding antineoplastic drugs. This shall include at least gloves and gowns with tight cuffs.

(c) Appropriate safety and containment techniques for compounding antineoplastic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.

(d) Disposal of antineoplastic waste shall comply with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of antineoplastic agents shall be developed and shall be included in the policy and procedure manual.

(f) Prepared doses of antineoplastic drugs shall be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(7) Quality Assurance:

(a) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, and preparations. Appropriate samples of finished preparations shall be examined to assure that the pharmacy is capable of consistently preparing sterile preparations meeting specifications:

1. All clean rooms and laminar flow hoods shall be certified by an independent contractor or National Sanitation Foundation Standard 49, for operational efficiency at least semiannually for high risk CSPs and annually for low and medium risk CSPs or any time the hood is relocated or the structure is altered and records shall be maintained for two years.

2. There shall be written procedures developed requiring sampling if microbial contamination is suspected for batches greater than 25 units.

3. High risk greater than 25 units have antimicrobial testing prior to dispensing.

4. There shall be referenced written justification of the chosen beyond-use-dates for compounded products.

5. There shall be documentation of quality assurance audits at regular planned intervals, including infection control and sterile technique audits.

(b) Compounding personnel shall be adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties:

1. Demonstrate by observation or test a functional understanding of USP Chapter 797 and definitions, to include Risk Category assessment;

2. Understand the characteristics of touch contamination and airborne microbial contaminants;

3. Perform antiseptic hand cleaning and disinfections of non-sterile compounding surfaces;

4. Select and appropriately don protective garb;

5. Demonstrate aseptic techniques and requirements while handling medications;

6. Maintain and achieve sterility of CSPs in ISO Class 5 (Class 100) primary engineering devices and protect personnel and compounding environments from contamination by antineoplastic and chemotoxic or other hazardous drugs or substances;

7. Manipulate sterile products aseptically, sterilize high-risk level CSPs (where applicable) and quality inspect CSPs;

8. Identify, weigh and measure ingredients;

9. Prepare product labeling requirements and "beyond use" requirements of product expiration;

10. Prepare equipment and barrier requirement work requirements to maintain sterility;

11. Prepare end point testing and demonstrated competencies for relevant risk levels;

12. Prepare media fills to test aseptic technique.

(8) Radiopharmaceuticals as Compounded Sterile Products

(a) Upon release of a Positron Emission Tomography (PET) radiopharmaceutical as a finished drug product from a PET production facility, the further manipulation, handling, or use of the product will be considered compounding and will be subject to the rules of this section.

(b) Radiopharmaceuticals compounded from sterile components in closed, sterile containers and with a volume of 100 ml or less for single dose injection or not more than 30 ml taken from a multiple dose container, shall be designated as, and conform to, the standards for low risk compounding.

(c) Radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning ISO Class 5 PEC (Primary Engineering Control), located in an ISO Class 8 or better buffer area environment in compliance with special handling, shielding, air flow requirements, and radiation safety programs to maintain radiation exposure as low as reasonably achievable.

(d) Radiopharmaceuticals designed for multi use, compounded with Tc-99m, exposed to an ISO Class 5 environment by components with no direct contact contamination, may be used up until the time indicated by manufacturers recommendations.

(e) Technetium 99/Molybdnenum 99 generator systems shall be stored and eluted in an ISO Class 8 or cleaner environment to permit special handling, shielding, and airflow requirements.

(f) Manipulation of blood or blood derived products (e.g. radiolabeling white blood cells) shall be conducted in an area that is clearly separated from routine material handling areas and equipment, and shall be controlled by specific standard operating procedures to avoid cross contamination of products. The buffer area for manipulation of blood or blood derived products shall be maintained as an ISO 7 environment and direct manipulations shall occur in an ISO 5 PEC suitable for these products (e.g. biological safety cabinet).

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.0155, 465.022 FS. History–New 6-18-08, Amended 1-7-10.

64B16-27.800 Requirement for Patient Records.

(1) A patient record system shall be maintained by all pharmacies for patients to whom new or refill prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing. The pharmacist shall ensure that a reasonable effort is made to obtain, record and maintain the following information:

(a) Full name of the patient for whom the drug is intended;

(b) Address and telephone number of the patient;

(c) Patient's age or date of birth;

(d) Patient's gender;

(e) A list of all new and refill prescriptions obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and

(f) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) The pharmacist shall ensure that a reasonable effort is made to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review. The pharmacist shall record any related information indicated by a licensed health care practitioner.

(3) A patient record shall be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(4) Patient records shall be maintained for prescriptions dispensed subsequent to the effective date of this regulation.

Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155 FS. History–New 8-18-93, Formerly 21S-27.800, 61F10-27.800, 59X-27.800, Amended 6-15-98.

64B16-27.810 Prospective Drug Use Review.

(1) A pharmacist shall review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness by identifying:

(a) Over-utilization or under-utilization;

(b) Therapeutic duplication;

(c) Drug-disease contraindications;

(d) Drug-drug interactions;

(e) Incorrect drug dosage or duration of drug treatment;

(f) Drug-allergy interactions;

(g) Clinical abuse/misuse.

(2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.

Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155 FS. History–New 8-18-93, Formerly 21S-27.810, 61F10-27.810, 59X-27.810.

64B16-27.820 Patient Counseling.

(1) Upon receipt of a new or refill prescription, the pharmacist shall ensure that a verbal and printed offer to counsel is made to the patient or the patient's agent when present. If the delivery of the drugs to the patient or the patient's agent is not made at the pharmacy the offer shall be in writing and shall provide for toll-free telephone access to the pharmacist. If the patient does not refuse such counseling, the pharmacist, or the pharmacy intern, acting under the direct and immediate personal supervision of a licensed pharmacist, shall review the patient's record and personally discuss matters which will enhance or optimize drug therapy with each patient or agent of such patient. Such discussion shall be in person, whenever practicable, or by toll-free telephonic communication and shall include appropriate elements of patient counseling. Such elements may include, in the professional judgment of the pharmacist, the following:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of drug therapy;

(c) Intended use of the drug and expected action (if indicated by the prescribing health care practitioner);

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) Techniques for self-monitoring drug therapy;

(g) Proper storage;

(h) Prescription refill information;

(i) Action to be taken in the event of a missed dose; and

(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) Patient counseling as described herein, shall not be required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s).

(3) A pharmacist shall not be required to counsel a patient or a patient's agent when the patient or patient's agent refuses such consultation.

Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155 FS. History–New 8-18-93, Formerly 21S-27.820, 61F10-27.820, 59X-27.820.

64B16-27.830 Standards of Practice - Drug Therapy Management.

(1) "Prescriber Care Plan" means an individualized assessment of a patient and orders for specific drugs, laboratory tests, and other pharmaceutical services intended to be dispensed or executed by a pharmacist. The Prescriber Care Plan shall be written by a physician licensed pursuant to Chapter 458, 459, 461, or 466, F.S., or similar statutory provision in another jurisdiction, and may be transmitted by any means of communication. The Prescriber Care Plan shall specify the conditions under which a pharmacist shall order laboratory tests, interpret laboratory values ordered for a patient, execute drug therapy orders for a patient, and notify the physician.

(2) "Drug Therapy Management" means any act or service by a pharmacist in compliance with orders in a Prescriber Care Plan.

(3) A pharmacist may provide Drug Therapy Management services for a patient, incidental to the dispensing of medicinal drugs or as a part of consulting concerning therapeutic values of medicinal drugs or as part of managing and monitoring the patient's drug

therapy. A pharmacist who provides Drug Therapy Management services for a patient shall comply with orders in a Prescriber Care Plan, insofar as they specify:

(a) Drug therapy to be initially dispensed to the patient by the pharmacist; or

(b) Laboratory values or tests to be ordered, monitored and interpreted by the pharmacist; or

(c) The conditions under which the duly licensed practitioner authorizes the execution of subsequent orders concerning the drug therapy for the patient; or

(d) The conditions under which the pharmacist shall contact or notify the physician.

(4) A pharmacist who provides Drug Therapy Management services shall do so only under the auspices of a pharmacy permit that provides the following:

(a) A transferable patient care record that includes:

1. A Prescriber Care Plan that includes a section noted as "orders" from a duly licensed physician for each patient for whom a pharmacist provides Drug Therapy Management services;

2. Progress notes; and

(b) A pharmaceutical care area that is private, distinct, and partitioned from any area in which activities other than patient care activities occur, and in which the pharmacist and patient may sit down during the provision of Drug Therapy Management services; and

(c) A continuous quality improvement program that includes standards and procedures to identify, evaluate, and constantly improve Drug Therapy Management services provided by a pharmacist.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(13), 465.0155, 465.022(1)(b) FS. History–New 4-4-00.

64B16-27.831 Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain.

(1) An order purporting to be a prescription that is not issued for a legitimate medical purpose is not a prescription and the pharmacist knowingly filling such a purported prescription shall be subject to penalties for violations of the law.

(2) The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:

(a) Frequent loss of controlled substance medications,

(b) Only controlled substance medications are prescribed for a patient,

(c) One person presents controlled substance prescriptions with different patient names,

(d) Same or similar controlled substance medication is prescribed by two or more prescribers at same time,

(e) Patient always pays cash and always insists on brand name product.

(3) If any of the criteria in (2) is met, the pharmacist shall:

(a) Require that the person to whom the medication is dispensed provide picture identification and the pharmacist should photocopy such picture identification for the pharmacist's records. If a photocopier is not available, the pharmacist should document on the back of the prescription complete descriptive information from the picture identification. If the person to whom medication is dispensed has no picture identification, the pharmacist should confirm the person's identity and document on the back of the prescription complete information on which the confirmation is based.

(b) Verify the prescription with the prescriber. A pharmacist who believes a prescription for a controlled substance medication to be valid, but who has not been able to verify it with the prescriber, may determine not to supply the full quantity and may dispense a partial supply, not to exceed a 72 hour supply. After verification by the prescriber, the pharmacist may dispense the balance of the prescription within a 72 hour time period following the initial partial filling, unless otherwise prohibited by law.

(4) Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 465.017(2), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substance medications being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substance medications being dispensed to a specific patient.

(5) Any pharmacist who has reason to believe that a prescriber of controlled substances is involved in the diversion of controlled substances shall report such prescriber to the Department of Health.

(6) Any pharmacist that dispenses a controlled substance subject to the requirements of this rule when dispensed by mail shall

be exempt from the requirements to obtain suitable identification.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 456.072(1)(i), 465.0155, 465.016(1)(i), (o), 465.017(2) FS. History–New 8-29-02, Amended 2-24-03, 11-18-07.

64B16-27.850 Standards of Practice for Orthotics and Pedorthics.

(1) Definitions.

(a) "Orthosis" means a medical device used to provide support, correction, or alleviation of neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity, but does not include the following assistive technology devices: upper extremity adaptive equipment used to facilitate the activities of daily living, including specialized utensils, combs, and brushes; finger splints; wheelchair seating and equipment that is an integral part of the wheelchair and not worn by the patient; elastic abdominal supports that do not have metal or plastic reinforcing stays; arch supports; nontherapeutic accommodative inlays and nontherapeutic accommodative footwear, regardless of method of manufacture; unmodified, over-the-counter shoes; prefabricated foot care products; durable medical equipment such as canes, crutches, or walkers; dental appliances; or devices implanted into the body by a physician. For purposes of this subsection, "accommodative" means designed with the primary goal of conforming to the individual's anatomy and "inlay" means any removable material upon which the foot directly rests inside the shoe and which may be an integral design component of the shoe.

(b) "Orthotics" means the practice, pursuant to a licensed physician's written prescription, of evaluating, treatment formulating, measuring, designing, fabricating, assembling, fitting, adjusting, servicing, or providing the initial training necessary to accomplish the fitting of an orthosis or pedorthic device; however, the repair, replacement, adjustment, or servicing of any existing orthosis may be performed without an additional prescription from the patient's physician, unless the original prescription states otherwise. If a patient is under the care of a licensed occupational therapist or physical therapist, the pharmacist must consult with the therapist if the therapist has requested consultation regarding the fitting, design, or fabrication of an orthosis or regarding treatment with an orthosis.

(c) "Pedorthic device" means therapeutic shoes, shoe modifications made for therapeutic purposes, prosthetic fillers of the forefoot, and foot orthoses for use from the ankle and below, but does not include arch supports; nontherapeutic accommodative inlays and nontherapeutic accommodative footwear, regardless of method of manufacture; unmodified, over-the-counter shoes; or prefabricated foot care products. For purposes of this subsection, "accommodative" means designed with the primary goal of conforming to the individual's anatomy and "inlay" means any removable material upon which the foot directly rests inside the shoe and which may be an integral design component of the shoe.

(d) "Pedorthics" means the practice, pursuant to a licensed physician's written prescription, of evaluating, treatment formulating, measuring, designing, fabricating, assembling, fitting, adjusting, servicing, or providing the initial training necessary to accomplish the fitting of a pedorthic device; however, the repair, replacement, adjustment, or servicing of any existing pedorthic device may be performed without an additional prescription from the patient's physician, unless the original prescription states otherwise. If a patient is under the care of a licensed occupational therapist or physical therapist, the pharmacist must consult with the therapist if the therapist has requested consultation regarding the fitting, design, or fabrication of a pedorthic device or regarding treatment with a pedorthic device.

(2) Pursuant to a licensed physician's written prescription, the pharmacist shall assume the responsibility for assessing the patient, planning the patient's treatment program, and directing the program. No pharmacist shall implement a prescription that, in the pharmacist's judgment, is contraindicated. No change shall be made in the prescription without the authorization of the prescribing physician.

(3) The pharmacist's professional responsibilities include:

(a) Ongoing consultation with the prescribing physician regarding information that will impact the patient's medical and functional outcomes.

(b) Orthotic and/or pedorthic evaluation of the patient.

(c) Identification and documentation of precautions, special problems, or contraindications.

(d) Development of a treatment plan including the short and long terms goals.

(e) Implementation of a treatment plan.

(f) Periodic review and update of the treatment plan, including reassessment of the patient in reference to goals and, when necessary, modification of the treatment plan.

(g) Collaboration with members of the health care team when appropriate.

(h) Advising the patient, in terms which the patient can understand, of the nature and purpose of the services to be rendered and the techniques for use and care of an orthosis or pedorthic device.

(i) Determination of the appropriateness of proper fit and function of any orthosis or pedorthic device.

(4) A pharmacist may delegate duties to nonlicensed supportive personnel if those duties are performed under the supervision of the pharmacist. In such instances the supervising pharmacist is responsible for all acts performed by such persons. It is below the standard of practice and prohibited for a pharmacist to delegate or assign activities, tasks or procedures that fall within the scope of any practice defined in Section 468.812(3), F.S., to support personnel, without providing supervision for the performance of the activities, tasks or procedures.

Rulemaking Authority 468.812(3) FS. Law Implemented 465.0155, 468.812(3) FS. History–New 5-2-07.

64B16-27.851 Record-Keeping for Orthotics and Pedorthics.

(1) The pharmacist or supportive personnel shall prepare and maintain in a timely manner patient records which include, at a minimum, the following:

(a) The patient name, address and telephone number;

(b) The location and dates of all treatment, evaluation or consultation;

(c) The name of the prescribing physician;

(d) All prescriptions pertaining to services provided to the patient;

(e) A treatment or service plan;

(f) Progress notes for each session;

(2) The licensee may charge a fee for the reproduction of records, which shall be no greater than $ 1.00 per page for the first 25 pages, and $0.50 per page for every page after 25. In addition, the actual cost of postage may be added. Reasonable costs of reproducing radiographs and such other kinds of records shall be the actual costs. "Actual costs" means the cost of the material and supplies used to duplicate the record and the labor and overhead costs associated with the duplication.

(3) The licensee shall retain the patient record for at least two years from the date of last entry, unless otherwise provided by law.

Rulemaking Authority 468.802, 468.812(3) FS. Law Implemented 456.057(16), 465.0155, 465.022, 468.802, 468.812(3) FS. History-New 5-2-07.

CHAPTER 64B16-28
GENERAL REQUIREMENTS – PERMITS

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64B16-28.101 Prescription Area Accessible to Inspection.

(1) The prescription department compounding room or any other place where prescriptions are compounded, filled, processed, accepted, dispensed, or stored in each pharmacy shall be so situated and located that authorized agents and employees of the Department or other persons authorized by law to enter and inspect, can observe and survey the confines of said department, room or area and can enter into said department, room or area after identifying themselves, for the purpose of inspection at a reasonable hour or when the practice of the profession of pharmacy is being carried on, as defined in Section 465.003, F.S., without having been previously detained or announced. Such inspection may be routinely conducted at any time by authorized agents of the Department to determine whether Chapter 465, F.S., or provisions of these rules have been violated or for other lawful purposes, and need not be in response to a complaint filed with the Department. There shall be a minimum of one (1) inspection per year except as otherwise provided herein or directed by the Board.

(a) A pharmacy shall be inspected twice during the first year of operation.

(b) A pharmacy which has had passing inspections for the most current three years, and no discipline during the most current three years shall be inspected every two years.

(c) A pharmacy which fails to obtain a passing inspection or which is disciplined during the two year inspection cycle will be inspected annually until it achieves passing inspections for the most current three years, and no discipline during the most current three years as set forth in this subsection.

(2) Authorized agents and employees of the Department or other persons authorized by law shall have the right to inspect invoices, shipping tickets, or any other document pertaining to the transfer of drugs or drug preparations, from or to all pharmacies and a reasonable amount of time shall be allowed for said information to be made available.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.017, 465.022 FS. History–Amended 5-19-72, 11-2-81, Formerly 21S-1.01, 21S-1.001, Amended 7-31-91, Formerly 21S-28.101, 61F10-28.101, 59X-28.101, Amended 5-4-05, 2-2-12.

64B16-28.102 Sink and Running Water, Sufficient Space, Refrigeration, Sanitation, Equipment.

There shall be provided for the prescription department of each pharmacy:

(1) An adequate sink in workable condition and running water easily accessible to the prescription counter that shall be available during the hours when the prescription department is normally open for the business related to prescriptions.

(2) Sufficient shelf, drawer or cabinet space for the neat and orderly storage of pharmaceutical stock, prescription containers, prescription labels, the required equipment, and all other items, articles or equipment stored therein and there shall be sufficient walking space and sufficient work counter space within each prescription department of said establishment so as to allow employees or pharmacists employed therein to adequately, safely, and accurately fulfill their duties related to prescriptions.

(3) Adequate facilities for the proper storage of pharmaceuticals which require refrigeration, and such pharmaceuticals shall be stored therein, and in such manner as to preserve their therapeutic activity.

(4) Adequate sanitation to insure the prescription department is operating under clean, sanitary, uncrowded, and healthy conditions.

(5) The following items:

(a) A current pharmacy reference compendium such as the United States Pharmacopoeia/National Formulary, the U.S. Dispensatory, USP DI, (United States Pharmacopoeial Drug Information), the Remington Practice of Pharmacy, Facts and Comparisons or an equivalent thereof sufficient in scope to meet the professional practice needs of that pharmacy, and a current

copy of the laws and rules governing the practice of pharmacy in the State of Florida. It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

(b) Such other equipment as is necessary to meet the needs of the professional practice of pharmacy.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.02, 21S-1.002, 21S-28.102, 61F10-28.102, 59X-28.102, Amended 5-4-05.

64B16-28.103 Sufficient Space in Prescription Department.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.03, 21S-1.003, 21S-28.103, 61F10-28.103, 59X-28.103, Repealed 5-4-05.

64B16-28.1035 Patient Consultation Area.

A community pharmacy shall provide a private consultation area so all patients of the pharmacy will be able to obtain counseling without being overheard by others in the prescription dispensing area of the pharmacy. The consultation area must be accessible by the patient from the outside of the prescription dispensing area of the pharmacy without having to traverse a stockroom or the prescription dispensing area. In determining whether the area is suitable, consideration shall be given to the proximity of the counseling area to the check-out or cash register area, the volume of pedestrian traffic in and around the consultation area, and the presence of walls or other barriers between the counseling area and the prescription dispensing area of the pharmacy. The consultation area may consist of designated private counter space. The area shall be designated with a sign bearing "Patient Consultation Area", or words that are substantially similar.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History-New 9-20-99, Amended 5-4-05.

64B16-28.104 Refrigeration.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.04, 21S-1.004, 21S-28.104, 61F10-28.104, 59X-28.104, Repealed 5-4-05.

64B16-28.105 Sanitation.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 1-29-80, Formerly 21S-1.07, 21S-1.007, Amended 7-31-91, Formerly 21S-28.105, 61F10-28.105, 59X-28.105, Repealed 5-4-05.

64B16-28.106 Right to Inspect Invoices.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.017 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, 4-30-85, Formerly 21S-1.008, 21S-28.106, 61F10-28.106, 59X-28.106, Repealed 5-4-05.

64B16-28.107 Pharmacy Equipment.

Rulemaking Authority 465.005, 465.022, 465.022(1)(h) FS. Law Implemented 465.022(1)(h) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 4-8-80, 4-26-84, Formerly 21S-1.10, Amended 4-4-88, Formerly 21S-1.010, Amended 7-31-91, Formerly 21S-28.107, 61F10-28.107, Amended 6-4-97, Formerly 59X-28.107, Amended 2-4-99, Repealed 5-4-05.

64B16-28.108 All Permits – Labels and Labeling of Medicinal Drugs.

Each container of medicinal drugs dispensed shall have a label or shall be accompanied by labeling.

(1) Definitions.

(a) "Controlled substance" means any substance named or described in Schedules II-V of Section 893.03, F.S.

(b) "Customized medication package" means a package that:

1. Is prepared by a pharmacist for a specific patient.
2. Is a series of containers.
3. Contains two (2) or more solid oral dosage forms.

(c) "Labeling" means a label or other written, printed, or graphic material upon an agent or product or any of its containers,

wrappers, drug carts, or compartments thereof, as well as a medication administration record (MAR) if a medication administration record is an integral part of the unit dose system.

(d) "Radiopharmaceutical" means any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any of those drugs intended to be made radioactive. This includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance, but does not include drugs which are carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(e) "Serial number" means a prescription number or other unique number by which a particular prescription or drug package can be identified.

(2) The label affixed to each container dispensed to a patient shall include:

(a) Name and address of the pharmacy.

(b) Date of dispensing.

(c) Serial number.

(d) Name of the patient or, if the patient is an animal, the name of the owner and the species of animal.

(e) Name of the prescriber.

(f) Name of the drug dispensed (except where the prescribing practitioner specifically requests that the name is to be withheld).

(g) Directions for use.

(h) Expiration date.

(i) If the medicinal drug is a controlled substance, a warning that it is a crime to transfer the drug to another person.

(3) The label on the immediate container of a repackaged product or a multiple unit prepackaged drug product shall include:

(a) Brand or generic name.

(b) Strength.

(c) Dosage form.

(d) Name of the manufacturer.

(e) Expiration date.

(f) Lot number:

1. Manufacturer's lot number, or

2. Number assigned by the dispenser or repackager which references the manufacturer's lot number.

(4) A medicinal drug dispensed in a unit dose system by a pharmacist shall be accompanied by labeling. The requirement will be satisfied if, to the extent not included on the label, the unit dose system indicates clearly the name of the resident or patient, the prescription number or other means utilized for readily retrieving the medication order, the directions for use, and the prescriber's name.

(5) A unit dose system shall provide a method for the separation and identification of drugs for the individual resident or patient.

(6) A customized patient medication package may be utilized if:

(a) The consent of the patient or the patient's agent has been secured, and

(b) The label includes:

1. Name, address and telephone number of the pharmacy.

2. Serial number for the customized medication package and a separate serial number for each medicinal drug dispensed.

3. Date of preparation of the customized patient medication package.

4. Patient's name.

5. Name of each prescriber.

6. Directions for use and any cautionary statements required for each medicinal drug.

7. Storage instructions.

8. Name, strength, quantity and physical description of each drug product.

9. A beyond use date that is not more than 60 days from the date of preparation of the customized patient medication package but shall not be later than any appropriate beyond use date for any medicinal drug included in the customized patient medication package.

(c) The customized patient medication package can be separated into individual medicinal drug containers, then each container shall identify the medicinal drug product contained.

(7) The label affixed to the immediate outer container shield of a radiopharmaceutical shall include:
(a) Name and address of the pharmacy.
(b) Name of the prescriber.
(c) Date of the original dispensing.
(d) The standard radiation symbol.
(e) The words "Caution Radioactive Material."
(f) Name of the procedure.
(g) Prescription order number.
(h) Radionuclide and chemical form.
(i) Amount of radioactivity and the calibration date and time.
(j) Expiration date and time.
(k) If a liquid, the volume.
(l) If a solid, the number of items or weight.
(m) If a gas, the number of ampules or vials.
(n) Molybdenum 99 content to the United States Pharmacopeia (UPS) limits.
(o) Name of the patient or the words "Physician's Use Only."
(8) The label affixed to the immediate inner container of a radiopharmaceutical to be distributed shall include:
(a) The standard radiation symbol.
(b) The words "Caution Radioactive Material."
(c) Radionuclide and chemical form.
(d) Name of the procedure.
(e) Prescription order number of the radiopharmaceutical.
(f) Name of the pharmacy.
(9) The labeling on a carton or package containing a medicinal drug or product dispensed from an Extended Scope Renal Dialysis (ESRD) pharmacy shall include:
(a) "Use as Directed" statement.
(b) The name and address of the person to whom the products will be delivered.
(c) Name of the prescriber.
(d) Name and address of the ESRD pharmacy location from which the products were shipped.
(e) Prescription number.
(f) Any special instructions regarding delivery dates or locations.
(g) Beyond use date or, if the medicinal drug or product is dispensed in an unopened sealed package, the manufacturer's expiration date.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, 9-18-84, 1-20-85, Formerly 21S-1.13, Amended 10-2-88, Formerly 21S-1.013, Amended 7-31-91, 10-1-92, 4-19-93, 7-12-93, Formerly 21S-28.108, 61F10-28.108, 59X-28.108, Amended 3-31-05.

64B16-28.1081 Regulation of Daily Operating Hours.
Any person who receives a community pharmacy permit pursuant to Section 465.018, F.S., and commences to operate such an establishment shall keep the prescription department of the establishment open for a minimum of forty (40) hours per week. The Board hereby approves exceptions to the requirements noted above and permits closing of the prescription department for the following holidays: New Year's Day, Memorial Day, Fourth of July (Independence Day), Labor Day, Veterans' Day, Thanksgiving, Christmas and any bona fide religious holiday provided that notice of such closing is given in a sign as set forth herein. A sign in block letters not less than one inch in height stating the hours the prescription department is open each day shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view. The prescription department manager may petition the Board in writing to operate the prescription department for less than forty (40) hours per week, but no less than twenty (20) hours per week. Prior to approving reduced hours, the Board may require the prescription department manager to appear before the Board to explain in detail the services that will be performed. Any pharmacy open less than 40 hours shall have a policy and procedure that provides a mechanism for access to a

pharmacist during the time the pharmacy is not open for the remainder of the forty hour week. Any pharmacy that is not open 40 hours a week, must post the days and hours that the pharmacy is open and the information for after-hours access. Any pharmacy open less than 40 hours shall also have a policy and procedure for transferring a prescription pursuant to Rule 64B16-27.105, F.A.C., or receiving an emergency dose pursuant to Section 465.0275, F.S. during the time the pharmacy is open less than 40 hours.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 4-10-05, Amended 2-1-12.

64B16-28.109 Prescription Department; Padlock; Sign: "Prescription Department Closed."

(1) The prescription department of any community pharmacy permittee shall be considered closed whenever the establishment is open and a pharmacist is not present and on duty. A sign with bold letters not less than two (2) inches in width and height, shall be displayed in a prominent place in the prescription department so that it may easily be read by patrons of that establishment. The sign shall contain the following language: "Prescription Department Closed."

(2) The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purpose of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, taking a meal break pursuant to Rule 64B16-27.1001, F.A.C., or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

(3) At all times when the prescription department is closed, either because of the absence of a pharmacist or for any other reason, it shall be separated from the remainder of the establishment by partition or other means of enclosure, thereby preventing access to the prescription department by persons not licensed in Florida to practice the profession of pharmacy.

(4) The partition or other means of enclosure shall be securely locked or padlocked and only a pharmacist shall have the means to gain access to the prescription department.

(5) Whenever the prescription department of any community pharmacy establishment is closed, no person other than a pharmacist shall enter, be permitted to enter or remain in the prescription department.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Amended 8-20-63, 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, Formerly 21S-1.14, 21S-1.014, Amended 7-31-91, Formerly 21S-28.109, 61F10-28.109, 59X-28.109, Amended 6-15-98, 4-10-05.

64B16-28.110 Outdated Pharmaceuticals.

Persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.17, 21S-1.017, 21S-28.110, 61F10-28.110, 59X-28.110.

64B16-28.111 Storage of Equipment.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Repromulgated 12-18-74, Formerly 21S-1.19, 21S-1.019, 21S-28.111, 61F10-28.111, 59X-28.111, Repealed 4-10-05.

64B16-28.112 Violations.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 8-20-63, Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.23, 21S-1.023, Amended 7-31-91, Formerly 21S-28.112, 61F10-28.112, 59X-28.112, Repealed 4-10-05.

64B16-28.113 Permits; Single Entity; Single Location.

A Board of Pharmacy permit shall be issued only to a single entity at a single location. The service provided by the permit shall be consistent with the issued permit. A single location shall be defined as:

(1) A contiguous area under the control of the permit holder. For purposes of this section, a public thoroughfare will be considered to have not broken the area of contiguity; and

(2) An area not more than one-half mile from the central location of the permit.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(10)(a), 465.018, 465.019, 465.0193, 465.0196 FS. History–New 1-30-96, Formerly 59X-28.113.

64B16-28.1135 Change of Ownership.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022(7) FS. History–New 4-19-00, Amended 1-2-02, Transferred to 64B16-28.2021.

64B16-28.114 Prescription Refills.

Rulemaking Authority 465.005, 465.016(1), 465.022, 465.022(1)(a), 893.04 FS. Law Implemented 465.022 FS. History–New 12-18-74, Formerly 21S-1.28, 21S-1.028, Amended 7-31-91, Formerly 21S-28.114, 61F10-28.114, 59X-28.114, Amended 2-4-02, 7-1-02, Repealed 10-5-09.

64B16-28.118 Unit Dose and Customized Patient Medication Package Returns by In-patients.

No pharmacist shall place into the stock of any pharmacy permittee any part of any prescription, compounded or dispensed, which is returned by a patient except under the following conditions:

(1) In a closed drug delivery system in which unit dose or customized patient medication packages are dispensed to in-patients, the unused medication may be returned to the pharmacy for redispensing only if each unit dose or customized patient medication package is individually sealed and if each unit dose or the unit dose system, or the customized patient medication package container or the customized patient medication package unit of which it is clearly a part is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any.

(2) In the case of controlled substances, as it is allowed by Federal Law.

(3) A "unit dose system" to which this rule applies means a system wherein all individually sealed unit doses are physically connected as a unit. For purpose of this section, a product in an unopened, sealed, manufacture's container is deemed to be a unit dose package.

(4) A "customized patient medication package" to which this rule applies means a system wherein all USP approved multi-dose units are physically connected and are referred to as a container. The use of customized patient medication packages must comply with the provisions of subsection 64B16-28.108(5), F.A.C.

(5) A "closed drug delivery system" to which this rule applies is a system in which the actual control of the unit dose or customized patient medication package is maintained by the facility rather than by the individual patient.

(6) All pharmacies utilizing unit dose or customized patient medication packages shall address specific policies and procedures regarding their preparation and use in their Policy and Procedures Manual.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.016(1)(l) FS. History–New 11-10-80, Formerly 21S-1.36, 21S-1.036, Amended 7-31-91, Formerly 21S-28.118, 61F10-28.118, 59X-28.118, Amended 9-23-99, 7-1-02.

64B16-28.119 Data Processing Systems in Pharmacy.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History–New 9-21-83, Formerly 21S-1.38, 21S-1.038, Amended 7-31-91, Formerly 21S-28.119, Amended 3-16-94, Formerly 61F10-28.119, 59X-28.119, Repealed 7-15-99.

64B16-28.1191 Unclaimed Prescriptions.

Prescriptions that are unclaimed may be retained by a pharmacy and reused for a period up to one year from the date of filling; however, any product reaching the product's expiration date prior to one year or any product subject to a recall shall not be reused.

Rulemaking Authority 465.0255 FS. Law Implemented 465.0255 FS. History–New 4-10-05.

64B16-28.120 All Permits – Storage of Legend Drugs; Prepackaging.

(1) All medicinal drugs or drug preparations as defined by Section 465.003(8), F.S., shall be stored:

(a) Within the confines of the prescription department of a community pharmacy permittee as defined in Section 465.018, F.S.

(b) In a Class II Institutional pharmacy as defined by Section 465.019(2)(b), F.S., within the confines of the pharmacy provided,

however, that those medicinal drugs established by the consultant pharmacist as supportive to treatment procedures such as medical drugs, surgical, obstetrical, diagnostic, etc., may be permitted to be stored in those areas where such treatment is conducted consistent with proper control procedures as provided by the policy and procedure manual of the pharmacy.

(2) All medicinal drugs or drug preparations as defined in Section 465.003(8), F.S., within Class I Institutional permittees as defined in Section 465.019(2)(a), F.S., and Special ALF Permit 64B16-28.870, F.A.C., shall:

(a) Be administered from individual prescription containers to the individual patient; and

(b) Be prohibited within the confines of Class I Institutional pharmacies unless obtained upon a proper prescription and properly labeled in accordance with Chapter 499, F.S., and the rules and regulations contained in Chapter 59A-4, F.A.C., incorporated by reference and effective August 1, 2006, pertaining to the licensure of nursing homes and related facilities.

(3) Prepackaging of medication, whether a part of a unit dose system or a part of a multiple dose drug distribution system in an extended care facility or hospital holding a valid Class II Institutional pharmacy permit, must be done in accordance with procedures set up by the consultant pharmacist of record in the policy and procedure manual; and in the case of a pharmacy holding a valid community pharmacy permit must be done in accordance with procedures set up by the prescription department manager.

(4) Medicinal drugs and proprietary preparations as identified above that are stored in treatment areas must be accessible only to licensed staff (pharmacists, nurses, physicians, advanced registered nurse practitioners, physician assistants, respiratory and physical therapist, radiology technicians and registered pharmacy technicians, etc.) in accordance with their license, practice act, or to other personnel specifically authorized by the institution.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 435.019(2), 465.003(7), 465.022 FS. History–New 9-18-84, Formerly 21S-1.44, 21S-1.044, Amended 7-31-91, Formerly 21S-28.120, 61F10-28.120, 59X-28.120, Amended 2-8-07, 8-16-10.

64B16-28.121 Permit Fees.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–New 7-31-91, Formerly 21S-28.121, 61F10-28.121, 59X-28.121, Amended 10-30-00, Repealed 4-10-05.

64B16-28.130 Transmission of Prescription Orders.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History–New 3-16-94, Formerly 61F10-28.130, 59X-28.130, Repealed 4-10-05.

64B16-28.140 Record Maintenance Systems for Community, Special-Limited Community, Special-Closed Systems, Special-Parenteral/Enteral, and Nuclear Permits.

(1) Requirements for records maintained in a data processing system.

(a) The pharmacy must comply with the provisions of 21 C.F.R. Section 1304.04 (a regulation of the Federal Drug Enforcement Administration), which is hereby incorporated by reference as of March 1, 1998, when such is applicable to operate such a data processing system if any controlled substances (as that term is used in Ch. 893, F.S.) are dispensed from the pharmacy.

(b) Any pharmacy using a data processing system must meet the requirements of 21 C.F.R. Section 1306.22, which is hereby incorporated by reference as of March 1, 1998.

(c) If a pharmacy's data processing system is not in compliance with this subsection, the pharmacy must maintain a manual recordkeeping system as specified in Rule 64B16-27.800, F.A.C., and Section 893.07, F.S.

(d) Original prescriptions, including prescriptions received as provided for in Rule 64B16-28.130, F.A.C., Transmission of Prescription Orders, shall be reduced to a hard copy if not received in written form. All original prescriptions shall be retained for a period of not less than two years from date of last filling. To the extent authorized by 21 C.F.R. Section 1304.04, a pharmacy may, in lieu of retaining the actual original prescriptions, use an electronic imaging recordkeeping system, provided such system is capable of capturing, storing, and reproducing the exact image of the prescription, including the reverse side of the prescription if necessary, and that such image be retained for a period of no less than two years from the date of last filling.

(e) Original prescriptions shall be maintained in a two or three file system as specified in 21 C.F.R. 1304.04(h).

(f) Requirements for back-up systems.

1. The pharmacy shall maintain a back-up copy of information stored in the data processing system using disk, tape or other electronic back-up system and update this back-up copy on a regular basis, at least weekly, to assure that data is not lost due to

system failure.

2. Data processing systems shall have a workable (electronic) data retention system which can produce an audit trail of drug usage for the preceding two years as specified in Rule 64B16-27.800, F.A.C.

(g) Change or discontinuance of a data processing system.

1. Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records of dispensing to the new data processing system; or

b. Purge the records of dispensing to a printout which contains the same information required on the daily printout as specified in paragraph (3)(b) of this section. The information on this hard-copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription chronologically.

2. Other records. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system; or

b. Purge the records to a printout which contains all of the information required on the original document.

3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(h) Loss of Data. The prescription department manager shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(2) All transfers of prescriptions must be strictly in accordance with the provisions of Section 465.026, F.S., and Rule 64B16-27.105, F.A.C.

(3) Records of dispensing.

(a) Each time a prescription drug order is filled or refilled, a record of such dispensing shall be entered into the data processing system.

(b) The data processing system shall have the capacity to produce a daily hard-copy printout of all original prescriptions dispensed and refilled. This hard copy printout shall contain the following information:

1. Unique identification number of the prescription;

2. Date of dispensing;

3. Patient name;

4. Prescribing practitioner's name;

5. Name and strength of the drug product actually dispensed, if generic name, the brand name or manufacturer of drug dispensed;

6. Quantity dispensed;

7. Initials or an identification code of the dispensing pharmacist; and

8. If not immediately retrievable via CRT display, the following shall also be included on the hard-copy printout:

a. Patient's address;

b. Prescribing practitioner's address;

c. Practitioner's DEA registration number, if the prescription drug order is for a controlled substance.

d. Quantity prescribed, if different from the quantity dispensed;

e. Date of issuance of the prescription drug order, if different from the date of dispensing; and

f. Total number of refills dispensed to date for that prescription drug order.

(c) The daily hard-copy printout shall be produced within 72 hours of the date on which the prescription drug orders were dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of non-controlled substances.

(d) Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document (e.g., J.H. Smith, or John H. Smith) within seven days from the date of dispensing.

(e) In lieu of producing the printout described in paragraphs (b) and (c) of this section, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing provided, however, that the data processing system can produce the hard-copy printout on demand by an authorized agent of the Department

of Health. If no printer is available on site, the hard-copy printout shall be available within 48 hours with a certification by the individual providing the printout, which states that the printout is true and correct as of the date of entry and such information has not been altered, amended or modified.

(f) The prescription department manager and the permit holder are responsible for the proper maintenance of such records and responsible that such data processing system can produce the records outlined in this section and that such system is in compliance with this subsection.

(g) Failure to provide the records set out in this section, either on site or within 48 hours for whatever reason, constitutes failure to keep and maintain records.

(h) In the event that a pharmacy which uses a data processing system experiences system downtime, the following is applicable;

1. An auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded or that authorization from the prescribing practitioner has been obtained prior to dispensing a refill; and

2. All of the appropriate data shall be retained for on-line data entry as soon as the system is available for use again.

(4) Compounding records. A written record shall be maintained for each batch/sub-batch of a compounded product under the provisions of Rule 64B16-27.700, F.A.C. This record shall include:

(a) Date of compounding.

(b) Control number for each batch/sub-batch of a compounded product. This may be the manufacture's lot number or new numbers assigned by the pharmacist. If the number is assigned by the pharmacist, the pharmacist shall also record the original manufacture's lot number and expiration dates. If the original numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the component.

(c) A complete formula for the compounded product maintained in a readily retrievable form including methodology and necessary equipment.

(d) A signature or initials of the pharmacist or pharmacy technician performing the compounding.

(e) A signature or initials of the pharmacist responsible for supervising pharmacy technicians involved in the compounding process.

(f) The name(s) of the manufacturer(s) of the raw materials used.

(g) The quantity in units of finished products or grams of raw materials.

(h) The package size and number of units prepared.

(i) The name of the patient who received the particular compounded product.

(5) Authorization of additional refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:

(a) On the daily hard-copy printout; or

(b) Via the CRT display.

(6) Any other records, policy and procedure manuals, or reference materials which are not specifically required by statute or rule to be kept in a hard copy may be kept in a readily retrievable data processing system which complies with the provisions of subparagraph (1)(f)1.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.003(14), 465.022, 465.026, 893.07 FS. History–New 3-16-94, Formerly 61F10-28.140, Amended 3-12-97, 6-4-97, Formerly 59X-28.140, Amended 10-29-97, 6-15-98, 11-11-98, 10-15-01.

64B16-28.141 Requirements for an Automated Pharmacy System in a Community Pharmacy.

(1) Definitions. "Automated pharmacy system" means a mechanical system, located within or adjacent to the prescription department, that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.

(2) General Requirements. A pharmacy may use an automated pharmacy system provided that:

(a) The pharmacy develops and maintains a policy and procedure manual that includes:

1. The type or name of the system including a serial number or other identifying nomenclature.

2. A method to ensure security of the system to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.

3. A process of filling and stocking the system with drugs; an electronic or hard copy record of medication filled into the system

including the product identification, lot number, and expiration date.

4. A method of identifying all the registered pharmacy interns or registered pharmacy technicians involved in the dispensing process.

5. Compliance with a Continuous Quality Improvement Program.

6. A method to ensure that patient confidentiality is maintained.

7. A process to enable the prescription department manager or designee to revoke, add, or change access at any time.

(b) The system ensures that each prescription is dispensed in compliance with the definition of dispense and the practice of the profession of pharmacy.

(c) The system shall maintain a readily retrievable electronic record to identify all pharmacists, registered pharmacy technicians, or other personnel involved in the dispensing of a prescription.

(d) The system shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(3) Additional Requirements for Patient Accessed Automated Pharmacy Systems. A pharmacy may use a patient accessed automated pharmacy system, provided that:

(a) Meets the requirements in subsection (2) above.

(b) The stocking or restocking of a medicinal drug shall only be completed by a Florida pharmacist, except as provided in paragraph (c) below.

(c) If the automated pharmacy system uses removable cartridges or container to store the drug, the stocking or restocking of the cartridges or containers may occur at a licensed repackaging facility and be sent to the provider pharmacy to be loaded by personnel designated by the pharmacist if:

1. A Florida pharmacist verifies the cartridge or container has been properly filled and labeled.

2. The individual cartridge or container is transported to the provider pharmacy in a secure, tamper-evident container.

3. The automated pharmacy system uses a bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the cartridge or container is accurately loaded into the automated pharmacy system.

4. The Florida pharmacist verifying the filling and labeling is responsible if the cartridge or container is stocked or restocked incorrectly by the personnel designated to load the cartridges or containers.

(d) The automated pharmacy system must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the proper medication is being dispensed from the automated system.

(e) The medication shall bear a patient specific label that complies with Rule 64B16-28.108, F.A.C.

(f) The record of transactions with the patient accessed automated pharmacy system shall be available to authorized agents of the Department of Health. The record of transactions shall include:

1. Name of the patient.

2. Name, strength, and dosage form of the drug product dispensed.

3. Quantity of drug dispensed.

4. Date and time of dispensing.

5. Name of provider pharmacy.

6. Prescription number.

7. Name of prescribing practitioner.

8. Identity of the pharmacist who approved the prescription or order.

9. Identity of the person to whom the drug was released.

(4) The Florida pharmacist responsible for filling, verifying, or loading the automated pharmacy system shall be responsible for her or his individual action.

(5) A prescription dispensed pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.022 FS. History–New 11-29-04, Amended 12-30-07, 1-1-10.

64B16-28.150 Record Maintenance Systems for Institutional and Animal Shelter Permits.

Rulemaking Authority 465.005, 465.0155, 465.022, 828.055 FS. Law Implemented 465.022, 465.019, 465.026, 893.07, 828.055 FS. History–New

4-12-95, Formerly 59X-28.150, Repealed 5-3-05.

64B16-28.201 Definitions.

Rulemaking Authority 465.005, 465.022, 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History–New 12-26-79, Amended 4-28-83, 4-30-85, Formerly 21S-16.01, 21S-16.001, Amended 7-31-91, Formerly 21S-28.201, 61F10-28.201, 59X-28.201, Repealed 4-5-05.

64B16-28.202 Closing of a Pharmacy; Transfer of Prescription Files.

(1) The term "prescription files" as used herein shall mean the drug dispensing records of a pharmacy which shall include all orders for drugs or medicinal supplies as defined by Section 465.003(7), F.S., inclusive of dispensing records for medicinal drugs listed within the provisions of Section 893.03, F.S., issued by a duly licensed practitioner, which serve to transfer possession of medicinal drugs from the pharmacy to the ultimate consumer.

(2) The term "closing of a pharmacy" as used herein shall mean the cessation or termination of professional and business activities within a pharmacy for which a permit has been issued under Chapter 465, F.S.

(3) Prior to closure of a pharmacy the permittee shall notify the Board of Pharmacy in writing as to the effective date of closure, and shall:

(a) Return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy;

(b) Advise the Board of Pharmacy which permittee is to receive the prescription files;

(4) On the date of closure of a pharmacy the former permittee shall:

(a) Physically deliver the prescription files to a pharmacy operating within reasonable proximity of the pharmacy being closed and within the same locality. This delivery of prescription files may occur prior to the return of the pharmacy permit to the Board of Pharmacy office; and

(b) Affix a prominent sign to the front entrance of the pharmacy advising the public of the new location of the former permittee's prescription files or otherwise provide a means by which to advise the public of the new location of their prescription files.

(5) After the closing of a pharmacy as defined herein, the custody of the prescription files of the pharmacy shall be transferred to the new permittee, unless the former permittee and the new permittee inform the Board in writing that custody of the prescription files have been or are to be transferred to a pharmacy other than the new permittee.

(6) A pharmacy receiving custody of prescription files from another pharmacy shall maintain the delivered prescriptions in separate files so as to prevent intermingling with the transferee pharmacy's prescription files.

Rulemaking Authority 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History–New 12-26-79, Formerly 21S-16.02, 21S-16.002, Amended 7-31-91, Formerly 21S-28.202, 61F10-28.202, 59X-28.202, Amended 4-5-05.

64B16-28.2021 Change of Ownership.

(1) A pharmacy permit is not transferable. Upon the sale of an existing pharmacy, a new application must be filed. In those cases where the permit is held by a corporation, the transfer of all the stock of said corporation to another person or entity does not constitute a change of ownership, provided that the initial corporation holding the permit continues to exist.

(2) A change in ownership (and issuance of a new permit number) requires that new records be started and old records closed. The process for closing a pharmacy, including the transfer of prescription files and medicinal drugs, as outlined in Rules 64B16-28.202 and 64B16-28.203, F.A.C., must be followed for the old permit. If the old permit has controlled substances, the new permit must record an "opening inventory" for DEA purposes. Both the new permit and the old permit must keep appropriate records for two (2) years for the transfer of legend drugs and controlled substances.

(3) A change in the company or person who leases the building where the permit is housed or a change in the management company which contracts with the owner of the permit for the operation of the permit does not constitute a change in ownership.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022(7) FS. History–New 4-19-00, Amended 1-2-02, Formerly 64B16-28.1135, Amended 4-5-05.

64B16-28.203 Transfer of Medicinal Drugs; Change of Ownership; Closing of a Pharmacy.
Ownership of medicinal drugs, including those medicinal drugs within the provisions of Section 893.03, F.S., may be transferred to a new owner upon the change of ownership of a pharmacy, as defined in Rule 64B16-28.2021, F.A.C., or upon the closing of a pharmacy, as defined in Rule 64B16-28.2021, F.A.C. The transferee entity acquiring ownership shall be authorized to prescribe, dispense or distribute such drugs. The transferor pharmacy shall provide the Florida Board of Pharmacy with the following information:

(1) The name, address, pharmacy permit number and D.E.A. registration number of the transferor pharmacy.

(2) The name, address, permit number, D.E.A. registration number (if available), and authorized business activity of the transferee entity.

(3) The date on which the transfer will occur.

(4) A complete inventory of all medicinal drugs within the provisions of Section 893.03, F.S., as of the date of transfer. If the medicinal drug is listed in Schedule II, the transferor shall make an exact count or measure of the contents. If the medicinal drugs are listed in Schedule III, IV, or V, the transferor shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents shall be made. This inventory shall serve as the final inventory of the permittee transferor and the transfer inventory of the transferee entity. The transferor and transferee shall each retain a copy of the inventory in their records and shall provide the Board of Pharmacy with a copy of such inventory. Transfer of any controlled substance in Schedule II shall require the use of order form, D.E.A. form number 222.

(5) Unless the permittee-transferor is informed by the Board of Pharmacy or the regional D.E.A. Administrator prior to the date on which the transfer was stated to occur, that the transfer may not occur, the permittee-transferor may proceed with the transfer.

(6) On the date of transfer of the medicinal drugs, all records required to be kept by the permittee-transferor of the transferred drugs which are listed in Section 893.03, F.S., shall be transferred to the permittee-transferor. Responsibility for the accuracy of records prior to the date of transfer remains with the permittee-transferor, but responsibility for custody and maintenance shall be upon the permittee-transferee. It is the responsibility of the permittee-transferor to return all unused Schedule II order forms (D.E.A. form no. 222) to the regional D.E.A. office.

Rulemaking Authority 465.005, 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History–New 12-26-79, Formerly 21S-16.03, 21S-16.003, 21S-28.203, 61F10-28.203, 59X-28.203, Amended 4-5-05.

64B16-28.301 Destruction of Controlled Substances – Institutional Pharmacies.

(1) Controlled substances that have been dispensed and not used by the patient shall not be returned to the pharmacy and shall be securely stored by the nursing home until destroyed.

