September 18, 2013

Eric Renker, Pharm.D.
Director of Pharmacy Services
Florida Hospital Tampa
3100 East Fletcher Avenue
Tampa, Florida 33613

RE: Request for Declaratory Statement

Dear Mr. Renker:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Tuesday, October 8, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II

FLORIDA HOSPITAL
TAMPA
The skill to heal. The spirit to care.®

5 September 2013

Petition for Declaratory Statement Before the Florida Board of Pharmacy

This petition is in reference to Florida Rule 64B16-28.605 entitled Class II Institutional Pharmacies – Automated Distribution and Packaging which discusses the process by which automated systems may be used in an institutional setting. Although there are clear guidelines which establish monitoring and audit systems, it is not clear whether immediate supervision of technicians is required.

The portion of 64B16-28.605 which is in question is question is paragraph (4).

(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.

We request that Rule 64B16-28.605 be reviewed to determine if the process of filling and checking medications which will be placed in an automated dispensing machine by State of Florida Registered Pharmacy Technicians and subject to the review required by 64B16-28.605(4) may be considered within the scope of practice of the Pharmacy Technician separate from the supervision requirement of Florida Statute 465 014.

Thank you for your consideration of this petition.

Sincerely,

Eric J. Renker, Pharm D.
Director of Pharmacy Services
Office telephone: (813) 61507114
Office Fax: (813) 615-8103

2201-11679

3100 East Fletcher Avenue · Tampa, Florida 33613 · 813.971.6000 · 813.615.7313 · FHTampa.org

September 18, 2013

Loreto Grimaldi
New York State & Ontario Bars
COO General Counsel & Regulatory
MedAvail Technologies Inc.
6665 Milcreek Drive, Unit #1
Mississauga, Ontario L5N 5M4

RE: Automated Pharmacy

Dear Loreto Grimaldi:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Tuesday, October 8, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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.

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

Sincerely,

James Cumbie
Regulatory Specialist II

VIA EMAIL AND SUBSEQUENT COURIER

September 3, 2013

Mr. Mark Whitten
Executive Director
Department of Health - Board of Pharmacy
4052 Bald Cypress Way
Bin C-04
Tallahassee, FL 32399-3258
e. Mark_Whitten@doh.state.fl.us

Dear Mr. Whitten,

Re: Board of Pharmacy Meeting - October 8-9, 2013

My name is Loreto Grimaldi and I am the COO and General Counsel of MedAvail Technologies Inc. - a US-owned company that has developed an automated, Pharmacist-centered Remote Dispensing / Telepharmacy technology that is unique in the world. We would appreciate an opportunity to present our solution to the Florida Board of Pharmacy at their upcoming meeting on October 8 and 9, 2013. In particular, we are seeking an opportunity to provide context and perspective as it relates to the "automated pharmacy" rules which we understand are to be discussed at the Rules Committee meeting.

We would greatly appreciate the opportunity at the October meeting to present our technology to the full Board, and also to review with the Rules Committee the various safety, privacy and security features which we believe allow pharmacists to increase patient access and enhance patient care by harmonizing world leading automation and technology with the traditional role of the pharmacist. Our HIPAA-compliant technology, known as the MedAvail MedCenter™, allows a pharmacist to interact with and dispense medications to a patient remotely via our safe and secure remote dispensing vault/kiosk, while maintaining direct patient contact through a live, two-way audio and video connection. The system requires pharmacist verification of all medication dispensed to the patient and preserves the judgement and accountability of the pharmacist.

Our solution is ideally suited to a variety of deployment scenarios - including doctor's clinics, hospital emergency rooms, employer campuses (as an adjunct offering to on-site healthcare facilities), and retail locations. We firmly believe, based on strong empirical evidence, that increasing access to medications at or near the point of care, promotes stronger medication adherence, better patient outcomes and decreased healthcare costs.

As you are well aware, the concept of "automated pharmacy systems" is defined in Chapter 465 of the Florida Statutes, with additional requirements specified in the Regulations (64B-16-28). Given that the current rules (and proposed amendments) are to be discussed at the October Board of Pharmacy meetings. We respectfully believe it would be useful to the Committee's and the Board's deliberation of the current/proposed rules, to understand our pharmacy kiosk technology, and in our view this provides a unique opportunity and forum for MedAvail to describe the system, and address any questions or concerns from the Board.

Specific agenda topics and background materials will be made available in advance for the Board's prior consideration, however we would look to include an overview of the technology (and a video demonstration), a review of how the technology fits into both the current Rules and those that are being proposed for discussion, and a view on our ideal deployment scenarios in the State of Florida.

Thank you - we await your kind reply.

Sincerely,

Loreto Grimaldi
COO General Counsel & Regulatory
c. 416-540-3601
e. lgrimaldi@medavail.com

cc: Ed Rickert, Krieg DeVault LLP erickert@kdlegal.com
Sunny Lalli, RPh, MedAvail Technologies Inc. slalli@MedAvail.com

An act relating to treatment programs for impaired licensees and applicants; amending s. 456.076, F.S.; exempting an entity retained by the Department of Health as an impaired practitioner consultant from certain licensure requirements; authorizing impaired practitioner consultants to contract with schools or programs to provide services to impaired students who are enrolled for the purpose of preparing for licensure as a specified health care practitioner or as a veterinarian; limiting the liability of those schools or programs when they refer a student to an impaired practitioner consultant; authorizing each board and profession within the division to delegate to its chair or other designee the authority to determine that an applicant for licensure under its jurisdiction may be impaired before certifying or declining to certify an application for licensure; authorizing the chair or other designee to refer the applicant to the consultant for an evaluation before the board certifies or declines to certify the applicant's application to the department; tolling the department's deadline for approving or denying the application until the evaluation is completed and the result of the evaluation and recommendation by the consultant is communicated to the board by the consultant if the applicant agrees to be evaluated by the consultant; requiring the board to certify or decline to certify the applicant's application to the

department notwithstanding the lack of an evaluation and recommendation by the consultant if the applicant declines to be evaluated by the consultant; providing that the impaired practitioner consultant is the official custodian of records relating to the referral of the licensee or applicant to the consultant and any other interaction between them; clarifying the circumstances under which an impaired practitioner consultant may disclose certain information concerning an impaired licensee or applicant; authorizing the Department of Health and others that contract with an impaired practitioner consultant to have administrative control over the consultant to the extent necessary to receive disclosures allowed under federal law; authorizing an impaired licensee to obtain confidential information from the department regarding a pending disciplinary proceeding; amending ss. 458.331 and 459.015, F.S.; conforming cross-references; creating s. 468.315, F.S.; providing that radiological personnel are subject to a treatment program for impaired licensees; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 456.076, Florida Statutes, is amended to read:

456.076 Treatment 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)(a) The department shall retain one or more impaired practitioner consultants who are each licensees~~. The consultant shall be a licensee~~ under the jurisdiction of the Division of Medical Quality Assurance within the department and who must be:

1. A practitioner or recovered practitioner licensed under chapter 458, chapter 459, or part I of chapter 464;~~,~~ or

2. An entity that employs: ~~employing~~

a. A medical director who must be a practitioner or recovered practitioner licensed under chapter 458 or~~,~~ chapter 459;~~,~~ or

b. An executive director who must be a registered nurse or a recovered registered nurse licensed under part I of chapter 464.

(b) An entity retained as an impaired practitioner consultant under this section which employs a medical director or an executive director is not required to be licensed as a

substance abuse provider or mental health treatment provider under chapter 394, chapter 395, or chapter 397 for purposes of providing services under this program.

(c)1. The consultant shall assist the probable cause panel and the department in carrying out the responsibilities of this section. This includes ~~shall include~~ working with department investigators to determine whether a practitioner is, in fact, impaired.

2. The consultant may contract with a school or program to provide ~~for~~ services to a student ~~be provided, for appropriate compensation, if requested by the school, for students~~ enrolled for the purpose of preparing ~~in schools~~ for licensure as a health care practitioner as defined in this chapter or as a veterinarian under chapter 474 if the student is allegedly ~~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 for the ~~costs of~~ care provided by approved treatment providers or a consultant~~, and the department is not responsible for paying the costs of consultants' services provided for students~~.

(d) A medical school accredited by the Liaison Committee on Medical Education or ~~of~~ the Commission on Osteopathic College Accreditation, or another ~~other~~ school providing for the education of students enrolled in preparation for licensure as a health care practitioner as defined in this chapter or a

veterinarian under chapter 474 ~~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) Each board and profession within the Division of Medical Quality Assurance may delegate to its chair or other designee its authority to determine, before certifying or declining to certify an application for licensure to the department, that an applicant for licensure under its jurisdiction may be impaired as a result of the misuse or abuse of alcohol or drugs, or both, or due to a mental or physical condition that could affect the applicant's ability to practice with skill and safety. Upon such determination, the chair or other designee may refer the applicant to the consultant for an evaluation before the board certifies or declines to certify his or her application to the department. If the applicant agrees to be evaluated by the consultant, the department's deadline for approving or denying the application pursuant to s. 120.60(1) is tolled until the evaluation is completed and the result of the

evaluation and recommendation by the consultant is communicated to the board by the consultant. If the applicant declines to be evaluated by the consultant, the board shall certify or decline to certify the applicant's application to the department notwithstanding the lack of an evaluation and recommendation by the consultant.

(4) ~~(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) and (7).

(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.

(5)~~(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.

(6)~~(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 (7)~~(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.

(7) ~~(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.

(8) ~~(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.

(9) An impaired practitioner consultant is the official custodian of records relating to the referral of an impaired licensee or applicant to that consultant and any other interaction between the licensee or applicant and the consultant. The consultant may disclose to the impaired licensee or applicant or his or her designee any information that is disclosed to or obtained by the consultant or that is confidential under paragraph (6)(a), but only to the extent that it is necessary to do so to carry out the consultant's duties under this section. The department, and any other entity that enters into a contract with the consultant to receive the

services of the consultant, has direct administrative control over the consultant to the extent necessary to receive disclosures from the consultant as allowed by federal law. If a disciplinary proceeding is pending, an impaired licensee may obtain such information from the department under s. 456.073.

Section 2. Paragraph (e) of subsection (1) of section 458.331, Florida Statutes, is amended to read:

458.331 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(e) Failing to report to the department any person who the licensee knows is in violation of this chapter or of the rules of the department or the board. A treatment provider approved pursuant to s. 456.076 shall provide the department or consultant with information in accordance with the requirements of s. 456.076(4), (5), (6), (7), and (9) ~~s. 456.076(3), (4), (5), and (6)~~.

Section 3. Paragraph (e) of subsection (1) of section 459.015, Florida Statutes, is amended to read:

459.015 Grounds for disciplinary action; action by the board and department.—

(1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(e) Failing to report to the department or the department's impaired professional consultant any person who the licensee or certificateholder knows is in violation of this chapter or of the rules of the department or the board. A treatment provider, approved pursuant to s. 456.076, shall provide the department or

consultant with information in accordance with the requirements of s. 456.076(4), (5), (6), (7), and (9) ~~s. 456.076(3), (4), (5), and (6)~~.

Section 4. Section 468.315, Florida Statutes, is created to read:

468.315 Treatment program for impaired radiological personnel.—Radiological personnel who are subject to certification under this part are governed by s. 456.076 as if they were under the jurisdiction of the Division of Medical Quality Assurance.

Section 5. This act shall take effect July 1, 2013.

BOARD OF PHARMACY

Rule Number	Rule Title	Rule Development Published	Notice Published	Adopted	Effective	Comments
Fla. Admin. Code R. 64B16-28.100	Pharmacy Permits - Applications and Permitting	7/3/2013	7/22/2013	9/3/2013	9/23/2013	Rec'd JAPC Ltr 7/31/13
Fla. Admin. Code R. 64B16-28.100	Pharmacy Permits - Applications and Permitting	1/3/2013				
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			JAPC Ltr. Rec'd 6/5/13, 7/9/13, 7/30/13 Resp 8/08/13
Fla. Admin. Code R. 64B16-28.450	Centralized Presciption Filling, Delivering and Returning	9/6/2013				
Fla. Admin. Code R. 64B16-28.802	Special Sterile Compounding Permits	7/3/2013	7/22/2013			Rec'd JAPC Ltr 7/31/13, pending response
Fla. Admin. Code R. 64B16-28.840	Special Non-Resident (mail-service)	1/3/2013				Pending SERC reqired forms and language.
Fla. Admin. Code R. 64B16-28.901	Nuclear Pharmacy-General Requirements	9/6/2013				
Fla. Admin. Code R. 64B16-30.001	Disciplinary Guidelines, Range of Penalties, Aggravating and Mitigating Circumstances	9/6/2013				

COMPAS DataMart Reporting System
New License Report for 2201 : Pharmacist
7/ 1/2013 - 8/31/2013

Sort Order: Original License Date

Processed: 9/12/2013 10:12:30AM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	50383	07/01/2013	Ashley, Jacqueline Anne	04/17/1977	Palm Beach Atlantic University		2040 58Th Ave	Vero Beach, FL 32966
PS	50384	07/01/2013	Brown, Douglas Lee	07/08/1986	University Of Florida		1324 Lakeland Hills Blvd	Lakeland, FL 33805
PS	50385	07/01/2013	Mossman, Daniel Michael	04/21/1989	University Of Florida		11600 Gladiolus Dr	Fort Myers, FL 33908
PS	50386	07/01/2013	Fletcher, Charles Andrew	08/06/1986	University Of Florida		11 East Merritt Island Causeway	Merritt Island, FL 3295
PS	50387	07/01/2013	Schreiner, Joseph John	02/22/1989	University Of Florida		4600 Summerlin Rd	Fort Myers, FL 33919
PS	50388	07/01/2013	Beard, Kerry Suzanne	11/28/1988	University Of Florida		2000 Sw College Rd	Ocala, FL 34471
PS	50389	07/01/2013	Glover, Kelly Nicole	12/28/1984	University Of Kentucky		4209 Lo. Culbreath Ave	Tampa, FL 33609
PS	50390	07/01/2013	Lopez, Elisse Nicole	06/25/1988	University Of Florida		6295 W Waters Ave	Tampa, FL 33634
PS	50391	07/01/2013	Hammond, Drayton Adam	09/21/1987	South Carolina College Of Pharmacy		1120 15Th Street	Augusta, GA 30904
PS	50392	07/01/2013	Lee, Casey Andrew	10/18/1987	University Of Florida		33343 Us 19 N	Palm Harbor, FL 34684
PS	50393	07/01/2013	Hewitt, Megan Sarah Elizabeth	08/07/1988	University Of Mississippi Main Campus		501 6Th Avenue S	St. Petersburg, FL 33701
PS	50394	07/01/2013	Jernigan, Anna Mcgee	07/21/1985	Auburn University Main Campus		3888 Hwy 90	Milton, FL 32571
PS	50395	07/01/2013	Rabbath, Peter Richard	02/24/1987		Massachusetts College Of Pharmacy	Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50396	07/01/2013	Smith, Brandon Joseph	07/23/1989	Florida A & M University		3343 Daniels Rd	Winter Garden, FL 34787
PS	50397	07/01/2013	Kim, Ki-Poong	10/05/1960	Nova Southeastern University		20300 W Country Club Drive #109	Aventura, FL 33180
PS	50398	07/01/2013	Shawaqfeh, Mohammad Saud	10/03/1970	University Of Iowa		11501 N Military Tr	Palm Beach Gardens, FL 33410
PS	50399	07/01/2013	Leung, Lena Yeenor	03/08/1972	University Of Illinois At Chicago		820 S. Damen Ave	Chicago, IL 60612
PS	50400	07/01/2013	Bentley, Kimberly Marie	12/06/1989	Belmont University		1 Shircliff Way	Jacksonville, FL 32204
PS	50401	07/01/2013	Mitrano, Benedetto	12/26/1985	University Of Florida		2200 Gulf To Bay Blvd.	Clearwater, FL 33759
PS	50402	07/01/2013	Jackson, Christopher David	07/16/1988	University Of Florida		800 Prudential Drive	Jacksonville, FL 32207
PS	50403	07/01/2013	Maltz, Jessica Marie	09/11/1987	University Of Florida		5420 9Th St N	Saint Petersburg, FL 33716
PS	50404	07/01/2013	Mendelsohn, Rachel Kaplan	10/28/1986	University Of Florida		900 E Main St	Lake Butler, FL 32054

COMPAS DataMart Reporting System
New License Report for 2201 : Pharmacist
7/ 1/2013 - 8/31/2013

Processed: 9/12/2013 10:12:30AM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	50405	07/01/2013	Mladenova, Izabela Issaeva	03/12/1989	Florida A & M University		2403 North Ponce De Leon Blvd	Saint Augustine, FL 32084
PS	50406	07/01/2013	Montgomery, Kayla Meghan	09/11/1989	University Of Florida		1324 Lakeland Hills Blvd	Lakeland, FL 33805
PS	50407	07/01/2013	Mungal, Wesley Shiva	11/12/1987	University Of Florida		412 St Helens Ave	Tacoma, WA 98402
PS	50408	07/01/2013	Oestreich, George Louis	05/19/1947	University Of Missouri-Kansas City		3714 Taylors Ridge Court	Jefferson City, MO 65109
PS	50409	07/01/2013	Aly, Ahmad Saeed	09/28/1985	Foreign Schools		340 W 23Rd St Ste D2	Panama City, FL 32405
PS	50410	07/01/2013	Smith, Carl Jonathan	02/22/1982	University Of Florida		7520 W. Newberry Road	Gainesville, FL 32606
PS	50411	07/01/2013	Tate, Lindsey Shea	02/21/1989	University Of Florida		800 Prudential Dr	Jacksonville, FL 32207
PS	50412	07/02/2013	Duane, Kevin Joseph	10/12/1987	University Of Florida		4893 Town Center Parkway	Jacksonville, FL 32246
PS	50413	07/02/2013	Janeway, Ryan Daniel	01/08/1984	University Of Florida		1070 E. Brandon Blvd	Brandon, FL 33511
PS	50414	07/02/2013	Brandner, Danny Manfredo	04/22/1984	University Of Florida		1800 St Rd 44	New Smyrna Beach, FL 32168
PS	50415	07/02/2013	Addie, Ashley Marie	12/20/1986	University Of Florida		686 Glades Rd	Boca Raton, FL 33431
PS	50416	07/02/2013	Heywood, Darren Oliver	07/15/1975	Temple University		1201 Main Street	Peekskill, NY 10566
PS	50417	07/02/2013	Langford, Sarah Clarice	03/07/1983	University Of Florida		12279 Lake Underhill Rd	Orlando, FL 32825
PS	50418	07/02/2013	Kuo, Min-Mei	11/16/1985	University Of Florida		9031 Sw 107Th Ave	Miami, FL 33176
PS	50419	07/02/2013	Aikman, Margherita Joy Warman	08/16/1973	University Of The Pacific		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50420	07/02/2013	Archibald, Erin Nicole	01/21/1988	Auburn University Main Campus		800 Prudential Drive	Jacksonville, FL 32207
PS	50421	07/02/2013	Carter, Lori Daniele	12/01/1988	University Of Florida		800 Prudential Drive	Jacksonville, FL 32207
PS	50422	07/02/2013	Chapman, Megan Elizabeth	01/27/1987	Auburn University Main Campus		6025 Mobile Hwy.	Pensacola, FL 32526
PS	50423	07/02/2013	Dodrill, Jason Matthew	10/15/1986	Palm Beach Atlantic University		6700 Bayshore Rd	North Fort Myers, FL 33917
PS	50424	07/02/2013	Duane, Alyssa Nicole	08/19/1988	University Of Florida		3634 Rogero Rd	Jacksonville, FL 32277
PS	50425	07/02/2013	Fogarty, Taylor Lynn	08/29/1988	University Of Florida		1700 S Tamiami Trail	Sarasota, FL 34239
PS	50426	07/02/2013	Tumbleston, Kyle Richard	11/11/1986	University Of Florida		315 W Platt Street	Tampa, FL 33607
PS	50427	07/02/2013	Gamba, Alyssa Lynn	09/10/1986	University Of Florida		2747 Gulf To Bay Blvd.	Clearwater, FL 33759
PS	50428	07/02/2013	Eyer, Rachel Lynn	09/07/1985	University Of Florida		6543 S Tamiami Trail	Sarasota, FL 34231

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	50429	07/02/2013	Rios, Lauren Alexis	10/07/1987	University Of Florida		655 West 8Th Street	Jacksonville, FL 32209
PS	50430	07/03/2013	Foskey, Daniel Blake	10/28/1988	University Of Florida		10000 Bay Pines Blvd	Bay Pines, FL 33744
PS	50431	07/03/2013	Fung, Brian Kwok-Wai	08/12/1987	University Of Florida		1700 South Tamiami Trail	Sarasota, FL 34239
PS	50432	07/03/2013	Mollohan, Sarah Elizabeth	07/07/1987	East Tennessee State University		1714 Highway 93 #11	Fall Branch, TN 37656
PS	50433	07/03/2013	Honein, Danielle	06/18/1988	University Of Florida		1700 S. Tamiami Trail	Sarasota, FL 34239
PS	50434	07/03/2013	Leonard, Paul Theodore	12/19/1985	University Of Florida		731 Duval Station Rd #4	Jacksonville, FL 32218
PS	50435	07/03/2013	Marandici, Christine Anne	12/12/1987	University Of Florida		10831 Fox Glen Drive	Boca Raton, FL 33428
PS	50436	07/03/2013	Mcallister, Matthew Wade	10/03/1986	Drake University		655 West 8Th Street	Jacksonville, FL 32209
PS	50437	07/03/2013	Brantley, Lisa Michele	06/20/1980	Mercer University		800 Rose St	Lexington, KY 40508
PS	50438	07/03/2013	Kareka, Steven Anthony	09/11/1984	University Of Florida		8905 Bryan Dairy Rd	Seminole, FL 33777
PS	50439	07/03/2013	Colletti, Courtney Christine	05/02/1988	University Of Florida		7575 Osceola Polk Line Road	Davenport, FL 33896
PS	50440	07/03/2013	Coleman, James David	10/22/1983	University Of Florida		2261 W Edgewood Ave	Jacksonville, FL 32209
PS	50441	07/03/2013	Miller, Anne Marie	08/17/1988	University Of Florida		1544 N Dale Mabry Hwy	Tampa, FL 33607
PS	50442	07/03/2013	Nguyen, Nam Huy	10/02/1985	University Of Florida		1 Shircliff Way	Jacksonville, FL 32204
PS	50443	07/03/2013	Opalenyk, Iryna V	04/10/1986	University Of Florida		1 Shircliff Way	Jacksonville, FL 32204
PS	50444	07/03/2013	Patel, Krishna Sanmukh	08/24/1989	University Of Florida		1601 Sw Archer Road	Gainesville, FL 32608
PS	50445	07/03/2013	Sessions, Katryna Jo	09/26/1979	University Of Florida		405 Se Braughton Street	Branford, FL 32008
PS	50446	07/03/2013	Shomo, Eileen Catherina	03/18/1988	University Of Florida		655 W 8Th Street	Jacksonville, FL 32209
PS	50447	07/03/2013	Trang, Joseph Hai	02/28/1989	University Of Florida		9734 Bosque Creek Circle Apt 303	Tampa, FL 33619
PS	50448	07/03/2013	Burbage, Sarah Elizabeth	03/04/1988	University Of Florida		2489 Diplomat Parkway East	Cape Coral, FL 33909
PS	50449	07/03/2013	So, Jeong Ho	08/06/1980	Palm Beach Atlantic University		520 S. Burnside Ave 11-H	Los Angeles, CA 90036
PS	50450	07/03/2013	Vasquez, Jackson	12/02/1988	University Of Florida		5500 Sw 77Th Ct Apt 209	Miami, FL 33155
PS	50451	07/05/2013	Adkins, David Shawn	05/21/1986	University Of Findlay		27841 Crown Lake Blvd	Bonita Springs, FL 34135
PS	50452	07/05/2013	Rakestraw, Katherine Rose	04/10/1986	Mercer University		2302 Jim Redman Pkwy	Plant City, FL 33563

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	50453	07/05/2013	Duffy, Caitlin Amber	08/05/1989	University Of Florida		800 North Orange Avenue	Green Cove Springs, FL 32043
PS	50454	07/08/2013	Medvid, Andrea Paula	09/09/1968	University Of Florida		800 Ocala Rd	Tallahassee, FL 32304
PS	50455	07/08/2013	Ellis, Catrina Altrell	06/10/1987	Florida A & M University		18290 Collins Ave	Sunny Isles, FL 33160
PS	50456	07/08/2013	Lockwood, Ashley Marie	05/18/1987	University Of Florida		1 Shircliff Way	Jacksonville, FL 32204
PS	50457	07/08/2013	Pezzoli, Maria Wells	09/02/1977	University Of Florida		4000 N Goldenrod Rd	Winter Park, FL 32792
PS	50458	07/08/2013	Sherman, Matthew Mark	01/03/1989	University Of Florida		10000 Bay Pines Blvd	Bay Pines, FL 33744
PS	50459	07/08/2013	Mazalewski, Kristen Lee	06/08/1987	University Of Florida		5881 N University Dr	Tamarac, FL 33321
PS	50460	07/08/2013	Healy, Karl Joseph	04/05/1986	University Of Florida		1630 E Marks St	Orlando, FL 32803
PS	50461	07/08/2013	Voils, Stacy Alan	08/29/1971	University Of Kentucky		401 N. 12Th St	Richmond, VA 23298
PS	50462	07/08/2013	Bullard, John Christopher	10/14/1986	University Of Georgia		619 S Marion Ave	Lake City, FL 32025
PS	50463	07/08/2013	Knizner, Megan Diane	08/13/1987	University Of Florida		9509 San Jose Blvd.	Jacksonville, FL 32257
PS	50464	07/08/2013	Young, Ryan B	02/19/1989	Palm Beach Atlantic University		1589 W Lantana Rd	Lantana, FL 33462
PS	50465	07/08/2013	Durand, Gabrielle Desiree	07/13/1986	University Of Florida		508 10Th St E	Palmetto, FL 34221
PS	50466	07/08/2013	Walters, Conrad Mario	03/08/1989	Florida A & M University		15600 Sw 146 Ave.	Miami, FL 33177
PS	50467	07/08/2013	Morris, Stewart Andrew	08/31/1976	University Of Florida		655 West 8Th Street	Jacksonville, FL 32209
PS	50468	07/08/2013	Sanz, Derek Anthony	03/10/1986	University Of Florida		12026 Anderson Rd	Tampa, FL 33625
PS	50469	07/08/2013	Mourafetis, Jennifer Anne	05/25/1965	University Of Illinois At Chicago		151 N Michigan Ave #3701	Chicago, IL 60601
PS	50470	07/08/2013	Jackson, Kimberly Joy	12/03/1989	University Of Florida		9143 Phillips Highway, Suite 533	Jacksonville, FL 32256
PS	50471	07/08/2013	Gamble, Ginger Price	02/07/1986	Campbell University Incorporated		1600 Archer Rd	Gainesville, FL 32610
PS	50472	07/08/2013	Padgett, Kimberly Diane	10/15/1984	Florida A & M University		11018 Aaron Fish Road	Glen Saint Mary, FL 32040
PS	50473	07/08/2013	Bailey, Hanna	10/22/1982	University Of Florida		1414 Kuhl Ave Mp 192	Orlando, FL 32806
PS	50474	07/08/2013	Bock, Cassandra Lee	10/20/1987	South Carolina College Of Pharmacy		10899 Baymeadows Road	Jacksonville, FL 32256
PS	50475	07/08/2013	Fields, Laura Middleton	09/25/1985	University Of Florida		2513 Us Highway 19	Holiday, FL 34691

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PS	50476	07/08/2013	Brown, Brian Keith	06/27/1987	University Of Georgia		1600 7Th Ave South	Birmingham, AL 35233
PS	50477	07/08/2013	Johnson, Lori Ann	11/20/1985	Florida A & M University		10936 Nw Judy Drive	Bristol, FL 32321
PS	50478	07/08/2013	Heil, Erin Barbara	07/05/1988	University Of Florida		2303 Sw 75Th St.	Gainesville, FL 32608
PS	50479	07/08/2013	Belin, Lauren Ashley	11/01/1987	Florida A & M University		2250 S. Ferdon Blvd	Crestview, FL 32536
PS	50480	07/08/2013	Pawlik, Erica Evona	01/30/1985	University Of Florida		2390 East Bay Drive	Largo, FL 33771
PS	50481	07/08/2013	Foster, Julie Marie	12/02/1987	University Of Florida		124 Sunflower Circle	Royal Palm Beach, FL 33411
PS	50482	07/09/2013	Ellis, Heather Jean	08/03/1988	St Louis College Of Pharmacy		6500 W Newberry Rd	Gainesville, FL 32605
PS	50483	07/09/2013	Beadle, Barbara Ann	08/31/1968	University Of Florida		4305 Norfolk Pkwy	West Melbourne, FL 32904
PS	50484	07/09/2013	Karara, Kareem Adel	11/28/1986	Philadelphia College Of Pharmacy And Sci		806G Barkwood Court	Linthicum, MD 21090
PS	50485	07/09/2013	Jarriel, Mallory Anne	03/14/1989	University Of Georgia		1300 Miccosukee Rd	Tallahassee, FL 32308
PS	50486	07/09/2013	Tucker, Amelia Nadine	04/01/1990	University Of Florida		120 W Walker Dr	Keystone Heights, FL 32656
PS	50487	07/09/2013	Vincent, Marc-Andre	08/02/1987	University Of Florida		1201 Nw 16Th St. #119	Miami, FL 33125
PS	50488	07/09/2013	Vogt, Jacqueline Cari Conrad	02/23/1988	University Of Florida		8801 West Linebaugh Avenue	Tampa, FL 33626
PS	50489	07/09/2013	Pham, Gina Thuy	05/20/1982	Palm Beach Atlantic University		15295 Collier Blvd	Naples, FL 34119
PS	50490	07/09/2013	Capehart, Jenelle	04/15/1985	Mercer University		704 W Mlk Blvd	Seffner, FL 33584
PS	50491	07/09/2013	Peterson, Jennifer Marie	10/06/1983	University Of Florida		2261 W New Haven Ave	West Melbourne, FL 32904
PS	50492	07/09/2013	Ryan, Kevin Michael	07/11/1987	University Of Florida		1835 W. Sand Lake Rd.	Orlando, FL 32809
PS	50493	07/09/2013	Wahid, Shabnam Y	03/18/1987	University Of Florida		7431 Atlantic Blvd	Jacksonville, FL 32211
PS	50494	07/09/2013	Alle, Michael Oluwole	03/25/1987	University Of Florida		850 Ives Dairy Rd Ste T-1	North Miami, FL 33179
PS	50495	07/09/2013	Hendrickson, Andrew Lawrence	11/15/1988	University Of Florida		3615 Se 171St Street	Hawthorne, FL 32640
PS	50496	07/09/2013	Quintana, Laurene Anne	03/21/1989	University Of Florida		150 Se 3Rd Ave	Miami, FL 33133
PS	50497	07/09/2013	Robertson, Heather Marie	11/28/1978	Palm Beach Atlantic University		2100 Se Salerno Road	Stuart, FL 34997
PS	50498	07/09/2013	Tran, Sylvia	05/04/1988	University Of Florida		1601 Sw Archer Road	Gainesville, FL 32608
PS	50499	07/09/2013	Vallejos, Ximena	10/10/1987	Nova Southeastern University		1201 Nw 16Th St	Miami, FL 33125

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PS	50500	07/09/2013	Rugay, Erika Joy	02/29/1988	University Of Florida		3001 W Dr Martin Luther King Jr Blv	Tampa, FL 33607
PS	50501	07/09/2013	Boles, Katherine Littig	06/28/1981	University Of Florida		1601 S.W. Archer Road	Gainesville, FL 32608
PS	50502	07/09/2013	Varghese, Maryann Joseph	10/11/1988	University Of Florida		9650 Sw 9Th Court	Pembroke Pines, FL 33025
PS	50503	07/09/2013	Capristo, Alexis Monica	12/20/1987	University Of Florida		8905 Bryan Dairy Rd	Largo, FL 33777
PS	50504	07/09/2013	Islam, Fahad	05/06/1984	Palm Beach Atlantic University		6464 N. Atlantic Ave	Delray Beach, FL 33484
PS	50505	07/09/2013	Lokken, Heather Dawn	01/11/1984	Wingate University School Of Pharmacy		2301 Moody Blvd	Flagler Beach, FL 32136
PS	50506	07/09/2013	Morales, Jose Ricardo	07/23/1986	Palm Beach Atlantic University		818 Southern Blvd	West Palm Beach, FL 33405
PS	50507	07/10/2013	Lieu, Siam	04/27/1976	Mercer University		1090 Spirit Lake Rd	Winter Haven, FL 33880
PS	50508	07/10/2013	Low, Yee Won	09/04/1981	Suny At Buffalo		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50509	07/10/2013	Cogan, Patrick Shane	11/10/1987	University Of Florida		4409 Sw 20Th Lane	Gainesville, FL 32607
PS	50510	07/10/2013	Schnell, Lauren Mariea	03/29/1983	University Of Florida		14550 St Augustine Rd	Jacksonville, FL 32258
PS	50511	07/10/2013	Falco, Ornella	04/19/1986	Palm Beach Atlantic University		800 State Rd 7	Wellington, FL 33414
PS	50512	07/10/2013	Ghonim, Ahmed Abdelmonem	09/20/1988	University Of Florida		619 S Marion Avenue	Lake City, FL 32025
PS	50513	07/10/2013	Haywood, Patti Michelle	09/13/1988	University Of Florida		25809 Sw Highway 19	Old Town, FL 32680
PS	50514	07/10/2013	Teman, Jason Marc	03/17/1986	Appalachian College Of Pharmacy		2109 State Rd 60 E	Valrico, FL 33594
PS	50515	07/10/2013	Badzinski, Marina Kaoli Repp	11/23/1987	University Of Florida		482 E. Altamonte Dr Ste 1005	Altamonte Springs, FL 32701
PS	50516	07/10/2013	Jackson, Alexandra Jaye	04/06/1989	Ohio Northern University		3 Cidermill Hgts	North Granby, CT 06060
PS	50517	07/10/2013	Peterson, Joel Aaron	11/13/1983	University Of Florida		667 Jamestown Blvd Apt 1066	Altamonte Springs, FL 32714
PS	50518	07/10/2013	Shaw, Cara Elizabeth	11/12/1979	Sullivan University College Of Pharmacy		8351 West Rockville Rd	Indianapolis, IN 46234
PS	50519	07/10/2013	Howard, Brooke Samantha	01/02/1984	Florida A & M University		3753 Winkler Avenue Ext Apt 936	Fort Myers, FL 33916
PS	50520	07/10/2013	Aramini, Richard Zachary	05/12/1986	University Of Florida		10000 Bay Pines Blvd N	Bay Pines, FL 33744

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PS	50521	07/10/2013	Arwood, Meghan Jane	02/12/1988	University Of Florida		1350 S. Hickory St.	Melbourne, FL 32901
PS	50522	07/10/2013	Baker, Katelyn Elizabeth	03/18/1987	Albany College Of Pharmacy		106 Lincoln Street	Sitka, AK 99835
PS	50523	07/10/2013	Burge, Tina E	12/27/1980	Florida A & M University		13000 Bruce B. Downs Blvd	Tampa, FL 33612
PS	50524	07/10/2013	Burke, Savita	07/07/1986	University Of Florida		2931 S. Mccall Rd	Englewood, FL 34224
PS	50525	07/10/2013	Calixte, Julie	06/26/1987	Temple University		500 South 11Th Street	Lake Wales, FL 33853
PS	50526	07/10/2013	Desai, Darshanaben Nikhildev	03/31/1984	Palm Beach Atlantic University		1634 S Federal Hwy	Boynton Beach, FL 33455
PS	50527	07/10/2013	Davis, Christine Louise	05/26/1987	University Of Florida		5301 Mcauley Drive	Ypsilanti, MI 48197
PS	50528	07/10/2013	Rodriguez, George David	06/10/1987	Florida A & M University		655 W 8Th St.	Jacksonville, FL 32209
PS	50529	07/10/2013	Stosh, Jennifer Marie	06/30/1987	University Of Florida		300 Pinellas St Ms #51	Clearwater, FL 33756
PS	50530	07/10/2013	Thibodeaux, Logan Scott	06/24/1988	University Of Louisiana At Monroe		655 W. Eighth St.	Jacksonville, FL 32209
PS	50531	07/10/2013	Dunham, Daniel Wade	08/17/1987	Palm Beach Atlantic University		4232 Ne Ocean Boulevard	Jensen Beach, FL 34957
PS	50532	07/10/2013	Fawaz, Tarek Ali	06/07/1988	University Of Florida		7405 Starkey Road	Largo, FL 33777
PS	50533	07/10/2013	Gejdel, Katarzyna	12/23/1980	Saint John'S University New York		1650 Grand Concourse	Bronx, NY 10457
PS	50534	07/10/2013	Ho, Lee Xuan	01/18/1986	University Of Florida		200 37 Ave N.	Saint Petersburg, FL 33704
PS	50535	07/10/2013	Hoang, Kim Nguyen	12/14/1986	University Of Florida		1601 Sw Archer Rd	Gainesville, FL 32608
PS	50536	07/10/2013	Huber, Don Raynes	11/15/1967	University Of Pittsburgh Central Office		49 Pine Grove Plaza	Grove City, PA 16127
PS	50537	07/10/2013	Jagat, Kameela Vashti	05/21/1989	Palm Beach Atlantic University		7621 N State Rd 7	Parkland, FL 33073
PS	50538	07/10/2013	Lefranc, Annette	10/30/1988	Florida A & M University		1301 Second Ave Sw	Largo, FL 33770
PS	50539	07/10/2013	Luxin, Assade Saimonth	09/12/1983	Florida A & M University		5201 Raymond Street	Orlando, FL 32803
PS	50540	07/10/2013	Mannen, Jared Matthew	03/05/1988	University Of Florida		1493 Excaliber Drive	Clearwater, FL 33764
PS	50541	07/10/2013	Mceldowney, Jessica Lynn	08/29/1983	Ohio State University Main Campus		2675 Taylor Rd Sw	Reynoldsburg, OH 43068
PS	50542	07/10/2013	Mcmahon, Andre James	06/01/1987	University Of Florida		777 Hemlock Street	Macon, GA 31201

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PS	50543	07/10/2013	Miller, Lauren Leigh	11/18/1988	Ohio Northern University		8383 N Davis Hwy	Pensacola, FL 32514
PS	50544	07/10/2013	Munyon, Lindsay Marie	07/17/1989	University Of Florida		1098 Montgomery Road	Altamonte Springs, FL 32714
PS	50545	07/10/2013	Murray, Bernard	09/18/1987	Howard University		13000 Bruce B Downs Blvd	Tampa, FL 33612
PS	50546	07/10/2013	Nettles, Kimberly Nicole	06/17/1989	Florida A & M University		15911 Pines Blvd	Pembroke Pines, FL 33027
PS	50547	07/10/2013	Pane, Olivia Renee	01/17/1989	University Of Florida		807 N. Myrtle Ave.	Clearwater, FL 33755
PS	50548	07/10/2013	Roth, Craig Matthew	10/03/1983	Palm Beach Atlantic University		3099 Nw 26Th Ct	Boca Raton, FL 33434
PS	50549	07/10/2013	Sainvil, Magdaline Duna	08/21/1990	Nova Southeastern University		5263 Palm Ridge Blvd	Delray Beach, FL 33484
PS	50550	07/10/2013	Stone, Mark David	10/18/1986	University Of Florida		701 6Th St S	Saint Petersburg, FL 33701
PS	50551	07/10/2013	Swift, Barbara Annemarie	11/10/1986	University Of Florida		3200 N. Federal Highway	Fort Lauderdale, FL 33306
PS	50552	07/10/2013	Glumova, Anastacia Sergeyevna	02/23/1987	University Of Florida		3001 W. Dr. M.L. King Jr Blvd	Tampa, FL 33607
PS	50553	07/11/2013	Trejo, Loreta Ileana	09/08/1979	Palm Beach Atlantic University		2500 Sw 22Nd St	Miami, FL 33145
PS	50554	07/11/2013	Walton, Je'Laune Latrece	03/18/1989	Florida A & M University		4500 San Pablo Road	Jacksonville, FL 32224
PS	50555	07/11/2013	Trowbridge, Erin Leigh	03/22/1985	Mercer University		4401 Commercial Way	Spring Hill, FL 34606
PS	50556	07/11/2013	Valentine, Sarah Beth	04/12/1988	University Of Florida		8275 Bay Pines Blvd	Saint Petersburg, FL 33709
PS	50557	07/11/2013	Varughese, Subin	11/04/1988	Palm Beach Atlantic University		3 S Pompano Pkwy	Pompano Beach, FL 33069
PS	50558	07/11/2013	Varughese, Bibin	11/10/1989	University Of Florida		11449 Palmetto Park Rd	Boca Raton, FL 33428
PS	50559	07/11/2013	Walters, Ryan Andrew	05/09/1987	University Of Florida		14838 Windigo Ln	Orlando, FL 32828
PS	50560	07/11/2013	Worrall, Stephanie Diana	07/22/1987	University Of Georgia		115 Creekside Dr.	Dallas, GA 30157
PS	50561	07/11/2013	Cullimore, Rachel Alexandra	09/17/1988	University Of Florida		2200 Gulf To Bay Blvd	Clearwater, FL 33765
PS	50562	07/11/2013	Davis, Tyler Calvin	11/25/1985	Mercer University		9150 Kings Crossing Rd	Fort Myers, FL 33912
PS	50563	07/11/2013	Dubois, Claudia Lynn	11/18/1987	University Of Maryland School Of Pharmacy		601 E Rollins St	Orlando, FL 32803