(2) A document must be completed showing the name and quantity of the drug, strength and dosage form, patient's name, prescription number and name of the institution. This documentation, at the time of destruction, shall be witnessed and signed by the consultant pharmacist, director of nursing, and the administrator or his designee, which may include a licensed physician, pharmacists, mid-level practitioner, or nurse.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.019 FS. History–New 4-21-87, Formerly 21S-19.001, Amended 7-31-91, Formerly 21S-28.301, 61F10-28.301, Amended 1-30-96, Formerly 59X-28.301, Amended 7-21-09.

64B16-28.303 Destruction of Controlled Substances All Permittees (excluding Nursing Homes).

(1) Controlled substances that cannot be retained as usable shall be securely stored in the prescription department of the permittee pharmacy until destroyed.

(2) Permittees are required to complete a United States Drug Enforcement Administration (D.E.A.) Form 41. This form, at the time of destruction, shall be witnessed and signed by the prescription department manager or the consultant pharmacist of record and D.E.A. agent, or a Department inspector. This method of destruction does not require prior approval from D.E.A., but does require that a copy of the completed and witnessed D.E.A. Form 41 be mailed to D.E.A. immediately after destruction.

(3) Another method of destruction shall be conducted by at least two persons who are either a licensed pharmacist, physician or nurse, or a sworn law enforcement officer or any combination thereof, to serve as the witnesses. A copy of the completed D.E.A. Form 41 and a letter providing the proposed date of destruction, the proposed method of destruction and the names and titles of the proposed witnesses must be received by D.E.A. at least two weeks prior to the proposed date of destruction which shall constitute a request for destruction. The drugs may not be destroyed until D.E.A. grants approval of the request for destruction. A copy of the

completed and witnessed D.E.A. Form 41 shall be mailed to D.E.A. immediately after destruction.

(4) In lieu of destruction on the premises, controlled substances may also be shipped to reverse distributors for destruction in conformity with federal guidelines.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.018 FS. History–New 4-21-87, Formerly 21S-19.003, Amended 7-31-91, Formerly 21S-28.303, 61F10-28.303, Amended 1-30-96, Formerly 59X-28.303, Amended 2-5-07, 10-27-09, 2-1-12.

64B16-28.402 Labels and Labeling of Medicinal Drugs – Community Pharmacy Permit.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1), 465.0255 FS. History–New 7-3-91, Formerly 21S-28.402, Amended 12-27-93, Formerly 61F10-28.402, 59X-28.402, Amended 9-17-97, Repealed 5-11-05.

64B16-28.404 Regulation of Daily Operating Hours.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 8-20-65, Amended 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, 3-31-81, Formerly 21S-1.24, Amended 7-14-88, Formerly 21S-1.024, Amended 7-31-91, 3-15-92, Formerly 21S-28.404, 61F10-28.404, Amended 9-21-94, Formerly 59X-28.404, 59X-28.404, Repealed 2-28-07.

64B16-28.404 Regulation of Daily Operating Hours (Repealed).

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 8-20-65, Amended 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, 3-31-81, Formerly 21S-1.24, Amended 7-14-88, Formerly 21S-1.024, Amended 7-31-91, 3-15-92, Formerly 21S-28.404, 61F10-28.404, Amended 9-21-94, Formerly 59X-28.404, 59X-28.404, Repealed 2-28-07.

64B16-28.450 Centralized Prescription Filling, Delivering and Returning.

(1) As used herein:

(a) The term "originating pharmacy" means a pharmacy wherein the prescription which will be filled by the central fill pharmacy is initially presented; and

(b) The term "central fill pharmacy" means a pharmacy which performs centralized prescription filling, delivering, and returning for one or more originating pharmacies.

(2) Pharmacies acting as the central fill pharmacy must be authorized to dispense medications under the provisions of Chapter 465, F.S., and the rules promulgated thereto.

(3) A community pharmacy which acts as the central fill pharmacy and which notifies the Board that its pharmacy practice is limited only to such practice shall be exempt from the following rules:

(a) Rule 64B16-28.1035, F.A.C., Patient Consultation Area;

(b) The signage requirement of subsection 64B16-28.109(1), F.A.C.; and

(c) Rule 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours.

(4) All central fill and originating pharmacies engaged in centralized prescription filling shall create and keep current a Policy and Procedure Manual which shall:

(a) Be maintained at the locations of the central fill and originating pharmacies;

(b) Include the information required in Sections 465.0265(2)(a)-(f), F.S.

(5) Delivery of medications. Delivery of medications must be made in a timely manner. The originating and central fill pharmacies shall each be identified on the prescription container.

(a) Delivery by central fill pharmacy to ultimate consumer. A central fill pharmacy may deliver medications for an originating pharmacy to the ultimate consumer or the consumer's agent under the following conditions:

1. The pharmacies are under the same ownership or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with federal and state laws, rules and regulations.

2. The pharmacies shall have a pharmacist available 40 hours a week, either in person or via two-way communication technology, such as a telephone, to provide patient counseling.

3. The pharmacies shall include a toll-free number that allows the patient to reach a pharmacist for the purposes of patient counseling.

4. The pharmacies shall each be identified on the prescription container label. The originating pharmacy shall be identified with pharmacy name and address. The central fill pharmacy may be identified by a code available at the originating pharmacy.

5. The central fill pharmacy shall only deliver via carrier to the ultimate consumer or the consumer's agent those medications which could have been delivered via carrier by the originating pharmacy.

6. The central fill pharmacy shall not deliver to the ultimate consumer or consumer's agent substances listed as controlled substances under Chapter 893, F.S.

(b) The delivery of a filled prescription by a central fill pharmacy to the ultimate consumer or the consumer's agent pursuant to a contract with an originating pharmacy shall not be considered dispensing within the definition set forth in Section 465.003(6), F.S.

(c) Each pharmacist that performs a specific function within the processing of the prescription shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.

(6) The supplying and receiving pharmacy shall each be identified on the prescription container label. The receiving pharmacy shall be identified with pharmacy name and address. The supplying pharmacy may be identified by a code available at the receiving pharmacy. Prescription and labeling requirements for pharmacies participating in central prescription filling, delivering and returning:

(a) Prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile. The originating pharmacy transmitting the prescription information must:

1. Write the word "central fill" on the face of the original prescription and record the name, address, and DEA registration number if a controlled substance of the originating pharmacy to which the prescription has been transmitted and the name of the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal;

2. Ensure all the information required to be on a prescription pursuant to Sections 456.0392 and 893.04, F.S., is transmitted to the central fill pharmacy either on the face of the prescription or in the electronic transmission of information;

3. Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;

4. Maintain the original prescription for a period of two years from the date the prescription was last refilled.

5. Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the originating pharmacy's employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

1. Keep a copy of the prescription if sent via facsimile, or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, and DEA registration number, if a controlled substance, of the originating pharmacy transmitting the prescription;

2. Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

3. Keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (private, common or contract carrier).

4. A central fill pharmacy's pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing the date of filling, the receiving pharmacy's name and address, a unique identifier (i.e. the supplying pharmacy's DEA registration number) indicating the prescription was filled at the central fill pharmacy, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

Rulemaking Authority 465.005, 465.0265 FS. Law Implemented 465.003(16), 465.0265 FS. History–New 9-23-03, Amended 7-27-04, 4-28-08.

64B16-28.451 Pharmacy Common Database.

(1) A pharmacy licensed under this chapter may perform prescription drug processing for other pharmacies, provided that all pharmacies are under common ownership, utilize a common database, and are properly licensed, permitted or registered in this state or another state. Nothing in this subsection shall prohibit a pharmacist employee of said pharmacies who is licensed in Florida or in another state from remotely accessing the pharmacy's electronic database from outside the pharmacy in order to process prescriptions, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(2) Prescription drug processing shall include the following:

(a) Receiving, interpreting, or clarifying a prescription;

(b) Entering prescription data into the pharmacy's record;

(c) Verifying or validating a prescription;

(d) Performing prospective drug review as defined by the Board;

(e) Obtaining refill and substitution authorizations;

(f) Interpreting or acting on clinical data;

(g) Performing therapeutic interventions;

(h) Providing drug information concerning a patient's prescription; and

(i) Providing patient counseling.

(3) Each pharmacist that performs a specific function within the prescription drug processing process via use of a common database shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.

(4) Each pharmacy performing prescription drug processing pursuant to this section must maintain a policy and procedure manual, which shall be made available to the Board or its agent upon request. The policy and procedures manual shall include the following information:

(a) A description for how each pharmacy will comply with federal and state laws, rules and regulations;

(b) The procedure for maintaining appropriate records to identify the pharmacies and pharmacists responsible for the prescription drug processing and dispensing of the prescription;

(c) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information; and

(d) The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.

(5) The prescription drug processing of a prescription by one pharmacy for another pursuant to this section shall not be construed as the transferring of a prescription as set forth in Section 465.026, F.S.

(6) In addition to all record requirements of Rule 64B16-28.140, F.A.C., all pharmacies participating in prescription drug processing, shall maintain appropriate records which identify, by prescription, the name(s), initials, or identification code(s) of each pharmacist or registered pharmacy technician who performs a processing function for a prescription. Such records shall be maintained:

(a) Separately by each pharmacy and pharmacist; or

(b) In a common electronic file, as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy, pharmacist, registered pharmacy intern and registered pharmacy technician.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0266 FS. History–New 3-24-08, Amended 1-1-10.

64B16-28.501 Institutional Permit – Consultant Pharmacist of Record.

Each facility holding a Class I, a Class II, or a Modified Class II Institutional permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within 10 days of any change in the consultant pharmacist of record. The consultant pharmacist of record for a Class I, Modified Class II, or a Special ALF permit shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor monthly the facility system for providing medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and or in the monthly facility inspection.

Rulemaking Authority 465.005, 465.0125, 465.022 FS. Law Implemented 465.0125, 465.019, 465.022 FS. History–New 7-18-94, Formerly 61F10-28.501, 59X-28.501, Amended 1-2-02, 12-30-07.

64B16-28.502 Class I Institutional Permit and Class II Institutional Permit – Labels and Labeling of Medicinal Drugs for Inpatients of a Nursing Home.

(1) The label affixed to a container used in conventional dispensing to a Class I Institutional permit or a Class II Institutional permit which, within the scope of its practice, services only the inpatients of a nursing home as defined by Section 400.021(5), F.S., shall contain at least the following information:

(a) The name of and address of the pharmacy;

(b) The name of the prescriber;

(c) The name of the patient;

(d) The date of the original filling or the refill date;

(e) The prescription number or other prescription identification adequate to readily identify the prescription;

(f) The directions for use;

(g) The name of the medicinal drug dispensed (except where the health care practitioner prescribing the drug specifically denotes that the name is to be withheld).

(h) The quantity of the drug in the container.

(2) The label affixed to a container used in dispensing substances listed in any of the schedules appearing in Chapter 893, F.S., in regard to conventional dispensing shall contain at least the following information:

(a) All of the information required by subsection (1) of this rule;

(b) The number of the prescription as recorded in the prescription files of the pharmacy in which it is filled; and

(c) A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 7-31-91, Amended 10-1-92, Formerly 21S-28.502, 61F10-28.502, 59X-28.502, Amended 8-16-10.

64B16-28.503 Transmission of Starter Dose Prescriptions for Patients in Class I Institutional or Modified II B Facilities.

(1) Definitions.

(a) "Vendor pharmacy" means a community pharmacy or special closed system pharmacy which has a contract to dispense a medicinal drug to a patient in a facility holding a Class I Institutional Permit or Modified II B Permit.

(b) "Starter dose pharmacy" means a pharmacy that dispenses a medicinal drug pursuant to a starter dose prescription to a patient in a facility served by the vendor pharmacy.

(c) "Starter dose prescription" means a prescription transmitted by a vendor pharmacy to a starter dose pharmacy for the purpose of initiating drug therapy for a patient in a facility served by the vendor pharmacy.

(2) A vendor pharmacy may transmit a starter dose prescription to a starter dose pharmacy if the vendor pharmacy:

(a) Has written authorization from the facility to utilize a starter dose pharmacy.

(b) Has a written contract with the starter dose pharmacy.

(c) Has written authorization from a prescribing practitioner to act as the practitioner's agent for the purpose of transmitting a starter dose prescription.

(d) Possess a valid prescription from the prescribing practitioner prior to transmitting the starter dose prescription.

(e) Maintains a record of each starter dose prescription.

(f) Maintains a policy and procedure manual that references starter dose prescriptions.

(3) A starter dose pharmacy may dispense a medicinal drug pursuant to a starter dose prescription for a patient in a facility that holds a Class I Institutional Permit or Modified II B Permit if the starter dose pharmacy:

(a) Has a written contract with the vendor pharmacy.

(b) Maintains a record of each starter dose prescription.

(c) Maintains a policy and procedure manual that references starter dose prescriptions.

(4) The contract between a vendor pharmacy and a prescribing practitioner shall:

(a) Be in writing.

(b) Identify each facility served by the vendor pharmacy for which the authorization is valid.

(c) Authorize the vendor pharmacy to transmit, as an agent of the practitioner, a starter dose prescription to a starter dose pharmacy.

(d) Be on file at the vendor pharmacy, at the facility served by the vendor pharmacy, and with the prescribing practitioner.
(e) Be available for inspection by agents of the Department of Health or the Board of Pharmacy.
(5) The contract between the vendor pharmacy and the starter dose pharmacy shall:
(a) Be in writing.
(b) Identify each facility served by the vendor pharmacy.
(c) Assign the responsibility for prospective drug use review required by Rule 64B16-27.810, F.A.C., to the vendor pharmacy.
(d) Assign the responsibility for patient counseling required by Rule 64B16-27.820, F.A.C., to the vendor pharmacy.
(e) Be referenced in the Policy and Procedure Manual of the vendor pharmacy and of the starter dose pharmacy.
(f) Be updated as necessary to identify facilities or practitioners.
(g) Be on file at the vendor pharmacy, at the starter dose pharmacy, and at the facility.
(h) Be available for inspection by authorized agents of the Department of Health and the Board of Pharmacy.
(6) A record of each starter dose prescription shall be:
(a) Readily retrievable.
(b) Maintained for two years.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.019, 465.022 FS. History–New 11-29-04.

64B16-28.602 Institutional Class II Dispensing.

(1) Pharmaceutical preparations which are administered to patients of a hospital by the personnel of such institution shall only be taken from the original container, or from a container which has been prepared by a Florida licensed pharmacist. Only single doses of such preparations shall be removed from the container, and then only after the preparation has been prescribed for a specific patient, and the order has been duly recorded upon the records of the institution. This requirement shall not apply to nor be construed as preventing the administration of treatment in bona fide emergency cases, or further as prohibiting any person who is a duly licensed physician from dispensing medicinal drugs as defined in Chapter 465, F.S. A single dose of medicinal drugs based upon a valid physician's drug order may also be obtained and administered under the supervision of the nurse in charge consistent with good institutional practice procedures as established by the consultant pharmacist of record and written in the policy and procedure manual which shall be available within the pharmacy.

(2) A Class II institutional pharmacy may contract with a Special Parenteral/Enteral Extended Scope pharmacy for the pharmacy services provided for by Rule 64B16-28.860, F.A.C.

(a) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity, including the following provisions:

1. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

2. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

3. A pharmacist for the institutional pharmacy shall provide drug utilization review and shall review each prescription order prior to transmission to the Special Parenteral/Enteral Extended Scope pharmacy.

(b) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(c) Prior to contracting for such services the institutional pharmacy shall ensure that the Special Parenteral/Enteral Extended Scope pharmacy is licensed under the provisions of Rule 64B16-28.860, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(b), 465.0196, 465.022(1) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, Formerly 21S-1.11, 21S-1.011, Amended 7-31-91, Formerly 21S-28.602, 61F10-28.602, Amended 9-4-96, Formerly 59X-28.602, Amended 8-16-10.

64B16-28.6021 Institutional Class II Pharmacy – Emergency Department Dispensing.

(1) Individuals licensed to prescribe medicinal drugs in this state may dispense from the emergency department of a hospital holding a class II institutional pharmacy permit. Such dispensing must meet the requirements provided in Section 465.019(4), F.S., and this section.

(2) The following records of prescribing and dispensing must be created by the prescriber/dispenser and maintained by the consultant pharmacist of record within the facility;

(a) Patient name and address.

(b) Drug and strength prescribed/dispensed.
(c) Quantity prescribed/dispensed.
(d) Directions for use.
(e) Prescriber/dispenser.
(f) Prescriber DEA registration, if applicable.
(g) Reason community pharmacy services were not readily accessible.
(3) Labeling of the prescription container must meet the requirements of Section 465.0276, F.S.
(4) Quantity dispensed must not exceed a 24-hour supply or the minimal dispensable quantity, whichever is greater.

Rulemaking Authority 465.005, 465.019(4), 465.022 FS. Law Implemented 465.019(2)(b), (4), 465.0196, 465.022(1) FS. History–New 9-20-99, Amended 8-16-10.

64B16-28.603 Class II Institutional Pharmacy Operating Hours.
Any person who receives a Class II Institutional permit pursuant to Section 465.019, F.S., and commences to operate such a pharmacy shall, for the benefit of the institutions' patients' health and welfare, keep the pharmacy of the establishment open for a sufficient number of daily operating hours required to provide adequate and quality pharmaceutical services to the patients of said institution.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 7-31-91, Formerly 21S-28.603, 61F10-28.603, 59X-28.603.

64B16-28.604 Class II Institutional Pharmacy Department Security.
The pharmacy department shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. At all times when the pharmacy department is closed, either because of the absence of a Florida licensed pharmacist or for any other reason, it shall be secured to prevent access. When the pharmacy department is closed, no person other than a Florida licensed pharmacist shall enter, except as authorized by subsection 465.019(2)(b), F.S., and Rule 64B16-28.602, F.A.C.

Rulemaking Authority 465.005, 465.022(1), 465.019 FS. Law Implemented 465.019, 465.022(1) FS. History–New 9-21-94, Formerly 59X-28.604.

64B16-28.605 Class II Institutional Pharmacies – Automated Distribution and Packaging.
(1) Definitions.
(a) "Automated medication system" means a robotic, mechanical or computerized device that is not used for medication compounding and is designed to:
1. Distribute medications in a licensed health care facility; or
2. Package medications for final distribution by a pharmacist.
(b) "Centralized automated medication system" means an automated medication system located in a pharmacy department from which medication is distributed or packaged for final distribution by a pharmacist.
(c) "Decentralized automated medication system" means an automated medication system that is located outside of a pharmacy department but within the same institution.
(d) "Distribute" or "Distribution" means the process of providing a drug to an individual authorized to administer medications and licensed as a health care provider in the state of Florida pursuant to an order issued by an authorized prescriber.
(e) "Medication" means a medicinal drug or proprietary preparation.
(f) "Override medication" means a single dose of medication that may be removed from a decentralized automated medication system prior to pharmacist review because a practitioner licensed pursuant to Chapter 458, 459 or 466, F.S., determined that the clinical status of the patient would be significantly compromised by delay.
(g) "Low risk override medication" is a medication determined by a practitioner licensed pursuant to Chapters 458, 459, or 466, F.S., to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, and may be removed from a decentralized automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.
(h) "Physician controlled medication" is medication distributed in an environment where a practitioner controls the order, preparation and administration of the medication.

(2) General Requirements for the Use of Automated Medication Systems.

(a) The consultant pharmacist of record shall be responsible for:

1. Maintaining a record of each transaction or operation;

2. Controlling access to the system;

3. Maintaining policies and procedures for;

a. Operation of the automated medication system;

b. Training personnel who use the automated medication system;

c. Maintaining patient services whenever the automated medication system is not operating; and

d. Defining a procedure for a pharmacist to grant or deny access to the medication in the system.

4. Security of the system;

5. Assuring that a patient receives the pharmacy services necessary for good pharmaceutical care in a timely manner;

6. Assuring that the system maintains the integrity of the information in the system and protects patient confidentiality;

7. Establishing a comprehensive Quality Assurance program;

8. Establishing a procedure for stocking or restocking the automated medication system; and

9. Ensuring compliance with all requirements for packaging and labeling.

(b) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a medication except an override medication, a low risk override medication or a physician controlled medication.

(c) A pharmacist shall perform retrospective drug use review for an override medication.

(3) Multidisciplinary Committee for Decentralized Automated Medication Systems.

(a) The consultant pharmacist of record shall convene or identify a multidisciplinary committee, which is charged with oversight of the decentralized automated medication system.

(b) The Multidisciplinary Committee shall:

1. Include at least one pharmacist;

2. Establish the criteria and process for determining which medication qualifies as an override medication or a low risk override medication in a decentralized automated medication system;

3. Develop policies and procedures regarding the decentralized automated medication system; and

4. Have its decisions reviewed and approved by the consultant pharmacist of record.

(4) Stocking or Restocking of a Decentralized Automated Medication System.

(a) Medications in a decentralized Automated Medication System shall be stocked or restocked by a pharmacist, registered pharmacy intern, or by a registered pharmacy technician supervised by a pharmacist.

(b) The stocking or restocking of a decentralized automated medication system shall follow one of the following procedures to assure correct medication selection:

1. A pharmacist shall conduct a daily audit of medications placed or to be placed into an automated medication system that includes random sampling.

2. A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification technology shall require an initial quality assurance validation followed by a monthly quality assurance review by a pharmacist.

(5) Centralized Automated Medication Systems. A pharmacist utilizing a centralized medication system may distribute patient specific medications within the licensed health care facility without checking each individual medication selected or packaged by the system, if:

(a) The initial medication order has been reviewed and approved by a pharmacist; and

(b) The medication is distributed for subsequent administration by a health care professional permitted by Florida law to administer medication; and

(c) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic verification, or similar verification technology shall require an initial quality assurance validation, followed by monthly quality assurance review by a pharmacist.

(6) Quality Assurance Program. The consultant pharmacist of record shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:

(a) Review of override and low risk override medication utilization;

(b) Investigation of a medication error related to the automated medication system;

(c) Review of a discrepancy or transaction reports and identify patterns of inappropriate use or access;

(d) Review of the operation of the system;

(e) Integration of the automated medication system quality assurance program with the overall continuous quality improvement of the pharmacy as defined in Rule 64B16-27.300, F.A.C.; and

(f) Assurance that individuals working with the automated medication system receive appropriate training on the operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(7) Record Keeping.

(a) The consultant pharmacist of record shall maintain records related to the automated medication system in a readily retrievable manner.

(b) The following records shall be maintained for at least 60 days:

1. Daily audits of stocking or restocking, if applicable;

2. Daily audits for the output of centralized automated medication system, if applicable; and

3. Transaction records for all non-controlled medications or devices distributed by the automated medication system.

(c) The following records shall be maintained for at least two (2) years:

1. Any report or analysis generated as part of the quality assurance program;

2. A report or database related to access to the system or any change in the access to the system or to medication in the system; and

3. Transaction records from the automated medication system for all controlled substances dispensed or distributed.

(8) Compliance. The consultant pharmacist of record shall assure compliance with all requirements of Chapter 465, F.S., and the rules of Chapter 64B16, F.A.C.

(9) Security. A decentralized automated medication system that contains controlled substances shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances, unless otherwise contained in labeled patient-specific form.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235, 465.026 FS. History–New 4-22-07, Amended 1-1-10.

64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies.

(1) Definitions.

(a) "Remote Medication Order Processing" includes any of the following activities performed for a Class II Institutional Pharmacy from a remote location:

1. Receiving, interpreting, or clarifying medication orders.

2. Entering or transferring medication order data.

3. Performing prospective drug use review.

4. Obtaining substitution authorizations.

5. Interpreting and acting on clinical data.

6. Performing therapeutic interventions.

7. Providing drug information.

8. Authorizing the release of a medication for administration.

(b) "Medication" means a medicinal drug or proprietary preparation.

(c) "Prospective drug use review" means an evaluation of medication orders and patient medication records for:

1. Over-utilization or under-utilization of medication.

2. Therapeutic duplication of medication.

3. Drug-disease contraindications.

4. Drug interactions.

5. Incorrect drug dosage or duration of drug treatment.

6. Clinical abuse or misuse of medication.

(2) General requirements.

(a) All pharmacists participating in remote medication order processing shall be Florida licensed pharmacists.

(b) A Class II Institutional pharmacy may utilize remote medication order processing if the pharmacist performing the remote medication order processing has access to sufficient patient information necessary for prospective drug use review and approval of medication orders.

(c) A pharmacist shall perform the final check of a medication order.

(d) If the pharmacist performing remote order processing is not an employee of the Class II Institutional pharmacy, the Class II Institutional pharmacy must have a written agreement or contract with the pharmacist or entity employing the pharmacist. The written agreement or contract shall:

1. Outline the services to be provided.

2. Delineate the responsibilities of each party including compliance with federal and state laws and regulations governing the practice of pharmacy as well as state and federal medical privacy requirements.

3. Require that the parties adopt a policies and procedures manual.

4. Provide that the parties have access to or share a common electronic file such that the pharmacist performing remote medication order processing has sufficient patient information necessary for prospective drug use review and approval of medication orders.

(3) Policy and Procedures. A policy and procedures manual shall:

(a) Be accessible to each party involved in remote medication order processing.

(b) Be available for inspection by the Board or an authorized agent of the Department.

(c) Outline the responsibilities of each party involved in remote medication order processing.

(d) Include a current list of the name, address, telephone number, and license number of each pharmacist involved in remote medication order processing.

(e) Include policies and procedures for:

1. Protecting the confidentiality and integrity of patient information.

2. Ensuring that a pharmacist performing prospective drug use review has access to appropriate drug information resources.

3. Ensuring that medical and nursing staff understand how to contact a pharmacist.

4. Maintaining records to identify the name, initials, or identification code of each person who performs a processing function for a medication order.

5. Complying with federal and state laws and regulations.

6. Operating or participating in a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

7. Reviewing the written policies and procedures and documenting the review every year.

(4) Records.

(a) A Class II Institutional Pharmacy involved in remote medication order processing shall maintain a record that identifies the name, initials, or identification code of each person who performed a processing function for every medication order. The record shall be available by medication order or by patient name.

(b) The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a processing function for a medication order.

(c) The record shall be readily retrievable for at least the past two (2) years.

(d) The record shall be available for inspection by the Board or an authorized agent of the Department.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.026 FS. History–New 11-29-04.

64B16-28.607 Automated Pharmacy System – Long Term Care, Hospice, and Prison.

(1) Definitions.

(a) "Automated pharmacy system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and delivery of a medicinal drug, and which collects, controls, and maintains a record of each transaction.

(b) "Provider pharmacy" means a pharmacy that provides pharmacy services by using an automated pharmacy system at a remote site.

(c) "Remote site" means a long term care facility or hospice licensed under Chapter 400, F.S., or a state correctional institution operated under Chapter 944, F.S., that is not located at the same location as the provider pharmacy, at which pharmacy services are provided using an automated pharmacy system.

(d) "Controlled substance" means a substance listed in Chapter 893, F.S., or 21 CFR Part 1308.

(2) Provider Pharmacy Requirements.

(a) A provider pharmacy may provide pharmacy services to a long term care facility or hospice licensed under Chapter 400, F.S., or a state correctional institution operated under Chapter 944, F.S., through the use of an automated pharmacy system.

(b) An automated pharmacy system shall only be used to provide pharmacy services to an inpatient or a resident of the remote site.

(c) Supervision of the automated pharmacy system shall be the responsibility of a Florida pharmacist employed by the provider pharmacy.

(d) Every medicinal drug stored in the automated pharmacy system shall be owned by the provider pharmacy.

(e) An automated pharmacy system shall be under the supervision of a pharmacist employed by the provider pharmacy. The pharmacist need not be physically present at the remote site if the system is supervised electronically.

(f) A provider pharmacy shall have policies and procedures to ensure adequate security.

(3) Prescription Department Manager Requirements.

(a) The prescription department manager shall ensure that the automated pharmacy system complies with Chapter 893, F.S., and 21 C.F.R., relating to the regulation of controlled substances, for each automated pharmacy system that contains a controlled substance.

(b) The prescription department manager shall ensure that the use of an automated pharmacy system does not compromise patient confidentiality.

(c) The prescription department manager or a designee shall:

1. Authorize or deny access to the data from an automated pharmacy system or to a drug stored inside the automated pharmacy system.

2. Document the training of each person who has access to the data from an automated pharmacy system or to a drug stored inside the automated pharmacy system.

(4) Automated Pharmacy System Requirements.

(a) A medicinal drug stored in bulk or unit-of-use in an automated pharmacy system is part of the inventory of the provider pharmacy and is not part of the inventory of any other pharmacy permit for the facility.

(b) A medicinal drug may be removed from an automated pharmacy system for administration to a patient only after a prescription or order has been received and approved by a pharmacist at the provider pharmacy. This provision does not apply to a medication designated as an emergency medication if the automated pharmacy system is also used as an emergency medication kit in compliance with Section 400.142, F.S. and Rule 59A-4.112, F.A.C.

(c) A pharmacist at the provider pharmacy shall control all operations of the automated pharmacy system and approve release of the initial dose of a prescription or order. A subsequent dose from an approved prescription or order may be released without additional approval of a pharmacist. However, any change made in a prescription or order shall require a new approval by a pharmacist to release the drug.

(d) A pharmacist at the provider pharmacy shall comply with the patient record requirements in Rule 64B16-27.800, F.A.C., and prospective drug use review requirements in Rule 64B16-27.810, F.A.C., for every medicinal drug delivered through an automated pharmacy system.

(e) If the facility where pharmacy services are being provided maintains a medication administration record that includes directions for use of the medication, a unit dose medication may be utilized if the provider pharmacy or the automated pharmacy system identifies and records the dispensing pharmacy, the prescription or order number, the name of the patient, and the name of the prescribing practitioner for each medicinal drug delivered.

(f) Stocking or Restocking of an Automated Pharmacy System.

1. The stocking or restocking of a medicinal drug in an automated pharmacy system at the remote site shall be completed by a pharmacist or other licensed personnel, except as provided in subparagraph 2. below of this section.

2. If the automated pharmacy system uses removable cartridges or containers to store the drug, the stocking or restocking of the cartridges or containers may occur at the provider pharmacy and be sent to the remote site to be loaded by personnel designated by the pharmacist if:

a. A pharmacist verifies the cartridge or container has been properly filled and labeled.

b. The individual cartridge or container is transported to the remote site in a secure, tamper-evident container.

c. The automated pharmacy system uses bar code verification, electronic verification, or similar process to assure that the cartridge or container is accurately loaded into the automated pharmacy system.

(g) A medicinal drug that has been removed from the automated pharmacy system shall not be replaced into the system unless a pharmacist has examined the medication, the packaging, and the labeling and determined that reuse of the medication is appropriate.

(h) Medication to be returned to the provider pharmacy's stock shall meet the requirements of Rule 64B16-28.118, F.A.C.

(5) Security Requirements.

(a) If a provider pharmacy intends to store a controlled substance in an automated pharmacy system:

1. It shall maintain a separate DEA registration for each remote site at which a controlled substance is stored.

2. It may utilize one DEA registration to include multiple automated pharmacy systems located at a single address.

(b) A provider pharmacy shall only store a medicinal drug at a remote site within an automated pharmacy system which is locked by a mechanism that prevents access to a drug or to data by unauthorized personnel.

(c) Access to the drugs shall be limited to a pharmacist or a registered pharmacy technician employed by the provider pharmacy or licensed personnel in the facility or institution who are authorized to administer medication.

(d) An automated pharmacy system that contains a controlled substance shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances.

(6) Emergency medication. If an automated pharmacy system is utilized for both a medication ordered for a specific patient and an emergency medication for which the review of a pharmacist is not required:

(a) The emergency medication shall be stored separately from other patient medications.

(b) The record shall identify the storage location from which the medication was released.

(c) The record shall include the name of the medication, the patient, the prescriber, the person who accessed the automated pharmacy system, and the date and time of the release.

(7) Record Keeping Requirements.

(a) The record of transactions with the automated pharmacy system shall be maintained in a readily retrievable manner.

(b) The record shall be available to an authorized agent of the Department of Health or the Board of Pharmacy.

(c) The record shall include:

1. Name or identification of the patient or resident.

2. Name, strength and dosage form of the drug product released.

3. Quantity of drug released.

4. Date and time of each release of a drug.

5. Name of provider pharmacy.

6. Prescription number or order number.

7. Name of prescribing practitioner.

8. Identity of the pharmacist who approved the prescription or order.

9. Identity of the person to whom the drug was released.

(d) A record of every transaction with the automated pharmacy system shall be maintained for two (2) years.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235 FS. History–New 4-22-07, Amended 1-1-10.

64B16-28.702 Modified Class II Institutional Pharmacies.

(1) Modified Class II Institutional Pharmacies are those Institutional Pharmacies which provide specialized pharmacy services restricted in scope of practice and designed to provide certain health care pharmacy services that are not generally obtainable from other pharmacy permittees. These specialized institutional pharmacy practices are generally identifiable with short-term or primary care treatment modalities in entities such as primary alcoholism treatment centers, free-standing emergency rooms, rapid in/out surgical centers, certain county health programs, and correctional institutions. Medicinal drugs may not be administered, except to patients of the institution for use on the premises of the institution, in any facility which has been issued a Modified Class II

Institutional Pharmacy Permit. All medicinal drugs as defined by Section 465.003(7), F.S., which are stocked in these pharmacies are only to be administered on premises as defined by Section 465.003(1), F.S., to inpatients on an inpatient or in-program basis. In-program patients are defined as those patients who have met program admission criteria required by the institution.

(2) Modified Class II Institutional Pharmacies are categorized according to the type of specialized pharmaceutical delivery system utilized and the following criteria (Categories are designated as Type "A", Type "B" and Type "C"):

(a) The type of the medicinal drug delivery system utilized at the facility, either a patient-specific or bulk drug system, and, the quantity of the medicinal drug formulary at the facility,

(b) Type "A" Modified Class II Institutional Pharmacies provide pharmacy services in a facility which has a formulary of not more than 15 medicinal drugs, excluding those medicinal drugs contained in an emergency box, and in which the medicinal drugs are stored in bulk and in which the consultant pharmacist shall provide on-site consultations not less than once every month, unless otherwise directed by the Board after review of the policy and procedure manual.

(c) Type "B" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and in bulk form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

(d) Type "C" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

(3) All Modified Class II Institutional Pharmacies shall be under the control and supervision of a certified consultant pharmacist.

(4) The consultant pharmacist of record for the Modified Class II Institutional Pharmacy shall be responsible for establishing a written protocol and a policy and procedure manual for the implementation of a drug delivery system to be utilized and the requirements of this rule.

(5) A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Modified Class II Institutional Pharmacy and shall be available for inspection by the Department of Health.

(6) Drugs as defined in Section 465.003(7), F.S., stocked in Modified Class II Institutional Pharmacies, Type "A" and Type "B" as provided herein, shall be those drugs generally utilized in the treatment modalities encompassed within the health care scope of the particular institutional care entity. The protocol and the policy and procedure manual for Type "A" and Type "B" Modified Class II Institutional Pharmacies shall contain definitive information as to drugs and strengths thereof to be stocked.

(a) The policy and procedure manual of facilities which are issued Type A Modified Class II Institutional Permits shall provide the following:

1. Definitive information as to drugs and strengths to be stored.
2. The establishment of a Pharmacy Services Committee which shall meet at least annually.
3. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.
4. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
5. Provisions for the utilization of proof-of-use forms for all medicinal drugs within the facility.
6. A diagram of the facility and the security and storage of the medicinal drugs.
7. Provisions for maintaining the records of consultations for not less than two (2) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(b) The policy and procedure manual of facilities which are issued Type B Modified Class II Institutional Permits shall provide the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.
2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.
3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
4. Provisions for the utilization of a perpetual inventory system for all controlled substances, injectables and other medicinal drugs as required by the Pharmacy Services Committee.
5. A diagram of the facility and the security and storage of the medicinal drugs.

6. Provisions for maintaining the records of consultations for not less than two (2) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(c) The policy and procedure manual of facilities which are issued Type C Modified Class II Institutional Permit shall provide the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.

2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.

3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.

4. Provisions for the utilization of a Medication Administration Record (MAR) for all medicinal drugs administered to patients of the facility.

5. A diagram of the facility and the security and storage of the medicinal drugs.

6. Provisions for maintaining the records of consultations for not less than two (2) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(7) Controlled drugs as defined in Chapter 893, F.S., stocked as provided herein within a Type "A" Modified Class II Institutional Pharmacy shall be stocked in unit size not to exceed 100 dosage units unless an exception thereto is granted by the Board of Pharmacy. Proof of use record sheets showing patient's name, date of administration, initials of person administering drug, and other pertinent control requirements are required for both controlled and noncontrolled substance medicinal drugs in Type "A" Modified Class II Institutional Pharmacies.

(8) A Modified Class II institutional pharmacy may contract with a Special Parenteral/Enteral Extended Scope pharmacy for the pharmacy services provided for by Rule 64B16-28.860, F.A.C.

(a) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity including the following provisions:

1. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

2. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

(b) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(c) Prior to contracting for such services the institutional pharmacy shall ensure that the Special Parenteral/Enteral Extended Scope pharmacy is licensed under the provisions of Rule 64B16-28.860, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(c) FS. History–New 4-22-82, Amended 11-5-85, Formerly 21S-1.37, Amended 4-16-86, Formerly 21S-1.037, Amended 7-31-91, Formerly 21S-28.702, 61F10-28.702, Amended 9-4-96, Formerly 59X-28.702, Amended 10-15-01.

64B16-28.800 Special Pharmacies.

(1) Special pharmacies are pharmacies providing miscellaneous specialized pharmacy service functions. The Board of Pharmacy, by this rule, provides for the establishment of the following special pharmacy permits:

(a) Special-Limited Community.

(b) Special-Parenteral and Enteral.

(c) Special-Closed System Pharmacy.

(d) Special-Non Resident (Mail Service).

(e) Special-End Stage Renal Disease.

(f) Special-Parenteral/Enteral Extended Scope.

(g) Special-ALF.

(2) An applicant for any special pharmacy permit shall provide the Board of Pharmacy with an application (Form DOH\PH105 Revised 7/23/98, effective 11/11/98, which is hereby incorporated by reference and which can be obtained from the Department of Health) and a Policy and Procedure Manual which sets forth a detailed description of the type of pharmacy services to be provided within the special pharmacy practice. The Policy and Procedure Manual shall contain detailed provisions for compliance with the provision of Section 465.0196, F.S., and other applicable requirements contained in this chapter.

(3) The Policy and Procedure Manual shall be prepared, maintained, and will be reviewed and is subject to approval by the Board of Pharmacy or its designee prior to the issuance of the permit and the initiation of the operation of the permittee. The policy and procedure manual is reviewed to determine if the operation of the facility will be in compliance with Chapters 465 and 893,

F.S., and Chapter 64B16, F.A.C. The Policy and Procedure Manual shall be made available upon request of the Board or its agents. The applicant who requests a special permit shall be subject to inspection prior to the issuance of the permit.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History–New 2-21-84, Formerly 21S-1.39, 21S-1.039, Amended 7-31-91, 10-14-91, Formerly 21S-28.800, 61F10-28.800, Amended 3-10-96, 6-4-97, Formerly 59X-28.800, Amended 11-11-98, 10-15-01.

64B16-28.810 Special Pharmacy – Limited Community Permit.

A Special-Limited Community Permit shall be obtained by a Class II Institutional Pharmacy that dispenses medicinal drugs, including controlled substances to:

(1) Employees, medical staff and their dependents for their personal use,

(2) Patients of the hospital who are under a continuation of a course of therapy not to exceed a three (3) day supply,

(3) Patients obtaining medical services in the facility's emergency room and, whenever it is otherwise appropriate, as indicated in the applicant's policy and procedure manual.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History–New 7-31-91, Formerly 21S-28.810, 61F10-28.810, 59X-28.810, Amended 7-17-05.

64B16-28.820 Sterile Products and Special Parenteral/Enteral Compounding.

(1) Sterile Products and Parenteral/Enteral Compounding.

(a) A sterile products and parenteral/enteral compounding pharmacy is a type of special pharmacy as provided by Section 465.0196, F.S., which is limited in scope of pharmacy practice to render sterile products and parenteral/enteral compounding functions. This pharmacy practice facilitates the utilization of certain institutional therapeutic measures by patients in the home environment or by patients in an institutional environment where such pharmacy service is unavailable. Pharmacy services, sterile products and parenteral/enteral products provided by a special sterile products and parenteral/enteral compounding pharmacy pursuant to prescription as defined by Section 465.003(13), F.S., shall be limited to the compounding and/or dispensing of:

1. Sterile preparations for parenteral therapy, parenteral nutrition, and/or
2. Sterile preparations for jejunostomy feeding and sterile irrigation solutions, and/or
3. Sterile preparations of cytotoxic or antineo-plastic agents, and/or
4. Sterile products (i.e., injectables, eye drops, etc.).

(b) Prior to engaging in a sterile products and parenteral/enteral compounding pharmacy practice an entity shall obtain a special sterile products and parenteral/enteral compounding pharmacy permit as provided herein.

(2) Pharmacy Environment. The compounding and dispensing of sterile products and parenteral/enteral prescription preparations within a special sterile products and parenteral/enteral compounding pharmacy shall be accomplished in a pharmacy environment subject to the pharmacy permit laws of this state and in accordance with those requirements for the safe handling of drugs. The environment for this practice shall be set apart, and designed, and equipped to facilitate controlled aseptic conditions. Aseptic techniques shall prevail in this practice to minimize the possibility of microbial contamination.

(3) General Requirements.

(a) A special sterile products and parenteral/enteral compounding pharmacy shall be under the control and supervision of a licensed pharmacist, who shall be designated prescription department manager on the application for a special sterile products and parenteral/enteral compounding pharmacy. The prescription department manager or other licensed qualified pharmacist as provided herein shall be present on duty during all hours of operation of said pharmacy. Changes in prescription department manager shall be reported to the Board of Pharmacy office within 10 days by the permit holder and prescription department manager of record. A prescription department manager of a special sterile products and parenteral/enteral compounding pharmacy shall not be designated prescription department manager of record of more than one special sterile products and parenteral/enteral compounding pharmacy, unless otherwise approved by the Board. The Board will consider the proximity of the facility as well as the administrative workload created by the two permits, in determining whether or not it will approve the designation of someone as a prescription department manager of more than one special sterile products and parenteral/enteral compounding pharmacy.

(b) A special sterile products and parenteral/enteral compounding pharmacy shall provide special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. All such preparations shall include the time and/or date of expiration on the label. Delivery from the pharmacy to the patient shall be made within a reasonable time. A special sterile products and parenteral/enteral

compounding pharmacy shall provide telephone accessibility to its pharmacist(s) for its patients at all hours.

(c) A patient profile shall be maintained for each patient. The profile must contain available medical information consistent with prevailing pharmacy standards which shall be confidential.

(d) A Policy and Procedure Manual shall be prepared and maintained at each special sterile products and parenteral/enteral compounding pharmacy, and be available for inspection by authorized agents of the Board of Pharmacy and the Department. The Policy and Procedure Manual shall set forth in detail the objectives and operational guidelines of the permittee. The Policy and Procedure Manual shall include a Quality Assurance Program which monitors personnel qualifications, training and performance, equipment facilities, and random production sampling consistent with recommended standards for compounding and dispensing intravenous admixtures as set forth by the Joint Commission on Accreditation of Health Organizations, the National Coordinating Committee and Large Volume Parenteral, and as provided by the Florida Board of Pharmacy.

(e) Compounding shall be conducted within an annually certified laminar air flow (LAF) hood, except in the existence of a Class 100 certified compounding environment, or certified mobile isolation chamber, in which case compounding may be conducted without the use of a certified laminar air flow hood. All cytotoxins must be compounded in a certified vertical laminar air flow hood or certified mobile isolation chamber. The use of a Type A or Type B LAF hood used shall be dependent upon the volume of work anticipated. All certifications shall be performed following manufacturer specification.

(f) Protective garb: gloves, face and eye, and gowns should be provided and used.

(g) Proper aseptic procedures must be used at all times to prevent bacterial contamination of the product as well as chemical contamination of the operator.

(h) All unused cytotoxic agents and material must be disposed of properly in accordance with accepted professional standards and applicable law.

(4) An applicant for a special sterile products and parenteral/enteral compounding pharmacy permit shall provide the Board of Pharmacy with the following:

(a) Completed Board of Pharmacy permit application form (Form DPR/PH/107/9-88).

(b) Copy of Policy and Procedure Manual.

(c) Permit fee as provided in Rule 64B16-28.121, F.A.C.

(5) Minimum Requirements for Space, Equipment, Supplies and Publications.

(a) To ensure compliance with the general requirements as set forth, the following minimum requirements for space, equipment, supplies and publications shall be met by a pharmacy which operates under the special permit of a sterile products and parenteral/enteral compounding pharmacy. These requirements are in addition to the minimum requirements for space and equipment required of other types of pharmacies when applicable. The minimum permit requirements are set forth as follows:

(b) Space:

1. The area for preparing sterile prescriptions as provided for by this rule referred to as the sterile admixture room shall be set apart from general work and storage areas. The room shall be adequately air conditioned or shall be under positive pressure.

2. The sterile admixture room shall provide space for a minimum of one laminar flow hood. Additionally, the space shall be of adequate size to accommodate other equipment as provided herein and sufficient space to allow pharmacists and other employees working therein to adequately, safely, and accurately fulfill their duties related to prescriptions.

(c) Equipment:

1. Laminar Air Flow Hood(s):

a. Horizontal and/or.

b. Vertical.

2. Refrigerator/freezer convenient to the clean room.

3. Sink and wash area convenient to the clean room.

4. Appropriate waste containers for:

a. Used needles and syringes.

b. All cytotoxic waste including apparel.

(d) Supplies:

1. Gloves, masks and gowns.

2. Needles and syringes of various standard sizes.

3. Disinfectant cleaning agents.

4. Clean towels.

5. Handwashing materials with bactericidal properties.

6. Vacuum containers and various transfer sets.

7. "Spill kits" for cytotoxic agent spills.

(e) Current References:

1. Chapter 465, F.S.

2. Chapter 499, F.S.

3. Chapter 893, F.S.

4. Title 64B16, F.A.C., Rules of the Florida Board of Pharmacy.

5. United States Pharmacopeia and National Formulary, or Remington Pharmaceutical Sciences, or the United States Dispensatory (along with the latest supplements), or an equivalent thereof sufficient in scope to meet the professional practice needs of the pharmacy, and a current authoritative therapeutic reference.

6. Handbook of Injectable Drugs by American Society of Hospital Pharmacists.

7. "Practice Guidelines For Personnel Dealing With Cytotoxic Drugs."

(6) A community pharmacy permittee may perform parenteral/enteral compounding or prepare sterile products without obtaining an additional permit under this section, so long as prior to entering into such activities, the community pharmacy meets the requirements of subsections (1)-(5) above and is inspected for compliance by the Department of Health. A community pharmacy permittee that was engaged in the preparation of sterile products other than parenteral/enteral products as of June 1, 2002 shall have until June 1, 2003 to meet the requirements of subsections (1)-(5) above for the preparation of sterile products other than parenteral/enteral products.

Rulemaking Authority 465.005, 465.007, 465.022 FS. Law Implemented 465.007, 465.018, 456.0196 FS. History–New 4-26-84, Formerly 21S-1.40, Amended 7-27-86, Formerly 21S-1.040, Amended 7-31-91, 10-14-91, Formerly 21S-28.820, 61F10-28.820, Amended 3-11-96, 6-4-97, Formerly 59X-28.820, Amended 7-1-02, 1-29-03.

64B16-28.830 Special – Closed System Pharmacy.

(1) A Special – Closed System Pharmacy permit is a type of special pharmacy as provided for by Section 465.0196, F.S., which dispenses medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, ALF's (Adult Congregate Living Facilities), ICF-MR's (Intermediate Care Facility/Mentally Retarded) or other custodial care facilities when defined by AHCA rules which the Board may approve.

(2) A special – closed system pharmacy permittee shall maintain a policy and procedure manual including drug procurement, storage, handling, compounding, dispensing, record keeping and disposition.

(3) A special – closed system pharmacy permittee shall provide twenty-four hour emergency and on-call service.

(4) A special – closed system pharmacy permittee may dispense parenteral and enteral medications as provided by rule.

(5) A special – closed system pharmacy permittee shall be under the supervision of a prescription department manager who is responsible for maintaining all drug records, providing security of the prescription department and following other rules as relate to the practice of pharmacy. The prescription department manager of a closed system pharmacy shall not be the prescription department manager of any other pharmacy permit except when the permit is within the premises of a community pharmacy permit.

(6) The utilization of registered pharmacy interns and registered pharmacy technicians is subject to the rules as provided by Rule 64B16-26.400, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196, 465.022 FS. History–New 7-31-91, Amended 10-1-92, Formerly 21S-28.830, 61F10-28.830, 59X-28.830, Amended 1-1-10.

64B16-28.840 Special – Non Resident (Mail Service).

(1) A Special – Non Resident (Mail Service) pharmacy is provided for by Section 465.0156, F.S. It is a pharmacy located outside this state delivering a dispensed medicinal drug in any manner into this state.

(2) The pharmacy and the pharmacist designated as the prescription department manager or equivalent, for dispensing into Florida, must be licensed in the state of location.

(3) Changes of location, corporate officers, and prescription department managers must be reported to the Board as required by Section 465.0156(1)(b), F.S.

(4) The pharmacy must have regular hours of operation of not less than six (6) days per week and not less than forty (40) hours per week. A toll-free telephone number must be available to patients.

(5) A pharmacy outside of this state and not registered as a Non Resident Pharmacy may make a one-time delivery of a dispensed medicinal drug to a patient in this state as provided by Section 465.0156(2), F.S.

Rulemaking Authority 465.005, 465.022, 465.0156 FS. Law Implemented 465.0156 FS. History–New 10-14-91, Formerly 21S-28.840, 61F10-28.840, 59X-28.840, Amended 10-27-09.

64B16-28.850 Special Pharmacy – ESRD.

(1) An ESRD Pharmacy is a type of special pharmacy as provided by Section 465.0196, F.S., which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address. Pharmacy services and dialysis supplies and products provided by an ESRD pharmacy shall be limited to the distribution and delivery of legend drugs included in schedule (3) below; or legend devices included in schedule (4) below; which are ordered by a physician for administration or delivery to a person with chronic kidney failure for self-administration at the person's home or specified address. All dialysis supplies and products provided by an ESRD pharmacy shall be prepackaged and shall be covered by an approved NDA or 510 (k) application issued by the Federal Food and Drug Administration.