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PS	50564	07/11/2013	Granados, Ronald	03/30/1987	University Of Florida		4600 Coconut Creek Pkwy	Coconut Creek, FL 33063
PS	50565	07/11/2013	Jones, Brett Allen	03/16/1987	Florida A & M University		3531 Thomasville Rd	Tallahassee, FL 32303
PS	50566	07/11/2013	Levangie, Jaimie Ryan	08/27/1987	University Of Florida		1450 Johns Lake Road	Clermont, FL 34711
PS	50567	07/11/2013	Linn, Chase Evan-Michael	11/13/1987	University Of Florida		2528 N Mcmullen Booth Rd	Clearwater, FL 33761
PS	50568	07/11/2013	Martinez, Mallory Danielle	10/05/1985	University Of Florida		1765 Gulf To Bay Boulevard	Clearwater, FL 33755
PS	50569	07/11/2013	Moore, Jonathan Charles	05/07/1988	University Of Florida		1670 Clairmont Rd	Decatur, GA 30033
PS	50570	07/11/2013	Patel, Ravin Hemant	05/19/1987	Auburn University Main Campus		1001 Scenic Hwy	Pensacola, FL 32503
PS	50571	07/11/2013	Thompson, Rochelle Alesha	09/13/1986	Florida A & M University		12394 Pleasant Green Way	Boynton Beach, FL 33437
PS	50572	07/11/2013	Westwood, Brittany Lauren	11/01/1988	University Of Florida		3001 W Dr Mlk Jr Blvd	Tampa, FL 33607
PS	50573	07/11/2013	Franck, Hugh Anthony	11/07/1984	Nova Southeastern University		2324 Se 15Th St.	Ocala, FL 34471
PS	50574	07/11/2013	Lentz, Jayme Michelle	10/18/1983	Campbell University Incorporated		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50575	07/11/2013	Deogan, Navdeep Singh	08/17/1982	University Of Florida		1618 Pink Guara Court	Trinity, FL 34655
PS	50576	07/11/2013	Baek, Hyeon Sop	05/25/1988	University Of Florida		3880 N 9Th Ave	Pensacola, FL 32503
PS	50577	07/11/2013	Bryant, Christina Marchan	03/08/1985	University Of Florida		1451 El Camino Real	The Villages, FL 32159
PS	50578	07/11/2013	Krasilova, Irina N	07/23/1985	University Of Florida		1950 Sr 19N	Eustis, FL 32726
PS	50579	07/11/2013	Channer, Debra Anne	10/21/1986	Florida A & M University		21950 S. Tamiami Tr.	Estero, FL 33928
PS	50580	07/11/2013	Fahmi, Bassem	07/09/1975	Midwestern State University		5000 S. Fifth Ave.	Hines, IL 60141
PS	50581	07/11/2013	Frederick, Corey Michael	04/18/1988	University Of Florida		1611 Nw 12Th Avenue	Miami, FL 33136
PS	50582	07/11/2013	Fuerte, Wilbert Jacinto	10/30/1980	Union University		6200 Sw 73Rd Street	Miami, FL 33143
PS	50583	07/11/2013	Gnecco, Christopher Michael	06/05/1988	University Of Florida		13697 W Colonial Dr	Winter Garden, FL 34787
PS	50584	07/11/2013	Grant, Richard Dennis	07/17/1960	University Of Illinois At Chicago		2020 West Harrison Street	Chicago, IL 60612

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	50585	07/11/2013	Hill, Renita Jakevia	05/24/1989	Florida A & M University		9359 Sheridan Street	Cooper City, FL 33024
PS	50586	07/11/2013	Hogrefe, Paula Lynn	07/04/1987	University Of Florida		5841 S. Maryland Ave	Chicago, IL 60637
PS	50587	07/11/2013	Jenkins, Leakesia Shaleem	05/23/1981	Florida A & M University		7410 Mcneil Dr	Austin, TX 78729
PS	50588	07/11/2013	Kanacheril, Shancy Varghese	09/03/1988	University Of Florida		9150 Kings Crossing Rd	Fort Myers, FL 33912
PS	50589	07/11/2013	Lund, Jeremy Alan	03/18/1987	University Of Florida		5255 Belcher Road	Clearwater, FL 33764
PS	50590	07/11/2013	Mathis, Alan Ryan	08/16/1985	University Of Florida		5375 N Socrum Loop Rd	Lakeland, FL 33809
PS	50591	07/11/2013	Mccray, Lora Ann	06/17/1988	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		101 N. Cattlemen Rd	Sarasota, FL 34243
PS	50592	07/11/2013	Pham, Susan Minh Nguyet	12/26/1988	University Of Florida		2800 Sw Williston Rd Apt 933	Gainesville, FL 32608
PS	50593	07/12/2013	Heath, Ryan Preston	12/30/1987	David Lipscomb University		2774 N. Cobb Pkwy	Kennesaw, GA 30152
PS	50594	07/12/2013	Pierre-Jean, Emmanuelle	03/29/1984	Mercer University		73 White Hall Drive	Palm Coast, FL 32164
PS	50595	07/12/2013	Kicilinski, Lukasz Jan	11/20/1986	Massachusetts College Of Phar & Allied H		12550 Professional Park Drive Unit 1	Fort Myers, FL 33913
PS	50596	07/12/2013	Busey, Kirsten Veronica	07/25/1987	University Of Georgia		655 W Eight Street	Jacksonville, FL 32209
PS	50597	07/12/2013	Harris, Jason Demetrius	01/13/1981	Florida A & M University		801 Vassar Drive Ne	Albuquerque, NM 87106
PS	50598	07/15/2013	Butler, Jesse Ivan	03/03/1984	University Of Tennessee-Knoxville		5151 N 9Th Ave	Pensacola, FL 32504
PS	50599	07/15/2013	Dewey, Todd H	06/07/1966	St. John Fisher College Wegmans School Of Pharmacy		15843 E. Hwy 40	Silver Springs, FL 34488
PS	50600	07/15/2013	Aguilar, Clare Marie	05/02/1989	University Of Florida		1000 Johnson Ferry Road Ne	Atlanta, GA 30342
PS	50601	07/15/2013	Sheth, Neeketa	09/04/1988	Nova Southeastern University		10360 Nw 60Th Place	Parkland, FL 33076
PS	50602	07/15/2013	Pinder, Kirstin Jade	09/21/1986	Palm Beach Atlantic University		69 Lazy Eight Drive	Port Orange, FL 32128
PS	50603	07/15/2013	Schneider, Bryan Victor	03/24/1984	Southern Illinois University		190 Florisant Rd	Ferguson, MO 63134
PS	50604	07/15/2013	Sorensen, Erik Andrew	09/18/1972	University Of Wisconsin-Madison		1101 N Ih-35 Frontage Rd	Georgetown, TX 78626
PS	50605	07/15/2013	Wendling, Christopher Michael	11/19/1964	Ohio State University Main Campus		8825 Us 42	Union, KY 41091

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	50606	07/15/2013	Woods, Gregory Scott	05/21/1985	University Of Florida		3212 Nw 17Th St	Gainesville, FL 32605
PS	50607	07/15/2013	Baron, Brianna Beverly	01/31/1989	Suny At Buffalo		901 N Woodland Blvd	Deland, FL 32720
PS	50608	07/15/2013	Bennett, Sharonda Lakeisha	04/19/1987	Florida A & M University		15851 N W 11Th Street	Pembroke Pines, FL 33028
PS	50609	07/15/2013	Cheung, Kevin Brian	02/16/1989	University Of Rhode Island		6117 Crystal View Drive	Orlando, FL 32819
PS	50610	07/15/2013	Davenport, Patrick Ryan	07/17/1982	David Lipscomb University		301 Memorial Medical Pkwy	Daytona Beach, FL 32117
PS	50611	07/15/2013	Evans, Darren Deon	06/19/1989	Florida A & M University		8018 Normandy Blvd	Jacksonville, FL 32221
PS	50612	07/15/2013	Barr, Drakeria Nate	01/06/1988	Florida A & M University		4252 Sw 20Th St.	West Park, FL 33023
PS	50613	07/15/2013	Estrada, Katherine Louise	12/12/1985	University Of Florida		1160 S Dixie Hwy	Coral Gables, FL 33146
PS	50614	07/15/2013	Eisenman, Robert Melvin	01/24/1954	Mercer University		110 Hawthorne Ave	Athens, GA 30606
PS	50615	07/15/2013	Fernandez, Jennifer Marie	12/09/1986	Nova Southeastern University		100004 W Mcnab Rd	Tamarac, FL 33321
PS	50616	07/15/2013	Hepler, Emily Lauren	04/27/1989	Duquesne University		3771 Clyde Morris Blvd	Port Orange, FL 32129
PS	50617	07/15/2013	Javanmardi, Cameron Asfeh	05/13/1980	Florida A & M University		1179 Iron Bridge Road	Havana, FL 32333
PS	50618	07/15/2013	Smith, Evgenia Gennadyevna	10/16/1983	University Of Florida		4109 Lazy Acres Rd	Middleburg, FL 32068
PS	50619	07/15/2013	Daniels, Melissa Dionne	10/27/1986	Florida A & M University		7924 U.S. Hwy 129 South	Jasper, FL 32052
PS	50620	07/15/2013	Lopez, Charlotte Marie	11/02/1988	University Of Florida		6025 Se Us Highway 301	Hawthorne, FL 32640
PS	50621	07/15/2013	Lopez, Benjamin Michael	03/23/1988	University Of Florida		1810 Nw 23Rd Blvd Apt 186	Gainesville, FL 32605
PS	50622	07/15/2013	Martino, Lauren Taylor	10/14/1984	University Of Mississippi Main Campus		8383 North Davis Highway	Pensacola, FL 32514
PS	50623	07/15/2013	Noriega, Melanie Solange	05/24/1989	University Of Florida		28740 S Dixie Hwy	Homestead, FL 33033
PS	50624	07/15/2013	Perkins, Alyce Mildred	01/01/1986	University Of Florida		1820 Cheney Highway	Titusville, FL 32780
PS	50625	07/15/2013	Ravani, Pankajkumar D	06/03/1984	Nova Southeastern University		2640 S University Dr #101	Davie, FL 33328

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	50626	07/15/2013	Regalado, Carlos Alberto	01/11/1988	Florida A & M University		2111 E. Busch Blvd	Tampa, FL 33612
PS	50627	07/15/2013	Santana, Elizabeth Easter	06/29/1989	University Of Florida		1120 Bichara Blvd	The Villages, FL 32159
PS	50628	07/15/2013	Snyder, Bradley James	12/06/1985	Palm Beach Atlantic University		416 Clematis St.	West Palm Beach, FL 33401
PS	50629	07/15/2013	Cho, Jonathan Chang Hyuk	11/06/1989	University Of The Pacific - Thomas J. Long School Of Pharmacy & Health Sciences		12042 Granite Woods Loop	Venice, FL 34292
PS	50630	07/15/2013	Jan, Anna Shiau-Huei	03/23/1986	University Of California-San Francisco		12902 Magnolia Drive	Tampa, FL 33612
PS	50631	07/16/2013	Hand, Stephanie Renee	03/11/1989	St Louis College Of Pharmacy		7721 Meto Lane	Jacksonville, AR 72076
PS	50632	07/16/2013	Charles, Miriam Kendra	01/18/1979	Florida A & M University		28 N. Brookwod Ave	Hamilton, OH 45013
PS	50633	07/16/2013	Dike, Chinyere Laura	09/10/1987	Florida A & M University		1708 N Monroe St	Tallahassee, FL 32303
PS	50634	07/16/2013	Williams, Crystal Marie	12/13/1987	Florida A & M University		613 Old Forest Way Rd	Panama City, FL 32404
PS	50635	07/16/2013	Dikas, Raphael Chinedu	12/21/1984	Husson University		6358 Forest Hill Blvd	West Palm Beach, FL 33415
PS	50636	07/16/2013	Altepeter, Stephanie Susan	08/18/1987	Butler University		3001 W. Dr. Martin Luther King Blvd	Tampa, FL 33607
PS	50637	07/16/2013	Caldas, Dasha	07/15/1963		St. John'S University New York	Presbytarian Hospital	Charlotte, NC 28204
PS	50638	07/16/2013	Jock, Melissa Joy	11/05/1976	University Of Florida		5647 Roosevelt Blvd	Jacksonville, FL 32210
PS	50639	07/16/2013	Karasiewicz, Rachael Nicole	03/22/1989	Ohio Northern University		13401 Summerlin Rd	Fort Myers, FL 33919
PS	50640	07/16/2013	Kiner, Hailey Jennifer	05/23/1984	University Of Florida		1011 Bloomingdale Ave	Valrico, FL 33594
PS	50641	07/16/2013	Milano, Joseph James	09/05/1986	University Of Florida		33670 Us Hwy 19	Palm Harbor, FL 34684
PS	50642	07/16/2013	Ramos, Miguel	08/12/1983	University Of Florida		1302 River Street	Palatka, FL 32177
PS	50643	07/16/2013	Saettele, Tonia Ann	02/18/1989	St Louis College Of Pharmacy		Baptist Health	Jacksonville, FL 32207
PS	50644	07/16/2013	Thomack, Caitlynn Ann	06/29/1987	St Louis College Of Pharmacy		8183 Thames Boulevard Apartment B	Boca Raton, FL 33433

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PS	50645	07/16/2013	Tran, Kim Thanh	11/12/1979	Virginia Commonwealth University		2924 E. 92Nd Street	Chicago, IL 60617
PS	50646	07/16/2013	Werling, Matthew Marshall	01/13/1982	Drake University		501 6Th Ave South	Saint Petersburg, FL 33701
PS	50647	07/16/2013	Williams, Sherifa Christina	10/20/1989	Florida A & M University		1106 Sandler Ridge Road	Tallahassee, FL 32317
PS	50648	07/16/2013	Al-Qaisi, Faraed Qais	06/11/1976	Foreign Schools		575 W Madison St Tower #2, Apt #3712	Chicago, IL 60661
PS	50649	07/16/2013	Buidens, Jeffrey Raymond	07/29/1981	University Of Florida		2528 N Mcmullen Booth Rd	Clearwater, FL 33761
PS	50650	07/16/2013	Fant, Erika Holly	12/04/1988	University Of Florida		2132 Dolphin Blvd S	Saint Petersburg, FL 33707
PS	50651	07/16/2013	Lorvinsky, Eden Lorna	06/18/1988	Florida A & M University		294 Indian Trace	Weston, FL 33326
PS	50652	07/16/2013	Green, Robert William	03/15/1989	University Of Rhode Island		11212 Dale Mabry Highway	Tampa, FL 33618
PS	50653	07/16/2013	Liu, Esther Chern-Ai	08/11/1989	Rutgers The State University Central Off		1 Tampa General Circle	Tampa, FL 33606
PS	50654	07/16/2013	Lloyd, Danielle Alexandra	02/24/1989	West Virginia University		1414 Kuhl Ave	Orlando, FL 32806
PS	50655	07/16/2013	Lopilato, Alex Chase	02/12/1988	Nova Southeastern University		1 Tampa General Circle	Tampa, FL 33606
PS	50656	07/16/2013	Courage, Jonathan Mitsuo	12/29/1988	Ohio Northern University		3502 54Th Avenue South	Saint Petersburg, FL 33711
PS	50657	07/16/2013	Long, Megan Corey	11/24/1986	Florida A & M University		4434 Gearheart Rd #302	Tallahassee, FL 32303
PS	50658	07/16/2013	Snyder, Katherine Marie	01/14/1988	University Of Florida		125 E. Main St	
PS	50659	07/16/2013	Oni, Amanda Hudson	10/11/1979	University Of Florida		1821 E Bridge St	Brighton, CO 80601
PS	50660	07/16/2013	Schneider, Frances Adele	05/01/1987	Southern Illinois University		305 Glenwood Drive	Glen Carbon, IL 62034
PS	50661	07/16/2013	Shin, June Heeyon	06/27/1989	Florida A & M University		3228 Whitman Way	Tallahassee, FL 32311
PS	50662	07/16/2013	Golden, Shara Melissa	01/29/1982	Nova Southeastern University		2121 N Ocean Blvd #1507E	Boca Raton, FL 33431
PS	50663	07/16/2013	Bryant, Devin Levon	07/11/1986	Florida A & M University		2260 East Park Avenue	Tallahassee, FL 32301
PS	50664	07/17/2013	Mohan, Ann Marie	10/15/1984	Howard University		11000 N Military Trail	Palm Beach Gardens, FL 33410

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PS	50665	07/17/2013	Skillman, Kathleen Rose	04/20/1987	Albany College Of Pharmacy		9578 Harding Ave	Surfside, FL 33154
PS	50666	07/17/2013	Brooks, Renetta Leigharnette	07/05/1988	Florida A & M University		1250 Greenview Shores Blvd	Wellington, FL 33414
PS	50667	07/17/2013	Taylor, Max-Alexander	09/09/1987	Palm Beach Atlantic University		214 N Dixie Hwy	Lake Worth, FL 33460
PS	50668	07/17/2013	Zlicha, Ariel Shlomo	07/30/1985	Nova Southeastern University		5900 State Rd 7	Lake Worth, FL 33449
PS	50669	07/17/2013	Glover, Brittany Christine	04/04/1989	South Carolina College Of Pharmacy		175 Forum Dr	Columbia, SC 29229
PS	50670	07/17/2013	Min, Han	03/12/1982	University Of Florida		200 South State Road 434	Altamonte Springs, FL 32714
PS	50671	07/17/2013	Stewart, Jebidah Danner	02/24/1981	Mercer University		2318 Frederica St	Owensboro, KY 42301
PS	50672	07/17/2013	Garrison, Mark Jacob	03/09/1985	University Of Arkansas For Medical Scien		720 S Sapodilla Ave #403	West Palm Beach, FL 33401
PS	50673	07/17/2013	Leung, Helen	11/16/1983	Regis University		3742 Terrapin Lane #2107	Coral Springs, FL 33067
PS	50674	07/17/2013	Witherow, Michael Anthony	08/27/1988	Ohio Northern University		11494 Bonita Beach Rd #96	Bonita Springs, FL 34135
PS	50675	07/17/2013	Bergin, Jonathan Ismeal	09/27/1986	University Of Florida		6160 26Th Ave N	Saint Petersburg, FL 33710
PS	50676	07/17/2013	Beshai, Amy	11/17/1982	Massachusetts College Of Phar & Allied H		2598 Bayshore Blvd	Dunedin, FL 34698
PS	50677	07/17/2013	Cooper, Melanie Brooke	05/02/1982	University Of Florida		1077 Lee-Jackson Hwy	Staunton, VA 24401
PS	50678	07/17/2013	Dephillips, Emily Sexton	09/18/1989	South University		790 Veterans Way	Pensacola, FL 32507
PS	50679	07/17/2013	Deshpande, Swapna	03/12/1977	University Of Florida		8 Nw Main St	Williston, FL 32696
PS	50680	07/17/2013	Ejiowhor, Nyemachi Crystal	02/16/1986	Howard University		753 Night Owl Court	Winter Springs, FL 32708
PS	50681	07/17/2013	Jacob, Steven	06/07/1989	Drake University		705 N Pebble Beach Blvd	Sun City Center, FL 33573
PS	50682	07/18/2013	Eljera, Michael Vincent	10/11/1985	University Of Florida		1141 Kendall Town Blvd #6107	Jacksonville, FL 32225
PS	50683	07/18/2013	Ewing, Christopher Ray	03/18/1981	Nova Southeastern University		460 Newton Place	Longwood, FL 32779
PS	50684	07/18/2013	Butler, Sarah Fitzgerald	04/17/1988	University Of Tennessee-Central Office		2237 West Nine Mile Rd	Pensacola, FL 32534

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PS	50685	07/18/2013	Ganesh, Omjoy Kumar	04/22/1976	University Of Florida		1329 Nw 16 St. Suite 2170	Gainesville, FL 32608
PS	50686	07/18/2013	Gazzia, Lauryn Rachel	05/15/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		1700 S. Tamiami Trail	Sarasota, FL 34239
PS	50687	07/18/2013	Huynh, Vu Phung	02/10/1984	Palm Beach Atlantic University		3501 Johnson Street	Hollywood, FL 33021
PS	50688	07/18/2013	Johnson, Kionna S	07/21/1989	Florida A & M University		615 Love Ave	Tifton, GA 31794
PS	50689	07/18/2013	Kong, Ben Ling	11/09/1986	Oregon State University		1600 Sw Archer Rd	Gainesville, FL 32608
PS	50690	07/18/2013	Kue, May Herning Vang	06/30/1974	University Of Wisconsin-Madison		2440 West Mason Street	Green Bay, WI 54303
PS	50691	07/18/2013	Lee, Stedman Jermaine	01/14/1989	Florida A & M University		1848 Farmer Road	Conyers, GA 30012
PS	50692	07/18/2013	Morales, Rosana	12/06/1986	Palm Beach Atlantic University		300 W Sugarland Hwy	Clewiston, FL 33440
PS	50693	07/18/2013	Adom, Atta Kwasi Nkansah	07/10/1982	Nova Southeastern University		6997 College Court Apt 205	Davie, FL 33317
PS	50694	07/18/2013	Morgan, Nora Dunne	08/23/1989	Albany College Of Pharmacy		1601 Archer Rd	Gainesville, FL 32608
PS	50695	07/18/2013	Patel, Jigna	06/04/1985	Palm Beach Atlantic University		1000 36Th Street	Vero Beach, FL 32960
PS	50696	07/18/2013	Piette, Nicole Marie	01/16/1987	St Johns College Main Campus		611 St. Joseph Ave	Marshfield, WI 54449
PS	50697	07/18/2013	Simpson, Christopher James	10/03/1976	Samford University		24333 Al Hwy 24 Suite A	Trinity, AL 35673
PS	50698	07/18/2013	Hunziker, Stephanie Jane	11/19/1978	St Louis College Of Pharmacy		8314 Tampa Point Blvd	Tampa, FL 33621
PS	50699	07/18/2013	Ullman, Seth Wilbert	11/12/1988	West Virginia University		9150 Kings Crossing Rd	Fort Myers, FL 33912
PS	50700	07/18/2013	Bushong, Stephanie Jade	05/05/1987	David Lipscomb University		852 Gulf Breeze Pkwy	Gulf Breeze, FL 32561
PS	50701	07/18/2013	Fricks, Matthew Robert	03/04/1987	David Lipscomb University		2090 S Hwy 29	Cantonment, FL 32533
PS	50702	07/18/2013	Griffin, Brian Charles	09/04/1987	University Of Georgia		4500 San Pablo Road	Jacksonville, FL 32224
PS	50703	07/18/2013	Walters, Erika Anne	04/19/1987	University Of Florida		16432 Edgemont Drive	Fort Myers, FL 33908
PS	50704	07/18/2013	Williams, Cheryl-Ann Nattiline	02/29/1972	Nova Southeastern University		900 South Sr 7	Hollywood, FL 33023
PS	50705	07/18/2013	Williams, Sherry Nichelle	07/22/1981	Chicago State University		12902 Magnolia Drive	Tampa, FL 33612

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PS	50706	07/18/2013	Willis, Crystal Lynn	08/10/1985	University Of Georgia		1920 County Road 581	Wesley Chapel, FL 33544
PS	50707	07/18/2013	Fisher, George Irving Ii	07/03/1989	Hampton University School Of Pharmacy		2302 Jim Redman Pkwy	Plant City, FL 33563
PS	50708	07/18/2013	Haynick, Marshall David	05/17/1987	University Of Florida		1611 Nw 12Th Ave	Miami, FL 33136
PS	50709	07/18/2013	Kurian, Kevin	12/22/1988	Nova Southeastern University		9728 Nw 1St Manor	Coral Springs, FL 33071
PS	50710	07/18/2013	Malo, Frank James	10/29/1985	University Of Florida		193 Old Oak Circle	Palm Harbor, FL 34683
PS	50711	07/18/2013	Pickens, Melvin S Jr	10/14/1985	Nova Southeastern University		14000 Us Hwy 1	North Palm Beach, FL 33404
PS	50712	07/18/2013	Tran, Jackie	02/11/1988	University Of Maryland School Of Pharmacy		1600 Sw Archer Rd	Gainesville, FL 32610
PS	50713	07/18/2013	Woeber, Matthew Anthony	11/24/1984	University Of Florida		1324 Lakeland Hills Blvd	Lakeland, FL 33805
PS	50714	07/19/2013	Butkevich, Zinaida	06/26/1988	University Of Florida		601 E. Commercial Blvd	
PS	50715	07/19/2013	Mathai, Anup K	01/09/1987	Palm Beach Atlantic University		670 E Oakland Park Blvd	Oakland Park, FL 33334
PS	50716	07/19/2013	Vila, Ivan	12/28/1984	Nova Southeastern University		1250 Providence Blvd	Deltona, FL 32725
PS	50717	07/19/2013	Kish, Milena	08/18/1970	St Johns College Main Campus		100 Grand Cove Way Apt 5C	Edgewater, NJ 07020
PS	50718	07/22/2013	Hernandez, Jason Edward	12/27/1974	University Of Texas At Austin		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50719	07/22/2013	Okaro, Osaneme Chuka	10/25/1985	Florida A & M University		13053 Cortez Blvd	Brooksville, FL 34613
PS	50720	07/22/2013	Maraldo, Gene Peter	11/13/1964	Philadelphia College Of Pharmacy And Sci		3535 N Tamiami Trail	Sarasota, FL 34234
PS	50721	07/22/2013	Walsh, Conor Thomas	02/12/1988	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		100 N Miramar	Indialantic, FL 32903
PS	50722	07/22/2013	Mahfuz, Sultan	08/11/1988	Nova Southeastern University		7534 Lake Worth Rd	Lake Worth, FL 33467
PS	50723	07/22/2013	Acosta, Shana Krieger	09/16/1984	Nova Southeastern University		23682 Us Hwy 19 North	Clearwater, FL 33765
PS	50724	07/23/2013	Pugh, April Nicole	01/09/1986	Florida A & M University		501 Se 18Th Ave	Boynton Beach, FL 33435
PS	50725	07/23/2013	Peil, Aaron Timothy	09/16/1985	Ohio State University Main Campus		7101 Radio Rd	Naples, FL 34104
PS	50726	07/23/2013	Mitrani, Adam Samuel	05/23/1986	Nova Southeastern University		2911 E Fowler Ave	Tampa, FL 33612

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PS	50727	07/23/2013	Lyn, Aisheik Jamie	12/15/1983	Harding Univeristy		14000 Us Highway 1	Juno Beach, FL 33408
PS	50728	07/23/2013	Thakkar, Chintankumar Arvindbhai	10/26/1985	Nova Southeastern University		2640 S University Dr Apt #101	Davie, FL 33328
PS	50729	07/23/2013	Benedikt, Danielle Elyse	08/10/1987	Nova Southeastern University		3580 N Federal Hwy	Lighthouse Point, FL 33064
PS	50730	07/23/2013	Reddy, Swathi G	06/06/1979	Massachusetts College Of Phar & Allied H		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50731	07/23/2013	Freese, Rebecca Anne	03/26/1989	University Of Florida		15880 San Carlos Blvd	Fort Myers, FL 33908
PS	50732	07/23/2013	Smith, Nakeisha Danyelle	12/24/1986	Florida A & M University		2039 N. Meridian Rd #177	Tallahassee, FL 32303
PS	50733	07/25/2013	Gaylord, Kevin Lee	02/26/1979	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		301 N. Alexander St	Plant City, FL 33563
PS	50734	07/25/2013	Axtell, Samantha Dawn	09/02/1979	Palm Beach Atlantic University		1223 Creekside Drive	Wellington, FL 33414
PS	50735	07/25/2013	Azis, Amanda Capriana	01/12/1986	Albany College Of Pharmacy		2225 Dancy Trail	Clermont, FL 34714
PS	50736	07/25/2013	Betanco, Linda Idarela	10/17/1974	University Of Florida		13870 Eagle Ridge Lakes Dr #101	Fort Myers, FL 33912
PS	50737	07/25/2013	Bhakta, Harivadankumar Narendra	11/22/1986	University Of Florida		10 Yvonne Court	Havana, FL 32333
PS	50738	07/25/2013	Cunningham, Kathryn Mae	06/08/1987	University Of Toledo		2333 Biddle Ave	Wyandotte, MI 48192
PS	50739	07/25/2013	Chuang, Shu-Hui	10/28/1984	Mercer University		1160 Malabar Rd Se	Palm Bay, FL 32907
PS	50740	07/25/2013	Dang, Chinh Thi Kieu	09/12/1983	Nova Southeastern University		602 W Main St	Inverness, FL 34450
PS	50741	07/25/2013	De La Barrera, Anabel	01/07/1978	Nova Southeastern University		2599 S.W. 147 Ave	Miami, FL 33185
PS	50742	07/25/2013	Debraganca, Ryan Walter	09/11/1984	Nova Southeastern University		1150 Ne 26Th St	Wilton Manors, FL 33305
PS	50743	07/25/2013	Dowd, Caitlin Marie	07/28/1989	University Of Rhode Island		1601 Sw Archer Rd	Gainesville, FL 32608
PS	50744	07/25/2013	Edquist, Nicole Kristen	03/09/1989	Palm Beach Atlantic University		2501 Broadway	Riviera Beach, FL 33404
PS	50745	07/25/2013	Demps, Jonathan Raymond	09/26/1985	Nova Southeastern University		1740 Palm Cove Blvd Apt 201	Delray Beach, FL 33445

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PS	50746	07/25/2013	Garbizo, Monica Leigh	09/26/1987	University Of Florida		1305 N. University Dr	Coral Springs, FL 33071
PS	50747	07/25/2013	Hoenstine, Ashley Morell	09/07/1985	University Of Florida		2871 Clayton Crossing Way	Oviedo, FL 32765
PS	50748	07/25/2013	Jacobs, Andrew Thomas	10/13/1986	Nova Southeastern University		1150 Ne 26Th St	Wilton Manors, FL 33071
PS	50749	07/25/2013	Le, Victoria Lanchi	11/04/1988	Florida A & M University		1025 Grove Park Circle	Boynton Beach, FL 33436
PS	50750	07/25/2013	Cadet, Guesline J	04/02/1987	Florida A & M University		200 Sw 13Th St	Miami, FL 33130
PS	50751	07/25/2013	Lee, Troy Jackson	06/29/1971	Campbell University Incorporated		30 Garfield Street Suite B	Asheville, NC 28803
PS	50752	07/25/2013	Mcfarlane, Jessica Joan	07/25/1988	Palm Beach Atlantic University		5388 East Leitner Drive	Coral Springs, FL 33067
PS	50753	07/25/2013	Dunaway, Shaina Nicole	07/21/1981	University Of Mississippi Main Campus		144 S. Thomas St. Suite 101-1	Tupelo, MS 38801
PS	50754	07/25/2013	Golding, Cassalee P	01/13/1988	Florida A & M University		7910 Nw 27Th Ave	Miami, FL 33147
PS	50755	07/25/2013	Gorski, Elizabeth Kimberly	01/13/1986	University Of Illinois At Chicago		9600 Gross Point Road	Skokie, IL 60076
PS	50756	07/25/2013	Guzman, Grace Mary	03/12/1986	Nova Southeastern University		5535 W 12Th Court	Hialeah, FL 33012
PS	50757	07/25/2013	Erhan, Analisa Cari	06/26/1989	University Of Florida		4271 Chelsea Harbor Drive West	Jacksonville, FL 32224
PS	50758	07/25/2013	Heng, Sokety	04/17/1984	Nova Southeastern University		566 Lancer Oak Drive	Apopka, FL 32712
PS	50759	07/25/2013	Holder, Martina Catherine	12/02/1986	Purdue University Main Campus		1600 Sw Archer Rd	Gainesville, FL 32610
PS	50760	07/25/2013	Chiaro, Maria Elaine	09/18/1962	University Of The Pacific		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50761	07/25/2013	Hurt, Leticia Anna	06/03/1988	Palm Beach Atlantic University		4617 Bougainvilla Dr	Lauderdale By The Se, FL 33308
PS	50762	07/25/2013	Jernigan, Meredith Grey	04/13/1986	University Of North Carolina Chapel Hill		650 Clinic Dr Suite 2100	Mobile, AL 36688
PS	50763	07/25/2013	Messinger, Mackenzie Clay	08/07/1987	Nova Southeastern University		4400 Nw 103 Drive	Coral Springs, FL 33065
PS	50764	07/25/2013	Milner, Abena Nyarkoa	05/27/1975	Temple University		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50765	07/25/2013	Mitchell, Natasha Katherine	09/15/1987	Florida A & M University		732 Woodyard Rd	Defuniak Springs, FL 32435

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	50766	07/25/2013	Moreland, Angela Marie	08/19/1968	Hampton University School Of Pharmacy		620 John Paul Jones Circle	Portsmouth, VA 23708
PS	50767	07/25/2013	Narcisse, Gilianne	09/01/1984	Ohio State University Main Campus		18261 N E 7Th Ct	North Miami Beach, FL 33162
PS	50768	07/25/2013	Parikh, Priya R	12/11/1988	University Of Florida		5451 Millenia Lakes Blvd Apt 161	Orlando, FL 32839
PS	50769	07/25/2013	Persad, Anand	06/08/1976	Nova Southeastern University		1700 S Federal Hwy	Fort Lauderdale, FL 33316
PS	50770	07/25/2013	Reinhartz, Lucas Donovan	11/25/1985	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		2438 Laurel Rd E	Venice, FL 34275
PS	50771	07/26/2013	Schmidt, Robert Woodrow	07/30/1985	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		1970 Roanoke Blvd	Salem, VA 24153
PS	50772	07/26/2013	Valiente, Cindy	04/25/1985	Nova Southeastern University		8695 Coral Way	Miami, FL 33155
PS	50773	07/26/2013	Ye, Xiaochun	02/07/1978	Nova Southeastern University		10001 Sheridan St	Cooper City, FL 33024
PS	50774	07/26/2013	Yonicova, Aleksandra H	12/24/1984	University Of Florida		3831 4Th St N	Saint Petersburg, FL 33703
PS	50775	07/26/2013	Handwerk, Alyssa Kristy	06/06/1989	Philadelphia College Of Pharmacy And Sci		2811 Clark Rd	Sarasota, FL 34231
PS	50776	07/26/2013	Merrill, David Joseph	04/08/1989	New England College Of Pharmacy		128 E Brandon Blvd	Brandon, FL 33511
PS	50777	07/26/2013	Patel, Dipali Harish	09/19/1986	University Of Florida		4401 W Gandy Blvd	Tampa, FL 33611
PS	50778	07/26/2013	Smith, Kareema Bilan	08/03/1983	University Of Florida		2330 Sw Williston Road Apt 2631	Gainesville, FL 32608
PS	50779	07/26/2013	Steinlage, Chantel Amy	09/28/1984	Nova Southeastern University		9031 Sw 107Th Ave	Miami, FL 33176
PS	50780	07/26/2013	Whitter, Richard Wilberforce	12/02/1986	Nova Southeastern University		10725 Wiles Road	Coral Springs, FL 33076
PS	50781	07/26/2013	Acheampong, Francis	02/12/1978	Nova Southeastern University		7000 Nova Drive Apt 307E	Davie, FL 33317
PS	50782	07/26/2013	Agbenowu, Senyo Kojo	04/12/1982	Nova Southeastern University		7000 Nova Drive Apt 307E	Davie, FL 33317
PS	50783	07/26/2013	Almassian, Halleh	10/25/1983	Nova Southeastern University		690 N W 57Th Ave	Miami, FL 33126
PS	50784	07/26/2013	Alonso, Jessica	11/03/1981	Creighton University		20345 Old Cutler Rd	Miami, FL 33189
PS	50785	07/26/2013	Bayne, Valencia Jaquita	12/09/1988	Florida A & M University		Box 14421	Tallahassee, FL 32317

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PS	50786	07/26/2013	Desai, Hemal	12/13/1984	Nova Southeastern University		4710 Palm Beach Blvd	Fort Myers, FL 33905
PS	50787	07/26/2013	Do, Patricia Thuy Truong	03/10/1982	Appalachian College Of Pharmacy		3838 Britton Plaza	Tampa, FL 33611
PS	50788	07/26/2013	Eisenman, Melissa Kaye	08/14/1988	Nova Southeastern University		324 Indian Trace Rd	Weston, FL 33326
PS	50789	07/26/2013	Giancarelli, Amanda Jo	03/07/1988	University Of Rhode Island		121 Dekalb Ave	Brooklyn, NY 11201
PS	50790	07/26/2013	Hincapie Castillo, Juan Manuel	06/23/1990	University Of Florida		8880 Old Kings Rd. S. Unit 92	Jacksonville, FL 32257
PS	50791	07/26/2013	Inza, Michael Thomas	06/29/1987	Nova Southeastern University		4599 Sheridan St	Hollywood, FL 33021
PS	50792	07/26/2013	King, Camille Jeanette	01/27/1987	Florida A & M University		1815 Stewart Place	Melbourne, FL 32935
PS	50793	07/26/2013	Lam, Maria Concepcion Puro	09/20/1975	University Of Florida		670 Marsh Landing Pkwy	Jacksonville, FL 32250
PS	50794	07/26/2013	Lopez, Arelys Maria	12/20/1985	Nova Southeastern University		101 Hialeah Drive	Hialeah, FL 33010
PS	50795	07/26/2013	Lopez, Osmar Ray	09/28/1988	Nova Southeastern University		227 Sw 8Th St	Miami, FL 33130
PS	50796	07/26/2013	Luces, Cristina Maria	05/03/1987	Nova Southeastern University		855 E 8Th Ave	Hialeah, FL 33010
PS	50797	07/26/2013	Marin, Jonathan	05/15/1987	Nova Southeastern University		10700 W. Flagler St	Miami, FL 33174
PS	50798	07/26/2013	Mehta, Niravkumar	09/20/1985	Nova Southeastern University		1745 Red Cedar Drive Apt # 12	Fort Myers, FL 33907
PS	50799	07/26/2013	Mitrani, Arlen David	04/15/1986	Nova Southeastern University		12650 S W 88 St	Miami, FL 33186
PS	50800	07/26/2013	Rodriguez, Jeanette Niurka	04/12/1986	Nova Southeastern University		2391 W 68Th St.	Hialeah, FL 33016
PS	50801	07/26/2013	Snyderman, Brett Harris	08/14/1984	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		4 South Brevard Ave	Arcadia, FL 34266
PS	50802	07/26/2013	Vanparia, Amishkumar Balubhai	04/15/1985	Nova Southeastern University		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50803	07/26/2013	Veselov, Kirill	08/11/1983	Nova Southeastern University		2974 Aventura Blvd	North Miami Beach, FL 33180
PS	50804	07/26/2013	Bond, David Ryan	09/05/1979	Nova Southeastern University		10142 W Indiantown Rd	Jupiter, FL 33478