(2) Prior to engaging in an ESRD pharmacy practice an entity shall obtain a special ESRD pharmacy permit as provided herein.

(3) Schedule of legend drugs:

(a) Saline Solutions.

(b) Porcine Heparin.

(c) Beef Heparin.

(d) Dextrose Solutions.

(e) Doxercalciferol.

(f) Epoetin Alfa.

(g) NACL INJ 50 MEQ/20 ML.

(h) Levocarnitine.

(i) Lidocaine.

(j) Vitamin Preparations (dialysate use only).

(k) Paricalcitrol.

(l) Peritoneal Dialysate Solutions.

(m) Protamine Sulfate.

(n) Potassium 20 MEQ/10ML (dialysate use only).

(o) Sodium Ferric Gluconate Complex or equivalent.

(p) Sterile Water for Irrigation.

(4) The schedule of legend devices includes:

(a) Hemodialyzers.

(b) Hemodialysis solutions.

(c) Bloodlines and Associated Connectology.

(d) Peritoneal Dialysis Tubing and Connectology.

(5) The provision of legend drugs and devices included in the schedule necessary to perform dialysis to a person with chronic kidney failure for self-administration at the person's home or specified address shall be under the professional supervision of an appropriate practitioner licensed under Florida law. The consultant pharmacist shall assure that the following occurs:

(a) The ESRD pharmacy receives a prescription from the prescribing practitioner directing the pharmacist to dispense and deliver to a person with chronic kidney failure (or such person's designee) any legend drugs and/or devices included in the formulary necessary for the self-administration of dialysis at such person's home or specified address.

(b) That no dispensing shall occur unless the person with chronic kidney failure has been trained in the proper use and administration of such products. Further, the consulting pharmacist shall ensure that the ESRD pharmacy has received records confirming the completion of such training.

(c) After the delivery of such products by the ESRD pharmacy, the ESRD pharmacy shall upon request therefor, make available to the prescribing practitioner documentation describing, in sufficient detail, the types and quantities of products dispensed and

delivered by the ESRD pharmacy. The ESRD pharmacy shall also, upon request, make available to the prescribing practitioner documentation confirming shipment of such products and receipt thereof by the person with chronic kidney failure.

(6) The licensed ESRD pharmacy shall comply with all applicable state and federal regulatory requirements and shall maintain in effect all applicable permits and licenses required to dispense and deliver legend drugs and/or devices included in the formulary described in this Section.

(7) The ESRD pharmacy shall deliver products to a person with chronic kidney failure only upon receipt of a valid prescription from a prescribing practitioner specifying or including:

(a) Documentation that the intended recipient of the products has been trained in home dialysis therapy and will require such products;

(b) The duration of prescribing practitioner's order; and

(c) The name and product code of each product prescribed and the quantity prescribed.

(d) The prescription may indicate the person with chronic kidney failure shall have the right to request refills of legend drugs, devices or both, included in the schedule and described in the order for a period of one year.

(8) The ESRD pharmacy shall assemble the products to be delivered pursuant to the prescribing practitioner's prescription. In assembling such products for delivery, the ESRD pharmacy shall take steps necessary to assure the following:

(a) The code numbers and quantities of the products assembled match the code numbers identified in the prescribing practitioner's prescription;

(b) With respect to any dated products, a minimum of three (3) full months of shelf-life remain; and

(c) All cartons and other packaging are properly labeled as noted below:

1. "Use as Directed" statement;
2. The name and address of the person to whom the products will be delivered;
3. The name of the prescribing practitioner;
4. The name and address of the ESRD pharmacy location from which the products were shipped;
5. The prescription number identifying the shipment to the order created by the prescribing practitioner; and
6. Any special instructions regarding delivery dates or locations.
7. The date after which the drug(s) and/or device(s) must be discarded. Notwithstanding any other rule, the ESRD pharmacy may use, in lieu of a discard after date, the manufactures expiration date when such is displayed in an unopened sealed package.

(d) All cartons and related packaging shall be visually inspected to confirm compliance with the specifications in paragraph (8)(c). Compliance with the requirements set forth in paragraph (8)(c) shall be conducted by the consulting pharmacist or independently by not less than two employees of the ESRD pharmacy trained in the performance of the foregoing activities, each of whom shall acknowledge in writing their completion of such activities with respect to each group of products assembled for delivery.

(9) The ESRD pharmacy permit holder shall assure through visual inspection and comparison of records that products assembled for delivery to persons with chronic kidney failure are consistent with the prescribing practitioner's order therefor.

(10) The products ordered by the prescribing practitioner under this Rule shall be delivered by either the ESRD pharmacy or a carrier authorized by the ESRD pharmacy.

(11) Upon delivery of the products by the ESRD pharmacy or its carrier to the person identified on the prescribing practitioner's order, the ESRD pharmacy or its carrier shall confirm receipt by the patient or the patient's designee that the number of units delivered equals the number of units identified on the appropriate documentation. Compliance with the foregoing requirements set forth above shall be conducted by an employee or agent of the ESRD pharmacy trained in the performance of such activities, who shall acknowledge in writing the delivery of the products and the completion of such activities with respect to each delivery.

(12) In addition to the foregoing operation requirements, an ESRD pharmacy shall comply with the following:

(a) The ESRD pharmacy license shall be displayed at each ESRD pharmacy location.

(b) The Board of Pharmacy shall be notified in writing of the Consulting Pharmacist responsible, at the time of application for the permit, for supervising the ESRD pharmacy operations and within 10 days, if the Consultant Pharmacist of record changes.

(c) The ESRD pharmacy's hours of business shall be posted. The ESRD pharmacy shall be open such hours as are necessary to safely and effectively dispense and deliver supplies to those persons designated by the applicable prescribing practitioner. An ESRD pharmacy shall provide twenty-four hour emergency and on-call service.

(d) The ESRD pharmacy shall have sufficient space and storage capabilities as are necessary to carry out its operation.

(e) All legend drugs and/or legend devices included in the formulary subject to this Rule shall be properly identified.

(f) The ESRD pharmacy shall maintain a current copy of the Florida pharmacy laws and rules.

(g) The ESRD pharmacy shall comply with patient counseling requirements of Rules 64B16-27.800-.810 and 64B16-27.820, F.A.C.

(13) ESRD Pharmacy Application Requirements. An applicant for an ESRD pharmacy permit shall provide the Board of Pharmacy with a Policy and Procedure Manual setting forth in detail the operational guidelines of the applicant. The Policy and Procedure Manual shall include a Quality Assurance Program which monitors personnel qualifications, training and performance.

(14) An ESRD pharmacy shall be under the control and supervision of licensed Consultant Pharmacist licensed under Section 465.0125, F.S. The Consulting Pharmacist shall be responsible for the drug/device delivery system.

(15) The Consultant Pharmacist of record for the ESRD Pharmacy shall be responsible for establishing a written protocol and Policy and Procedure Manual for the implementation of a delivery system to be utilized in compliance with the requirements of this Rule.

(16) The Consultant Pharmacist shall inspect the permitted ESRD pharmacy on a monthly basis.

(17) A copy of the ESRD pharmacy's Policy and Procedure Manual as provided above shall accompany the permit application, shall be kept within the ESRD Pharmacy, and shall be available for inspection by the Department of Health. Changes in the Policy and Procedure Manual shall be approved by the Consulting Pharmacist.

Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0196, 465.022 FS. History–New 10-2-94, Formerly 59X-28.850, Amended 9-20-99, 7-17-05, 6-24-08.

64B16-28.860 Special Pharmacy – Parenteral/Enteral Extended Scope Permit.

(1)(a) A Special Parenteral/Enteral Extended Scope permit, as authorized by Section 465.0196, F.S., is required for pharmacies to compound patient specific enteral/parenteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied. Prior to engaging in a parenteral/enteral compounding pharmacy practice as described in this section, an entity shall obtain a Special Parenteral/Enteral Extended Scope pharmacy permit.

(b) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity, including the following provisions:

1. When dispensing patient specific prescriptions provided by an institutional pharmacy permit, the Special Parenteral/Enteral Extended Scope pharmacy shall confirm accuracy of the prescription and dosage.

2. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

3. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

4. A pharmacist for the Class II institutional pharmacy shall provide drug utilization review and shall review each prescription order prior to transmission to the Special Parenteral/Enteral Extended Scope pharmacy.

5. The Policy and Procedure Manual for a Special Parenteral/Enteral Extended Scope pharmacy shall also meet the policy and procedure manual requirements of paragraph 64B16-28.820(3)(d), F.A.C.

(c) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(2) Facilities obtaining this permit may also provide services described in paragraph 64B16-28.820(1)(a), F.A.C., without obtaining an additional permit. Pharmacy services and parenteral/enteral products provided by a Special Parenteral/Enteral Extended Scope pharmacy shall be limited to the compounding and/or dispensing of sterile:

(a) Preparations for parental therapy, parenteral nutrition, and/or

(b) Preparations for enteral feeding and sterile irrigation solutions, and/or

(c) Preparations of cytotoxic or antineoplastic agents.

(3) Facilities operating under this permit may provide all necessary supplies and delivery systems so that the medicinal drugs listed herein may be properly administered.

(4) Pharmacy Environment. The compounding and dispensing of sterile parenteral/enteral prescription preparations within a Special Parenteral/Enteral Extended Scope pharmacy shall be accomplished in a pharmacy environment subject to the pharmacy permit laws contained in Chapter 465, F.S., and in accordance with those requirements for the safe handling of drugs. Special Parenteral/Enteral Extended Scope permittees shall comply with the requirements contained in subsections 64B16-28.820(3) through (4), F.A.C., and the following:

(a) Shall include an active and ongoing end product testing program to ensure stability, sterility, and quantitative integrity of finished prescriptions.

(b) Shall insure each compounding process undergoes an initial and thereafter annual sterility validation utilizing media fill to ensure the integrity and validity of the compounding process.

(5) Records.

(a) Special Parenteral/Enteral Extended Scope pharmacies shall comply with the record maintenance requirements as contained in Rule 64B16-28.140, F.A.C.

(b) Special Parenteral/Enteral Extended Scope pharmacies dispensing medicinal products to patients under the provisions of paragraph 64B16-28.820(1)(a), F.A.C., or to patients of Modified Class II institutional pharmacies under the provisions of Rule 64B16-28.860, F.A.C., shall comply with the records, utilization review, and patient counseling requirements of Rules 64B16-27.800, 64B16-27.810 and 64B16-27.820, F.A.C.

(c) Special Parenteral/Enteral Extended Scope pharmacies dispensing medicinal products to patients of Class II institutional pharmacies under the provisions of Rule 64B16-28.860, F.A.C., shall be exempt from the records, utilization review, and patient counseling requirements of Rules 64B16-27.800, 64B16-27.810 and 64B16-27.820, F.A.C.

(d) Compounding records shall be organized in such a manner as to include: lot number traceability of components used during compounding, documentation of any equipment used during compounding, documentation of staff performing compounding, and records recording ultimate dispensing of the compounded product.

Rulemaking Authority 465.005 FS. Law Implemented 465.0196, 465.022 FS. History–New 9-4-96, Formerly 59X-28.860, Amended 7-17-05.

64B16-28.870 Special-ALF.

The Special-ALF permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging. All medicinal drugs must be maintained in individual prescription containers for the individual patient. Medicinal drugs may not be dispensed on the premises. Medicinal drugs dispensed to patients of Special-ALF permits may be returned to the dispensing pharmacy's stock under the provisions of Rule 64B16-28.118, F.A.C. Dispensed controlled substances that have been discontinued shall be disposed of under the provisions of Rule 64B16-28.301, F.A.C. Medicinal drugs dispensed to the residents of a Special-ALF permit shall meet the labeling requirements of Rule 64B16-28.502 and paragraph 64B16-28.402(1)(h), F.A.C. Each facility holding a Special-ALF permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within 10 days of any change in the consultant pharmacist of record. The consultant pharmacist of record shall be responsible for the preparation of the Policy and Procedure Manual required by subsection 64B16-28.800(2), F.A.C. Policy and Procedure Manuals must provide for the appropriate storage conditions and security of the medicinal drugs stored at the facility. The consultant pharmacist of record shall inspect the facility and prepare a written report to be filed at the permitted facility at least monthly.

Rulemaking Authority 465.022 FS. Law Implemented 465.0196 FS. History–New 2-23-98.

64B16-28.900 Definitions – Nuclear Pharmacy.

(1) A "nuclear pharmacy" is a pharmacy which provides radiopharmaceutical services.

(2) A "nuclear pharmacist" is a pharmacist who has met the training qualifications as described in Rule 64B16-28.903, F.A.C., and has been licensed by the Board of Pharmacy.

(3) A "radiopharmaceutical service" shall include, but shall not be limited to, the procurement, storage, preparation, labeling, quality assurance testing, distribution, record keeping and disposal of radiopharmaceuticals.

(4) A "radiopharmaceutical" is any substance defined as a drug by section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(5) "Radiopharmaceutical quality assurance" includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals, and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

(6) "Authentication of product history" includes, but is not limited to, identifying the purchasing source, the ultimate fate, and

intermediate handling of any component of a radiopharmaceutical or other drug.

Rulemaking Authority 465.005 FS. Law Implemented 465.003(14), 465.022(1)(e) FS. History–New 1-7-76, Formerly 21S-3.01, Amended 4-4-88, Formerly 21S-3.001, Amended 7-31-91, 4-15-92, 10-1-92, Formerly 21S-28.900, 61F10-28.900, 59X-28.900, Amended 4-5-05.

64B16-28.901 Nuclear Pharmacy – General Requirements.

The process employed by any permit holder in this state concerning the handling of radioactive materials must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials. In order to insure the public health and safety in this respect, a nuclear pharmacy in this state shall meet the following general requirements:

(1) Each nuclear pharmacy shall designate a nuclear pharmacist as the prescription department manager who shall be responsible for compliance with all laws and regulations, both state and federal pertaining to radiopharmaceuticals and radiopharmaceutical services. A nuclear pharmacist must personally supervise the operation of only one nuclear pharmacy during all times when radiopharmaceutical services are being performed.

(2) The nuclear pharmacy area shall be secured from access by unauthorized personnel.

(3) Each nuclear pharmacy shall maintain accurate records of the acquisition, inventory, distribution, and disposal of all radiopharmaceuticals.

(4) All nuclear pharmacies shall provide a secured radioactive storage and decay area.

(5) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies for the procurement, secure storage, inventory, preparation, distribution and disposal of radiopharmaceuticals and other drugs.

(6) Radiopharmaceuticals are to be distributed only upon a prescription order from an authorized licensed medical practitioner or through the practitioner's agent.

(7) A nuclear pharmacist may transfer radioactive materials in accordance with all applicable laws and regulations.

(8) A nuclear pharmacist upon receiving an oral prescription order for a radiopharmaceutical shall immediately have the prescription order reduced to writing. The pharmacist may delegate this duty to a registered pharmacy technician only as authorized by Rule 64B16-27.410, F.A.C. The prescription order shall contain at least the following:

(a) The name of the user or his agent;

(b) The date of distribution and the time of administration of the radiopharmaceutical;

(c) The name of the procedure;

(d) The name of the radiopharmaceutical;

(e) The dose or quantity of the radiopharmaceutical;

(f) The serial number assigned to the prescription order for the radiopharmaceutical;

(g) Any specific instructions; and

(h) The initials of the person who received the prescription order.

(i) The patient's name must be obtained and recorded prior to dispensing, if the prescription order is for a therapeutic or blood product radiopharmaceutical.

(9) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

(a) The name of and address of the pharmacy;

(b) The name of the prescriber;

(c) The date of the original filling;

(d) The standard radiation symbol;

(e) The words "Caution Radioactive Material";

(f) The name of the procedure;

(g) The prescription order number of the radiopharmaceutical;

(h) The radionuclide and chemical form;

(i) The amount of radioactivity and the calibration date and time;

(j) The expiration date and time;

(k) The volume if a liquid;

(l) The number of items or weight, if a solid;

(m) The number of ampules or vials, if a gas;

(n) Molybdenum 99 content to USP limits, applies only to TC 99M products; and

(o) The name of the patient or the words "Physician's Use Only" in the absence of a patient name. If the prescription order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

(p) The initials of the pharmacist who dispensed the medication.

(10) The immediate inner container label of a radiopharmaceutical to be distributed shall be labeled with:

(a) The standard radiation symbol;

(b) The words "Caution Radioactive Material";

(c) The radionuclide;

(d) The chemical form;

(e) The prescription order number of the radiopharmaceutical.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(14), 465.0126, 465.014 FS. History–New 1-7-76, Formerly 21S-3.03, Amended 12-11-86, 4-4-88, Formerly 21S-3.003, 21S-28.901, 61F10-28.901, Amended 2-26-95, Formerly 59X-28.901, Amended 4-5-05, 1-1-10.

64B16-28.902 Nuclear Pharmacy – Minimum Requirements.

In order to insure compliance with the general safety requirements as previously set forth above, the following minimum requirements shall be met by a nuclear pharmacy. These requirements are in addition to the general requirements for space and equipment for other types of pharmacies, the requirements of the Department of Health for the control of radiation hazards, and the applicable requirements of the Federal Food and Drug Administration. Such minimum permit requirements are set forth as follows:

(1) Space:

(a) The area for the storage, compounding, distribution and disposal of radiopharmaceuticals shall be adequate to completely separate such radioactive pharmaceuticals from pharmacy areas which contain non-radioactive medicinal drugs;

(b) The Hot lab, storage area, and compounding and dispensing area shall be a minimum of 150 square feet.

(2) Equipment:

(a) Fume hood with appropriate air sampling equipment;

(b) Shielded radiation containment drawing station;

(c) Dose calibrator;

(d) Well scintillation counters;

(e) Area rate meters;

(f) Geiger-Mueller (GM) Survey meters;

(g) Refrigerator;

(h) Microscope;

(i) Syringe shields; and

(j) Personnel radiation detection devices.

(3) Supplies:

(a) Syringes and vials required to perform practice;

(b) Disposable gloves and protective lab coats;

(c) Appropriate supplies to ensure sterile practices for I.V. solutions;

(d) Appropriate supplies to perform thin layer chromotography;

(e) Lead transport shields for syringes and vials. No person shall utilize reusable unit dose transport containers for radioactive doses without either an effective process to decontaminate the transport container of blood and other biohazardous substances or an effective mechanism to avoid contamination of the transport container. No person shall re-use a unit dose transport container that remains contaminated with blood or other biohazardous subtances. Any unit dose transport container that is returned with the tamper-evident seal broken and the unit dose syringe included shall be considered to be contaminated.

(f) D.O.T. Type 7A approved transport containers and other labels and supplies for shipping radioactive materials.

(4) Current references:

(a) Chapter 465, F.S.;

(b) Chapter 404, F.S.;

(c) Chapter 893, F.S.;

(d) Chapters 64B16-26 and 64B16-28, F.A.C., Rules of the Florida Board of Pharmacy;

(e) Chapter 64E-5, F.A.C., Rules of the Department of Health;
(f) Title 10 C.F.R., Code of Federal Regulations, FDA Regulations;
(g) Title 49 C.F.R., Code of Federal Regulations, Department of Transportation Regulations;
(h) United States Pharmacopeia/National Formulary;
(i) USP-DI.

It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0193, 465.022(1) FS. History–New 1-7-76, Formerly 21S-3.04, Amended 12-11-86, 4-4-88, Formerly 21S-3.004, Amended 7-31-91, Formerly 21S-28.902, 61F10-28.902, Amended 2-26-95, Formerly 59X-28.902, Amended 4-26-01, 4-5-05.

64B16-28.903 Training Qualifications.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(14), 465.0126 FS. History–New 4-17-76, Amended 4-8-80, 6-23-83, Formerly 21S-3.05, Amended 8-11-86, 4-4-88, Formerly 21S-3.005, Amended 7-31-91, Formerly 21S-28.903, 61F10-28.903, Amended 6-12-96, Formerly 59X-28.903, Repealed 1-18-05.

64B16-28.904 Nuclear Pharmacist – Continuing Education.

Rulemaking Authority 465.0126, 465.022 FS. Law Implemented 465.009(5), 465.0126 FS. History–New 10-28-91, Formerly 21S-28.904, 61F10-28.904, 59X-28.904, Amended 1-12-03, 10-19-03, Repealed 1-18-05.

CHAPTER 64B16-29
ANIMAL CONTROL SHELTER PERMITS

64B16-29.001 Definition
64B16-29.002 General Requirements
64B16-29.003 Drug Requirement (Repealed)
64B16-29.004 Records
64B16-29.0041 Record Maintenance Systems for Animal Shelter Permits
64B16-29.005 Storage

64B16-29.001 Definition.

An "animal control shelter" is a county or municipal animal control agency or Humane Society registered with the Secretary of State which holds a modified Class II Institutional Pharmacy permit issued by the Department of Health pursuant to certification of compliance with Rule 64B16-29.002, F.A.C., by the Board of Pharmacy. An animal control shelter is issued a pharmacy permit for the sole purpose of obtaining the drugs, sodium pentobarbital and sodium pentobarbital with lidocaine, for euthanization of animals within their lawful possession.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History–New 10-17-79, Formerly 21S-14.01, Amended 4-24-88, Formerly 21S-14.001, 21S-29.001, 61F10-29.001, 59X-29.001.

64B16-29.002 General Requirements.

(1) Application for an Animal Control Shelter Pharmacy permit shall be made on Board of Pharmacy approved form DOH-MQA/PH/107 "Animal Control Pharmacy Permit Application and Information," effective October 2009, which is incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850) 488-0595, or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy.

(a) The application fee for animal shelters applying for the Modified Class II Institutional permit shall be fifty dollars ($50).

(b) The biennial permit renewal fee for animal shelters holding the Modified Class II Institutional permit shall be fifty dollars ($50).

(2) The applicant shall apply to the Drug Enforcement Administration, United States Department of Justice, by the appropriate DEA form, for Registration as a practitioner, to be designated as "Animal Shelter" on the appropriate DEA form.

(3) The applicant shall be certified by the Board of Pharmacy to the Department as having met the requirements of this rule chapter prior to issuance of a permit. The certification process shall require prior inspection of the facility by authorized persons.

(4) The consultant pharmacist requirement of Section 465.019(5), F.S., is waived as being inapplicable to this special restricted permit.

(5) Authorized employees of the Department shall inspect animal control shelters not less than twice per year to determine compliance with this rule.

(6) Each animal control shelter permittee shall designate an on-site manager of the shelter. The on-site manager and permittee shall notify the Department within ten (10) days of any change in the on-site manager of the shelter.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History–New 10-17-79, Formerly 21S-14.02, Amended 4-24-88, Formerly 21S-14.002, Amended 10-1-92, Formerly 21S-29.002, Amended 7-18-94, Formerly 61F10-29.002, 59X-29.002, Amended 5-11-10.

64B16-29.003 Drug Requirement.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History–New 10-17-79, Formerly 21S-14.03, Amended 4-24-88, Formerly 21S-14.003, 21S-29.003, 61F10-29.003, 59X-29.003, Repealed 3-28-12.

64B16-29.004 Records.

Animal control shelter permittees shall maintain records of purchases and administration of sodium pentobarbital and sodium pentobarbital with lidocaine for a period of not less than two (2) years. Records of administration shall contain:

(1) The date of use;

(2) Identification of the animal;

(3) The amount of the drug used;

(4) The signature of the person administering the drug;

(5) The signature of the on-site manager certifying the accuracy of the administration of sodium pentobarbital and sodium pentobarbital with lidocaine not less than once per month; and

(6) The signature of the on-site manager certifying to the accuracy of the records. These records are subject to audit by the Drug Enforcement Administration or authorized employees of the Department to determine adequacy, accuracy and validity of the record keeping.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History–New 10-17-79, Formerly 21S-14.04, Amended 4-24-88, Formerly 21S-14.004, 21S-29.004, 61F10-29.004, 59X-29.004.

64B16-29.0041 Record Maintenance Systems for Animal Shelter Permits.

(1) General requirements for records maintained in an electronic system.

(a) If a permitted animal shelter's data processing system is not in compliance with the Board's data processing requirements, the facility must maintain a manual recordkeeping system meeting the requirements of Rule 64B16-29.004, F.A.C.

(b) Requirements for back-up systems. The facility shall maintain a back-up copy of information stored in the data processing system using disk, tape, or other electronic back-up and up-date this back-up copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.

(c) Change or discontinuance of a data processing system.

1. Records of dispensed and returned medicinal drugs. A permitted animal shelter that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system; or

b. Purge the records to a printout which contains the same information as required on the audit trail printout as specified in Rule 64B16-29.004, F.A.C.

2. Other records. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system; or

b. Purge the records to a printout which contains all of the information required on the original document.

3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(d) Loss of data. The shelter manager for permitted animal shelters shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(2) The permitted animal shelter shall maintain a system(s) which can produce the information required in Rule 64B16-29.004, F.A.C., for the preceding two years. The information required in this paragraph shall be supplied by the permitted animal shelter within seven working days if requested.

(3) Failure to maintain records. Failure to provide records set out in this subsection, either on site or within 7 working days for whatever reason, constitutes failure to keep and maintain records.

(4) Data processing system downtime. In the event that a permitted animal shelter which uses a data processing system experiences system downtime, the permitted animal shelter must have an auxiliary procedure which will ensure that all data is retained.

Rulemaking Authority 465.005, 465.0155, 465.022, 828.055 FS. Law Implemented 465.019, 465.022, 465.026, 893.07, 828.055 FS. History–New 3-31-05.

64B16-29.005 Storage.

Sodium pentobarbital and sodium pentobarbital with lidocaine shall be stored in a safe place. At a minimum, this shall require that the drugs be kept in a securely locked cabinet within a locked storage room. Schedule II order forms are to be stored under the same conditions. Records of purchases of sodium pentobarbital and sodium pentobarbital with lidocaine shall be maintained in a separate file from the records of administration. The records of purchases and administration shall be maintained at the location.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History–New 10-17-79, Formerly 21S-14.05, Amended 4-24-88, Formerly 21S-14.005, 21S-29.005, 61F10-29.005, 59X-29.005.

CHAPTER 64B16-30
DISCIPLINARY GUIDELINES

64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances
64B16-30.002 Minor Violations
64B16-30.003 Citations
64B16-30.0035 Mediation

64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances.

(1) The board sets forth below a range of disciplinary guidelines from which disciplinary penalties will be imposed upon licensees guilty of violating Chapter 465, F.S. The purpose of the disciplinary guidelines is to give notice to licensees of the range of penalties which will normally be imposed upon violations of particular provisions of Chapter 465, F.S. The term license means any permit, registation, certificate, or license, including a provisional license, issued by the Department. The minimum penalty range is based upon a first time single count violation of each provision listed. The maximum penalty range is based upon multiple or repeated violations of the same provision of Chapter 465, F.S., or the rules promulgated thereto. All penalties at the upper range of the sanctions set forth in the guidelines, i.e., suspension, revocation, etc., include lesser penalties, i.e., fine, probation or reprimand which may be included in the final penalty at the board's discretion. Probation may be subject to conditions, including restriction from practice in certain settings, restricting the licensee to working only under designated conditions or in certain settings, requiring continuing or remedial education, or any other restriction found to be necessary for the protection of the public health, safety and welfare. In addition to any other discipline imposed under these guidelines, the board shall assess costs relating to the investigation and prosecution of the case.

(2) The following disciplinary guidelines shall be followed by the board in imposing disciplinary penalties upon licensees and permittees for violation of the below mentioned statutes and rules. For the purposes of this rule, the descriptions of the violations are abbrieviated and the full statute or rule cited should be consulted to determine the prohibited conduct.

	PENALTY RANGE	
VIOLATION	MINIMUM	MAXIMUM
(a) Obtaining a license or permit by misrepresentation, fraud or error (Section 465.016(1)(a), F.S.) (Section 465.023(1)(a), F.S.)	$10,000 fine for each count and Revocation	$10,000 fine for each count and Revocation
(b) Procuring a license or permit by false representation (Section 465.016(1)(b), F.S.) (Section 465.023(1)(b), F.S.	$10,000 fine for each count and Revocation	$10,000 fine for each count and Revocation
(c) Permitting unlicensed persons to practice pharmacy (Section 465.016(1)(c), F.S.)	$2,500 fine and 12 hours Laws & Rules course or Multistate Pharmacy Jurisprudence Exam (MPJE)	Revocation
(d) Being unfit or incompetent to practice pharmacy (Section 465.016(1)(d), (m), F.S.)	$250 fine, indefinite suspension with PRN review and board appearance	Revocation or, at the licensee's discretion, voluntarily relinquishment with reinstatement under the terms and conditions approved by the board
(e) Violating laws		

governing the practice of pharmacy (Section 465.016(1)(e), F.S.) (Section 465.023(1)(c), F.S.)		
1. Chapter 465, F.S.:		
a. Failure to supervise registered pharmacy technician (Section 465.014, F.S.)	$250 fine and one (1) year probation and 12 hour Laws & Rules Course or MPJE	Revocation
b. Operating a pharmacy that is not registered (Section 465.015(1)(a), F.S.)	$500 per month to maximum of $5,000 (penalty will require permittee to renew permit or cease practice)	Revocation
c. Operating a pharmacy where an unlicensed and unsupervised person practices pharmacy (Section 465.015(1)(b), F.S.)	$5,000 fine and one (1) year probation	Revocation
d. Making a false or fraudulent statement to the board (Section 465.015(2)(a), F.S.)	$10,000 fine for each count	$10,000 fine for each count and Revocation
e. Practicing pharmacy as an inactive licensee (Section 465.015(2)(b), F.S.)	Fine based on length of time in practice while inactive; $500/month	Revocation
f. Selling or dispensing drugs without a prescription (Section 465.015(2)(c), F.S.)		
(i) Non-scheduled legend drugs	$1,500 fine	Revocation
(ii) Scheduled (controlled substances) legend drugs	$5,000 fine and one (1) year probation	Revocation
g. Selling samples or complimentary drugs (Section 465.015(2)(d), F.S.)		
(i) Non-scheduled legend drugs	$1,500 fine	Revocation
(ii) Scheduled (controlled Substances) legend drugs	$5,000 fine and one (1) year probation	Revocation

h. Failure to notify the board of or not to have a prescription department manager or consultant pharmacist Sections 465.018, .019, .0193, .0196, or .0197, F.S. (Section 465.022(10), (11), F.S.)		
(i) Failure to notify (Section 465.018, F.S.)	Fine based on length of time prior to notifying board. $500 per month	$7,500 maximum (penalty requires notification or ceasing practice)
(ii) Failure to have prescription department manager or consultant pharmacist of record	Fine based on length of time prior to notifying board, $750 per month and one (1) year probation	Revocation
i. Failure to comply with required substitution of legend drug requirements (Sections 465.025(2), (3), (4), F.S.)	$500 fine and 12 hour Laws & Rules Course or MPJE	$2,500 fine
j. Failure to follow negative formulary requirements (Section 465.025(6), F.S.) (Rule 64B16-27.500, F.A.C.)	$1,000 fine and 12 hours Laws & Rules Course or MPJE	$2,500 fine and one (1) year probation
k. Failure to follow emergency prescription requirements (Section 465.0275, F.S.)	$500 fine	$1,000 fine and one (1) year probation
l. Engage in prohibited rebate scheme (Section 465.185, F.S.)	$1,500 fine	Revocation
m. Failure to comply with pharmacist dispensing requirements (Section 465.186, F.S.)		
(i) Failure to follow procedure, but dispense drug appearing on formulary (Section 465.186(3), F.S.) (Rule 64B16-27.210, F.A.C.)	$500 fine	$1,000 fine, one (1) year probation and suspension of right to dispense
(ii) Dispensing drug not on the formulary (Section 465.186(2), F.S.)	$1,500 fine	Revocation

(Rules 64B16-27.220, .230, F.A.C.)

2. Chapter 499, F.S.

a. Adulteration of a drug (Section 499.005(2), (3), F.S.) (Section 499.006, F.S.)	$1,000 fine	Revocation
b. Misbranding a drug (Section 499.005(2), (3), F.S.) (Section 499.007, F.S.)		
(i) Incomplete or inaccurate labeling (Section 499.007, F.S.) (Rule 64B16-28.108, F.A.C.)	$250 fine and 12 hour Laws & Rules Course or MPJE	$2,500 fine and one (1) year probation
(ii) Fraudulent misbranding of legend drugs (Section 499.007, F.S.)	$2,500 fine and one (1) year suspension	Revocation
c. Prescriptions Drug Pedigree	$500 fine and 12 hour Laws & Rules Course or MPJE	Revocation
d. Recordkeeping requirement	$500 fine and 12 hour Laws & Rules Course or MPJE	Revocation
e. Storage of drugs	$500 fine and 12 hour Laws & Course or MPJE	Revocation

3. Chapter 893, F.S.
(Controlled substances)

a. Filling a prescription for controlled substances that does not meet the requirements of Chapter 893, F.S. (Section 893.04(1)(b), F.S.)	$1,500 fine	$5,000 fine and one (1) year probation
b. Failing to retain prescription records for two (2) years (Section 893.04(1)(d), F.S.)	$1,000 fine	Revocation
c. Failing to appropriately label (Section 893.04(1)(e), F.S.)	$250 fine and 12 hour Laws & Rules Course or MPJE	$2,500 fine and one (1) year probation
d. Dispensing a Schedule II drug inappropriately with a	$5,000 fine and one (1) year probation	Revocation

non-written prescription (Section 893.04(1)(f), F.S.)		
e. Inappropriate refilling of Schedule III, IV, or V drugs (Section 893.04(1)(g), F.S.)	$1,750 fine and one (1) year probation	One (1) year suspension
f. Receiving controlled substances without an appropriate order form (Section 893.06(1), F.S.)	$2,500 fine	Revocation
g. Unlawful possession of controlled substances (Section 893.06(2), F.S.)	$2,500 fine and one (1) year probation	Revocation
h. Failure to take a biennial inventory (Section 893.07(1)(a), (2), (3), (4), (5), F.S.)	$1,000 fine	$2,500 fine and one (1) year probation
i. Failure to maintain a complete and accurate record of controlled substances (Section 893.07(1)(b), (2), (3), (4), (5), F.S.)	$1,000 fine and one (1) year probation	Revocation
j. Dispensing controlled substances in other than good faith (Section 893.08(3)(b), F.S.)	$5,000 fine and one (1) year probation	Revocation
k. Inappropriate selling of Schedule V controlled substance (Section 893.08(3)(c), F.S.)	$1,500 fine and one (1) year probation	One (1) year suspension
l. Unlawful possession of controlled substance (Section 893.13, F.S.)	$5,000 fine and two (2) years probation	Revocation
4. Violation of Federal Drug Abuse Act 21 U. S. C. 821 et seq.	$500 fine and one (1) year probation	Revocation
(f) Criminal conviction related to pharmacy (Section 465.016(1)(f), F.S.) (Section 465.023(1)(d), F.S.)		

(i) Misdemeanor	$1,000 fine	Revocation
(ii) Felony	One (1) year suspension, two (2) years probation & $5,000 fine	Revocation
(g) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in Section 465.019(6), F.S. or Section 465.025, F.S., or compounding,dispensing or distributing legend drugs outside professional practice of pharmacy (Section 465.016(1)(g), F.S.) (Section 465.016(1)(i), F.S.)	$250 fine and and complete approved CE course in the prevention of medication errors of no less than eight (8) hours	Revocation
(h) Filing a false report or failing to file a report required by law		
1. Knowing violation	$2,000 fine and one (1) year probation	Revocation
2. Negligent violation	Reprimand	One (1) year probation and $1,000 fine
(i) Failure to make prescription price information available (Section 465.016(1)(k), F.S.)	$250 fine and 12 hour Laws & Rules Course or MPJE	$1,000 fine and one (1) year probation
(j) Improperly placing returned drugs into the stock of a pharmacy (Section 465.016(1)(l), F.S.)	$1,500 fine	$3,000 fine and one (1) year probation
(k) Violating a rule or order of the board or Department (Section 465.016(1)(n), F.S.)		
1. Rules of Board of Pharmacy		
a. Rules 64B16-28.101 to 64B16-28.1035, F.A.C. Rule 64B16-27.100, F.A.C. Rule 64B16-28.109, F.A.C.	$500 fine and 12 hour Laws & Rules or MPJE	One (1) year probation and $2,000 fine

Rule 64B16-27.103, F.A.C. Rule 64B16-27.104, F.A.C. Rule 64B16-26.400, F.A.C. Rule 64B16-26.2032, F.A.C. Rule 64B16-28.1081, F.A.C. Rule 64B16-26.301, F.A.C. Rule 64B16-28.114, F.A.C. Rule 64B16-27.105, F.A.C. Rule 64B16-27.211, F.A.C. Rule 64B16-28.113, F.A.C. Rule 64B16-28.2021, F.A.C. Rule 64B16-28.603, F.A.C.		
b. Rule 64B16-28.102, F.A.C.	Suspension until compliance	Revocation
c. Rule 64B16-27.101, F.A.C. (counterfeit drugs)	$1,000 fine for dispensing	Revocation
d. Rule 64B16-28.110, F.A.C. (outdated pharmaceuticals)	$500 fine for possession $1,000 fine for dispensing	Revocation
e. Rules 64B16-28.301, 64B16-28.303, F.A.C. (destruction of controlled substances) (violations)	$500 fine and 12 hour Laws & Rules or MPJE	Revocation
f. Rule 64B16-26.300, F.A.C (Serving as consultant pharmacist without being licensed as a consultant pharmacist)	$500 per month up to $5,000 fine (fine based upon the length of time the person is serving as a consultant without being licensed as a consultant pharmacist)	Revocation
g. Rule 64B16-28.140, F.A.C. (Data processing systems)	$1,000 fine	Revocation
h. Rule 64B16-28.120, F.A.C. (Location of legend drugs)	$1,000 fine	Revocation
i. Practicing nuclear pharmacy without being licensed as a nuclear pharmacist (Rule 64B16-26.303, F.A.C.)	$500 per month up to $5,000 fine (fine based upon the length of time the person is practicing without being licensed as a nuclear pharmacist)	Revocation
j. Failure to follow technical requirements (Rules 64B16-28.901 and 64B16-28.902, F.A.C.)	One (1) year probation and $1,000 fine	Revocation
k. Rules 64B16-28.202 and	$1,500 fine	Revocation

64B16-28.203, F.A.C. (transfer of prescription files and drugs)		
l. Failure to complete the required continuing education during the biennial licensure period. (Rule 64B16-26.103, F.A.C.)		
1. Failure to complete less than ten (10) hours	$500 fine	$1,500 fine
2. Failure to complete ten (10) or more hours In addition, licensees shall take two additional hours of continuing edcuation for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.	$1,000 fine	$2,500 fine
m. Failure to maintain program requirements for certification, training, or continuing education programs or providers. (Rule 64B16-26.601, F.A.C.)	$500 fine	Revocation
n. Failure to retain continuing education records. (Rule 64B16-26.603, F.A.C.)	$250 fine	$1,500 fine
o. Failure to practice in accordance with established practice standards. (Rules 64B16-27.1001, .104, F.A.C.)		
1. Pharmacist	$500 fine	Revocation
2. Pharmacy Intern	$250 fine	Revocation
3. Permittee	$500 fine	Revocation
p. Failure to have current policies and procedures. (Rules 64B16-28.141, .450, F.A.C.)	$500 fine	Revocation
q. Failure to have or maintain standards for an automated pharmacy system in a community	$500 fine and 12 hours Laws & Rules MJPE	Revocation

pharmacy. (Rule 64B16-28.141, F.A.C.)		
r. Failure to have or maintain standards for a central fill pharmacy. (Rule 64B16-28.450, F.A.C.)	$500 fine and 12 hour Laws & Rules or MJPE	Revocation
s. Failure to have or maintain standards for an institutional pharmacy. (Rules 64B16-28.602, .6021, .605, .606, .702, F.A.C.)	$500 fine and 12 hour Laws & Rules or MJPE	
t. Failuare to maintain or have standards for a special pharmacy. (Rules 64B16-28.800, .810, .820, .840, .850, .860, .870, F.A.C.)	$500 fine and 12 hour Laws & Rules or MJPE	
u. Failure to maintain standards for animal control shelters	$500 Fine	Revocation
2. Violation of orders of Board or Department	$2,500 fine and one (1) year probation	Revocation
(l) License disciplined by another jurisdiction (Section 465.016(1)(h), F.S.)	Same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes	
(m) Failure to comply with Board's rule on patient counseling (Rules 64B16-27.800, .810, .820, F.A.C.)	$750 fine	$2,500 fine and, one year probation
(n) Abandoning or allowing permit to become null and void after notice of disciplinary proceedings. (Section 465.018(3), F.S.)	Revocation	Revocation
(o) Violating 456.072, F.S.		
1. Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession.	$1,500 fine and one (1) year probation	Revocation
2. Intentionally violating	$2,500 fine and two (2) years	Revocation

any rule adopted by the Board or the Department.	probation	
3. Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.		
(i) Misdemanor	$1,000 fine	Revocation
(ii) Felony	$3,000 fine and one (1) year probation	Revocation
4. Failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome, or medical errors.	$500 fine	$1,000 fine
5. Having a license or the authority to practice the regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law. The licensing authority's acceptance of a relinquishment of licensure, stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as action against the license.	Same penalty as imposed in other jurisdiction or as closely as possible to penalties for similar violation	
6. Having been found liable in a civil proceeding for	$3,000 fine	Revocation

knowingly filing a false report or complaint with the Department against another licensee.		
7. Attempting to obtain, obtaining, or renewing a license to practice a profession by bribery, by fraudulent misrepresentation, or through an error of the Department or the Board.	Revocation or denial of license application	
8. Except as provided in Section 465.016, F.S., failing to report to the Department any person who the licensee knows is in violation of this part, the chapter regulating the alleged violator, or the rules of the Department or the Board.	$500 fine and one (1) year probation	Revocation
9. Aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice a profession contrary to this part, the chapter regulating the profession, or the rules of the Department or the Board.	$2,000 fine	Revocation
10. Failing to perform any statutory or legal obligation placed upon a licensee.	$2,000 fine	Revocation
11. Making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing another person to do so. Such reports or records shall include only those that are signed in the	$2,500 fine and two (2) years probation	Revocation

capacity of a licensee.		
12. Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or a scheme in or related to the practice of a profession.	$10,000 fine and two (2) years probation	Revocation $10,000 fine and one (1) year suspension
13. Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party.	$3,000 fine and two (2) years probation	Revocation
14. Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform.	$2,000 fine and two (2) years probation	Revocation
15. Delegating or contracting for the performance of professional responsibilities by a person when the licensee delegating or contracting for performance of such responsibilities knows, or has reason to know, such person is not qualified by training, experience, and authorization when required to perform them.	$2,000 fine and two (2) years probation	Revocation
16. Violating any provision of this part, the applicable professional practice act, a rule of the Department or the Board, or a lawful order of the Department or the Board, or failing to comply with a lawfully issued subpoena of the Department.	$1,000 fine	Revocation
17. Improperly interfering	$2,500 fine and two (2) years	Revocation

with an investigation or inspection authorized by statute, or with any disciplinary proceeding.	probation	
18. Failing to report to the board in writing within 30 days after the licensee has been convicted or found guilty or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction.	$1,000 fine	Revocation
19. Testing positive for any drug, as defined in Section 112.0455, F.S., on any confirmed preemployment or employer ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using such drug.	$1,500 fine PRN evaluvation and two (2) years probation or compliance with PRN contract	Revocation
20. Being terminated from or failing to successfully complete an impaired practitioners treatment program. (Section 456.072(1)(hh), F.S.)	Suspension until successful completion or receipt of written confirmation of compliance with ongoing treatment and a fine of up to $1,000.	Revocation
21. Being convicted of, or entering a plea of guilty or nolo contendere to any misdemeanor or felony, regardless of adjudication, under 18 USC s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518, or 42 USC ss. 1320a-7b, relating to the Medicaid program. (Section 456.072(1)(ii), F.S.)	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.	
22. Failing to remit the sum owed to the state for overpayment from the Medicaid program pursuant to a final order, judgment, or settlement.	From a letter of concern to probation, and a fine of $500 to $5,000.	From a reprimand to revocation, and a fine of $2,500 to $5,000.

(Section 456.072(1)(jj), F.S.)		
23. Being terminated from the state Medicaid program, or any other state Medicaid program, or the federal Medicare program. (Section 456.072(1)(kk), F.S.)	From a letter of concern to suspension, and a fine of $1,000 to $5,000.	From a reprimand to revocation, and a fine of $5,000 to $10,000.
24. Being convicted of, or entering into a plea of guilty or nolo contendere to any misdemeanor or felony, regardless of adjudication, which relates to health care fraud. (Section 456.072(1)(ll), F.S.)	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.	

(3) The board shall be entitled to deviate from the above-mentioned guidelines upon a showing of aggravating or mitigating circumstances by clear and convincing evidence presented to the board prior to the imposition of a final penalty. The fact that an Administrative Law Judge of the Division of Administrative Hearings may or may not have been aware of the below-mentioned aggravating or mitigating circumstances prior to a recommendation of penalty in a Recommended Order shall not obviate the duty of the board to consider aggravating and mitigating circumstances brought to its attention prior to the issuance of a Final Order.

(a) Aggravating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the enhancement of a penalty beyond the maximum level of discipline in the guidelines shall include but not be limited to the following:

1. History of previous violations of the practice act and the rules promulgated thereto.
2. In the case of negligent acts, the magnitude and scope of the damage or potential damage inflicted upon the patient or the general public by the licensee's misfeasance.
3. Evidence of violation of professional practice acts in other jurisdictions wherein the licensee has been disciplined by the appropriate regulatory authority.
4. Violation of the provision of the practice act wherein a letter of guidance as provided in Section 456.073(3), F.S., has previously been issued to the licensee.

(b) Mitigating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the lessening of a penalty beyond the minimum level of discipline in the guidelines shall include but not be limited to the following:

1. In cases of negligent acts, the minor nature of the damage or potential damage to the patient's or the public's health, safety and welfare resulting from the licensee's misfeasance.
2. Lack of previous disciplinary history in this or any other jurisdiction wherein the licensee practices his profession.
3. Restitution of any monetary damage suffered by the patient.
4. The licensee's professional standing among his peers.
5. Steps taken by the licensee to insure the non-occurrence of similar violations in the future including continuing education.
6. The degree of financial hardship incurred by a licensee as a result of the imposition of fines or the suspension of his practice.

(4) All fines imposed by the Board shall be paid within a period of niney (90) days from the date of the final ordered entered by the Board. This time limitation may be modified by the Board for good cause shown in order to prevent undue hardship.

Rulemaking Authority 456.072, 456.079, 465.005 FS. Law Implemented 456.072, 456.079 FS. History–New 3-1-87, Amended 5-11-88, Formerly 21S-17.001, 21S-30.001, 61F10-30.001, Amended 6-26-95, 1-30-96, Formerly 59X-30.001, Amended 12-3-97, 11-15-98, 5-3-00, 1-2-02, 11-29-06, 9-26-12.

64B16-30.002 Minor Violations.

(1) The Board sets forth the following guidelines for use by Department investigators when a licensee is in noncompliance of an initial offense of a minor violation. The Board deems the following violations, depending upon severity, to be consistent with

Section 456.073(3), F.S.

(a) Outdated pharmaceuticals – Rule 64B16-28.110, F.A.C.

(b) Failure to meet regulation of daily operating hours – Rule 64B16-28.404, F.A.C.

(c) Generic substitution sign not displayed – Section 465.025(7), F.S.

(d) Information required on controlled substance prescriptions: practitioner's address, practitioner's DEA registration number, patient's address – Section 893.04, F.S.

(e) Failure to have certified by dispensing pharmacists the daily hard-copy printout or daily log – paragraph 64B16-28.140(3)(c) or (e), F.A.C.

(f) Failure to have pharmacy minimally equipped i.e. references, compounding equipment, and a current copy of the laws and rules governing the practice of pharmacy in the State of Florida – Rule 64B16-28.107, F.A.C.

(g) Failure to properly identify pharmacy technicians – Rule 64B16-27.410, F.A.C.

(h) Results of P&E quality assurance program not documented or available for inspection – paragraph 64B16-28.820(3)(d), F.A.C.

(i) Improper storage of legend drugs – Rule 64B16-28.120, F.A.C.

(j) Improper documentation of destruction of controlled substances – Rules 64B16-28.301, 64B16-28.303, F.A.C.

(k) Consultant pharmacist's monthly reports not current or available for inspection – Rule 64B16-28.501, subsection 64B16-28.702(2), F.A.C.

(l) Controlled substance prescription labels lack transfer crime warning labeling – paragraph 64B16-28.502(2)(c), F.A.C.

(2) The Department's investigator may issue a Notice of Deficiencies when the above conditions occur and the requirements of Section 456.073(3), F.S., are met. In such cases licensees shall correct the violation and respond to the investigator on forms provided by the Department and with other evidence of compliance as may be necessary, within 30 days, to certify current compliance. Failure to do so shall subject the licensee to further proceedings.

Rulemaking Authority 456.073(3), 465.005 FS. Law Implemented 456.073(3) FS. History–New 11-12-90, Formerly 21S-17.002, 21S-30.002, 61F10-30.002, 59X-30.002, Amended 12-9-98, 8-26-02.

64B16-30.003 Citations.

(1) Pursuant to Section 456.077, F.S., the Board sets forth in (3) of this rule those violations for which there is no substantial threat to the public health, safety and welfare; or, if there is a substantial threat to the public health, safety and welfare, such potential for harm has been removed prior to the issuance of the citation. Next to each violation is the fine to be imposed.

(2) Prior to issuance of the citation, the Department must confirm that the violation has been corrected or is in the process of being corrected. If the violation is a substantial threat to the public health, safety and welfare, such potential for harm must be removed prior to issuance of the citation.

(3) The following violations with accompanying fines may be disposed of by citation:

(a) Practicing pharmacy as an inactive licensee (465.015(2)(b), F.S.)	Fine based on length of time in practice while inactive; $200/month or $5,000 maximum (penalty will require licensee to renew license or cease practice).
(b) Operating a pharmacy with an inactive permit (465.015(1)(a), F.S.)	$500 per month to a maximum of $5000 (penalty will require permittee to renew permit or cease practice).

(c) First time failure to complete the required continuing education during the biennial licensure period.(456.072(3), F.S.)