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PS	50805	07/26/2013	Hackbarth, Steven Arthur	04/20/1986	University Of Tennessee-Central Office		99434 Overseas Hwy	Key Largo, FL 33037
PS	50806	07/26/2013	Pearce Pearson, Pamela Pearlene	06/02/1984	Nova Southeastern University		10241 W Broward Blvd	Plantation, FL 33324
PS	50807	07/26/2013	Taylor, Dahlia Olivia	12/26/1981	Nova Southeastern University		1501 S Federal Highway	Pompano Beach, FL 33062
PS	50808	07/26/2013	Sleeper, Kara Rose	10/23/1988	University Of New England		45 Lebanon St.	Sanford, ME 04073
PS	50809	07/29/2013	Montilone, Ralph David	11/27/1985	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		1903 Sr 60 East	
PS	50810	07/29/2013	Mandela, Nicketris Lekendra Simmons	01/23/1989	Florida A & M University		5701 N W 183Rd St	Hialeah, FL 33015
PS	50811	07/29/2013	Shoyoye, Joseph A	11/10/1982	Florida A & M University		152 Rollin Drive	Orange Park, FL 32073
PS	50812	07/29/2013	Llamazares, Laura	01/21/1988	Nova Southeastern University		9675 Ne 41St St	Miami, FL 33178
PS	50813	07/29/2013	Vaghani, Nileshkumar Batukbhai	11/06/1983	Nova Southeastern University		6961 College Court Apt #01-201	Davie, FL 33317
PS	50814	07/29/2013	Le, Vu Van	12/09/1983	Nova Southeastern University		1000 36Th Street Indian River Medical Center	Vero Beach, FL 32960
PS	50815	07/29/2013	Mcintosh, Kerry-Ann Antoinette	09/20/1985	Florida A & M University		7221 Normandy Blvd	Jacksonville, FL 32205
PS	50816	07/29/2013	Sanchez, Anthony Harris	08/02/1980	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		5357 Ehrlich Rd	Tampa, FL 33625
PS	50817	07/29/2013	Saintil, Myrlande	01/13/1986	Mercer University		110 N E 44Th Street	Oakland Park, FL 33334
PS	50818	07/29/2013	Vazquez, Dairon	01/29/1986	Nova Southeastern University		692 W 29Th St	Hialeah, FL 33012
PS	50819	07/29/2013	Moosapanah, Mielad	08/13/1987	Nova Southeastern University		111 N. 12Th Street Unit 1702	Tampa, FL 33602
PS	50820	07/29/2013	Khan, Bibi Haseena	04/21/1987	Nova Southeastern University		7 South Valencia Drive	Davie, FL 33324
PS	50821	07/29/2013	Patel, Kunal Ravjibhai	06/21/1984	Nova Southeastern University		215 Ne 11Th Street Apt 21	Okeechobee, FL 34972
PS	50822	07/29/2013	Schock, Brittany Anne	04/09/1982	University Of Colorado Health Sciences C		Wellcare Health Plans, Inc	
PS	50823	07/29/2013	Silva, Pamela Erica	07/30/1982	Nova Southeastern University		630 N 71 Ter	Hollywood, FL 33024

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PS	50824	07/29/2013	Smythe, William Patrick	10/02/1982	University Of Florida		347 Sw Main Blvd	Lake City, FL 32025
PS	50825	07/29/2013	Thomas, Michael J	11/08/1978	University Of Florida		2201 Arlington Pl	Clearwater, FL 33765
PS	50826	07/30/2013	Salinas, Guillermo Abraham	08/23/1980	Creighton University		11233 Nw 1St St	Miami, FL 33172
PS	50827	07/30/2013	Predelus, Jude	09/09/1987	Florida A & M University		2261 Edgewood Ave. W	Jacksonville, FL 32209
PS	50828	07/30/2013	Willcoxon, Erica Leigh	05/13/1989	University Of Florida		4301 W. 7Th St Slot 119	Little Rock, AR 72205
PS	50829	07/30/2013	Thornton, Jessica Rene	11/08/1988	Florida A & M University		3505 University Blvd W	Jacksonville, FL 32217
PS	50830	07/30/2013	Galano, Anabel	04/03/1987	Nova Southeastern University		70 N University Dr	Pembroke Pines, FL 33024
PS	50831	07/30/2013	Nwankwo, Nneamaka Adaobi	09/21/1986	Nova Southeastern University		13113 Sw 47Th St	Miramar, FL 33027
PS	50832	07/30/2013	Tran, Thu Ha Thi	09/23/1985	Palm Beach Atlantic University		1490 Rock Springs Rd	
PS	50833	07/30/2013	Wilson, Robert Anthony Ii	09/06/1988	Florida A & M University		3775 Maple Grove Ct	Port Orange, FL 32129
PS	50834	07/30/2013	Patel, Mihirkumar Ishvarbhai	05/22/1985	Foreign Schools		9309 Se Maricamp Rd	Ocala, FL 34472
PS	50835	07/30/2013	Young, Stacy	11/04/1973	Palm Beach Atlantic University		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50836	07/30/2013	Zepf, April Lorraine	07/11/1989	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		9441 Health Center Drive	Land O Lakes, FL 34637
PS	50837	07/30/2013	Beacom, Julianne	09/18/1988	Palm Beach Atlantic University		1000 36Th Street	Vero Beach, FL 32960
PS	50838	07/30/2013	Curran, Matthew Vincent	10/04/1985	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		4500 San Pablo Road	Jacksonville, FL 32224
PS	50839	07/30/2013	Ebrahimi, Ali	05/11/1986	Nova Southeastern University		21200 St Andrews Blvd Suite 5.6	Boca Raton, FL 33433
PS	50840	07/30/2013	Hoag, Brian Douglas	10/24/1985	Palm Beach Atlantic University		31226 Cove Rd	Tavares, FL 32778
PS	50841	07/30/2013	Jaume, Alyssia Joy	08/19/1988	University Of Florida		11806 Sw Grapefruit Ct.	Palm City, FL 34990
PS	50842	07/30/2013	Jones, Ioana Roxana	10/12/1973	Palm Beach Atlantic University		900 Ne 12Th Ave Apt 507	Hallandale Beach, FL 33009
PS	50843	07/30/2013	Lonneman, David James Jr	12/08/1988	Nova Southeastern University		7672 Nw 5Th St #1J	Plantation, FL 33324

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PS	50844	07/30/2013	Patel, Jinal Janak	08/20/1986	Nova Southeastern University		400 Celebration Place	Celebration, FL 34747
PS	50845	07/30/2013	Tahiliani, Rohit Arun	09/28/1987	University Of Florida		6820 Southpoint Parkway Ste 9	Jacksonville, FL 36265
PS	50846	07/30/2013	Kent, Robin Chase	07/24/1979	Idaho State University		1413 City Creek	Pocatello, ID 83204
PS	50847	07/30/2013	Truong, Sandy Thi	03/01/1983	Nova Southeastern University		600 N University Dr	Pembroke Pines, FL 33024
PS	50848	07/30/2013	Wells, Emily Eileen	06/18/1987	Samford University		5151 N 9Th Ave	Pensacola, FL 32504
PS	50849	07/30/2013	Alderman, Dominique Jahnay	06/18/1989	Florida A & M University		27440 Us Hwy 27	
PS	50850	07/30/2013	Alfonso, Nathalie Fe	08/18/1988	University Of Florida		340 Sw 110Th Ave	Ocala, FL 34481
PS	50851	07/30/2013	Antoine, Marie Gennyka	11/15/1988	Florida A & M University		807 E. Silver Sprg	
PS	50852	07/31/2013	Santos, Micaela Rachel-Lynette	05/15/1987	Florida A & M University		1632 W Jefferson St	Quincy, FL 32351
PS	50853	07/31/2013	Vaughn, Haley Marie	11/29/1985	Samford University		1909 East Nine Mile Rd	Pensacola, FL 32514
PS	50854	07/31/2013	Jodoin, Kathleen P	04/14/1987	University Of Florida		585 Schenectady Ave	Brooklyn, NY 11203
PS	50855	07/31/2013	Kanosh, Deborah Jean	04/09/1971	Massachusetts College Of Phar & Allied H		660 S Galtran Blvd	Clearwater Beach, FL 33767
PS	50856	07/31/2013	Lin, Yang-Yi	08/30/1986	Nova Southeastern University		9420 Tangerine Place Apt #201	Davie, FL 33324
PS	50857	07/31/2013	Novoa, Tenim Sosa	07/07/1983	Nova Southeastern University		10065 Cleary Blvd	Plantation, FL 33324
PS	50858	07/31/2013	Peyton, Nicole Patrice	05/17/1989	Florida A & M University		1932 Windwood Way	Tallahassee, FL 32311
PS	50859	07/31/2013	Roberts, Courtney Elise	10/02/1988	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		1313 S. Dale Mabry	Tampa, FL 33629
PS	50860	07/31/2013	Uhm, Tae Hoon	05/30/1985	Nova Southeastern University		10406 Seaside Way	Tampa, FL 33615
PS	50861	07/31/2013	Crane, Joseph Henry	08/28/1983	University Of Tennessee-Central Office		3880 N 9Th Ave	Pensacola, FL 32503
PS	50862	07/31/2013	Dabady, Fabiola	10/04/1984	Nova Southeastern University		1201 Nw 16Th Street	Miami, FL 33125
PS	50863	07/31/2013	Eisenman, Monica Lynn	08/14/1988	Nova Southeastern University		686 Golden Beach Drive	Golden Beach, FL 33160
PS	50864	07/31/2013	Vasallo, Livernay	08/18/1976	Albany College Of Pharmacy		65 Winooski Falls Way Apt # 404	Winooski, VT 05404
PS	50865	07/31/2013	Stone, Tristin Nemitz	03/19/1988	University Of Florida		6000 49Th Street North	St. Petersburg, FL 33709

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PS	50866	07/31/2013	Dalton, Orijane Alma	11/01/1985	Auburn University Main Campus		853 Harbor Blvd	Destin, FL 43474
PS	50867	08/01/2013	Walsh, Mark Doughty	07/27/1981	University Of Rhode Island		1475 Nw 12Th Ave	Miami, FL 33136
PS	50868	08/01/2013	Parikh, Kruti	06/18/1985	Suny At Buffalo		7701 S Raeford Rd	Fayetteville, NC 28304
PS	50869	08/01/2013	Balsara, Pinang G	05/20/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		317 Sunderland Way	Stockbridge, GA 30281
PS	50870	08/01/2013	Patel, Reshma Narhari	08/14/1983	Mercer University		3351 South Pine Ave	Ocala, FL 34471
PS	50871	08/02/2013	Erdman, Michael Joseph	01/24/1987	Butler University		1275 Union Ave	Memphis, TN 38102
PS	50872	08/02/2013	Arcebido, Rebecca Tullao	04/27/1984	University Of Osteopathic Medicine And H		121 Dekalb Avenue	Brooklyn, NY 11201
PS	50873	08/02/2013	Bakht, Alia Lynn	05/06/1988	University Of Florida		1000 36Th Street	Vero Beach, FL 32960
PS	50874	08/02/2013	Quiroga, Leticia	07/07/1984	University Of Florida		200 Sw 13Th St	Miami, FL 33130
PS	50875	08/02/2013	Walker, Cucnhat Phung	04/20/1981	University Of Iowa		601 North 30Th St	Omaha, NE 68131
PS	50876	08/02/2013	Boss, Tchialann Good	03/20/1984	Florida A & M University		24170 Hwy 27	Lake Wales, FL 33859
PS	50877	08/02/2013	Buchanan, Melinda Nguyen	09/07/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		325 N Alafaya Tr	Orlando, FL 32828
PS	50878	08/02/2013	Tysiak, Marissa Faye	01/16/1985	University Of Rhode Island		1400 Nw 12Th Avenue	Miami, FL 33136
PS	50879	08/02/2013	Bui, Tri Minh	07/05/1985	University Of Florida		12514 Sophia Marie Loop	Orlando, FL 32828
PS	50880	08/02/2013	Campbell, Misty Shay	08/24/1974	University Of Georgia		1601 Hwy 40 East	Kingsland, GA 31548
PS	50881	08/02/2013	Gonzaga, Joedell Muon	12/17/1973	Northeastern University		200 Lothrop St	Pittsburgh, PA 15213
PS	50882	08/02/2013	Chapman, Mackenzie Keck	03/02/1989	South University		611 Zeagler Drive	Palatka, FL 32177
PS	50883	08/02/2013	Sordo, Eileen Mercedes	11/26/1984	Touro College Of Pharmacy		1201 Nw 16Th Street	Miami, FL 33125
PS	50884	08/02/2013	Donalies, Shelley Lynn	01/22/1971	Duquesne University		222 S Herlong Avenue	Rock Hill, SC 29730
PS	50885	08/02/2013	Davawala, Ronak Alkesh	05/14/1984	Nova Southeastern University		6151 Palm Trace Landings Drive Apt 206	Davie, FL 33314
PS	50886	08/02/2013	Doan, Anh Hoang	10/29/1989	University Of Florida		12279 Lake Underhill	Orlando, FL 32837

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PS	50887	08/02/2013	Fernandez, Daniel Luis	08/14/1986	Palm Beach Atlantic University		4700 S Flamingo Rd	Cooper City, FL 33330
PS	50888	08/02/2013	Vilella, Antonia Leigh-Pettit	07/08/1972	Texas Tech University Health Sciences Center Of Pharmacy		5000 Lakewood Ranch Blvd	Bradenton, FL 34211
PS	50889	08/02/2013	Hardaway, Aimee Noelle	12/01/1986	University Of Florida		2340 Highway 77	Panama City, FL 32405
PS	50890	08/02/2013	Haslam, Spencer Dane	09/28/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		105 67Th St Nw	Bradenton, FL 34209
PS	50891	08/02/2013	Hoewt, Karen Lynn	12/29/1977	University Of Florida		101 Derby Woods Drive	Lynn Haven, FL 32444
PS	50892	08/02/2013	Hood, Evan Anyo	01/01/1987	University Of Arizona		2046 Ne Waldo Road Suite 2250	Gainesville, FL 32609
PS	50893	08/02/2013	Ibekweh, Queenet Oluchi	07/18/1990	Xavier University		12902 Magnolia Drive	Tampa, FL 33612
PS	50894	08/02/2013	Jane, Jack	12/12/1989	Palm Beach Atlantic University		11690 Sw 72Nd St	Miami, FL 33173
PS	50895	08/02/2013	Kauffman, Eric Daniel	03/12/1981	University Of Missouri-Kansas City		54 Hospital Drive	Osage Beach, MO 65065
PS	50896	08/02/2013	Kuloba, Valerie Khayanga	04/16/1988	Florida A & M University		9251 University Pkwy	Pensacola, FL 32514
PS	50897	08/02/2013	Lee, Jee	02/11/1980	Palm Beach Atlantic University		540 Amador Ln. Unit 5	West Palm Beach, FL 33401
PS	50898	08/02/2013	Lee, Jimin	09/19/1987	Oregon State University		1600 Sw Archer Road	Gainesville, FL 32610
PS	50899	08/05/2013	Manuel, Maria Francesa	09/18/1984	Nova Southeastern University		10101 Forest Hill Blvd	Wellington, FL 33414
PS	50900	08/05/2013	Medina, Kathya Maria	04/25/1986	Nova Southeastern University		15771 Sw 152Nd St	Miami, FL 33187
PS	50901	08/05/2013	Moore, Stephanie Ann	04/09/1985	University Of Florida		16800 S.W. 88Th Street	Miami, FL 33196
PS	50902	08/05/2013	Mulugeta, Nathneal Getachew	11/30/1986	Palm Beach Atlantic University		15601 San Carlos Blvd	Fort Myers, FL 33902
PS	50903	08/05/2013	Neilen, James Andrew	01/31/1985	Nova Southeastern University		1033 Northern Way	Winter Springs, FL 32708
PS	50904	08/05/2013	Nguyen, Lily Thi	03/08/1983	University Of Florida		3913 Kiawa Drive	Orlando, FL 32837
PS	50905	08/05/2013	Oji, Chinelo Yvette	12/15/1989	Hampton University School Of Pharmacy		2337 Sw Archer Rd Apt 3013	Gainesville, FL 32608
PS	50906	08/05/2013	Ozdzinski, Anna	04/23/1986	Palm Beach Atlantic University		550 Okeechobee Blvd. Apt. #414	West Palm Beach, FL 33401

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	50907	08/05/2013	Quach, Kimmy	10/08/1987	Nova Southeastern University		11270 Sw 47 Street	Miami, FL 33165
PS	50908	08/05/2013	Raymundo, Rodel Christian	10/31/1985	University Of Florida		7430 South West Archer	Gainesville, FL 32608
PS	50909	08/05/2013	Rees, William Eugene	11/30/1982	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		105 So Pebble Beach Blvd	Sun City Center, FL 33573
PS	50910	08/05/2013	Rodriguez, Christianne Eugenia	07/31/1988	Nova Southeastern University		7199 Sw 117Th Ave	Kendall, FL 33183
PS	50911	08/05/2013	Villanueva, Christina	05/12/1982	University Of Florida		390 State Road 13	Jacksonville, FL 32259
PS	50912	08/05/2013	Sedeno Martinez, Anabel	08/14/1983	Nova Southeastern University		4705 Nw 7Th St Apt 410	Miami, FL 33126
PS	50913	08/05/2013	Patel, Dhruvang Bipin	08/03/1990	Nova Southeastern University		8790 W Mcnab Rd	Tamarac, FL 33321
PS	50914	08/05/2013	Sirota, Daniel James	03/22/1984	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		111 North Tamiami Trail	Nokomis, FL 34275
PS	50915	08/05/2013	Soussan, Gabrielle Nicole	08/03/1989	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		2773 Fruitville Road	Sarasota, FL 34237
PS	50916	08/05/2013	Mccue-Emery, Donna Lee	02/16/1961	University Of Florida		33343 Us Hwy 19 N	Palm Harbor, FL 34684
PS	50917	08/05/2013	Kovarik, Charles Joseph Iii	12/28/1988	South University		4567 River City Drive	Jacksonville, FL 32246
PS	50918	08/05/2013	Kosek, Kurt Robert	12/01/1988	Palm Beach Atlantic University		6627 W. Boynton Beach Blvd	Boynton Beach, FL 33437
PS	50919	08/05/2013	Klinger, Robin N	09/09/1983	Palm Beach Atlantic University		1601 S. Congress Ave	Boynton Beach, FL 33426
PS	50920	08/05/2013	Ingargiola, Sara Christine	08/18/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		535 South Tamiami Trl	Venice, FL 34285
PS	50921	08/05/2013	Hamilton, Amah Olufumilayo	06/03/1989	Florida A & M University		17369 48Th Court North	Loxahatchee, FL 33470
PS	50922	08/05/2013	Fonarov, Mikhail	09/11/1972	Creighton University		600 Sw 10 St	Hallandale Beach, FL 33009
PS	50923	08/05/2013	Chung, Ashley Halima	09/18/1987	Florida A & M University		1024 Corby Ct	Tallahassee, FL 32317
PS	50924	08/05/2013	Chok, Steven Anthony	08/10/1988	University Of Florida		13851 S.W. 153 Ave	Miami, FL 33196
PS	50925	08/05/2013	Chawhan, Mitisha Kapadia	11/15/1987	University Of Florida		400 Celebration Place	Celebration, FL 34747

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	50926	08/05/2013	Gutierrez, Ariel	12/06/1971	Foreign Schools		8129 W 8Th Ave	Hialeah, FL 33014
PS	50927	08/05/2013	Bullard, Haley Gay	04/08/1989	South University		347 S W Main Blvd	Lake City, FL 32025
PS	50928	08/05/2013	Cartwright, Elizabeth Joanna	09/12/1973	University Of Florida		1245 N Hercules Ave	Clearwater, FL 33765
PS	50929	08/05/2013	Zeitler, Kristen Elizabeth	09/23/1984	Suny At Buffalo		1 Tampa General Circle	Tampa, FL 33606
PS	50930	08/05/2013	Whipkey, Heidi Elizabeth	07/01/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		2875 University Pkwy	Sarasota, FL 34243
PS	50931	08/05/2013	Tate, Chelsey Hunter	09/21/1979	University Of Tennessee-Central Office		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50932	08/05/2013	Stephens, Clinton Lamar	07/29/1986	Samford University		398 Alabama St	Crestview, FL 32536
PS	50933	08/05/2013	Shah, Kushal	09/22/1989	Massachusetts College Of Phar & Allied H		905 Cape Coral Parkway	Cape Coral, FL 33904
PS	50934	08/06/2013	Nguyen, Tuynh Van	09/22/1989	Philadelphia College Of Pharmacy And Sci		23 W. Industrial Blvd	Paoli, PA 19301
PS	50935	08/06/2013	Schmahl, Brian Douglas	10/22/1979	Nova Southeastern University		1005 S. Federal Hwy	Deerfield Beach, FL 33441
PS	50936	08/06/2013	Bader, Thomas Karl	10/02/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		2725 Florida Rd	Arcadia, FL 34266
PS	50937	08/06/2013	Castano, Marcela	09/25/1986	Nova Southeastern University		14740 Mustang Trail	Southwest Ranches, FL 33330
PS	50938	08/06/2013	Chaudhari, Heli L	03/22/1986	Nova Southeastern University		5161 Counselor Dr #207	Zephyrhills, FL 33541
PS	50939	08/06/2013	Christofferson, Scott Dominic	12/01/1977	Drake University		4420 Lake Boone Trail	Raleigh, NC 27607
PS	50940	08/06/2013	Dixon, Daniel Rustin	08/19/1988	South University		1422 Coxstill Rd	Adel, GA 31620
PS	50941	08/06/2013	Greenstein, Stephanie Ann	10/27/1987	Nova Southeastern University		10181 W Broward Blvd	Plantation, FL 33324
PS	50942	08/06/2013	Gustafson, Ashley Brett	03/30/1986	Nova Southeastern University		11631 Ashridge Place	Orlando, FL 32824
PS	50943	08/06/2013	Hollist, Abraham Olanrewaju	03/27/1983	Howard University		20 Sw 12Th Ave	Deerfield Beach, FL 33442
PS	50944	08/06/2013	Ludolph, Kristin Lynn	07/15/1988	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		20311 Grande Oak Shoppes Blvd	Estero, FL 33928

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	50945	08/06/2013	Lyutov, Yevgeniy Nikolayevich	05/22/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		9252 San Jose Blvd Unit 101	Jacksonville, FL 32257
PS	50946	08/06/2013	Parikh, Ishita G	01/15/1989	Palm Beach Atlantic University		2200 Palm Beach Lakes Blvd	West Palm Beach, FL 33409
PS	50947	08/06/2013	Riley, Carmen Hendrix	11/15/1981	University Of Mississippi Main Campus		144 S. Thomas St Suite 101-1	Tupelo, MS 38801
PS	50948	08/06/2013	Rush, Brie Taylor	10/14/1988	South University		3770 N Goldenrod Rd	Winter Park, FL 32792
PS	50949	08/06/2013	Sarsah, Sakyi Kobina	03/02/1971	Florida A & M University		20070 Cortez Blvd	Brooksville, FL 34601
PS	50950	08/06/2013	Scagnegatti, Melissa Elyse	03/06/1988	Nova Southeastern University		12721 Trotter Blvd	Davie, FL 33330
PS	50951	08/06/2013	Souders, Gary Dee	05/18/1950	Butler University		1415 Tulane Ave	New Orleans, LA 70112
PS	50952	08/06/2013	Collazo, Carlos	02/08/1988	Suny At Buffalo		1102 North 15Th Street	Immokalee, FL 34142
PS	50953	08/06/2013	Freed, Nelida Pendleton	01/05/1987	Massachusetts College Of Phar & Allied H		8345 Sw 107Th Ave Apt H	Miami, FL 33173
PS	50954	08/06/2013	Martin, Analia	09/26/1980	Nova Southeastern University		14501 Miramar Pkwy	Miramar, FL 33027
PS	50955	08/07/2013	Ayala, Keila Ilushka	01/12/1985	Nova Southeastern University		156 Alt Sabaneras	Sabana Grande, PR 00637
PS	50956	08/07/2013	Brown, Stephanie Nicole	02/16/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		6820 Gulfport Blvd S	Saint Petersburg, FL 33707
PS	50957	08/07/2013	Fike, Yesenia Toro	03/11/1987	Nova Southeastern University		1800 N. Nob Hill Rd	Plantation, FL 33322
PS	50958	08/07/2013	Nelson, Joelle Elyse	07/09/1987	Midwestern State University		1600 Uf Health Shands Sw Archer Rd	Gainesville, FL 32608
PS	50959	08/07/2013	Lopez, Jacquelyn Lauren	12/15/1984	Nova Southeastern University		10340 Nw 11Th Street	Plantation, FL 33322
PS	50960	08/07/2013	Munn, Jonathan Edward	01/14/1988	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		4478 Tamiami Trail	
PS	50961	08/07/2013	Peterson, Sunshine Gabrielle Amorette	07/04/1988	Palm Beach Atlantic University		801 South Olive Ave Unit #235	West Palm Beach, FL 33401
PS	50962	08/07/2013	White, John P	09/08/1988	Florida A & M University		5701 Nw 183Rd St	Hialeah, FL 33015
PS	50963	08/07/2013	Crowell, Kimberly Ann	12/29/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		60 S Holiday Dr	Miramar Beach, FL 32550

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PS	50964	08/07/2013	Patel, Darshan H	12/28/1985	Nova Southeastern University		586 Regal Lady Court	Lawrenceville, GA 30044
PS	50965	08/09/2013	Bernstein, Alicia Kay	02/06/1987	Nova Southeastern University		650 N. Congress Avenue	Boynton Beach, FL 33426
PS	50966	08/09/2013	Patel, Raj Mahendra	11/06/1982	University Of Florida		4215 Sw 9Th Street	Vero Beach, FL 32968
PS	50967	08/09/2013	Hilliard, Stacey Noel	09/29/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		15880 San Carlos Blvd	Fort Myers, FL 33908
PS	50968	08/12/2013	Winegar, Joshua Robert	01/26/1987	University Of Florida		8174 Eider Dr	Orlando, FL 32825
PS	50969	08/12/2013	Kumar, Nipum Nitin	12/09/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		1315 Monte Lake Drive	Valrico, FL 33596
PS	50970	08/12/2013	Miazga, Frank John	11/10/1967	Samford University		648 Ridgewood Street	Altamonte Springs, FL 32701
PS	50971	08/12/2013	Allison, Hannah Megan	10/20/1981	Philadelphia College Of Pharmacy And Sci		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	50972	08/12/2013	Buchanan, Bridget Maria	10/19/1965	Creighton University		10805 Old Halls Ferry Rd.	Ferguson, MO 63136
PS	50973	08/12/2013	Copeland, Lindsey Marie	12/18/1988	Florida A & M University		7003 Presidents Drive Suite 250	Orlando, FL 32809
PS	50974	08/12/2013	Fiorenza, Mallory Ann	09/20/1987	Albany College Of Pharmacy		2776 Cleveland Ave	Fort Myers, FL 33901
PS	50975	08/12/2013	Harkness, Ryan Criag	09/13/1989	West Virginia University		221 Valley Mills Dr.	Parkersburg, WV 26104
PS	50976	08/12/2013	Kagan, Dara Whitney	10/05/1976	Nova Southeastern University		138 Keswick Manor Drive	Tyrone, GA 30290
PS	50977	08/12/2013	Martinez, Leanne Marie	09/13/1987	Nova Southeastern University		3014 Sw 99 Ct	Miami, FL 33165
PS	50978	08/12/2013	Owens, Tamisha Rachelle	04/15/1980	Florida A & M University		1904 Lochshyre Loop	Ocoee, FL 34761
PS	50979	08/12/2013	Pachelli, Lisa Marie	10/02/1986	Nova Southeastern University		6570 North State Road 7	Coconut Creek, FL 33073
PS	50980	08/12/2013	Riley, Stephanie Janae	05/20/1987	South Carolina College Of Pharmacy		5201 Raymond Street	Orlando, FL 32802
PS	50981	08/13/2013	Riyad, Paul	06/30/1989	Massachusetts College Of Phar & Allied H		5432 Little Rd	New Port Richey, FL 34655
PS	50982	08/13/2013	Velazquez Garcia, Pedro Pascual	05/06/1975	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		1904 North Allendale Ave	Sarasota, FL 34234

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PS	50983	08/13/2013	Victoria, Vivian	12/27/1983	Nova Southeastern University		11499 Sw 40Th St	Miami, FL 33165
PS	50984	08/13/2013	Woo, Sung Kyun	11/29/1983	University Of Florida		9022 Nw 40Th St	Coral Springs, FL 33065
PS	50985	08/13/2013	Zagvazdin, Alexander	05/28/1987	Nova Southeastern University		2104 W. Oakland Park	Oakland Park, FL 33311
PS	50986	08/13/2013	Anumudu, Ezinne	01/31/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		7305 N Military Trail	West Palm Beach, FL 33410
PS	50987	08/13/2013	Chang, Youngil	02/07/1973	Palm Beach Atlantic University		753 Lake Wellington Dr	Wellington, FL 33414
PS	50988	08/13/2013	Glenn, Stephanie Nicole	06/01/1983	Florida A & M University		7790 Blanding Blvd	Jacksonville, FL 32244
PS	50989	08/13/2013	Madzhidova, Shirin	07/08/1988	Nova Southeastern University		2401 San Pietro Circle	Palm Beach Gardens, FL 33410
PS	50990	08/13/2013	Trinh, Trang Doan	12/15/1985	University Of Maryland School Of Pharmacy		1600 Sw Archer Rd	Gainesville, FL 32608
PS	50991	08/13/2013	Watson, Danielle Lynn	08/31/1989	Massachusetts College Of Phar & Allied H		7229 W. Oakland Park	Lauderdale, FL 33313
PS	50992	08/13/2013	Adunlin, Elisabeth A	05/17/1954	Florida A & M University		925 E Magnolia Dr Apt O5	Tallahassee, FL 32301
PS	50993	08/13/2013	Ahmad, Saba	03/30/1986	Nova Southeastern University		14631 S.W. 110Th Terrace	Miami, FL 33186
PS	50994	08/13/2013	Beeloo, Michelle Marie	06/01/1968	University Of Florida		710 150Th Ave	Madeira Beach, FL 33708
PS	50995	08/13/2013	Carragher, Tania Maria	02/13/1984	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		15222 Municipal Drive	Madeira Beach, FL 33708
PS	50996	08/13/2013	Chantara, Aliya April	04/14/1986	Nova Southeastern University		3858 Villa Rose Ln	Orlando, FL 32808
PS	50997	08/13/2013	Doshi, Shimoli Nitinkumar	09/24/1986	Nova Southeastern University		19204 Inlet Cove Ct	Lutz, FL 33558
PS	50998	08/13/2013	Francisco, Jon Carlo C	07/06/1985	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		701 6Th St. S	Saint Petersburg, FL 33701
PS	50999	08/13/2013	Garcia, Elyana Yvette	01/06/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		2102 W. Baker Street	Plant City, FL 33563
PS	51000	08/13/2013	Gomez, Melenie Anne	12/24/1982	Nova Southeastern University		15421 Sw 81 Circle Lane Apt 28	Miami, FL 33193
PS	51001	08/13/2013	Jellots, Nicholas Murray	12/14/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		15103 Searobbin Drive	Bradenton, FL 34202

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PS	51002	08/13/2013	Moore, Whitney Michelle	10/17/1988	Florida A & M University		15502 Stoneybrook West Pkwy Suite 100	Winter Garden, FL 34787
PS	51003	08/13/2013	O'Connor, Kristen Marie	06/21/1978	Massachusetts College Of Phar & Allied H		91 Shields Rd.	Mashpee, MA 02649
PS	51004	08/13/2013	Sequete, Alyssa Theresa	01/06/1989	Duquesne University		805 Cape Coral Parkway	Cape Coral, FL 33904
PS	51005	08/13/2013	Veksler, Irwin Y	12/23/1981	Rutgers The State University Central Off		2932 W 5Th St Bldg 6B Apt #16G	Brooklyn, NY 11224
PS	51006	08/13/2013	Atanasow, Martin Manuel	05/08/1988	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		101 N Cattlemen Road	Sarasota, FL 34243
PS	51007	08/13/2013	Ballard, Brendan Gene	08/29/1981	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		5701 22Nd Ave S.	Gulfport, FL 33707
PS	51008	08/13/2013	Potter, Jonathan Mark	07/29/1983	Nova Southeastern University		5525 Sw 118Th Ave	Cooper City, FL 33330
PS	51009	08/13/2013	Edwards, David Kyle	05/18/1987	South University		341 Saddle Brook Road	Nicholls, GA 31554
PS	51010	08/13/2013	Meeks, Megan Irene	05/07/1989	Florida A & M University		1875 Cap Cir N E	Tallahassee, FL 32308
PS	51011	08/14/2013	Johnson, Brandi Noel	12/25/1985	Florida A & M University		Cvs Pharmacy	Savannah, GA 31419
PS	51012	08/14/2013	Andrews, Kimberly Marie	04/18/1985	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		716 N. Us Highway 441	The Villages, FL 32159
PS	51013	08/14/2013	Arp, Christopher Allan	08/23/1985	University Of Iowa		981090 Nebraska Medical Center	Omaha, NE 68198
PS	51014	08/14/2013	Berger, Jeff Scott	02/14/1986	Nova Southeastern University		4849 Coconut Creek Pkwy	Coconut Creek, FL 33063
PS	51015	08/14/2013	Chen, Yancy	01/05/1985	Nova Southeastern University		828 Southern Blvd	West Palm Beach, FL 33405
PS	51016	08/14/2013	Cohen, Matthew Bradley	04/15/1987	Nova Southeastern University		22829 Sr 54	Land O Lakes, FL 34637
PS	51017	08/14/2013	Costa, Crystal	02/19/1986	Nova Southeastern University		11204 W. Sr 84	Davie, FL 33324
PS	51018	08/14/2013	Cyriac, Royce Jose	10/22/1988	Drake University		4110 George Rd Suite 300	Tampa, FL 33634
PS	51019	08/14/2013	Desir, Judelyne	08/30/1982	Palm Beach Atlantic University		317 Nw 43Rd Street Apt 2	Oakland Park, FL 33309
PS	51020	08/14/2013	Eng, Lisa Ann	04/16/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		860 A1A North	Ponte Vedra Beach, FL 32082

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PS	51021	08/14/2013	Exposito, Aileen Caridad	04/29/1985	Nova Southeastern University		3100 Sw 62 Avenue	Miami, FL 33155
PS	51022	08/15/2013	Rankins, Barbara Denice	05/09/1987	University Of Florida		125 E. Main St	Apopka, FL 32703
PS	51023	08/15/2013	Young, Kendra Mindell	02/27/1986	University Of Tennessee-Central Office		3515 Park Avenue	Memphis, TN 38111
PS	51024	08/15/2013	Rocco, Lauren Marie	03/17/1987	Nova Southeastern University		2757 N E 29Th Ct	Fort Lauderdale, FL 33306
PS	51025	08/15/2013	Pierre, Shinelle T	01/24/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		10000 Bay Pines Blvd	
PS	51026	08/15/2013	Lahr, Bradley Shane	09/16/1988	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		210 3Rd St W Apt 7104	Bradenton, FL 34205
PS	51027	08/15/2013	Fernandez, Merlyn Veronica	02/05/1977	Nova Southeastern University		4240 W 10 Ct	Hialeah, FL 33012
PS	51028	08/15/2013	Eason, Jonathan Ryan	08/09/1987	Nova Southeastern University		8211 Hall Lane	Saint Augustine, FL 32092
PS	51029	08/15/2013	Arvay, Brandie Lee	09/28/1984	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		210 3Rd St W Apt 7104	Bradenton, FL 34205
PS	51030	08/15/2013	Young, John Raymond	01/20/1983	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		13130 N Dale Mabry Hwy	Tampa, FL 33618
PS	51031	08/15/2013	Wright, Rhondalyn Cutie	11/24/1988	Florida A & M University		1200 Floral Springs Blvd Apt #3-102	Port Orange, FL 32129
PS	51032	08/15/2013	Williamson, Chelsea Nicole	10/31/1986	Nova Southeastern University		5505 Nw St. James Dr	Port Saint Lucie, FL 34983
PS	51033	08/15/2013	Taylor, Catherine Paige	11/24/1983	Nova Southeastern University		1633 Village Center Dr. Apt 106	Lakeland, FL 33803
PS	51034	08/15/2013	Renard, Naderge	05/17/1988	Nova Southeastern University		600 Ne 178Th Street	North Miami Beach, FL 33162
PS	51035	08/15/2013	Pham, Tammy Thu	07/26/1986	Touro College Of Pharmacy		1200 7Th Ave N	Saint Petersburg, FL 33705
PS	51036	08/15/2013	Nguyen, Van Huynh	11/24/1986	Nova Southeastern University		6001 Toscana Drive #938	Davie, FL 33314
PS	51037	08/15/2013	Nguyen, Danny Viet	10/29/1984	University Of Florida		4050 Tall Tree Dr.	Orlando, FL 32810
PS	51038	08/15/2013	Nesbitt, Matthew Ian	04/29/1988	Nova Southeastern University		6801 Nw 24 Terrace	Fort Lauderdale, FL 33309

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PS	51039	08/15/2013	Nguyen, Ami Thanh Kim	10/25/1986	Nova Southeastern University		6001 Toscana Drive #938	Davie, FL 33314
PS	51040	08/15/2013	Miller, Bella	02/15/1974	Long Island University Brooklyn Campus		8610 Bay Parkway	Brooklyn, NY 11214
PS	51041	08/15/2013	Mains, Kyle Robert	11/22/1985	Palm Beach Atlantic University		800 Meadows Rd	Boca Raton, FL 33486
PS	51042	08/15/2013	Haque, Ahsanul	07/28/1962	University Of Georgia		Floater Pharmacist	Fredericksburg, VA 22407
PS	51043	08/15/2013	Kandepi, Sirisha	10/20/1980	Nova Southeastern University		5817 Eagle Cay Lane	Coconut Creek, FL 33073
PS	51044	08/15/2013	Gandhi, Jasneet Singh	11/21/1985	Washington State University		12633 Gettysburg Circle	Orlando, FL 32837
PS	51045	08/15/2013	Hacker-Finey, Neisha Melanie	12/12/1976	Albany College Of Pharmacy		2001 W. 68Th Street	Hialeah, FL 33016
PS	51046	08/15/2013	Wysock, Katie Ellen	05/02/1987	University Of Florida		824 Ellwood Ave	Orlando, FL 32804
PS	51047	08/16/2013	Thaker, Priya	06/20/1985	Auburn University Main Campus		17103 N Bay Road	Sunny Isles Beach, FL 33160
PS	51048	08/19/2013	Barsoum, Stephanie Nichole	10/18/1983	Palm Beach Atlantic University		9850 Zenith Meridian Drive #8-207	Englewood, CO 80112
PS	51049	08/19/2013	Duran, Diana Carolina	12/06/1986	Palm Beach Atlantic University		3527 Ne 168Th St Apt 206	North Miami Beach, FL 33160
PS	51050	08/19/2013	Hudson, Albreka Sherrie	07/06/1981	Florida A & M University		Box 21183	Tallahassee, FL 32316
PS	51051	08/19/2013	Odongo, Daniel Miguya	03/12/1986	South Carolina College Of Pharmacy		6651 Old Winter Garden Rd	Orlando, FL 32835
PS	51052	08/19/2013	Perez, Arelys	10/30/1986	Nova Southeastern University		2660 Sw 156 Pl	Miami, FL 33185
PS	51053	08/19/2013	Swan, Kelly Clare	04/19/1987	Nova Southeastern University		770 Ne 98 Street	Miami Shores, FL 33138
PS	51054	08/19/2013	Tran, Hieu Trung	01/06/1986	Nova Southeastern University		13073 S W 28Th Street	Miramar, FL 33027
PS	51055	08/19/2013	Villalba, Diego Andres	02/06/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		70563 Durk Blvd	Seminole, FL 33776
PS	51056	08/19/2013	Mann, Mark Christopher	03/15/1983	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		9150 Kings Crossing Rd	Fort Myers, FL 33912
PS	51057	08/19/2013	Smoak, Megan Marie Richardson	04/23/1987	University Of Florida		10899 Baymeadows Rd	Jacksonville, FL 32256
PS	51058	08/19/2013	Bhagwandeen, Shivanne	10/12/1986	Nova Southeastern University		7313 Sw 3Rd Ct	North Lauderdale, FL 33068