Failure to complete less than 10 hours	$500
Failure to complete 10 or more hours	$1000

In addition, licensees shall take two additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.

(d) Failure to timely pay a fine or costs imposed by a final order.	$500 per month late to a maximum of $5,000 (penalty will require permittee or licensee to also pay the original fine and/or costs).

(e) Failure to display any sign, license or permit required by statute or rule.	$500
(f) Failure to have any reference material required by statute or rule available.	$500
(g) Failure to notify the board of a change in a prescription department manager or consultant pharmacist.	Fine based on the length of time prior to notifying board. $200 a month to $5,000 maximum.
(h) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in Section 465.019(6) or 465.025, F.S.; or dispensing a medication with dosage instructions different in any way than prescribed, provided that the medication was not used or ingested.	$250 fine, Completion of an approved CE course in the prevention of medication errors of no less than 8 hours.
(i) Tendering a check payable to the Board of Pharmacy or to the Department of Health that is dishonored by the Institution upon which it is drawn.	$100 fine plus payment of the check within 30 days.
(j) Failing to comply with the Educational course requirements for Human immunodeficiency virus and Aquired immune deficiency syndrome (HIV/AIDS), or medical errors	$500
(k) Failure to correct Minor violation as listed in Rule 64B16-30.002, F.A.C.	$250
(l) Failure to retain continuing education records	$250

(4) Once the citation becomes a final order, the citation and complaint become a public record pursuant to Chapter 119, F.S., unless otherwise exempt from the provisions thereof. The citation and complaint may be considered as aggravating circumstances in future disciplinary actions pursuant to paragraph 64B16-30.001(3)(a), F.A.C.

(5) The procedures described herein apply only for an initial offense of the alleged violation. Subsequent violation(s) of the same rule or statute shall require the procedures of Section 456.073, F.S., to be applied. In addition, should an initial offense for which a citation could be issued occur in conjunction with violations not described herein, then the procedures of Section 456.073, F.S., shall apply.

Rulemaking Authority 456.073, 456.077, 465.005 FS. Law Implemented 456.077 FS. History–New 12-22-91, Formerly 21S-30.003, 61F10-30.003, 59X-30.003, Amended 4-3-00, 1-2-02, 8-26-02, 1-12-03, 2-1-12.

64B16-30.0035 Mediation.

(1) "Mediation" means a process whereby a mediator appointed by the Department acts to encourage and facilitate resolution of a legally sufficient complaint. It is an informal and nonadversarial process with the objective of assisting the parties to reach a mutually acceptable agreement.

(2) The Board finds that mediation is an acceptable method of dispute resolution for the following violation as it is economic in

nature or can be remedied by the licensee: failure of the licensee to timely pay any assessed administrative fines or costs.

(3) A "mediator" means a person who is certified in mediation by the Florida Bar, the Florida Supreme Court, or the Division of Administrative Hearings.

Rulemaking Authority 456.078 FS. Law Implemented 456.078 FS. History–New 11-21-94, Formerly 59X-30.0035.

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Pharmaceutical Compounding—
Sterile Preparations

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⟨797⟩ PHARMACEUTICAL COMPOUNDING–STERILE PREPARATIONS

INTRODUCTION

The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see "official" and "article" in the *General Notices and Requirements*) or 10% for nonofficial articles, (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in compounded sterile preparations (CSPs). Contaminated CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins (see *Bacterial Endotoxins Test* ⟨85⟩), they are potentially most hazardous to patients when administered into the central nervous system.

Despite the extensive attention in this chapter to the provision, maintenance, and evaluation of air quality, the avoidance of direct or physical contact contamination is paramount. It is generally acknowledged that direct or physical contact of critical sites of CSPs with contaminants, especially microbial sources, poses the greatest probability of risk to patients. Therefore, compounding personnel must be meticulously conscientious in precluding contact contamination of CSPs both within and outside ISO Class 5 (see *Table 1*) areas.

To achieve the above five conditions and practices, this chapter provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices. The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein. The standards in this chapter do not pertain to the *clinical administration* of CSPs to patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration. Four specific categories of CSPs are described in this chapter: low-risk level, medium-risk level, and high-risk level, and immediate use. Sterile compounding differs from nonsterile compounding (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩ and *Good Compounding Practices* ⟨1075⟩) primarily by requiring the maintenance of sterility when compounding exclusively with sterile ingredients and components (i.e., with immediate-use CSPs, low-risk level CSPs, and medium-risk level CSPs) and the achievement of sterility when compounding with nonsterile ingredients and components (i.e., with high-risk level CSPs). Some differences between standards for sterile compounding in this chapter and those for nonsterile compounding in *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩ include, but are not limited to, ISO-classified air environments (see *Table 1*); personnel garbing and gloving; personnel training and testing in principles and practices of aseptic manipulations and sterilization; environmental quality specifications and monitoring; and disinfection of gloves and surfaces of ISO Class 5 (see *Table 1*) sources.

Table 1. ISO Classification of Particulate Matter in Room Air
(limits are in particles of 0.5 µm and larger per cubic meter [current ISO] and cubic feet [former Federal Standard No. 209E, FS 209E])*

Class Name		Particle Count	
ISO Class	U.S. FS 209E	ISO, m^3	FS 209E, ft^3
3	Class 1	35.2	1
4	Class 10	352	10
5	Class 100	3,520	100
6	Class 1,000	35,200	1,000
7	Class 10,000	352,000	10,000
8	Class 100,000	3,520,000	100,000

*Adapted from former Federal Standard No. 209E, General Services Administration, Washington, DC, 20407 (September 11, 1992) and ISO 14644-1:1999, Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness. For example, 3,520 particles of 0.5 µm per m^3 or larger (ISO Class 5) is equivalent to 100 particles per ft^3 (Class 100) (1 m^3 = 35.2 ft^3).

The standards in this chapter are intended to apply to all persons who prepare CSPs and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians' practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported). Persons who perform sterile compounding include pharmacists, nurses, pharmacy technicians, and physicians. These terms recognize that most sterile compounding is performed by or under the supervision of pharmacists in pharmacies and also that this chapter applies to all healthcare personnel who prepare, store, and transport CSPs. For the purposes of this chapter, CSPs include any of the following:

(1) Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

(2) Manufactured sterile products that are either prepared strictly according to the instructions appearing in manufacturers' approved labeling (product package inserts) or prepared differently than published in such labeling. [NOTE—The FDA states that "Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling" [21 USC 321 (k) and (m)]. However, the FDA-approved labeling (product package insert) rarely describes environmental quality (e.g., ISO Class air designation, exposure durations to non-ISO classified air, personnel garbing and gloving, and other aseptic precautions by which sterile products are to be prepared for administration). Beyond-use exposure and storage dates or times (see *General Notices and Requirements* and *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩) for sterile products that have been either opened or prepared for administration are not specified in all package inserts for all sterile products. Furthermore, when such durations are specified, they may refer to chemical stability and not necessarily to microbiological purity or safety.]

ORGANIZATION OF THIS CHAPTER

The sections in this chapter are organized to facilitate the practitioner's understanding of the fundamental accuracy and quality practices for preparing CSPs. They provide a

foundation for the development and implementation of essential procedures for the safe preparation of low-risk, medium-risk, and high-risk level CSPs and immediate-use CSPs, which are classified according to the potential for microbial, chemical, and physical contamination. The chapter is divided into the following main sections:

- Definitions
- Responsibility of Compounding Personnel
- CSP Microbial Contamination Risk Levels
- Personnel Training and Evaluation in Aseptic Manipulation Skills
- Immediate-Use CSPs
- Single-Dose and Multiple-Dose Containers
- Hazardous Drugs as CSPs
- Radiopharmaceuticals as CSPs
- Allergen Extracts as CSPs
- Verification of Compounding Accuracy and Sterility
- Environmental Quality and Control
- Suggested Standard Operating Procedures (SOPs)
- Elements of Quality Control
- Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding
- Finished Preparation Release Checks and Tests
- Storage and Beyond-Use Dating
- Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs
- Patient or Caregiver Training
- Patient Monitoring and Adverse Events Reporting
- Quality Assurance (QA) Program
- Abbreviations and Acronyms
- Appendices I–V

The requirements and recommendations in this chapter are summarized in *Appendix I*. A list of abbreviations and acronyms is included at the end of the main text, before the *Appendices*.

All personnel who prepare CSPs shall be responsible for understanding these fundamental practices and precautions, for developing and implementing appropriate procedures, and for continually evaluating these procedures and the quality of final CSPs to prevent harm.

DEFINITIONS

Ante-Area—An ISO Class 8 (see *Table 1*) or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate-generating activities are performed. It is also a transition area that (1) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas and (2) reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.[1]

Aseptic Processing (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩)—A mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and of the package (containers–closures or packaging material for medical devices) and the transfer of the product into the container and its closure under at least ISO Class 5 (see *Table 1*) conditions.

Beyond-Use Date (BUD) (see *General Notices and Requirements* and *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩)—For the purpose of this chapter, the date or time after which a CSP shall not be stored or transported. The date is determined from the date or time the preparation is compounded.

Biological Safety Cabinet (BSC)—A ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

Buffer Area—An area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.

Clean Room (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩ and also the definition of *Buffer Area*)—A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

Compounding Aseptic Containment Isolator (CACI)—A compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

Compounding Aseptic Isolator (CAI)—A form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbially retentive filter (HEPA minimum).[2]

Critical Area—An ISO Class 5 (see *Table 1*) environment.

Critical Site—A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

Direct Compounding Area (DCA)—A critical area within the ISO Class 5 (see *Table 1*) primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

Disinfectant—An agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.

First Air—The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

Hazardous Drugs—Drugs are classified as hazardous if studies in animals or humans indicate that exposures to them have a potential for causing cancer, development or reproductive toxicity, or harm to organs. (See current NIOSH publication.)

Labeling [see *General Notices and Requirements* and 21 USC 321 (k) and (m)]—A term that designates all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.

[1] See *American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. (ASHRAE), Laboratory Design Guide.*

[2] *CETA Applications Guide for the Use of Compounding Isolators in Compounding Sterile Preparations in Healthcare Facilities*, CAG-001-2005, Controlled Environment Testing Association (CETA), November 8, 2005.

Media-Fill Test (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩)—A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. During this test, a microbiological growth medium such as Soybean–Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding.[3] The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

Multiple-Dose Container (see *General Notices and Requirements* and *Containers for Injections* under *Injections* ⟨1⟩)—A multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives. The beyond-use date (BUD) for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days (see *Antimicrobial Effectiveness Testing* ⟨51⟩), unless otherwise specified by the manufacturer.

Negative Pressure Room—A room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is *into* the room.[1]

Pharmacy Bulk Package (see *Containers for Injections* under *Injections* ⟨1⟩)—A container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

Where a container is offered as a pharmacy bulk package, the label shall (a) state prominently "Pharmacy Bulk Package—Not for Direct Infusion," (b) contain or refer to information on proper techniques to help ensure safe use of the product, and (c) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.

Primary Engineering Control (PEC)—A device or room that provides an ISO Class 5 (see *Table 1*) environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

Preparation—A preparation, or a CSP, that is a sterile drug or nutrient compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

Product—A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

Positive Pressure Room—A room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is *out of* the room.[1]

Single-Dose Container (see *General Notices and Requirements* and *Containers for Injections* under *Injections* ⟨1⟩)—A single-dose container is a single-unit container for articles (see *General Notices and Requirements*) or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

Segregated Compounding Area—A designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 (see *Table 1*) air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.

Sterilizing Grade Membranes—Membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22-µm or 0.2-µm nominal pore size, depending on the manufacturer's practice.

Sterilization by Filtration—Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

Terminal Sterilization—The application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10^{-6}, or a probability of less than one in one million of a nonsterile unit.[3]

Unidirectional Flow (see footnote 3)—An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

RESPONSIBILITY OF COMPOUNDING PERSONNEL

Compounding personnel are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed. These performance responsibilities include maintaining appropriate cleanliness conditions and providing labeling and supplementary instructions for the proper clinical administration of CSPs.

Compounding supervisors shall ensure, through either direct measurement or appropriate information sources, that specific CSPs maintain their labeled strength within monograph limits for *USP* articles, or within 10% if not specified, until their BUDs. All CSPs are prepared in a manner that maintains sterility and minimizes the introduction of particulate matter.

A written quality assurance procedure includes the following in-process checks that are applied, as appropriate, to specific CSPs: accuracy and precision of measuring and weighing; the requirement for sterility; methods of sterilization and purification; safe limits and ranges for strength of ingredients, bacterial endotoxins, and particulate matter; pH; labeling accuracy and completeness; BUD assignment; and packaging and storage requirements. The dispenser shall, when appropriate and practicable, obtain and evaluate results of testing for identity, strength, purity, and sterility before a CSP is dispensed. Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved:

1. Compounding personnel are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties:
   a. perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces;
   b. select and appropriately don protective garb;
   c. maintain or achieve sterility of CSPs in ISO Class 5 (see *Table 1*) PEC devices and protect personnel and compounding environments from contamination by radioactive, cytotoxic, and chemotoxic

[3] U.S. Food and Drug Administration, Guidance for Industry, *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice*, September 2004.

drugs (see *Hazardous Drugs as CSPs* and *Radiopharmaceuticals as CSPs*);
d. identify, weigh, and measure ingredients; and
e. manipulate sterile products aseptically, sterilize high-risk level CSPs, and label and quality inspect CSPs.

2. Ingredients have their correct identity, quality, and purity.
3. Opened or partially used packages of ingredients for subsequent use in CSPs are properly stored under restricted access conditions in the compounding facility. Such packages cannot be used when visual inspection detects unauthorized breaks in the container, closure, and seal; when the contents do not possess the expected appearance, aroma, and texture; when the contents do not pass identification tests specified by the compounding facility; and when either the BUD or expiration date has been exceeded.
4. Water-containing CSPs that are nonsterile during any phase of the compounding procedure are sterilized within 6 hours after completing the preparation in order to minimize the generation of bacterial endotoxins.
5. Sterilization methods achieve sterility of CSPs while maintaining the labeled strength of active ingredients and the physical integrity of packaging.
6. Measuring, mixing, sterilizing, and purifying devices are clean, appropriately accurate, and effective for their intended use.
7. Potential harm from added substances and differences in rate and extent of bioavailability of active ingredients for other than oral route of administration are carefully evaluated before such CSPs are dispensed and administered.
8. Packaging selected for CSPs is appropriate to preserve the sterility and strength until the BUD.
9. While being used, the compounding environment maintains the sterility or the presterilization purity, whichever is appropriate, of the CSP.
10. Labels on CSPs list the names and amounts or concentrations of active ingredients, and the labels or labeling of injections (see *Preservation, Packaging, Storage, and Labeling* in the *General Notices and Requirements*) list the names and amounts or concentrations of all ingredients (see *Injections* ⟨1⟩). Before being dispensed or administered, the clarity of solutions is visually confirmed; also, the identity and amounts of ingredients, procedures to prepare and sterilize CSPs, and specific release criteria are reviewed to ensure their accuracy and completeness.
11. BUDs are assigned on the basis of direct testing or extrapolation from reliable literature sources and other documentation (see *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).
12. Procedures for measuring, mixing, dilution, purification, sterilization, packaging, and labeling conform to the correct sequence and quality established for the specified CSP.
13. Deficiencies in compounding, labeling, packaging, and quality testing and inspection can be rapidly identified and corrected.
14. When time and personnel availability so permit, compounding manipulations and procedures are separated from postcompounding quality inspection and review before CSPs are dispensed.

This chapter emphasizes the need to maintain high standards for the quality and control of processes, components, and environments and for the skill and knowledge of personnel who prepare CSPs. The rigor of in-process quality-control checks and of postcompounding quality inspection and testing increases with the potential hazard of the route of administration. For example, nonsterility, excessive bacterial endotoxin contamination, large errors in strength of correct ingredients, and incorrect ingredients in CSPs are potentially more dangerous to patients when the CSPs are administered into the vascular and central nervous systems than when administered by most other routes.

CSP MICROBIAL CONTAMINATION RISK LEVELS

The three contamination categories for CSPs described in this section are assigned primarily according to the potential for microbial contamination during the compounding of low-risk level CSPs and medium-risk level CSPs or the potential for not sterilizing high-risk level CSPs, any of which would subject patients to risk of harm, including death. High-risk level CSPs must be sterilized before being administered to patients. The appropriate risk level—low, medium, or high—is assigned according to the corresponding probability of contaminating a CSP with (1) microbial contamination (e.g., microbial organisms, spores, endotoxins) and (2) chemical and physical contamination (e.g., foreign chemicals, physical matter). Potential sources of contamination include, but are not limited to, solid and liquid matter from compounding personnel and objects; nonsterile components employed and incorporated before terminal sterilization; inappropriate conditions within the restricted compounding environment; prolonged presterilization procedures with aqueous preparations; and nonsterile dosage forms used to compound CSPs.

The characteristics described below for low-, medium-, and high-risk level CSPs are intended as a guide to the breadth and depth of care necessary in compounding, but they are neither exhaustive nor prescriptive. The licensed healthcare professionals who supervise compounding are responsible for determining the procedural and environmental quality practices and attributes that are necessary for the risk level they assign to specific CSPs.

These risk levels apply to the quality of CSPs immediately after the final aseptic mixing or filling or immediately after the final sterilization, unless precluded by the specific characteristics of the preparation. Upon subsequent storage and shipping of freshly finished CSPs, an increase in the risks of chemical degradation of ingredients, contamination from physical damage to packaging, and permeability of plastic and elastomeric packaging is expected. In such cases, compounding personnel are responsible for considering the potential additional risks to the integrity of CSPs when assigning BUDs. The pre-administration storage duration and temperature limits specified in the following subsections apply in the absence of direct sterility testing results that justify different limits for specific CSPs.

Low-Risk Level CSPs

CSPs compounded under all the following conditions are at a low risk of contamination.

Low-Risk Conditions—

1. The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 (see *Table 1*) or better air quality using only sterile ingredients, products, components, and devices.
2. The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP.
3. Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

4. For a low-risk level preparation, in the absence of passing a sterility test (see *Sterility Tests* ⟨71⟩), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 14 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid frozen state between −25° and −10°.

Examples of Low-Risk Compounding—

1. Single-volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampuls should be passed through a sterile filter to remove any particles.
2. Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.

Low-Risk Level CSPs with 12-Hour or Less BUD—If the PEC is a CAI or CACI that does not meet the requirements described in *Placement of Primary Engineering Controls* or is a laminar airflow workbench (LAFW) or a biological safety cabinet (BSC) that cannot be located within an ISO Class 7 (see *Table 1*) buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician's order for a specific patient may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. Low-risk level CSPs with a 12-hour or less BUD shall meet all of the following four criteria:

1. PECs (LAFWs, BSCs, CAIs, CACIs,) shall be certified and maintain ISO Class 5 (see *Table 1*) as described in *Facility Design and Environmental Controls* for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination.
2. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Note that this list is not intended to be all inclusive.
3. Personnel shall follow the procedures described in *Personnel Cleansing and Garbing* and *Additional Personnel Requirements* prior to compounding. Sinks should not be located adjacent to the ISO Class 5 (see *Table 1*) PEC. Sinks should be separated from the immediate area of the ISO Class 5 (see *Table 1*) PEC device.
4. The specifications in *Cleaning and Disinfecting the Sterile Compounding Areas, Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures,* and *Viable and Nonviable Environmental Sampling (ES) Testing* shall be followed as described in the chapter.

Compounding personnel must recognize that the absence of an ISO Class 7 (see *Table 1*) buffer area environment in a general uncontrolled environment increases the potential of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization, and thus for patient harm, especially in critically ill or immunocompromised patients.

Quality Assurance—Quality assurance practices include, but are not limited to the following:

1. Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 (see *Table 1*) air quality.
2. Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, including eye protection and face masks.
3. Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.
4. Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

Media-Fill Test Procedure—This test or an equivalent test is performed at least annually by each person authorized to compound in a low-risk level environment under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level CSPs. Once begun, this test is completed without interruption. *Example of test procedure:* within an ISO Class 5 (see *Table 1*) air quality environment, three sets of four 5-mL aliquots of sterile Soybean–Casein Digest Medium (also known as trypticase soy broth or trypticase soy agar [TSA]) are transferred with the same sterile 10-mL syringe and vented needle combination into separate sealed, empty, sterile 30-mL clear vials (i.e., four 5-mL aliquots into each of three 30-mL vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, then the vials are incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩). Inspect for microbial growth over 14 days as described in *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.*

Medium-Risk Level CSPs

When CSPs are compounded aseptically under *Low-Risk Conditions* and one or more of the following conditions exists, such CSPs are at a medium risk of contamination.

Medium-Risk Conditions—

1. Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.
2. The compounding process includes complex aseptic manipulations other than the single-volume transfer.
3. The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing.
4. For a medium-risk preparation, in the absence of passing a sterility test (see *Sterility Tests* ⟨71⟩), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 9 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid frozen state between −25° and −10°.

Examples of Medium-Risk Compounding—

1. Compounding of total parenteral nutrition fluids using manual or automated devices during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.
2. Filling of reservoirs of injection and infusion devices with more than three sterile drug products and evacuation of air from those reservoirs before the filled device is dispensed.
3. Transfer of volumes from multiple ampuls or vials into one or more final sterile containers.

Quality Assurance—Quality assurance procedures for medium-risk level CSPs include all those for low-risk level CSPs, as well as a more challenging media-fill test passed annually or more frequently.

Media-Fill Test Procedure—This test or an equivalent test is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. Once begun, this test is completed without interruption. *Example of test procedure:* within an ISO Class 5 (see *Table 1*) air quality environment, six 100-mL aliquots of sterile Soybean–Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-mL syringe and 18-gauge needle combination is used to exchange two 5-mL aliquots of medium from one container to the other container in the pair. For example, after a 5-mL aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-mL aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-mL aliquot is transferred from it back to the second container in the pair. Following the two 5-mL aliquot exchanges in each pair of containers, a 5-mL aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-mL clear vial, using a sterile 10-mL syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, then the vials are incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩). Inspect for microbial growth over 14 days as described in *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.*

High-Risk Level CSPs

CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated.

High-Risk Conditions—

1. Nonsterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral), are incorporated or a nonsterile device is employed before terminal sterilization.
2. Any of the following are exposed to air quality worse than ISO Class 5 (see *Table 1*) for more than 1 hour (see *Immediate-Use CSPs*):
   - sterile contents of commercially manufactured products,
   - CSPs that lack effective antimicrobial preservatives, and
   - sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.
3. Compounding personnel are improperly garbed and gloved (see *Personnel Cleansing and Use of Barrier Protective Equipment*).
4. Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized.
5. It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients (see *Ingredient Selection* under *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

For a sterilized high-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 24 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 3 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid frozen state between −25° and −10°. [NOTE—Sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units.]

All nonsterile measuring, mixing, and purifying devices are rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk compounding. All high-risk level CSP solutions subjected to terminal sterilization are prefiltered by passing through a filter with a nominal pore size not larger than 1.2 µm preceding or during filling into their final containers to remove particulate matter. Sterilization of high-risk level CSPs by filtration shall be performed with a sterile 0.2-µm or 0.22-µm nominal pore size filter entirely within an ISO Class 5 (see *Table 1*) or superior air quality environment.

Examples of High-Risk Conditions—

1. Dissolving nonsterile bulk drug and nutrient powders to make solutions that will be terminally sterilized.
2. Exposing the sterile ingredients and components used to prepare and package CSPs to room air quality worse than ISO Class 5 (see *Table 1*) for more than 1 hour (see *Immediate-Use CSPs*).
3. Measuring and mixing sterile ingredients in nonsterile devices before sterilization is performed.
4. Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

Quality Assurance—Quality assurance procedures for high-risk level CSPs include all those for low-risk level CSPs. In addition, a media-fill test that represents high-risk level compounding is performed semiannually by each person authorized to compound high-risk level CSPs.

Media-Fill Test Procedure for CSPs Sterilized by Filtration—This test or an equivalent test is performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level CSPs. Once begun, this test is completed without interruption. *Example of test procedure* (in the following sequence):

1. Dissolve 3 g of nonsterile commercially available Soybean–Casein Digest Medium in 100 mL of nonbacteriostatic water to make a 3% nonsterile solution.
2. Draw 25 mL of the medium into each of three 30-mL sterile syringes. Transfer 5 mL from each syringe into separate sterile 10-mL vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.
3. Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-µm or 0.22-µm nominal pore size filter unit and a 20-gauge needle to each syringe. Inject the next 10 mL from each syringe into three separate 10-mL sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩). Inspect for microbial growth over 14 days as described in *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.*

PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATION SKILLS

Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through audio–video instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 (see *Table 1*) environmental conditions before they begin to prepare CSPs. Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding. Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

Media-Fill Challenge Testing—The skill of personnel to aseptically prepare CSPs may be evaluated using sterile fluid bacterial culture media-fill verification[3] (i.e., sterile bacterial culture medium transfer via a sterile syringe and needle). Media-fill testing is used to assess the quality of the aseptic skill of compounding personnel. Media-fill tests represent the most challenging or stressful conditions actually encountered by the personnel being evaluated when they prepare particular risk level CSPs and when sterilizing high-risk level CSPs. Media-fill challenge tests that simulate high-risk level compounding are also used to verify the capability of the compounding environment and process to produce a sterile preparation.

Commercially available sterile fluid culture media, such as Soybean–Casein Digest Medium (see *Sterility Tests* ⟨71⟩), shall be able to promote exponential colonization of bacteria that are most likely to be transmitted to CSPs from the compounding personnel and environment. Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩). Failure is indicated by visible turbidity in the medium on or before 14 days.

IMMEDIATE-USE CSPs

The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for *Low-Risk Level CSPs* subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs.

Immediate-use CSPs are exempt from the requirements described for *Low-Risk Level CSPs* only when all of the following criteria are met:

1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.
2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.
3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.
4. Administration begins not later than 1 hour following the start of the preparation of the CSP.
5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.
6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.

Compounding in worse than ISO Class 5 (see *Table 1*) conditions increases the likelihood of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization and thus for patient harm, especially in critically ill or immunocompromised patients.

SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS

Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 (see *Table 1*) air quality (see *Immediate-Use CSPs*), and any remaining contents must be discarded. Single-dose vials exposed to ISO Class 5 (see *Table 1*) or cleaner air may be used up to 6 hours after initial needle puncture. Opened single-dose ampuls shall not be stored for any time period. Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days (see *Antimicrobial Effectiveness Testing* ⟨51⟩) unless otherwise specified by the manufacturer.

HAZARDOUS DRUGS AS CSPs

Although the potential therapeutic benefits of compounded sterile hazardous drug preparations generally outweigh the risks of their adverse effects in ill patients, exposed healthcare workers risk similar adverse effects with no therapeutic benefit. Occupational exposure to hazardous drugs can result in (1) acute effects, such as skin rashes; (2) chronic effects, including adverse reproductive events; and (3) possibly cancer (see Appendix A of NIOSH Publication no. 2004-165).

Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas. Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. Many hazardous drugs have sufficient vapor pressures that allow volatilization at room temperature; thus storage is preferably within a containment area such as a negative pressure room. The storage area should have sufficient gen-

eral exhaust ventilation, at least 12 air changes per hour (ACPH)[4] to dilute and remove any airborne contaminants.

Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal. Hazardous drugs shall be prepared in an ISO Class 5 (see *Table 1*) environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels defined in this chapter. Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation.

All hazardous drugs shall be prepared in a BSC[5] or a CACI that meets or exceeds the standards for CACI in this chapter. The ISO Class 5 (see *Table 1*) BSC or CACI shall be placed in an ISO Class 7 (see *Table 1*) area that is physically separated (i.e., a different area from other preparation areas) and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 (see *Table 1*) or better ante-areas, thus providing inward airflow to contain any airborne drug. A pressure indicator shall be installed that can be readily monitored for correct room pressurization. The BSC and CACI optimally should be 100% vented to the outside air through HEPA filtration.

If a CACI that meets the requirements of this chapter is used outside of a buffer area, the compounding area shall maintain a minimum negative pressure of 0.01-inch water column and have a minimum of 12 ACPHs.

When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within the ISO Class 5 (see *Table 1*) environment of a BSC or CACI. The use of a CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.

Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices. PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI.

All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually. This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace. Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs. The training shall include at least the following: (1) safe aseptic manipulation practices; (2) negative pressure techniques when utilizing a BSC or CACI; (3) correct use of CSTD devices; (4) containment, cleanup, and disposal procedures for breakages and spills; and (5) treatment of personnel contact and inhalation exposure.

NOTE—*Because standards of assay and unacceptable quantities of contamination of each drug have not been established in the literature, the following paragraph is a recommendation only. Future standards will be adopted as these assay methods are developed and proven.*

In order to ensure containment, especially in operations preparing large volumes of hazardous drugs, environmental sampling to detect uncontained hazardous drugs should be performed routinely (e.g., initially as a benchmark and at least every 6 months or more often as needed to verify containment). This sampling should include surface wipe sampling of the working area of BSCs and CACIs; counter tops where finished preparations are placed; areas adjacent to BSCs and CACIs, including the floor directly under the working area; and patient administration areas. Common marker hazardous drugs that can be assayed include cyclophosphamide, ifosfamide, methotrexate, and fluorouracil. If any measurable contamination (cyclophosphamide levels greater than 1.00 ng per cm^2 have been found to cause human uptake) is found by any of these quality assurance procedures, practitioners shall make the decision to identify, document, and contain the cause of contamination. Such action may include retraining, thorough cleaning (utilizing high-pH soap and water), and improving engineering controls. Examples of improving engineering controls are (1) venting BSCs or CACIs 100% to the outside, (2) implementing a CSTD, or (3) re-assessing types of BSCs or CACIs.

Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.

RADIOPHARMACEUTICALS AS CSPs

In the case of production of radiopharmaceuticals for positron emission tomography (PET), general test chapter *Radiopharmaceuticals for Positron Emission Tomography—Compounding* ⟨823⟩ supersedes this chapter. Upon release of a PET radiopharmaceutical as a finished drug product from a production facility, the further handling, manipulation, or use of the product will be considered compounding, and the content of this section and chapter is applicable.

For the purposes of this chapter, radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container (see *Injections* ⟨1⟩) shall be designated as, and conform to, the standards for *Low-Risk Level CSPs.*

These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see *Table 1*) PEC located in an ISO Class 8 (see *Table 1*) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements.

Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 (see *Table 1*) environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturers' recommendations. Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.

Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations. Such generator systems shall be eluted in an ISO Class 8 (see *Table 1*) or cleaner air environment to permit special handling, shielding, and air flow requirements. To limit acute and chronic radiation exposure of inspecting personnel to a level that is as low as reasonably achievable (ALARA), direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity shall be conducted in accordance with ALARA.

Radiopharmaceuticals prepared as *Low-Risk Level CSPs with 12-Hour or Less BUD* shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment area shall not

[4] Guidelines for Environmental Infection Control in Health-Care Facilities, Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), MMWR, vol. 52, no. RR-10, June 6, 2003, figure 3, pg. 12.
[5] NSF/ANSI 49.

cross a line of demarcation into the segregated compounding area.

ALLERGEN EXTRACTS AS CSPs

Allergen extracts as CSPs are single-dose and multiple-dose *intradermal or subcutaneous injections* that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all *CSP Microbial Contamination Risk Levels* in this chapter only when all of the following criteria are met:

1. The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).
2. All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.
3. Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either nonantimicrobial or antimicrobial soap and water.
4. Compounding personnel don hair covers, facial hair covers, gowns, and face masks.
5. Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity.
6. Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.
7. Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts as CSPs.
8. Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.
9. The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).
10. The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.
11. Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.

Personnel who compound allergen extracts as CSPs must be aware of greater potential risk of microbial and foreign material contamination when allergen extracts as CSPs are compounded in compliance with the foregoing criteria instead of the more rigorous standards in this chapter for *CSP Microbial Contamination Risk Levels*. Although contaminated allergen extracts as CSPs can pose health risks to patients when they are injected *intradermally or subcutaneously*, these risks are substantially greater if the extract is inadvertently injected *intravenously*.

VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY

The compounding procedures and sterilization methods for CSPs correspond to correctly designed and verified written documentation in the compounding facility. Verification requires planned testing, monitoring, and documentation to demonstrate adherence to environmental quality requirements, personnel practices, and procedures critical to achieving and maintaining sterility, accuracy, and purity of finished CSPs. For example, sterility testing (see *Test for Sterility of the Product To Be Examined* under *Sterility Tests* ⟨71⟩) may be applied to specimens of low- and medium-risk level CSPs, and standard self-contained biological indicators (BI) shall be added to nondispensable specimens of high-risk level CSPs before terminal sterilization for subsequent evaluation to determine whether the sterilization cycle was adequate (see *Biological Indicators for Sterilization* ⟨1035⟩). Packaged and labeled CSPs shall be visually inspected for physical integrity and expected appearance, including final fill amount. The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers. When the correct identity, purity, strength, and sterility of ingredients and components of CSPs cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampuls, punctured stoppers of vials and bags, containers of ingredients with incomplete labeling), such ingredients and components shall be discarded immediately.

Some individual ingredients, such as bulk drug substances, are not labeled with expiration dates when they are stable indefinitely in their commercial packages under their labeled storage conditions. However, despite retaining full chemical stability, such ingredients may gain or lose moisture during storage and use. Changes in moisture content may require testing (see *Loss on Drying* ⟨731⟩) to determine the correct amount to weigh for accurate content of active chemical moieties in CSPs (see *Pharmaceutical Calculations in Prescription Compounding* ⟨1160⟩).

Although not required, a quantitative stability-indicating chemical assay is recommended to ensure compounding accuracy of CSPs, especially those that contain drug ingredients with a narrow therapeutic plasma concentration range.

Sterilization Methods

The licensed healthcare professionals who supervise compounding shall be responsible for determining that the selected sterilization method (see *Methods of Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩) both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPs. The selected sterilization process is obtained from experience and appropriate information sources (e.g., see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩)—and, preferably, verified wherever possible—to achieve sterility in the particular CSPs. General guidelines for matching CSPs and components to appropriate sterilization methods include the following:

1. CSPs have been ascertained to remain physically and chemically stable when subjected to the selected sterilization method.
2. Glass and metal devices may be covered tightly with aluminum foil, then exposed to dry heat in an oven at a mean temperature of 250° for 30 minutes to achieve sterility and depyrogenation (see *Dry-Heat Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Bacterial Endotoxins Test* ⟨85⟩). Such items are either used immediately or stored until use in an environment suitable for com-

pounding *Low-Risk Level CSPs* and *Medium-Risk Level CSPs*.

3. Personnel ascertain from appropriate information sources that the sterile microporous membrane filter used to sterilize CSP solutions, during either compounding or administration, is chemically and physically compatible with the CSP.

STERILIZATION OF HIGH-RISK LEVEL CSPS BY FILTRATION

Commercially available sterile filters shall be approved for human-use applications in sterilizing pharmaceutical fluids. Sterile filters used to sterilize CSPs shall be pyrogen free and have a nominal pore size of 0.2 or 0.22 µm. They shall be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* on each square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be sterilized (see *High-Risk Conditions* in *High-Risk Level CSPs*).

The compounding supervisor shall ensure, directly or from appropriate documentation, that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality, including strength of ingredients of the specific CSP. The filter dimensions and liquid material to be sterile-filtered shall permit the sterilization process to be completed rapidly, without the replacement of the filter during the process. When CSPs are known to contain excessive particulate matter, a prefilter of larger nominal pore size membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants in order to maximize the efficiency of the sterilizing filter.

Filter units used to sterilize CSPs shall also be subjected to manufacturers' recommended integrity test, such as the bubble point test.

Compounding personnel shall ascertain that selected filters will achieve sterilization of the particular CSPs being sterilized. Large deviations from usual or expected chemical and physical properties of CSPs (e.g., water-miscible alcohols) may cause undetectable damage to filter integrity and shrinkage of microorganisms to sizes smaller than filter nominal pore size.

STERILIZATION OF HIGH-RISK LEVEL CSPS BY STEAM

The process of thermal sterilization employing saturated steam under pressure, or autoclaving, is the preferred method to terminally sterilize aqueous preparations that have been verified to maintain their full chemical and physical stability under the conditions employed (see *Steam Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩). To achieve sterility, all materials are to be exposed to steam at 121° under a pressure of about 1 atmosphere or 15 psi for the duration verified by testing to achieve sterility of the items, which is usually 20 to 60 minutes for CSPs. An allowance shall be made for the time required for the material to reach 121° before the sterilization exposure duration is timed.

Not directly exposing items to pressurized steam may result in survival of microbial organisms and spores. Before their sterilization, plastic, glass, and metal devices are tightly wrapped in low-particle-shedding paper or fabrics or sealed in envelopes that prevent poststerilization microbial penetration. Immediately before filling ampuls and vials that will be steam sterilized, solutions are passed through a filter having a nominal pore size not larger than 1.2 µm for removal of particulate matter. Sealed containers shall be able to generate steam internally; thus, stoppered and crimped empty vials shall contain a small amount of moisture to generate steam.

The description of steam sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of steam sterilization shall be verified using appropriate BIs of *Bacillus stearothermophilus* (see *Biological Indicators* ⟨1035⟩) and other confirmation methods such as temperature-sensing devices (see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Sterility Tests* ⟨71⟩).

STERILIZATION OF HIGH-RISK LEVEL CSPS BY DRY HEAT

Dry heat sterilization is usually done as a batch process in an oven designed for sterilization. Heated filtered air shall be evenly distributed throughout the chamber by a blower device. The oven should be equipped with a system for controlling temperature and exposure period. Sterilization by dry heat requires higher temperatures and longer exposure times than does sterilization by steam. Dry heat shall be used only for those materials that cannot be sterilized by steam, when either the moisture would damage the material or the material is impermeable. During sterilization, sufficient space shall be left between materials to allow for good circulation of the hot air. The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of dry heat sterilization shall be verified using appropriate BIs of *Bacillus subtilis* (see *Biological Indicators* ⟨1035⟩) and other confirmation methods such as temperature-sensing devices (see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Sterility Tests* ⟨71⟩). [NOTE—Dry heat sterilization may be performed at a lower temperature than may be effective for depyrogenation].

Depyrogenation by Dry Heat

Dry heat depyrogenation shall be used to render glassware or containers such as vials free from pyrogens as well as viable microbes. A typical cycle would be 30 minutes at 250°. The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs). The bacterial endotoxin test should be performed on the ECVs to verify that the cycle is capable of achieving a 3-log reduction in endotoxin (see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Bacterial Endotoxins Test* ⟨85⟩).

ENVIRONMENTAL QUALITY AND CONTROL

Achieving and maintaining sterility and overall freedom from contamination of a CSP is dependent on the quality status of the components incorporated, the process utilized, personnel performance, and the environmental conditions under which the process is performed. The standards required for the environmental conditions depend on the amount of exposure of the CSP to the immediate environment anticipated during processing. The quality and control of environmental conditions for each risk level of operation are explained in this section. In addition, operations using nonsterile components require the use of a method of preparation designed to produce a sterile preparation.

Exposure of Critical Sites

Maintaining the sterility and cleanliness (i.e., freedom from sterile foreign materials) of critical sites is a primary safeguard for CSPs. Critical sites are locations that include any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral

and mucosal secretions), or touch contamination. The risk of, or potential for, critical sites to be contaminated with microorganisms and foreign matter increases with increasing exposed area of the critical sites, the density or concentration of contaminants, and exposure duration to worse than ISO Class 5 (see *Table 1*) air. Examples include an opened ampul or vial stopper on a 10-mL or larger vial or an injection port on a package of intravenous solution having an area larger than the point of a needle or the tip of a syringe.

The nature of a critical site also affects the risk of contamination. The relatively rough, permeable surface of an elastomeric closure retains microorganisms and other contaminants after swabbing with a sterile 70% IPA pad more readily than does the smoother glass surface of the neck of an ampul. Therefore, the surface disinfection can be expected to be more effective for an ampul.

Protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice. Airborne contaminants, especially those generated by sterile compounding personnel, are much more likely to reach critical sites than are contaminants that are adhering to the floor or other surfaces below the work level. Furthermore, large and high-density particles that are generated and introduced by compounding manipulations and personnel have the potential to settle on critical sites even when those critical sites are exposed within ISO Class 5 (see *Table 1*) air.

ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas

The most common sources of ISO Class 5 (see *Table 1*) air quality for exposure of critical sites are horizontal and vertical LAFWs, CAIs, and CACIs. A clean room (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩) is a compounding environment that is supplied with HEPA or HEPA-filtered air that meets ISO Class 7 (see *Table 1*), the access to which is limited to personnel trained and authorized to perform sterile compounding and facility cleaning. A buffer area is an area that provides at least ISO Class 7 (see *Table 1*) air quality.

Figure 1 is a conceptual representation of the placement of an ISO Class 5 (see *Table 1*) PEC in a segregated compounding area used for low-risk level CSPs with 12-hour or less BUD. This plan depicts the most critical operation area located within the PEC in a designated area (see definition of *Segregated Compounding Area*) separated from activities not essential to the preparation of CSPs. Placement of devices (e.g., computers, printers) and objects (e.g., carts, cabinets) that are not essential to compounding in the segregated area should be restricted or limited, depending on their effect on air quality in the ISO Class 5 (see *Table 1*) PEC.

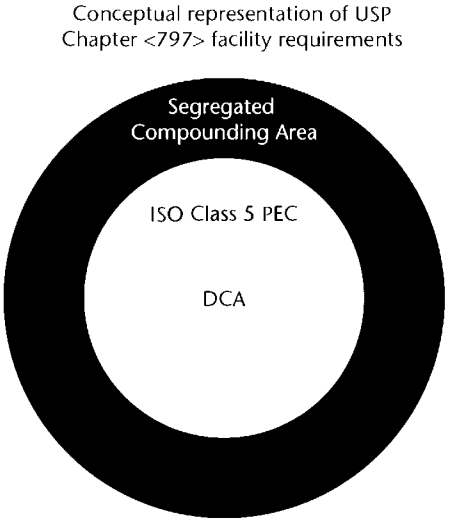

Figure 1. Conceptual representation of the placement of an ISO Class 5 PEC in a segregated compounding area used for low-risk level CSPs with 12-hour or less BUD.

Figure 2 is a conceptual representation of the arrangement of a facility for preparation of CSPs categorized as low-, medium-, and high-risk level. The quality of the environmental air increases with movement from the outer boundary to the direct compounding area (DCA). Placement of devices in ante-areas and buffer areas is dictated by their effect on the designated environmental quality of atmospheres and surfaces, which shall be verified by monitoring (see *Viable and Nonviable Environmental Sampling (ES) Testing*). It is the responsibility of each compounding facility to ensure that each source of ISO Class 5 (see *Table 1*) environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.

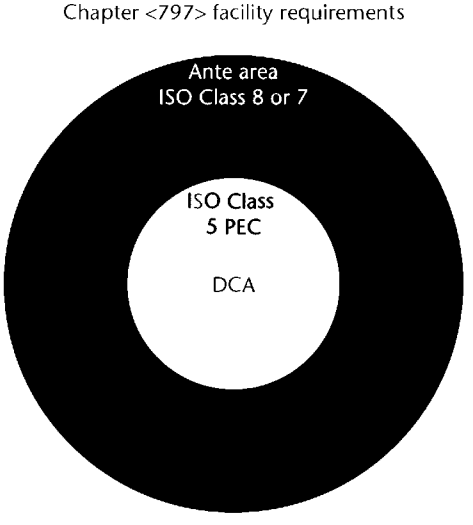

Figure 2. Conceptual representation of the arrangement of a facility for preparation of CSPs categorized as low-, medium-, and high-risk level.

Placement of devices (e.g., computers, printers) and objects (e.g., carts, cabinets) that are not essential to compounding in buffer areas is dictated by their effect on the required environmental quality of air atmospheres and surfaces, which shall be verified by monitoring (see *Viable and Nonviable Environmental Sampling (ES) Testing*). It is the responsibility of each compounding facility to ensure that

each source of ISO Class 5 (see *Table 1*) environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.

Facility Design and Environmental Controls

Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. These facilities shall also provide a comfortable and well-lighted working environment, which typically includes a temperature of 20° or cooler, to maintain comfortable conditions for compounding personnel to perform flawlessly when attired in the required aseptic compounding garb. PECs typically include, but are not limited to, LAFWs, BSCs, CAIs, and CACIs, which provide an ISO Class 5 (see *Table 1*) environment for the exposure of critical sites. PECs shall maintain ISO Class 5 (see *Table 1*) or better conditions for 0.5-µm particles (dynamic operating conditions) while compounding CSPs. Secondary engineering controls such as buffer areas and ante-areas generally serve as a core for the location of the PEC. Buffer areas are designed to maintain at least ISO Class 7 (see *Table 1*) conditions for 0.5-µm particles under dynamic conditions and ISO Class 8 (see *Table 1*) conditions for 0.5-µm and larger particles under dynamic conditions for the ante-areas. Airborne contamination control is achieved in the PEC through the use of HEPA filters. The airflow in the PEC shall be unidirectional (laminar flow), and because of the particle collection efficiency of the filter, the "first air" at the face of the filter is, for the purposes of aseptic compounding, free from airborne particulate contamination. HEPA-filtered air shall be supplied in critical areas (ISO Class 5, see *Table 1*) at a velocity sufficient to sweep particles away from the compounding area and maintain unidirectional airflow during operations. Proper design and control prevents turbulence and stagnant air in the critical area. In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.

The principles of HEPA-filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions. Policies and procedures for maintaining and working within the PEC area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities utilized during the preparation of the CSPs. The CSP work environment is designed to have the cleanest work surfaces (PEC) located in a buffer area. The buffer area shall maintain at least ISO Class 7 (see *Table 1*) conditions for 0.5-µm and larger particles under dynamic operating conditions. The room shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation shall be continuously monitored. For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area.

The displacement concept shall not be used for high-risk compounding.[6] The PEC shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. For example, strong air currents from opened doors, personnel traffic, or air streams from the HVAC systems can disrupt the unidirectional airflow in open-faced workbenches. The operators may also create disruptions in airflow by their own movements and by the placement of objects onto the work surface. The PEC shall be placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross-drafts. Room air exchanges are typically expressed as ACPHs. Adequate HEPA-filtered airflow supplied to the buffer area and ante-area is required to maintain cleanliness classification during operational activity through the number of ACPHs. Factors that should be considered when determining air-change requirements include number of personnel working in the room and compounding processes that generate particulates, as well as temperature effects. An ISO Class 7 (see *Table 1*) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30. The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see *Table 1*) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. More air changes may be required, depending on the number of personnel and processes. HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall, creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended. All HEPA filters should be efficiency tested using the most penetrating particle size and should be leak tested at the factory and then leak tested again in situ after installation.[7]

Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable, and resistant to disinfectants. Whenever such items are brought into the area, they shall first be cleaned and disinfected. Whenever possible, equipment and other items used in the buffer area shall not be taken out of the area except for calibration, servicing, or other activities associated with the proper maintenance of the item.

The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents. Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame. Walls may be constructed of flexible material (e.g., heavy gauge polymer), panels locked together and sealed, or of epoxy-coated gypsum board. Preferably, floors are overlaid with wide sheet vinyl flooring with heat-welded seams and coving to the sidewall. Dust-collecting overhangs, such as ceiling utility pipes, and ledges, such as windowsills, should be avoided. The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls shall be sealed. The buffer area shall not contain sources of water (sinks) or floor drains. Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. Carts should be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility. Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshed-

[6] ISO 14644-4:2001 Cleanrooms and associated controlled environments—Design, construction, and start-up, *Case Postale 56*, CH-1211 Geneve 20, Switzerland, tel. +41 22 749 01 11.

[7] By definition (IEST RP CC 001.4), HEPA filters are a minimum of 99.97% efficient when tested using 0.3-µm thermally generated particles and a photometer or rated at their most penetrating particle size using a particle counter.

ding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection.

Placement of Primary Engineering Controls

PECs (LAFWs, BSCs, CAIs, and CACIs) shall be located within a restricted access ISO Class 7 (see *Table 1*) buffer area (see *Figure 1*), with the following CAI/CACI exceptions below:

- Only authorized personnel and materials required for compounding and cleaning shall be permitted in the buffer area.
- Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 (see *Table 1*) environment.
- PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.

CAIs and CACIs shall be placed in an ISO Class 7 (see *Table 1*) buffer area *unless* they meet all of the following conditions:

- The isolator shall provide isolation from the room and maintain ISO Class 5 (see *Table 1*) during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
- Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 (see *Table 1*) levels during compounding operations.
- Not more than 3520 particles (0.5 µm and larger) per m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.[8]

It is incumbent on the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 (see *Table 1*) for 0.5-µm and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 (see *Table 1*) air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

If the PEC is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 (see *Table 1*) buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.

Viable and Nonviable Environmental Sampling (ES) Testing

The ES program should provide information to staff and leadership to demonstrate that the PEC is maintaining an environment within the compounding area that consistently ensures acceptably low viable and nonviable particle levels. The compounding area includes the ISO Class 5 (see *Table 1*) PEC (LAFWs, BSCs, CAIs, and CACIs), buffer areas, ante-areas, and segregated compounding areas.

Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally under any of the following conditions:

- as part of the commissioning and certification of new facilities and equipment;
- following any servicing of facilities and equipment;
- as part of the re-certification of facilities and equipment (i.e., every 6 months);
- in response to identified problems with end products or staff technique; or
- in response to issues with CSPs, observed compounding personnel work practices, or patient-related infections (where the CSP is being considered as a potential source of the infection).

ENVIRONMENTAL NONVIABLE PARTICLE TESTING PROGRAM

A program to sample nonviable airborne particles differs from that for viable particles in that it is intended to directly measure the performance of the engineering controls used to create the various levels of air cleanliness, for example, ISO Class 5, 7, or 8 (see *Table 1*).

Engineering Control Performance Verification—PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante-areas) are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits. Certification procedures such as those outlined in *Certification Guide for Sterile Compounding Facilities* (CAG-003-2006)[9] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.

Total Particle Counts—Certification that each ISO classified area, for example, ISO Class 5, 7, and 8 (see *Table 1*), is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered. Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results of the following:

- ISO Class 5: not more than 3520 particles 0.5 µm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI;
- ISO Class 7: not more than 352,000 particles of 0.5 µm size and larger per cubic meter of air for any buffer area;
- ISO Class 8: not more than 3,520,000 particles or 0.5 µm size and larger per cubic meter of air for any ante-area.