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51059	08/19/2013	Dempsey, Sara Kathlene	06/16/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		20741 Bruce B Downs	Tampa, FL 33647
PS	51060	08/19/2013	Downing, Jack Reed	09/05/1968	Samford University		2824 Scottsville Rd	Bowling Green, KY 42104
PS	51061	08/19/2013	Elko, Kayla Marie	03/12/1989	Massachusetts College Of Phar & Allied H		2409 Santa Barbara Blvd	Cape Coral, FL 33914
PS	51062	08/19/2013	Goree, Justin Robert	07/07/1985	University Of Florida		1545 Rock Springs Rd	Apopka, FL 32712
PS	51063	08/19/2013	Kelly, Kathleen Lidiette	02/23/1978	Nova Southeastern University		13923 Sw 153Rd Terrace	Miami, FL 33177
PS	51064	08/19/2013	Mackie, Anthony Dewayne	04/05/1988	Florida A & M University		2221 S. Sherman Circ. Apt E-410	Miramar, FL 33025
PS	51065	08/19/2013	Wilder, Justin Cole	05/05/1987	Appalachian College Of Pharmacy		1 Medical Park Boulevard	Bristol, TN 37620
PS	51066	08/19/2013	Golding, Michael Mark	04/17/1985	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		2310 Pine Ridge Rd.	Naples, FL 34109
PS	51067	08/19/2013	Rodriguez, Mitchelle Indhira	08/21/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		5515 Peach Street	Erie, PA 16509
PS	51068	08/21/2013	Lugo, Eileen Zoe	12/01/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		2202 James L Redman Pkwy	Plant City, FL 33563
PS	51069	08/21/2013	Buabeng, Donae Alana	09/25/1983	Long Island University Brooklyn Campus		350 South Broadway	Tarrytown, NY 10591
PS	51070	08/21/2013	Hanlon, Laura Elizabeth	11/24/1986	Nova Southeastern University		7000 Nw 17Th St #405	Plantation, FL 33313
PS	51071	08/21/2013	Berardelli, Emilia	01/11/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		3015 S W Pine Island Rd	Cape Coral, FL 33991
PS	51072	08/21/2013	Efkovics, Brandee Marie	09/24/1981	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		3275 Garden St	Titusville, FL 32796
PS	51073	08/21/2013	Moynihan, Annie Gay	10/04/1982	University Of Florida		197 Boston Turnpike Rte. 9	Shrewsbury, MA 01545
PS	51074	08/22/2013	Castro, Edward Kenneth	04/26/1988	University Of Florida		819 Maple Tree Lane	Orlando, FL 32828
PS	51075	08/22/2013	Okobi, Nwamaka Chiagozie	07/29/1989	Rutgers The State University Central Off		1489 South Orange Blossom Trail	Apopka, FL 32703
PS	51076	08/22/2013	Beltran, Elizabeth	04/19/1983	Auburn University Main Campus		1566 Crossbeam Dr	Casselberry, FL 32707

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51077	08/22/2013	Truong, Thuy H D	11/24/1984	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		3770 Tampa Rd	Oldsmar, FL 34677
PS	51078	08/23/2013	Buabeng, Calvin Baafi	06/19/1982	Long Island University Brooklyn Campus		100 East Lake Boulevard	Mahopac, NY 10541-
PS	51079	08/23/2013	Ahmed, Rehana Helen	08/22/1978	Nova Southeastern University		8866 S W 126Th Street	Miami, FL 33176
PS	51080	08/23/2013	Ayubi, Nora Reyhana	04/29/1983	University Of Florida		120 Lost Beach Lane	Ponte Vedra Beach, FL 32082
PS	51081	08/23/2013	Boadi, Victor Owuraku	08/04/1982	Nova Southeastern University		7321 Nw 16Th Street Apt A106	Plantation, FL 33313
PS	51082	08/23/2013	Boatright, Tracy Helen	04/26/1968	St Louis College Of Pharmacy		733 W Springfield Rd	Gerald, MO 63037
PS	51083	08/23/2013	Bonfin, Sandy Patricia	03/17/1983	Palm Beach Atlantic University		416 1/2 Westwood Road	West Palm Beach, FL 33401
PS	51084	08/23/2013	Brockman, Michael Daniel	02/01/1988	Butler University		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51085	08/23/2013	Chiodo, Jaclyn Marie	12/06/1983	University Of Tennessee-Central Office		7105 W Mcnab Rd	North Lauderdale, FL 33068
PS	51086	08/23/2013	Cifelli, Albert Vincent	06/21/1986	Washington State University		7921 Reflection Cove Dr Apt 102	Fort Myers, FL 33907
PS	51087	08/23/2013	Peno, Migena	06/18/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		10411 Ulmerton Rd	Largo, FL 33771
PS	51088	08/23/2013	Shontz-Buttery, Stacy Lyn	07/07/1975	University Of Pittsburgh Central Office		1606 West Whispering Winds Dr.	Phoenix, AZ 85085
PS	51089	08/23/2013	Solari, Magda Suyen	11/22/1967	University Of Texas At Austin		1234 Lakeshore Dr	Coppell, TX 75019
PS	51090	08/23/2013	Wassif, Mary	11/26/1987	St Johns College Main Campus		8900 Vanwyck Expressway	Ozone Park, NY 11416
PS	51091	08/23/2013	Harden, Cierra Jessica	05/27/1986	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		702 51St St E Apt 615B	Bradenton, FL 34208
PS	51092	08/23/2013	Zafrullah, Zubair Ullah	10/09/1985	University Of Florida		7325 Hw 54	New Port Richey, FL 34653
PS	51093	08/23/2013	Askinazi, Jessica Lynn	01/17/1986	Nova Southeastern University		605 Nw 90Th Terrace	Plantation, FL 33324
PS	51094	08/26/2013	Cortes, Vivian	02/23/1986	Howard University		180 Sw 104 Ct	Miami, FL 33174

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51095	08/26/2013	Mansour, Elizabeth	06/04/1990	Florida A & M University		1995 Sr 19 North	Eustis, FL 32726
PS	51096	08/27/2013	Sypolt, Erin Christine	03/11/1989	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		3601 Bee Ridge Rd	Sarasota, FL 34233
PS	51097	08/27/2013	Bessler, Steven Joseph	11/24/1987	Palm Beach Atlantic University		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51098	08/27/2013	Cabrera, Luliesky	03/27/1986	Nova Southeastern University		8109 Sw 158Th Ave	Miami, FL 33193
PS	51099	08/27/2013	Cantualla, Lela Dagmar	01/09/1974	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		6570 Anchor Loop #207	Bradenton, FL 34212
PS	51100	08/27/2013	Cox, Prem Lidsey	06/04/1983	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		5804 Bee Ridge Rd.	Sarasota, FL 34233
PS	51101	08/27/2013	Doxsee, Caleb Taylor	04/08/1985	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		4220 Manatee Ave W	Bradenton, FL 34205
PS	51102	08/27/2013	Draucker, Tanya Lynn	09/06/1987	St Louis College Of Pharmacy		449 W 23Rd Street	Panama City, FL 32405
PS	51103	08/27/2013	Froman, Hilary Ellen	06/24/1988	Purdue University Main Campus		14335 Gnatcatcher Terrace	Lakewood Ranch, FL 34202
PS	51104	08/27/2013	Grubbs, Willa Tamika	06/19/1976	Nova Southeastern University		7479 Lake Worth Road	Lake Worth, FL 33467
PS	51105	08/27/2013	Luu, Hong Yen	11/15/1987	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		7001 N. Coolidge Ave	Tampa, FL 33614
PS	51106	08/27/2013	Maceri, Christopher Peter	08/18/1986	Nova Southeastern University		8520 Sw 27 Place	Davie, FL 33328
PS	51107	08/27/2013	Webster, Matthew Thomas	03/02/1989	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		6003 14Th St W	Bradenton, FL 34207
PS	51108	08/27/2013	Agaj, Sadina	06/13/1982	University Of Florida		11665 Fox Creek Dr	Tampa, FL 33635
PS	51109	08/28/2013	Heath, Emily Elizabeth	03/23/1989	Northeastern University		Sarasota Memorial Hospital	Sarasota, FL 34239
PS	51110	08/28/2013	Chung, Jiyang	09/27/1988	Albany College Of Pharmacy		12 California Avenue Apt B307	Albany, NY 12205
PS	51111	08/28/2013	Ascanio, Alina	05/22/1980	Nova Southeastern University		14953 Sw 32 Terr	Miami, FL 33185
PS	51112	08/28/2013	Furgiuele, Peter Joseph	05/06/1983	University Of Maryland School Of Pharmacy		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320

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PS	51113	08/28/2013	Lopez, Giovanni	07/31/1977	Nova Southeastern University		11375 Sw 57Th Terrace	Miami, FL 33173
PS	51114	08/28/2013	Machado-Gonzalez, Mae	11/25/1982	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		395 Cypress Pkwy	Kissimmee, FL 34759
PS	51115	08/28/2013	Rameshwar, Shivani	04/08/1983	St Johns College Main Campus		163-30 Cross Bay Boulevard	Howard Beach, NY 11414
PS	51116	08/28/2013	Pham, Christine Diem-Chau	01/06/1984	Pacific University Of Oregon		2627 Trimble Rd	San Jose, CA 95132
PS	51117	08/28/2013	Skaria, Jason Philip	01/25/1988	Philadelphia College Of Pharmacy And Sci		710 Burmont Rd	Drexel Hill, PA 19026
PS	51118	08/30/2013	Markowitz, John Seth	02/23/1961	University Of Tennessee-Central Office		1600 Sw Archer Rd	Gainesville, FL 32601
PS	51119	08/30/2013	Gonzalez, Christina Marie	03/03/1979	Mercer University		6880 Magnolia Park Lane	Norcross, GA 30093

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Profession	File Nbr	Licensee Name	Eligible Date	Exam Modifiers
2201	23903	Novak, Inna	11/30/1999	Mpje Registration; Nabp Registration
2201	24784	Khanum, Shahida	09/27/2001	
2201	26040	German, Tatyana	01/22/2002	
2201	24784	Khanum, Shahida	07/18/2002	
2201	27407	Merchant, Michael Cameron	05/28/2003	
2201	27407	Merchant, Michael Cameron	05/28/2003	
2201	31324	Tonnu-Pham, Hoanganh	05/16/2005	
2201	31335	Hess, Gary Alan	05/16/2005	
2201	31339	Barnes, Lorna Marjorie	05/16/2005	
2201	31307	Cook, Brandie Leigh	05/23/2005	
2201	31557	Dillingham, Julie	05/23/2005	
2201	31595	Patel, Sonal Nareshkumar	05/25/2005	
2201	30405	Rehmat, Raheeba J	05/27/2005	
2201	31266	Ake, Thomas Robert	05/27/2005	
2201	31616	Goldstein, Arnold Stanley	05/31/2005	
2201	31608	Lafrance, Brandi Centrelle	06/01/2005	
2201	31379	Choe, Sunyi	06/02/2005	
2201	31562	Choi, Helen	06/06/2005	
2201	31283	Choi, Hyoung Suk	06/07/2005	
2201	29382	Kim, Jennifer J	06/08/2005	
2201	31674	Sturrup, Stephanie Lynn	06/10/2005	
2201	31695	Amirsadri, Sara	06/14/2005	
2201	31104	Monteith, David L	06/16/2005	
2201	31844	Carlozzi, John A	06/16/2005	
2201	31856	Douglass, Sabrina Denise	06/16/2005	
2201	31344	Kelani, Fatimat Bolanle	06/17/2005	
2201	31700	Tran, Vi Vuho	06/17/2005	
2201	31884	Cabellero, Irene J	06/17/2005	
2201	31107	Delgado, Edwin	06/21/2005	
2201	31828	Echeandia-Feo, Arleen Yamira	06/28/2005	
2201	29465	Torres Perez, Aida I	07/01/2005	
2201	31166	Liu, Jui-Chieh	07/06/2005	
2201	31711	Rodriguez, Anibal	07/07/2005	
2201	31892	Williams, Melanie Ann	07/07/2005	
2201	32016	Lane, Jeremy Heath	07/08/2005	
2201	29540	Wong, Irina Patricia	07/15/2005	
2201	31926	Tran, Phillip	07/15/2005	
2201	32047	Zhu, Kui	07/22/2005	
2201	32049	Thottempudi, Venkata D	07/22/2005	
2201	32061	Ivey, Rhonda Gail	08/03/2005	
2201	32140	Gade, Laxmi	08/08/2005	
2201	31636	Christopher, Lonnie Robert	08/12/2005	
2201	32051	Douglas, Jacqueline Nadine	08/12/2005	
2201	24245	Carreno, Imelda	08/15/2005	
2201	32060	Hunt, Libbye Denise	08/15/2005	

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2201	31884	Cabellero, Irene J	08/26/2005	
2201	32120	Patel, Leena Bhupendra	08/29/2005	
2201	31385	Jermyn, Diana	09/01/2005	
2201	31974	Patel, Swati V	09/02/2005	
2201	31826	Marquess, Jonathan Griffin	09/19/2005	
2201	32205	Pazon, Abigail Solonga	09/28/2005	
2201	32204	Khanum, Shahida	09/29/2005	
2201	31974	Patel, Swati V	10/04/2005	
2201	31992	Huynh, Kevin M	10/04/2005	
2201	32027	Onyeabor, George O	10/05/2005	
2201	29486	Kasemkhani, Farrah	10/07/2005	
2201	32280	Valencia, Joni	10/11/2005	
2201	32178	Darji, Lataben B	10/14/2005	
2201	32125	Zachel, Theresa Marie	10/20/2005	
2201	32255	Chang, Jeannie Uijin	11/02/2005	
2201	32347	Anil, Anu	11/02/2005	
2201	32332	Macas, Luzminda Dingding	11/07/2005	
2201	32346	Torres, Hilda M	11/14/2005	
2201	31420	North, Breanna M	11/16/2005	
2201	27667	Reyes, Ivette	11/17/2005	
2201	32249	Tran, Hung Van	11/28/2005	
2201	32370	Downs, John W	12/01/2005	
2201	32395	Ung, Robert	01/11/2006	
2201	32475	Chance, Pamela	01/13/2006	
2201	32481	Cordy, Catherine Ann	01/13/2006	
2201	29594	Levy, Jean-Baptise Pierre	01/18/2006	
2201	31713	Nguyen, Tina Thuy	01/23/2006	
2201	32499	Zayas, Norma Olga	01/24/2006	
2201	32411	Robinson, Barbara Evadnie	01/31/2006	
2201	32448	Blinkoff, Charles Nelson	02/01/2006	
2201	32404	Spellman, Lisa Marie	02/10/2006	
2201	32599	Azab, Noha Moustafa Abd El-Latif	02/23/2006	
2201	32640	Carlson, Curt J	03/13/2006	
2201	24611	Otegbola, Adenike Adedoyin	03/23/2006	
2201	32573	Rosendo, Luz M	03/29/2006	
2201	32578	Patel, Vipulkumar A	03/29/2006	
2201	32676	Asghedom, Bererti Maasho	04/05/2006	
2201	32681	Patel, Dipika	04/05/2006	
2201	32505	Whitesides, Cicely Rhea	04/07/2006	
2201	29361	Gangadari, Sunil Raj	04/10/2006	
2201	28137	Azeez, Raheem Olawale	04/11/2006	
2201	32721	Lerner, Inessa	04/19/2006	
2201	32722	Jose, Sunitha	04/19/2006	
2201	32675	Corpuz, Milagros M	04/21/2006	
2201	32571	Mensah-Narh, Steven	04/26/2006	

Profession	File Nbr	Licensee Name	Eligible Date	Exam Modifiers
2201	32470	Murphy, Jeffrey Stephen	04/27/2006	
2201	31270	Octavio De Pinaud, Lolita	05/01/2006	
2201	24712	Orta, Norma I	05/02/2006	
2201	32556	Cabranes Torres, Hedda J	05/02/2006	
2201	30968	Muhammad, Naweed	05/12/2006	
2201	32904	Nguyen, Huong Thi	05/18/2006	
2201	32932	Patel, Ritesh Dilip	05/18/2006	
2201	32933	Patel, Roshni	05/19/2006	
2201	33014	Jacobs, Angela Marie	05/31/2006	
2201	32693	Pham, Theresa Luyen	06/01/2006	
2201	31595	Patel, Sonal Nareshkumar	06/05/2006	
2201	33134	Gorgi, Haidy S	06/07/2006	
2201	32715	Havican, Suzanne Nadra N	06/09/2006	
2201	33201	Nguyen, Diep Ngoc	06/09/2006	
2201	32625	Stevens, John D	06/13/2006	
2201	33184	Lewis, Angela Holston	06/13/2006	
2201	32566	Edmons, Thomas Lee	06/14/2006	
2201	33140	Pallo, Matthew Jason	06/15/2006	
2201	33150	Biancotti, Richard Alan	06/19/2006	
2201	33291	Quella, Holli Erin	06/19/2006	
2201	32613	Tran, Bichlien Jenny	06/20/2006	
2201	32871	Vo, Nguyen-Ngoc Thi	06/21/2006	
2201	32734	Bohn, Stacey J	06/27/2006	
2201	33306	Bennett, Dana Marie	06/27/2006	
2201	33332	Lagares, Alexis	06/27/2006	
2201	33333	Gonzalez-Mercado, Noel A	06/27/2006	
2201	33290	Tierno, Antonio Nicola	06/29/2006	
2201	33389	Mathews, Jeji T	07/03/2006	
2201	32608	Dinh, Thomas Huan	07/06/2006	
2201	33400	Nasser, Temur	07/06/2006	
2201	31943	Torres, Aida I	07/11/2006	
2201	33390	Nasser, Sabbah S	07/12/2006	
2201	33420	Robertson, Kimberley Ann	07/12/2006	
2201	32752	Dow, Loida Estella	07/19/2006	
2201	33454	De Jesus Torres, Irian	07/20/2006	
2201	32503	Franklin, Lishunda Marie	07/24/2006	
2201	33466	Bell, Amber Vivian	07/26/2006	
2201	32665	Rosenhaft, Cindy Miller	08/01/2006	
2201	33525	Patel, Leena Bhupendra	08/03/2006	
2201	33415	Taylor, Heather Renee	08/04/2006	
2201	33538	Solon, Happymarie Fajardo	08/04/2006	
2201	33523	Hamel, Susan	08/07/2006	
2201	33531	Masintapan, Nattaya	08/07/2006	
2201	33540	Lemons, Jason K	08/07/2006	
2201	33541	Jackson, Daphne Michelle	08/07/2006	

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2201	33552	Torres, Carelis Marie	08/07/2006	
2201	33517	Grove, Hannah Joy	08/08/2006	
2201	33309	Melendez, Yolyedmy Walesca	08/09/2006	
2201	33563	Parks, Brittani Anna Stackis	08/16/2006	
2201	33602	Chevere-Robles, Katiria M	08/28/2006	
2201	32990	Martin, Jon R	08/30/2006	
2201	32049	Thottempudi, Venkata D	09/07/2006	
2201	33504	Drucker, Linda Ann	09/12/2006	
2201	33609	Khodak, Alexander	09/13/2006	
2201	33622	Carrasco, Jose H	09/15/2006	
2201	32819	Veltry, Lauren Grace	09/26/2006	
2201	33606	Mahase, Vidhyanand	09/26/2006	
2201	33628	Allen, Debra Mae	09/29/2006	
2201	23965	Amaxas, Nicholas	10/09/2006	
2201	33431	Gulick, Shaney Marie	10/09/2006	
2201	33616	Awosegun, Victoria Oluwatoyin	10/09/2006	
2201	32550	Singh, Satender Pal	10/11/2006	
2201	33644	Carpenter, Brenda D	10/11/2006	
2201	33656	Mello, Lilian F L C	10/17/2006	
2201	32624	Patel, Purviben Purvaj	10/23/2006	
2201	32726	Pierre, Kathleen	10/23/2006	
2201	33354	Mitringa, Slavko O	10/23/2006	
2201	32419	Kauchak, James David Jr	10/30/2006	
2201	33621	Rodriguez, Rafael A	11/13/2006	
2201	31711	Rodriguez, Anibal	11/17/2006	
2201	33650	Troxtel, Kathilyn	11/17/2006	
2201	33706	Lynn, Jennifer Kay	11/17/2006	
2201	33715	Lee, James	11/21/2006	
2201	32444	Tabuteau, Ronald	12/06/2006	
2201	33646	Carter, David J	12/14/2006	
2201	33756	Chiti, Jennifer Lynn	01/03/2007	
2201	33559	Ezekwueche, Eugene Chikwelu	01/08/2007	
2201	33717	Gagliardo, Lou Matteo	01/17/2007	
2201	32762	Montfort, Dwight Randolph	01/25/2007	
2201	33581	Labella, James Paul	02/01/2007	
2201	33696	Nachowitz, Sidney	02/15/2007	
2201	33724	Martinson, Thomas Brian	02/20/2007	
2201	33881	Ghobrial, Cicil	02/22/2007	
2201	33880	Pierce, Brenda A	03/02/2007	
2201	33864	Pisiechko, John J	03/06/2007	
2201	33895	Joblin, Michael Andrew	03/22/2007	
2201	33922	Salam, Abdus	03/30/2007	
2201	32743	Bullard, Wallene Zerlina	04/03/2007	
2201	33871	Lewis, Daniel H	04/09/2007	
2201	33869	Tran, Robert T	04/12/2007	

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2201	33889	Sills, Tammy Renea	04/12/2007	
2201	33807	Kahl, Robert Alfred	04/13/2007	
2201	33909	George, Jacob	04/17/2007	
2201	33979	Hassam, Vadooda Saher	04/19/2007	
2201	34024	Ramineni, Bharath Shyam	05/02/2007	
2201	33725	Bernardo, Troy Anthony	05/08/2007	
2201	33926	Bui, Loc Thi	05/08/2007	
2201	33648	Williams, Corrina Lynne	05/09/2007	
2201	34037	Wiggins, Shelley Chantel	05/17/2007	
2201	33933	Hamadeh, Nader A	05/29/2007	
2201	34260	Clem, Cortney Jo	06/01/2007	
2201	34409	Aladro, Christina Marie	06/01/2007	
2201	34445	Kehoe, Joy Marie	06/05/2007	
2201	33347	Foran, John Huston Jr	06/08/2007	
2201	33721	Mckinney, Kareem Quinten	06/14/2007	
2201	34649	Scuro, Joseph Peter	06/14/2007	
2201	34286	King, Jesse Clifford	06/20/2007	
2201	34388	Patel, Samir J	06/21/2007	
2201	34631	Davis, Christian Nicole	06/21/2007	
2201	34650	Kane, Mabintou	06/22/2007	
2201	33995	Onyenekwe, Pearl Oluchi	06/25/2007	
2201	34348	Patel, Dipak Narendra	06/25/2007	
2201	34799	Doshi, Snehal Himanshu	07/03/2007	
2201	34374	Khamissizadeh, Farhad	07/12/2007	
2201	34432	Thai, Uy Thanh	07/16/2007	
2201	34435	Duro Emanuel, Folasade	07/17/2007	
2201	34681	Ordenana, Noemi Ester	07/17/2007	
2201	33885	Salu, Beverly Leonie	07/25/2007	
2201	33812	Jass, Narina	08/01/2007	
2201	34473	Makvandi, Farokh	08/24/2007	
2201	34766	Brewer, Osric S	08/30/2007	
2201	34961	Velez Rosado, Alexandra	08/30/2007	
2201	33976	Lambert, Cynthia Maria	09/17/2007	
2201	35015	Huynh, Kinh Van	09/17/2007	
2201	34995	Taft-Ellington, Jowanda L	09/18/2007	
2201	33797	Thompson, Jeannette Marie	09/19/2007	
2201	34982	Tseng, Catherine Chih-Wen	09/24/2007	
2201	34933	Waldroup, Michael William	09/25/2007	
2201	34989	Burt, Catherine Donahue	09/26/2007	
2201	35045	Ho, Thao Trang	10/05/2007	
2201	35047	Awosegun, Victoria Oluwatotin	10/05/2007	
2201	31080	Martinez, Maria Isabel	10/10/2007	
2201	34952	Essayas, Lulit	10/10/2007	
2201	34965	Morales, Andrea E	10/23/2007	
2201	35066	Torres-Marrero, Cristina Teresa	10/23/2007	

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2201	35082	Townsend, Sandi Thibodeaux	11/01/2007	
2201	35079	Patel, Tejas Pravinchandra	11/15/2007	
2201	35145	Dang, Willis	11/28/2007	
2201	35072	Wilkerson, Nancy Karen	12/11/2007	
2201	35170	Lee, James	12/27/2007	
2201	35196	Kogut, Jennifer A	01/04/2008	
2201	24778	Castro, Luz C	01/09/2008	
2201	34864	Obianwu, Uchenna Azuka	01/10/2008	
2201	34898	Phung, Hallien Thi	01/10/2008	
2201	35195	D'Agostino, Edward A	01/11/2008	
2201	35224	Meyervich, Jane	01/17/2008	
2201	35226	Perez-Miranda, Loida	01/17/2008	
2201	35227	Calabrese, Michelle Nicole	01/17/2008	
2201	35255	Cintron, Lizzandra Enid	02/01/2008	
2201	35289	Kerklingh, Brenda Teresa	02/14/2008	
2201	35045	Ho, Thao Trang	02/20/2008	
2201	35312	Daniel, Joshua Paul	02/27/2008	
2201	35050	Lin, Sally C	03/04/2008	
2201	35272	Freeman, Nicole Monique	03/18/2008	
2201	35326	Van Nest, Clifford Ian	03/18/2008	
2201	24637	Sultan, Habib	04/15/2008	
2201	35301	Hynds, Raymond Russell	04/16/2008	
2201	35331	Santos, Maria M	04/16/2008	
2201	35139	Hendrickson Yee, Holly Renee	05/01/2008	
2201	35406	Polit, Robert Ronald	05/08/2008	
2201	35612	Tyler, Ashley Marie	05/15/2008	
2201	35553	Arunmanakul, Poukwan	05/16/2008	
2201	35683	Ward, Catherine Ashton	05/21/2008	
2201	35684	Jessup, Jessica Lynne	05/21/2008	
2201	35383	Herndon, James Charles	05/23/2008	
2201	34420	Ott, Nathan John	05/29/2008	
2201	35788	Castillo, Kathryn Elizabeth	06/03/2008	
2201	35789	Fernandez, Alfred John	06/03/2008	
2201	35818	Schwartz, Natalia	06/04/2008	
2201	35824	Georgelos, Harriet J	06/05/2008	
2201	35932	Sioris, Kelly Marie	06/09/2008	
2201	36015	Colon, Sheila Damaris	06/19/2008	
2201	36116	Maddox, Mia Antionette	06/24/2008	
2201	36126	Osborne, Joel Arthur	07/01/2008	
2201	35364	Clark, Tiffany C	07/22/2008	
2201	36196	White, Edward Christopher	07/22/2008	
2201	36222	Morgan, Charlotte Regine	07/22/2008	
2201	36230	Thomas, Kori Latay	07/22/2008	
2201	36226	Dunn, William Charles	07/24/2008	
2201	35266	Kim, Yeong Ae	07/25/2008	

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2201	36268	Davis, Vanessa Denise	08/07/2008	
2201	36269	Do, Trin C	08/07/2008	
2201	36299	Stanley, Robert L	08/07/2008	
2201	35347	Nixon, Johnie Paul	08/19/2008	
2201	35053	Egbuonu, Flora Nkechi	08/21/2008	
2201	35264	Mridha, Md A Samad	08/21/2008	
2201	34957	Khan, Niaz Ali	08/22/2008	
2201	35171	Lee, Juhyun	08/22/2008	
2201	36297	Engram, Samaiyah Geneise	08/22/2008	
2201	36138	Page, Robert Nicholas	08/26/2008	
2201	35688	Aaron, Marieta Gamutan	09/03/2008	
2201	36042	Gulinski, Victoria T	09/03/2008	
2201	36363	Ruiz, Jairo Alonso	09/09/2008	
2201	35395	Diviak, Michael John	10/09/2008	
2201	36365	Sigal, Korina	10/20/2008	
2201	36170	Bazzi, Ali S	10/22/2008	
2201	36381	Lantaff-Herrero, Isabel	10/22/2008	
2201	36211	Oliver, Aaron Jeremy	10/23/2008	
2201	31713	Nguyen, Tina Thuy	10/27/2008	
2201	36454	Sepulveda, Lavimar	10/27/2008	
2201	36447	Aher, Vivekanand Yashwant	10/28/2008	
2201	36386	Mancini, Rosa	10/30/2008	
2201	36444	Kandula, Lakshmi Sirisha	11/05/2008	
2201	36508	Faour, Mhd Salem	12/04/2008	
2201	36506	Placette, Allen Wayne	12/10/2008	
2201	36557	Gitelman, Radmila	12/11/2008	
2201	36544	Garas, Lydia Raduf	12/12/2008	
2201	36486	Stell, Lawrence Edwin	12/18/2008	
2201	36466	Stifter, Timothy Francis	12/30/2008	
2201	36554	Tucker, Angelina Rohanna	12/30/2008	
2201	35411	Rothstein, Alvin	01/06/2009	
2201	36581	Pathumsaengthona, Aphinya	01/06/2009	
2201	36585	Mercado, Lysandra	01/06/2009	
2201	36597	Suwanphattana, Piraporn	01/06/2009	
2201	36387	Peller, Allen Leonard	01/08/2009	
2201	36572	Genova, Rositsa Gencheva	01/08/2009	
2201	36601	Punzalan, Elmer Ignacio	01/08/2009	
2201	36616	Shehzad, Khurram	01/08/2009	
2201	36568	Huang, Chia Yu	01/09/2009	
2201	36586	Bakar, Kombo Abdulla	01/22/2009	
2201	36605	Eadula, Sandeep Reddy	01/23/2009	
2201	36666	Patel, Brijal Ganpatbhai	01/26/2009	
2201	36565	Howell, Sandra Kay	01/27/2009	
2201	36610	Dhulia, Umadevi Neil	01/27/2009	
2201	36611	Gill, Sukhdial Singh	01/27/2009	

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Profession	File Nbr	Licensee Name	Eligible Date	Exam Modifiers
2201	36620	Vasou, Christos Michael	01/28/2009	
2201	36621	Parlitsis-Vasou, Ellen	01/28/2009	
2201	36560	Taylor, Bruce Samuel	02/02/2009	
2201	36636	Patel, Avani Karshanbhai	02/02/2009	
2201	36647	Ting, Wanyi	02/02/2009	
2201	35255	Cintron, Lizzandra Enid	02/13/2009	
2201	36682	Dougherty, Susan Hammami	02/16/2009	
2201	35312	Daniel, Joshua Paul	02/25/2009	
2201	36703	Joseph, Jeen	02/25/2009	
2201	35334	Mcclure, Joshua Nathan	02/26/2009	
2201	35404	Majethia, Sunil Mulji	02/26/2009	
2201	36598	Skariah, Lisa Kelakombil	03/02/2009	
2201	36397	Gonzalez, Gloria Maria	03/09/2009	
2201	36681	Hudgins, Nicole	03/09/2009	
2201	36673	Shah, Snehal J	03/10/2009	
2201	36704	Shakeel, Qaisar	03/10/2009	
2201	36723	Khanafer, Ramez	03/18/2009	
2201	36738	Losch, Andrew Philip	03/18/2009	
2201	36757	Chen, Chien-Pei	03/18/2009	
2201	35015	Huynh, Kinh Van	03/27/2009	
2201	35170	Lee, James	03/27/2009	
2201	32051	Douglas, Jacqueline Nadine	03/31/2009	
2201	35343	Hershfield, David Alan	04/07/2009	
2201	36537	Vallecillo, Yamile M	04/22/2009	
2201	36769	Hildebrand, Chad Allan	04/22/2009	
2201	35264	Mridha, Md A Samad	05/04/2009	
2201	36538	Baltodano, Elizabeth	05/04/2009	
2201	36427	Miller, Penney Kay	05/07/2009	
2201	35742	Jackson, Kesha Alyse	05/08/2009	
2201	36828	Smith, Laura Elizabeth	05/12/2009	
2201	37152	Young, Cole David	05/18/2009	
2201	37130	Allen, Kimberly Michelle	05/19/2009	
2201	37173	Islam, Sumaiya Parveen	05/21/2009	
2201	33922	Salam, Abdus	05/28/2009	
2201	36970	Erickson, Charles Paul	05/28/2009	
2201	33895	Joblin, Michael Andrew	06/15/2009	
2201	32477	Berkeley, Karen Lynette	06/16/2009	
2201	36820	Chen, Charlene Marie	06/16/2009	
2201	35411	Rothstein, Alvin	06/17/2009	
2201	36699	Horowitz, Richard	06/17/2009	
2201	37429	Foster, Andrew Michael	06/17/2009	
2201	37432	Gyapong, Eugenia	06/17/2009	
2201	37439	Belani, Anjali S	06/17/2009	
2201	36763	Stagg, Julie Rae	06/23/2009	
2201	36955	Bandy, Michael Craig	06/24/2009	

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2201	36982	Hill, Naomi Ruthia	06/24/2009	
2201	36996	Donaldson, Brandon	06/24/2009	
2201	37200	Girgis, Jacob Adel	06/24/2009	
2201	37281	Thompson, Crystal Maria	06/25/2009	
2201	37441	Church, Cassandra Lee	06/25/2009	
2201	36462	Elgadi, Mohamed I	06/26/2009	
2201	37524	Finamore, Ashley Brooks	06/26/2009	
2201	37003	Mccormick, Juliet Gothelf	06/30/2009	
2201	37586	Medrano, Gladys Elena	06/30/2009	
2201	36577	Thomas, Mathew	07/02/2009	
2201	37616	Harvey, Stephen Scott	07/07/2009	
2201	37352	Martinez, Karla	07/08/2009	
2201	37468	Allen, Kari Meredith	07/10/2009	
2201	37670	Brewer, Michael Shane	07/10/2009	
2201	37750	Samir, Ayman	07/13/2009	
2201	37751	Pendyala, Ramarao	07/13/2009	
2201	37711	Abid, Joseph Shenouda	07/14/2009	
2201	37712	Abid, Salwa Shenouda	07/14/2009	
2201	37706	Ramos-Mercado, Debra	07/15/2009	
2201	36844	Gattu, Sandhyarani	07/23/2009	
2201	37762	Natsheh, Feda M	07/27/2009	
2201	37805	Fleurinor, Jussien	07/28/2009	
2201	37833	Roque, Jacqueline	07/30/2009	
2201	37810	Kohli, Ashok	08/04/2009	
2201	36862	Donovan, Cortney Leigh	08/06/2009	
2201	37607	Bliss, Arthur Richard	08/06/2009	
2201	24568	Anderson, Glen Keith	08/12/2009	
2201	37638	Hauser, Jennifer Mary	08/12/2009	
2201	37820	Torres Torres, Jose Angel	08/20/2009	
2201	36222	Morgan, Charlotte Regine	08/25/2009	
2201	36299	Stanley, Robert L	09/03/2009	
2201	36230	Thomas, Kori Latay	09/14/2009	
2201	31061	Brunner, James William	09/15/2009	
2201	36297	Engram, Samaiyah Geneise	09/15/2009	
2201	36782	Qureshi, Azam Ali	09/17/2009	
2201	36116	Maddox, Mia Antionette	09/21/2009	
2201	35069	Patel, Bhura Joita Bhai	09/24/2009	
2201	37764	Narayanan, Anand	09/30/2009	
2201	37855	Sharpe, Marian Yvonne	10/05/2009	
2201	37972	Denson, Benea Ousley	10/06/2009	
2201	36381	Lantaff-Herrero, Isabel	10/07/2009	
2201	37935	Cortes, Zaida	10/07/2009	
2201	37941	Hernandez, Ismary Enid	10/07/2009	
2201	37951	Cruz-Perez, Wendy Mariet	10/07/2009	
2201	37962	Jamin, Yuniarti Utami	10/08/2009	

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2201	35053	Egbuonu, Flora Nkechi	10/14/2009	
2201	32444	Tabuteau, Ronald	10/19/2009	
2201	37714	Philip, Prasad Kunnel	10/19/2009	
2201	37943	Ramirez-Sanchez, Karina Ines	10/21/2009	
2201	37985	Heintz, Kyle Michael	10/23/2009	
2201	36444	Kandula, Lakshmi Sirisha	10/28/2009	
2201	37983	Abellard, Jean Roland	10/29/2009	
2201	37293	Bernstein, Jeffrey Alan	11/03/2009	
2201	37858	Burgess, Ricky Edward	11/03/2009	
2201	38002	Simonds, Maureen Elizabeth	11/23/2009	
2201	36196	White, Edward Christopher	11/30/2009	
2201	36592	Nkangnia-Njomo, Chantal Sylvie	12/08/2009	
2201	36508	Faour, Mhd Salem	12/24/2009	
2201	38092	Knight, Cedric O Ii	12/28/2009	
2201	32120	Patel, Leena Bhupendra	01/04/2010	
2201	37865	Sivick, Larrow Anthony	01/04/2010	
2201	38117	Gorasiya, Ileshkumar Popatlal	01/14/2010	
2201	38133	Lama, Bimala	01/14/2010	
2201	38142	Lin, Yijun	01/14/2010	
2201	38143	Kankanala, Ragini	01/14/2010	
2201	38091	Patel, Hitesh H	01/19/2010	
2201	38093	Okaro, Obinna Nwabunwanne	01/19/2010	
2201	38114	Yadav, Kumari Unnati Vajesjnh	01/19/2010	
2201	38115	Patel, Nikunjkmar Jivanlal	01/19/2010	
2201	38129	Tan, Li-Hua	01/20/2010	
2201	38130	Shah, Kaushal Pankajkumar	01/20/2010	
2201	33616	Awosegun, Victoria Oluwatoyin	01/21/2010	
2201	38136	Bessette, Daniel Robert	01/25/2010	
2201	38148	Toolsie, Shivana	01/26/2010	
2201	38156	Patel, Rajvi Hemant	01/26/2010	
2201	38161	Patel, Swatibahen C	02/08/2010	
2201	27505	Sevak, Ravi Prafull	02/09/2010	
2201	36616	Shehzad, Khurram	02/09/2010	
2201	32204	Khanum, Shahida	02/16/2010	
2201	38224	Ferguson, Leida Marie	02/16/2010	
2201	38157	Hilaire, Nathalie Alexandra	03/03/2010	
2201	38244	Kelly, Jennifer Lee	03/09/2010	
2201	24689	Maldonado, Teresa	03/10/2010	
2201	36427	Miller, Penney Kay	03/10/2010	
2201	38034	Newman-Mckenzie, Diane Fiona	03/10/2010	
2201	38235	Naso, Joanne V	03/10/2010	
2201	38246	O'Neil, Collin James	03/10/2010	
2201	38260	Gandhi, Ruchika	03/18/2010	
2201	34961	Velez Rosado, Alexandra	03/22/2010	
2201	25845	Galli, Robert Michael	03/23/2010	

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2201	38269	Johnsey, Jeremy Hudson	03/23/2010	
2201	38265	Tameze, Auguste Aouanang	03/25/2010	
2201	37755	Rizzetto, Geny Besa	03/30/2010	
2201	38203	Sakharkar, Prashant Raghunath	03/31/2010	
2201	36699	Horowitz, Richard	04/01/2010	
2201	36874	Nakaya, Morey Mamoru	04/13/2010	
2201	37744	Sedrak, Emad	04/14/2010	
2201	32092	Ahmad, Usman	04/15/2010	
2201	38308	Burt, Lauren Elizabeth	04/15/2010	
2201	38283	Mowery, Daniel Frederick	04/19/2010	
2201	37525	Abdelmelek, Mervat Yasaker Yacoub	04/20/2010	
2201	38343	Kodersha, Albert D	04/20/2010	
2201	38359	Ghali, Christine Boulos	04/22/2010	
2201	31071	Kanaparthy, Manjula	04/28/2010	
2201	32574	Preminger, Deborah	04/28/2010	
2201	38387	Zeigler, Ricky L	04/28/2010	
2201	38403	Sanchez, Reylene	04/28/2010	
2201	38338	Kolhe, Amolkumar	05/06/2010	
2201	36744	Rooprai, Supreeti	05/10/2010	
2201	38288	Morales, Ana Mercedes	05/18/2010	
2201	38527	Fuller, Christine Elaine	05/18/2010	
2201	38532	Cabug, Jamie-Nell Andrada	05/19/2010	
2201	38150	Mcguire, Thomas Warren	05/24/2010	
2201	38232	Whitney, Dennis John	05/24/2010	
2201	38424	Oliva, Gigi Rosemary	05/24/2010	
2201	38556	Issa Ossais, Carimi Marina	05/24/2010	
2201	38564	Ratkovic, Jelena	05/24/2010	
2201	38345	Ailor, James Johnson Jr	05/26/2010	
2201	38385	Rodriguez Manrique, Rafael Antonio	06/02/2010	
2201	38797	Hilaire, Jean Bellevue	06/02/2010	
2201	38801	Ngo, Kiet Tuan	06/02/2010	
2201	38833	Jump, Brandon Michael	06/08/2010	
2201	38950	Shah, Shreya Amit	06/15/2010	
2201	38959	Fasonu, Olalekan Olatunbosun	06/16/2010	
2201	38769	Fowowe, Olayinka	06/17/2010	
2201	38917	Xu, Eric Duo	06/17/2010	
2201	38891	Limoncelli, Nicholas	06/21/2010	
2201	38430	Schuman, William I	06/22/2010	
2201	39088	Heffron, Bradley Thomas	06/28/2010	
2201	39096	Vacha, Sharon Lee	06/28/2010	
2201	38325	Fronton, Elizabeth Louise	06/29/2010	
2201	38561	Wolnerman, Michael	06/29/2010	
2201	39092	Pitts, Jacqueline Nicole	06/30/2010	