All certification records shall be maintained and reviewed by supervising personnel or other designated employees to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and ACPHs.

PRESSURE DIFFERENTIAL MONITORING

A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 (see *Table 1*) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.

[8] Sample procedures are detailed in CETA Applications Guide CAG-002-2006–section 2.09.

[9] Controlled Environment Testing Association, 1500 Sunday Drive, Ste. 102, Raleigh, NC 27607; www.CETAinternational.org.

ENVIRONMENTAL VIABLE AIRBORNE PARTICLE TESTING PROGRAM

The risk of contaminating a CSP prepared under low-risk level and medium-risk level conditions is highly dependent on proper hand hygiene and garbing practices, compounding personnel aseptic technique, and the presence of surface contamination, assuming that all work is performed in a certified and properly functioning ISO Class 5 (see *Table 1*) PEC and secondary engineering controls, ISO Class 7 (see *Table 1*) buffer area, and ISO Class 8 (see *Table 1*) ante-area. High-risk level CSPs pose the greatest threat to patients because compounding personnel are tasked with the requirement of processing nonsterile components and devices in order to achieve sterility.

A sampling program in conjunction with an observational audit is designed to evaluate the competency of compounding personnel work practices, allowing for the implementation of corrective actions on an ongoing basis (see *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*).

Sampling Plan—An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed.

Selected sampling sites shall include locations within each ISO Class 5 (see *Table 1*) environment and in the ISO Class 7 and 8 (see *Table 1*) areas and in the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 [see *Table 1*] environment, counters near doors, pass-through boxes). The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.

Review of the data generated during a sampling event may detect elevated amounts of airborne microbial bioburden; such changes may be indicative of adverse changes within the environment. It is recommended that compounding personnel refer to *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩ and the CDC's "Guidelines for Environmental Infection Control in Healthcare Facilities, 2003" for more information.

Growth Medium—A general microbiological growth medium such as Soybean–Casein Digest Medium shall be used to support the growth of bacteria. Malt extract agar or some other media that supports the growth of fungi shall be used in high-risk level compounding environments. Media used for surface sampling must be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80).

Viable Air Sampling—Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments (LAFWs, CAIs, clean room or buffer areas, and ante-areas) shall be performed by properly trained individuals for all compounding risk levels.

Impaction shall be the preferred method of volumetric air sampling. Use of settling plates for qualitative air sampling may not be able to determine adequately the quality of air in the controlled environment. The settling of particles by gravity onto culture plates depends on the particle size and may be influenced by air movement. Consequently, the number of colony-forming units (cfu) on a settling plate may not always relate to the concentrations of viable particles in the sampled environment.

For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within LAFW and other areas where air backwash turbulence may enter the compounding area (doorways, in and around ISO Class 5 [see *Table 1*] PEC and environments). Consideration should be given to the overall effect the chosen sampling method will have on the unidirectional airflow within a compounding environment.

For low-risk level CSPs with 12-hour or less BUD prepared in a PEC (LAFWs, BSCs, CAIs) that maintains an ISO Class 5 (see *Table 1*), air sampling shall be performed at locations inside the ISO Class 5 (see *Table 1*) environment and other areas that are in close proximity to the ISO Class 5 (see *Table 1*) environment during the certification of the PEC.

Air Sampling Devices—There are a number of manufacturers of electronic air sampling equipment. It is important that personnel refer to the manufacturer's recommended procedures when using the equipment to perform volumetric air sampling procedures. The instructions in the manufacturer's user's manual for verification and use of electric air samplers that actively collect volumes of air for evaluation must be followed. A sufficient volume of air (400 to 1000 liters) shall be tested at each location in order to maximize sensitivity. The volumetric air sampling devices need to be serviced and calibrated as recommended by the manufacturer.

It is recommended that compounding personnel also refer to *Methodology and Instrumentation for Quantitation of Viable Airborne Microorganisms* under *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩, which provides more information on the use of volumetric air samplers and volume of air that should be sampled to detect environmental bioburden excursions.

Air Sampling Frequency and Process—Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-certification of facilities and equipment. If compounding occurs in multiple locations within an institution (e.g., main pharmacy, satellites), environmental sampling is required for each individual compounding area. A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed. Any facility construction or equipment servicing may require that air sampling be performed during these events.

Incubation Period—At the end of the designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers secured (e.g., taped), and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. TSA should be incubated at 30° to 35° for 48 to 72 hours. Malt extract agar or other suitable fungal media should be incubated at 26° to 30° for 5 to 7 days. The number of discrete colonies of microorganisms are counted and reported as cfu and documented on an environmental sampling form. Counts from air sampling need to be transformed into cfu per cubic meter of air and evaluated for adverse trends.

Action Levels, Documentation, and Data Evaluation—The value of viable microbial sampling of the air in the compounding environment is realized when the data are used to identify and correct an unacceptable situation. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.

Any cfu count that exceeds its respective action level (see *Table 2*) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.

Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in *Table 2* should be used only as guidelines. Regardless of the number of cfu identified in the pharmacy, further corrective ac-

tions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

Table 2. Recommended Action Levels for Microbial Contamination*

†(cfu per cubic meter [1000 liters] of air per plate)

Classification	Air Sample†
ISO Class 5	> 1
ISO Class 7	> 10
ISO Class 8 or worse	> 100

* Guidance for Industry–Sterile Drug Products Produced by Aseptic Processing–Current Good Manufacturing Practice–US HHS, FDA September 2004.

Additional Personnel Requirements

Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where components and ingredients of CSPs are present. When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific SOPs in order to avoid any cross-contamination. Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small- and large-volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA), when possible in an ante-area of ISO Class 8 (see *Table 1*) air quality, before being passed into the buffer areas. Personnel hand hygiene and garbing procedures are also performed in the ante-area, which may contain a sink that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination. There shall be some demarcation designation that separates the ante-area from the buffer area. Adequate provision for performing antiseptic hand cleansing using an alcohol-based surgical hand scrub with persistent activity followed by the donning of sterile gloves should be provided after entry into the buffer area.

Cleaning and Disinfecting the Compounding Area

Environmental contact is a major source of microbial contamination of CSPs. Consequently, scrupulous attention to cleaning and disinfecting the sterile compounding areas is required to minimize this as a source of CSP contamination.

The cleaning and disinfecting practices and frequencies in this section apply to ISO Class 5 (see *Table 1*) compounding areas for exposure of critical sites as well as buffer areas, ante-areas, and segregated compounding areas. Compounding personnel are responsible for ensuring that the frequency of cleaning is in accordance with the requirements stated in *Table 3* and determining the cleaning and disinfecting products to be used (see *Appendix II*). Any organizational or institutional policies regarding disinfectant selection should be considered by compounding personnel. All cleaning and disinfecting practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel.

The selection and use of disinfectants in healthcare facilities is guided by several properties, such as microbicidal activity, inactivation by organic matter, residue, and shelf life (see *Appendix II*). In general, highly toxic disinfectants, such as glutaraldehyde, are not used on housekeeping surfaces (e.g., floors, countertops). Many disinfectants registered by the EPA are one-step disinfectants. This means that the disinfectant has been formulated to be effective in the presence of light to moderate soiling without a pre-cleaning step.

Surfaces in LAFWs, BSCs, CAIs, and CACIs, which are intimate to the exposure of critical sites, require disinfecting more frequently than do housekeeping surfaces such as walls and ceilings. Disinfecting sterile compounding areas shall occur on a regular basis at the intervals noted in *Table 3* when spills occur, when the surfaces are visibly soiled, and when microbial contamination is known to have been or is suspected of having been introduced into the compounding areas.

When the surface to be disinfected has heavy soiling, a cleaning step is recommended prior to the application of the disinfectant. Trained compounding personnel are responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the DCAs written in the SOPs. Cleaning and disinfecting shall occur before compounding is performed. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills; for example, water-soluble solid residues are removed with sterile water (for injection or irrigation) and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent such as sterile 70% IPA, which is allowed to dry before compounding begins.

Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs are the most critical practices before the preparation of CSPs. Consequently, such surfaces shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.

Work surfaces in the ISO Class 7 (see *Table 1*) buffer areas and ISO Class 8 (see *Table 1*) ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily, and dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 (see *Table 1*) air quality (see *Disinfectants and Antiseptics* ⟨1072⟩).

Table 3. Minimum Frequency of Cleaning and Disinfecting Compounding Areas

Site	Minimum Frequency
ISO Class 5 (see *Table 1*) Primary Engineering Control (e.g., LAFW, BSC, CAI, CACI)	At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or suspected
Counters and easily cleanable work surfaces	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage shelving	Monthly

Floors in the buffer or clean area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and

procedures described in the written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly. In the buffer or clean area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents are to be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues (see *Appendix II*). Their schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial or compounding personnel.

All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer or clean area and ante-area, but only in that order. Ideally, all cleaning tools are discarded after one use by collection in suitable plastic bags and removed with minimal agitation. If cleaning materials (e.g., mops) are reused, procedures shall be developed (based on manufacturers' recommendations) that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned.

Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes.

Wiping with small sterile 70% IPA swabs that are commercially available in individual foil-sealed packages (or a comparable method) is preferred for disinfecting entry points on bags and vials, allowing the IPA to dry before piercing stoppers with sterile needles and breaking necks of ampuls. The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point. Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.

When sterile supplies are received in sealed pouches designed to keep them sterile until opening, the sterile supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 (see *Table 1*) PEC (LAFW, BSC, CAI, CACI) without the need to disinfect the individual sterile supply items. No shipping or other external cartons may be taken into the buffer or clean area or segregated compounding area.

Personnel Cleansing and Garbing

The careful cleansing of hands and arms and the correct donning of PPE by compounding personnel constitute the first major step in preventing microbial contamination in CSPs. Personnel shall also be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs. Squamous cells are normally shed from the human body at a rate of 10^6 or more per hour, and those skin particles are laden with microorganisms.[10, 11] When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear cosmetics, they shed these particles at even higher rates. Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. Therefore, compounding personnel with such conditions as mentioned above shall be excluded from working in ISO Class 5 (see *Table 1*) and ISO Class 7 (see *Table 1*) compounding areas until their conditions are remedied.

Before entering the buffer area or segregated compounding area (see *Low-Risk Level CSPs with 12-Hour or Less BUD*), compounding personnel shall remove personal outer garments (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves). The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.

Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face masks/eye shields. Eye shields are optional unless working with irritants such as germicidal disinfecting agents or when preparing hazardous drugs.

After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, a hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) and water while in the ante-area. The use of antimicrobial scrub brushes is not recommended because they can cause skin irritation and skin damage. Hands and forearms to the elbows will be completely dried using either lint-free disposable towels or an electronic hand dryer. After completion of hand washing, a nonshedding gown with sleeves that fit snugly around the wrists and enclosed at the neck is donned. Gowns designated for buffer area use shall be worn, and preferably they should be disposable. If reusable gowns are worn, they should be laundered appropriately for buffer area use.

Once inside the buffer area or segregated compounding area (see *Low-Risk Level CSPs with 12-Hour or Less BUD*), and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity[12] following manufacturers' recommendations. Hands are allowed to dry thoroughly before donning sterile gloves.

Sterile gloves shall be the last item donned before compounding begins. Gloves become contaminated when they contact nonsterile surfaces during compounding activities. Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70% IPA to all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Only use gloves that have been tested for compatibility with alcohol disinfection by the manufacturer. Routine application of sterile 70% IPA shall occur throughout the compounding process and whenever nonsterile surfaces (e.g. vials, counter tops, chairs, carts) are touched. Gloves on hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected. Antiseptic hand cleansing shall be performed as indicated above. Compounding personnel shall be trained and evaluated in the avoidance of touching critical sites.

When compounding personnel exit the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face masks/eye shields, and gloves shall be replaced with new ones before re-entering the compounding area, and proper hand hygiene shall be performed.

During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing of nonster-

[10] Agalloco J, Akers JE. Aseptic Processing: A Vision of the Future. *Pharmaceutical Technology*, 2005. Aseptic Processing supplement, s16.

[11] Eaton T. Microbial Risk Assessment for Aseptically Prepared Products. *Am Pharm Rev.* 2005; 8 (5, Sep/Oct): 46–51.

[12] *Guideline for Hand Hygiene in Health care Settings*, MMWR, October 25, 2002, vol. 51, No. RR-16 available on the Internet at http://www.cdc.gov/handhygiene/.

ile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 (see *Table 1*) environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 (see *Table 1*) shall re-garb PPE along with washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 (see *Table 1*) buffer area. When CAIs and CACIs are the source of the ISO Class 5 (see *Table 1*) environment, the garbing and gloving requirements for compounding personnel should be as described above, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required.

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures

Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through multimedia instructional sources and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 (see *Table 1*) environmental conditions, and cleaning and disinfection procedures. This training shall be completed and documented before any compounding personnel begin to prepare CSPs. Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media-fill testing (see *Appendices III–V*).

Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding and semiannually for high-risk level compounding.

Compounding personnel who fail written tests or observational audits or whose media-fill test vials have one or more units showing visible microbial contamination shall be reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Compounding personnel shall pass all evaluations prior to resuming compounding of sterile preparations. In addition to didactic evaluation and aseptic media fill, compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures.

In the event that cleaning and disinfecting procedures are also performed by other support personnel (e.g., institutional environmental services, housekeeping), thorough training of proper hand hygiene, garbing, and cleaning and disinfection procedures shall be done by a qualified aseptic compounding expert. After completion of training, support personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert.

COMPETENCY EVALUATION OF GARBING AND ASEPTIC WORK PRACTICE

The risk of contaminating a CSP prepared under low-risk level and medium-risk level conditions is highly dependent on proper hand hygiene and garbing practices, compounding personnel aseptic technique, and the presence of surface contamination, assuming that all work is performed in a certified and properly functioning ISO Class 5 (see *Table 1*) PEC and secondary engineering controls, ISO Class 7 (see *Table 1*) buffer area, and ISO Class 8 (see *Table 1*) ante-area. High-risk level CSPs pose the greatest threat to patients because compounding personnel are tasked with the requirement of processing nonsterile components and devices in order to achieve sterility. Compounding personnel shall be evaluated initially prior to beginning compounding CSPs and whenever an aseptic media fill is performed using a form such as the *Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel* (see *Appendix III*) and the personnel glove fingertip sampling procedures indicated below.

Aseptic Work Practice Assessment and Evaluation via Personnel Glove Fingertip Sampling—Sampling of compounding personnel glove fingertips shall be performed for all CSP risk level compounding because direct touch contamination is the most likely source of introducing microorganisms into CSPs prepared by humans. Glove fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices, which include frequent and repeated glove disinfection using sterile 70% IPA during actual compounding of CSPs. All personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands).

Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing in order to assess garbing competency and after completing the media-fill preparation (without applying sterile 70% IPA) in order to assess the adequacy of aseptic work practices prior to being initially allowed to prepare CSPs for human use and for more experienced personnel to maintain their qualifications to prepare CSPs for human use.

Garbing And Gloving Competency Evaluation—Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures (see *Personnel Cleansing and Garbing* under *Personnel Training and Evaluation in Aseptic Manipulation Skills* above). The visual observation shall be documented on a form such as the *Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel* (see *Appendix III*) and maintained to provide a permanent record and long-term assessment of personnel competency.

Gloved Fingertip Sampling—All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use. Immediately after the compounding employee completes the hand hygiene and garbing procedure (e.g., donning of sterile gloves prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding employee onto appropriate agar plates by lightly pressing each fingertip into the agar. The plates will be incubated for the appropriate incubation period and at the appropriate temperature (see *Incubation Period*). After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs and semiannually for personnel who compound high-risk level CSPs using one or more sample collections during any media-fill test procedure before they are allowed to continue compounding CSPs for human use.

Immediately prior to sampling, gloves shall not be disinfected with sterile 70% IPA. Disinfecting gloves immediately before sampling will provide false negative results. Plates filled with nutrient agar with neutralizing agents such as lecithin and polysorbate 80 added shall be used when sampling personnel fingertips. Personnel shall "touch" the agar with the fingertips of both hands in separate plates in a manner to create a slight impression in the agar. The sampled gloves shall be immediately discarded and proper hand hygiene performed after sampling. The nutrient agar plates shall be incubated as stated below (see *Incubation Period*). Results should be reported separately as number of cfu per employee per hand (left hand, right hand). The cfu action

level for gloved hands will be based on the total number of cfu on both gloves, not per hand.

Incubation Period—At the end of the designated sampling period for compounding personnel competency assessment activities (surface or personnel), the agar plates are recovered and covers secured and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. TSA with lecithin and polysorbate 80 shall be incubated at 30° to 35° for 48 to 72 hours.

Aseptic Manipulation Competency Evaluation—After successful completion of an initial Hand Hygiene and Garbing Competency Evaluation, all compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the *Media-Fill Test Procedure* and subsequent annual or semi-annual *Media-Fill Test Procedures*. Records of these evaluations will be maintained using a form such as the *Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel* (see *Appendix IV*) and maintained to provide a permanent record of and long-term assessment of personnel competency.

Media-Fill Test Procedure—The skill of personnel to aseptically prepare CSPs shall be evaluated using sterile fluid bacterial culture media-fill verification, (i.e., sterile bacterial culture medium transfer via a sterile syringe and needle). Media-fill testing is used to assess the quality of the aseptic skill of compounding personnel. Media-fill tests shall represent the most challenging or stressful conditions actually encountered by the personnel being evaluated when they prepare low- and medium-risk level CSPs and when sterilizing high-risk level CSPs. Media-fill challenge tests are also used to verify the capability of the compounding environment and processes to produce sterile preparations.

A commercially available sterile fluid culture media, such as Soybean–Casein Digest Medium (see *Sterility Tests* ⟨71⟩), that is able to promote exponential colonization of bacteria that are most likely to be transmitted to CSPs from the compounding personnel and environment is commonly used. For high-risk level CSPs nonsterile commercially available Soybean–Casein Digest Medium may be used to make a 3% solution. Normal processing steps, including filter sterilization, shall be mimicked. Media-filled vials shall be incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩). Failure is indicated by visible turbidity in any one of the media-fill units on or before 14 days. Other methodologies recommended by a competent microbiologist to enhance recovery time and sensitivity to detect microbial contamination may be considered (see *CSP Microbial Contamination Risk Levels* for examples of media-fill procedures).

SURFACE CLEANING AND DISINFECTION SAMPLING AND ASSESSMENT

Surface sampling is an important component of the maintenance of a suitable microbially controlled environment for compounding CSPs, especially since transfer of microbial contamination from improperly disinfected work surfaces via inadvertent touch contact by compounding personnel can be a potential source of contamination into CSPs. It is useful for evaluating facility and work surface cleaning and disinfecting procedures and employee competency in work practices such as disinfection of component/vial surface cleaning. Surface sampling shall be performed in all ISO classified areas on a periodic basis. Sampling can be accomplished using contact plates or swabs, and it shall be done at the conclusion of compounding. Locations to be sampled shall be defined in a sample plan or on a form. The size of the plate to be used for each sampled location usually ranges from 24 to 30 cm^2. Contact plates are filled with general solid agar growth medium and neutralizing agents above the rim of the plate, and they are used for sampling regular or flat surfaces. Swabs may be used for sampling irregular surfaces, especially for equipment (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩).

Cleaning and Disinfecting Competency Evaluation—Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of performing cleaning and disinfecting procedures, during initial personnel training on cleaning procedures, during changes in cleaning staff, and at the completion of any media-fill test procedure (see *Cleaning and Disinfecting of Compounding Areas*).

The visual observation shall be documented using a form such as the *Sample Form for Assessing Cleaning and Disinfection Procedures* (see *Appendix V*) and maintained to provide a permanent record and long-term assessment of personnel competency.

Surface Collection Methods—To sample surfaces using a contact plate, gently touch the sample area with the agar surface and roll the plate across the surface to be sampled. The contact plate will leave a growth media residue behind; therefore, immediately after sampling with the contact plate, the sampled area shall be thoroughly wiped with a nonshedding wipe soaked in sterile 70% IPA.

If an area is sampled via the swab method, collection of the sample is processed by using appropriate procedures that will result in the surface location equivalent to that of a contact plate. After swabbing the surface to be sampled, swabs are placed in an appropriate diluent; an aliquot is planted on or in the specified nutrient agar. Results should be reported as cfu per unit of surface area.

Action Levels, Documentation, and Data Evaluation

The value of viable microbial monitoring of gloved fingertips and surfaces of components and the compounding environment are realized when the data are used to identify and correct an unacceptable work practice. Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.

Any cfu count that exceeds its respective action level (see *Table 4*) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or working practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.

When gloved fingertip sample results exceed action levels after proper incubation, a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices shall be performed and documented. Employee training may be required to correct the source of the problem.

Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in *Table 4* should be used only as guidelines. Regardless of the number of cfu identified in the compounding facility, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bi-

oburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and shall be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

Table 4. Recommended Action Levels for Microbial Contamination*

Classification	Fingertip Sample	Surface Sample (Contact Plate) (cfu per plate)
ISO Class 5	> 3	> 3
ISO Class 7	N/A	> 5
ISO Class 8 or worse	N/A	> 100

* Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products Annexes PE 009-6, 5 April 2007.

SUGGESTED STANDARD OPERATING PROCEDURES (SOPs)

The compounding facility shall have written, properly approved SOPs designed to ensure the quality of the environment in which a CSP is prepared. The following procedures are recommended:

1. Access to the buffer area is restricted to qualified personnel with specific responsibilities or assigned tasks in the compounding area.
2. All cartoned supplies are decontaminated in the area by removing them from shipping cartons and wiping or spraying them with a nonresidue-generating disinfecting agent while they are being transferred to a clean and properly disinfected cart or other conveyance for introduction into the buffer area. Manufacturers' directions or published data for minimum contact time will be followed. Individual pouched sterile supplies need not be wiped because the pouches can be removed as these sterile supplies are introduced into the buffer area.
3. Supplies that are required frequently or otherwise needed close at hand but not necessarily needed for the scheduled operations of the shift are decontaminated and stored on shelving in the ante-area.
4. Carts used to bring supplies from the storeroom cannot be rolled beyond the demarcation line in the ante-area, and carts used in the buffer area cannot be rolled outward beyond the demarcation line unless cleaned and disinfected before returning.
5. Generally, supplies required for the scheduled operations of the shift are wiped down with an appropriate disinfecting agent and brought into the buffer area, preferably on one or more movable carts. Supplies that are required for back-up or general support of operations may be stored on the designated shelving in the buffer area, but excessive amounts of supplies are to be avoided.
6. Nonessential objects that shed particles shall not be brought into the buffer area, including pencils, cardboard cartons, paper towels, and cotton items (e.g., gauze pads).
7. Essential paper-related products (e.g., paper syringe overwraps, work records contained in a protective sleeve) shall be wiped down with an appropriate disinfecting agent prior to being brought into the buffer area.
8. Traffic flow in and out of the buffer area shall be minimized.
9. Personnel preparing to enter the buffer area shall remove all personal outer garments, cosmetics (because they shed flakes and particles), and all hand, wrist, and other visible jewelry or piercings that can interfere with the effectiveness of PPE.
10. Personnel entering the ante-area shall don attire as described in *Personnel Cleansing and Garbing* and *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.*
11. Personnel shall then thoroughly wash hands and forearms to the elbow with soap and water for at least 30 seconds. An air dryer or disposable nonshedding towels are used to dry hands and forearms after washing.
12. Personnel entering the buffer area shall perform antiseptic hand cleansing prior to donning sterile gloves using a waterless alcohol-based surgical hand scrub with persistent activity.
13. Chewing gum, drinks, candy, or food items shall not be brought into the buffer area or ante-area. Materials exposed in patient care and treatment areas shall never be introduced into areas where components and ingredients for CSPs are present.
14. At the beginning of each compounding activity session, and whenever liquids are spilled, the surfaces of the direct compounding environment are first cleaned with USP Purified Water to remove water-soluble residues. Immediately thereafter, the same surfaces are disinfected with a nonresidue-generating agent using a nonlinting wipe.
15. Primary engineering controls shall be operated continuously during compounding activity. When the blower is turned off and before other personnel enter to perform compounding activities, only one person shall enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and disinfecting the work surfaces.
16. Traffic in the area of the DCA is minimized and controlled.
17. Supplies used in the DCA for the planned procedures are accumulated and then decontaminated by wiping or spraying the outer surface with sterile 70% IPA or removing the outer wrap at the edge of the DCA as the item is introduced into the aseptic work area.
18. All supply items are arranged in the DCA so as to reduce clutter and provide maximum efficiency and order for the flow of work.
19. After proper introduction into the DCA of supply items required for and limited to the assigned operations, they are so arranged that a clear, uninterrupted path of HEPA-filtered air will bathe all critical sites at all times during the planned procedures. That is, no objects may be placed between the first air from HEPA filters and an exposed critical site.
20. All procedures are performed in a manner designed to minimize the risk of touch contamination. Gloves are disinfected with adequate frequency with an approved disinfectant such as sterile 70% IPA.
21. All rubber stoppers of vials and bottles and the necks of ampuls are disinfected by wiping with sterile 70% IPA and waiting for at least 10 seconds before they are used to prepare CSPs.
22. After the preparation of every CSP, the contents of the container are thoroughly mixed and then inspected for the presence of particulate matter, evidence of incompatibility, or other defects.
23. After procedures are completed, used syringes, bottles, vials, and other supplies are removed, but with a minimum of exit and re-entry into the DCA so as to minimize the risk of introducing contamination into the aseptic workspace.

ELEMENTS OF QUALITY CONTROL

A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile products shall be developed for each site. This program equips personnel with the appropriate knowledge and trains them in the required skills necessary to perform the assigned tasks. Each person assigned to the aseptic area in the preparation of sterile products shall successfully complete specialized training in aseptic techniques and aseptic area practices prior to preparing CSPs (see *Personnel Training and Evaluation in Aseptic Manipulation Skills* and *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*).

Ingredients and Devices

Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality using the following information: vendor labels, labeling, certificates of analysis, direct chemical analysis, and knowledge of compounding facility storage conditions.

STERILE INGREDIENTS AND DEVICES

Commercially available sterile drug products, sterile ready-to-use containers, and devices are examples of sterile components. A written procedure for unit-by-unit physical inspection preparatory to use is followed to ensure that these components are sterile, free from defects, and otherwise suitable for their intended use.

NONSTERILE INGREDIENTS AND DEVICES

If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk. Nonsterile active ingredients and added substances or excipients for CSPs should preferably be official *USP* or *NF* articles. When nonofficial ingredients are used, they shall be accompanied by certificates of analysis from their suppliers to aid compounding personnel in judging the identity, quality, and purity in relation to the intended use in a particular CSP. Physical inspection of a package of ingredients is necessary in order to detect breaks in the container, looseness in the cap or closure, and deviation from the expected appearance, aroma, and texture of the contents.

Bulk or unformulated drug substances and added substances or excipients shall be stored in tightly closed containers under temperature, humidity, and lighting conditions that are either indicated in official monographs or approved by suppliers. The date of receipt by the compounding facility shall be clearly and indelibly marked on each package of ingredient. After receipt by the compounding facility, packages of ingredients that lack a supplier's expiration date cannot be used after 1 year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in CSPs.

Careful consideration and evaluation of nonsterile ingredient sources is especially warranted when the CSP will be administered into the vascular system, central nervous system, or eyes.

Upon receipt of each lot of the bulk drug substance or excipient used for CSPs, the individual compounding the preparation performs a visual inspection of the lot for evidence of deterioration, other types of unacceptable quality, and wrong identification. For bulk drug substances or excipients, visual inspection is performed on a routine basis as described in the written protocol.

Equipment

It is necessary that equipment, apparatus, and devices used to compound a CSP be consistently capable of operating properly and within acceptable tolerance limits. Written procedures outlining required equipment calibration, annual maintenance, monitoring for proper function, and controlled procedures for use of the equipment and specified time frames for these activities are established and followed. Routine maintenance and frequencies shall be outlined in these SOPs. Results from the equipment calibration, annual maintenance reports, and routine maintenance are kept on file for the lifetime of the equipment. Personnel are prepared through an appropriate combination of specific training and experience to operate or manipulate any piece of equipment, apparatus, or device they may use when preparing CSPs. Training includes gaining the ability to determine whether any item of equipment is operating properly or is malfunctioning.

VERIFICATION OF AUTOMATED COMPOUNDING DEVICES (ACDs) FOR PARENTERAL NUTRITION COMPOUNDING

ACDs for the preparation of parenteral nutrition admixtures are widely used by pharmacists in hospitals and other healthcare settings. They are designed to streamline the labor-intensive processes involved in the compounding of these multiple-component formulations by automatically delivering the individual nutritional components in a predetermined sequence under computerized control. Parenteral nutrition admixtures often contain 20 or more individual additives representing as many as 50 or more individual components (e.g., 15 to 20 crystalline amino acids, dextrose monohydrate, and lipids; 10 to 12 electrolyte salts; 5 to 7 trace minerals; and 12 vitamins). Thus, ACDs can provide improved accuracy and precision of the compounding process over the traditional manual compounding methods.

Accuracy

The accuracy of an ACD can be determined in various ways to ensure that the correct quantities of nutrients, electrolytes, or other nutritional components are delivered to the final infusion container. Initially, the ACD is tested for its volume and weight accuracy. For volume accuracy, a suitable volume of Sterile Water for Injection, USP, which represents a typical additive volume (e.g., 40 mL for small-volume range of 1 to 100 mL, 300 mL for large-volume range of 100 to 1000 mL), is programmed into the ACD and delivered to the appropriate volumetric container. The compounding personnel should then consult *Volumetric Apparatus* ⟨31⟩ for appropriate parameters to assess the volumetric performance of the ACD. For gravimetric accuracy, the balance used in conjunction with the ACD is tested using various weight sizes that represent the amounts typically used to deliver the various additives. Compounding personnel should consult *Weights and Balances* ⟨41⟩ for acceptable tolerances of the weights used. In addition, the same volume of *Sterile Water for Injection* used to assess volumetric accuracy is then weighed on the balance used in conjunction with the ACD. For example, if 40 mL of water was used in the volumetric assessment, its corresponding weight should be about 40 g (assuming the relative density of water is 1.0). In addition, during the use of the ACD, certain additives, such as potassium chloride (corrected for density differences), can also be tested in the same manner as with an in-process test.

Finally, additional tests of accuracy may be employed that determine the content of certain ingredients in the final volume of the parenteral nutrition admixture. Generally, pharmacy departments do not have the capability to routinely

perform chemical analyses such as analyses of dextrose or electrolyte concentrations. Consequently, hospital or institutional laboratories may be called upon to perform these quality assurance tests. However, the methods in such laboratories are often designed for biological, not pharmaceutical, systems. Thus, their testing procedures shall be verified to meet the *USP* requirements stated in the individual monograph for the component being tested. For example, under *Dextrose Injection*, the following is stated: It contains not less than 95.0% and not more than 105.0% of the labeled amount of $C_6H_{12}O_6 \cdot H_2O$. The hospital or institutional chemistry laboratories must validate their methods to apply to this range and correct for their typical measurement of anhydrous dextrose versus dextrose monohydrate. Similar ranges and issues exist, for example, for injections of calcium gluconate, magnesium sulfate, and potassium chloride. The critical point is the use of *USP* references and possible laboratory procedural differences.

Precision

The intermediate precision of the ACD can be determined on the basis of the day-to-day variations in performance of the accuracy measures. Thus, compounding personnel shall keep a daily record of the above-described accuracy assessments and review the results over time. This review shall occur at least at weekly intervals to avoid potentially clinically significant cumulative errors over time. This is especially true for additives with a narrow therapeutic index, such as potassium chloride.

FINISHED PREPARATION RELEASE CHECKS AND TESTS

The following quality metrics shall be performed for all CSPs before they are dispensed or administered.

Inspection of Solution Dosage Forms and Review of Compounding Procedures

All CSPs that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed. The prescription orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels are inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.

PHYSICAL INSPECTION

Finished CSPs are individually inspected in accordance with written procedures after compounding. If not distributed promptly, these CSPs are individually inspected just prior to leaving the storage area. Those CSPs that are not immediately distributed are stored in an appropriate location as described in the written procedures. Immediately after compounding, and as a condition of release, each CSP unit, where possible, should be inspected against lighted white or black background or both for evidence of visible particulates or other foreign matter. Prerelease inspection also includes container–closure integrity and any other apparent visual defect. CSPs with observed defects should be immediately discarded or marked and segregated from acceptable products in a manner that prevents their administration. When CSPs are not distributed promptly after preparation, a predistribution inspection is conducted to ensure that a CSP with defects, such as precipitation, cloudiness, and leakage, which may develop between the time of release and the time of distribution, is not released.

Compounding Accuracy Checks

Written procedures for double-checking compounding accuracy shall be followed for every CSP during preparation and immediately prior to release. The double-check system should meet state regulations and include label accuracy and accuracy of the addition of all drug products or ingredients used to prepare the finished product and their volumes or quantities. The used additive containers and, for those additives for which the entire container was not expended, the syringes used to measure the additive should be quarantined with the final products until the final product check is completed. Compounding personnel shall visually confirm that ingredients measured in syringes match the written order being compounded. Preferably, a person other than the compounder can verify that correct volumes of correct ingredients were measured to make each CSP. For example, compounding personnel would pull the syringe plunger back to the volume measured.

When practical, the accuracy of measurements is confirmed by weighing a volume of the measured fluid, then calculating that volume by dividing the weight by the accurate value of the density, or specific gravity, of the measured fluid. Correct density or specific gravity values programmed in ACDs, which measure by weight using the quotient of the programmed volume divided by the density or specific gravity, shall be confirmed to be accurate before and after delivering volumes of the liquids assigned to each channel or port. These volume accuracy checks and the following additional safety and accuracy checks in this section shall be included in the SOP manual of the CSP facility.

Sterility Testing

All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test (see *Sterility Tests* ⟨71⟩) before they are dispensed or administered. The *Membrane Filtration* method is the method of choice where feasible (e.g., components are compatible with the membrane). A method not described in the *USP* may be used if verification results demonstrate that the alternative is at least as effective and reliable as the *USP Membrane Filtration* method or the *USP Direct Inoculation of the Culture Medium* method where the *Membrane Filtration* method is not feasible.

When high-risk level CSPs are dispensed before receiving the results of their sterility tests, there shall be a written procedure requiring daily observation of the incubating test specimens and immediate recall of the dispensed CSPs when there is any evidence of microbial growth in the test specimens. In addition, the patient and the physician of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. Positive sterility test results should prompt a rapid and systematic investigation of aseptic technique, environmental control, and other sterility assurance controls to identify sources of contamination and correct problems in the methods or processes.

Bacterial Endotoxin (Pyrogen) Testing

All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins (see

Bacterial Endotoxins Test ⟨85⟩ and *Pyrogen Test* ⟨151⟩). In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in *Bacterial Endotoxins Test* ⟨85⟩ referenced above for the appropriate route of administration.

Identity and Strength Verification of Ingredients

Compounding facilities shall have at least the following written procedures for verifying the correct identity and quality of CSPs before they are dispensed and administered:

1. That labels of CSPs bear correct names and amounts or concentrations of ingredients, the total volume, the BUD, the appropriate route(s) of administration, the storage conditions, and other information for safe use.
2. That there are correct identities, purities, and amounts of ingredients by comparing the original written order with the written compounding record for the CSP.
3. That correct fill volumes in CSPs and correct quantities of filled units of the CSPs were obtained. When the strength of finished CSPs cannot be confirmed to be accurate, based on the above three inspections, the CSPs shall be assayed by methods that are specific for the active ingredients.

STORAGE AND BEYOND-USE DATING

BUDs for compounded preparations are usually assigned on the basis of professional experience, which should include careful interpretation of appropriate information sources for the same or similar formulations (see *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩). BUDs for CSPs are rarely based on preparation-specific chemical assay results, which are used with the Arrhenius equation to determine expiration dates (see *General Notices and Requirements*) for manufactured products. The majority of CSPs are aqueous solutions in which hydrolysis of dissolved ingredients is the most common chemical degradation reaction. The extent of hydrolysis and other heat-catalyzed degradation reactions at any particular time point in the life of a CSP represents the thermodynamic sum of exposure temperatures and durations. Such lifetime stability exposure is represented in the mean kinetic temperature calculation (see *Pharmaceutical Calculations in Prescription Compounding* ⟨1160⟩). Drug hydrolysis rates increase exponentially with arithmetic temperature increase; thus, exposure of a beta-lactam antibiotic solution for 1 day at controlled room temperature (see *General Notices and Requirements*) will have an equivalent effect on the extent of hydrolysis of approximately 3 to 5 days in cold temperatures (see *General Notices and Requirements*).

Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs. When CSPs are known to have been exposed to temperatures warmer than the warmest labeled limit or to temperatures exceeding 40° (see *General Notices and Requirements*) for more than 4 hours, such CSPs should be discarded unless direct assay data or appropriate documentation confirms their continued stability.

Determining Beyond-Use Dates

BUDs and expiration dates are not the same (see *General Notices and Requirements*). Expiration dates for the chemical and physical stability of manufactured sterile products are determined from results of rigorous analytical and performance testing, and they are specific for a particular formulation in its container and at stated exposure conditions of illumination and temperature. When CSPs deviate from conditions in the approved labeling of manufactured products contained in CSPs, compounding personnel may consult the manufacturer of particular products for advice on assigning BUDs based on chemical and physical stability parameters. BUDs for CSPs that are prepared strictly in accordance with manufacturers' product labeling shall be those specified in that labeling or from appropriate literature sources or direct testing. BUDs for CSPs that lack justification from either appropriate literature sources or by direct testing evidence shall be assigned as described in *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩.

In addition, compounding personnel may refer to applicable publications to obtain relevant stability, compatibility, and degradation information regarding the drug or its congeners. When assigning a beyond-use date, compounding personnel should consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy (see *Expiration Date and Beyond-Use Date* under *Labeling* in the *General Notices and Requirements*). Stability information must be carefully interpreted in relation to the actual compounded formulation and conditions for storage and use. Predictions based on other evidence, such as publications, charts, and tables, would result in theoretical BUDs. Theoretically predicted beyond-use dating introduces varying degrees of assumptions and, hence, a likelihood of error or at least inaccuracy. The degree of error or inaccuracy would be dependent on the extent of differences between the CSPs' characteristics (e.g., composition, concentration of ingredients, fill volume, container type and material) and the characteristics of the products from which stability data or information is to be extrapolated. The greater the doubt of the accuracy of theoretically predicted beyond-use dating, the greater the need to determine dating periods experimentally. Theoretically predicted beyond-use dating periods should be carefully considered for CSPs prepared from nonsterile bulk active ingredients having therapeutic activity, especially where these CSPs are expected to be compounded routinely. When CSPs will be distributed to and administered in residential locations other than healthcare facilities, the effect of potentially uncontrolled and unmonitored temperature conditions shall be considered when assigning BUDs. It must be ascertained that CSPs will not be exposed to warm temperatures (see *General Notices and Requirements*) unless the compounding facility has evidence to justify stability of CSPs during such exposure.

It should be recognized that the truly valid evidence of stability for predicting beyond-use dating can be obtained only through product-specific experimental studies. Semiquantitative procedures such as thin-layer chromatography (TLC) may be acceptable for many CSPs. However, quantitative stability-indicating assays such as high-performance liquid chromatographic (HPLC) assays would be more appropriate for certain CSPs. Examples include CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity; where a theoretically established beyond-use dating period is supported by only marginal evidence; or where a significant margin of safety cannot be verified for the proposed beyond-use dating period. In short, because beyond-use dating periods established from product-specific data acquired from the appropriate instrumental analyses are clearly more reliable than those predicted theoretically, the former approach is strongly urged to support dating periods exceeding 30 days.

To ensure consistent practices in determining and assigning BUDs, the compounding facility should have written policies and procedures governing the determination of the BUDs for all compounded products. When attempting to

predict a theoretical BUD, a compounded or an admixed preparation should be considered as a unique system that has physical and chemical properties and stability characteristics that differ from its components. For example, antioxidant, buffering, or antimicrobial properties of a sterile vial for injection (SVI) might be lost upon its dilution, with the potential of seriously compromising the chemical stability of the SVI's active ingredient or the physical or microbiological stability of the SVI formulation in general. Thus, the properties stabilized in the SVI formulation usually cannot be expected to be carried over to the compounded or admixed preparation. Preparation-specific, experimentally determined stability data evaluation protocols are preferable to published stability information. Compounding personnel should consult general information chapter *Pharmaceutical Stability* ⟨1150⟩ for the appropriate stability parameters to be considered when initiating or evaluating a preparation-specific stability study.

Compounding personnel who assign BUDs to CSPs when lacking direct chemical assay results must critically interpret and evaluate the most appropriate available information sources to determine a conservative and safe BUD. The SOP manual of the compounding facility and each specific CSP formula record shall describe the general basis used to assign the BUD and storage conditions.

When manufactured MDVs (see *Multiple-Dose Container* under *Preservation, Packaging, Storage,* and *Labeling* in the *General Notices and Requirements*) of sterile ingredients are used in CSPs, the stoppers of the MDVs are inspected for physical integrity and disinfected by wiping with a sterile 70% IPA swab before each penetration with a sterile withdrawal device. When contaminants or abnormal properties are suspected or observed in MDVs, such MDVs shall be discarded. The BUD after initially entering or opening (e.g., needle puncturing) multiple-dose containers is 28 days (see *Antimicrobial Effectiveness Testing* ⟨51⟩) unless otherwise specified by the manufacturer.

Proprietary Bag and Vial Systems

The sterility storage and stability beyond-use times for attached and activated (where activated is defined as allowing contact of the previously separate diluent and drug contents) container pairs of drug products for intravascular administration (e.g., ADD-Vantage®, Mini Bag Plus®) shall be applied as indicated by the manufacturer. In other words, follow manufacturers' instructions for handling and storing ADD-Vantage®, Mini Bag Plus®, Add A Vial®, Add-Ease® products, and any others.

Monitoring Controlled Storage Areas

To ensure that product potency is retained through the manufacturer's labeled expiration date, compounding personnel shall monitor the drug storage areas within the compounding facility. Controlled temperature areas in compounding facilities include controlled room temperature, 20° to 25° with mean kinetic temperature 25°; controlled cold temperature, 2° to 8° with mean kinetic temperature 8°; cold temperature, 2° to 8°; freezing temperature, −25° and −10° (see *General Notices and Requirements)* if needed to achieve freezing, and the media-specific temperature range for microbial culture media. A controlled temperature area shall be monitored at least once daily and the results documented on a temperature log. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberrations. Suitable temperature recording devices may include a calibrated continuous recording device or a National Institute of Standards and Technology (NIST) calibrated thermometer that has adequate accuracy and sensitivity for the intended purpose, and it shall be properly calibrated at suitable intervals. If the compounding facility uses a continuous temperature recording device, compounding personnel shall verify at least once daily that the recording device itself is functioning properly.

The temperature-sensing mechanisms shall be suitably placed in the controlled temperature storage space to reflect accurately its true temperature. In addition, the compounding facility shall adhere to appropriate procedures of all controlled storage spaces to ensure that such spaces are not subject to significantly prolonged temperature fluctuations as may occur, for example, by leaving a refrigerator door open too long.

MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs

This section summarizes the responsibilities of compounding facilities for maintaining quality and control of CSPs that are dispensed and administered within their parent healthcare organizations.

Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients. In fulfilling this general responsibility, the compounding facility is responsible for the proper packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions. The compounding facility should assist in the education and training of noncompounding personnel responsible for carrying out any aspect of these functions.

Establishing, maintaining, and ensuring compliance with comprehensive written policies and procedures encompassing these responsibilities is a further responsibility of the compounding facility. Where noncompounding personnel are assigned tasks involving any of these responsibilities, the policies and procedures encompassing those tasks should be developed by compounding supervisors. The quality and control activities related to distribution of CSPs are summarized in the following five subsections. Activities or concerns that should be addressed as the compounding facility fulfills these responsibilities are as follows.

Packaging, Handling, and Transport

Inappropriate processes or techniques involved with packaging, handling, and transport can adversely affect quality and package integrity of CSPs. Although compounding personnel routinely perform many of the tasks associated with these functions, some tasks, such as transport, handling, and placement into storage, may be fulfilled by noncompounding personnel who are not under the direct administrative control of the compounding facility. Under these circumstances, appropriate SOPs shall be established by the compounding facility with the involvement of other departments or services whose personnel are responsible for carrying out those CSP-related functions for which the compounding facility has a direct interest. The performance of the noncompounding personnel is monitored for compliance to established policies and procedures.

The critical requirements that are unique to CSPs and that are necessary to ensure CSP quality and packaging integrity shall be addressed in SOPs. For example, techniques should be specified to prevent the depression of syringe plungers or dislodging of syringe tips during handling and transport. Additionally, disconnection of system components (e.g., where CSPs are dispensed with administration sets attached to them) shall be prevented through the BUD of the CSP. Foam padding or inserts are particularly useful where CSPs are transported by pneumatic tube systems. Regardless of the methods used, the compounding facility must evaluate their effectiveness and the reliability of the intended protec-

tion. Evaluation should be continuous—for example, through a surveillance system, including a system of problem reporting to the compounding facility.

Inappropriate transport and handling can adversely affect the quality of certain CSPs having unique stability concerns. For example, the physical shaking that might occur during pneumatic tube transport or undue exposure to heat or light must be addressed on a preparation-specific basis. Alternative transport modes or special packaging measures might be needed for the proper assurance of quality of these CSPs. The use of tamper-evident closures and seals on CSP ports can add an additional measure of security to ensure product integrity regardless of the transport method used.

Chemotoxic and other hazardous CSPs require safeguards to maintain the integrity of the CSP and to minimize the exposure potential of these products to the environment and to personnel who may come in contact with them. Transportation by pneumatic tube should be discouraged because of potential breakage and contamination. Special requirements associated with the packaging, transport, and handling of these agents include the prevention of accidental exposures or spills and the training of personnel in the event of an exposure or spill. Examples of special requirements of these agents also include exposure-reducing strategies such as the use of Luer lock syringes and connections, syringe caps, the capping of container ports, sealed plastic bags, impact-resistant containers, and cautionary labeling.

Use and Storage

The compounding facility is responsible for ensuring that CSPs in the patient-care setting maintain their quality until administered. The immediate labeling of the CSP container will display prominently and understandably the requirements for proper storage and expiration dating. Delivery and patient-care-setting personnel shall be properly trained to deliver the CSP to the appropriate storage location. Outdated and unused CSPs shall be returned to the compounding facility for disposition.

SOPs must exist to ensure that storage conditions in the patient-care setting are suitable for the CSP-specific storage requirements. Procedures include daily monitoring and documentation of drug storage refrigerators to ensure temperatures between 2° and 8° and the monthly inspection of all drug storage locations by compounding personnel. Inspections shall confirm compliance with appropriate storage conditions, separation of drugs and food, proper use of MDVs, and the avoidance of using single-dose products as MDVs. CSPs, as well as all other drug products, shall be stored in the patient-care area in such a way as to secure them from unauthorized personnel, visitors, and patients.

Readying for Administration

Procedures essential for generally ensuring quality, especially sterility assurance, when readying a CSP for its subsequent administration include proper hand washing, aseptic technique, site care, and change of administration sets. Additional procedures may also be essential for certain CSPs, devices, or techniques. Examples where such special procedures are needed include in-line filtration, the operation of automated infusion control devices, and the replenishment of CSPs into the reservoirs of implantable or portable infusion pumps. When CSPs are likely to be exposed to warmer than 30° for more than 1 hour during their administration to patients, the maintenance of their sterility and stability should be confirmed from either relevant and reliable sources or direct testing.

Redispensed CSPs

The compounding facility shall have the sole authority to determine when unopened, returned CSPs may be redispensed. Returned CSPs may be redispensed only when personnel responsible for sterile compounding can ensure that such CSPs are sterile, pure, and stable (contain labeled strength of ingredients). The following may provide such assurance: the CSPs were maintained under continuous refrigeration and protected from light, if required, and no evidence of tampering or any readying for use outside the compounding facility exists. Assignment of new storage times and BUDs that exceed the original dates for returned CSPs is permitted only when there is supporting evidence from sterility testing and quantitative assay of ingredients. Thus, initial preparation and thaw times should be documented and reliable measures should have been taken to prevent and detect tampering. Compliance with all procedures associated with maintaining product quality is essential. The CSPs shall not be redispensed if there is not adequate assurance that preparation quality and packaging integrity (including the connections of devices, where applicable) were continuously maintained between the time the CSPs left and the time they were returned. Additionally, CSPs shall not be redispensed if redispensing cannot be supported by the originally assigned BUD.

Education and Training

The assurance of CSPs' quality and packaging integrity is highly dependent on the proper adherence of all personnel to the pertinent SOPs. Compounding personnel shall design, implement, and maintain a formal education, training, and competency assessment program that encompasses all the functions and tasks addressed in the foregoing sections and all personnel to whom such functions and tasks are assigned. This program includes the assessment and documentation of procedural breaches, administration mishaps, side effects, allergic reactions, and complications associated with dosage or administration, such as extravasation. This program should be coordinated with the institution's adverse-events and incident reporting programs.

Packing and Transporting CSPs

The following sections describe how to maintain sterility and stability of CSPs until they are delivered to patient care locations for administration.

PACKING CSPS FOR TRANSIT

When CSPs are distributed to locations outside the premises in which they are compounded, compounding personnel select packing containers and materials that are expected to maintain physical integrity, sterility, and stability of CSPs during transit. Packing is selected that simultaneously protects CSPs from damage, leakage, contamination, and degradation, and protects personnel who transport packed CSPs from harm. The SOP manual of the compounding facility specifically describes appropriate packing containers and insulating and stuffing materials, based on information from product specifications, vendors, and experience of compounding personnel. Written instructions that clearly explain how to safely open containers of packed CSPs are provided to patients and other recipients.

TRANSIT OF CSPs

Compounding facilities that ship CSPs to locations outside their own premises shall select modes of transport that are expected to deliver properly packed CSPs in undamaged, sterile, and stable condition to recipients.

Compounding personnel should ascertain that temperatures of CSPs during transit by the selected mode will not exceed the warmest temperature specified on the storage temperature range on CSP labels. It is recommended that compounding personnel communicate directly with the couriers to learn shipping durations and exposure conditions that CSPs may encounter.

Compounding personnel shall include specific handling and exposure instructions on the exteriors of containers packed with CSPs to be transported and obtain reasonable assurance of compliance therewith from transporters. Compounding personnel shall periodically review the delivery performance of couriers to ascertain that CSPs are being efficiently and properly transported.

Storage in Locations Outside Compounding Facilities

Compounding facilities that ship CSPs to patients and other recipients outside their own premises shall ascertain or provide, whichever is appropriate, the following assurances:

1. Labels and accessory labeling for CSPs include clearly readable BUDs, storage instructions, and disposal instructions for out-of-date units.
2. Each patient or other recipient is able to store the CSPs properly, including the use of a properly functioning refrigerator and freezer if CSPs are labeled for such storage.

PATIENT OR CAREGIVER TRAINING

A formal training program is provided as a means to ensure understanding and compliance with the many special and complex responsibilities placed on the patient or caregiver for the storage, handling, and administration of CSPs. The instructional objectives for the training program include all home care responsibilities expected of the patient or caregiver and is specified in terms of patient or caregiver competencies.

Upon the conclusion of the training program, the patient or caregiver should, correctly and consistently, be able to do the following:

1. Describe the therapy involved, including the disease or condition for which the CSPs are prescribed, goals of therapy, expected therapeutic outcome, and potential side effects of the CSPs.
2. Inspect all drug products, CSPs, devices, equipment, and supplies on receipt to ensure that proper temperatures were maintained during transport and that goods received show no evidence of deterioration or defects.
3. Handle, store, and monitor all drug products, CSPs, and related supplies and equipment in the home, including all special requirements related to same.
4. Visually inspect all drug products, CSPs, devices, and other items the patient or caregiver is required to use immediately prior to administration in a manner to ensure that all items are acceptable for use. For example, CSPs must be free from leakage, container cracks, particulates, precipitate, haziness, discoloration, or other deviations from the normal expected appearance, and the immediate packages of sterile devices must be completely sealed, with no evidence of loss of package integrity.
5. Check labels immediately prior to administration to ensure the right drug, dose, patient, and time of administration.
6. Clean the in-home preparation area, scrub hands, use proper aseptic technique, and manipulate all containers, equipment, apparatus, devices, and supplies used in conjunction with administration.
7. Employ all techniques and precautions associated with CSP administration; for example, preparing supplies and equipment, handling of devices, priming the tubing, and discontinuing an infusion.
8. Care for catheters, change dressings, and maintain site patency as indicated.
9. Monitor for and detect occurrences of therapeutic complications such as infection, phlebitis, electrolyte imbalance, and catheter misplacement.
10. Respond immediately to emergency or critical situations such as catheter breakage or displacement, tubing disconnection, clot formation, flow blockage, and equipment malfunction.
11. Know when to seek and how to obtain professional emergency services or professional advice.
12. Handle, contain, and dispose of wastes, such as needles, syringes, devices, biohazardous spills or residuals, and infectious substances.

Training programs include a hands-on demonstration and practice with actual items that the patient or caregiver is expected to use, such as CSP containers, devices, and equipment. The patient or caregiver practices aseptic and injection technique under the direct observation of a health professional.

The compounding facility, in conjunction with nursing or medical personnel, is responsible for ensuring initially and on an ongoing basis that the patient or caregiver understands, has mastered, and is capable of and willing to comply with all of these home care responsibilities. This is achieved through a formal, written assessment program. All specified competencies in the patient or caregiver training program are formally assessed. The patient or caregiver is expected to demonstrate to appropriate healthcare personnel mastery of assigned activities before being allowed to administer CSPs unsupervised by a health professional.

Printed material such as checklists or instructions provided during training may serve as continuing post-training reinforcement of learning or as reminders of specific patient or caregiver responsibilities. Post-training verbal counseling can also be used periodically, as appropriate, to reinforce training and to ensure continuing correct and complete fulfillment of responsibilities.

PATIENT MONITORING AND ADVERSE EVENTS REPORTING

Compounding facilities shall clinically monitor patients treated with CSPs according to the regulations and guidelines of their respective state healthcare practitioner licensure boards or of accepted standards of practice. Compounding facilities shall provide patients and other recipients of CSPs with a way to address their questions and report any concerns that they may have with CSPs and their administration devices.

The SOP manuals of compounding facilities shall describe specific instructions for receiving, acknowledging, and dating receipts, and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with CSPs. Reports of adverse events with CSPs shall be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences. Compounding personnel are encouraged to participate in adverse event reporting and product defects programs of the FDA and USP.

QUALITY ASSURANCE (QA) PROGRAM

A provider of CSPs shall have in place a formal QA program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this chapter. Emphasis in the QA program is placed on maintaining and improving the quality of systems and the provision of patient care. In addition, the QA program ensures that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions were performed.[13]

Characteristics of a QA program include the following:

1. Formalization in writing;
2. Consideration of all aspects of the preparations and dispensing of products as described in this chapter, including environmental testing and verification results;
3. Description of specific monitoring and evaluation activities;
4. Specification of how results are to be reported and evaluated;
5. Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded; and
6. Delineation of the individuals responsible for each aspect of the QA program.

In developing a specific plan, focus is on establishing objective, measurable indicators for monitoring activities and processes that are deemed high risk, high volume, or problem prone. In general, the selection of indicators and the effectiveness of the overall QA program is reassessed on an annual basis.

ABBREVIATIONS AND ACRONYMS

ACD	automated compounding device
ACPH	air changes per hour
ALARA	as low as reasonably achievable
ASHRAE	American Society of Heating, Refrigerating and Air-Conditioning Engineers
BI	biological indicator
BSC	biological safety cabinet
BUD	beyond-use date
CACI	compounding aseptic containment isolator
CAI	compounding aseptic isolator
CDC	Centers for Disease Control and Prevention
CETA	Controlled Environment Testing Association
cfu	colony-forming unit(s)
CSP	compounded sterile preparation
CSTD	closed-system vial-transfer device
DCA	direct compounding area
ECV	endotoxin challenge vial
EU	Endotoxin Unit
FDA	Food and Drug Administration
HEPA	high efficiency particulate air
HICPAC	Healthcare Infection Control Practices Advisory Committee
HVAC	heating, ventilation, and air conditioning
IPA	isopropyl alcohol
ISO	International Organization for Standardization
LAFW	laminar airflow workbench
MDVs	multiple-dose vials
MMWR	Morbidity and Mortality Weekly Report
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
PEC	primary engineering control
PET	positron emission tomography
PPE	personnel protective equipment
psi	pounds per square inch
QA	quality assurance
SOP	standard operating procedure
SVI	sterile vial for injection
TSA	trypticase soy agar
USP	United States Pharmacopeia

[13] The use of additional resources, such as the Accreditation Manual for Home Care from the Joint Commission on Accreditation of Healthcare Organizations, may prove helpful in the development of a QA plan.

APPENDICES

Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩

NOTE—This tabular appendix selectively abstracts and condenses the full text of ⟨797⟩ for rapid reference only. Compounding personnel are responsible for reading, understanding and complying with the full text and all official USP terminology, content, and conditions therein.

INTRODUCTION

‡ Chapter purpose is to prevent harm and death to patients treated with CSPs.

† Chapter pertains to preparation, storage, and transportation, but not administration, of CSPs.

† Personnel and facilities to which ⟨797⟩ applies; therefore, for whom and which it may be enforced by regulatory and accreditation authorities.

† Types of preparations designated to be CSPs according to their physical forms, and their sites and routes of administration to patients.

† Compounding personnel must be meticulously conscientious to preclude contact contamination of CSPs both within and outside ISO Class 5 areas.

ORGANIZATION

† All compounding personnel shall be responsible for understanding fundamental practices and precautions within USP ⟨797⟩, for developing and implementing appropriate procedures, and for continually evaluating these procedures and the quality of final CSPs to prevent harm.

DEFINITIONS

† Twenty-eight terms are defined and integral to complying with USP ⟨797⟩.

RESPONSIBILITY OF COMPOUNDING PERSONNEL

† Practices and quality assurances required to prepare, store, and transport CSPs that are sterile, and acceptably accurate, pure, and stable.

CSP MICROBIAL CONTAMINATION RISK LEVELS

† Proper training and evaluation of personnel, proper cleansing and garbing of personnel, proper cleaning and disinfecting of compounding work environments, and proper maintenance and monitoring of controlled environmental locations (all of which are detailed in their respective sections).

Low-Risk Level CSPs

† Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and entries into any container.

† In absence of passing sterility test, store not more than 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in solid frozen state at −25° to −10° or colder.

† Media-fill test at least annually by compounding personnel.

Low-Risk Level CSPs with 12-Hour or Less BUD

† Fully comply with all four specific criteria.

‡ Sinks should not be located adjacent to the ISO Class 5 primary engineering control.

‡ Sinks should be separated from the immediate area of the ISO Class 5 primary engineering control device.

Medium-Risk Level CSPs

† Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs.

† In absence of passing sterility test, store not more than 30 hours at controlled room temperature, 9 days at cold temperature, and 45 days in solid frozen state at −25° to −10° or colder.

†Media-fill test at least annually by compounding personnel.

High-Risk Level CSPs

† Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization.

† Sterilization method verified to achieve sterility for the quantity and type of containers.

† Meet allowable limits for bacterial endotoxins.

† Maintain acceptable strength and purity of ingredients and integrity of containers after sterilization.

† In absence of passing sterility test, store not more than 24 hours at controlled room temperature, 3 days at cold temperature, and 45 days in solid frozen state at −25° to −10° or colder.

† Media-fill test at least semiannually by compounding personnel.

PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATIONS SKILLS

† Pass didactic, practical skill assessment and media-fill testing initially, followed by an annual assessment for a low- and medium-risk level compounding and semi-annual assessment for high-risk level compounding.

† Compounding personnel who fail written tests, or whose media-fill test vials result in gross microbial colonization, shall be immediately reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

IMMEDIATE-USE CSPs

† Fully comply with all six specified criteria.

APPENDICES

Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS

† Beyond-use date 28 days, unless specified otherwise by the manufacturer, for closure sealed multiple-dose containers after initial opening or entry.

† Beyond-use time of 6 hours, unless specified otherwise by the manufacturer, for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry.

† Beyond-use time of 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air.

† Storage of opened single-dose ampuls is not permitted.

HAZARDOUS DRUGS AS CSPs

† Appropriate personnel protective equipment.

† Appropriate primary engineering controls (BSCs and CACIs) are used for concurrent personnel protection and exposure of critical sites.

† Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.

† At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located.

† Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal.

† Hazardous drugs shall be prepared in an ISO Class 5 environment with protective engineering controls in place, and following aseptic practices specified for the appropriate contamination risk levels.

† Access to drug preparation areas shall be limited to authorized personnel.

† A pressure indicator shall be installed that can readily monitor room pressurization, which is documented daily.

† Annual documentation of full training of personnel regarding storage, handling, and disposal of hazardous drugs.

† When used, a CSTD shall be used in an ISO Class 5 primary engineering control device.

† At least 0.01 inch water column negative pressure is required for compounding of hazardous drugs.

‡ Negative-pressure buffer area is not required for low-volume compounding operations when CSTD is used in BSC or CACI.

† Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.

† Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations.

‡ Total external exhaust of primary engineering controls.

‡ Assay of surface wipe samples every 6 months.

RADIOPHARMACEUTICALS AS CSPs

† Positron Emission Tomography is according to USP chapter ⟨823⟩.

† Appropriate primary engineering controls and radioactivity containment and shielding.

† Radiopharmaceuticals compounded from sterile components, in closed sterile containers, with volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container shall be designated as and conform to the standards for low-risk level CSPs.

† Radiopharmaceutical vials, designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturers' recommendations.

† Location of primary engineering controls permitted in ISO Class 8 controlled environment.

† Technetium-99m/Molybdenum-99 generators used according to manufacturer, state, and federal requirements.

† Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD shall be prepared in a segregated compounding area.

† Materials and garb exposed in patient-care and treatment area shall not cross a line of demarcation into the segregated compounding area.

† Technetium-99m/Molybdenum-99 generators must be eluted in ISO Class 8 conditions.

† Segregated compounding area will be designated with a line of demarcation.

‡ Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.

ALLERGEN EXTRACTS AS CSPs

† Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels when certain criteria are met.

VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY

† Review labels and document correct measurements, aseptic manipulations, and sterilization procedures to confirm correct identity, purity, and strength of ingredients in, and sterility of, CSPs.

‡ Assay finished CSPs to confirm correct identity and, or, strength of ingredients.

‡ Sterility test finished CSPs.

Sterilization Methods

† Verify that methods achieve sterility while maintaining appropriate strength, purity, quality, and packaging integrity.

‡ Prove effectiveness by USP chapter ⟨71⟩, equivalent, or superior sterility testing.

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Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

Sterilization of High-Risk Level CSPs by Filtration

† Nominal 0.2-µm pore size sterile membranes that are chemically and physically compatible with the CSP.

† Complete rapidly without filter replacement.

† Subject filter to manufacturer's recommended integrity test (e.g., bubble point test) after filtering CSPs.

Sterilization of High-Risk Level CSPs by Steam

† Test to verify the mass of containers to be sterilized will be sterile after the selected exposure duration in the particular autoclave.

† Ensure live steam contacts all ingredients and surfaces to be sterilized.

† Pass solutions through a 1.2-µm or smaller nominal pore size filter into final containers to remove particulates before sterilization.

† Heated filtered air shall be evenly distributed throughout the chamber by a blower device.

† Dry heat shall only be used for those materials that cannot be sterilized by steam, when the moisture would either damage or be impermeable to the materials.

† Sufficient space shall be left between materials to allow for good circulation of the hot air.

† The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of dry heat sterilization shall be verified using appropriate biological indicators and other confirmation.

‡ The oven should be equipped with a system for controlling temperature and exposure period.

Depyrogenation by Dry Heat

† Dry heat depyrogenation shall be used to render glassware or containers, such as vials free from pyrogens as well as viable microbes.

† The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility.

† The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs).

‡ The bacterial endotoxin test should be performed on the ECVs to verify the cycle is capable of achieving a 3 log reduction in endotoxin.

ENVIRONMENTAL QUALITY AND CONTROL

Exposure of Critical Sites

† ISO Class 5 or better air.

† Preclude direct contact (e.g., touch and secretions) contamination.

ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas

† A buffer area is an area that provides at least ISO Class 7 air quality.

† New representations of facility layouts.

† Each compounding facility shall ensure that each source of ISO Class 5 environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.

† Devices (e.g., computers and printers) and objects (e.g., carts and cabinets) can be placed in buffer areas and shall be verified by testing or monitoring.

Viable and Nonviable Environmental Sampling (ES) Testing

† Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally when several conditions exist.

‡ The ES program should provide information to staff and leadership to demonstrate that the engineering controls are maintaining an environment within the compounding area that consistently maintains acceptably low viable and nonviable particle levels.

Environmental Nonviable Particle Testing Program

† Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used.

Total Particle Counts

† Certification that each ISO classified area (e.g., ISO Class 5, 7 and 8) is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer room or ante-area has been altered.

† Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results meeting ISO Class 5, 7, or 8 depending on the requirements of the area.

† All certification records shall be maintained and reviewed by supervising personnel or other designated employee to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour.

Pressure Differential Monitoring

† A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area.

† The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device.

† The pressure between the ISO Class 7 and general pharmacy area shall not be less than 5 Pa (0.02 inch water column (w.c.)).

† In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meter/second (40 fpm) between buffer area and ante-area.

Environmental Viable Airborne Particle Testing Program—Sampling Plan

† An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed.

† Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes).

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Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

† The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.

‡ It is recommended that compounding personnel refer to USP Chapter *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩ and the CDC Guidelines for Environmental Infection Control in Healthcare Facilities-2003 for more information.

Growth Media

† A general microbiological growth medium such as Soybean–Casein Digest Medium (also known as trypticase soy broth (TSB) or agar (TSA)) shall be used to support the growth of bacteria.

† Malt extract agar (MEA) or some other media that supports the growth of fungi shall be used in high-risk level compounding environments.

† Media used for surface sampling shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80).

Viable Air Sampling

† Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounding risk levels.

† Impaction shall be the preferred method of volumetric air sampling.

† For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities like staging, labeling, gowning, and cleaning.

† Locations shall include zones of air backwash turbulence within laminar airflow workbench and other areas where air backwash turbulence may enter the compounding area.

† For low-risk level CSPs with 12-hour or less BUD, air sampling shall be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment, during the certification of the primary engineering control.

‡ Consideration should be given to the overall effect the chosen sampling method will have on the unidirectional airflow within a compounding environment.

Air Sampling Devices

† The instructions in the manufacturer's user manual for verification and use of electric air samplers that actively collect volumes of air for evaluation shall be followed.

† A sufficient volume of air (400–1000 liters) shall be tested at each location in order to maximize sensitivity.

‡ It is recommended that compounding personnel also refer to USP Chapter ⟨1116⟩, which can provide more information on the use of volumetric air samplers and volume of air that should be sampled to detect environmental bioburden excursions.

Air Sampling Frequency and Process

† Air sampling shall be performed at least semiannually (i.e. every 6 months), as part of the re-certification of facilities and equipment for area where primary engineering controls are located.

† A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed.

‡ Any facility construction or equipment servicing may require the need to perform air sampling during these events.

Incubation Period

† The microbial growth media plates used to collect environmental sampling are recovered, covers secured (e.g., taped), inverted, and incubated at a temperature and for a time period conducive to multiplication of microorganisms.

† The number of discrete colonies of microorganisms shall be counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring need to be transformed into cfu/cubic meter of air and evaluated for adverse trends.

‡ TSA should be incubated at 35° ± 2 ° for 2–3 days.

‡ MEA or other suitable fungal media should be incubated at 28° ± 2 ° for 5–7 days.

Action Levels, Documentation and Data Evaluation

† Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment.

† Competent microbiology personnel shall be consulted if an environmental sampling consistently shows elevated levels of microbial growth.

† An investigation into the source of the environmental contamination shall be conducted.

‡ Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.

‡ Table titled, Recommended Action Levels for Microbial Contamination should only be used as a guideline

Facility Design and Environmental Controls

† Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.

† Compounding facilities shall provide a comfortable and well-lighted working environment, which typically includes a temperature of 20° or cooler to maintain comfortable conditions for compounding personnel when attired in the required aseptic compounding garb.

† Primary engineering controls provide unidirectional (i.e., laminar) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites.

† In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.

† Policies and procedures for maintaining and working within the primary engineering control area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities used during the preparation of the CSPs.

† The principles of HEPA-filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions.

† Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour.

† Buffer areas maintain 0.02- to 0.05-inch water column positive pressure, and do not contain sinks or drains.

† Air velocity from buffer rooms or zones to ante-areas is at least 40 feet/minute.

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Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

† The primary engineering controls shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation.

† The primary engineering controls shall be placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross-drafts.

† HEPA-filtered supply air shall be introduced at the ceiling.

† All HEPA filters shall be efficiency tested using the most penetrating particle size and shall be leak tested at the factory and then leak tested again in situ after installation.

† Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment.

† Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the room.

† Surfaces and essential furniture in buffer rooms or zones and clean rooms shall be nonporous, smooth, nonshedding, impermeable, cleanable, and resistant to disinfectants.

† The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate.

† The surfaces shall be resistant to damage by disinfectant agents.

† Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate.

† Ceiling tiles shall be caulked around each perimeter to seal them to the support frame.

† The exterior lens surface of ceiling lighting fixtures shall be smooth, mounted flush, and sealed.

† Any other penetrations through the ceiling or walls shall be sealed.

† The buffer area shall not contain sources of water (sinks) or floor drains. Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected.

† Carts shall be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility.

† Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable.

† Their number, design, and manner of installation the itmes above shall promote effective cleaning and disinfection.

‡ If ceilings consist of inlaid panels, the panels should be impregnated with a polymer to render them impervious and hydrophobic.

‡ Dust-collecting overhangs, such as ceiling utility pipes, or ledges, such as windowsills, should be avoided.

‡ Air returns should be mounted low on the wall creating a general top-down dilution of room air with HEPA-filtered make-up air.

Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas

† Primary engineering controls for nonhazardous and nonradioactive CSPs are located in buffer areas, except for CAIs that are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7.

† Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.

† Primary engineering controls shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.

† When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

† When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or a donor's white blood cells), the manipulations shall be clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific standard operating procedures in order to avoid any cross-contamination.

† Food, drinks, and items exposed in patient care areas, and unpacking of bulk supplies and personnel cleansing and garbing are prohibited from buffer areas or rooms.

† Demarcation designation between buffer areas or rooms and ante-areas.

† Antiseptic hand cleansing and sterile gloves in buffer areas or rooms.

‡ Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small- and large-volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA) when possible in an ante-area, of ISO Class 8 air quality, before being passed into the buffer areas.

Cleaning and Disinfecting the Sterile Compounding Areas

† Trained personnel write detailed procedures including cleansers, disinfectants, and non-shedding wipe and mop materials.

† Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.

† Trained compounding personnel are responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the DCAs written in the SOPs.

† Cleaning and disinfecting shall occur before compounding is performed. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water (for Injection or Irrigation) and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins.

† Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily.

† Dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies, using a method that does not degrade the ISO Class 7 or 8 air quality.

† Floors in ISO Class 7 and 8 areas are cleaned daily when no compounding occurs.

† IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs.

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Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

† Emptied shelving, walls, and ceilings in ante-areas are cleaned and disinfected at least monthly.

† Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs.

† Cleaning and disinfecting agents, their schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial and/or compounding personnel.

† All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, or ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal.

† If cleaning materials are reused (e.g., mops), procedures shall be developed (based on manufacturer recommendations) that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned.

† Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method.

† After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, and during this time the item shall not be used for compounding purposes.

† Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.

Personnel Cleansing and Garbing

† Personnel shall also be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs.

† Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, and cosmetics are prohibited from preparing CSPs.

† Compounding personnel shall remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck.

† Order of compounding garb and cleansing in ante-area: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown.

† Order of cleansing and gloving in buffer room or area: hand cleansing with a persistently active alcohol-based product with persistent activity; allow hands to dry; don sterile gloves.

† Routinely disinfect gloves with sterile 70% IPA after contacting nonsterile objects.

† Inspect gloves for holes and replace when breaches are detected.

† Personnel repeat proper procedures after they are exposed to direct contact contamination or worse than ISO Class 8 air.

† These requirements are exempted only for immediate-use CSPs and CAIs for which manufacturers provide written documentation based on validated testing that such personnel practices are not required to maintain sterility in CSPs.

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures

† Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel, multi-media instructional sources, and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures.

† This training shall be completed and documented before any compounding personnel begin to prepare CSPs.

† Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media-fill testing.

† Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding; and semiannually for high-risk level compounding.

† Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, shall be reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies.

† Compounding personnel shall pass all evaluations prior to resuming compounding of sterile preparations.

† Compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures in addition to didactic evaluation and aseptic media fill.

† Cleaning and disinfecting procedures performed by other support personnel shall be thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert.

† Support personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert.

Competency Evaluation of Garbing and Aseptic Work Practices

† Compounding personnel shall be evaluated initially prior to beginning compounding CSPs and whenever an aseptic media fill is performed using a Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel and the personnel glove fingertip sampling procedures.

Aseptic Work Practice Assessment and Evaluation via Personnel Glove Fingertip Sampling

† Monitoring of compounding personnel glove fingertips shall be performed for all CSP risk level compounding.

† Glove fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices.

† All personnel shall demonstrate competency in proper hand hygiene and garbing procedures in addition to aseptic work practices.

† Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing to assess garbing competency and after completing the media-fill preparation.

† Gloves shall not be disinfected with sterile 70% IPA immediately prior to sampling.

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Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

Garbing and Gloving Competency Evaluation

† Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures.

† The visual observation shall be documented on a Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel and maintained to provide a permanent record of and long-term assessment of personnel competency.

Gloved Fingertip Sampling

† Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator shall collect a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates by lightly pressing each finger tip into the agar.

† The plates shall be incubated for the appropriate incubation period and at the appropriate temperature.

† All employees shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use.

† After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel shall occur at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs.

† Gloves shall not be disinfected with sterile 70% IPA prior to testing.

† The sampled gloves shall be immediately discarded and proper hand hygiene performed after sampling. The nutrient agar plates shall be incubated as stated below.

† The cfu action level for gloved hands shall be based on the total number of cfu on both gloves and not per hand.

‡ Results should be reported separately as number of cfu per employee per hand (left hand, right hand).

Incubation Period

† At the end of the designated sampling period, the agar plates are recovered, covers secured, inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. Trypticase soy agar (TSA) with lecithin and polysorbate 80 shall be incubated at 35°± 2° for 2–3 days.

Aseptic Manipulation Competency Evaluation

† All compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the media-fill test procedure and subsequent annual or semiannual media-fill test procedures on the Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel.

Media-Fill Test Procedure

† The skill of personnel to aseptically prepare CSPs shall be evaluated using sterile fluid bacterial culture media-fill verification.

† Media-filled vials shall be incubated within a range of 35° ± 2° for 14 days.

Surface Cleaning and Disinfection Sampling and Assessment

† Surface sampling shall be performed in all ISO classified areas on a periodic basis and can be accomplished using contact plates and/or swabs and shall be done at the conclusion of compounding.

† Locations to be sampled shall be defined in a sample plan or on a form.

Cleaning and Disinfecting Competency Evaluation

† Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of performing cleaning and disinfecting procedures during initial personnel training on cleaning procedures, changes in cleaning staff and at the completion of any Media-Fill Test Procedure.

† Visual observation shall be documented on a Sample Form for Assessing Cleaning and Disinfection Procedures and maintained to provide a permanent record of, and long-term assessment of, personnel competency.

Surface Collection Methods

† Immediately after sampling a surface with the contact plate, the sampled area shall be thoroughly wiped with a non-shedding wipe soaked in sterile 70% IPA.

‡ Results should be reported as cfu per unit of surface area.

Action Levels, Documentation, and Data Evaluation

† Environmental sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment.

† If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.

† An investigation into the source of the contamination shall be conducted.

† When gloved fingertip sample results exceeds action levels after proper incubation, a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices shall be performed and documented.

‡ Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.

SUGGESTED STANDARD OPERATING PROCEDURES

† All facilities are required to have these, and they must include at least the items enumerated in this section.

FINISHED PREPARATION RELEASE CHECKS AND TESTS

Inspection of Solution Dosage Forms and Review of Compounding Procedures

† Review procedures and documents to ensure sterility, purity, correct identities and amounts of ingredients, and stability.

† Visually inspect for abnormal particulate matter and color, and intact containers and seals.

Sterility Testing

† High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized.

APPENDICES

Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

Bacterial Endotoxin (Pyrogen) Testing

† High-risk level CSPs, excluding those for inhalation and ophthalmic administration, prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized.

Identity and Strength Verification of Ingredients

† Written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs.

† Written procedures to ensure labels of CSPs contain correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration.

STORAGE AND BEYOND-USE DATING

Determining Beyond-Use Dates

† Use the general criteria in USP ⟨795⟩ in the absence of direct stability-indicating assays or authoritative literature that supports longer durations.

MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs

† Written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs.

Redispensed CSPs

† When sterility, and acceptable purity, strength, and quality can be ensured.

† Assignment of sterility storage times and stability beyond-use dates that occur later than those of originally dispensed CSPs must be based on results of sterility testing and quantitative assay of ingredients.

Packaging and Transporting CSPs

† Packaging maintains physical integrity, sterility, stability, and purity of CSPs.

† Modes of transport that maintain appropriate temperatures and prevent damage to CSPs.

PATIENT OR CAREGIVER TRAINING

† Multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs.

PATIENT MONITORING AND ADVERSE EVENTS REPORTING

† Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems.

‡ Adverse events and defects with CSPs reported to FDA's MedWatch and USP's MEDMARX programs.

Appendix II. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties[1]

		Chemical Category of Disinfectant					
		Isopropyl alcohol	**Accelerated hydrogen peroxide**	**Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)**	**Phenolics**	**Chlorine (e.g., sodium hypochlorite)**	**Iodophors (e.g., povidone-iodine)**
Concentration Used		**60–95%**	**0.5%[3]**	**0.4–1.6% aq**	**0.4–1.6% aq**	**100–5000 ppm**	**30–50 ppm**
Microbial Inactivation[2]	Bacteria	+	+	+	+	+	+
	Lipophilic viruses	+	+	+	+	+	+
	Hydrophilic viruses	±	+	±	±	+	±
	M.tuberculosis	+	+	±	+	+	±
	Mycotic agents (fungi)	+	+	+	+	+	±
	Bacterial Spores	–	–	–	–	+	–
Important Chemical & Physical Properties	Shelf life >1 week	+	+	+	+	+	+
	Corrosive or deleterious effects	±	–	–	–	±	±
	Non-evaporable residue	–	–	+	+	–	+
	Inactivated by organic matter	+	±	+	±	+	+
	Skin irritant	±	–	+	+	+	±
	Eye irritant	+	–	+	+	+	+
	Respiratory irritant	–	–	–	–	+	–
	Systemic toxicity	+	–	+	+	+	+

Key to abbreviation and symbols: aq = diluted with water; ppm = parts per million; + = yes; – = no; ± = variable results.

[1] Modified from World Health Organization, Laboratory Bio Safety Manual 1983 and Rutala WA, "Antisepsis, disinfection and sterilization in the hospital and related institutions," *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, DC, 1995, pages 227-245.

[2] Inactivation of the most common microorganisms (i.e., bacteria) occurs with a contact time of ≤1 minute; inactivation of spores requires longer contact times (e.g., 5-10 minutes for 5,000 ppm chlorine solution against *C. difficile spores*). *Reference: Perez J, Springthorpe VS, Sattar SA, "Activity of selected oxidizing microbicides against the spores of Clostridium difficile: Relevance to environmental control," American Journal of Infection Control, August 2005, pages 320-325.*

[3] *Accelerated* hydrogen peroxide is a new generation of hydrogen peroxide-based germicides in which the potency and performance of the active ingredient have been enhanced and accelerated through the use of appropriate acids and detergents.

Appendix III. Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel

Printed name and position/title of person assessed: _____

Name of facility or location: _____

Hand Hygiene and Garbing Practices: The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

_____ Presents in a clean appropriate attire and manner.
_____ Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into ante-areas.
_____ Brings no food or drinks into or stored in the ante-areas or buffer areas.
_____ Is aware of the line of demarcation separating clean and dirty sides and observes required activities.
_____ Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.
_____ Dons beard cover if necessary.
_____ Dons head cover assuring that all hair is covered.
_____ Dons face mask to cover bridge of nose down to include chin.
_____ Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.
_____ Dries hands and forearms using lint-free towel or hand dryer.
_____ Selects the appropriate sized gown examining for any holes, tears, or other defects.
_____ Dons gown and ensures full closure.
_____ Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly before donning sterile gloves.
_____ Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.
_____ Examines gloves ensuring that there are no defects, holes, or tears.
_____ While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.
_____ Removes PPE on the clean side of the ante-area.
_____ Removes gloves and performs hand hygiene.
_____ Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.
_____ Removes and discards mask, head cover, and beard cover (if used).
_____ Removes shoe covers or shoes one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and performs hand hygiene again. (Removes and discards shoe covers every time the compounding area is exited).

***The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.**

Signature of Person Assessed	Printed Name	Date
Signature of Qualified Evaluator	Printed Name	Date

Appendix IV. Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel

Printed name and position/title of person assessed: _____

Name of facility or location: _____

Aseptic Technique, Safety, and Quality Assurance Practices: The qualified evaluator checks each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

_____ Completes the Hand Hygiene and Garbing Competency Assessment Form.
_____ Performs proper hand hygiene, garbing, and gloving procedures according to SOPs.
_____ Disinfects ISO Class 5 device surfaces with an appropriate agent.
_____ Disinfects components/vials with an appropriate agent prior to placing into ISO Class 5 work area.
_____ Introduces only essential materials in a proper arrangement in the ISO Class 5 work area.
_____ Does not interrupt, impede, or divert flow of first-air to critical sites.
_____ Ensures syringes, needles, and tubing remain in their individual packaging and are only opened in ISO Class 5 work area.
_____ Performs manipulations only in the appropriate DCA of the ISO Class 5 device.
_____ Does not expose critical sites to contact contamination or worse than ISO Class 5 air.
_____ Disinfects stoppers, injection ports, and ampul necks by wiping with sterile 70% IPA and allows sufficient time to dry.
_____ Affixes needles to syringes without contact contamination.
_____ Punctures vial stoppers and spikes infusion ports without contact contamination.
_____ Labels preparation(s) correctly.
_____ Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations.
_____ Cleans, sets up, and calibrates automated compounding device (e.g., "TPN compounder") according to manufacturer's instructions.
_____ Disposes of sharps and waste according to institutional policy or recognized guidelines.

***The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.**

Signature of Person Assessed	Printed Name	Date
Signature of Qualified Evaluator	Printed Name	Date

Appendix V. Sample Form for Assessing Cleaning and Disinfection Procedures

Printed name and position/title of person assessed: _____

Name of facility or location: _____

Cleaning and Disinfection Practices: The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

Daily Tasks:

_____ Prepares correct concentration of disinfectant solution according to manufacturer's instructions.

_____ Uses appropriately labeled container for the type of surface to be cleaned (floor, wall, production bins, etc.).

_____ Documents disinfectant solution preparation.

_____ Follows garbing procedures when performing any cleaning activities.

_____ At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding in the following order: walls, IV bar, automated compounders, and work surface.

_____ Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.

_____ Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.

_____ Cleans all counters and easily cleanable work surfaces.

_____ Mops floors, using the mop labeled "floors," starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.

_____ In the ante-area, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.

Monthly Tasks:

_____ Performs monthly cleaning on a designated day. Prepares a disinfectant solution as stated in daily tasks that is appropriate for the surfaces to be cleaned.

_____ Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.

_____ Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.

_____ Cleans all buffer area totes and storage shelves by removing contents and using a germicidal detergent soaked lint free wipe, cleans the inside surfaces of the tote and then the entire exterior surfaces of the tote. Allows totes to dry. Prior to replacing contents into tote, wipes tote with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.

_____ Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint-free wipe to remove any disinfectant residue. Uses new wipe as needed.

_____ Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.

_____ Documents all cleaning activities as to who performed such activities with date and time noted.

***The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.**

Signature of Person Assessed	Printed Name	Date
Signature of Qualified Evaluator	Printed Name	Date

of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs.

"(6) The existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

"(7) The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.

"(8) The effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers."

§ 353a. Pharmacy compounding

(a) In general

Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

(1) is by—

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(i) the licensed pharmacist or licensed physician; and

(ii)(I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

A drug product may be compounded under subsection (a) of this section if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

(i) that—

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d) of this section;

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition

For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) Drug product

A drug product may be compounded under subsection (a) only if—

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State—

(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

(c) Advertising and promotion

A drug may be compounded under subsection (a) of this section only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

(d) Regulations

(1) In general

The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A) of this section, the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

(2) Limiting compounding

The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) of this section for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(e) Application

This section shall not apply to—

(1) compounded positron emission tomography drugs as defined in section 321(ii) of this title; or

(2) radiopharmaceuticals.

(f) "Compounding" defined

As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(June 25, 1938, ch. 675, § 503A, as added Pub. L. 105–115, title I, § 127(a), Nov. 21, 1997, 111 Stat. 2328.)

EFFECTIVE DATE

Section 127(b) of Pub. L. 105–115 provided that: "Section 503A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353a], added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act [Nov. 21, 1997]."

§ 353b. Prereview of television advertisements

(a) In general

The Secretary may require the submission of any television advertisement for a drug (including any script, story board, rough, or a completed video production of the television advertisement) to the Secretary for review under this section not later than 45 days before dissemination of the television advertisement.

(b) Review

In conducting a review of a television advertisement under this section, the Secretary may make recommendations with respect to information included in the label of the drug—

(1) on changes that are—

(A) necessary to protect the consumer good and well-being; or

(B) consistent with prescribing information for the product under review; and

(2) if appropriate and if information exists, on statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific population groups, including elderly populations, children, and racial and ethnic minorities.

(c) No authority to require changes

Except as provided by subsection (e), this section does not authorize the Secretary to make or direct changes in any material submitted pursuant to subsection (a).

(d) Elderly populations, children, racially and ethnically diverse communities

In formulating recommendations under subsection (b), the Secretary shall take into consideration the impact of the advertised drug on elderly populations, children, and racially and ethnically diverse communities.

(e) Specific disclosures

(1) Serious risk; safety protocol

In conducting a review of a television advertisement under this section, if the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved, the Secretary may require inclusion of such disclosure in the advertisement.

(2) Date of approval

In conducting a review of a television advertisement under this section, the Secretary

THE COMMITTEE ON ENERGY AND COMMERCE

November 12, 2012

MAJORITY MEMORANDUM

TO: Members, Subcommittee on Oversight and Investigations

FROM: Subcommittee on Oversight and Investigations Staff

RE: Hearing on "The Fungal Meningitis Outbreak: Could It Have Been Prevented?"

On Wednesday, November 14, 2012, at 10:00 a.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled "The Fungal Meningitis Outbreak: Could It Have Been Prevented?"

This hearing will examine the facts surrounding the recent outbreak of fungal meningitis and other infections linked to contaminated injectable products made and distributed by the New England Compounding Center (NECC) in Framingham, Massachusetts. This hearing will also examine the history of complaints associated with NECC and its affiliated entities as well as related inspections and actions taken by the U.S. Food and Drug Administration (FDA) and the Massachusetts Department of Public Health (MDPH).

I. WITNESSES

Panel One

Ms. Joyce Lovelace

Panel Two

Mr. Barry J. Cadden
President, Co-Owner and Director of Pharmacy
New England Compounding Center

Panel Three

The Honorable Margaret A. Hamburg, MD
Commissioner
U.S. Food and Drug Administration (FDA)

Dr. Lauren Smith, MD, MPH
Interim Commissioner
Massachusetts Department of Public Health (MDPH)

II. BACKGROUND – THE CURRENT OUTBREAK

This section of the memorandum details the facts surrounding the current outbreak and the investigation of the outbreak by State and Federal regulators. In Part III, the memorandum describes the history of Federal and State inspections of NECC and resulting regulatory actions since the Massachusetts Board of Registration in Pharmacy (MBP or Massachusetts Board of Pharmacy) approved the company's pharmacy license in 1998.

A. The Fungal Meningitis Outbreak

As of November 9, 2012, the Centers for Disease Control and Prevention (CDC) has confirmed that 32 people have died and 438 people have been sickened across 19 states after receiving contaminated injectable products made and distributed by NECC .

The first case of meningitis connected to this outbreak was confirmed on September 18, 2012, in Tennessee. On September 21, 2012, CDC was notified by the Tennessee Department of Health (TDH) of a patient with the onset of meningitis approximately 19 days after receiving an epidural steroid injection at an ambulatory surgical center in Nashville. By September 24, 2012, TDH officials contacted MDPH informing them that it was investigating an outbreak of fungal meningitis in six patients at the same Nashville facility, with onsets between July 30 and September 18, 2012. All six patients had received the same injectable steroid, preservative-free methylprednisolone acetate (80 mg/ml), compounded and distributed by NECC.

On September 25, 2012, CDC informed FDA of the situation and that three lots of methylprednisolone acetate were suspected. Methylprednisolone acetate is a type of injectable steroid suspension often used to treat pain and swelling. MDPH convened a multi-agency teleconference with CDC, FDA, and Tennessee officials. Mr. Barry Cadden and Mr. Gregory Conigliaro, principal owners of NECC, joined the call as well. Mr. Cadden and Mr. Conigliaro immediately provided documentation of all facilities that had received shipments from the three suspect lots of methylprednisolone acetate. On September 26, 2012, NECC instituted a voluntary recall of the suspect lots. In total, 17,676 doses had been shipped to customers in 23 states. More than 14,000 patients had already received a potentially contaminated injection. Based on surveillance efforts, CDC soon identified a patient in North Carolina displaying symptoms of meningitis after receiving an injection from one of the suspect lots.

From September 26, 2012, through October 5, 2012, investigators from FDA's New England District Office (FDA NWE-DO) and MDPH inspected the NECC facility. During their inspection, State and Federal investigators observed visible black particulate matter in sealed vials of purportedly sterile methylprednisolone acetate that had been returned to NECC. MDPH noted that NECC's records showed inconsistencies in sterilization processes. The Massachusetts Board of Pharmacy voted to obtain a voluntary surrender of NECC's license, which NECC

agreed to on October 3. NECC also agreed to a voluntary recall of all products intended for injection into the area around the spinal cord or brain. On October 4, FDA and MDPH confirmed that fungal contamination had been identified in a vial from one of the suspect lots. FDA and CDC recommended that all health care professionals cease use and remove any material produced by NECC from their facilities.[1] On October 6, NECC announced a voluntary recall of all NECC products currently in circulation. On October 8, Mr. Cadden and Mr. Glenn Chin[2] voluntarily ceased practice as pharmacists pending completion of the investigation.[3] In addition to the evidence of contamination, investigators also found evidence that the NECC had not been compounding drugs for patient-specific prescriptions. Instead, the NECC accepted patient lists generated by a clinical facility and provided to NECC for the purpose of obtaining its products. On October 16, agents from FDA's Office of Criminal Investigations, along with local authorities, raided the NECC Framingham, Massachusetts facility.

The MDPH and FDA also inspected two other companies owned by Barry Cadden, Ameridose, LLC (Ameridose) and Alaunus Pharmaceutical, LLC (Alaunus) on October 10, 2012, and October 14, 2012, respectively. NECC, Ameridose, and Alaunus share common ownership and corporate structures. Cadden is a co-owner of Ameridose, a pharmacy and wholesaler based in Westborough, Massachusetts, and Alaunus, a wholesaler located next to NECC in Framingham. Cadden, his wife, Lisa Conigliaro-Cadden, her brother, Gregory Conigliaro, and his wife, Carla Conigliaro, serve as directors of all three companies. Based on their shared ownership, MDPH requested that Ameridose and Alaunus cease all pharmacy operations and the manufacturing and distribution of any products. According to MDPH, Mr. Cadden agreed to immediately resign as manager, director and from any other management position at NECC, Ameridose, and Alaunus.

The FDA's investigation of the fungal meningitis outbreak has expanded beyond NECC's methylprednisolone acetate product. For example, FDA confirmed the report of a patient with meningitis-like symptoms potentially caused by epidural injection of a different NECC product, triamcinolone acetonide. In addition, one transplant patient developed a fungal infection after having been administered NECC-produced cardioplegic solution during surgery. Based on these reports, FDA announced that the sterility of any injectable drugs, including ophthalmic drugs that are injectable or used in conjunction with eye surgery, and cardioplegic solutions produced by NECC are of significant concern. FDA recommended that patients who received these products on or after May 21, 2012, be alerted to the potential risk of infection.

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[1] FDA subsequently released definitive laboratory confirmation of the presence of fungal contaminants in sealed vials of methylprednisolone acetate in two of the three suspected lots from NECC. As of November 3, 2012, testing of the third lot, as well as other NECC products, was ongoing.

[2] MDPH referred to Mr. Chin as a "leader[ ] at NECC" in its preliminary investigative report. MASS. DEP'T OF PUB. HEALTH, NEW ENGLAND COMPOUNDING CENTER (NECC) PRELIMINARY INVESTIGATION FINDINGS: BD. OF REGISTRATION IN PHARMACY REPORT, at 7 (Oct. 23, 2012) [hereinafter, "MDPH OCT. 23, 2012 REPORT"]. In a discussion with Committee staff, Mr. Chin's counsel stated that he started with the company on April 21, 2004 and was the compounding pharmacist in one of NECC's clean rooms until the company ceased operations.

[3] On October 22, 2012, MBP authorized MDPH staff to request voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, and Lisa Conigliaro-Cadden, as well as NECC. According to MDPH, in response to an inquiry from Committee staff on November 4, this process is ongoing.

FDA reported on October 31, 2012, that Ameridose was voluntarily recalling all of its unexpired products in circulation. While the investigation remained open at the time of the announcement, FDA stated that its preliminary findings raised sterility concerns. The agency further clarified that the recall was not based on reports of patients with infections associated with any Ameridose product.

On November 1, 2012, FDA and CDC released laboratory results that confirmed contaminants in two other NECC products: preservative-free betamethasone repository injection and cardioplegia solution. Bacteria were present in three separate lots of betamethasone and in a single lot of cardioplegia solution. CDC continues to investigate reports of potential infections in patients receiving NECC products. As of November 1, CDC had not received reports of laboratory-confirmed cases of infection due to bacteria present in betamethasone or cardioplegia solution from NECC.

B. Preliminary Findings Released by State and Federal Regulators Regarding the Outbreak

On October 23, 2012, MDPH issued a Board of Registration in Pharmacy Report setting forth its preliminary findings relating to the ongoing investigation into the outbreak.[4] In addition, on October 26, 2012, FDA released its inspectional observations as well as a corresponding Form FDA 483 (483) to NECC.[5]

As previously discussed, investigators from FDA NWE-DO and MDPH first visited the NECC facility in connection with this outbreak on September 26, 2012. According to MDPH, upon arriving at NECC, investigators found NECC employees cleaning sterile compounding areas. They also detected signs of bleach decontamination.[6] Despite NECC's apparent attempt to present the facility as compliant, State investigators still identified "serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk."[7]

During the facility inspections, MDPH documented numerous deficiencies and violations, including the following:

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[4] *See* MDPH OCT. 23, 2012 REPORT, *supra* note 2. MDPH noted that this report constitutes early findings that may be subject to revision as the investigation unfolds. *Id.* at 2.

[5] *See* U.S. FOOD & DRUG ADMIN., NEW ENGLAND COMPOUNDING CENTER FORM FDA 483 (Oct. 26, 2012), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM325980.pdf [hereinafter, "FDA OCT. 26, 2012 FORM 483"]. FDA issues a Form 483 at the end of an inspection when the investigators believe that the observed conditions or practices, in their judgment, may indicate violations of the Food, Drug, and Cosmetic Act or any related regulations. FDA has stated that its goal in issuing a 483 is to have the company act quickly to correct potential violations. The FDA considers the 483 along with an Establishment Inspection Report (EIR), prepared by FDA investigators, and any other information, including any responses received from the company. The agency then considers whether further action is appropriate.

[6] MDPH OCT. 23, 2012 REPORT, *supra* note 2, at 6.

[7] *Id.* at 2.

- NECC distributed large batches of compounded sterile products directly to facilities for apparent general use rather than requiring a prescription for an individual patient.[8]

- NECC distributed two of the recalled lots of methylprednisolone acetate prior to receiving results of sterility testing.[9]

- Final sterilization of product did not follow proper standards pursuant to United States Pharmacopeia Standard 797 (USP 797) and NECC's own Standard Operating Procedures.[10]

- NECC failed to test its autoclaves to ensure proper function.[11]

- Visible black particulate matter was seen in several recalled sealed vials of methylprednisolone acetate.[12]

- "Tacky" mats located outside the clean room were visibly soiled with assorted debris, violating USP 797.[13]

- A leaking boiler adjacent to the clean room had created a pool of water, an environment susceptible to contaminant growth.[14]

FDA investigators documented similar observations in the 483, as well as additional problems with NECC's ability to maintain its clean room and ensure the sterility of its products, as further supported by sample testing results. FDA's observations included the following:

- Eighty-three vials out of a bin containing 321 vials of methylprednisolone acetate from one of the suspect lots contained what appeared to be greenish black foreign matter. Seventeen vials from the same bin were observed to contain what appeared to be white filamentous material. Fifty of these vials were sent to an FDA laboratory for testing and all 50 tested positive for microbial contamination.[15]

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[8] *Id.* at 3.
[9] *Id.* at 4. MDPH noted that while NECC's records showed that the sterility tests found no contamination, the adequacy of NECC's sterility testing methods remained under examination.
[10] *Id.*
[11] *Id.* An autoclave is a device used to sterilize equipment by subjecting it to high pressure steam. If done properly, all bacteria and fungi would be inactivated.
[12] *Id.*
[13] *Id.* A clean room is an enclosed space that is designed and maintained to have a controlled environment with low levels of airborne particles and surface contamination. Production of sterile drug products in a properly functioning and maintained clean room reduces the risk of the introduction of microbial contamination into the drug during processing, including filling into its final container.
[14] *Id.* at 5.
[15] FDA OCT. 26, 2012 FORM 483, *supra* note 5, at 1.

- NECC provided no documentation or evidence to support that the autoclave used to sterilize suspensions formulated using non-sterile active pharmaceutical ingredients and raw materials was effective.[16]

- NECC is abutted to the rear by a recycling facility producing airborne particulates. NECC rooftop HVAC units were estimated to be located approximately 100 feet from the recycling facility.[17]

- NECC's air conditioning was turned off at night, including in the clean rooms, despite the importance of maintaining a consistent temperature and level of humidity.[18]

- NECC's own environmental monitoring program yielded violative levels of bacteria and mold in clean rooms used for the production of sterile drug products, between January 2012 and September 2012. Despite the company's action limits having been exceeded, there was no investigation conducted by the company, no identification of the isolates, no product impact assessments conducted, and no documented corrective actions taken to remove the microbial contamination from the facility.[19]

Further, according to Steven Lynn, Director of FDA's Office of Manufacturing and Product Quality, on an October 26, 2012, media call describing FDA's observations and test results, there was overgrowth of bacteria or fungi in at least one sample testing dish. When asked to clarify what he meant, Mr. Lynn stated, "Think of a plant just growing out of control."[20]

III. HISTORY OF STATE AND FEDERAL INVESTIGATIONS OF NECC

While investigating the meningitis outbreak over the last six weeks, FDA and MDPH investigators have observed many serious deficiencies and significant violations of law and good compounding practices. These violations, however, were not a first for NECC. Documents produced to the Committee by the FDA and the Massachusetts Board show that NECC has a long history of very similar, if not identical, underlying misconduct. Some of the violations observed by regulators as early as 2002 include the company's failure to maintain adequate safeguards for sterile injectable products – the very issue at the center of the current meningitis outbreak. In fact, since the company's formation, FDA conducted three prior series of inspections of NECC, each based on a separate set of allegations or events, issuing two Form 483s in 2002 and 2003 and one Warning Letter in 2006. The Massachusetts Board of Pharmacy has an even more extensive history with NECC. Prior to this outbreak, the Board had investigated at least twelve separate complaints concerning NECC or Mr. Cadden, issued at least

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[16] *Id.*
[17] *Id.* at 7.
[18] *Id.* at 1.
[19] *Id.*
[20] Media Call, U.S. Food & Drug Admin., FDA Media Call: Fungal Meningitis Outbreak – FDA Inspection Observations (Form 483) at NECC (Oct. 26, 2012) (statement of Steven Lynn, Dir., Office of Mfg. & Product Quality, Office of Compliance, Ctr. for Drug Evaluation & Research, FDA).

four advisory letters and/or informal reprimands, and entered into a consent agreement with the company in 2006.