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2201	39125	Monks, Helen Anne	06/30/2010	
2201	35170	Lee, James	07/06/2010	
2201	39151	Alegre, Jessica Ria	07/06/2010	
2201	39161	Rivera, Lilliam Teresa	07/12/2010	
2201	39167	Garcia Concepcion, Rosa De Lourdes	07/12/2010	
2201	39185	Rivera, Enid	07/12/2010	
2201	39241	Thaudboina, Venkateshwarlu	07/14/2010	
2201	39258	Nguyen, Huong-Thuy Thi	07/15/2010	
2201	39208	Gibson, Julia Louisa	07/16/2010	
2201	39171	Almodovar-Rodriguez, Ingrid Mariel	07/21/2010	
2201	39277	Bach, Thanh-Huy Le	07/21/2010	
2201	39286	Gomez, Aisha Kwanza	07/26/2010	
2201	39290	Gordon, Ivory Alexis	07/26/2010	
2201	39306	Collazo-Gerena, Monica	07/27/2010	
2201	39202	Titak, John Adam	07/28/2010	
2201	36397	Gonzalez, Gloria Maria	07/29/2010	
2201	36769	Hildebrand, Chad Allan	08/02/2010	
2201	37764	Narayanan, Anand	08/03/2010	
2201	39313	Roberts, Yolanda April	08/03/2010	
2201	36681	Hudgins, Nicole	08/09/2010	
2201	39336	Demian, Nancy	08/09/2010	
2201	36268	Davis, Vanessa Denise	08/25/2010	
2201	35008	Chintamaneni, Amelia Randeo	08/30/2010	
2201	39377	Pierce, Tracy Nease	08/30/2010	
2201	33922	Salam, Abdus	09/07/2010	
2201	38458	Gupta, Adarsh	09/13/2010	
2201	39404	Edward, Hany S	09/13/2010	
2201	39339	Yirgu, Derege Hailu	09/14/2010	
2201	36844	Gattu, Sandhyarani	09/15/2010	
2201	33707	Martinez, Maria Isabel	09/22/2010	
2201	39426	Robinson, Tamika Renee	09/22/2010	
2201	39436	Lawal, Erica Ayisat	09/22/2010	
2201	37833	Roque, Jacqueline	09/23/2010	
2201	39439	Hernandez-Lassalle, Aixa Lynn	09/23/2010	
2201	37751	Pendyala, Ramarao	09/27/2010	
2201	37951	Cruz-Perez, Wendy Mariet	09/27/2010	
2201	39474	Oboh, Onovughode Tega	10/07/2010	
2201	36299	Stanley, Robert L	10/18/2010	
2201	39405	Teferi, Gashaw Takele	10/19/2010	
2201	39433	Forbes, Theresa Thomas	10/20/2010	
2201	38041	Lin, Phyllis Hungyu	10/25/2010	
2201	39307	Olem, Andrew Marc	10/25/2010	
2201	31713	Nguyen, Tina Thuy	11/02/2010	
2201	39400	Choque, Jesus Alejandro	11/04/2010	

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2201	32120	Patel, Leena Bhupendra	11/08/2010	
2201	39447	Wisthoff, Bruce James	11/08/2010	
2201	38230	Laham, Josephine	11/10/2010	
2201	39419	Awadalla, Michael	12/08/2010	
2201	37855	Sharpe, Marian Yvonne	12/13/2010	
2201	36808	Smolen, Arnold Kent	12/14/2010	
2201	39480	Sanchez, Katherine	12/14/2010	
2201	33616	Awosegun, Victoria Oluwatoyin	12/15/2010	
2201	39537	Crouse, Matthew Stephens	12/20/2010	
2201	35264	Mridha, Md A Samad	12/21/2010	
2201	39618	Samaan, Joseph Tannous	01/12/2011	
2201	24356	Ulanow, Gail Lorraine	01/13/2011	
2201	37762	Natsheh, Feda M	01/18/2011	
2201	39655	Nakagawa, Naoto	01/18/2011	
2201	39478	Duong, Phong Xuan	01/19/2011	
2201	39613	Chen, Shiow-Yan	01/19/2011	
2201	39616	Cheng, Ting	01/19/2011	
2201	39617	Patel, Hetalkumar Sankalchand	01/19/2011	
2201	39623	Xiong, Lianjie	01/19/2011	
2201	36560	Taylor, Bruce Samuel	01/20/2011	
2201	39517	Ta-Sie, Kayly	01/20/2011	
2201	39632	Gramer, Jeanine Marie	01/20/2011	
2201	39667	West, Pamela Kay	01/24/2011	
2201	36560	Taylor, Bruce Samuel	01/25/2011	
2201	39634	Watts-Johnson, Dorothy Lee	01/25/2011	
2201	33646	Carter, David J	01/27/2011	
2201	35343	Hershfield, David Alan	01/27/2011	
2201	39175	Alvaro, Fred	01/27/2011	
2201	39557	Snyder, Robert Bruce	02/01/2011	
2201	39679	Rajyaguru, Komal Ratilal	02/01/2011	
2201	32444	Tabuteau, Ronald	02/07/2011	
2201	39432	Sanzen, Richard Ralph	02/08/2011	
2201	39059	Ikpeazu, Maureen A C	02/09/2011	
2201	39659	Floyd, Andrea Marie	02/09/2011	
2201	39694	Shah, Kahani Shaileshkumar	02/09/2011	
2201	39686	Hsu, Chan-Chien	02/10/2011	
2201	39261	Patrick, Ronald Kevin	02/14/2011	
2201	39681	Zilban, Natalie	02/14/2011	
2201	36508	Faour, Mhd Salem	02/16/2011	
2201	39547	Hsu, Ellen	02/16/2011	
2201	39764	Mayers, Natalie Ann	02/28/2011	
2201	39647	White, Jasmine Doreen	03/03/2011	
2201	38260	Gandhi, Ruchika	03/21/2011	
2201	36381	Lantaff-Herrero, Isabel	03/31/2011	
2201	39746	Hamed, Sabri Hassan	04/05/2011	

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2201	39769	Louie, Raymond	04/05/2011	
2201	39780	Lowery, Rachael Nielsen	04/05/2011	
2201	38041	Lin, Phyllis Hungyu	04/06/2011	
2201	39900	Kapidzic, Munevera	04/07/2011	
2201	39779	Macdonald, Sotiria Makris	04/12/2011	
2201	39902	Punnoose, Brian	04/14/2011	
2201	32049	Thottempudi, Venkata D	04/18/2011	
2201	34961	Velez Rosado, Alexandra	04/19/2011	
2201	24784	Khanum, Shahida	04/20/2011	
2201	39598	Botts, Leann Renee	04/20/2011	
2201	39676	Jones, William Russell	04/20/2011	
2201	39948	Moussa, Maha Samir Kyrillos	04/25/2011	
2201	39891	Dellegrotti, Sarah Mae	04/26/2011	
2201	39923	Ramos Mercado, Adlin	04/26/2011	
2201	38093	Okaro, Obinna Nwabunwanne	04/27/2011	
2201	39761	Granader, Hadar	05/02/2011	
2201	39869	Toney, Colleen Marie	05/03/2011	
2201	36616	Shehzad, Khurram	05/04/2011	
2201	39894	Garces, Idalmis Catalina	05/04/2011	
2201	39909	Beliard, Regine Christina	05/09/2011	
2201	39986	Merkel, Jennifer Jean	05/10/2011	
2201	39929	Zabala, Clara	05/12/2011	
2201	39924	Rodriguez, Deborah Ivette	05/19/2011	
2201	31071	Kanaparthy, Manjula	05/20/2011	
2201	40185	Hok, Saly	05/20/2011	
2201	39969	Robl, Jacob Maurice	05/23/2011	
2201	39985	Moreau, Lisa Kay	05/23/2011	
2201	23687	Malinsky, Julia	05/24/2011	
2201	40166	Roberts, Michelle Eliza	05/24/2011	
2201	40299	Pham, Trung Minh	05/24/2011	
2201	40272	Roark, Krista Page	05/25/2011	
2201	40351	Bradley, Monet Shambria	05/26/2011	
2201	40396	Abalkhail, Abdullah Ibrahim	05/31/2011	
2201	39915	Xiong, Yang	06/06/2011	
2201	39921	Menendez Sanabria, Daniel Alejandro	06/07/2011	
2201	40479	Porter, Tiffany Marie	06/08/2011	
2201	40462	Lee, Yi-Yun	06/10/2011	
2201	40465	Kehrberg, Andrew Robert	06/10/2011	
2201	40497	Benjamin, Phaneze	06/10/2011	
2201	40562	Mattson, James Joshua	06/10/2011	
2201	40589	Morrow, Ashley Dawn	06/10/2011	
2201	36230	Thomas, Kori Latay	06/13/2011	
2201	40478	Shafiee, Mohammad Amin	06/13/2011	
2201	40093	Macedo, Livia Rodrigues	06/14/2011	

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2201	33723	Onwuanaibe, Louis	06/15/2011	
2201	39767	Morrill, Richard Arthur	06/15/2011	
2201	36447	Aher, Vivekanand Yashwant	06/20/2011	
2201	39872	Ha, Hien Dien	06/21/2011	
2201	39890	Richardson, Bradley Neil	06/21/2011	
2201	40364	Wasik, Dawn Marie	06/21/2011	
2201	40680	Hatala, Alexis Brenna	06/21/2011	
2201	40695	Patel, Devangi Deval	06/21/2011	
2201	40727	Colbert, Kristyn Lynn	06/23/2011	
2201	40111	Cooper, Mark Charles	06/27/2011	
2201	40759	Patel, Trushaar Maganbhai	06/27/2011	
2201	40763	Poon, Chi Ki	06/27/2011	
2201	39839	Gharad, Hayat Mohamed	06/28/2011	
2201	40665	Khounsombath, Kathy	07/05/2011	
2201	40783	Pereira, Ninoshka	07/06/2011	
2201	40784	Jimenez Rosario, Jacqueline	07/06/2011	
2201	40787	Hillyard, Magan Ogden	07/06/2011	
2201	40790	Goodson, James William	07/06/2011	
2201	40795	Jacobs, Brooke Ashley	07/06/2011	
2201	40805	Rodriguez-Rivero, Ana J	07/06/2011	
2201	40819	Shaker, Marlene Kerolos	07/08/2011	
2201	40824	Dolan, Megan Jean	07/12/2011	
2201	40602	Keeth, Kimberly Erin	07/18/2011	
2201	40863	Al-Baldawi, Ruaa Nabil	07/18/2011	
2201	40871	Lee, Jammy	07/19/2011	
2201	39908	Rivers, Shellie Ann	07/20/2011	
2201	39989	Moise, Tamara Chrystele	07/20/2011	
2201	40883	Haass-Koffler, Carolina Luisa	07/20/2011	
2201	40714	Duncan, Douglas Eugene	07/25/2011	
2201	40906	Creel, Amanda Holloway	07/26/2011	
2201	40912	Vargas-Torres, Yarimar	07/27/2011	
2201	40764	Hernandez, Mabel Teresa	07/28/2011	
2201	40885	Perez, Bonnie Marie	08/01/2011	
2201	40684	Guerrero, Cynthia Barbara	08/02/2011	
2201	40864	Beidoe, Gabriel Kweku	08/02/2011	
2201	40968	Johnson, Jeremie Thomas	08/03/2011	
2201	40960	Neissari, Sara	08/08/2011	
2201	36297	Engram, Samaiyah Geneise	08/10/2011	
2201	40976	Newton, Alan Dalton	08/10/2011	
2201	40983	Caraballo-Feliciano, Alexis	08/10/2011	
2201	40776	More, Lisy V	08/11/2011	
2201	40987	Santana Colon, Vanessa	08/11/2011	
2201	40348	Stallings, Amanda Joy	08/12/2011	
2201	40997	Kotecha, Palak	08/17/2011	
2201	41003	Eugene, Christina Marie Louise	08/17/2011	

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2201	30218	Dominguez, Ileana	08/18/2011	
2201	41014	Lugo, Raquel	08/23/2011	
2201	39313	Roberts, Yolanda April	08/24/2011	
2201	41025	Rivera Feliciano, Marangely	08/24/2011	
2201	41026	Young, Jenny Hui-Shan	08/24/2011	
2201	39646	Sakyi, Stephanie Agyepomaa	09/01/2011	
2201	39861	Paine, Cassie Cole	09/01/2011	
2201	39307	Olem, Andrew Marc	09/06/2011	
2201	39446	Stolarski, Shirley Charlotte	09/08/2011	
2201	41041	Espada Torres, Anabel	09/08/2011	
2201	38556	Issa Ossais, Carimi Marina	09/12/2011	
2201	41045	Garcia, Nirma Rebecca	09/12/2011	
2201	39400	Choque, Jesus Alejandro	09/15/2011	
2201	39742	Komandur, Sushma	09/20/2011	
2201	41077	Albarran, Jennifer Denisse	09/20/2011	
2201	41079	Rodriguez, Sandra Ivette	09/26/2011	
2201	39904	Economy, Andrea Mary	09/27/2011	
2201	39940	Lue, Mark Anthony	09/27/2011	
2201	41099	Adu Siaw, Angela Naa Korkoi	10/03/2011	
2201	40891	Phillips, Christopher Matthew	10/06/2011	
2201	41050	Rice, David John	10/06/2011	
2201	41066	Delgado Nazario, Frank Javier	10/06/2011	
2201	38385	Rodriguez Manrique, Rafael Antonio	10/14/2011	
2201	39884	Bullington, Jeffrey Thomas	10/14/2011	
2201	41083	Higginson, Chase Bradford	10/14/2011	
2201	41109	Hosseinyar, Kathy Tahereh	10/18/2011	
2201	26075	Jules, Nelly Carmelle	10/20/2011	
2201	36222	Morgan, Charlotte Regine	10/20/2011	
2201	41057	Schultz, Kristen Ann	10/25/2011	
2201	41110	Seidman, Richard Niles	10/25/2011	
2201	41127	Farrell, Alison Nancy	10/25/2011	
2201	33922	Salam, Abdus	10/26/2011	
2201	40845	Black, Melissa Montgomery	10/27/2011	
2201	41145	Smith, Deborah Ann	10/28/2011	
2201	38377	Trista, Maria Del Carmen	10/31/2011	
2201	41034	Geeza, Elham	11/01/2011	
2201	41176	Wolfson, Edward Donald	11/08/2011	
2201	41092	Patel, Sunny J	11/21/2011	
2201	39426	Robinson, Tamika Renee	11/22/2011	
2201	41187	Robinson, Rose Lee	11/22/2011	
2201	38041	Lin, Phyllis Hungyu	11/30/2011	
2201	39436	Lawal, Erica Ayisat	12/07/2011	
2201	34024	Ramineni, Bharath Shyam	12/19/2011	
2201	41115	Harreld, William Grady	12/19/2011	

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2201	41239	Lopez Ruiz, Ivonne Marie	12/29/2011	
2201	37751	Pendyala, Ramarao	12/30/2011	
2201	41267	Sales, Maria Lovella Brucal	01/04/2012	
2201	41225	Depasquale, Seth Herbert	01/05/2012	
2201	41243	Faldu, Gaurav Bhagvanjibhai	01/09/2012	
2201	41245	Savalia, Rahulbhai Mahendrabhai	01/09/2012	
2201	41246	Shah, Daivik Kirankumar	01/09/2012	
2201	41260	Shah, Anandkumar Natvarlal	01/09/2012	
2201	38034	Newman-Mckenzie, Diane Fiona	01/12/2012	
2201	40985	Williams, Jimmy Lee	01/12/2012	
2201	39665	Rosenfeld, Avery Moss	01/17/2012	
2201	41282	Chun, Pusoon	01/17/2012	
2201	41292	Liu, Rui	01/23/2012	
2201	41293	Lu, Lingyun	01/23/2012	
2201	41319	Phan, Yvonne Le	01/30/2012	
2201	40877	Shah, Dhruva Harish	02/08/2012	
2201	41268	Surana, Neha	02/08/2012	
2201	24784	Khanum, Shahida	02/13/2012	
2201	41341	Riwes, Basant Diaa	02/13/2012	
2201	33616	Awosegun, Victoria Oluwatoyin	02/20/2012	
2201	39795	Molnar, Zita	02/20/2012	
2201	41339	Hakim, Wafaa Dakhlallah	02/20/2012	
2201	41364	Markovic, Johhny Chris	02/21/2012	
2201	41333	Rezakhani, Tina	02/22/2012	
2201	41312	Fowler, Jessica Renee	02/27/2012	
2201	41376	Davis, David Anthony	02/27/2012	
2201	41387	Rodriguez-Morales, Glamaris	02/27/2012	
2201	41235	Plagakis, James Lee	02/29/2012	
2201	37833	Roque, Jacqueline	03/05/2012	
2201	41249	Aboueid, George	03/05/2012	
2201	39767	Morrill, Richard Arthur	03/07/2012	
2201	41402	Wen, Hsiang-Chun	03/07/2012	
2201	36808	Smolen, Arnold Kent	03/14/2012	
2201	41375	Whaley, Ronald Carl	03/14/2012	
2201	31943	Torres, Aida I	03/15/2012	
2201	41306	Khoshbaf Khiabanian, Shirin	03/27/2012	
2201	32444	Tabuteau, Ronald	03/28/2012	
2201	41450	Fernandez Gonzalez, Alexis	04/04/2012	
2201	41377	Davis, Kristy Lauren	04/09/2012	
2201	41418	Wilborn, Courtney Anne	04/09/2012	
2201	41431	Wassef, Mina Moneer	04/10/2012	
2201	41455	Alvarez De Dolan, Lil Del C	04/10/2012	
2201	41458	Maharaj, Reena	04/10/2012	
2201	34961	Velez Rosado, Alexandra	04/16/2012	
2201	39929	Zabala, Clara	04/18/2012	

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2201	41206	Stanford, Laura Michelle	04/18/2012	
2201	39923	Ramos Mercado, Adlin	04/23/2012	
2201	39948	Moussa, Maha Samir Kyrillos	04/23/2012	
2201	36508	Faour, Mhd Salem	04/30/2012	
2201	39894	Garces, Idalmis Catalina	05/07/2012	
2201	34766	Brewer, Osric S	05/11/2012	
2201	39779	Macdonald, Sotiria Makris	05/14/2012	
2201	41388	Ibrahim, Iman Fathy	05/14/2012	
2201	41434	Jackson, Blair Christine	05/15/2012	
2201	41192	Pierre-Louis, Linda	05/16/2012	
2201	41481	Harris, Michelle Marie	05/16/2012	
2201	41611	Leal, Alexia Maria	05/21/2012	
2201	41860	Albury, Kristin Lee	05/23/2012	
2201	41933	Gonzalez, Danny Steve	05/23/2012	
2201	41874	Mcghee, Ashlee Kaye	05/24/2012	
2201	39241	Thaudboina, Venkateshwarlu	05/25/2012	
2201	41919	Ho, Vivian Wai Yan	05/25/2012	
2201	41937	Ngo, Bronson Xuan	05/25/2012	
2201	33602	Chevere-Robles, Katiria M	05/29/2012	
2201	42047	Wu, Han-Tuo	05/29/2012	
2201	42056	Weddle, Derrik Loyal	05/29/2012	
2201	42084	Abanah, Prisca Obiamaka	05/30/2012	
2201	41905	Henry, Laura Bess	05/31/2012	
2201	42102	Williams, Joy Marcelle	05/31/2012	
2201	41496	Gonzalez, Ileana Maria	06/04/2012	
2201	24274	Petion, Yves Andre	06/05/2012	
2201	41498	Strollo, Mark Alan	06/05/2012	
2201	42051	Ho, Chien Thanh	06/05/2012	
2201	42121	Masoud, Monika	06/05/2012	
2201	42145	Trieu, Hoc Quang	06/05/2012	
2201	42180	Courson, Alesa	06/08/2012	
2201	40843	Harland, Clifford Allen Jr	06/11/2012	
2201	41535	Abraham, Katri Ann	06/11/2012	
2201	42120	Espinal, Liliana	06/11/2012	
2201	42160	Rivera Cruz, Marieli	06/12/2012	
2201	42237	Nguyen, Katherine Mai Tram	06/13/2012	
2201	42241	Nguyen, Tan Eric	06/13/2012	
2201	42146	Syne, Dr Qaysara Zahra	06/15/2012	
2201	42188	Roy, Brittney Erin	06/15/2012	
2201	42284	Moir, Crystal Gail	06/15/2012	
2201	42242	Shah, Shreya Priyen	06/18/2012	
2201	42299	Mathai, Shaila	06/19/2012	
2201	41689	Hui, Ka Tung	06/20/2012	
2201	42187	Reed, Lilian Loraine Lim	06/20/2012	
2201	27505	Sevak, Ravi Prafull	06/21/2012	

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2201	40478	Shafiee, Mohammad Amin	06/21/2012	
2201	42353	Crane, Michelle Antoinette	06/22/2012	
2201	42379	Gonzalez, Harold Humberto	06/26/2012	
2201	42383	Learmond, Latoya Krystle	06/26/2012	
2201	41776	Graber, Arthur	06/27/2012	
2201	39151	Alegre, Jessica Ria	07/09/2012	
2201	42390	Pabst, Steven John	07/16/2012	
2201	39730	Sherwin, Laura Marie	07/17/2012	
2201	36447	Aher, Vivekanand Yashwant	07/25/2012	
2201	38093	Okaro, Obinna Nwabunwanne	07/31/2012	
2201	40497	Benjamin, Phaneze	07/31/2012	
2201	42268	Adeniye, Adesola Oluwayemisi	07/31/2012	
2201	42423	Patel, Dhvani	07/31/2012	
2201	42465	Lluch, Patricia Lynnette	07/31/2012	
2201	42474	Montalvo Arroyo, Lysvette	08/02/2012	
2201	42488	Perez, Jonathan Albert	08/06/2012	
2201	42500	Tshimbalanga, John Tumba	08/07/2012	
2201	42450	Mehdi, Fatima Mohamad	08/09/2012	
2201	30063	Palmquist, Dan Charles	08/13/2012	
2201	42525	Rhoades, Jenna Alison	08/13/2012	
2201	42585	Butler, Austin Porter	08/23/2012	
2201	40871	Lee, Jammy	08/24/2012	
2201	39869	Toney, Colleen Marie	08/28/2012	
2201	40819	Shaker, Marlene Kerolos	09/04/2012	
2201	42498	Au, Yilam	09/05/2012	
2201	42557	O'Donnell, Kathleen Mary	09/05/2012	
2201	42559	Adebiyi, Abosede Mojisola	09/07/2012	
2201	42601	Cunliffe, Thomas Edward	09/13/2012	
2201	41480	Wandler, Judith Ann	09/17/2012	
2201	42431	Gastaldo, Matthew Michael	09/18/2012	
2201	42460	Meador, Joshua Mark	09/18/2012	
2201	41099	Adu Siaw, Angela Naa Korkoi	09/21/2012	
2201	41393	Nguyen, Ngoctuyen Than	09/21/2012	
2201	40396	Abalkhail, Abdullah Ibrahim	09/27/2012	
2201	41518	Wolner, Chantelle Marie Beliste	10/03/2012	
2201	42441	Froendhoff, Karen Ann	10/04/2012	
2201	42643	Sitner-Medredovsky, Gabriella Ilona	10/04/2012	
2201	42637	Tran, Andrew	10/05/2012	
2201	42478	Vo, Thuy-Linh Thi	10/09/2012	
2201	42569	Roberts, Drew Stephen	10/09/2012	
2201	37983	Abellard, Jean Roland	10/11/2012	
2201	39313	Roberts, Yolanda April	10/11/2012	
2201	39428	Marcelin, Anthony	10/11/2012	
2201	41563	Pham, Hoanghai Huy	10/11/2012	
2201	42579	Mitchell, William Braden	10/11/2012	

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2201	41171	Certo, Stephen Paul	10/15/2012	
2201	40843	Harland, Clifford Allen Jr	10/19/2012	
2201	42666	Hernandez, Daniel	10/19/2012	
2201	42667	Morales, Jorge Luis	10/19/2012	
2201	39730	Sherwin, Laura Marie	10/22/2012	
2201	42634	Kumsaitong, Soranarom Belle	10/22/2012	
2201	42266	Faltaoos, John Kamel Habeb	10/24/2012	
2201	42451	Rosenberger, Melissa Hill	10/24/2012	
2201	42464	Stabley, Amber Alicia	10/24/2012	
2201	42506	Byron, Constance Louise	10/26/2012	
2201	36230	Thomas, Kori Latay	10/29/2012	
2201	39686	Hsu, Chan-Chien	10/29/2012	
2201	42660	Truong, Peter	10/29/2012	
2201	42683	Morales-Ramirez, Jessica Grisselle	10/29/2012	
2201	42662	Douglas, Katie Nicole	11/02/2012	
2201	42461	Lindsay, Marjorie Lynne	11/06/2012	
2201	42566	Feeney, Charles Patrick	11/06/2012	
2201	42645	Khan, Shazad Ahmed	11/06/2012	
2201	42673	Soni, Vipul Jagdishchandra	11/06/2012	
2201	41171	Certo, Stephen Paul	11/08/2012	
2201	39419	Awadalla, Michael	11/13/2012	
2201	40968	Johnson, Jeremie Thomas	11/13/2012	
2201	42505	Lindsay, Joshua Lee	11/13/2012	
2201	38556	Issa Ossais, Carimi Marina	11/14/2012	
2201	40943	Campbell, Brad Ernest	11/16/2012	
2201	38385	Rodriguez Manrique, Rafael Antonio	11/27/2012	
2201	42628	Madasu, Madhavi	11/28/2012	
2201	32566	Edmons, Thomas Lee	11/29/2012	
2201	42702	Ionan, Elena	11/30/2012	
2201	42686	Alhamzawi, Khaled	12/03/2012	
2201	42430	Wheeler, Cheryl Ann	12/05/2012	
2201	42722	Marin, Julie Ivette	12/05/2012	
2201	41231	Perez, Maite Enid	12/07/2012	
2201	42737	Mankaryous, Nancy	12/13/2012	
2201	41318	Fanou, Nisa Ekarohita	12/17/2012	
2201	38265	Tameze, Auguste Aouanang	12/18/2012	
2201	42697	Sloban, Stuart Alan	12/19/2012	
2201	42724	Sokale, Olubusola Titilope	12/19/2012	
2201	42734	Nashed, Nadine Adel	12/20/2012	
2201	42749	Arce Bulted, Osmarily	12/20/2012	
2201	42739	Henry, Velma Ellen	12/26/2012	
2201	42765	Baker, Nichole Renee	12/27/2012	
2201	42718	Feder, Gail Debra	01/03/2013	
2201	42787	Antoun, Christina Youssry	01/03/2013	

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2201	42009	Distefano, Janet A	01/09/2013	
2201	41508	Zayas-Reyes, Mayra Enid	01/16/2013	
2201	42405	Day, Derrick Dustin	01/16/2013	
2201	42778	Uddin, Erum Ghayas	01/17/2013	
2201	42682	Mansfield, Brian Peter	01/23/2013	
2201	40997	Kotecha, Palak	01/24/2013	
2201	42803	Graumenz, Mitchell Lee	01/24/2013	
2201	42806	Patel, Archita Niranjan	01/24/2013	
2201	42773	Pantelakis, Maria	01/25/2013	
2201	41003	Eugene, Christina Marie Louise	01/28/2013	
2201	41368	Colon-Ocasio, Magaly	01/29/2013	
2201	42301	Salami, Shadi	01/30/2013	
2201	41231	Perez, Maite Enid	02/05/2013	
2201	42775	Abinanti, Joseph Thomas	02/05/2013	
2201	42797	Uddin, Shahana Naseer	02/05/2013	
2201	31071	Kanaparthy, Manjula	02/08/2013	
2201	42829	Van Bogaert, Bret Charles	02/08/2013	
2201	42807	Zaky, Myriam Magdy	02/13/2013	
2201	41491	Williams, Cheryl	02/18/2013	
2201	42791	Armontrout, Jennifer Renee	02/18/2013	
2201	39376	Patel, Hinaben Hetalkumar	02/22/2013	
2201	39426	Robinson, Tamika Renee	02/22/2013	
2201	39742	Komandur, Sushma	02/22/2013	
2201	42864	Omar, Omneya Abdelmoneim	02/22/2013	
2201	42823	Evoghlian, Mojgan Farzaneh	02/25/2013	
2201	36927	Bobo, Herbert Otis Jr	03/04/2013	
2201	41318	Fanou, Nisa Ekarohita	03/04/2013	
2201	42655	Levine, Andrew Ross	03/04/2013	
2201	42879	Avolio, Anna Elizabeth	03/05/2013	
2201	42842	Nguyen, Theresa Minh	03/06/2013	
2201	41393	Nguyen, Ngoctuyen Than	03/07/2013	
2201	33616	Awosegun, Victoria Oluwatoyin	03/08/2013	
2201	42894	Ratchick, Peggy Ruth	03/08/2013	
2201	42834	Truong, Gai T	03/12/2013	
2201	42896	Hammer, Toni Marie	03/13/2013	
2201	42911	Bernard, Venitia Bianca	03/13/2013	
2201	38377	Trista, Maria Del Carmen	03/15/2013	
2201	42907	Quach, Quynh Ho	03/18/2013	
2201	42922	Negron, Aurea Esther	03/18/2013	
2201	41267	Sales, Maria Lovella Brucal	03/19/2013	
2201	42850	Botteicher, Amanda	03/21/2013	
2201	42780	Mcdaniel, Steven Dale	03/22/2013	
2201	42824	Biedenharn, Todd Christopher	03/22/2013	
2201	42833	Thomas, George Anthony	03/22/2013	
2201	42873	Nairn, Shawn R	03/22/2013	

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2201	42905	Tawadrous, Shady Mahrous John	03/22/2013	
2201	42760	Santos Vazquez, Yeneisi	03/27/2013	
2201	42867	Paramo, Sara Vanessa	04/01/2013	
2201	42871	Olatunji, Olukemi Abosede	04/01/2013	
2201	42897	Stein, Karen Jane	04/01/2013	
2201	42904	Kabassu, Leonard Mitu	04/01/2013	
2201	42936	Silverman, David Howard	04/01/2013	
2201	42945	Saleeb Bebawy, Sameh Tharwat	04/02/2013	
2201	41450	Fernandez Gonzalez, Alexis	04/10/2013	
2201	42981	Neason, Deanna Trudy	04/15/2013	
2201	42881	Manawelian, Herayer Kevork	04/17/2013	
2201	42902	Gilbert, Theresa Vivian	04/17/2013	
2201	42957	Mccluskey, Patti Lynn	04/17/2013	
2201	42952	Kertman, Robert John	04/18/2013	
2201	42987	Youwakim, Ledia Morcos Salama	04/18/2013	
2201	42927	Rehmat, Raheeba	04/19/2013	
2201	42677	Valle-Corali, Magda	04/23/2013	
2201	42828	Sanger, Matthew Karl	04/23/2013	
2201	42865	Ontko, Samuel	04/25/2013	
2201	42941	Simon, Tony Cherukara	04/26/2013	
2201	42766	Miller, Michael Shane	05/02/2013	
2201	42820	Barriger, Robert Guy	05/06/2013	
2201	42958	Patel, Hiren Indravadan	05/06/2013	
2201	41508	Zayas-Reyes, Mayra Enid	05/07/2013	
2201	42935	Patel, Jayesh Vinu	05/07/2013	
2201	40665	Khounsombath, Kathy	05/13/2013	
2201	42635	Allison, Richard Dale	05/13/2013	
2201	43122	Cathey, Carl William Iii	05/13/2013	
2201	43123	Nguebo, Patricia	05/13/2013	
2201	42720	Quach, Kevin Manh	05/14/2013	
2201	42959	Horrigan, Meaghan Marie	05/14/2013	
2201	43008	Dahl, Steven Hurst	05/14/2013	
2201	43040	Natsagdorj, Enkhtuul Annie	05/14/2013	
2201	43053	Sims, Ti'Shea Lemarah	05/14/2013	
2201	43081	Matta, Mark John	05/14/2013	
2201	43195	Rathgeber, Abigail Michelle	05/14/2013	
2201	43231	Jarek, Ashley Nicole	05/14/2013	
2201	43105	Owens, Brittany Ellen	05/15/2013	
2201	43107	Weaver, Haley Susan	05/15/2013	
2201	43050	Balsam, Jeffrey Lawrence	05/16/2013	
2201	43083	Cowden, Thomas Welch Jr	05/16/2013	
2201	43169	Parmar, Deesa Gunvant	05/16/2013	
2201	43224	Haumschild, Ryan James	05/16/2013	
2201	41340	Brower, Neil Bryan Sr	05/17/2013	
2201	42961	Friesleben, Melinda Kristine	05/17/2013	

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2201	43029	Ayoub, Mariam	05/17/2013	
2201	43270	Bhuiyan, Navela	05/17/2013	
2201	42972	Patel, Jaymish Navinchandra	05/20/2013	
2201	43299	Kim, Ji Yeon	05/20/2013	
2201	43317	Robertson, Kristie Marie	05/20/2013	
2201	43324	Tran, Long Thuan	05/20/2013	
2201	43331	Ferry, Matthew Kyle	05/20/2013	
2201	43332	Kolta, Nancy Edward	05/22/2013	
2201	43358	Pham, Julie Ngoc	05/22/2013	
2201	43378	Cales, Scott Gary	05/23/2013	
2201	43385	Mckinnon, Ta'Shae Durrell	05/23/2013	
2201	43403	Kupferberg, Ellen Dara	05/23/2013	
2201	42884	Henegar, Mark Brandon	05/24/2013	
2201	42930	Truong, Bobby J	05/24/2013	
2201	42942	Manfredi, Lorraine Ann	05/24/2013	
2201	42946	Kovacs, James Allen	05/24/2013	
2201	43041	Quirk, Fatmeh	05/24/2013	
2201	43046	Mcgrath, Bobbi Jo	05/24/2013	
2201	43234	Jhobalia, Neel Sunil	05/24/2013	
2201	43408	Emekekwue, Linda Ujunwa	05/24/2013	
2201	43413	Rouhani, Ali	05/24/2013	
2201	43418	Patel, Natasha	05/24/2013	
2201	43417	Martinez, Miteisy	05/28/2013	
2201	43434	Rook, Alan Olsen	05/28/2013	
2201	43437	Persaud, Robert Anthony	05/28/2013	
2201	43076	Shahin, Margarette	05/29/2013	
2201	43355	Ngo, Christina Mui	05/29/2013	
2201	43456	Reddie, Denique Crysta-Gaye	05/29/2013	
2201	43476	Reed, Andrew Taylor	05/29/2013	
2201	43488	Sikka, Amit	05/29/2013	
2201	43470	Lipshutz, Andrew Marc	05/30/2013	
2201	37833	Roque, Jacqueline	05/31/2013	
2201	42784	Varghese, Roy	05/31/2013	
2201	42877	Fields, Robin Maxwell	05/31/2013	
2201	42944	Lipo, David Richard	05/31/2013	
2201	42996	Dean, Kathryn Joy	05/31/2013	
2201	43111	Frost, Kimberly Christine	05/31/2013	
2201	43278	Castex, Arielle Patrice	05/31/2013	
2201	43489	Raquipo, Jennifer Ann	05/31/2013	
2201	43509	Retcho, Kristina Marie	05/31/2013	
2201	43530	Tucker, Alan Patrick	05/31/2013	
2201	43531	Bastien, Roudelyne	05/31/2013	
2201	43532	Coltea, Gloria	05/31/2013	
2201	43534	Christiansen, Emily	05/31/2013	
2201	42975	James, Edwin	06/03/2013	

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2201	43051	Hale, Genevieve Marie	06/03/2013	
2201	43080	Haas, Adam Justin Sandler	06/03/2013	
2201	43601	Stoneking, Joshua Samuel	06/03/2013	
2201	33602	Chevere-Robles, Katiria M	06/04/2013	
2201	43222	Nguyen, Vinh Xuan	06/04/2013	
2201	43545	Simpson, Nadya Natasha	06/04/2013	
2201	43549	Phelan, George Raymond Iv	06/04/2013	
2201	43563	Hernandez, Vivian D	06/04/2013	
2201	43592	Landeta, Lauren Nicole	06/04/2013	
2201	42890	Bottoms, James Franklin	06/05/2013	
2201	43465	Francois, Jean Dominique	06/05/2013	
2201	43565	Nguyen, Mai	06/05/2013	
2201	43566	Ulysse, Shasly	06/05/2013	
2201	43593	Nguyen, Ryan Tan	06/05/2013	
2201	43597	Allen, Travis Lawrence	06/05/2013	
2201	43604	Castor, Veronese	06/05/2013	
2201	43606	Patel, Megha Ashvinrumar	06/05/2013	
2201	43616	Joseph, Lorneka Shavell	06/05/2013	
2201	43619	Hallmon, Nasiya Denise	06/05/2013	
2201	43633	Weatherington, Erika Denise	06/05/2013	
2201	43636	Coke, Shelly-Ann Tiffany	06/05/2013	
2201	43642	Donlow, Latricia Yvonne	06/05/2013	
2201	43648	Ngo, Kiet Anh	06/05/2013	
2201	43649	Jean-Simon, Tricy Merlande	06/05/2013	
2201	39241	Thaudboina, Venkateshwarlu	06/06/2013	
2201	43615	Schultz, Michael Gregory	06/06/2013	
2201	42642	Burgess, Leslie Jean	06/07/2013	
2201	42965	Ghali, May Mary	06/07/2013	
2201	43062	Ilkevitch, Alina	06/07/2013	
2201	43339	Camacho, Felipe	06/07/2013	
2201	43500	Delgado, Samantha Anne	06/07/2013	
2201	43653	Nada, Lilyan	06/07/2013	
2201	38260	Gandhi, Ruchika	06/11/2013	
2201	43529	Williams, Candra Jameka	06/11/2013	
2201	43659	Walker, Emilio Nathanien	06/12/2013	
2201	43696	Awad, Marina Youssef	06/12/2013	
2201	43697	Beshara, Mina Samir	06/12/2013	
2201	43708	Yang, Jessie Shu	06/12/2013	
2201	43716	Shah, Venus Ashwin	06/12/2013	
2201	43315	Gerena-Carrillo, Eniliz Eileen	06/13/2013	
2201	43348	Syed, Ayesha	06/13/2013	
2201	43395	Manduca, Arlyn	06/13/2013	
2201	43681	Maxwell, Abigail Leigh	06/13/2013	
2201	43711	Ramsaroop, Marisa Ann	06/13/2013	
2201	43723	Kohane, Angel Nicole	06/13/2013	

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2201	43724	Nguyen, Vy Nina Duy	06/13/2013	
2201	43734	Nguyen, Trang Ngoc	06/13/2013	
2201	43740	Popp, Shannon Kathleen	06/13/2013	
2201	43743	Vo, Loan Anh Thi	06/13/2013	
2201	43747	Le, Trang Bao Huynh	06/13/2013	
2201	43757	Kheireddine, Sunny Rockhill	06/13/2013	
2201	42993	Horn, Robin Ruth	06/14/2013	
2201	43070	Jimenez, Barbara Charis	06/14/2013	
2201	43168	Doan, Binh Hoa	06/14/2013	
2201	43204	Ragoonathsingh, Faria Anika	06/14/2013	
2201	43360	Temples, John Frederick	06/14/2013	
2201	43419	Soto Aybar, Jessica Marilys	06/14/2013	
2201	43446	Park, Pauline	06/14/2013	
2201	43766	Alvarez, Cristina Isabel	06/14/2013	
2201	43768	Almanzar Paredes, Anarelis	06/14/2013	
2201	43769	Enos, Merin Elsa	06/14/2013	
2201	41974	Barton, Penny Ruth	06/17/2013	
2201	42601	Cunliffe, Thomas Edward	06/17/2013	
2201	43675	Terala, Soumya	06/17/2013	
2201	43751	Woods, Jessica Lynne	06/17/2013	
2201	43760	Farag, Georgina Victor	06/17/2013	
2201	43770	Alexander, Mi'Chelle Juanita	06/17/2013	
2201	43774	Duncan, Jamie Shirlene	06/17/2013	
2201	43776	Jannu, Smruthi	06/17/2013	
2201	43779	Lu, Yueh-Hsun	06/17/2013	
2201	43783	Rodriguez Gomez, Edelmiro M	06/17/2013	
2201	43784	Emmanuelli, Giselle	06/17/2013	
2201	43786	George, Ashlynn Autumn	06/17/2013	
2201	43793	Moskovits, Jessica Sara	06/17/2013	
2201	43794	Walters, Adam Lee	06/17/2013	
2201	43778	Tran, Nhu Mai Thi	06/18/2013	
2201	43782	Johnson, Natalie Dianne	06/18/2013	
2201	43795	Soles, Lauren Dominique	06/19/2013	
2201	43801	Gutierrez, Carlos David	06/19/2013	
2201	43802	Beasley, Ronald Anthony	06/19/2013	
2201	43837	Kim, Ju Hyeun	06/19/2013	
2201	39306	Collazo-Gerena, Monica	06/20/2013	
2201	43570	Tran, Luong Hoang	06/20/2013	
2201	43627	Rios-Gonzalez, Rosa I	06/20/2013	
2201	43698	Ogden, Lauren Elizabeth	06/20/2013	
2201	43820	Barragan, Monica Inneb	06/20/2013	
2201	43822	Salibi, Julie	06/20/2013	
2201	42121	Masoud, Monika	06/21/2013	
2201	43831	Villarreal, Jimmy Ryan	06/21/2013	
2201	43839	Mayoz, Jessica Ann	06/21/2013	