Set forth below is the chronology of FDA's and the Massachusetts Board's inspections and involvement with the NECC, including any resulting administrative actions.

A. Formation of NECC

On May 12, 1998, MBP approved NECC's pharmacy license. Mr. Barry Cadden was listed as the managing pharmacist. Less than a year later, in April 1999, MBP filed a complaint against Mr. Cadden for providing a practitioner with blank prescription pads referring to NECC, in clear violation of MBP regulations.[21] The MBP Complaint Committee reviewed the complaint on October 19, 1999, and voted to issue an informal reprimand to Mr. Cadden and NECC and dismiss the case.

NECC's efforts to market its products were the subject of additional complaints starting in 2001. On June 27, 2001, MBP staff completed an investigation into a report submitted by the Idaho Board of Pharmacy that NECC was soliciting business for drug products which should have been discontinued by the manufacturer. In addition, on April 18, 2002, MBP received a letter from the Nevada Board of Pharmacy describing allegations of NECC selling non FDA-approved products to physicians in Nevada. Committee staff is unaware of any additional administrative or disciplinary actions taken as a result of these reports.

Further, based on various complaints of unprofessional conduct and failure to adhere to standards of practice between 2002 and 2004, MBP issued three advisory letters to Mr. Cadden and NECC on September 30, 2004. Each of the advisory letters addressed complaints made by out-of-state pharmacists or practitioners in Texas, South Dakota, Iowa, and Wisconsin. Each of these complaints related to NECC's solicitation of out-of-state prescriptions for office use. The three advisory letters issued by the Massachusetts Board stated that the letters did not constitute disciplinary action but communicated the Board's concern regarding the conduct that was the basis for the complaint. The letters requested that NECC adopt "quality assurance measures . . . to reduce the risk of recurrence."[22]

B. 2002 Inspections Related to Betamethasone Repository Injection

In March 2002, two adverse events were reported to FDA through its MedWatch system.[23] Both adverse events involved epidural betamethasone repository injections

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[21] 247 CMR § 9.01(1),(13).

[22] Advisory Letter from James T. Devita, President, Mass. Bd. of Registration in Pharmacy, to Barry Cadden, Manager of Record, New England Compounding Ctr. (Sept. 30, 2004) (Docket Nos. DS-03-060, PH-03-070 – Texas). *See also* Advisory Letter from James T. Devita, President, Mass. Bd. of Registration in Pharmacy, to Barry Cadden, Manager of Record, New England Compounding Ctr. (Sept. 30, 2004) (Docket Nos. DS-04-062, PH-04-161 – Iowa and Wisconsin) *and* Advisory Letter from James T. Devita, President, Mass. Bd. of Registration in Pharmacy, to Barry Cadden, Manager of Record, New England Compounding Ctr. (Sept. 30, 2004) (Docket Nos. DS-03-036, PH-03-042 – South Dakota).

[23] The investigative report corresponding to an April 16, 2002 FDA Form 483 states that FDA investigators contacted the MedWatch reporter who informed them that "a total of probably 5 incidents occurred after using

(betamethasone acetate and betamethasone sodium phosphate suspension 6 mg/ml), from the same lot compounded and distributed by NECC. Like methylprednisolone acetate, betamethasone repository injections are steroid solutions often used to treat pain and swelling. FDA alerted the MBP and invited them to participate in an inspection commencing April 9, 2002. FDA noted in its investigative report that the agency had no previous investigation or inspection history with the firm, though MBP had inspected NECC in the past.

While the investigation was underway, FDA investigators were informed of the fact that this was the same formulation compounded by a pharmacy in California that was associated with numerous hospitalizations (including five cases of meningitis, three of which were fatal) in Walnut Creek, California the previous year. Before detailing areas of concern and related discussions with NECC management, FDA's investigative report states, "Very similar operational problems existed with the California Compounding Pharmacy that were encountered with NEC[C]."[24]

On the day the inspection began, Barry Cadden was identified as the Owner and Director of Pharmacy at NECC. He identified his wife, Lisa Cadden, as Vice President and introduced her to investigators on the second day of the inspection. According to the report, Mr. Cadden stated that NECC had eight employees, three of whom were involved in compounding, though he was the only individual who compounded sterile product. He informed investigators that "they fill patient specific prescriptions only, and that they have no wholesale functions.[25]

According to FDA's inspection report, on the first day of the inspection, "Mr. Cadden was cooperative [and] supplied some documents. The second day of the inspection, Mr. Cadden had a complete change in attitude [and] basically would not provide any additional information either by responding to questions or providing records. Mr. Cadden challenged FDA jurisdiction/authority to be at his pharmacy."[26] FDA investigators were initially "allowed to review and were furnished with copies of records related to the compounding of Betamethasone Repository Injection," though by the second day, "Mr. Cadden stated that he was no longer willing to provide us with any additional records, unless we would identify the specific lot . . .

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subject Betamethasone on patients." U.S. FOOD & DRUG ADMIN., FDA INSPECTION REPORT OF NEW ENGLAND COMPOUNDING PHARMACY, INC., at 4 (Apr. 16, 2002) [hereinafter, "FDA APR. 16, 2002 INSPECTION REPORT"]. In a February 2003 presentation to MBP, FDA identified the adverse events as "dizziness, shortness of breath, diaphoresis, drop in blood pressure to 55/44." U.S. Food & Drug Admin., *Inspectional History of New England Compounding Center (NECC)*, Presentation to Bd. of Registration in Pharmacy, Div. of Health Professions Licensure, Dep't of Pub. Health, Commonwealth of Mass. (Feb. 5, 2003) [hereinafter, "Feb. 5, 2003 FDA Presentation"].

[24] FDA APR. 16, 2002 INSPECTION REPORT, *supra* note 23, at 3.

[25] *Id.* at 6.

[26] *Id.* at 2. Questions and discussion regarding issues related to FDA's jurisdiction and authority are addressed in detail later in this memorandum. With respect to the April 2002 inspection, the FDA investigative report cites § 704(a) of the FDCA, which describes the nature of FDA inspectional authority with regard to drug manufacturers, pharmacies, and other entities, and specifically excludes traditional retail pharmacies, operating in accordance with local pharmacy laws, from being obligated to furnish certain records. The report summarizes, that the investigators' inspectional authority at pharmacies operating in a retail capacity consists of being able to "enter, at reasonable times (Section 704(a)(1)(A), and inspect, at reasonable times, and within reasonable limits and in a reasonable manner (Section 704(a)(1)(b), the establishment and its equipment and operations. However, the owner of the pharmacy is not obligated to furnish records, as is normally the case when a facility that processes drug products is being inspected." *Id.*

that was the focus of this investigation. Since we had been specifically directed by [FDA's Office of Compliance in the Center for Drug Evaluation and Research (CDER)] not to divulge this lot number, we were not in a position to comply with Mr. Cadden's request. From this point on, no additional records were provided or collected."[27]

Nonetheless, FDA investigators had managed to obtain a printout of the betamethasone products compounded by NECC in 2002 and identified the suspect lot on the list, which according to the lot number was compounded on February 1, 2002. Mr. Cadden informed FDA that there were no compounding records associated with the suspect lot number. According to FDA's report, Mr. Cadden stated that he did not believe betamethasone was ever compounded for that lot number, although FDA noted that Mr. Cadden "could not provide any documents to support his belief, such as a cancelled lot etc."[28] Further, FDA investigators contacted the healthcare professional who reported the adverse events to confirm that the suspect lot existed. That individual informed FDA that he had returned the betamethasone product to NECC and, in fact, had spoken by telephone to Mr. Cadden about the incident.[29]

While FDA's investigative report did not mention any test results of the suspect lot in question, the MBP report stated, "The FDA was concerned regarding a specific date the Batch of Betamethasone Repository 6mg/ml was compounded. The error was first reported in March 2002. The unnamed facility conducted sterility and Endotoxin tests on the product prepared by NECC, the results indicated a positive test for Endotoxin."[30] While FDA did not include this specific test result in its investigative report, FDA did discuss other positive endotoxin test results of betamethasone samples from NECC lots.

According to the FDA report, on April 9, 2002, "Mr. Cadden stated on/about 3/19/02 through 4/6/02 he received ARL [(Analytical Research Laboratories)] results positive for endotoxin (greater than 100 ppb). . . . He stated these lots (about 4 lots total) were awaiting disposal at his facility."[31] After changing the suspending agent based on research he conducted, Mr. Cadden informed investigators that he made an additional lot on April 6, 2002. He stated that he "sent his samples to ARL, then left the product beaker covered with aluminum foil on the magnetic stirrer in the hood awaiting lab results" and that it "could take anywhere from seven to ten days to obtain lab results."[32] When questioned about this practice, "Mr. Cadden stated he didn't want to waste the money on vials or the effort in transfilling the vials if the 4/6/02 lot failed testing. He stated he would transfill the vials upon receiving satisfactory lab results."[33] FDA investigators "discussed with Mr. Cadden that this was not an acceptable process for maintaining product sterility."[34] When FDA investigators returned to NECC on April 10, "the

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[27] *Id.* at 3.
[28] *Id.* at 4.
[29] *Id.*
[30] MASS. DEP'T OF PUB. HEALTH, INVESTIGATION REPORT OF NEW ENGLAND COMPOUNDING CENTER & BARRY CADDEN, at 5 (Mar. 4, 2004) [hereinafter, "MDPH MAR. 4, 2004 INVESTIGATION REPORT"].
[31] FDA APR. 16, 2002 INSPECTION REPORT, *supra* note 23, at 7. Analytical Research Laboratories (ARL) is a third-party analytical testing lab located in Oklahoma City, Oklahoma that NECC has sent samples to for sterility and endotoxin testing since at least 2002.
[32] *Id.*
[33] *Id.*
[34] *Id.*

hood was clean and Mr. Cadden was asked the whereabouts of the 4/06/02 lot. He stated he received negative lab results the night before, and had transfilled the lot into vials that morning. He accredited the positive endotoxins to the previous suspending agent."[35] FDA did not comment on this assertion, nor is it known how long Mr. Cadden had been using the previous suspending agent. According to the report, "The FDA investigator suggested to Mr. Cadden that he retest the 4/6/02 lot again after transfilling the vials since the product sat in a beaker for 5 days," which he agreed to do.[36]

After completing the inspection, FDA investigators concluded that "[d]ue to jurisdiction/confidentiality restrictions, this FDA investigation could not proceed to any definitive resolution of issues raised in the [FDA] Headquarters assignment" and that individuals in CDER's Office of Compliance "were fully informed of problems/barriers that were encountered throughout the inspection."[37] FDA's investigative report was finalized on April 16, 2002. Prior to concluding the investigation, FDA investigators spoke with officials in CDER's Office of Compliance and FDA NWE-DO about NECC's "poor practices and areas of concern" and "impressed upon [them] that due to limitations on information gathering and access to records, the FD-483 observations could not/would not be supported with documentation."[38] Nonetheless, "FDA Investigators were directed to issue the 483 (even in light of the lack of documentation)."[39] The observations in the 483 focused primarily on two violations: the sterility of the betamethasone product and NECC's failure to account for records related to the suspect lot of betamethasone, which subsequently tested positive for endotoxin.[40]

After issuing the 483, Mr. Cadden was given an opportunity to respond to FDA investigators' observations during an exit interview. With regard to the sterility of the beaker, and keeping the solution in the beaker for seven to ten days while waiting for test results, Mr. Cadden claimed that this was not his usual practice.[41] FDA's report also indicated that Mr. Cadden provided contradictory information to the agency. During the exit interview, Mr. Cadden claimed that the beaker capped with foil "didn't contain the betamethasone repository."[42]

The report completed by the Massachusetts Board substantiated FDA's observations about NECC's practices. Specifically, it noted that the beaker remained in the hood capped with foil while tests were conducted, a process which could take up to seven days.[43]

In February 2003, following the April 2002 inspections with FDA, the MBP filed formal complaints against NECC and Mr. Cadden "based on the failure to adhere to standards of practice for compounding prescriptions. Specifically, the pharmacy and pharmacist engaged in unprofessional conduct as exhibited by[:] failing to follow guidelines, sterility procedures, record

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[35] *Id.*
[36] *Id.*
[37] *Id.* at 5.
[38] *Id.*
[39] *Id.*
[40] *See* U.S. FOOD & DRUG ADMIN., NEW ENGLAND COMPOUNDING PHARMACY, INC. FORM FDA 483 (Apr. 16, 2002) [hereinafter, "FDA APR. 16, 2002 FORM 483"].
[41] *See* FDA APR. 16, 2002 INSPECTION REPORT, *supra* note 23, at 10.
[42] *Id.*
[43] *See* MDPH MAR. 4, 2004 INVESTIGATION REPORT, *supra* note 30, at 6.

keeping requirements, [and] batch records [requirements], [and] failing to provide certificates of analysis, proof of sterility testing, Endotoxin test results, batch numbers and prescriptions upon request."[44]

On February 7, 2003, the MBP investigator requested that NECC provide responses to certain questions raised during the investigation. Documents produced to the Committee show that the Massachusetts Board found that NECC took certain corrective measures in February 2003, including hiring a consultant to develop policy and procedures.[45] The MBP subsequently conducted follow-up inspections on February 20, 2003, and one year later on February 20, 2004. According to the MBP report, the investigator found the facility was in compliance.[46] Even so, the MBP investigator recommended that the Board issue a formal reprimand to NECC. According to the report, which was signed by the investigator and her supervisor on March 4, 2004, the investigator based her decision on NECC's "history as it relate[d] to prior concerns of the Board agents since 1999[.]"[47]

One particular concern, which was raised between the investigator's April 2002 inspections with FDA and her recommendation for formal reprimand, may have informed her decision. In October 2002, FDA investigators informed the MBP that a second incident with NECC had occurred, this one involving methylprednisolone acetate.[48]

C. 2002 Inspections Related to Methylprednisolone Acetate

On October 2, 2002, CDER's Office of Compliance requested an FDA NWE-DO investigation to obtain information regarding three MedWatch reports associated with the use of methylprednisolone acetate that was compounded by NECC in May 2002. According to FDA's investigative report, the three MedWatch reports were reported by a physician and the chief pharmacist at a hospital in Rochester, New York and detailed adverse events that occurred in two patients on July 17, 2002, after they had received inrathecal injections. After speaking with hospital staff, FDA documented that both patients were hospitalized with meningitis-like symptoms, received antibiotics, and fully recovered. Hospital staff reported that the vials from the same lot distributed by NECC were tested at the hospital and confirmed positive for bacteria. When asked about actions taken by the hospital, the hospital's chief pharmacist stated that he "instructed his staff to remove all the methylprednisolone acetate injectable with the affected lot number from the hospital floors."[49] The hospital's quality assurance supervisor stated that she first contacted Mr. Cadden on or about July 23, 2002, "to make him aware of the adverse events."[50] She informed the FDA investigator that "she does not believe [the hospital] returned any of the vials to NECC" and that "[s]he believes they were all retained for FDA sampling and hospital investigative purpose."[51]

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[44] *Id.* at 4.
[45] *Id.* at 6.
[46] *See id.* at Attachment 1.
[47] *Id.* at 9.
[48] *Id.* at 7.
[49] U.S. FOOD & DRUG ADMIN., FDA INSPECTION REPORT OF NEW ENGLAND COMPOUNDING CENTER, at 4 (Feb. 10, 2003) [hereinafter, "FDA FEB. 10, 2003 INSPECTION REPORT"].
[50] *Id.* at 5.
[51] *Id.*

On September 9, 2002, FDA's New York District Office collected a sample from the hospital, purportedly from the suspect lot. The sample was then sent to FDA's Northeast Regional Lab (NRL) for sterility and endotoxin testing. However, according to FDA's report, NRL "was unable to perform the sample analysis until 4 days after the compounded product's expiration date" and the sample collected from the hospital was from "a different lot than the MedWatch reports."[52]

FDA and MBP investigators first visited NECC in relation to the adverse events associated with methylprednisolone acetate on October 24, 2002. FDA's investigation report noted that FDA last inspected NECC in April 2002 and a 483 was issued to Mr. Cadden citing "sterility issues pertaining to the transfilling practices for betamethasone repository injection."[53] The report further stated that "[t]he practices that were cited on the previous FDA 483 were not in place and therefore the correction of these items was not an issue" during the current inspection.[54] The report also highlighted the fact that since April 2002, NECC's operating space approximately doubled in size and it was now "planning on marketing and selling compounded products in all 50 U.S. states per Mr. Cadden." [55]

Mr. Cadden informed the FDA inspector that he had been "telephoned by an employee from [the Rochester hospital] to notify him of the adverse reactions" and that the employee "told him the adverse reactions were due to 'administration errors' since the injections were administered intrathecally."[56] According to FDA's investigator, Mr. Cadden stated that the hospital had in fact "returned vials of the affected product to the firm and that NECC sent a sample of the returned product to its contract laboratory [ARL] for testing."[57] The test results, which were reported to the FDA investigator on August 22, 2002, came back negative for endotoxin content and microbial contamination.

On December 11, 2002, FDA NRL informed FDA NWE-DO that four out of fourteen of the vials it sampled from the lot provided by the New York District Office tested positive for bacteria. On December 12, FDA and MBP investigations returned to NECC with the test results to "determine what his intentions would be regarding the compounded product."[58] Mr. Cadden informed them that "NECC had conducted a recall of the product in August 2002,"[59] a fact that he failed to share with the investigators during the October 24 inspection. When asked about details of the recall, Mr. Cadden stated that he had "received 500-600 vials back from customers as a result of the recall. He retested one (1) of these vials for sterility and endotoxin and the results were negative."[60] The inspectors were understandably concerned that this was not a

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[52] *Id.*
[53] *Id.* at 3.
[54] *Id.* at 1.
[55] *Id.* at 3.
[56] *Id.* at 7.
[57] *Id.*
[58] *Id.* at 8.
[59] *Id.*
[60] *Id.*

representative sample and explained to Mr. Cadden that "the USP contains guidance on sample sizes in relation to lot quantities."[61]

While at the firm on December 12 and again on December 18, 2002, inspectors collected samples of methylprednisolone acetate as well as betamethasone repository injection. According to FDA's report, "[t]hese compounds were chosen because they were associated with the current and April 2002 MedWatch reports" and are "compounded by similar methods according to Mr. Cadden."[62] One FDA investigator returned to NECC on January 14 and 15, 2003. Mr. Cadden notified him that "if [he] had any other requests or questions pertaining to any of their procedures and compounding activities, [he] was to put [his] requests or questions in writing."[63] According to the investigator, Mr. Cadden brought this up when the investigator "requested the address and name of customers who received [the suspect lot of] methylprednisolone . . . [acetate] injection. . . ."[64] The investigator followed up after the inspection with a written request for the names and customers. Neither Mr. Cadden nor his lawyer chose to respond to the written request and still had not done so when, weeks later on February 10, 2003, the FDA issued NECC a 483 that detailed concerns observed during the inspections.[65]

On February 5, 2003, prior to FDA's issuance of the Form 483 to NECC, a meeting was convened with officials from FDA NWE-DO, CDER's Office of Compliance, and MBP in order to "review the inspectional history of the New England Compounding Center and develop a joint strategy for achieving safe compounding practices at the firm."[66] The immediate concern was determining how to ensure the outstanding violative betamethasone was removed from commerce. Asserting its authority under section 501(b) of the FDCA, FDA discussed its ability to seize the adulterated lot that "is still within expiry."[67] While NECC did ultimately agree to a voluntary recall, officials also discussed alternative courses of action they should consider. CDER officials "reminded everyone that in a similar situation with a South Carolina compounding pharmacy, FDA issued a press release when the firm failed to take recall action in a timely manner."[68] Based on a PowerPoint slide deck attached to an FDA memorandum describing the February 5, 2003, meeting, it is clear that FDA was discussing a fungal meningitis outbreak that had occurred a few months prior in South Carolina associated with methylprednisolone acetate compounded by a facility in Spartanburg, South Carolina, which ultimately resulted in two deaths.[69]

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[61] *Id.* Mr. Cadden informed investigators on December 18, 2002, in a related discussion about sample sizes, that he "used the recommendations of his contract laboratory (ARL)." *Id.* at 9.
[62] *Id.* at 8.
[63] *Id.* at 11.
[64] *Id.*
[65] *See id.*
[66] Memorandum from Kristina Joyce, Consumer Safety Officer, New England Dist. Office, FDA & Mark Lookabaugh, Compliance Officer, New England Dist. Office, FDA, to Central File, *February 5, 2003 Meeting with Massachusetts Board of Pharmacy/Division of Professional Licensure (239 Causeway Street, Boston, MA 02114)*, at 1 (Feb. 24, 2003) [hereinafter, "Feb. 24, 2003 FDA Memorandum"].
[67] *Id.* at 2.
[68] *Id.*
[69] *See* Feb. 5, 2003 FDA Presentation, *supra* note 23, at 7-8. *See also* David Brown, *Previous Fungal Meningitis Outbreak a Decade Ago Resulted in No Oversight Changes*, WASH. POST (Nov. 5, 2012), http://www.washingtonpost.com/national/health-science/previous-fungal-meningitis-outbreak-a-decade-ago-resulted-in-no-oversight-changes/2012/11/05/8417d84e-1fa8-11e2-9cd5-b55c38388962_story.html.

At this point, "[a] discussion was held to decide if NECC should be considered a manufacturer or a compounder," which would govern how to handle the betamethasone recall, but also inform ways to address "NECC's poor compounding practices [that] would not necessarily be ultimately resolved by such an action."[70] It was decided that "current findings supported a compounding role" and that "the state would be in a better position to gain compliance or take regulatory action against NECC as necessary."[71] It is noteworthy that after closing out the inspection report by issuing the 483 and convening this meeting with State officials, FDA's primary NECC investigator and her supervisor recommended that the "firm be prohibited from manufacturing until they can demonstrate ability to make product reproducibly and dependably."[72] They further noted that if the State was "unwilling to take action, [they] recommend[ed the] firm be enjoined for GMP deficiencies."[73]

With respect to next steps, it was agreed that the State would ask Mr. Cadden "to appear before the Board of Pharmacy to answer to the current complaints."[74] MBP counsel Susan Manning discussed the fact that "Massachusetts pharmacy law states that pharmacists must act in accordance with USP recommendations" and that "this alone would imply he could be held to those standards by the state."[75] In addition, she stated that "although the state's authority does not include the ability to fine pharmacists, the state is able to take actions against a pharmacy's license, including revocation and suspension."[76] It was agreed that CDER's Office of Compliance "would work on documenting the deviations from USP standards for the state."[77] Furthermore, among other things, the State requested from FDA examples of previous consent agreements and MedWatch reports regarding adverse events from products compounded by NECC.[78]

The February 5, 2003, meeting concluded by FDA "emphasizing the potential for serious public health consequences if NECC's compounding practices, in particular those relating to sterile products, are not improved."[79] FDA acknowledged that "so long as a pharmacy's operations fall within the scope of the practice of pharmacy (as outlined in FDA's Compliance Policy Guide 460.200), FDA will generally continue to defer to state authorities for regulatory oversight. In such cases FDA will seek to engage cooperative efforts aimed at achieving regulatory compliance and ensuring the safety and quality of compounded products."[80]

On February 10, 2003, FDA issued a Form 483 to NECC and met with Mr. Cadden to review the documented observations, which included inadequate documentation to verify whether sterile drug products met set standards, a failure to maintain complaint files, and a lack

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[70] Feb. 24, 2003 FDA Memorandum, *supra* note 66, at 2.
[71] *Id.*
[72] U.S. FOOD & DRUG ADMIN., FDA ESTABLISHMENT INSPECTION REPORT OF NEW ENGLAND COMPOUNDING CENTER, at 1 (Feb. 10, 2003) [hereinafter, "FDA FEB. 10, 2003 ESTABLISHMENT INSPECTION REPORT"].
[73] *Id.*
[74] Feb. 24, 2003 FDA Memorandum, *supra* note 66, at 3.
[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] *See id.*
[79] *Id.*
[80] *Id.* at 3-4.

of documentation for the reported adverse events associated with the suspect lot of methylprednisolone acetate.[81] In addition, FDA noted in the corresponding inspection report that results from the samples investigators collected from NECC "revealed that the firm has sterility and potency issues with injectable steroid suspensions (betamethasone repository USP and methylprednisolone acetate USP)."[82] During the meeting, Mr. Cadden was informed that "at this point the FDA is considering NECC a pharmacy compounder and not a drug manufacturer."[83]

On February 26, 2003, Mr. Cadden responded in writing to the 483 detailing a variety of corrective measures. He stated, "We are committed to complying with applicable laws and regulations, to ensuring high-quality care for our patients, and to upgrading our compounding procedures."[84] This letter was supplemented on May 16, 2003, detailing additional standard operating procedures that were being implemented at the facility related to compounding, as well as product and environmental testing protocols. Mr. Cadden noted "that while we are validating NECC sterile [injectable] preparation processes, we are not subject to (nor are we voluntarily subjecting ourselves to) current good manufacturing practices (cGMPs) as promulgated by FDA, since we are a compounding pharmacy, not a manufacturer."[85]

With respect to Massachusetts, the MBP did not commence any regulatory actions until well over a year later, on September 21, 2004, when the Board voted unanimously in favor of proposing a consent agreement to NECC and Mr. Cadden to resolve the aforementioned complaints received and violations observed. Then-Executive Director of the MBP, Charles Young, formally offered Mr. Cadden the consent agreement on October 4, 2004, noting in a letter "that if you choose not to enter into the Agreement, the Board will proceed to a formal hearing."[86]

According to the terms of the proposed consent agreement, NECC would have to agree that it was entered into "as a result of an adverse event complaint report investigated by the U.S. Food and Drug Administration" alleging that NECC "failed to comply with accepted standards in compounding a certain order for methylprednisolone acetate."[87] In addition, NECC would agree that this conduct "constitutes professional misconduct warranting disciplinary action by the Board" and that NECC and Mr. Cadden would be "REPRIMANDED by the Board and [NECC's] pharmacy registration and [Mr. Cadden's] pharmacist license [would be] placed on

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[81] *See* U.S. FOOD & DRUG ADMIN., NEW ENGLAND COMPOUNDING CENTER FORM FDA 483 (Feb. 10, 2003) [hereinafter, "FDA FEB. 10, 2003 FORM 483"].
[82] FDA FEB. 10, 2003 ESTABLISHMENT INSPECTION REPORT, *supra* note 72, at 1.
[83] FDA FEB. 10, 2003 INSPECTION REPORT, *supra* note 49, at 20.
[84] Letter from Barry Cadden, Manager, New England Compounding Center, Inc., to Daryl A. Dewoskin, Investigator, FDA & Kristina M. Joyce, Investigator, FDA (Feb. 26, 2003) [hereinafter, "Feb. 26, 2003 Cadden Letter"].
[85] Letter from Barry Cadden, Manager, New England Compounding Center, Inc., to Daryl A. Dewoskin, Investigator, FDA & Kristina M. Joyce, Investigator, FDA (May 16, 2003) [hereinafter, "May 16, 2003 Cadden Letter"].
[86] Letter from Charles R. Young, Executive Dir., Mass. Bd. of Registration in Pharmacy, to Barry J. Cadden, Manager of Record, New England Compounding Ctr. (Oct. 4, 2004) (attaching proposed Consent Agreement).
[87] Proposed Consent Agreement, *In the Matter of New England Compounding Center Registration No. 2848 Barry J. Cadden, R.Ph. License No. 21239*, Docket Nos. DS-03-055, PH-03-066, at 1 (Mass. Bd. of Registration in Pharmacy, Oct. 4, 2004) [hereinafter, "MPB Proposed Consent Agreement"].

probation for a minimum three (3) year period."[88] During the probationary period, among other things, NECC and Mr. Cadden would have been required to develop and implement various policies and procedures, update the Board on a quarterly basis, and keep written reports of each adverse event reported.[89] Finally, the agreement would have required NECC and Mr. Cadden to apply in writing for termination of the probationary period, which would be granted only if all the conditions had been met.[90]

On November 11, 2004, counsel for NECC and Mr. Cadden responded to MBP's offer of the consent agreement. Similar to the company's prior responses to FDA, the letter, addressed to MBP counsel Susan Manning detailed the various corrective measures that NECC had implemented and noted that they "address –and in some instances exceed – the proposed probationary conditions."[91] After noting subsequent inspections that had been conducted "without incident," NECC's counsel stated, "While I think it is fair to say that the product of NECC's interaction with the Board . . . is a success story, such would not be the case if the resolution were to include a disciplinary sanction (including the reprimand proposed in Mr. Young's letter). The collateral consequences to many, if not all of NECC's 42 other [state] licenses, would be potentially fatal to the business. Such a catastrophe is clearly not the intended result of the Board's proposed reprimand, nor is it warranted in this case. The Board's mandate is to protect the public health safety and welfare, not to punish its licensees."[92] In conclusion, the attorney stated, "Mr. Cadden and NECC have demonstrated their commitment to remediation, and are prepared to continue to do so. In that regard, NECC and Mr. Cadden will agree to all of the probationary terms offered in Mr. Young's letter, and will further agree to bear the burden and cost of monitoring and reporting their compliance. That result could be accomplished through a non-disciplinary resolution such as a continuance (pending a period of monitoring) or a 'stayed probation.'"[93] On November 23, 2004, the MBP reviewed the "NECC response to [the] proposed Consent Agreement" and voted unanimously "to deny [the] request to revise terms."[94]

Despite the October 4, 2004, letter stating that if NECC and Mr. Cadden chose not to enter into the consent agreement, the Board would proceed to a formal hearing, there is no documentation of any such hearing having occurred. However, on January 6, 2006, NECC and Mr. Cadden did sign a consent agreement with MBP, though the terms were significantly different from those proposed by the Board in 2004. As set forth in the next section of this memorandum, NECC and the Massachusetts Board eventually agreed to only a stayed probationary period of one year.

D. 2004 Inspections and the 2006 Massachusetts Board Consent Agreement with NECC

As evidence that MBP was aware of NECC's corrective measures and disciplinary action was unwarranted, NECC's counsel pointed out in his November 11, 2004, response letter that

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[88] *Id.* at 1-2.
[89] *Id.* at 2.
[90] *Id.*
[91] Letter from Paul R. Cirel, Counsel to Barry Cadden & New England Compounding Ctr., to Susan Manning, Counsel to Mass. Bd. of Registration in Pharmacy, at 1 (Nov. 11, 2004) [hereinafter, "Nov. 11, 2004 Cirel Letter"].
[92] *Id.* at 2-3 (internal citations omitted).
[93] *Id.* at 3 (internal citations omitted).
[94] Minutes of the Meeting of the Mass. Bd. of Registration in Pharmacy, at 2 (Nov. 23, 2004).

MBP had "inspected the facility three times since last February (twice, with a representative from the FDA)."[95] However, the two inspections with FDA were not to follow up on the underlying complaints and violations covered in the proposed consent agreement, but were to investigate new allegations. Further, these inspections revealed additional violations by NECC.

On April 27, 2004, MBP had received a complaint from a Wisconsin pharmacist that raised concerns about the safety and legality of a product NECC was soliciting. According to the complaint, an NECC representative offered "a product to our plastic surgery physician that he calls extra strength triple anesthetic cream."[96] During the conversation, NECC "related to [the individual] that he would need a prescription for the product and that we could use the name of a staff member if we wanted to. He said 'other institutions have used a nurse[']s name."[97] When questioned about the legality of this approach, "He assured her it was legal. He indicated that after we received the product it was up to us how we used it and to whom it was administered."[98] Separate from this complaint, MBP received "an e-mail sent to the Board by a pharmacist practicing in Iowa. According to the complaint . . . [NECC] is advertising compounded prescription products which may constitute manufacturing since they purport to be used by multiple patients using the same prescription order."[99]

On September 21, 2004, MBP assigned an investigator to "conduct a joint/inspection with FDA . . . It is alleged that [NECC] is compound[ing] non-FDA product Trypan Blue Dye to be used as a capillary stain during cardiac procedures. This dye is not approved for this use."[100] On September 23, 2004, investigators from MBP and FDA NWE-DO visited NECC. According to a January 26, 2005, memorandum drafted by the FDA investigator, "This investigation was mainly to obtain information about the firm's compounding practices, as they relate to the compounding of Trypan blue products."[101] When investigators arrived, Mr. Cadden "acknowledged that he is the most responsible person in the firm" but also introduced them to Gregory Conigliaro who "reported that he just joined the company about eight months ago [and] that he is a Civil Engineer by profession."[102]

When FDA's investigator asked Mr. Cadden whether he had Trypan blue in stock, "He said no, because he just compounds the drug if he receives the prescriptions for certain patients."[103] However, when the FDA investigator was shown the clean room, he noticed a drawer that was identified as "Trypan Blue." He requested that Mr. Cadden open the drawer and when he did, the investigator noted that there were 189 vials of the product. After being

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[95] Nov. 11, 2004 Cirel Letter, *supra* note 91, at 2.The letter lists three inspection dates: February 20, 2004, September 23, 2004, and September 28, 2004. The letter further notes that the second and third inspections included a "representative from the FDA."
[96] E-mail from Wisconsin Dir. of Pharmacy, to James D. Coffey, Dir., Mass. Bd. of Registration in Pharmacy (Apr. 27, 2004, 11:33 AM).
[97] *Id.*
[98] *Id.*
[99] Mass. Div. of Prof'l Licensure Office of Investigations, *Request for Staff Assignment* (requested May 27, 2004).
[100] Mass. Div. of Prof'l Licensure Office of Investigations, *Request for Staff Assignment* (assigned Sept. 21, 2004).
[101] Memorandum from Investigator, New England Dist. Office, FDA, to Acting Team Leader, Div. of New Drugs & Labeling Compliance, FDA, *Inspection/Investigation of New England Compounding Center 697 Waverly Street Framingham, MA 01702*, at 1 (Jan. 26, 2005) [hereinafter, "Jan. 26, 2005 FDA Memorandum"].
[102] *Id.*
[103] *Id.* at 2.

informed that it was not an approved product and that NECC should not be compounding it, Mr. Cadden stated that he "did not know that it is not an approved product."[104] He then "told one of the employees in the laboratory to put the vials in quarantine which he told us will be eventually destroyed."[105]

FDA and MBP investigators returned to NECC on September 28, 2004. When asked about the Trypan blue, Mr. Cadden asserted that his lawyer informed him that he did not have to quarantine the product and that "there is no regulation which states that Compounding Pharmacies cannot compound FDA non-approved drugs."[106] In addition he informed the investigators that he dispensed the product the day after the last inspection and that he intends to do so "until FDA/MABP will put in writing that they cannot compound it [and] dispense it and the reason why."[107] When FDA's investigator asked Mr. Conigliaro additional questions, "he became indignant [and] he said that he does not really have the time to sit with us [and] answer all those questions."[108] Further, according to the investigator, Mr. Cadden told Mr. Conigliaro, "'Don't answer any more questions!'"[109] Prior to leaving, FDA wrote down the questions in the assignment and left them with Mr. Conigliaro. On October 1, 2004, Mr. Conigliaro responded to the questions in writing, which were shared with FDA compliance staff.[110]

On October 27, 2004, MBP's investigator sent Mr. Cadden a letter with requests for responses and additional information related to Trypan blue production and distribution, including a fill log and a copy of all prescriptions dispensed "containing more than two (2) doses per patient."[111] On November 8, 2004, Mr. Cadden responded to the letter with the requested information, along with corrective actions taken, and stated, "In summary, we regret that the invalid patient names were not discovered by our pharmacy processing staff. We have taken immediate action to insure that physicians provide, and we verify, accurate patient names in the future."[112] This response was shared with FDA's investigator. On January 19, 2005, the FDA investigator notified Mr. Cadden by phone that the district office was "closing out the inspection based on his response letter to [MBP], indicating his plan of corrective actions, which will also be forwarded to headquarters."[113]

While FDA closed out its inspection, MBP voted on November 23, 2004, to file a formal complaint based on the investigator's findings.[114] This was the same day the Board unanimously voted to deny NECC's request to revise the terms of the consent agreement that had been proposed on October 4, 2004, covering the complaints and violations associated with

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[104] *Id.*
[105] *Id.*
[106] *Id.* at 3.
[107] *Id.*
[108] *Id.*
[109] *Id.*
[110] *See id.* at 4.
[111] Letter from Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center, to Investigator, Mass. Div. of Health Professions Licensure Office of Investigations, at 2 (Nov. 8, 2004).
[112] *Id.*
[113] Jan. 26, 2005 FDA Memorandum, *supra* note 101, at 4.
[114] *See* MASS. DEP'T OF PUB. HEALTH, INVESTIGATION REPORT OF BARRY CADDEN, at 2 (Nov. 23, 2004) [hereinafter, "MDPH NOV. 23, 2004 INVESTIGATION REPORT"].

betamethasone repository injection and methylprednisolone acetate. It is unclear as to whether these decisions were related.

Based on the new terms of the amended consent agreement, the complaint related to distribution of Trypan blue products without valid prescriptions was subsumed into the agreement. Despite the fact that the underlying matters were now more extensive, the amended consent agreement no longer called for a formal reprimand for professional misconduct, a three year probationary period, or a number of mandatory conditions that would have been required prior to the Board terminating the probation. The amended consent agreement included a probationary period of one year that was stayed pending satisfactory documentation related to an inspection having been conducted by Pharmacy Support, Inc. (PSI), a Board-approved evaluator, within 45 days of the effective date of the agreement. Further, NECC had to provide MBP with satisfactory documentation that PSI's recommendations were implemented and that a second inspection was conducted within six months. If such conditions were met, neither NECC's registration nor Mr. Cadden's license would be placed on probation.[115]

On January 30, 2006, PSI sent its initial audit report to Mr. Cadden and the MBP, noting that the assessment was conducted on January 17 and 18. The cover letter accompanying the report conlcuded, "Although your facility has seen significant upgrades in facility design for sterile compounding operation, there were numerous significant gaps identified during the assessment therefore, it is the opinion of the auditors that your operation needs to be upgraded and enhanced to be in substantial compliance with United States Pharmacopeia <795> or <797>."[116] The letter noted that major areas of concern included the fact that good documentation practices were inadequate; written procedures were admittedly not routinely followed; procedures were not in strict accordance with USP standards; end product testing was often performed on "stock solutions" and not the end product that is required; and validation of sterilization cycles and media fills were inadequate.[117] Numerous corrective actions were recommended, including a plan to attain compliance.

On April 7, 2006, PSI issued the final report, which concluded that "[NECC] has made significant improvements over the past several months. They have demonstrated the ability to be compliant with all state and federal regulations. The[y] have appropriate equipment, procedures, basic facility design and environmental controls."[118] However, PSI stated that, among other things, "it is the opinion of our firm that in order for NECC to be in substantial compliance . . . [a] [r]edesign of clean room 1 where sterile preparations are compounded (Floor, Ceiling, and HVAC)" must occur.[119]

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[115] *See* Consent Agreement, *In the Matter of New England Compounding Center Registration No. 2848 Barry J. Cadden, R.Ph. License No. 21239*, Docket Nos. DS-03-055, PH-03-066, DS-05-040 (Mass. Bd. of Registration in Pharmacy, Jan. 10, 2006) [hereinafter, "MPB-NECC Consent Agreement"].
[116] Letter from Vice President for Quality Operations, Pharm. Systems, Inc., to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center et al., at 2 (Jan. 30, 2006) (attaching initial audit report entitled "Observations Requiring Corrective Action").
[117] *See id.* at 1-11.
[118] PHARM. SYSTEMS, INC., FINAL REPORT: USP <795>/<797> IMPLEMENTATION – NEW ENGLAND COMPOUNDING CENTER, FRAMINGHAM, MA, at 1 (Apr. 7, 2006) [hereinafter, "PSI Final NECC Report"].
[119] *Id.*

On April 12, 2006, MBP "commend[ed] NECC on the progress to date" and requested that the firm "advise the Board in writing regarding NECC's intentions" with respect to the outstanding recommendations of PSI as well as "projected timelines for completion."[120] Mr. Cadden responded on April 19 as to how NECC would address PSI's remaining concerns. Regarding the "[r]edesign of clean room 1," Mr. Cadden stated, "It should first be noted that all sterile preparations are compounded within Class 10 Microenvironments, within 'clean room 1.' The room is not maintained as a certified clean room, nor was it ever our intent."[121] Mr. Cadden did, however, assert that the "HVAC unit in that room will be improved per PSI's suggestions. The work has been scheduled . . . and is expected to be completed by May 18, 2006."[122] On May 10, 2006, MBP requested of NECC written confirmation of HVAC work completion, along with two other items, which Mr. Cadden confirmed on May 22.[123] The next day, the Board voted to advise Mr. Cadden that NECC had satisfactorily completed the terms and conditions in the consent agreement. This decision was communicated to Mr. Cadden on June 2, 2006.[124] Apparently the MBP never shared the PSI report with the FDA.

E. FDA Warning Letter Relating to September 2004 Inspections

Based on violations of the Food, Drug, and Cosmetic Act (FDCA) either observed during FDA's joint inspections of NECC in September 2004, or otherwise brought to the agency's attention, FDA issued a Warning Letter to the company on December 4, 2006.[125] According to FDA's Regulatory Procedures Manual, "Warning Letters are issued to achieve voluntary compliance and to establish prior notice. . . . The agency position is that Warning Letters are issued only for violations of regulatory significance. Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected."[126]

The NECC Warning Letter set forth FDA's position on the agency's jurisdiction over new drugs, including compounded drugs, and its enforcement policy with respect to them. The Warning Letter referenced Compliance Policy Guide (CPG), section 460.200 ["Pharmacy Compounding"], which was issued by FDA on May 29, 2002, and several of the factors laid out in the CPG that influence FDA's enforcement policy in specific cases. The Warning Letter then

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[120] Letter from George A. Cayer, President, Mass. Bd. of Registration in Pharmacy, to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center (Apr. 12, 2006).
[121] Letter from Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center, to George A. Cayer, President, Mass. Bd. of Registration in Pharmacy, at 1 (Apr. 19, 2006).
[122] *Id.*
[123] *See* Letter from George A. Cayer, President, Mass. Bd. of Registration in Pharmacy, to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center (May 10, 2006) *and* Letter from Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center, to George A. Cayer, President, Mass. Bd. of Registration in Pharmacy (May 22, 2006).
[124] *See* Letter from George A. Cayer, President, Mass. Bd. of Registration in Pharmacy, to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center (June 2, 2006).
[125] *See* Warning Letter (NEW-06-07W) from Gail T. Costello, Dist. Dir., New England Dist. Office, FDA, to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center (Dec. 4, 2006) [hereinafter, "FDA Warning Letter"].
[126] U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL, at § 4-1-1 (2011), *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm.

discussed four primary areas of NECC activity that constituted violations of the FDCA for which the agency would not exercise its enforcement discretion.[127]

First, FDA noted that NECC may be compounding copies of commercially available drug products. Specifically, FDA highlighted Trypan blue products and the fact that "on December 16, 2006, trypan blue ophthalmic solution was approved by FDA and it is commercially available."[128] In addition, according to the Warning Letter, FDA also learned that NECC "may be compounding 20% aminolevulinic acid solution," another commercially available, FDA-approved product.[129] FDA informed NECC that "FDA does not sanction the compounding of copies of FDA-approved, commercially available drugs and the agency will not exercise its enforcement discretion regarding the trypan blue and ALA products compounded by your firm."[130]

Second, FDA detailed how NECC had developed a standardized anesthetic drug product, promoted and sold it under the name "Extra Strength Triple Anesthetic Cream," and generated sales by giving physicians free samples. In addition to noting the public health risks associated with high dose local anesthetic creams, FDA stated, "These actions are not consistent with the traditional practice of pharmacy compounding, in which pharmacists extemporaneously compound reasonable quantities of drugs upon receipt of valid prescriptions from licensed practitioners to meet the unique medical needs of individual patients."[131]

Third, FDA informed Mr. Cadden that it was "in receipt of a complaint alleging that [NECC was] repackaging the approved injectable drug, Avastin, into syringes for subsequent promotion and sale to health professionals."[132] The Warning Letter explained that FDA has an established policy, articulated in the CPG, concerning the manipulation of approved sterile drug products outside the scope of FDA approval and that FDA was "especially concerned with the potential microbial contamination associated with splitting Avastin – a single-use, preservative-free, vial – into multiple doses."[133]

Finally, FDA stated that the agency had been informed that "although [NECC] advises physicians that a prescription for an individually identified patient is necessary to receive compounded drugs, [the] firm has reportedly also told physicians' offices that using a staff member's name on the prescription would suffice."[134]

FDA concluded the Warning Letter by informing Mr. Cadden that "[f]ailure to promptly correct these deviations may result in additional regulatory action without further notice, including seizure or injunction against you and your firm."[135] The agency asked to be notified in

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[127] *See* FDA Warning Letter, *supra* note 125, at 2-5.
[128] *Id.* at 2.
[129] *Id.*
[130] *Id.* at 2-3.
[131] *Id.* at 3.
[132] *Id.* at 4.
[133] *Id.*
[134] *Id.* at 5.
[135] *Id.*

writing of "any steps that you will take to correct the noted violations, including an explanation of the steps taken to prevent the recurrence of similar violations."[136]

On January 5, 2007, Mr. Cadden responded to FDA by noting at the outset that "the Warning Letter is based on an inspection of NECC that started on September 23, 2004, approximately twenty-eight months ago . . . FDA has not contacted us since concluding the inspection. Some of the letter's assertions no longer apply to NECC's operations."[137] After disputing FDA's claim to having jurisdiction over compounded drugs, Mr. Cadden stated that "NECC does not compound copies of FDA-approved commercially available drugs, introduce unapproved new drugs into interstate commerce, does not need approved [New Drug Applications] before dispensing its compounded medications, and does not process or repackage approved drugs in a manner that would subject us to FDA regulation. Nor are our compounded medications misbranded. NECC dispenses compounded medications upon the receipt of valid prescriptions."[138]

Without agreeing with the Warning Letter's assertions, Mr. Cadden informed FDA that, for business reasons, NECC stopped filling prescriptions for Trypan blue in August 2005 (sixteen months before the Warning Letter) and for 20% aminolevulinic acid solution in May 2006 (seven months before the Warning Letter).[139]

With respect to the topical anesthetic cream, Mr. Cadden asserted that NECC currently used the term "'triple anesthetic cream' . . . but only as a way to literally describe the compounded medication as a convenience to our prescribing physicians. The term is in no way trademarked or branded."[140] Further, Mr. Cadden noted, "Although we do provide a very small quantity of medications (less than ten per month) free of charge, we do so only upon receipt of a valid prescription from a licensed practitioner to meet the unique medical needs of a particular patient. . . . A valid prescription does not become unlawful just because we do not charge the physician or patient. Should the FDA believe our position on this matter is incorrect, please advise."[141]

Regarding the repackaging of Avastin, Mr. Cadden stated that it did not constitute manufacturing, that NECC only did so "upon receipt of a valid, patient-specific prescription," and that "[a]ll aspects of our sterile compounding and repacking operations were recently reviewed by an independent expert, who confirmed that NECC is in compliance with [USP standards]."[142]

Lastly, in response to FDA's assertion that NECC reportedly told physicians that the company would fill prescription written in the name of a staff member, Mr. Cadden stated, "This

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[136] *Id.*
[137] Letter from Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center, to Compliance Officer, New England Dist. Office, FDA et al., at 1 (Jan. 5, 2007).
[138] *Id.* at 3.
[139] *See id.* at 3.
[140] *Id.* at 4.
[141] *Id.* at 4-5.
[142] *Id.* at 5.

allegation contradicts all of our standard operating procedures. NECC has not made such a representation to anyone, and has no idea how or why FDA arrived at this allegation."[143]

FDA did not respond to Mr. Cadden's letter until almost two years later, on October 31, 2008. In its reply, the agency "acknowledge[d] and apologize[d] for the significant delay in this correspondence."[144] Again, FDA presented an extensive summary of its authority over compounded drugs and factors the agency would consider in determining whether to exercise enforcement discretion. FDA accepted the firm's assertions with respect to the discontinued products; however, NECC's letter did not alleviate FDA's concerns regarding the manner in which the company was promoting its products and the manipulation of sterile injectables.[145]

FDA concluded by stating, "We agree that the length of intervening period was unusual. This in no way diminishes our serious concerns about your firm's operation. Your firm must promptly correct the violations noted in the December 4, 2006, Warning Letter, and establish procedures to assure that such violations do not occur. Its failure to do so may result in enforcement action including seizure of the firm's products and/or an injunction against the firm and its principals. In a future inspection, we will confirm the commitments that you made in your response. We also will verify that your firm's compounding practices are consistent with the policy articulated in the CPG, and that your firm's operation is not otherwise at odds with the conditions under which the agency exercises enforcement discretion towards pharmacy compounding."[146] This letter, which was dated October 31, 2008 and sent in follow-up to an inspection that occurred in September 2004, is the last documented correspondence between FDA and NECC until the recent outbreak.

F. Recent Colorado Complaints Related to NECC and Corresponding Actions

With respect to additional correspondence between NECC and State authorities, the next interaction between the parties was a satisfactory MBP inspection conducted on May 24, 2011, in connection with the renovation and expansion of NECC's Framingham facility. This was the last inspection of NECC's facility prior to the meningitis outbreak.

On July 26, 2012, however, an inspector for the Colorado Board of Pharmacy notified MBP Director James Coffey that NECC had violated the terms of a Cease and Desist Order the State had issued the company on April 15, 2011, based on NECC's distribution of "a stock compounded prescription drug . . . to a prescription drug outlet in the State of Colorado."[147] Mr. Coffey was informed that, during the course of a routine hospital pharmacy inspection in Colorado on July 17, 2012, the inspector observed a number of invoices and products from NECC. After this conversation, on July 26, 2012, the Colorado inspector emailed Mr. Coffey a copy of "the Special Report submitted to the Chief Inspector for the Pharmacy Board in

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[143] *Id.* at 6.
[144] Letter from Compliance Officer, New England Dist. Office, FDA, to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center, at 1 (Oct. 31, 2008).
[145] *See id.* at 2-4.
[146] *Id.* at 4.
[147] *See* Cease and Desist Order, *In the Matter of the Unauthorized and Unlawful Distribution of Prescription Drugs and/or Compounded Prescription Drugs in Colorado by New England Compounding Center, Inc.*, Case No. 2011-3973 (Colo. State Bd. of Pharmacy, Apr. 15, 2011).