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2201	39204	Soliman, Ayman G	06/24/2013	
2201	42923	Galitskiy, Alla	06/24/2013	
2201	42997	Duran, Jason David	06/24/2013	
2201	43017	Kandinov, Raisa	06/24/2013	
2201	43075	Khan, Tabraiz Mohamed	06/24/2013	
2201	43113	Perdue, Rebecca Susan	06/24/2013	
2201	43372	Sier, Marc Phillip	06/24/2013	
2201	43789	Forero, Mikel	06/24/2013	
2201	43824	Kebede, Mekebebe Girmachew	06/24/2013	
2201	43846	Medina Morales, Viviana	06/25/2013	
2201	43860	Sheikh, Mohammed Hasib	06/26/2013	
2201	43861	Makar, Sarah Helmy Aziz	06/26/2013	
2201	43863	Rodriguez-Almodovar, Nashira Mari	06/26/2013	
2201	43865	Irvin, Cadesia Gail	06/26/2013	
2201	43876	Tripathi, Pathik B	06/26/2013	
2201	43799	Malsom, Richard David	06/27/2013	
2201	43842	Konds, Fady Helal	06/27/2013	
2201	43883	Joachin, Sabine	06/27/2013	
2201	43885	John, Jaimy Mary	06/27/2013	
2201	43886	Ecker, Ashley Nell	06/27/2013	
2201	43888	Sianosyan, Margarita	06/27/2013	
2201	43901	Ransbottom, Heath Matthew	06/27/2013	
2201	43896	Fulmer, Marques Eugene	06/28/2013	
2201	43905	Joseph, Mikhil	06/28/2013	
2201	43907	Nguyen, Hong An	06/28/2013	
2201	43908	Delerme, Marco Marcel	06/28/2013	
2201	39681	Zilban, Natalie	07/01/2013	
2201	43691	Nguyen, Lena Cucphuong	07/01/2013	
2201	43915	Gray, Deanna Nacole	07/02/2013	
2201	43916	Patel, Ketal	07/02/2013	
2201	43918	Galuzina, Olesya Aleksandra	07/02/2013	
2201	43919	Nguyen, Huy	07/02/2013	
2201	43922	Nguyen, Tuan Ngoc	07/02/2013	
2201	43924	Oh, Jin Seung	07/02/2013	
2201	43930	Muniz-Battle, Janice	07/02/2013	
2201	43933	Gelada Santos, Lidia Esther	07/03/2013	
2201	43945	Tripathi, Shalini	07/03/2013	
2201	43950	Johnson, Colleen Ann	07/03/2013	
2201	43951	St Jean, Erika Beatrice	07/08/2013	
2201	43001	Codianne, Natalie Grace	07/09/2013	
2201	43611	Wiley, Thomas William	07/09/2013	
2201	43955	Ruiz-Torres, Michelle Marie	07/09/2013	
2201	39948	Moussa, Maha Samir Kyrillos	07/10/2013	
2201	43028	Bahorik, John Scott	07/10/2013	
2201	43965	Drapikowski, Adam Joseph	07/10/2013	

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2201	39894	Garces, Idalmis Catalina	07/11/2013	
2201	43970	Sully, Michael	07/11/2013	
2201	42901	Ray, David William	07/12/2013	
2201	43943	Bell, Amanda Marie	07/12/2013	
2201	43975	Abraham, Peter	07/12/2013	
2201	43981	Brooks, Gabriel Andrew	07/15/2013	
2201	43983	Luu, Tuan Minh	07/15/2013	
2201	43990	Lange, Raquel Maria	07/15/2013	
2201	43996	Vickers, Lee Tramell	07/15/2013	
2201	44000	Vaddi, Haranath Kumar	07/16/2013	
2201	42861	Fout, Amanda Elaine	07/17/2013	
2201	43826	Joshi, Gargi G	07/17/2013	
2201	43833	Macdonald, Adam Joseph	07/17/2013	
2201	43912	Abraham, Blessy Mary	07/17/2013	
2201	43958	O'Neel, Cory Dean	07/17/2013	
2201	42929	Alvarez Villavicencio, Yarelis	07/18/2013	
2201	43170	Bollaert, Sara Elizabeth	07/18/2013	
2201	43579	Rivers, Gayle Latisha	07/19/2013	
2201	44004	Abaza, Noha	07/19/2013	
2201	34374	Khamissizadeh, Farhad	07/22/2013	
2201	42710	Cruzado, Juan R	07/22/2013	
2201	43856	Hankel, Jeffrey S	07/22/2013	
2201	43857	Hankel, Catherine A	07/22/2013	
2201	43902	Alfonso Hernandez, Danay	07/22/2013	
2201	44008	Munoz Robledo, Lyn Gabriel	07/22/2013	
2201	44009	Frank, Damien Anthony	07/22/2013	
2201	44011	Caldero Quinones, Leilani C	07/22/2013	
2201	43829	Jennings, Heath Randel	07/23/2013	
2201	44016	Rollins, Kandice Natasha	07/23/2013	
2201	44017	Mohamad Awad, Jalal	07/23/2013	
2201	44018	Farid, Marina Mohsen	07/23/2013	
2201	43995	Tumino, Joseph S	07/25/2013	
2201	44024	Nieves Ortiz, Waldemar Julio	07/26/2013	
2201	44046	Betanco, Linda Idarela	07/26/2013	
2201	43527	Ng Wong, Shuk Ling	07/29/2013	
2201	44027	Guzman, Mayra Iveth	07/29/2013	
2201	43683	Bradley, Gregory	07/30/2013	
2201	43689	Nunez Roman, Yesenia	07/30/2013	
2201	43764	Gandelman, Yana	07/30/2013	
2201	43780	Chittle, Dennis James	07/30/2013	
2201	43971	Patel, Nitinkumar Parshotambhai	07/30/2013	
2201	41322	Yambao, Rosed Aquino	07/31/2013	
2201	43994	Jagasia, Kunal K	07/31/2013	
2201	44030	Zell, Amanda Elyse	07/31/2013	
2201	41388	Ibrahim, Iman Fathy	08/01/2013	

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2201	43732	Hettinger, Claire Abelardo	08/01/2013	
2201	43737	Patel, Kalpeshkumar Himmatbhai	08/01/2013	
2201	43745	Youssef, John Gamal Amin	08/01/2013	
2201	44032	Cuevas, Mary Jane Sales	08/01/2013	
2201	44033	Lai, Deborah Yan	08/01/2013	
2201	44034	Dulin, Matthew William	08/01/2013	
2201	44035	Williamson, Jerome Patrick	08/01/2013	
2201	44036	Jerry, Quaneshia Latoya	08/02/2013	
2201	44042	Smith-Benson, Joshua Francois	08/05/2013	
2201	44043	White, Kelly Michelle	08/05/2013	
2201	44044	Umar, Asmau A	08/05/2013	
2201	43843	Smith, Patria Shiree	08/06/2013	
2201	44029	Kocher, Keith Noel	08/06/2013	
2201	42638	Patel, Vaishali Manubhai	08/07/2013	
2201	42937	Dittus, Krystal Star	08/07/2013	
2201	43914	Settle, Janet Michelle	08/07/2013	
2201	43959	Mangino, Michael Paul	08/07/2013	
2201	44053	Jennings, Douglas Lee	08/07/2013	
2201	42899	Holt, Gretchen Marie	08/08/2013	
2201	43567	Anderson, Kimberly Erin	08/08/2013	
2201	44054	Diaz-Latorre, Edgardo L	08/08/2013	
2201	44055	Byard, Alan Richard	08/08/2013	
2201	44056	Dance, Richard Nathaniel	08/08/2013	
2201	36268	Davis, Vanessa Denise	08/09/2013	
2201	42977	Teconchuk-Yount, Amy Lynne	08/09/2013	
2201	44062	Rivera, Edgar	08/09/2013	
2201	44063	Bacon, David Jr	08/09/2013	
2201	44064	Paup, Jeffrey Eugene	08/09/2013	
2201	38093	Okaro, Obinna Nwabunwanne	08/12/2013	
2201	43984	Ghogomu, Jinwi Tapisi	08/12/2013	
2201	44059	Bhukhan, Shilpesh B	08/12/2013	
2201	44067	Galician, Korey Matthew	08/12/2013	
2201	43016	Otto, Jennifer A	08/13/2013	
2201	43942	Kwon, Jessica B	08/13/2013	
2201	43960	Norman, Darby Reynolds	08/13/2013	
2201	43986	Schrenk, Regina Anne	08/13/2013	
2201	44028	Spears, Eric Stephen	08/13/2013	
2201	44047	Abbasi, Ghalib Adel	08/13/2013	
2201	44049	Lee, Medina	08/13/2013	
2201	44051	Wallace, Marquita Terrieka	08/13/2013	
2201	43937	Mani, Reeba E	08/14/2013	
2201	44072	Murphy, Hanna V	08/14/2013	
2201	44073	Rezkallah, Nada Nagy	08/14/2013	
2201	44050	Anam, Areeba	08/15/2013	
2201	44075	Lord, Patrick Joseph	08/15/2013	

COMPAS DataMart Reporting System
Exam Eligibility Report For Testing of 2201 : Pharmacist
September 12, 2013

Sort Order: Eligibility Date

Processed: 9/12/2013 10:06:31AM

Profession	File Nbr	Licensee Name	Eligible Date	Exam Modifiers
2201	41146	Hernandez Arnaldy, Christie Marie	08/16/2013	
2201	43573	Tiitto, Markus Ville	08/16/2013	
2201	43580	Sosa, Louis P	08/16/2013	
2201	42939	Canada, Natalie Plummer	08/20/2013	
2201	43772	Gowler, Aimee Joy	08/20/2013	
2201	43972	Villegas-Medina, Nivia Griselle	08/21/2013	
2201	43974	Barrett, Jill Williamson	08/21/2013	
2201	44089	Rener, Timothy J	08/21/2013	
2201	42992	Garcia Vazquez, Maria Magdalena	08/22/2013	
2201	44093	Lebron, Carolina	08/22/2013	
2201	44094	Pham, Anjulie	08/22/2013	
2201	44095	Ezepue, Julius Chukwugekwu	08/22/2013	
2201	44104	Guess, Charles Jordan	08/22/2013	
2201	43872	Mikhail, Diana	08/23/2013	
2201	43909	Ershadi, Mahro M	08/23/2013	
2201	44060	Zoellner, Michelle Elise	08/23/2013	
2201	36447	Aher, Vivekanand Yashwant	08/26/2013	
2201	37788	Azzolin, Michael Tate	08/26/2013	
2201	43669	Hire, Ryan Richard	08/26/2013	
2201	44025	Gurbuz, Mujgan	08/26/2013	
2201	43928	Major, John Stephen	08/27/2013	
2201	44019	West, Jason Bruce	08/27/2013	
2201	44109	Hall, Meticia Michelle	08/27/2013	
2201	44110	Sivkov, Alexander	08/27/2013	
2201	44111	Belcourt, Todd Henry Jr	08/27/2013	
2201	44112	Geh, Deizenmai Njawkah	08/27/2013	
2201	44113	Patel, Sajel Shailesh	08/27/2013	
2201	44120	Hawkins, Brittany Lauren	08/28/2013	
2201	44045	Davidson, Tam Nhu	08/29/2013	
2201	44052	Starkman, Andrew T	08/29/2013	
2201	44077	Fred, Ruth Daliana	08/30/2013	
2201	44124	Zakaria, Alexander Sarkis	08/30/2013	
2201	44132	Muniz-Ramos, Franchesca	08/30/2013	
2201	44133	Le, Phuoc Huy	08/30/2013	
2201	42084	Abanah, Prisca Obiamaka	09/05/2013	
2201	43612	Lance, James Earl	09/05/2013	
2201	44121	Wolbrink, Christopher Steven	09/06/2013	
2201	44141	Green, Amy Ruth	09/06/2013	
2201	44088	Bloom, Timothy Douglas	09/09/2013	
2201	44082	Patel, Rupal	09/10/2013	
2201	44103	Williams, Brent Austin	09/10/2013	
2201	44108	Aquino, Lizbet	09/10/2013	
2201	44129	Nayak, Ankur Mahesh	09/11/2013	
2201	43987	Brodlieb, Rebecca Jane	09/12/2013	

COMPAS DataMart Reporting System
Exam Eligibility Report For Testing of 2201 : Pharmacist
September 12, 2013

Sort Order: Eligibility Date

Profession	File Nbr	Licensee Name	Eligible Date	Exam Modifiers

Total Number of Eligible Applications: 1,298

Division of Medical Quality Assurance

MQA

Processed: 9/12/2013 11:20:56AM

COMPAS DataMart Reporting System
New License Report for 2202 : Pharmacist Intern
7/ 1/2013 - 8/31/2013

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	30983	07/01/2013	Tuttle, Kathy Marie	12/17/1987			20 Hamilton Ave.	Wheeling, WV 26003
PSI	30984	07/02/2013	Joudeh, Hania	11/09/1974			403 Port Royal Way	Pensacola, FL 32502
PSI	30985	07/08/2013	Kruckeberg, Emily Jane	12/12/1989			1000 36Th St	Vero Beach, FL 32960
PSI	30986	07/08/2013	Pucel, Rachel Janene	02/14/1990			820 Grande Dr.	Minooka, IL 60447
PSI	30987	07/08/2013	Mousa, Christine Kamallabib	10/20/1981			1527 Starlight Cove	Tarpon Springs, FL 34689
PSI	30988	07/11/2013	Brache Hernandez, Osvaldo	02/28/1978			2730 Nw 99 St	Miami, FL 33147
PSI	30989	07/11/2013	Andrews, Kimberly Marie	04/18/1985			11897 Archer Hill Road	Randolph, NY 14772
PSI	30990	07/11/2013	Schnackenberg, Michael Jonathan	06/29/1989			5430 Se 28Th Street	Des Moines, IA 50320
PSI	30991	07/11/2013	Salama, Ramy	04/07/1984			219 S 4Th Ln S W	Vero Beach, FL 32962
PSI	30992	07/12/2013	Barrett, Brandon Leon	04/23/1985			983 Harborview Road	Charleston, SC 29412
PSI	30993	07/12/2013	Day, Kevin Christopher	11/04/1990			3841 Powner Road	Cincinnati, OH 45248
PSI	30994	07/12/2013	Cheslek, Michelle Lee	09/24/1985			301 N. Main St	Summerville, SC 29483
PSI	30995	07/15/2013	Olberding, Tiffany Lynn	07/07/1990			104 S Franktort St	Minster, OH 45865
PSI	30996	07/16/2013	Ding, Jennifer	07/03/1990			1026 Mesa Dr.	Peoria, IL 61607
PSI	30997	07/17/2013	Lopez Alminaque, Claudia Rosa	08/18/1979			6105 Sw 129Th Place Unit 1807	Miami, FL 33183
PSI	30998	07/17/2013	Joseph, Raumi Ezzat	10/02/1979			26 Portland Street Apt 207	Worcester, MA 01608
PSI	30999	07/17/2013	Hedrick, Zachary Adam	08/31/1989			17176 Glynwood New Knoxville Rd	Wapakoneta, OH 45895
PSI	31000	07/18/2013	Acosta Dominguez, Maria Eugenia	01/20/1975			3020 S. Combee Rd.	Lakeland, FL 33803
PSI	31001	07/18/2013	Hayes, Kristine Gabrielle	06/22/1990			32 Glen Laurel Dr.	Saint Johns, FL 32259
PSI	31002	07/23/2013	Miklich, Margaret Ann	01/13/1988			4889 Abbotsbury Lane	Syracuse, NY 13215
PSI	31003	07/23/2013	Klefeker, Alexis Elaine	06/16/1989			402 W Plaza Dr	Columbia City, IN 46725
PSI	31004	07/23/2013	Amin, Mina Amin Halim	03/15/1987			123 Lake Suran Drive	West Palm Beach, FL 33411
PSI	31005	07/23/2013	Morrisette, Matthew Joseph	11/12/1986			3679 Everhope Rd	Mount Pleasant, SC 29466
PSI	31006	07/23/2013	Fisher, Marion				1000 Duluth Hwy Apt 206	Lawrenceville, GA 30043

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	31007	07/23/2013	El-Banna, Mary Maged	02/21/1987			1904 Emmett Street	Charlottesville, VA 22901
PSI	31008	07/24/2013	Brannock, Justine Janette	06/19/1990			100 Old Cherokee Rd.	Lexington, SC 29072
PSI	31009	07/25/2013	Thekkedam, Jose John	06/11/1977			2450 N Orange Blossom Trail	Kissimmee, FL 34744
PSI	31010	07/25/2013	Pierce, Jessica Marie	09/07/1989			179 Pelican Way	Panama City, FL 32408
PSI	31011	07/25/2013	Hichez, Deidry	08/02/1971			10720 Sw 72 St	Miami, FL 33173
PSI	31012	07/25/2013	Williamson, Jerome Patrick	11/04/1960			2007 N. Sedgwick #406	Chicago, IL 60614
PSI	31013	07/25/2013	Takla, Mohab Mokhtar Shoukry	06/26/1979			43659 Corte Deloro	La Quinta, CA 92253
PSI	31014	07/25/2013	Famuboni, Adeola Yewande	01/29/1976			123 Sturgess Avenue	
PSI	31015	07/26/2013	Salama, Lilian Adel Naguib	01/12/1988			240 Nandina Terrace	Winter Springs, FL 32708
PSI	31016	07/26/2013	West, Misty Lee	03/31/1975			122 Wc Bryant Parkway	Calhoun, GA 30701
PSI	31017	07/26/2013	Oh, Jin Seung	01/11/1974			3340 Sw 27Th St.	Miami, FL 33133
PSI	31018	07/26/2013	Bancroft-Lavin, Yelaine	07/10/1970			1418 Michigan Dr	Lake Worth, FL 33461
PSI	31019	07/26/2013	Pearson, Bethany Paige	05/10/1990			4121 Sw 34Th St	Orlando, FL 32811
PSI	31020	07/26/2013	Melroe, Corey Scott	12/30/1987			555 40 St S Apt 123	Fargo, ND 58103
PSI	31021	07/29/2013	Diaz-Latorre, Edgardo L	03/18/1985			3242 Abiaka Dr	Kissimmee, FL 34743
PSI	31022	07/30/2013	Maykel, Perez	11/22/1979			1119 Sw 139Th Place	Miami, FL 33184
PSI	31023	07/30/2013	Ellis, Jennifer Monsod	08/01/1977			7840 Sonoma Springs Circle Apt 204	Lake Worth, FL 33463
PSI	31024	07/30/2013	Cole, Mirella Lynn	05/07/1990			6285 East Fowler Ave	Tampa, FL 33617
PSI	31025	08/06/2013	Jones, Kayla Ashley	07/06/1987			3700 Whispering Pines Rd Apt 47 D	Mobile, AL 36608
PSI	31026	08/06/2013	Janovsky, Kayla Jean	07/14/1988			175 Ferum Dr	Columbia, SC 29229
PSI	31027	08/06/2013	Sonchaiwanich, Suvimol	11/26/1980			550 Peachtree St	Atlanta, GA 30308
PSI	31028	08/06/2013	Smoody, Derek Joseph	06/24/1989			1901 Lincoln Hwy	North Versailles, PA 15137
PSI	31029	08/06/2013	Ahmed, Karim Kamel Ibrahim	06/26/1986			2403 41St Ave Apartment 15	Long Island City, NY 11101

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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	31030	08/06/2013	Anstine, Joshua Michael	11/17/1988			12080 German Church St	Alliance, OH 44601
PSI	31031	08/07/2013	Coutts, Elizabeth Alice	07/26/1989			205 Spring Wood Ct	North Augusta, SC 29841
PSI	31032	08/07/2013	Fiorenza, Mallory Ann	09/20/1987			2776 Cleveland Ave.	Fort Myers, FL 33901
PSI	31033	08/08/2013	Masiarczyk, Bliss Marie	10/28/1983			409 Grace Hills Drive	Blountville, TN 37617
PSI	31034	08/08/2013	Tsirogiannis, Kaliope Chrisula	08/14/1983			12028 Majestic Blvd	Hudson, FL 34667
PSI	31035	08/08/2013	Walsh, Dalton Reid	05/07/1989			3077 Brookhill Drive	Birmingham, AL 35242
PSI	31036	08/12/2013	Sookhan, Vinesh Arkash	04/20/1985			100 Union Drive	Albany, NY 12208
PSI	31037	08/12/2013	Sookhan, Trang Thi Thu Huynh	08/06/1986			100 Union Drive	Albany, NY 12208
PSI	31038	08/12/2013	Meyers, Jessica Lynn	07/27/1990			Elm And Carlton	Buffalo, NY 14263
PSI	31039	08/13/2013	Fernandez Eloy, Rosa Beatriz	07/04/1969			Comfort Pharmacy	
PSI	31040	08/13/2013	Weekley, Justin Reid	05/26/1989			1114 Mohawk St Unit H2	Savannah, GA 31419
PSI	31041	08/13/2013	Breeden, Joshua Michael	12/11/1988			134 Susina Dr.	Leesburg, GA 31763
PSI	31042	08/13/2013	Kamel, Tamer Talaat Fakhry	01/10/1973			2882 Willow Bay Terrace	Casselberry, FL 32707
PSI	31043	08/14/2013	De Vera, Katherine Brezina	09/16/1982			12454 Sw 125 Terrace	Miami, FL 33186
PSI	31044	08/15/2013	Asaad, Sylvia Samir Shehala	11/04/1975			2882 Willow Bay Terrace	Casselberry, FL 32707
PSI	31045	08/16/2013	Vila Hernandez, Tanit	09/23/1973			14347 Sw 62Nd St	Miami, FL 33183
PSI	31046	08/20/2013	Ball, Jasmin Maria	04/20/1990			505 Mall Blvd Apt #605	Savannah, GA 31406
PSI	31047	08/21/2013	Littlefield, Audrey Jane	08/03/1990			6J Talcott Forest Rd	Farmington, CT 06032
PSI	31048	08/21/2013	Patel, Nishma	05/20/1989			1000 Peachtree Industrial Blvd	Suwanee, GA 30024
PSI	31049	08/21/2013	Morkos, Magdy Farouk	07/01/1976			Trust Pharmacy	Palm Harbor, FL 34684
PSI	31050	08/21/2013	Patel, Sarjuben Govindbhai	01/14/1987			640 Celebration Ct	San Jose, CA 95134
PSI	31051	08/26/2013	Lambert, Candler Brooke	11/02/1980			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416

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	31052	08/26/2013	Lee, Tina Coleen	02/29/1972			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31053	08/26/2013	Jones, Stephanie Nicole	03/08/1994			901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31054	08/26/2013	Lewis, Tristin Leigh	03/14/1989			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31055	08/26/2013	Luinord, Sofonie	04/13/1990			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31056	08/26/2013	Lin, Xiao Yan	10/25/1990			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31057	08/26/2013	Mella, Lisa Carmen	03/11/1991			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31058	08/26/2013	Tor, Larry Mey	08/29/1987			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31059	08/26/2013	Mcleary, Tanice Melissa	01/02/1989			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31060	08/26/2013	Soule, Amanda Mary	09/06/1989			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31061	08/26/2013	Mcintyre, Kayla Monique	12/24/1990			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31062	08/26/2013	Watchek, Sarah Marie	05/07/1989			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31063	08/26/2013	Menzel, David Andrew	07/21/1988			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31064	08/26/2013	Wahba, Beshoi Ashraf	08/23/1991			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31065	08/26/2013	Melton, Charles Patrick	05/19/1985			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31066	08/26/2013	Mella, Natalie Marie	03/11/1991			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31067	08/26/2013	Mezentsef, Andrea Christine	12/01/1989			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31068	08/26/2013	Mijares, Jennifer Marie	08/03/1987			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	31069	08/26/2013	Vasquez, Veena Repique	09/30/1992			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31070	08/26/2013	Parrish, Shara Lynn	11/26/1985			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31071	08/26/2013	Pessa, Kurt Hunter	11/02/1985			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31072	08/26/2013	Laporte, Kyle John	04/10/1989			21900 River Oaks Dr	Fergus Falls, MN 56537
PSI	31073	08/26/2013	Mims, Natalie	03/28/1983			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31074	08/26/2013	Nguyen, Truong The	04/02/1984			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31075	08/26/2013	Nguyen-Bui, James Minh	12/29/1989			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31076	08/26/2013	Patel, Payal Bhavan	10/30/1986			13270 Sycamore Ave	Chino, CA 91710
PSI	31077	08/26/2013	St Leger, Sandra Marie	10/10/1980			15 Brasseler Blvd Apt #K38	Savannah, GA 31419
PSI	31078	08/27/2013	Zecca, Joshua Philip	09/08/1980			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31079	08/27/2013	Williams, James Anthony	12/31/1992			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31080	08/27/2013	Williams, Anthony Jarreau	12/08/1981			901 S Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31081	08/27/2013	Wight, Charles Everett	04/13/1990			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31082	08/27/2013	Segovia, Jocelyn	04/11/1969			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31083	08/27/2013	Sieunarine, Roxanne	05/04/1988			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31084	08/27/2013	Skruck, Mary Lynn	05/11/1993			901 S. Flagler Drive	West Palm Beach, FL 33416

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	31085	08/27/2013	Richardson, Jonathan Patrick	11/07/1988			901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31086	08/27/2013	Rodriguez, Naivys	07/29/1989			901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31087	08/27/2013	Reonegro, Emily Rose	04/17/1992			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31088	08/27/2013	Quach, Hung Tin	03/18/1989			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31089	08/27/2013	Remick, Adam Jaye	09/08/1988			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31090	08/27/2013	Retinskiy, Veniamin S	05/20/1992			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31091	08/27/2013	Santalo, Oscar				901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31092	08/27/2013	Albanese, Maxwell Patrick	01/01/1979			105 Orange St	Satellite Beach, FL 32937
PSI	31093	08/27/2013	Freimuth, Jocelyn Marie	08/12/1991			901 S. Flagler Dr	West Palm Beach, FL 33416
PSI	31094	08/27/2013	Gabarda, Sharlynn Mae Duran	05/12/1990			901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31095	08/27/2013	Geneus, Kenel	09/11/1970			901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31096	08/27/2013	Gerking, Allison Skye	04/15/1993			901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31097	08/27/2013	Gonzalez-Abreu, Patricia	12/06/1988			901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31098	08/27/2013	Hernandez, David Jose	11/23/1976			901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31099	08/27/2013	Hill, Kylene Frances	09/07/1992			901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31100	08/27/2013	Huynh-Hoa, Diane				901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31101	08/27/2013	Kuruppumadom, Arun Shajan	04/04/1991			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31102	08/27/2013	Dealmeida, Kristen E	08/13/1988			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	31103	08/27/2013	Dela Cruz, Joseph Patrick Robledo	11/17/1989			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31104	08/27/2013	Do, Hanh Dinh Nu Thien				901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31105	08/27/2013	Amin, Nikesh R	12/08/1988			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31106	08/27/2013	Bandhan, Brent Wayne	12/01/1990			901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31107	08/27/2013	Bartomioli, Holly Marie	12/21/1991			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31108	08/27/2013	Beat, Craig John	02/16/1989			901 S. Flagler Drive	West Palm Beach, FL 33416
PSI	31109	08/27/2013	Bensin, Amanda Elizabeth	04/17/1980			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31110	08/27/2013	Blandon, Andrea Karina	03/03/1992			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31111	08/28/2013	Blount, Robert Matthew	12/19/1987			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31112	08/28/2013	Campeau, Angelea Sloan	02/21/1990			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31113	08/29/2013	Capussi, Laura Leanne	02/03/1989			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31114	08/29/2013	Dakwa, David	01/07/1989			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31115	08/29/2013	Carranza, Abel Ruben	02/06/1989			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31116	08/29/2013	Claude, Relande	11/09/1983			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31117	08/29/2013	Clinton, Kelsey Nicole	05/18/1992			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31118	08/29/2013	Cyca, Ali Nicole	07/26/1990			6852 Amherst Dr #2108	Northfield, OH 44067
PSI	31119	08/29/2013	Craver, William Jay	08/17/1992			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31120	08/29/2013	Contreras, Kristina Marie	09/02/1985			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416

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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	31121	08/29/2013	Driscoll, Shayna Marie	03/19/1992			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31122	08/29/2013	Das, Timothy John	08/12/1987			901 S. Flagler Drive Box 24708	West Palm Beach, FL 33416
PSI	31123	08/29/2013	Eble, Kossivi Guy	09/10/1978			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31124	08/29/2013	Ellis, Stephanie Jean	06/22/1977			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31125	08/29/2013	Ewart, Ashley Diana	05/20/1989			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31126	08/29/2013	Fateru, Oluwabukola Adenike	05/01/1976			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31127	08/29/2013	Fernandez, Jennifer Marie	08/01/1990			5821 W 3Rd Ct	Hialeah, FL 33012
PSI	31128	08/29/2013	Dias, Elizeu Teixeira Jr	08/09/1982			901 S Flagler Drive Box 24708 Palm Beach Atlantic Univ.	West Palm Beach, FL 33416
PSI	31129	08/29/2013	Caslavka, Shane Matthew	06/26/1990			1401 Albrecht Blvd 103 Sudro Hall	Fargo, ND 58102
PSI	31130	08/29/2013	Yassa, Diana Farid	11/16/1987			1008 Green Pine Blvd Apt B2	West Palm Beach, FL 33409
PSI	31131	08/30/2013	Garciarena-Kraftchenko, Mae	04/01/1976			8590 Long Point Road	Houston, TX 77055
PSI	31132	08/30/2013	Buchanan, Richard Tyler	04/21/1986			2467 Shelby Creek Rd W	Jacksonville, FL 32221

Total Records: **150**

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	49128	07/01/2013	Cunningham, Yajaira Ayesha	07/29/1991	Other	Miami Dade College	30237 Sw 162 Ave	Homestead, FL 33033
RPT	49129	07/01/2013	Hawes, Ebony Antoinise	10/23/1981			6621 Fannin St	Houston, TX 77030
RPT	49130	07/01/2013	Michel, Harold Brown	05/17/1993			700 Ne 6Th Avenue	Delray Beach, FL 33483
RPT	49131	07/01/2013	Nottingham, Nicole Leslee	11/27/1971	Other		8342 N. Santos Drive	Citrus Springs, FL 34434
RPT	49132	07/01/2013	Hesly-Brown, Deborah Marie	08/15/1958	Walgreens		2257 Vista Parkway Suites 14-15	West Palm Beach, FL 33411
RPT	49133	07/01/2013	Akins, Kaylee Ann	09/14/1992			2117 Byron Butler Parkway	Perry, FL 32348
RPT	49134	07/01/2013	Fagan, Dezarae Catherine	02/03/1994	Walgreens		12001 Southern Blvd	Loxahatchee, FL 33470
RPT	49135	07/01/2013	Martin, Chinita Vonshea	02/05/1987	Other	Traviss Career Center	4355 Corporate Ave Apt 143	Lakeland, FL 33809
RPT	49136	07/01/2013	Sosslau, Seth Brian	04/07/1975			3699 Mission Court	Largo, FL 33771
RPT	49137	07/01/2013	Tiglao, Maria Christina	05/02/1982	Other	Pass Assured Simfarose Pharmacy	10016 Pines Blvd	Pembroke Pines, FL 33024
RPT	49138	07/01/2013	Bogus, Gary Alan	03/27/1968			801 Bunker Circle	Winter Haven, FL 33881
RPT	49139	07/01/2013	Benham, Kristen	03/13/1989	Other	Ultimate Medical Academy	24195 Us Highway 19 North Lot 422	Clearwater, FL 33763
RPT	49140	07/01/2013	Gonzalez, Kasandra	07/27/1985	Other	Ultimate Medical Academy	885 W 69Th St	Hialeah, FL 33014
RPT	49141	07/01/2013	Curka, Kim Suzanne	08/21/1967			2424 Sandmine Road	Davenport, FL 33897
RPT	49142	07/01/2013	Rodriguez, Jesus Manuel	11/25/1990			951 Sw 7Th St #5	Miami, FL 33130
RPT	49143	07/01/2013	Wood, Elizabeth Anne	08/21/1970		Rasmussen College	10168 Lake Miona Way	Oxford, FL 34484
RPT	49144	07/01/2013	Surguine, Lindsay Deeann	08/18/1986			3372 Canoe Creek Rd	Saint Cloud, FL 34772
RPT	49145	07/01/2013	Stecko, Laurette M	02/16/1951	Publix Super Market, Inc.	04302013	1400 Coral Ridge Drive	Coral Springs, FL 33071
RPT	49146	07/01/2013	Williams, Sielean Smith	02/01/1973	Wal-Mart		1450 Johns Lake Rd	Clermont, FL 34711
RPT	49147	07/01/2013	Prieto Gomez, Sorangel	06/28/1971			1911 Sw 2Nd St #1	Miami, FL 33135
RPT	49148	07/01/2013	Mckinney, Danielle Lynn	08/11/1973			14320 Springhill Dr	Spring Hill, FL 34609
RPT	49149	07/01/2013	Owens, Montario Leshawn	06/25/1989			9209 Oviedo Road	Jacksonville, FL 32221

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	49150	07/01/2013	Brannen, Larissa Nicolle	07/24/1994	Cvs Caremark		14039 Cr 127	Sanderson, FL 32087
RPT	49151	07/01/2013	Murphy, Ariel Dominique	02/09/1992			8833 Tamiami Trail North	Naples, FL 34108
RPT	49152	07/01/2013	Mateo, Jorge Luis	02/21/1979			3636 Harden Blvd	Lakeland, FL 33803
RPT	49153	07/01/2013	Lewis, Alden Rex	08/09/1960			3520 Fox Hollow Drive	Orlando, FL 32829
RPT	49154	07/01/2013	Hamilton, Ginny Renee	03/09/1973	Publix Super Market, Inc.		13455 County Line Road	Spring Hill, FL 34609
RPT	49155	07/01/2013	Kirkwood, Mercedes Kiara	08/21/1991			902 Old Polk City Rd	Haines City, FL 33844
RPT	49156	07/01/2013	Nason, Michael Edwin	11/25/1964			36428 East Dr	Fruitland Park, FL 34731
RPT	49157	07/02/2013	Morales, Lourdes	08/06/1975	Other	Professional Training Centers	3900 Sw 78 Ct	Miami, FL 33155
RPT	49158	07/02/2013	Ortiz, Azany	03/23/1991	Other	Professional Training Centers	3130 Sw 149 Ave	Miami, FL 33185
RPT	49159	07/02/2013	Stober, Lacrecia Maria	08/03/1974	Cvs Caremark		7930 Woodland Center Pkwy Suite 500	Tampa, FL 33614
RPT	49160	07/02/2013	Fils, Erika V	03/13/1990			3562 Wind River Run	Clermont, FL 34711
RPT	49161	07/02/2013	Baker, Raya Maria	02/03/1975			1110 Gulf Breeze Pkwy	Gulf Breeze, FL 32562
RPT	49162	07/02/2013	Clark, Annmarie	04/08/1970			628 El Prado Apt #1	Belle Glade, FL 33430
RPT	49163	07/02/2013	Carney, Brandon Michael	10/05/1994			717 N 14Th St	Leesburg, FL 34748
RPT	49164	07/02/2013	Klasinski, Joshua Stephen	06/25/1983			5736 Clark Rd	Sarasota, FL 34233
RPT	49165	07/02/2013	Converse, Suzanne Maree	05/28/1958			415 21St St	Vero Beach, FL 32960
RPT	49166	07/02/2013	Holzendorf, Keshon Shennette	01/31/1986	Other	Everest University Jacksonville	16Th 207 East	Woodbine, GA 31569
RPT	49167	07/02/2013	Woo, Michael Lo	01/14/1980	Other	University Of Florida - College Of Pharmacy	3627 Half Moon Dr	Orlando, FL 32812
RPT	49168	07/02/2013	William, Laila	05/27/1962		Mcfatter Technical Center	6721 Nw 61St Street	Tamarac, FL 33321
RPT	49169	07/02/2013	Hall, Kimberly Shavone	08/23/1982			214 S. U S Hwy 41	Inverness, FL 34450
RPT	49170	07/02/2013	Ryan, Aquil Shakir	05/31/1995			2933 Azalea Rd	Apopka, FL 32703
RPT	49171	07/02/2013	Clark, Dontee R	05/22/1987			7920 Merrill Rd #1106	Jacksonville, FL 32277
RPT	49172	07/02/2013	Mccoy, Douglas Gregory	10/12/1992			2160 Howland Blvd	Deltona, FL 32738

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	49173	07/02/2013	Quinn, Rachele Deborah	04/14/1973		Mcfatter Technical Center	4920 Nw 2Nd Ct	Boca Raton, FL 33431
RPT	49174	07/02/2013	Pentycofe, Mitzi Charlene	11/13/1963			4417 Nw Blitchton Road	Ocala, FL 34482
RPT	49175	07/02/2013	Dumontier-Hiott, Jasmine	01/21/1992			1295 S Missouri Ave	Clearwater, FL 33756
RPT	49176	07/02/2013	Schmidt, Chelsea Nicole	03/25/1990	Publix Super Market, Inc.		2038 Us Hwy 98	Santa Rosa Beach, FL 32459
RPT	49177	07/02/2013	Diaz, Isabel	07/14/1993			5200 Sw 34Th St	Gainesville, FL 32608
RPT	49178	07/02/2013	Bellman, Katrina Michelle	11/01/1990			3500 Se Maricamp Rd	Ocala, FL 34471
RPT	49179	07/02/2013	Gonzalez, James Edward	07/17/1962			8880 Taurus Circle South	Jacksonville, FL 32222
RPT	49180	07/02/2013	Cornejo, Stephanie Ivette	01/09/1994			1910 N. John Young Pkwy	Kissimmee, FL 34741
RPT	49181	07/02/2013	Curry, Kiersten Nichelle	04/01/1990			550 N. Pine Island Road	Plantation, FL 33324
RPT	49182	07/02/2013	Gonzalez, Ane	10/09/1975			900 Byscaine Blv	Miami, FL 33132
RPT	49183	07/02/2013	Everett, Amber Leigh	03/07/1989			1228 Tech Blvd	Tampa, FL 33619
RPT	49184	07/02/2013	Novak, Nicole Ashley	07/27/1992	Publix Super Market, Inc.		522 Saddlewood Lane	Winter Springs, FL 32708
RPT	49185	07/02/2013	Scott, Ashley	06/30/1987	Other	Ultimate Medical Academy	1019 23Rd St	Orlando, FL 32805
RPT	49186	07/02/2013	Culpepper, Tyler	08/22/1986	Publix Super Market, Inc.		5609 Nw 69Th Lane	Gainesville, FL 32653
RPT	49187	07/02/2013	Dowell, Darby Lynn	05/15/1979	Other	Everest University	8616 Tom Costine Rd.	Lakeland, FL 33809
RPT	49188	07/03/2013	Ward, Debby Kay	10/16/1954	Publix Super Market, Inc.		1765 Hopper #2	Niceville, FL 32578
RPT	49189	07/03/2013	Werner, Tamara Ann	04/03/1984	Other	University Of Florida - College Of Pharmacy	2002 2002 Blind Pond Ave	Lutz, FL 33549
RPT	49190	07/05/2013	Lucena, Suzette M	10/30/1990			11120 S. Crown Way Suite 11	Wellington, FL 33414
RPT	49191	07/05/2013	Metzner, Juliana	11/19/1989			6700 Bayshore Rd	North Fort Myers, FL 33917
RPT	49192	07/05/2013	Patel, Hiral M	01/31/1991			13731 Antler Point Dr	Tampa, FL 33626
RPT	49193	07/05/2013	Morgan, Mark Alan	06/13/1964			4703 34Th Ave W	Bradenton, FL 34209
RPT	49194	07/05/2013	Lund, Judith Lynn	02/28/1955			857 West Bay Dr	Largo, FL 33770
RPT	49195	07/05/2013	Lara, Alexis Nohemi	08/23/1993			10016 Pines Blvd	Pembroke Pines, FL 33024

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	49196	07/05/2013	Ponce, Laura Veronica	09/14/1973			5028 Okeechobee Blvd	West Palm Beach, FL 33417
RPT	49197	07/05/2013	Pledger, Karen Leigh	06/19/1978			4829 Cherokee Hts. Rd	Panama City, FL 32404
RPT	49198	07/05/2013	Llanes Ramirez, Maria	05/27/1990			11398 Quail Roost Dr	Miami, FL 33157
RPT	49199	07/08/2013	Pozo, Hilda M	04/21/1964			5247 N W 4Th Terr	Miami, FL 33126
RPT	49200	07/08/2013	Lopez, Eulalia Elexia	02/12/1963			8331 N W South River Dr	Medley, FL 33166
RPT	49201	07/08/2013	Phillips, Bret Jonathan	09/15/1985			11120 South Crown Way Ste 11	Wellington, FL 33414
RPT	49202	07/08/2013	Monteagudo, Larissa	11/10/1977			3715 Nw 7Th St	Miami, FL 33126
RPT	49203	07/08/2013	Addison-Pinellas, Flatia L	11/22/1977	Wal-Mart		3501 Pine Ridge Court	Orlando, FL 32808
RPT	49204	07/08/2013	Ramos, Mitchel Yasel	02/10/1978	Other	Everest Institute	8848 Sw 72Nd St #H148	Miami, FL 33173
RPT	49205	07/08/2013	Singson, Randall Mae L	05/20/1987	Other	University Of Florida-College Of Pharmacy	9190 108Th Ave. North	Largo, FL 33777
RPT	49206	07/08/2013	Rozinek, Courtney	12/13/1991	Cvs Caremark		1255 Jeffords St Apt 226A	Clearwater, FL 33756
RPT	49207	07/08/2013	Roman, Ivon	12/10/1960	Other	University Of Florida	403 Mallard Way	Kissimmee, FL 34759
RPT	49208	07/08/2013	Sanchez, Yanara	11/29/1989	Other	Professional Training Centers	9307 Jamaica Drive	Cutler Bay, FL 33189
RPT	49209	07/08/2013	Stewart, Melinda Elaine	05/23/1964	Shands At University Of Florida		1301 Shapiro Ave	Deland, FL 32724
RPT	49210	07/08/2013	Monsalve, Amber Leigh	12/03/1986	Walgreens		4340 South Florida Avenue	Lakeland, FL 33813
RPT	49211	07/09/2013	Garcia Guillot, Irma Lisbet	07/09/1976			574 Westward Drive	Miami Springs, FL 33166
RPT	49212	07/09/2013	Derenoncourt, Farah	08/29/1990	Other	Mc Fatter Technical Center	8008 Nw 106 Ave	Tamarac, FL 33321
RPT	49213	07/09/2013	Crossett, David Carl	01/07/1965	Other	Southeastern College	706 Toledo Place	Brandon, FL 33511
RPT	49214	07/09/2013	Choute, Estival	07/06/1991	Other	Everest University	220 Sw 27Th Terrace #2	Fort Lauderdale, FL 33312
RPT	49215	07/09/2013	Babu, Albin Kunjummen	10/25/1993	Cvs Caremark		38819 6Th Ave	Zephyrhills, FL 33542
RPT	49216	07/09/2013	Berth, Evan Anthony	08/10/1994			611 Burnt Store Rd. S.	Cape Coral, FL 33991
RPT	49217	07/09/2013	Floyd, Jasmine Vonsha	02/19/1991	Cvs Caremark		1026 Country Lane Court	Lakeland, FL 33810
RPT	49218	07/09/2013	Jn Baptiste, D'Jonson	04/29/1977			6731 Nw 26Th Street	Margate, FL 33063
RPT	49219	07/09/2013	Harris, Devon Lee	12/07/1991	Target Corporation		9350 Dynasty Drive	Fort Myers, FL 33905

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	49220	07/09/2013	Gewolb, Dayna	04/11/1991	Shands At University Of Florida		1759 Cocoplum Ct	Longwood, FL 32779
RPT	49221	07/09/2013	Braithwaite, Tennille Iona	09/16/1976	Other	2419 University Of Florida - College Of Pharmacy	4190 Plantation Oaks Blvd Unit 822	Orange Park, FL 32065
RPT	49222	07/09/2013	Hall, Christopher Robert	01/27/1992	Other	2419 University Of Florida - College Of Pharmacy	2756 Mystic Lake Drive 114	Oviedo, FL 32765
RPT	49223	07/09/2013	Allen, Samuel Brit	10/16/1981	Cvs Caremark		6909 North Lagoon Drive Unit E2	Panama City Beach, FL 32405
RPT	49224	07/09/2013	Hannon, Nikki Lynn	05/07/1990	Other	University Of Florida-College Of Pharmacy	2940 S. Mccall Rd.	Englewood, FL 34224
RPT	49225	07/09/2013	Davitian, Alexis Mercedes	08/02/1992	Cvs Caremark		12140 Nw 12Th St	Plantation, FL 33323
RPT	49226	07/09/2013	Ojeda Sanchez, Dina	10/05/1991		Kmart Corp.	4955 Golden Gate Parkway	Naples, FL 34116
RPT	49227	07/09/2013	Rivera, Veronica	06/09/1973	Cvs Caremark		2353 University Drive	Coral Springs, FL 33065
RPT	49228	07/09/2013	Felix, Gesper	01/18/1977	Other	Everest University	11002 Wizard Way 302	Orlando, FL 32836
RPT	49229	07/09/2013	Amador, Claritza	01/22/1970	Other	Everest University	4431 S. Texas Ave. Apartment # 109	Orlando, FL 32839
RPT	49230	07/09/2013	Rivera Gonzalez, Karla Jaeliz	04/26/1991	Other	Everest University	924 Club Sylvan Drive Apt. E	Orlando, FL 32825
RPT	49231	07/09/2013	Chavez, Mayrin	07/27/1983	Other	Everest University	2160 Running Horse Trail	Saint Cloud, FL 34771
RPT	49232	07/09/2013	Gonzalez, Ada Yanet	04/29/1980	Other	Fortis College	301 West Park Drive Apt 101	Miami, FL 33172
RPT	49233	07/09/2013	Gomez, Norma M	09/08/1954	Other	Everest Institute	10401 Sw 144 Ct	Miami, FL 33186
RPT	49234	07/09/2013	Jenkins, Tarshia Laverne	10/19/1971			5781 Lee Blvd	Lehigh Acres, FL 33971
RPT	49235	07/09/2013	Daniels, Breaunna	03/03/1992	Other	Everest Institute	2350 Ne 135 Street Apt. # 1503	North Miami, FL 33181
RPT	49236	07/09/2013	Fields, Clinique	08/03/1992	Other	Everest Institute	775 Nw 168 Drive	Miami Gardens, FL 33169
RPT	49237	07/09/2013	Cook, Laura Chanel	01/01/1986	Cvs Caremark		2889 Camp Grace Road	Pace, FL 32571
RPT	49238	07/09/2013	Gonzalez, Asiel	07/16/1989	Other	Everest Institute	2735 W. 61 Place Apt. 107	Hialeah, FL 33016
RPT	49239	07/09/2013	Gay, Aminah	09/06/1993	Other	Sanford-Brown Institute Tampa, Florida	6310 Castelven Dr. Unit 105	Orlando, FL 32835
RPT	49240	07/09/2013	Bush, Tereasa J	08/25/1985		Virginia College - Jacksonville	5554 Ortega Bluff Ln	Jacksonville, FL 32244
RPT	49241	07/09/2013	Cordero, Rosa Elena	03/17/1978			St Joseph'S Hospital	Tampa, FL 33607
RPT	49242	07/09/2013	Leiseca, Julio Publio	10/01/1952			7000 Sw 23Rd St Apt 49	Miami, FL 33155

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	49243	07/09/2013	Lai, Leah Lan	09/24/1971			2965 Stockwood Drive	Clearwater, FL 33761
RPT	49244	07/09/2013	Shelton, Alyssa Marie	02/15/1989	Publix Super Market, Inc.		2685 N. Forest Ridge Blvd	Hernando, FL 34442
RPT	49245	07/09/2013	Wilson, Theresa Michelle	08/31/1957		Mcfatter Technical Center	820 Oriole Ave	Miami Springs, FL 33166
RPT	49246	07/09/2013	Rodriguez-Rivera, Angel Javier	03/24/1993	Publix Super Market, Inc.		10615 Narccossee Rd	Orlando, FL 32832
RPT	49247	07/09/2013	Tenhet, Tina M	11/05/1966		Ridge Career Center	1124 Sunshine Way	Winter Haven, FL 33880
RPT	49248	07/10/2013	James-Mckie, Candace Michele	03/27/1971			3535 N. Tamiami Trl	Sarasota, FL 34234
RPT	49249	07/10/2013	Paez, Deisi	10/06/1967	Other	Hialeah Adult Education Center	11501 Sw 40Th St	Miami, FL 33165
RPT	49250	07/10/2013	Nikolov, Krassimir Krassimirov	10/04/1992	Cvs Caremark		1190 Dunn Avenue	Jacksonville, FL 32218
RPT	49251	07/10/2013	Lee, Amanda Devi	01/22/1990	Other	Mcfatter Technical Center	46Th 9525 Nw 46Th Street	Sunrise, FL 33351
RPT	49252	07/10/2013	Manson, Lisa Tujana	02/28/1966	Other	Everest University	2420 Ponkan Summit Dr.	Apopka, FL 32712
RPT	49253	07/10/2013	James, Ashley Monique	11/18/1992	Other	Everest University	1754 Nw 58Th Ave	Lauderhill, FL 33313
RPT	49254	07/10/2013	Mccray, Linette Ann	10/27/1986	Other	Everest Institute	13363 Sw 257 Terr	Homestead, FL 33032
RPT	49255	07/10/2013	Moore, Michael Darnell	03/30/1989	Other	Everest University	5077 Park Central Dr. Apt. 1525	Orlando, FL 32839
RPT	49256	07/10/2013	Mckinnon, Brittany	12/27/1991	Other	Everest Institute	1092 Nw 74 Street	Miami, FL 33150
RPT	49257	07/10/2013	Love, Maletha	11/18/1987	Other	Sanford Brown Institute Tampa	5229 Sonora Court #4	Tampa, FL 33617
RPT	49258	07/10/2013	Nunez, Osvaldo	03/03/1944	Other	Complete Pharmacy And Medical Solutions	5829 Nw 158Th Street	Miami Lakes, FL 33014
RPT	49259	07/10/2013	Duran, Xochilt Stephanny	07/05/1991	Other	Everest Institute	4010 Sw 137 St	Miami, FL 33175
RPT	49260	07/10/2013	Irizarry, Juliana Barbosa	03/07/1981	Cvs Caremark		3606 Nw 24Th Blvd Apt# 111	Gainesville, FL 32605
RPT	49261	07/10/2013	Marin-Santana, Jose Ernesto	07/17/1976	Other	Professional Training Centers	25410 Sw 137Th Ave #103	Homestead, FL 33032
RPT	49262	07/10/2013	Khan, Nosheen	07/07/1993	Cvs Caremark		2325 Tybee Road	St. Cloud, FL 34769
RPT	49263	07/10/2013	Knowles, Viviana	10/12/1975	Other	Southeastern College	19460 19460 Nw 59Th Ave	Miami Gardens, FL 33015
RPT	49264	07/10/2013	Hall, Rachael Lynn	12/12/1991			3316 4Th Ave N	Bonifay, FL 32425

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	49265	07/10/2013	Valdes, Mariam Mukaty	03/26/1976		Barry Univ	6050 S. Dixie Highway	South Miami, FL 33143
RPT	49266	07/10/2013	Rodriguez, Lorenia	11/18/1978		Florida Education Institute	201 N W 72Nd Ave #410	Miami, FL 33126
RPT	49267	07/10/2013	Cook, Joshua Thomas	08/09/1993			4299 Wilderness Rd	Vernon, FL 32462
RPT	49268	07/10/2013	Futch, Jessica Ray	12/10/1988			3909 Canary Palm Cir.	Plant City, FL 33566
RPT	49269	07/10/2013	Graepel, Dana Marie	05/27/1987			280 Port St Lucie Blvd	Port Saint Lucie, FL 34984
RPT	49270	07/10/2013	Torres, Dina Jacqueline	08/23/1968		Florida Education Institute	2357 Yalta Terr	North Port, FL 34286
RPT	49271	07/10/2013	Mccumber, Terri Michael	03/12/1987			424 Banana Street	Bowling Green, FL 33834
RPT	49272	07/10/2013	Oliver, Lakysha Tywhan	11/13/1972	Other	Certified Pharmacy Technician Board	209 Susan St.	Perry, FL 32348
RPT	49273	07/10/2013	Nielsen, Toriee Mariee	09/29/1992	Other	Pass Assured	4233 Auckland Rd	Pace, FL 32571
RPT	49274	07/10/2013	Sigler, Patricia Annette	07/16/1970		Hialeah Hospital	651 East 25 Street	Hialeah, FL 33013
RPT	49275	07/10/2013	Nazareno, Mark	12/14/1988	Other	University Of Florida	10944 Witchaven St	Jacksonville, FL 32246
RPT	49276	07/10/2013	Courville, Jeliena Nadine	05/13/1993			599 Oak River Court	Osprey, FL 34229
RPT	49277	07/10/2013	Masic, Arnela	07/01/1993	Cvs Caremark		1433 S Belcher Road Apt. F-17	Clearwater, FL 33764
RPT	49278	07/10/2013	Morand, Hollie Linn	05/25/1992	Publix Super Market, Inc.		2809 39Th St W	Bradenton, FL 34205
RPT	49279	07/10/2013	Thomas, Melissa Lee		Cvs Caremark		602 W Main Street	Inverness, FL 34450
RPT	49280	07/10/2013	O'Quinn, Kaitlyn Rachelle	09/10/1993	Publix Super Market, Inc.		1070 Stardust Way	Deland, FL 32720
RPT	49281	07/10/2013	James, Chakia Nakia	05/26/1990	Cvs Caremark		2316 5Th Ave Drv Est	Palmetto, FL 34221
RPT	49282	07/10/2013	Hotz, Emily Laing	01/26/1994			2400 S Ridgewood Ave	South Daytona, FL 32119
RPT	49283	07/10/2013	Jean, Lycerda	12/15/1990	Cvs Caremark		2418 Sw Brescia St	Port Saint Lucie, FL 34953
RPT	49284	07/10/2013	Kakareka, Karina Marie	04/23/1991	Cvs Caremark		6005 St Augustine Rd	Jacksonville, FL 32217
RPT	49285	07/10/2013	Peden, Curtis Arthur	09/14/1963	Other	Everestt University Jacksonville,	577 S.W.Dextercircle Apt. 102	Lake City, FL 32025
RPT	49286	07/10/2013	Poucher, Terri Lyn	08/18/1961	Other	University Of Florida-College Of Pharmacy	2038 Nw 50Th Ave	Ocala, FL 34482

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	49287	07/10/2013	Moser, Ashley Marie	09/28/1985	Cvs Caremark		6783 Veronica Court	St Augustine, FL 32806
RPT	49288	07/10/2013	Olimpo, Judith Gabrido	11/09/1992			601 E. Altamonte Dr.	Altamonte Springs, FL 32701
RPT	49289	07/10/2013	Pehr, Jill Anne	06/23/1990	Walgreens		340 Lowndes Ave	Ormond Beach, FL 32174
RPT	49290	07/10/2013	Moran, Kimberly Louise	09/23/1963	Cvs Caremark		101 North Walbash Ave	Lakeland, FL 33815
RPT	49291	07/10/2013	Innocent, Nadina Ashley	04/29/1990	Walgreens		2010 Sw College Rd	Ocala, FL 34474
RPT	49292	07/10/2013	Castillo, Maria Paula	07/29/1992			4351 Us 27	Clermont, FL 34711
RPT	49293	07/10/2013	Budding, Edie Nichole	07/28/1981			9902 South Thomas Dr #1001	Panama City Beach, FL 32408
RPT	49294	07/10/2013	Ahlstrom, Meghann Kathleen	06/03/1983			403 Anastasia Blvd	Saint Augustine, FL 32080
RPT	49295	07/10/2013	Herrera, Nicole Kathleen	09/11/1994			3375 Boggy Creek Rd	Kissimmee, FL 34744
RPT	49296	07/10/2013	Bates, Caitlin Michelle	09/14/1988			4100 Military Trail	Jupiter, FL 33458
RPT	49297	07/10/2013	Alvarado, Pamela Jean	07/13/1965			2814 N. University Dr	Coral Springs, FL 33065
RPT	49298	07/10/2013	Diaz Araujo, Stephanie Carolina	07/02/1992			5280 Sw 89Th Ave	Cooper City, FL 33328
RPT	49299	07/10/2013	Catoggio, Alisa Christine	07/16/1981	Cvs Caremark		10437 Bow Court	Boca Raton, FL 33498
RPT	49300	07/10/2013	Cooper, Keara Martice	06/06/1988			3405 Londonderry Blv	Orlando, FL 32808
RPT	49301	07/10/2013	Henry, Camisha Shanay	02/13/1995			7160 Forest City Rd Apt 122	Orlando, FL 32810
RPT	49302	07/10/2013	Cruz, Elizabeth	04/13/1993	Other	Medical Institute Of Palm Beach	4750 10Th Avenue N	Greenacres, FL 33463
RPT	49303	07/10/2013	Hill, Cheryl	10/22/1959	Publix Super Market, Inc.		511 Wilderness Circle	Sebring, FL 33872
RPT	49304	07/10/2013	Anshassi, Mira Nibal	08/12/1993	Cvs Caremark		8203 Collier Pl	Tampa, FL 33637
RPT	49305	07/10/2013	Crenshaw, Kristen Leigh	05/20/1986	Cvs Caremark		2071 Lakewood Dr	Clearwater, FL 33763
RPT	49306	07/10/2013	Hernandez, Jesus Rafael	06/12/1989	Walgreens		6003 14Th St West	Bradenton, FL 34207
RPT	49307	07/10/2013	De Pasion, Jenelle Leanne	09/30/1993	Cvs Caremark		3874 Wood Thrush Drive	Kissimmee, FL 34744
RPT	49308	07/10/2013	Bailiff, Austin Tate	04/09/1991	Other	University Of Florida College Of Pharmacy	2708 Ne Waldo Rd	Gainesville, FL 32609

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RPT	49309	07/10/2013	Anderson, Heather Grace	12/06/1986	Other	Everest University	3280 Starratt Rd	Jacksonville, FL 32226
RPT	49310	07/10/2013	Figueredo Perez, Blanca	08/26/1962			1675 Sw 67 Ave	Miami, FL 33155
RPT	49311	07/11/2013	Fefe, Rolanda	09/20/1987	Other	Medical Institute Of Palm Beach	1425 Banyan Lane	West Palm Beach, FL 33415
RPT	49312	07/11/2013	Gordon, Karen D	08/12/1971	Other	Mcfatter Technical Center	4850 Nw, 29Th Court Apt. 230	Lauderdale Lakes, FL 33313
RPT	49313	07/11/2013	Fernandez, Rita	12/24/1986	Other	Professional Training Centers	15601 Sw 137Th Ave #183	Miami, FL 33177
RPT	49314	07/11/2013	Amiot, Rebeca	01/24/1975	Other	Professional Training Centers	13933 Sw 46Th Terr Apt A	Miami, FL 33175
RPT	49315	07/11/2013	Cajuste, Milene	08/05/1984			337 S. Northlake Blvd Suite 1024	Altamonte Springs, FL 32701
RPT	49316	07/11/2013	Gray, Tamerlan	05/09/1985			3210 N Palm Ave	Hollywood, FL 33026
RPT	49317	07/11/2013	Ruiz-Colindres, Monica	01/29/1993			5701 Coral Ridge Drive	Coral Springs, FL 33076
RPT	49318	07/11/2013	Chang, Liaymargarita	02/28/1984			4411 W. Jean St	Tampa, FL 33614
RPT	49319	07/11/2013	Horowitz, Jodi Alise	07/17/1985			717 North 14Th Street	Leesburg, FL 34748
RPT	49320	07/11/2013	Blankenbiller, Cristina Marleny	11/14/1991			950 Blanding Blvd	Orange Park, FL 32065
RPT	49321	07/11/2013	Boyd, Lynnaye Essie	11/02/1990			2425 Mission Rd Apt 1201	Tallahassee, FL 32304
RPT	49322	07/11/2013	Garcia, Luisa	04/07/1978			3187 S. Congress Ave	Palm Springs, FL 33461
RPT	49323	07/11/2013	Le, Sandy Nhatrang	02/13/1985			10150 Bloomingdale Ave	Riverview, FL 33578
RPT	49324	07/11/2013	Esquivel, Magdalys	08/31/1971			3187 S Congress Ave	Palm Springs, FL 33461
RPT	49325	07/11/2013	Bradford, Vonceil	09/26/1989	Cvs Caremark		2672 Blanding Blvd	Middleburg, FL 32068
RPT	49326	07/11/2013	Trenholm, Trina Camille	09/10/1961		Coastalmed Of Fl	24 W. Oak Avenue	Panama City, FL 32401
RPT	49327	07/11/2013	Gazarek, Lawrence John	10/08/1947			2261 Gulf To Bay Lot 134	Clearwater, FL 33765
RPT	49328	07/11/2013	Gibson, Sheila Rose	03/20/1953			851 S State Rd 434	Altamonte Springs, FL 32714
RPT	49329	07/11/2013	Walsh, Jeffrey Philip	10/05/1990	Publix Super Market, Inc.		2724 W. Hillsborough Ave	Tampa, FL 33614
RPT	49330	07/11/2013	Reyes, Michelle	11/05/1981	Walgreens		2050 E. Osceola Pkwy	Kissimmee, FL 34743
RPT	49331	07/11/2013	Holguin, Natalia B	04/04/1988			3700 Commerce Pkwy	Miramar, FL 33025
RPT	49332	07/11/2013	Garrett, Keivonya Unique	12/18/1989			2425 Mission Rd Apt 2002	Tallahassee, FL 32304

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RPT	49333	07/11/2013	Chasteen-Casares, Caryn Dawn	06/08/1971			3891 Commerce Pkwy	Miramar, FL 33025
RPT	49334	07/11/2013	Murphy, Stacia Lynn	08/04/1976			17050 S Tamiami Trail	Fort Myers, FL 33908
RPT	49335	07/11/2013	Marchadie, Shelly Marie	09/07/1985			2623 Sw 20Th Cir	Ocala, FL 34474
RPT	49336	07/11/2013	Perez-Machado, Dulce Maria	09/25/1961			4290 S.W. 2 Terr	Miami, FL 33134
RPT	49337	07/11/2013	Francois, Gregory	05/14/1983			1726 Washington St #7	Hollywood, FL 33020
RPT	49338	07/11/2013	Yearwood, Mindy Lee	01/20/1987		Gulf Coaset State College	24 West Oak Ave	Panama City, FL 32401
RPT	49339	07/11/2013	Douglas, Kyrsten Marie	02/27/1990			865 Hibernia Rd	Fleming Island, FL 32003
RPT	49340	07/11/2013	Basraj, Gabriel	02/06/1984			2480 Pga Blvd	Palm Beach Gardens, FL 33410
RPT	49341	07/11/2013	Berkley, Alyssa Elaine	08/21/1989			7403 Aloma Ave	Winter Park, FL 32792
RPT	49342	07/11/2013	Bean, Erika	11/21/1989			6050 So. Dixie Hwy	Miami, FL 33143
RPT	49343	07/11/2013	Colon Vega, Jean C	07/24/1982			5660 Curryford Rd	Orlando, FL 32822
RPT	49344	07/11/2013	Hernandez, Minerva	11/28/1970			201 Sw 27 Ave	Miami, FL 33135
RPT	49345	07/12/2013	Christy, Renee	07/29/1971	Publix Super Market, Inc.		55 N. Indiana Ave	Englewood, FL 34223
RPT	49346	07/12/2013	Bermudez, Vicky Christina				8903 N W 171 Lane	Miami Lakes, FL 33018
RPT	49347	07/12/2013	Alfonso, Saviel				4307 N Armenia Ave	Tampa, FL 33607
RPT	49348	07/12/2013	Equevilley, Wendi La Chelle	09/17/1969			1950 State Road 19 North	Eustis, FL 32726
RPT	49349	07/12/2013	Covington, Albert Lewis Jr	09/08/1987			11036 Creighton Dr	Orlando, FL 32817
RPT	49350	07/12/2013	Chhouk, Dawn Frances	06/06/1961			119-41 223Rd Street	Cambria Heights, NY 11411
RPT	49351	07/12/2013	Edwards, James	04/23/1968	Other	Southeastern College	7811 Duck Pond Ct.	Hudson, FL 34667
RPT	49352	07/12/2013	Raby, Sylvia Lynn	09/28/1992	Cvs Caremark		5905 Us Hwy 301S.	Riverview, FL 33578
RPT	49353	07/15/2013	Wyllie, Janis Elise	08/22/1979	Publix Super Market, Inc.		152 S. Arabella Way	Saint Johns, FL 32259
RPT	49354	07/15/2013	Solla, Jennifer Nicole	01/07/1993		Technical Center Of Osceola	1130 Cambourne Drive	Kissimmee, FL 34758
RPT	49355	07/15/2013	Bitterman, Murray Jay	03/31/1954	Other	Mcfatter Technical Center	7250 N.W. First Street Apt #207	Margate, FL 33063

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RPT	49356	07/15/2013	Rousseau, Karen	02/19/1994	Publix Super Market, Inc.		10913 N. Military Trial	Palm Beach Gardens, FL 33410
RPT	49357	07/15/2013	Meeks, Melissa Kimberly	04/17/1990			1300 E. Hallandale Bch Blvd	Hallandale, FL 33009
RPT	49358	07/15/2013	Nguyen, Quynh Anh	10/16/1991	Cvs Caremark		6536 Sandy Oaks Lane	Orlando, FL 32809
RPT	49359	07/15/2013	Ross, Derek Robert	07/07/1971	Cvs Caremark		4090 South Tamiami Trail	Venice, FL 34293
RPT	49360	07/16/2013	Azevedo, Rhonda	01/08/1955	Other	Ultimate Medical Academy	14404 Timothy Lane	Hudson, FL 34669
RPT	49361	07/16/2013	Alicea, Jacquelyn Dezerey	02/08/1990			100 E. International Speedway Blvd	Deland, FL 32724
RPT	49362	07/16/2013	Mushrush, April	03/18/1987	Other	Ultimate Medical Academy	878 N. Ridgewood Ave.	Ormand Beach, FL 32174
RPT	49363	07/16/2013	Hoyt, Vicki Richards	06/25/1962			400 E. Central Blvd	Orlando, FL 32801
RPT	49364	07/16/2013	Smith, Agnes A	03/12/1965		Everst University	3686 Sw Foremost Drive	Port Saint Lucie, FL 34953
RPT	49365	07/16/2013	Boot, Martha R	10/28/1945			4530 Lantana Rd	Lake Worth, FL 33463
RPT	49366	07/16/2013	Demonte, Joshua Adam	11/21/1991	Cvs Caremark		13410 Sw 3Rd Ct	Ocala, FL 34473
RPT	49367	07/16/2013	Denum-Hochstetler, Aaron Casey	01/18/1994	Other	Everest University	1201 Seminole Blvd Apt 433	Largo, FL 33770
RPT	49368	07/16/2013	Djuric, Nikolina	08/21/1991	Cvs Caremark		2200 34Th Street N	Saint Petersburg, FL 33713
RPT	49369	07/16/2013	Durmisevic, Amra	08/12/1992	Cvs Caremark		845 4Th St N	Saint Petersburg, FL 33701
RPT	49370	07/16/2013	Beshara, Ereny Wahba Labib	12/16/1975	Cvs Caremark		Us 19N 25350 Us Hwy 19 North Apt # 218	Clearwater, FL 33763
RPT	49371	07/16/2013	Davis, Deloise	02/18/1973	Other	Everest University	3829 Avenue J. Nw	Winter Haven, FL 33881
RPT	49372	07/16/2013	Quinones, Chelsey Mariah	01/27/1992	Cvs Caremark		14441 Mirabelle Vista Circle	Tampa, FL 33626
RPT	49373	07/16/2013	Armand, Amber Nicole	02/14/1992	Publix Super Market, Inc.		9739 Fredericksburg Rd	Tampa, FL 33635
RPT	49374	07/16/2013	Gomez Almazan, Perla Brigitte	09/14/1981	Cvs Caremark		19249 Sw 119 Pl	Miami, FL 33177
RPT	49375	07/16/2013	Chen, Teng	09/20/1988	Cvs Caremark		3634 Rogero Road	Jacksonville, FL 32277
RPT	49376	07/16/2013	Clarke, Mary Jude	04/18/1959	Cvs Caremark		46 E Watson Rd	Saint Augustine, FL 32086
RPT	49377	07/16/2013	Duren, Lisa	02/25/1980	Wal-Mart		7450 Cypress Gardens Blvd	Winter Haven, FL 33884
RPT	49378	07/16/2013	Gianoly, Renee Marie	11/20/1975	Walgreens		2511 Middlehurst Rd.	Titusville, FL 32796

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RPT	49379	07/16/2013	Consalvo, Claudia Danielle	02/02/1995	Other	Mcfatter Technical High School	6644 Atlanta St.	Hollywood, FL 33024
RPT	49380	07/16/2013	Hamm, Alexis Carol	02/28/1990	Publix Super Market, Inc.		0533 6753 Thomasville Rd	Tallahassee, FL 32312
RPT	49381	07/16/2013	Arford, Taylor Leigh	07/20/1992	Publix Super Market, Inc.		3750 Roscommon Drive 1 King Edward Drive	Ormond Beach, FL 32174
RPT	49382	07/16/2013	Charleston, Louinette Lynesey	11/11/1973	Other	Walgreen	1318 17Th Street Ct E 1318 17Th Street Ct E	Bradenton, FL 34208
RPT	49383	07/16/2013	Huggard, Sharon Elaine	07/11/1957	Other	Everest University	2261 Gulf To Bay Blvd Lot 135	Clearwater, FL 33765
RPT	49384	07/16/2013	Denton, Dannielle Irma	08/16/1989	Target Corporation		2000 College Road	Ocala, FL 34471
RPT	49385	07/16/2013	Allan, Alexandra Victoria	04/24/1990	Other	Everest University	5846 Illinois Ave	New Port Richey, FL 34652
RPT	49386	07/16/2013	Carey, Richard Brian	03/26/1979	Other	Olympia Compounding Pharmacy	7389 Spring Villas Cir	Orlando, FL 32819
RPT	49387	07/16/2013	Ferronato, Erika	08/24/1977	Other	Professional Training Centers	210 Sw 11 St Apt 303	Miami, FL 33130
RPT	49388	07/16/2013	Folan, Brad Dunham	05/22/1984	Cvs Caremark		295 Clifton Street	Attleboro, MA 02703
RPT	49389	07/16/2013	Fumero-Fong, Ana	10/16/1971	Other	Professional Training Centers	6321 Sw 80Th St.	Miami, FL 33143
RPT	49390	07/16/2013	Fabregas, Ivon	11/13/1966	Other	Professional Training Centers	15326 Sw 138Th Ct	Miami, FL 33177
RPT	49391	07/16/2013	Johnson, Alicia Nicole	12/12/1979			4250 Phillips Hwy	Jacksonville, FL 32207
RPT	49392	07/16/2013	Burge, Taylor A	12/04/1992	Other	Everest University	112 Se 14Th St	Deerfield Beach, FL 33441
RPT	49393	07/16/2013	Goldberg, Christopher Frederick	07/04/1979	Other	Everest University	252 Fanshaw F	Boca Raton, FL 33434
RPT	49394	07/16/2013	Gadberry, Chelsie Jade	07/18/1992	Other	Southeastern College	3125 Buckley Ave	Lake Worth, FL 33461
RPT	49395	07/16/2013	Exalus, Nelen	09/27/1980	Other	Southeastern College	815 2Nd Street Apt 4	West Palm Beach, FL 33401
RPT	49396	07/16/2013	Jones, Chad Dominique	12/31/1989			24 Pecan Course Loop	Ocala, FL 34472
RPT	49397	07/16/2013	Clark, Lachare	10/01/1992	Other	Southeastern College	2031 Dock St. Apt.B	West Palm Beach, FL 33401
RPT	49398	07/16/2013	Palacio, Laura	10/30/1993			1100 N John Young Pkwy	Kissimmee, FL 34744
RPT	49399	07/16/2013	Dang, Linh Khanhtong	11/25/1993	Publix Super Market, Inc.		4849 4849 S Military Trl Greenacres	Greenacres, FL 33463-5310

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RPT	49400	07/16/2013	Forbes, Rodger	09/17/1973	Other	Everest Institute	3020 Nw 204 Terrace	Miami Gardens, FL 33056
RPT	49401	07/16/2013	Francillon, Cherna	09/30/1980	Other	Everest Institute	783 Nw 102 Street	Miami, FL 33150
RPT	49402	07/16/2013	Humphrey, Kache Angelique	03/09/1994	Other	Sanford Brown Institute	6888 6888 Nw 29Th Street	Sunrise, FL 33313
RPT	49403	07/16/2013	Gonzalez, Rolando Jose	12/16/1993	Other	Everest Institute	770 E 13Th Street	Hialeah, FL 33010
RPT	49404	07/16/2013	Flannigan, Carol Lee	02/07/1963			2031 19Th Ave W	Bradenton, FL 34205
RPT	49405	07/16/2013	Bumgarner, Jami Elizabeth	01/20/1985	Cvs Caremark		19Th 3503 19Th St East	Bradenton, FL 34208
RPT	49406	07/17/2013	Anderson, Julie Michelle	02/02/1983	Other	University Of Florida - College Of Pharmacy	7157 Gas Line Road	Keystone Heights, FL 32656
RPT	49407	07/17/2013	Hetzel, Michele Denine	06/19/1966	Walgreens		9025 N. Golfview Drive	Citrus Springs, FL 34434
RPT	49408	07/17/2013	De La Cruz, Deyanira	06/23/1975	Other	Everest Institute	9760 Sw 184 St Apt 11B	Miami, FL 33157
RPT	49409	07/17/2013	Berns, Allison	07/08/1970	Other	University Of Florida - College Of Pharmacy	1483 73Rd Circle Ne	St. Petersburg, FL 33702
RPT	49410	07/17/2013	Cruz, Freddy	06/21/1991	Cvs Caremark		4050 Rocky Circle Unit A 202B	Tampa, FL 33613
RPT	49411	07/17/2013	Formby, Melissa Rae	06/18/1988	Target Corporation		541 Roanoke St	Dunedin, FL 34698
RPT	49412	07/17/2013	Amaya, Lauren M	08/16/1995	Other	Mcfatter Technical High School	7440 Nw 4Th St. Apt 206	Plantation, FL 33317
RPT	49413	07/17/2013	Codio, Frandeline	09/28/1989	Other	Homestead Jobcorps Center	Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
RPT	49414	07/17/2013	Moore, Dovie Nicole	11/04/1984	Walgreens		11430 Beach Blvd	Jacksonville, FL 32246
RPT	49415	07/17/2013	Miller, Laura Emily	03/20/1989			1295 S. Missouri Ave	Clearwater, FL 33756
RPT	49416	07/17/2013	Hebibi, Anisa	03/13/1993	Other	Ultimate Medical Academy	601 Rosery Rd Ne #2053	Largo, FL 33770
RPT	49417	07/17/2013	Klein, Donna Marie	03/16/1959			146 Mecca St	Port Charlotte, FL 33954
RPT	49418	07/17/2013	Huffman, Vanessa Michelle	06/09/1990	Cvs Caremark		3800 Ne 168St	North Miami Beach, FL 33160
RPT	49419	07/17/2013	Bynum, Kiara T	07/08/1991	Wal-Mart		5800 Us 98 N	Lakeland, FL 33809
RPT	49420	07/17/2013	Huckaby, Elizabeth Rachel	05/03/1994	Cvs Caremark		1300 Apalachee Pkwy	Tallahassee, FL 32301
RPT	49421	07/17/2013	Koleva, Monika Hristova	08/21/1992			2015 Edgewater Dr	Orlando, FL 32804
RPT	49422	07/17/2013	Campbell, Ramiek Okeem	10/05/1991	Cvs Caremark		266 Windwood Oaks Dr. Apt 201	Tampa, FL 33613
RPT	49423	07/17/2013	Conlon, Helena Catherine	05/15/1956	Cvs Caremark		1275 Teahouse Drive	Clearwater, FL 33764

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RPT	49424	07/17/2013	Hernandez, Kiara Angelic	05/13/1995			1010 Orly Dr.	Kissimmee, FL 34759
RPT	49425	07/17/2013	Gonzalez, Ulyses Santiago	04/29/1989			407 Lakeview Dr Apt 102	Weston, FL 33326
RPT	49426	07/17/2013	Yates, Vassah Sha-Lea	03/07/1993		Washington-Holmes Technical Center	2605 West 23Rd Street	Panama City, FL 32405
RPT	49427	07/17/2013	Ruggles, Linda Lee	01/28/1965	Target Corporation		3709 Andelusia Blvd	Cape Coral, FL 33909
RPT	49428	07/17/2013	Hernandez, Leyania	12/15/1980			201 Sw Beacom Blvd	Miami, FL 33135
RPT	49429	07/18/2013	Vega, Maria J	04/15/1985	Other	Professional Training Centers	11249 N. Kendall Dr. Apt G101	Miami, FL 33176
RPT	49430	07/18/2013	Bergsma, Emilie Jean	09/24/1993			21297 Olean Blvd Unit B	Port Charlotte, FL 33952
RPT	49431	07/18/2013	Sanford, George Ray	06/03/1989	Other	Everest University	3252 Columbus Dr	Holiday, FL 34691
RPT	49432	07/18/2013	Hinckley, Jessica Anne-Lee	05/29/1991			4701 Park Blvd	Pinellas Park, FL 33781
RPT	49433	07/18/2013	Triana-Reyes, Madaisy	10/08/1973	Other	Professional Training Center	6525 West 24 Ave Apt 211	Hialeah, FL 33016
RPT	49434	07/18/2013	Troupe, Ashley	08/30/1986	Other	Sanford Brown Institute Tampa	2605 E 29Th Ave	Tampa, FL 33605
RPT	49435	07/18/2013	Simmons, Lorenza Giuseppina	11/29/1965	Cvs Caremark		2356 Robin Road	West Palm Beach, FL 33409
RPT	49436	07/18/2013	Damelio, John John	12/01/1965			6082 Crayfish Drive	Orlando, FL 32822
RPT	49437	07/18/2013	Brown, Jennifer S	03/18/1992			9855 Lake Worth Rd	Lake Worth, FL 33467
RPT	49438	07/18/2013	Cuff, Erinn S	07/06/1989	Other	Ultimate Medical Academy	9054 Bridgecreek Dr	Jacksonville, FL 32244
RPT	49439	07/18/2013	Assih Eyana, Afeignidu	04/20/1982			932 B Essex St	Jacksonville, FL 32227
RPT	49440	07/18/2013	Harrison, Nancy Kay	08/19/1959			4849 Coconut Creek Pkwy	Coconut Creek, FL 33063
RPT	49441	07/18/2013	Copeland, Dorothy Jean	05/05/1954			301 West Road	Ocoee, FL 34761
RPT	49442	07/18/2013	Harris, Delecia Anneizer	12/28/1989			7304 Claudia Way	Panama City, FL 32404
RPT	49443	07/18/2013	Dunlap, Amanda Jeanne	08/11/1985			123 Fairfield Drive	Saint Marys, GA 31558
RPT	49444	07/18/2013	Dries, Taylor Michele	10/01/1990			9975 Arnold Rd Apt	Jacksonville, FL 32246
RPT	49445	07/18/2013	Antonelos, Anthony Christopher	08/16/1990			9427 South Suncoast Blvd	Homosassa, FL 34446
RPT	49446	07/18/2013	Hernandez, Vicente Thomas	03/05/1979			4520 Bray Rd	Tampa, FL 33634
RPT	49447	07/18/2013	Wall, Brittany Lynn	03/15/1988	Cvs Caremark		320 East Canfield Street	Avon Park, FL 33825