Colorado concerning the receipt of non-patient specific compounded products into Colorado."[148] The inspector asked Mr. Coffey for "any information that the Massachusetts Board could provide concerning if this practice is allowed under Massachusetts pharmacy law."[149] Mr. Coffey responded on July 27, "The Massachusetts Board of Pharmacy will respond as soon as possible following a thorough review and analysis of the same."[150] Mr. Coffey then forwarded his correspondence with the Colorado inspector, along with the report, to MBP counsel Susan Manning and others in the MDPH, including several past NECC inspectors.[151]

Included in the Colorado report is email correspondence from May 2011 between FDA's Denver and New England District Offices relating to NECC's "illegal distribution of compounded drugs to hospitals in the Denver metropolitan area."[152] Several FDA employees were on this email chain, including at least one NWE-DO compliance officer involved in past NECC actions. Based on the Committee's investigation, it appears that FDA did not contact the MBP about the Colorado Board's concerns in May 2011 or any time thereafter, as Mr. Coffey was first informed by the Colorado inspector on July 26, 2012.

MDPH officials informed Committee staff that they first became aware of this complaint from Colorado while reviewing responsive documents pursuant to the Committee's investigation. On November 6, 2012, Dr. Lauren Smith, MDPH Interim Commissioner, issued a statement that Mr. Coffey had been terminated and Susan Manning had been placed on administrative leave. According to Dr. Smith, "The director of the Board is responsible for ordering investigations. Mr. Coffey failed to order an investigation or take any other action on the Colorado complaint. It is incomprehensible that Mr. Coffey and Ms. Manning did not act on the Colorado complaint given NECC's past, and their responsibility to investigate complaints. Following the outbreak, staff also failed to disclose the existence of Colorado's complaint to leadership at DPH."[153] Dr. Smith stated that "[t]here is no evidence at this time that staff informed Board [of Pharmacy] members about the Colorado issues. We continue to interview all Board members as part of our investigation into their handling of this situation and will not hesitate to make further changes and personnel actions if we deem them to be necessary."[154] However, it has come to the Committee's attention that as of November 8, 2012, the current President of the Board has yet to be interviewed.

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[148] E-mail from Pharmacy Inspector, Colo. State Bd. of Pharmacy, to James D. Coffey, Dir., Mass. Bd. of Registration in Pharmacy (July 26, 2012, 3:06 PM).
[149] *Id.*
[150] E-mail from James D. Coffey, Dir., Mass. Bd. of Registration in Pharmacy, to Pharmacy Inspector, Colo. State Bd. of Pharmacy (July 27, 2012, 7:33 AM).
[151] *See* E-mail from James D. Coffey, Dir., Mass. Bd. of Registration in Pharmacy, to Susan Manning, Counsel to Mass. Bd. of Registration in Pharmacy et al. (July 27, 2012, 7:34 AM) (forwarding Colorado "Special Report").
[152] E-mail from Senior Case Review Expert, Denver Dist. Office, FDA, to Supervising Consumer Safety Officer, New England Dist. Office, FDA et al. (May 10, 2011, 4:19 PM).
[153] Press Release, Mass. Dep't of Pub. Health, Statement of Interim Commissioner Dr. Lauren Smith on NECC Investigation (Nov. 7, 2012), *available at* http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/121107-statement-from-lauren-smith.pdf.
[154] *Id.*

IV. ISSUES

The following issues will be explored at the hearing:

- Both State and Federal inspectors documented a number of deficiencies and violations at NECC since as early as 2002, many of which are similar to those at issue in the ongoing meningitis investigation. Were the FDA's and the Massachusetts Board of Pharmacy's enforcement actions appropriate?

- Why didn't FDA pursue any enforcement actions against the NECC despite having emphasized in 2003 the potential for serious public health consequences if the company's compounding practices, in particular those relating to sterile products, were not improved?

- Prior to this outbreak, the Massachusetts Board of Pharmacy had investigated at least twelve separate complaints relating to NECC and its management. While many of these complaints covered NECC's sales and marketing tactics, several were associated with serious adverse events and uncovered deficiencies with NECC's compounding operations. How was NECC able to maintain its pharmacy license despite repeated violations?

- What did State and Federal authorities do to confirm that sufficient corrective measures were taken after these inspections? How did they communicate with each other to ensure such responses were adequate to protect the public health?

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Karen Christian or John Stone with the Subcommittee on Oversight and Investigations at (202) 225-2927.

MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

Sterile Compounding Pharmacy Information Sheet

Massachusetts pharmacies that are licensed by the Massachusetts Board of Registration in Pharmacy (Board) and engage in the compounding of sterile products that have completed and submitted a Sterile Compounding Pharmacy Attestation of Compliance are required to **complete this Information Sheet and return it with the requested documents to the Board by 12 Noon on Friday, November 9, 2012.**

FAILURE of any Massachusetts pharmacy that performs sterile compounding to complete and return this Information Sheet and other requested information to the Board by 12 Noon on Friday, NOVEMBER 9, 2012 will be a ground for discipline of the pharmacy license by the Board as a violation of 247 CMR 10.03(q).

Please direct any questions regarding this request to pharmacy.admin@massmail.state.ma.us

Name of Massachusetts Pharmacy _____
Street Address _____
City/Town _____ Zip Code _____
Tel. No. _____ Fax No. _____

Name of Manager of Record _____ Lic. No. PH_____
Signature_____ Date_____
E-mail _____

1. Hours of operation: Weekdays: _____ Weekends: _____
2. Staffing:

   Total No. Pharmacy Staff: Pharmacists: _____ Technicians: _____ Interns:_____

   No. staff preparing sterile products: Pharmacists:_____ Technicians:_____ Interns: _____
3. Job descriptions for individuals involved with compounding of sterile products (attach)
4. Competency training documents (attach)
5. Size of and number of clean rooms: _____
6. Number of laminar flow hoods: _____
7. List all non-sterile active pharmaceutical ingredients (API) used for sterile compounding: _____
   _____
   _____
8. Describe methods of sterilizing (e.g., filtration, autoclave): _____
   _____
9. Describe process of environmental sampling: _____
   _____
10. Describe process to determine Beyond-Use-Dating (BUD): _____
    _____
11. List of sterile products compounded (attach)

Name of Pharmacy: _____

12. List of customers (attach)

I, _____ (Print Name) ATTEST, under the pains and penalties of perjury, to the truthfulness of the information provided herein.

Signature: _____ Date:_____

Please direct any questions regarding this Pharmacy Information Sheet to pharmacy.admin@massmail.state.ma.us

Please FAX (617 973 0980) OR SCAN (pharmacy.admin@massmail.state.ma.us) a completed and signed Information Sheet and other requested information to the Massachusetts Board of Registration Pharmacy BY 12 NOON ON FRIDAY, NOVEMBER 9, 2012. Please mail an original signed form AND requested information to the Board at the address below:

Board of Registration in Pharmacy
ATTN: Sterile Compounding Pharmacy Information Sheet
239 Causeway Street, 5th floor
Boston, MA 02114

Florida Pharmacy Association

Supporting Florida Pharmacy Since 1887

November 13, 2012

Mr. Mark Whitten
Executive Director
Florida Board of Pharmacy
4052 Bald cypress Way, C-04
Tallahassee, Florida 32399

Re: Pharmacists' Commitment to Patient Safety and Compounding Quality

Dear Mr. Whitten:

As a state organization representing pharmacy practitioners in all settings, we offer our deepest sympathy and condolences to patients and families affected by the fungal meningitis outbreak due to contaminated injectable products. The pharmacy profession is dedicated to ensuring patient safety and access to quality medications that meet patients' needs. Based on our understanding of this tragedy, the entity involved was not engaged in traditional compounding practices specific to particular patients or in-office use by a physician that is integral to all aspects of pharmacy practice, but was possibly engaged in unregulated, unlicensed drug manufacturing.

Pharmacists compound medications in response to a prescription from a physician or other legally-authorized prescriber to meet patient-specific needs. Under Florida law, patients may receive compounded medications when they have a need for a customized medication, when a drug shortage or product discontinuation occurs, when the needed strength or dosage form is not available from a manufacturer, or when an allergen-free version of a medication is needed. Pharmacists provide these compounded products to patients under a patient-specific prescription or for in-office use by a prescribing practitioner. Pharmacists also compound prescriptions for veterinary needs.

It is not uncommon for a patient who needs a particular medication yet is unable to swallow a solid oral dosage form due to the insertion of a nasogastric tube. In these cases and many others similar to this there is a need for a compounded form of the medication prescribed. Pharmacists can prepare a liquid version of that drug to allow for insertion into the tube. This is considered basic compounding.

We believe that patients must continue to have access to high quality compounded medications that are not commercially available from a manufacturer. Pharmacists working in all practice settings such as hospitals and health systems, community pharmacies, long-term care and assisted-living settings, and even our nation's uniformed services must work to meet defined quality standards and to comply with state boards of pharmacy regulations in pharmacy sterile and nonsterile compounding

practices. Importantly, all practice settings and health professionals providing sterile compounding should follow defined quality standards. Many of these standards can be found published on the Pharmacy Compounding Accreditation Board (PCAB) web site. Pharmacies may also be held to accreditation and certification requirements when compounding sterile products to further assure quality and compliance. The Florida Pharmacy Association at its August 2006 Executive Committee supports the voluntary participation of Florida providers to become accredited with PCAB.

The Florida Pharmacy Association as well as our national pharmacy organizations and our colleague state pharmacy associations throughout the country are committed to working with Congress; state legislatures; state boards of pharmacy regulating the practice of pharmacy; and the Department of Business and Professional Regulation and the United States Food and Drug Administration (FDA), which regulates pharmaceutical manufacturers and distributors, on compounding issues. In addition, we will collaborate with physicians, other prescribers, and other key stakeholders to prevent further tragedy.

Florida has one of the most comprehensive regulatory structures governing the practice of pharmacy in our country. Florida's rules on sterile compounding clearly prohibit the activities leading to the New England tragedy and the Florida Board of Pharmacy holds the legal authority to take appropriate action to suspend or revoke the non-resident pharmacy permit of NECC. The Florida Pharmacy Association believes Florida should hold nonresident pharmacies, such as NECC, to the stringent compliance standards established under current Florida compounding law for all Florida-permitted pharmacies. The Florida Pharmacy Association further urges the Board to consider recommending legislative changes that would require non-resident pharmacy permit holders to have a Florida licensed pharmacist manager acting in nonresident pharmacies as is required by a number of other states, particular if such out-of-state pharmacy is dispensing compounded medications into our State. The pedigree laws that apply to in-state permitted pharmacies must more clearly apply to non-resident pharmacy permit holders. If a non-resident pharmacy permit holder, such as NECC, is engaged in the manufacturing of drugs, the Board of Pharmacy must have the clear authority and the resources to take action against such non-resident pharmacy's permit and the Department of Business and Regulation must be clearly authorized to require a full prescription drug pedigree or any medications dispensed in this state, regardless of where the dispensing pharmacy is located.

Finally, the FPA recommends that the Department of Health invest in resources to train our state's inspection team on the complexities of compounding services. We understand that resources of the Department are strained with the state struggling to balance its budget. Practitioner licensing fees that have in recent years been diverted from Medical Quality Assurance trust funds must be restored and used to address enforcement, compliance and quality issues. The lack of enforcement in the Northeast has shown us that adequate enforcement resources are essential to patient safety.

We are prepared to be a resource for policymakers and stakeholders to work toward identification of a clear delineation between drug manufacturing and traditional pharmacy compounding, to ensure that state pharmacy boards, DBPR and the FDA have the resources necessary for effective enforcement in areas within their jurisdiction,

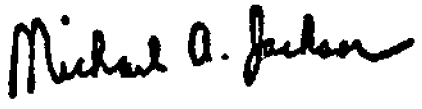
and to find an appropriate, balanced approach to assure public safety and continued access to compounded medications.

The Florida Pharmacy Association is the oldest and largest organization representing the profession of pharmacy in Florida. The members include pharmacists with expertise in community, institutional, long term care, consulting, managed care, nuclear, compounding, infusion therapy, academic and governmental service. The Association has networked with over 30 local invited and affiliated pharmacy organizations with outreach to most Florida licensed pharmacists. The FPA has advocated for and implemented a number of quality improvement and pharmacist patient care initiatives in this state and has served the profession since 1887.

Florida Pharmacy Association is the professional society representing Florida pharmacists, united to improve public health and patient care, enhance professional development and advocate for the interest of the profession. The Association is organized to preserve and advance the practice of pharmacy and to serve the professional needs of all pharmacists, pharmacy students, and pharmacy technicians.

We thank you for this opportunity to allow us to comment on this issue and on behalf of the leadership and members of the FPA, I am available for any questions that you may have.

With kindest regards,



Michael A. Jackson, BPharm
Executive Vice President and CEO

Cc: FPA Board of Directors

United States Senate
HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE

The New England Compounding Center and the Meningitis Outbreak of 2012: A Failure to Address Risk to the Public Health

Committee Staff Report

November 15, 2012

On September 26, 2012, as a result of the rapid work of the Tennessee Department of Public Health and the Centers for Disease Control and Prevention (CDCP), an outbreak of an unusual strain of fungal meningitis was identified. Preservative free methylprednisolone acetate (MPA), administered via spinal injection, was quickly identified as a likely source of the infections. The MPA was traced back to a compounding pharmacy in Framingham Massachusetts, the New England Compounding Pharmacy Inc., doing business as the New England Compounding Center (NECC). The Food and Drug Administration (FDA) subsequently determined that three separate lots of MPA, totaling over 17,000 doses produced by NECC between May 21, 2012 and August 10, 2012, were contaminated with the *exserohilum rostratum* fungus.[i]

To date, NECC's failure to produce a sterile and safe product has led to more than 30 deaths and over 450 serious illnesses requiring treatment with high risk anti-fungal medications. The efforts of the CDCP and the Tennessee Department of Public Health allowed public health officials in 23 states to rapidly track and begin monitoring the approximately 14,000 possible recipients of the contaminated drug. But thousands of people around the country continue to wait and see whether they will develop meningitis, joint infections, spinal abscesses, or arachnoiditis. Those treated will face the risk of kidney and liver damage from the powerful anti-fungal drugs.

While the quick work of the public health community has led to early identification and treatment of many cases of meningitis, and reduced the fatalities resulting from the administration of the contaminated MPA, the Committee's investigation demonstrates that this crisis should have, and could have, been avoided entirely.

Since its creation in 1998, inspections of NECC by state, federal, and independent investigators have identified and documented profound deficiencies in the company's production of sterile drugs. The company has also been cited on multiple occasions for improper use of prescription blanks to solicit orders and failure to comply with state regulations requiring patient-specific prescriptions for compounded drugs.

Moreover, the same drug at issue in the current outbreak, NECC-produced MPA, had previously been a suspected cause of at least two cases with bacterial meningitis-like symptoms. These reports triggered an FDA inspection of the facility ten years prior to the current outbreak, in August 2002.

While the FDA sampling of NECC-produced MPA proved sterile at the time, other MPA samples were found to contain bacteria.[ii] As an FDA employee stated in a power point presentation to the Massachusetts Board of Registration in Pharmacy (Board) at the time, "Sterilization techniques and aseptic practices continue to raise questions, despite no positive (nonsterile) results from latest samples. Absence of evidence is not evidence of absence."[1]

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[i] Testing of the third lot is ongoing.

[ii] An outbreak of fungal meningitis caused by MPA compounded by a South Carolina pharmacy also occurred in mid-2002.

Four years later in 2006, an independent evaluator reported to NECC manager and co-owner Barry Cadden that major areas of concern included "inadequate and incomplete documentation," that "end product testing is often performed on 'stock solutions' and not the end product that is required," "process controls including validation of sterilization cycles and media fills are inadequate," and "in many cases the procedures are not in strict accordance with USP 795/797" as required by Massachusetts state law.[2]

In view of these repeated concerns with regard to the ability of NECC to safely produce compound drugs, it is difficult to understand why definitive action was never taken to either revoke its license or, at a minimum, closely monitor the company's operations. Instead, the company was allowed to grow and expand operations, ultimately holding licenses to ship drugs to at least 45 states. The same owners were subsequently permitted to open the far larger Ameridose, which supplied compounded drugs to hospitals around the country. Also, that company now has been found to lack adequate procedures to ensure that the compounds produced are safe, uniform or sterile.

This report is based on information obtained in the course of the Committee's investigation. It is intended to recount the known history of NECC, its related companies and their interactions with federal and state regulators as of November 15, 2012 to better understand the events leading to the current public health crisis.

The New England Compounding Company

NECC was created in 1998 by the Conigliaro family. Three Conigliaro siblings and their spouses own the company: Douglas and Carla Conigliaro; Barry Cadden and Lisa Conigliaro Cadden; and Gregory Conigliaro. Ownership and management of the company have remained essentially unchanged since 1998. Pharmacists Barry Cadden and Lisa Conigliaro Cadden own 25 percent of the company, Carla Conigliaro owns 65 percent, and Gregory Conigliaro owns 10 percent. Gregory Conigliaro also owns a neighboring recycling business. Barry Cadden was in charge of operations and significant amounts of the actual compounding at NECC during the entire period of operations. The three siblings and spouses also own Ameridose and Alaunus, two companies created in 2006, in similar proportions.

NECC was granted a special pharmacy license by the Board in June 1998. That license allowed the company to produce compounded pharmaceutical products without operating a full-service pharmacy, but still subject to the state requirement that the company to have an individual patient prescription for each dose compounded. Massachusetts also adopted United States Pharmacopeia Standard <797>, which sets forth standards for compounding pharmacies including requirements for clean facilities, specific training for operators, and air quality evaluations.[3]

The first enforcement action against NECC began just 10 months after issuance of the license. In April of 1999, the Board filed a complaint against NECC for including blank prescriptions in solicitations to practitioners, a practice that violated state law. Six months later, in November of 1999, the Board resolved the complaint by issuing a warning to NECC in a private non-disciplinary advisory letter.[4]

In June 2001, the Idaho Board of Pharmacy complained to the Massachusetts Board that NECC was, among other things, including unapproved prescription forms in its solicitations to Idaho practitioners. Documents are unclear regarding whether the Board took formal action on this complaint. In fact, as detailed below, it appears that the Board has a dysfunctional system for logging incoming complaints and evaluating whether a complaint warrants assignment to an inspector.[5] Documents received by the Committee make clear, however, that NECC was investigated or warned for prescription-related concerns on at least 5 other occasions in the following 10 years.

Adverse Events

To the Committee's knowledge, the first time the safety of NECC's products was called into question was in early 2002. In March 2002, a prescribing doctor reported to the FDA that as many as five patients became ill following an epidural injection of NECC-produced betamethasone repositories.[6] He reported the illnesses to the FDA, alerted NECC about the issue, and returned unused doses to NECC without taking samples.[7] However, when the FDA arrived to inspect NECC on April 9, 2002, there were no records for the drugs in question.[8]

The FDA, joined for part of the inspection by the Board, spent three days inspecting NECC's facilities. When searching NECC's database, the FDA found a "date made" entry for the lot-number of drugs cited in the report but noted that "no associated records could be retrieved."[9] The FDA inspection report recounts that Barry Cadden asserted that the lot had never been produced but could provide no documentation that the lot had been cancelled.[10] Additionally, although the FDA contacted the physician making the report and confirmed he had returned the unused portion to NECC, FDA inspectors could find no record of the return.[11]

In the course of the inspection, FDA inspectors were told by Barry Cadden that approximately 4 lots of product produced between March and April 2002 had tested positive for endotoxin and were awaiting disposal.[12] FDA inspectors documented that NECC had sampled betamethasone repositories immediately after sterilization in the autoclave, and then left the product for up to 7 to 10 days before placing it in individual vials.[13] FDA inspectors reported an additional 8 areas of concern including a lack of procedures to ensure the operation of the autoclave, use of expired products, and inaccurate beyond use (i.e. expiration) dating.[14, iii]

In August of 2002, another series of adverse events were reported to the FDA.[15] These reports indicated that at least 2 patients were hospitalized for meningitis-like symptoms, and that the suspected sources of the infections were epidural injections of NECC-produced MPA, the same drug at issue in the current outbreak.[16]

The FDA, joined for part of the inspection by the Board, returned to NECC for a series of six days of inspections between October 2002 and February 2003. At that time Barry Cadden indicated to FDA inspectors that NECC was in the process of drastically expanding its operations. Since the FDA's prior inspection, NECC had doubled its square footage and hired

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[iii] Two days after the inspections, on April 18, 2002, the Nevada Board of Pharmacy submitted a complaint to the Board, alleging that NECC was selling non-FDA approved products in the state. It is unclear if the Board took any action as a result of this complaint.

additional staff. Further, NECC's manager stated his intent to expand sales to all 50 states, up from the 13 states in which it was then licensed.[17]

FDA tested unused vials of the MPA collected from the location of the adverse event report, and found that 5 of the 16 vials were contaminated with bacteria. The FDA also tested other vials obtained during inspections of NECC and found problems with super potent MPA and sub-potent betamethasone repositories.[18] Investigators again documented the use of procedures insufficient to ensure safe compounding. Those concerns included a "lack of documentation to verify that the autoclave itself is maintained and calibrated to perform its intended function," as well as a concern regarding a lack of safe procedures to ensure that "the transfer of bulk drug product and equipment from the autoclave… to another room … is not introducing contamination into the finished product."[19] The FDA's inspectors concluded, "Sample results revealed that the firm has sterility and potency issues with injectable steroid suspensions (betamethasone repository USP and methylprednisolone acetate USP)."[20]

In April 2002, prior to these inspections, the United States Supreme Court in *Thompson v. Western States Medical Center* ruled that section 503A of the Food Drug and Cosmetics Act included an impermissible restriction on commercial speech. The Supreme Court did not address provisions that clarified FDA's authority to regulate certain compound pharmacies, which the lower court held was not severable from the unconstitutional commercial speech restrictions. While NECC would likely have been subject to FDA regulation pursuant to section 503A of the Food Drug and Cosmetics Act, FDA's authority with regard to NECC under 503A was unclear after *Western States*, although FDA's general authority against unapproved new drugs, misbranded, or adulterated product was not in dispute. Despite the ambiguity regarding 503A, in May 2002 the FDA issued guidance which reasserted its authority to inspect compounding pharmacies and provided a non-exhaustive list of factors that the agency would consider in determining whether to take enforcement action when the scope and nature of a pharmacy's activities raise the kind of concerns ordinarily associated with drug manufacturing.

In this case, FDA took the position that the Board was better situated to take action against NECC. An FDA memo documenting a February 5, 2003, meeting between the FDA and the staff of the Board states that "a discussion was held to determine if NECC should be considered a manufacturer or a compounder" and that "current findings supported a compounding role."[21] The memo concludes:

> Mr. Elder [from FDA] concluded the meeting by summarizing the discussions and *emphasizing the potential for serious public health consequences if NECC's compounding practices, in particular those relating to specific sterile products are not improved*. The point was made that so long as a pharmacy's operations fall within the scope of the practice of pharmacy…FDA will generally defer to state authorities for regulatory oversight. In such cases FDA will seek to engage cooperative efforts aimed at achieving regulatory compliance and ensuring the safety and quality of compounded products.[22]

The FDA then officially stated in the NECC Inspection Report issued February 10, 2003, "[R]eferral to Massachusetts State Board of Pharmacy. Recommend firm be prohibited from manufacturing until they can demonstrate ability to make product reproducibly and dependably.

If state is unwilling to take action, recommend firm be enjoined for [Good Manufacturing Practices] deficiencies."[23]

Despite the formal recommendation that the state take action, it is unclear whether the Board took any additional action for the next year.[iv] It also does not appear that FDA conducted any follow-up to verify whether Massachusetts' response was sufficient to protect public health and safety.

Finally, on February 20, 2004, the Board staff conducted a compliance inspection and noted that NECC had taken corrective actions for the safety concerns identified in 2002 and 2003.[24] Nonetheless, the Board's staff recommended a public reprimand of NECC for its prior misconduct.[25]

On September 21, 2004, more than two years after the first reported cases of meningitis and other adverse events, and apparently acting on the staff recommendation, the Board voted to seek a public censure and probation for NECC's misconduct leading to the infections.[26,v] As was the Board's custom, they sent a consent decree to NECC that, if agreed to, would impose the relevant discipline and monitoring requirements for a three-year period.[27] The Board's staff transmitted its proposed consent decree to NECC on October 4, 2004.[28]

NECC did not agree to the proposed consent decree. NECC wrote to the Board asking it to instead consider non-public disciplinary action, to better protect NECC's business interest.[29] Counsel for NECC wrote: "once disclosed, the reprimand will surely result in inquiries/investigations in [other] jurisdictions. Regardless of the derivative actions taken, the attendant legal and administrative costs will be devastating."[30] The Board voted in November of 2004 to decline NECC's request for modifications to the consent decree.[31] Following that action by the Board, Committee interviews with Board staff suggest that the consent decree was referred for formal action to prosecuting attorneys within the Massachusetts Department of Public Health.[32]

For over a year, the record shows no formal order was filed and no hearing was held. Instead, it appears that attorneys for the Department of Public Health negotiated a modified consent agreement approved by the Board with an effective date of January 10, 2006.[33] The revised consent decree required that NECC submit to two inspections over a six-month period by a third-party evaluator, as well as a series of written assurances that recommended improvements had been made, in exchange for a suspended period of non-public probation.[34] The agreement

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[iv] FDA's investigation report also notes that Mr. Cadden, the manager of NECC, was serving on a committee for the state of Massachusetts, created to revise state regulations controlling compounding pharmacies. (FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, R. Ph, Owner and Director of Pharmacy, New England Compounding Pharmacy, Inc., February 10, 2003.) The committee's work, however, became moot after the release of USP 797, which then was adopted by Massachusetts. 247 CMR 9.01(3)

[v] Between the Board staff report recommending censure and the Board vote to issue the consent decree, pharmacist Sophia Pasedis was appointed to the eleven-member Board. Ms. Pasedis appears to have been an employee of NECC in some capacity at the time of her appointment, and thus recused herself from the Board consideration of the consent decree. Ms. Pasedis is currently a manager of the Conigliaros' other drug company, Ameridose.

was referred to as "non-disciplinary" and was "not reported to the National Association of State Boards of Pharmacy or other outside report agencies[.]"[35]

Thus, almost four years after the two series of adverse events, including hospitalizations, likely caused by MPA, and three years after the FDA had stressed "the potential for serious public health consequences if NECC's compounding practices, in particular those relating to specific sterile products are not improved,"[36] the Board merely required NECC to hire an outside monitor, and made no mention of suspension or revocation of NECC's license.

PSI Monitoring

Pursuant to the revised consent decree, a third-party auditor, Pharmacy Support, Inc. (PSI) was selected to evaluate NECC's compliance with United States Pharmacopeia Standard 797, which the Board had recently adopted as the governing standard for Massachusetts.[37] PSI inspected NECC in January 2006 and noted multiple concerns, including sterility concerns. Among them, PSI noted a range of fundamental problems, including:

- NECC had "no requirements for donning proper attire or hand washing" when compounding medicines;
- "Mixing instructions are not specific and do not always indicate time and temperature;"
- "No quality control procedures are defined;"
- "Non-sterile 70% IPA is used to sanitize;"
- "Beard covers not worn;"
- "Hairnets and beard covers were not worn properly;"
- "Environmental monitoring procedures are inadequate;"
- "Calibrations are not performed properly;"
- "Floors in the unclassified/hybrid buffer area have not been sanitized in 3 months of use;"
- "[Beyond use dates] assigned incorrectly;"
- "There are no written procedures for receipt, storage, and accountability of controlled substances;"
- "[Standard Operating Procedures] are inadequate or not followed;"
- "Complaint forms were not available for some complaints logged in the complaint log;"
- "Most sections of complaint forms are not complete;"
- "Lot numbers are not assigned appropriately;"
- "4 out of 8 gloves observed had holes while CSP was compounded;" and
- Dry heat "sterilization equipment has not been verified."[38]

NECC took significant corrective measures, including replacing deficient equipment, conducting several training sessions for staff, and adopting a wide range of new standard operating procedures.[39] PSI submitted a final report on April 7, 2006, stating that NECC was largely compliant with pharmaceutical standards.[40,vi] In April and May, the Board received two

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[vi] Six days later, at the end of an 8-week jury trial and three-year indictment, both PSI's CEO and Chief Compliance Officer were criminally convicted on 19 counts including fraud, mail fraud, and a violation of the Food and Drug Control Act. *US v. Caputo*, No. 03 CR 0126 (N.D. Ill. Oct 16, 2003). It is unclear how PSI was selected as the Massachusetts Board of Pharmacy has been unable to identify or produce documents discussing the selection of PSI in detail. Documents do show that PSI submitted a proposal to

more cursory letters from NECC assuring compliance with its remaining open issues.[41] On June 2, 2006, the Board informed NECC that it had fulfilled the requirements of its consent decree and that it considered the matter closed.[42]

Additional NECC Complaints

At the time the Board acted to send the initial consent decree to NECC, it also acted to resolve three additional complaints against NECC in September 2004.[43] Despite ongoing investigations relating to serious adverse events, the Board issued three *non-disciplinary* private advisory letters to NECC resolving complaints submitted during the prior two years from practitioners in South Dakota, Texas, and Wisconsin.[44] While the advisory letters fail to spell out the specifics of the complaints, and the original complaints have not been reviewed by the Committee to date, it appears that NECC may have been soliciting bulk orders rather than patient-specific prescriptions, conduct that NECC was initially reprimanded for in 1999. A Board inspection report from around that time specifically notes that NECC "continues to reduce to writing orders on bulk purchase order forms and not on the approved prescription blanks. An issue previously addressed with Mr. Cadden."[45]

Additionally, in April 2004, five months before issuance of the advisory letters, the Board received a new complaint from a practitioner regarding the safety of NECC compounded triple anesthetic cream. The complaint states "My second concern is that [redacted] related to the purchasing technician that he would need a prescription for the product and that we could use the name of a staff member if we wanted to. He said 'other' institutions have used a nurses name....He assured her that it was legal. He indicated that after we received the product it was up to us how we used it and whom it was administered to."[46] It appears that this complaint triggered a Board inspection on November 2004. When questioned about the use of false names, Cadden responded "a review of the same documentation provided to you does show what would appear to be incorrect or repetitive names being provided by several of our prescribing physicians."[47] Yet the Board staff again recommended issuance of yet another non-disciplinary advisory letter dismissing this complaint.

On November 7, 2012, Department of Public Health officials informed the Committee that a July 2012 complaint against NECC, from the Colorado Board, for producing drugs in the absence of a patient-specific prescription had been discovered in the email of the Board's Executive Director. The complaint, which was received while the contaminated lots of MPA were still being produced by NECC, provided clear photographic evidence that NECC was shipping products in the absence of patient-specific prescriptions.[48] Further, Colorado had issued a cease and desist order to NECC in 2011 regarding this practice.[49] Board staff never acted on the July 2012 complaint, and it is unclear that the Board itself was aware of the complaint.[vii]

While Massachusetts state law requires that a compounding pharmacy possess a patient-specific prescription before preparing a compound drug, it appears that NECC has been

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the Massachusetts Board and the prosecutor negotiating the consent agreement provided contact information to NECC's counsel.

[vii] The Board also informed the Committee that it had terminated the Executive Director and placed the Board's Counsel on administrative leave as a result of this discovery.

consistently preparing and shipping batch products either in the absence of a prescription or to false prescription recipients since 1998. No regulatory entity appears to have undertaken a serious investigation of this ongoing practice, and the Board instead routinely dismissed and/or failed to act upon these repeated complaints.

Additional FDA Action

Two days after the Board finally voted to issue the consent decree in September 2004, the FDA and the Board returned to NECC, this time pursuant to a complaint regarding the company's improper production of an injectable dye used in ophthalmic procedures, Trypan Blue.[50] After Barry Cadden initially denied that any Trypan Blue was in stock, FDA inspectors located 189 vials of the product. Trypan Blue is commercially available and should not be compounded.[51]

This inspection led to the issuance of a December 4, 2006 FDA Warning Letter to NECC. The Warning Letter details issues including: the sale of compounded drugs without a patient-specific prescription; compounding copies of commercially-available drugs; selling misbranded compounding drugs; and compounding standardized non-approved drugs, with associated public health risks, on a large scale. It specifically notes that NECC "has reportedly told physicians' offices that using a staff member name on a prescription would suffice."[52]

While the FDA Warning Letter seeks corrective action within 15 days and threatens that failure to correct could result in further regulatory action including seizure or injunction, it does not appear that any further action was contemplated or that any efforts to ensure that corrective action were sought by the agency. Moreover, FDA chose to issue this Warning Letter without having learned from the Board what, if any, disciplinary actions had been taken in response to the inspections from October 2002-February 2003.[53] In January 2007 NECC responded to the Warning Letter, and in October 2008 the FDA re-asserted its authority to take "enforcement action, including seizure of the firm's products and/or an injunction against the firm and its principals" if violations noted in the Warning Letter were not corrected. The FDA also stated that "[i]n a future inspection, we will … verify that your firm's compounding practices are consistent with the policy articulated in the [Compliance Policy Guidelines.]"[54] This response came two years from the date of FDA's initial Warning Letter and four years from the date of the relevant inspection. FDA took no further action until the recent outbreak.

Further, a May 2011 email exchange shows that FDA staff, including the signatory to the October 2008 letter re-asserting FDA inspection authority, received a copy of a Colorado Cease and Desist Order issued to NECC in 2011 as the result of distribution of non-patient specific compounded drugs to hospitals in the Denver area. FDA staff apparently did not share the Cease and Desist order with the Massachusetts Board, or suggest that the Colorado Board do so until Colorado inspectors again discovered NECC stock compound drugs in another Colorado hospital in July 2012.[55]

Inspection Findings Subsequent to the Outbreak

Unfortunately the long history of concerns was borne out in inspections by FDA and the Board following the 2012 fungal meningitis outbreak. The Massachusetts Board began a series

of inspections of NECC on September 26, 2012. The Board and/or the FDA continued inspecting NECC from that date until October 26, 2012. The findings demonstrate a basic lack of compliance with USP <797> or with safe compounding as evidenced most clearly by the fact that "[v]isible black particulate matter was seen in several recalled sealed vials of Methylprednisolone Acetate."[56] Perhaps most critically, the FDA inspection found that NECC's environmental monitoring system documented 61 instances between January and August 2012 when either bacteria or mold was detected in concentrations exceeding action-level thresholds.[57]

The inspection reports found that while sterility testing conducted on the contaminated lots did not reveal unacceptably high levels of endotoxins, the sample provided was insufficient relative to the batch size. In fact when FDA sampled 50 vials of returned MPA it determined all fifty were contaminated with microbial growth despite the fact that sterility tests on one sample from the same lot in August 2012 has proven clear.[58] The FDA and Board inspections unsurprisingly again document a basic lack of procedure to ensure sterile products were being compounded safely including:

- Inspectors observed "greenish yellow discoloration" lining one of two autoclaves used to sterilize various components and equipment;[59]

- Inspectors observed "yellow residue lining the rear return of Weigh Station 2 Hood and greenish residue lining the rear return of Weigh Station 3 Hood…used to weigh active ingredients and other raw materials;" [60]

- "Residual powder was visually observed within the [powder] hood during inspection;"

- "[Tacky] mats, which are used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry…were visibly soiled with assorted debris;"[61] and

- "A leaking boiler adjacent to the requisite clean room created an environment susceptible to contaminant growth."[62]

The inspections also documented a continued disregard for the requirements of a patient-specific prescription for each compounded product. The state's preliminary investigation report noted: "NECC distributed large batches of compounded sterile products directly to facilities apparently for general use rather than requiring a prescription for an individual patient."

Ameridose

One month after the terms of NECC's 2006 consent decree were deemed satisfied, the Board approved a license for a new company, Ameridose, owned by the Conigliaro family.[63, viii] Massachusetts Board Member Sophia Pasedis has been a manager of record for the company.[64] According to media reports, Douglas Conigliaro, although not listed as an owner or manager, plays a significant role at Ameridose.[65]

[viii] The ownership distribution is essentially the same with Carla Conigliaro owning 65 percent, Barry and Lisa Cadden owning 25 percent and Gregory Conigliaro owning 10 percent. (11-9-12 HELP Committee staff interview with NECC attorneys.)

Ameridose is also a sterile compounding company, but because it produces batch drugs for hospitals rather than patient-specific prescriptions, it is registered as a manufacturer with the FDA as well as with the Massachusetts Board.[66] The company does not manufacture any FDA approved product but rather is exclusively a large-scale compounder.

Until the outbreak, Ameridose contracted with Novation, the largest group purchasing organization in the country. Thus, Ameridose products were available to Novation's 3,000 hospital members as well as 22,000 other providers and facilities. Despite the history of problems with NECC and the joint ownership of the two companies, neither the licensure of Ameridose nor the large scale of its operations appears to have raised any concerns amongst the Board or the Board staff. Documents suggest that Ameridose was subject to routine pre-announced inspections by the Board in 2008 and 2011.[67]

However, the FDA had serious concerns with Ameridose. The FDA inspected the company in 2008 and found serious problems with the company's operations. Despite the large scale of Ameridose's operations even in 2008, investigators documented that products were shipped immediately without waiting for the results of sterility testing, that testing for potency and dose uniformity is not routinely performed and procedures were insufficient, and that the company was generally not in compliance with the requirements of USP 797 as required by Massachusetts law. As an example, management could not locate test results for 3 of 17 active ingredients inspected. Results of sampling tests taken at the August 2008 inspection returned a finding of superpotent Oxytocin, resulting in a recall of the product and an additional inspection in September 2008.[68] FDA staff placed Ameridose on the work plan for high risk facilities and recommended that a warning letter be issued to the company although no such letter was actually issued.[69]

While Ameridose was also the subject of at least 9 reports to the FDA of adverse events, faulty products, or medication errors, it is unclear that any of these triggered an inspection or investigation.[70] Following NECC's identification as the source of the fungal meningitis, the Board secured a temporary stop of Ameridose operations, though the company continues to hold a valid license. After the FDA began inspections on October 31, 2012, Ameridose issued a voluntary recall of all products.[71]

On November 12, 2012, the FDA issued a preliminary inspection report for Ameridose, finding startlingly similar problems to those they found NECC. Although the FDA has not reported any findings of contaminated drugs from Ameridose, the agency's preliminary findings "raised concerns about a lack of sterility assurance for products produced at and distributed by this facility."[72]

The FDA's inspection found that, like at NECC, there were clear problems with ensuring that drugs were sterile, or that doses were uniform. The FDA found that batches of drug product were not tested to ensure sterility, and that procedures were not established, written, or followed to prevent microbiological contamination of sterile drug products. What procedures were available did not include adequate validation of sterilization. The report also notes that the company failed to write or follow procedures detailing other aspects of their business.[73]

Moreover, the FDA found that testing of Ameridose's product did not include appropriate laboratory determination of conformance to the identity and strength of each active ingredient. And there were no written procedures for production and process controls to assure that the drug products had the identity, strength, quality and purity they purported to possess.[74]

Additionally, the FDA found that the buildings were not in good repair, that equipment and utensils were not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination. The company further lacked suitable procedures to facilitate cleaning and maintenance, lacked equipment for adequate control over air pressure, and were infested with vermin.[75]

Conclusion

Given the history of NECC, the fact that the company produced and shipped a contaminated product that has led to 32 deaths and 461 infections to date is not a surprise. The surprise is that they were allowed to continue to engage in drug compounding for over a decade with this record.

Both federal and state regulators were well aware that NECC and its owners posed a risk to the public health. Both had documented that the company routinely flouted requirements that it compound products only when a patient specific prescription was received, compounded unapproved and commercially available products, potentially destroyed documents and samples relevant to adverse events, and most critically, repeatedly failed to demonstrate that the company could safely compound sterile products. There were a number of authorities and mechanisms for both federal and state regulators to address this issue, but bureaucratic inertia appears to be what allowed a bad actor to repeatedly risk public health.

The Committee will continue its investigation to determine how this tragic failure of oversight occurred, and how it can best be prevented in the future.

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[1] FDA Internal Memorandum, February 24, 2003, re: *February 5, 2003 Meeting with Massachusetts Board of Pharmacy / Division of Professional Licensure (239 Causeway Street, Boston, MA 02114)*, p. 10 of Attachment 1.
[2] Letter from Pharmacy Support, Inc., to New England Compounding Center, January 30, 2006, and enclosure: *Compounding Sterile and Non Sterile Preparations Observations and Recommendations Final Report.*
[3] 247 CMR 9.01(3).
[4] Committee staff interview with Board inspectors 11/9/12.
[5] Senate HELP Committee staff interviews of Massachusetts Department of Public Health staff, October and November, 2012.
[6] FDA *Investigative Report,* re: FACTS 298826, New England Compounding Pharmacy Inc. EI 4/9, 4/10, 4/16/02; FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, R. Ph, Owner and Director of Pharmacy, New England Compounding Pharmacy, Inc., April 16, 2002.
[7] FDA *Investigative Report,* re: FACTS 298826, New England Compounding Pharmacy Inc. EI 4/9, 4/10, 4/16/02.
[8] Id.
[9] FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, R. Ph, Owner and Director of Pharmacy, New England Compounding Pharmacy, Inc., April 16, 2002, p. 4.

[10] Id. at 4.
[11] Id. at 4.
[12] Id. at 7.
[13] Id. at 7.
[14] Id. at 8.
[15] FDA *Establishment Inspection Report and Continuation Sheet,* re: FACTS 332851, New England Compounding Pharmacy Inc., EI Start: 10/24/02, EI End: 2/10/03; FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, R. Ph, Owner and Director of Pharmacy, New England Compounding Pharmacy, Inc., February 10, 2003, p. 5.
[16] FDA *Establishment Inspection Report and Continuation Sheet,* re: FACTS 332851, New England Compounding Pharmacy Inc., EI Start: 10/24/02, EI End: 2/10/03, pp. 4-5.
[17] Id.
[18] Id.
[19] FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, R. Ph, Owner and Director of Pharmacy, New England Compounding Pharmacy, Inc., February 10, 2003, p. 1.
[20] Id. at 2.
[21] FDA Internal Memorandum, February 24, 2003, re: *February 5, 2003 Meeting with Massachusetts Board of Pharmacy / Division of Professional Licensure (239 Causeway Street, Boston, MA 02114)*, p. 2.
[22] Id. at 3-4.
[23] FDA *Establishment Inspection Report,* re: FACTS 332851, New England Compounding Pharmacy Inc., EI Start: 10/24/02, EI End: 2/10/03, p. 1.
[24] Massachusetts Department of Public Health – Division of Health Professions Licensure, *Investigation Report*, Re: New England Compounding Center, DS 03 055, and Barry Cadden, PH 03 066, March 4, 2004, p. 9.
[25] Id. at 9.
[26] Massachusetts Board of Registration in Pharmacy, *Pharmacy Board Meeting Minutes: Tuesday, September 21, 2004,* p. 9.
[27] Letter from the Massachusetts Board of Registration in Pharmacy to New England Compounding Center, re: *Docket Number DS-03-055/PH-03-066/ New England Compounding Center (Permit #2848) and Barry Cadden, R.Ph., License No. 21239,* October 4, 2004; Massachusetts Board of Registration in Pharmacy, *Consent Agreement* re: *Docket No. DS-03-055, PH-03-066.*
[28] Id.
[29] Letter from Paul Cirel, counsel for New England Compounding Center, to Board of Registration in Pharmacy, re: *Docket Number DS-03-055/PH-03-066/ New England Compounding Center (Permit #2848) and Barry Cadden, R.Ph., License No. 21239,* November 11, 2004.
[30] Id. at 4.
[31] Massachusetts Board of Registration in Pharmacy, *Pharmacy Board Meeting Minutes: Tuesday, November 23, 2004*, p2.
[32] Senate HELP Committee staff interviews of Massachusetts Department of Public Health staff, October and November, 2012.
[33] Massachusetts Board of Registration in Pharmacy, *Consent Agreement* re: *Docket No. DS-03-055, PH-03-066, DS-05-040,* January 10, 2006.
[34] Id.
[35] Id. at 1.
[36] FDA Internal Memorandum, February 24, 2003, re: *February 5, 2003 Meeting with Massachusetts Board of Pharmacy / Division of Professional Licensure (239 Causeway Street, Boston, MA 02114)*, p. 2.
[37] Letter from Pharmacy Support, Inc., to New England Compounding Center, January 30, 2006, and enclosure: *Compounding Sterile and Non Sterile Preparations Observations and Recommendations Final Report.*
[38] Id.

[39] Pharmacy Support, Inc., *Final Report USP <795>/<797> Implementation New England Compounding Center Framingham, Ma,* April 7, 2006.
[40] Id.
[41] Letters between Board and NECC, April 12, 2006, April 19, 2006, May 10, 2006, and May 22, 2006.
[42] Letter from MA Board to NECC, June 2, 2006.
[43] Massachusetts Board of Registration in Pharmacy, *Pharmacy Board Meeting Minutes: Tuesday, September 21, 2004.*
[44] Letter from the Massachusetts Board of Registration in Pharmacy to New England Compounding Center, re: *In the matter of DS-03-038 and PH-03-042 – New England Compounding Center (Permit #2848),* September 30, 2004; Massachusetts Board of Registration in Pharmacy, *Advisory Letter* re: *Docket No. DS-03-036, PH-03-042,* September 30, 2004; Letter from the Massachusetts Board of Registration in Pharmacy to New England Compounding Center, re: *In the matter of DS-03-060 and PH-03-070 – New England Compounding Center (Permit #2848),* September 30, 2004; Massachusetts Board of Registration in Pharmacy, *Advisory Letter* re: *Docket No. DS-03-060, PH-03-070,* September 30, 2004; Massachusetts Board of Registration in Pharmacy, *Advisory Letter* re: *Docket No. DS-04-062, PH-04-161,* September 30, 2004.
[45] Massachusetts Department of Public Health – Division of Health Professions Licensure, *Investigation Report*, Re: New England Compounding Center, DS 03 055, and Barry Cadden, PH 03 066, March 4, 2004 at 7.
[46] Email from [redacted] to Massachusetts Board of Registration in Pharmacy, re: *New England Compounding Center Activity in the State of Wisconsin*, April 27, 2004.
[47] Massachusetts Department of Public Health – Division of Health Professions Licensure, *Investigation Report*, Re: New England Compounding Center, DS 05 040, reviewed by Board Members on November 23, 2004.
[48] E-mail from Colorado Department of Regulatory Agencies to Massachusetts Board of Registration in Pharmacy, re: *New England Compounding Center,* July 26, 2012; Colorado State Board of Pharmacy, *Special Report*, re: *New Egland Compounding Pharmacy, Inc. (WHO 7832),* July 20, 2012.
[49] Id.
[50] FDA Internal Memorandum, Re: *Inspection/Investigation of New England Compounding Center,* January 26, 2005.
[51] Id. at 2.
[52] FDA Warning Letter to NECC, Dec 4, 2006.
[53] FDA Internal Memorandum, Re: *Inspection/Investigation of New England Compounding Center,* January 26, 2005 at 4.
[54] Letter from FDA to NECC, Oct 31, 2008.
[55] E-mails between Colorado Board of Pharmacy and FDA, May 10, 2011 and July 16, 2012; Colorado State Board of Pharmacy, Special Report, re: New England Compounding Pharmacy, Inc. (WHO 7832), July 20, 2012.
[56] Massachusetts Board of Registration in Pharmacy Report, *NECC Preliminary Investigation Findings*, October 23, 2012, at 4.
[57] FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, Owner, New England Compounding Pharmacy, Inc., d/b/a/ New England Compounding Center, October 26, 2012.
[58] FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, Owner, New England Compounding Pharmacy, Inc., d/b/a/ New England Compounding Center, October 26, 2012.
[59] Massachusetts Board of Registration in Pharmacy Report, *NECC Preliminary Investigation Findings*, October 23, 2012 at 1.
[60] Id. at 7.
[61] Massachusetts Board of Registration in Pharmacy Report, *NECC Preliminary Investigation Findings*, October 23, 2012 at 4.
[62] Id. at 5.

[63] Ameridose, LLC, *Application for a New Store – 50 Fountain Street*, 2006.
[64] Id.
[65] Abby Goodnough *et. al.*, "Spotlight Put on Founders of Drug Firm in Outbreak," *New York Times,* October 24, 2012, http://www.nytimes.com/2012/10/25/health/with-meningitis-outbreak-a-spotlight-on-family-behind-compounding-pharmacy.html?pagewanted=all (accessed November 14, 2012).
[66] *See, e.g.* FDA *Establishment Inspection Report, Ameridose, LLC*, January 16, 2008, p. 1; Ameridose, LLC, *Application for a New Store – 50 Fountain Street*, 2006.
[67] The Commonwealth of Massachusetts, Division of Health Professions Licensure, *Inspection Report*, 11/19/08; The Commonwealth of Massachusetts, Division of Health Professions Licensure, *Inspection Report*, 11/7/11.
[68] FDA *Establishment Inspection Report, Ameridose, LLC*, EI Start: 09/17/2008, EI End: 09/18/2008.
[69] FDA *Establishment Inspection Report, Ameridose, LLC*, August 22, 2008, p. 1.
[70] FDA, *FAERS search results for suspect drugs labeled as Ameridose, New England Compounding Center or Alaunus, Reports initially received by FDA from 1/1/02 to 9/25/12*, provided to Committee on November 8, 2012; *See also,* Letter from Wiley Rein, LLP to Massachusetts Board of Registration in Pharmacy, re: *Complaint Against Ameridose LLC for Unlawful Manufacturing and Distribution of Pre-Mixed Nicardipine Injection Products,* June 30, 2010 (the resulting investigation was administratively closed).
[71] FDA Press release: *FDA reports voluntary recall of all Ameridose drug products,* October 31, 2012, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm326361.htm, (accessed November 14, 2012).
[72] Id.
[73] FDA *Inspectional Observations*, Form FDA483, issued to Gary Conigliaro, Vice President and General Manager, Ameridose, LLC, November 9, 2012.
[74] Id.
[75] Id.