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RPT	49448	07/18/2013	Pedraza Guerrero, Liset	11/21/1989			1360 Nw 28Th St	Miami, FL 33142
RPT	49449	07/18/2013	Rosario, Victor M	06/06/1991	Other	Ultimate Medical Academy	10903 N. Hyacinth Avenue	Tampa, FL 33612
RPT	49450	07/18/2013	Alvarez-Yong, Vivianna I	09/15/1976	Other	Ultimate Medical Academy	2843 Meadow Wood Drive	Clearwater, FL 33761
RPT	49451	07/18/2013	Wright, Heather C	04/09/1993	Cvs Caremark		920 Calhoun Ave	Pensacola, FL 32507
RPT	49452	07/18/2013	Atta, Irene Sarpomaa	01/18/1982			8802 Rocky Creek Dr Ste 105	Tampa, FL 33615
RPT	49453	07/18/2013	Wright, Tabatha Allice	04/02/1992	Other	Ridge Career Center	8824 Buena Pl Apt. 2107	Windermere, FL 34786
RPT	49454	07/18/2013	Reynolds, Charity A	03/10/1990	Cvs Caremark		1668 Crooked Oak Drive	Orange Park, FL 32065
RPT	49455	07/18/2013	Ackerman, Janelle Yvonne	10/03/1988	Wal-Mart		3930 Easy St	Southport, FL 32409
RPT	49456	07/18/2013	Szala, Candice	04/29/1989	Target Corporation		16400 State Road 54	Odessa, FL 33556
RPT	49457	07/18/2013	Caban, Alejandra	01/17/1976	Other	Everest Institute	2927 Nw 97 Street	Miami, FL 33147
RPT	49458	07/18/2013	Folgar, Keilan	12/05/1989	Other	Everest Institute	3020 Congress Park Drive Apt# 216	Lake Worth, FL 33461
RPT	49459	07/18/2013	Crego, Leticia	11/05/1970	Other	Everest Institute	7640 W. 29 Way Apt.# 101	Hialeah, FL 33018
RPT	49460	07/18/2013	Hendry, Robyn Nicole	12/26/1991	Wal-Mart		3351 S Ferdon Blvd	Crestview, FL 32536
RPT	49461	07/18/2013	Gilkes, Lerone Elihu	08/07/1983	Other	Everest University	7625 Sugarbend Dr.	Orlando, FL 32819
RPT	49462	07/18/2013	Tippet, Gavin Michael	04/07/1994	Other	Everest University Jacksonville	2524 White Horse Rd E	Jacksonville, FL 32246
RPT	49463	07/18/2013	Guerra, Lazara Eyleen	11/12/1971	Other	Everest Institute	15365 Sw 73 Terr Cir Apt#2	Miami, FL 33193
RPT	49464	07/19/2013	Hutchinson, Samantha Lynn	06/28/1987			2725 Deer Berry Ct	Longwood, FL 32779
RPT	49465	07/19/2013	Nicol, Karen Ann	12/27/1976	Other	University Of Florida	1421 Quailey Street	Orlando, FL 32804
RPT	49466	07/19/2013	Griffin, Stephanie Leanne	05/01/1987			153 West James Circle	Hampton, GA 30228
RPT	49467	07/19/2013	Denler, Steven James	09/12/1958			25 Ne 23Rd Terrace	Cape Coral, FL 33909
RPT	49468	07/19/2013	Fernandez Saroza, Livia M	12/08/1975			6504 Sw 114Th Pl Apt D	Miami, FL 33173
RPT	49469	07/19/2013	Sardin, Megan Elizabeth	12/17/1990	Publix Super Market, Inc.		2515 Thonotosassa Rd	Plant City, FL 33563
RPT	49470	07/19/2013	Walter, Cynthia I	06/24/1969	Target Corporation		9600 Westview Dr	Coral Springs, FL 33076
RPT	49471	07/19/2013	Arreaga, Jonathan Jafet	05/09/1989	Cvs Caremark		3180 Safe Harbor Dr	Naples, FL 34117

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RPT	49472	07/19/2013	Ramic, Anel	03/25/1992	Publix Super Market, Inc.		1555 S. Highland Ave	Clearwater, FL 33756
RPT	49473	07/19/2013	Charles, Latoya Merrille	05/01/1984			1545 Rock Springs Rd	Apopka, FL 32712
RPT	49474	07/19/2013	Loria, Flor	08/14/1961	Other	Everest University	3231 Ne 15Th Street	Pompano Beach, FL 33062
RPT	49475	07/19/2013	Jordan, Laquanda L	03/26/1988	Other	Everest Institute	10830 Sw 154 Street	Miami, FL 33157
RPT	49476	07/19/2013	Wood, Kyle	09/25/1990	Cvs Caremark		3247 Finch Dr	Holiday, FL 34691
RPT	49477	07/19/2013	Contreras, Jenna Marie	07/17/1986	Other	Rasmussen College	11311 Stoneybrook Path	Port Richey, FL 34668
RPT	49478	07/19/2013	Morgan, Danny Joe Jr	06/20/1985	Other	Everest University	398 Turtle Dove Drive	Jacksonville, FL 32073
RPT	49479	07/19/2013	Maguire, Rodney Reith	12/08/1970			7800 Reflecting Pond Ct #1521	Fort Myers, FL 33907
RPT	49480	07/19/2013	Joseph, Shernell Nakiesha	12/31/1982	Other	Mc Fatter Technical Center	4160 Nw 21St Unit F214	Lauderhill, FL 33313
RPT	49481	07/19/2013	Lee, Albert Vernon	02/14/1990	Other	Everest University	345 Sonja Circle	Davenport, FL 33897
RPT	49482	07/19/2013	Montes, Diana Margarita	10/27/1969	Other	Fortis College	3086 Nw 2 Street	Miami, FL 33125
RPT	49483	07/19/2013	Williams, Natricia Lafane	11/23/1977	Other	Everest Institute	9875 Sw 183 Street	Miami, FL 33157
RPT	49484	07/19/2013	Pritchett, Laura Sites	09/10/1985	Walgreens		7401 5Th Ave N #9	Saint Petersburg, FL 33710
RPT	49485	07/19/2013	Ogborn, Sharon Faye	04/13/1951			13489 Grebe Rd	Weeki Wachee, FL 34614
RPT	49486	07/19/2013	Preka, Kristjan	03/08/1993	Other	Pharmacy Technician Certification Board	600145 Argyle Forest Blvd	Jacksonville, FL 32244
RPT	49487	07/19/2013	Phan, Kim Si	07/26/1971	Other	195-V&T Pharmacy	4040 W. Waters Ave Ste 105	Tampa, FL 33614
RPT	49488	07/19/2013	Kalata, April Eileen	10/02/1989	Cvs Caremark		1867 Gatewood Dr.	Deltona, FL 32738
RPT	49489	07/19/2013	Khalil, Issa S	08/13/1994	Publix Super Market, Inc.		3400 Avalon Park East Blvd	Orlando, FL 32828
RPT	49490	07/19/2013	Palma, Yailyn	04/16/1989	Other	Miami Lakes Educational Center	6195 W 18 Ave Apt 207	Hialeah, FL 33012
RPT	49491	07/19/2013	Leyva, Mirta M	11/25/1994	Other	Everest Institute	880 E. 23 Street	Hialeah, FL 33013
RPT	49492	07/19/2013	Lopez, Beleida	01/06/1975	Other	Everest Institute	1465 Ne 121 Street Apt B502	North Miami, FL 33161
RPT	49493	07/19/2013	Mckenzie, Jamie Lee	08/30/1988	Other	University Of Florida	615 S Pine St	New Smyrna Beach, FL 32169

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RPT	49494	07/19/2013	Monogyios, Margarita Stella	02/07/1994	Other	Everest University	3211 N Federal Hwy	Pompano Beach, FL 33064
RPT	49495	07/19/2013	Munroe, Kelly Jennell	09/24/1964			2201 West Sample Road	Pompano Beach, FL 33073
RPT	49496	07/19/2013	Livingston, Nicole Anne	03/26/1992	Cvs Caremark		1601 1601 Johns Lake Road Apt. 431	Clermont, FL 34711
RPT	49497	07/19/2013	Nguyen, Diana Kim	10/28/1992	Cvs Caremark		6503 Penton Street	Pensacola, FL 32506
RPT	49498	07/19/2013	Mcmillian, Desmond Maurice	05/20/1991	Cvs Caremark		219 Altamonte Bay Club Cir Apt 106	Altamonte Springs, FL 32701
RPT	49499	07/19/2013	Weaver, Anne Marie	04/18/1990	Cvs Caremark		5801 Central Avenue	Saint Petersburg, FL 33710
RPT	49500	07/19/2013	Roberson, Fanteline Linda	05/27/1982	Cvs Caremark		2958 Green St	Marianna, FL 32446
RPT	49501	07/19/2013	Carlos, Joseph James Paras	04/02/1992	Other	Jacksonville Job Corps Center	10960 Delago Drive	Jacksonville, FL 32246
RPT	49502	07/19/2013	Gilkey, Jessica Nicole	11/30/1989			18236 Old Palestine Rd	Crofton, KY 42217
RPT	49503	07/19/2013	Tassone, Alexis-Danielle	08/13/1994	Cvs Caremark		4632 Van Kleeck Drive	New Smyrna Beach, FL 32169
RPT	49504	07/19/2013	Yang. Corey Fu	10/21/1992	Cvs Caremark		1765 Gulf To Bay Blvd	Clearwater, FL 33764
RPT	49505	07/19/2013	Malbec, Linda L	07/12/1963			1467 Sunset Way	Weston, FL 33327
RPT	49506	07/19/2013	James, Lorena	09/19/1984	Other	Everest Institute	1079 W. 70 Place	Hialeah, FL 33014
RPT	49507	07/19/2013	Muir, Jacqueline Carolina	10/19/1991	Other	Online Classes	5212 Sw 141St Pl	Miami, FL 33175
RPT	49508	07/19/2013	Kraujalis, Sara Ann	03/24/1990	Other	Heritage Institute	1311 S.E 14Th Terrace	Cape Coral, FL 33990
RPT	49509	07/19/2013	Keith, John D	03/02/1993	Publix Super Market, Inc.		8407 Arbour Lake Dr Apartment 104	Leesburg, FL 34788
RPT	49510	07/19/2013	Taulbee, Krysta Lea	01/24/1983	Cvs Caremark		20 Seminole Trl	Pensacola, FL 32506
RPT	49511	07/19/2013	Linton, Shawnci Monet	12/22/1989	Publix Super Market, Inc.		3115 Castaway Lane Apt 4-101	Oviedo, FL 32765
RPT	49512	07/19/2013	Rush, Sarah Ann	10/07/1986	Cvs Caremark		2400 Enterprise	Orange City, FL 32763
RPT	49513	07/19/2013	Rizvi, Diana M	11/05/1978	Target Corporation		8465 Ridgewood Circle	Seminole, FL 33772
RPT	49514	07/19/2013	Leino, Kristen Danielle	11/22/1984	Other	Everest University	266 Sesame St	Middleburg, FL 32068
RPT	49515	07/19/2013	Kapusta, Crystal Marie	05/24/1993	Cvs Caremark		905 Ruby Place	Panama City, FL 32404
RPT	49516	07/22/2013	Rothenberger, Andrew Scott	11/24/1989		Univ. Of Florida	449 Heron Ave	Naples, FL 34108

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RPT	49517	07/22/2013	Vesselov, Kirill	10/25/1985		United Pharmacy	3951 N. Haverhill Rd #120-121	West Palm Beach, FL 33417
RPT	49518	07/22/2013	Terry, Debra Ann	01/13/1964	Publix Super Market, Inc.		8780 Boynton Beach Blvd	Boynton Beach, FL 33472
RPT	49519	07/22/2013	Diaz, Yulien	01/19/1990	Other	Everest Institute	11865A Sw 26 Street	Miami, FL 33175
RPT	49520	07/22/2013	Urbon, Emily Elizabeth	10/15/1992	Target Corporation		10401 Hwy 441	Leesburg, FL 34788
RPT	49521	07/22/2013	Stanner, Tyana Renee June	12/28/1979	Ominicare, Inc.		4150 Church Street	Sanford, FL 32771
RPT	49522	07/22/2013	Marquez Romero, Arelys D	04/15/1990			5900 N W 183 St	Miami Gardens, FL 33015
RPT	49523	07/22/2013	Thermezi, Tyrrell Jamar	02/10/1982			2415 S Fraser St	Georgetown, SC 29440
RPT	49524	07/23/2013	Mckinnon, Lenethreia Jayvon	05/20/1983			3355 Claire Lane #911	Jacksonville, FL 32223
RPT	49525	07/23/2013	Lopez, Maria I	07/22/1967			859 W Lumsden Road	Brandon, FL 33511
RPT	49526	07/23/2013	Dubia, Christopher Daniel	11/01/1985			630 N. Maitland R	
RPT	49527	07/23/2013	Walker, Chelsie Summer	09/13/1991	Wal-Mart		4770 Colonial Blvd	Fort Myers, FL 33966
RPT	49528	07/23/2013	Vanlaningham, Richard John	11/18/1972	Other	Sanford Brown Institute	6711 6711 Meade St	Hollywood, FL 33024
RPT	49529	07/23/2013	Threat, Monica Elizabeth	11/13/1974	Other	Concorde Career College	4795 Nw 113 Ter	Sunrise, FL 33323
RPT	49530	07/23/2013	Torres, Lisa	02/20/1992	Other	Everest Institute	15800 Nw 27 Court	Miami, FL 33054
RPT	49531	07/23/2013	Dixon, Reginald	03/02/1963			702 New York Dr	Pensacola, FL 32505
RPT	49532	07/23/2013	Martinez Mendoza, Oraince	04/29/1985			3501 Sw 87Th Ave	Miami, FL 33165
RPT	49533	07/23/2013	Denis, Serge	05/27/1978			150 West Camino Real	Boca Raton, FL 33432
RPT	49534	07/23/2013	Armstead, C'Jon M	07/19/1991			3407 10Th Avenue N	Palm Springs, FL 33461
RPT	49535	07/23/2013	Ortiz, Joseph A	02/01/1995			6210 Frost Dr	Tampa, FL 33625
RPT	49536	07/23/2013	Vilmar, Widlen	07/18/1990	Other	Everest University	535 Jaeger Drive	Delray Beach, FL 33444
RPT	49537	07/23/2013	Harris, Joseph Perry	10/06/1990			2738 Grand Bay Court	Navarre, FL 32566
RPT	49538	07/23/2013	Workman, Stacie Lee	10/28/1972	Walgreens		7422 Loblolly Bay Trail	Bradenton, FL 34202
RPT	49539	07/23/2013	Pereira, Jerrie Aleana	11/14/1974			6194 Gulf Shore Pkwy Unit G4	Gulf Shores, AL 36542
RPT	49540	07/23/2013	Maupin, Victoria Lynn	08/13/1970			6632 Hertz Street	Pensacola, FL 32526

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RPT	49541	07/23/2013	Fernandes, Jocelyn Barbosa	04/22/1995			572 Bitterwood Ct	Kissimmee, FL 34743
RPT	49542	07/23/2013	Gonzalez, Elizabeth Yaniz	11/22/1978			6500 E. Rogers Circle #A	Boca Raton, FL 33487
RPT	49543	07/23/2013	Oldread, Michelle Allesandra	12/26/1986			5609 Government Drive	Gulf Breeze, FL 32563
RPT	49544	07/23/2013	Lawrence, Janica Ramona	07/25/1982			4530 Lantana Road	Lake Worth, FL 33463
RPT	49545	07/24/2013	Garcia, Yanisleidi	11/18/1987			910 State Street	Lake Worth, FL 33461
RPT	49546	07/24/2013	Matos, Ashley Marie	07/21/1994	Cvs Caremark		3841 Safflower Terr	Oviedo, FL 32766
RPT	49547	07/24/2013	Haskew, Jacqueline Suzanne	09/30/1966			3625 W. Gandy Blvd	Tampa, FL 33611
RPT	49548	07/24/2013	Reyes Garcia, Lisset			A-1 Pharmacy	265 Ne 24 St	Miami, FL 33137
RPT	49549	07/24/2013	Appiahene, Samuel	01/27/1994	Other	University Of Florida - College Of Pharmacy	3030 E. Semoran Blvd	Apopka, FL 32703
RPT	49550	07/24/2013	Davis, Ashton Stanford	11/04/1993	Publix Super Market, Inc.		7830 Land O Lakes Blvd	Land O Lakes, FL 34638
RPT	49551	07/24/2013	Sturgess, Michelle Rene	08/24/1977	Winn Dixie		1028 S 3Rd Street	Jacksonville Beach, FL 32250
RPT	49552	07/24/2013	Ballek, Alexander Joseph	05/27/1993	Other	University Of Florida #2419	24019 Madaca Lane Bldg 14 Apt 101	Port Charlotte, FL 33954
RPT	49553	07/24/2013	Thorndike, Melissa Frances	10/26/1970	Publix Super Market, Inc.		5185 Us Hwy 98 S.	Lakeland, FL 33812
RPT	49554	07/24/2013	Pavicic, Marino	12/08/1992	Cvs Caremark		1020 1020 85Th Ave N Apt 218	Saint Petersburg, FL 33702
RPT	49555	07/24/2013	Bell, Theadosha Felisha	10/08/1990	Cvs Caremark		2575 Oakdal St S	St Petersburg, FL 33705
RPT	49556	07/24/2013	Price, Tiffany Marie	04/30/1988	Cvs Caremark		5517 Cr 579	Seffner, FL 33584
RPT	49557	07/24/2013	Harripersaud, Stephanie Lisa	11/20/1992	Cvs Caremark		605 Manatee Ave.	Holmes Beach, FL 34217
RPT	49558	07/24/2013	Jung, Samanta Sylvia	10/02/1990	Cvs Caremark		7851 115Th St N	Seminole, FL 33772
RPT	49559	07/24/2013	Toussaint, Lovensk Remy	08/11/1990	Wal-Mart		3201 East Palm Dr	Boynton Beach, FL 33435
RPT	49560	07/24/2013	Tensley, Erika	07/07/1989	Other	University Of Florida - College Of Pharmacy	736 13Th Ave South	St.Petersburg, FL 33701
RPT	49561	07/24/2013	Sanders, Andrea Leilani	06/22/1990		Manatee Technical Institute	6403 Se Pine Island Rd	Arcadia, FL 34266
RPT	49562	07/24/2013	Theodore, Geraldine	11/17/1985	Walgreens		9498 Nw 7Th Ave	Miami, FL 33150
RPT	49563	07/24/2013	Bojaxhi, Kristi	04/15/1990			30535 Us Highway 19 N	Palm Harbor, FL 34684

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RPT	49564	07/24/2013	Shinn, Kathy Ginn	04/05/1970	Walgreens		3014 Midway Rd	Plant City, FL 33565
RPT	49565	07/24/2013	Robillard, Susan Lynn	09/06/1969	Walgreens		919 Brookview Lane	Rockledge, FL 32955
RPT	49566	07/24/2013	Brown, Katia Shauntell	02/11/1987	Other	Everest University	10931 Tangora Street	Orlando, FL 32825
RPT	49567	07/24/2013	Calkins, Evan Charles	02/24/1980	Cvs Caremark		26101 Meadow Breeze Ln.	Leesburg, FL 34748
RPT	49568	07/24/2013	Kepler, Thomas Vincent	06/28/1992			9223 83Rd Street North	Largo, FL 33777
RPT	49569	07/24/2013	Young, Joshua David	04/10/1990	Walgreens		3340 Canoe Creek Rd	St. Cloud, FL 34772
RPT	49570	07/24/2013	Monsalve, Juanita Maria	05/06/1993			8330 Market Street	Bradenton, FL 34202
RPT	49571	07/24/2013	Jackson, Alexander Bishop	11/03/1990			2256 W Nine Mile Rd	Pensacola, FL 32534
RPT	49572	07/24/2013	Prossick, Ashley Suzanne	02/16/1988			2419 Thomas Dr	Panama City Beach, FL 32408
RPT	49573	07/24/2013	Vuong, Nih	12/05/1988	Cvs Caremark		23208 Front Beach Road	Panama City Beach, FL 32413
RPT	49574	07/24/2013	Watson, Samantha Christine	03/04/1987	Cvs Caremark		3602 Spring Lake Rd	Jacksonville, FL 32210
RPT	49575	07/24/2013	Echevarria, Maria Gumbayan	09/17/1987	Cvs Caremark		13170 Atlantic Blvd	Jacksonville, FL 32225
RPT	49576	07/24/2013	Carvajal, Jacqueline	01/03/1971	Other	Professional Training Centers	11190 Sw 107Th St. #305	Miami, FL 33176
RPT	49577	07/24/2013	Deneus, Jenny Jackson	08/05/1992			6013 1St St. East	Bradenton, FL 34203
RPT	49578	07/24/2013	Hussein, Munir Sultanali	07/02/1967	Other	Guilford Technical Community College	1125 Pointe Cove Apt 103	Lake Mary, FL 32746
RPT	49579	07/24/2013	Ayala, Claudia Zuleide	10/26/1992			500 S 11Th Street	Lake Wales, FL 33853
RPT	49580	07/24/2013	Adamson, Jonathan Ian	05/24/1992	Cvs Caremark		103 103 Missouri Ave.	Lynn Haven, FL 32444
RPT	49581	07/24/2013	Dean, Jordan Mark	05/01/1992			5424 4Th St Ct E	Bradenton, FL 34203
RPT	49582	07/25/2013	Nicolas Bertrand, Marie Majorie	07/30/1973			41 Carver Street	Belle Glade, FL 33430
RPT	49583	07/25/2013	Martin, Tara Zoeann	01/31/1984			24 N Lime Ave	Sarasota, FL 34237
RPT	49584	07/25/2013	Manila, Alexandria Kathleen	10/17/1988			8745 S.R. 54	New Port Richey, FL 34654
RPT	49585	07/25/2013	Machado Santana, Marianela	03/30/1975			3360 N W 18Th Terr.	Miami, FL 33125

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RPT	49586	07/25/2013	Nunez Mercado, Cesar Augusto	01/25/1993			3481 Sw 152Nd Place	Miami, FL 33185
RPT	49587	07/25/2013	Nam, Allen Franklin	08/27/1993			14851 State Road 52	Hudson, FL 34669
RPT	49588	07/25/2013	Herchenroder, Nathan James	06/27/1993	Target Corporation		1201 Wp Ball Blvd	Sanford, FL 32771
RPT	49589	07/25/2013	Rivera-Young, Shannon Renee	05/22/1977		Virginia College - Jacksonville	8528 Star Leaf Ct	Jacksonville, FL 32210
RPT	49590	07/25/2013	Yoder, Amanda Lee	08/11/1977		Virginia College - Jacksonville	5 Ivey Lane	Flagler Beach, FL 32136
RPT	49591	07/25/2013	Rogers, Vasheta Necola			Virginia College - Pensacola	716 North 10Th Ave	Pensacola, FL 32501
RPT	49592	07/25/2013	Flint, Angela Nicole	12/21/1983			4196 Skates Circle	Fort Myers, FL 33905
RPT	49593	07/25/2013	Gomez, Carlos Andres	05/18/1995			2738 Corybrooke Lane	Kissimmee, FL 34744
RPT	49594	07/25/2013	Graham, Pamela Ann	04/10/1956			1802 Mourning Dove Lane	Jacksonville Beach, FL 32250
RPT	49595	07/25/2013	Gordon, Margaret June	11/21/1990			265 Sunset Drive	Brooksville, FL 34601
RPT	49596	07/25/2013	Alvarez, Sarita Katheryn	10/14/1988			7985 Airport Pulling Road	Naples, FL 34109
RPT	49597	07/25/2013	Finney, Carol A	01/25/1944			8808 Beach Blvd	Jacksonville, FL 32216
RPT	49598	07/25/2013	Perez, Evelin	09/14/1971		Hialeah Adult Education Center	561 E 26 St	Hialeah, FL 33013
RPT	49599	07/25/2013	Hicka, Annabel Alexis	03/16/1992	Other	University Of Florida - College Of Pharmacy	3618 East Grant Street	Orlando, FL 32812
RPT	49600	07/25/2013	Evelyn, Na'Dieya Shiniece	12/22/1992	Other	Everest University	1832 Hawkins Ave	Sanford, FL 32771
RPT	49601	07/25/2013	Collazo, Silvia	08/30/1972	Other	Heritage Institute	3677 Central Ave. Suite A	Ft. Myers, FL 33901
RPT	49602	07/25/2013	Batista, Rolando	07/25/1950	Other	Fortis College Miami	8025 Nw 7 St Apt #102	Miami, FL 33126
RPT	49603	07/25/2013	Gray, Naketa Ta Shaw	04/03/1981			2545 North Road	Cottondale, FL 32431
RPT	49604	07/25/2013	Rodriguez Capeles, Kristina	11/26/1991	Cvs Caremark		1569 Roble Ln	Deltona, FL 32738
RPT	49605	07/25/2013	Del Risco, Kevin	06/02/1994			7605 W 33Rd Court	Hialeah, FL 33018
RPT	49606	07/25/2013	Dawd, Giovanni	12/22/1992	Cvs Caremark		2875 M 2875 Majestic Oaks Lane 2875 Majestic Oak Lane	Green Cove Springs, FL 32043
RPT	49607	07/25/2013	Delise, Jhouleine	06/04/1992	Other	Mci Institute Of Technology	3940 Nw 30Th Terr Apt4	Lauder-Lakes, FL 33309

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RPT	49608	07/25/2013	Gallagher, Keenan James	11/17/1981	Wal-Mart		17861 South Us Highway 441	Summerfield, FL 34491
RPT	49609	07/26/2013	Tubella, Norisleny	03/01/1990			6709 Precourt Dr	Orlando, FL 32809
RPT	49610	07/26/2013	Gutzmore-Stewart, Jessica Patricia	10/24/1987	Other	Southeastern College	7030 Sw 27Th St	Miramar, FL 33023
RPT	49611	07/26/2013	Aktel, Selim Yetkin	10/13/1969	Cvs Caremark		2175 Main Street	Dunedin, FL 34698
RPT	49612	07/26/2013	Crutchley, John Eric	06/26/1991	Cvs Caremark		2621 Bermuda Lake Drive Apt 202	Brandon, FL 33510
RPT	49613	07/26/2013	Gelinas, Donna	08/17/1979	Cvs Caremark		25937 Bloomsbury Court	Land O Lakes, FL 34639
RPT	49614	07/26/2013	Donatiu Gomez, Arelis	09/26/1988	Other	National University College	3459 Patterson Heights Dr	Haines City, FL 33844
RPT	49615	07/26/2013	Hernandez, Kyle	10/20/1988	Cvs Caremark		4327 Fawn Meadows Cir.	Clermont, FL 34711
RPT	49616	07/26/2013	Scurry, Christopher Jerome	10/03/1988	Other	Heritage Institute	3950 Lora St. Apt. 208	Fort Myers, FL 33916
RPT	49617	07/26/2013	Farmer, Emmanuel Saah	10/13/1990	Cvs Caremark		7431 Atlantic Blvd	Jacksonville, FL 32211
RPT	49618	07/26/2013	Bivens, Cassandra Marie	12/14/1992	Cvs Caremark		4824 Foxrun	Lakeland, FL 33813
RPT	49619	07/26/2013	Hill, Mark David	09/22/1984	Wal-Mart		1590 Dunlawton Ave	Port Orange, FL 32127
RPT	49620	07/26/2013	Richo, Alicia Renee	02/19/1981	Wal-Mart		131 Donna St	Cordova, SC 29039
RPT	49621	07/29/2013	Lugo, Alexia Yasmin	07/04/1994	Cvs Caremark		10717 Ayrshire Drive	Tampa, FL 33626
RPT	49622	07/29/2013	Montes, Gabriel	08/28/1986	Other	Barry University	1109 E Hallandale Beach Blvd	Hallandale Beach, FL 33009
RPT	49623	07/29/2013	Pinero, Yemlis	03/09/1974	Other	Fortis College	3020 Sw 96 Ave	Miami, FL 33165
RPT	49624	07/29/2013	Miller, Jennifer Nicole	09/26/1985	Walgreens		5730 Eden Falls Place	Apollo Beach, FL 33572
RPT	49625	07/29/2013	Miller, Paris Shanquelle	12/26/1990	Other	Everest Institute	1044 Nw 52 Street	Miami, FL 33127
RPT	49626	07/29/2013	Mohamed, Farah Reiana	12/28/1990	Other	Everest Institute	14363 Sw 163 Terr	Miami, FL 33177
RPT	49627	07/29/2013	Gust, Linda Diana Ms	05/19/1967	Walgreens		4174 Highland Loop	New Port Richey, FL 34652
RPT	49628	07/29/2013	Pomales-Massey, Joanny Liz	12/23/1984	Other	Everest University Brandon Campus	1406 Astor Commons Place Apt 301	Brandon, FL 33511
RPT	49629	07/29/2013	Reed, Jaime Lynne	11/01/1978	Cvs Caremark		1330 Jefferson Ave Apt B	Orange Park, FL 32065
RPT	49630	07/29/2013	Rivera, Darelys	11/28/1973	Other	Everest Institute	7445 Indian Creek Drive Apt. 201	Miami Beach, FL 33141
RPT	49631	07/29/2013	Pierre, Alonzo	07/27/1992	Publix Super Market, Inc.		16489 Sw 28 Ct	Miramar, FL 33027

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RPT	49632	07/29/2013	Ramirez Diaz, Yanela	12/21/1979		Florida Education Institute	606 Sw 96Th Court	Miami, FL 33174
RPT	49633	07/29/2013	Janz, Meghan Lynn	05/07/1992	Walgreens		2806 Larkin St C	Pensacola, FL 32514
RPT	49634	07/29/2013	Paschke, Katherine Ann	05/04/1992			4173 Us 41 South	Venice, FL 34293
RPT	49635	07/29/2013	Tran, Anthony Duong	11/08/1993	Other	University Of Florida - College Of Pharmacy	1008 1008 Sw 115Th Street	Gainesville, FL 32607
RPT	49636	07/29/2013	Mccray, Keith Neal	06/04/1975	Other	New Era	661 Sw158Th Terr	Pembroke Pines, FL 33027
RPT	49637	07/29/2013	Kussrath, Louella Lorraine	11/09/1963	Publix Super Market, Inc.		21094 7Th Avenue	Cudjoe Key, FL 33042
RPT	49638	07/29/2013	Menendez, Maria Magdalena	09/01/1965	Other	Everest University	2245 Sw 22Nd Ave #S-104	Delray Beach, FL 33445
RPT	49639	07/29/2013	Ross, Debbie Ann	07/28/1987	Publix Super Market, Inc.		540 S Hunt Club Blvd	Apopka, FL 32703
RPT	49640	07/29/2013	Leon, Sergio Esteban	11/06/1992	Cvs Caremark		5044 Forest Hill Blvd	West Palm Beach, FL 33415
RPT	49641	07/29/2013	Nguyen, Vivian Havi	01/29/1991	Target Corporation		386 Haversham Road	Deltona, FL 32725
RPT	49642	07/29/2013	Lebrun, Virginia Ruth	04/26/1990	Target Corporation		1201 W P Ball Blvd	Sanford, FL 32771
RPT	49643	07/29/2013	Mitchell, Patrick Ross	09/28/1986	Cvs Caremark		3644 Coolidge Ct	Tallahassee, FL 32311
RPT	49644	07/29/2013	Perez, Sigfredo	03/19/1960	Other	Ultimate Medical Academy	1702 West Avon Ct Tampa	Tampa, FL 33603
RPT	49645	07/29/2013	Perez, Marilyn	09/02/1977	Other	University Of Florida College Of Pharmacy	10315 Woodward Winds Dr	Orlando, FL 32827
RPT	49646	07/29/2013	Pergrossi, Christopher Jon	06/15/1987	Other	University Of Florida - College Of Pharmacy	3515 3515 Sw 39Th Blvd Apt 25B	Gainesville, FL 32608
RPT	49647	07/29/2013	Rey, Karen	10/14/1989		Florida Education Institute	13951 Sw 39Th St	Miami, FL 33175
RPT	49648	07/29/2013	Pereira, Jannalee	10/14/1990	Ominicare, Inc.		1952 Peoria St	Deltona, FL 32728
RPT	49649	07/29/2013	Sucharski, Nicole Lynn	10/29/1991	Other	Pointe Med Pharmacy	1316 Oaklanding Ln	Fleming Island, FL 32003
RPT	49650	07/29/2013	Mortell, Elena	03/03/1975	Other	University Of Florida - College Of Pharmacy	8042 Chaucer Drive	Weeki Wachee, FL 34607
RPT	49651	07/29/2013	Oquendo, Juan Jr	06/30/1994	Walgreens		4113 Constantine Loop	Wesley Chapel, FL 33543
RPT	49652	07/29/2013	Snyder, Michael Joseph	11/12/1986		Miami Dade College	9760 Sw 148 Ave	Miami, FL 33196
RPT	49653	07/29/2013	Revels, Patricia Ann	03/17/1981		Piersonc Community Pharmacy	112 E. First Ave	Pierson, FL 32180
RPT	49654	07/29/2013	Yantek, Kate Ashley	04/16/1988	Target Corporation		2412 50Th Street Ct E	Palmetto, FL 34221
RPT	49655	07/29/2013	Villanueva, Julio Jr	07/06/1956	Other	Heritage Institute	18387 Fern Road	Fort Myers, FL 33967

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RPT	49656	07/29/2013	Washington, Javia Renee	09/18/1989		Lively Technical Center	3106 Layla St	Tallahassee, FL 32303
RPT	49657	07/29/2013	Uddin, Jasim	09/01/1980	Walgreens		8337 South Park Cir.	Orlando, FL 32819
RPT	49658	07/30/2013	Marrero, Nayla	11/18/1985			2700 W Flagler St	Miami, FL 33135
RPT	49659	07/30/2013	Patterson, Benjamin Floyd	09/19/1988			6716 Conetta Dr	Sarasota, FL 34243
RPT	49660	07/30/2013	Udvardi, Mary Catherine	04/09/1947	Cvs Caremark		17925 Se 100Th Terrace	Summerfield, FL 34491
RPT	49661	07/30/2013	Sailes, Ileana Shakira	10/17/1985		Manatee Technical Institute	2402 9Th Ave E	Bradenton, FL 34208
RPT	49662	07/30/2013	Cruz, Albano	05/20/1990			3133 Commerce Pkwy	Miramar, FL 33025
RPT	49663	07/30/2013	Genhold, Bobbie Renae	08/23/1986	Cvs Caremark		3611 Atlantis Drive	Holiday, FL 34691
RPT	49664	07/30/2013	Roberts, Rasheda C	04/12/1991	Cvs Caremark		686 Glades Road	Boca Raton, FL 33431
RPT	49665	07/30/2013	Frederick, Anitra Yvette	06/06/1981	Cvs Caremark		2428 Willow Ave	Sanford, FL 32771
RPT	49666	07/30/2013	Redding, Theresa Ann	03/10/1965		Univ Of Florida	7200 Sw 8 Ave #61	Gainesville, FL 32607
RPT	49667	07/30/2013	Hale, Penelope Marie	11/03/1974	Other	Career College Northern Nevada	302 S Spring Garden Apt# C2	Deland, FL 32720
RPT	49668	07/30/2013	Rocha, Vanessa	12/30/1992	Other	Everest Institute	2238 Monroe Street Apt. 307	Hollywood, FL 33021
RPT	49669	07/30/2013	Chachere, Erica Elizabeth	10/09/1988	Other	Heritage Institute	3267 Elkcam Blvd	Port Charlotte, FL 33952
RPT	49670	07/30/2013	Crooks, Roni Leigh	09/21/1992	Cvs Caremark		11110 Atlantic Blvd 1004	Jacksonville, FL 32225
RPT	49671	07/30/2013	Tookes, Andrea Nicole	11/23/1985		Virginia College - Jacksonville	303 Arabian Ct #1	Jacksonville, FL 32216
RPT	49672	07/30/2013	Shelton, Ami Christine	03/05/1988	Walgreens		3906 Barrel Palm Way	Plant City, FL 33566
RPT	49673	07/30/2013	Reyno, Kelly Christine	08/31/1986	Other	Everest/Brandon/764	4701 Christa Ct Apt 341	Tampa, FL 33614
RPT	49674	07/30/2013	Shikha, Shahela Akter	01/01/1986	Other	Heritage Institute	170 Brooks Road	North Fort Myers, FL 33917
RPT	49675	07/30/2013	Fernandez-Gonzalez, Kimberly	10/06/1991	Other	Blinn College	2302 De Lee St	Bryan, TX 77802
RPT	49676	07/30/2013	Simmons, Jacqueline Nicole	09/21/1989	Publix Super Market, Inc.		14702 71St Place North	Loxahatchee, FL 33470
RPT	49677	07/30/2013	Daugherty, Christopher Wayne	03/01/1984			520 S. Federal Hwy	Boca Raton, FL 33432

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RPT	49678	07/30/2013	Hosein, Nadeera Karlene	03/14/1990			686 Glades Road	Boca Raton, FL 33431
RPT	49679	07/31/2013	Land, Pamela Anne	08/14/1949			4840 S. Tamiami Trail	Sarasota, FL 34231
RPT	49680	07/31/2013	Davis, Brenda Jeanette	07/01/1969			7477 Farmers Rd	Pensacola, FL 32526
RPT	49681	07/31/2013	Delaney, Denise	03/27/1956			11251 80Th Ave Apt 201	Seminole, FL 33772
RPT	49682	07/31/2013	Oneal, Breanna Shanae	01/13/1993			3434 6Th Ave North	Saint Petersburg, FL 33713
RPT	49683	07/31/2013	Lemoniades, Ryan Christopher	02/20/1989			22829 State Road 54	Land O' Lakes, FL 34639
RPT	49684	07/31/2013	Fields, Leo Walter	12/09/1989			11912 Harbour Cove Dr S	Jacksonville, FL 32225
RPT	49685	07/31/2013	Martinez, Yohandris	08/23/1994			6201 N Grady Ave	Tampa, FL 33616
RPT	49686	07/31/2013	Bush, Carmen Cribbs	07/27/1975			5200 Sw 34Th Str	Gainesville, FL 32608
RPT	49687	07/31/2013	Paul, Dawn Kelli	05/13/1972			1478 West Granada Blvd	Ormond Beach, FL 32174
RPT	49688	07/31/2013	Raven, Jathiya Ihsan	11/01/1982		Kennesaw State Univ.	299 Sierra Rd	Havana, FL 32333
RPT	49689	07/31/2013	Lopez, Victor	11/18/1992			52 East Palm Drive	Florida City, FL 33034
RPT	49690	07/31/2013	Cartes, Johany Michelle	05/19/1982			8250 Mills Dr	Miami, FL 33183
RPT	49691	07/31/2013	Taylor, Ashley Brooke	05/03/1990		Sams Club	300 N Cattleman Rd	Sarasota, FL 34232
RPT	49692	07/31/2013	Rathburn, Mary Lucille	09/14/1956	Walgreens		3700 34Th Street North	Saint Petersburg, FL 33713
RPT	49693	07/31/2013	Villarreal, Ana Maria	11/05/1983	Walgreens		2209 Delightful Dr	Ruskin, FL 33570
RPT	49694	07/31/2013	Valdes, Ailen Melissa	03/16/1993		Simfarose Pharmacy	10016 Pines Blvd	Pembroke Pines, FL 33024
RPT	49695	07/31/2013	Talutis, Marilyn Beth	03/30/1957		Manatee Technical Institute	141 North Street	Englewood, FL 34223
RPT	49696	07/31/2013	Vega Reyes, Marbelys	01/07/1977		Florida Education Institute	198 N W 46Th Ave #37	Miami, FL 33126
RPT	49697	07/31/2013	Rollins, Cornicole Rochelle	08/25/1979	Publix Super Market, Inc.		4234 3Rd Ave South	Saint Petersburg, FL 33711
RPT	49698	07/31/2013	Roebuck, Danielle Marie	02/07/1979	Other	University Of Florida-College Of Pharmacy	11164 Wyndham Hollow Lane	Jacksonville, FL 32246
RPT	49699	07/31/2013	Restrepo Ossa, Alvaro	12/30/1953	Walgreens		8337 South Park Cir	Orlando, FL 32819
RPT	49700	07/31/2013	Lopez, Julie Yvette	05/19/1991	Cvs Caremark		1110 Ne Childress Ave	Arcadia, FL 34266
RPT	49701	07/31/2013	Martinez, Olga M	04/17/1984	Other	Ultimate Medical Academy	6516 Saline Street	Tampa, FL 33634

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RPT	49702	07/31/2013	Burt, Nathaniel Clarke	05/29/1984			3986 Boulevard Center Drive Suite #1	Jacksonville, FL 32207
RPT	49703	07/31/2013	Rios, Michael	01/11/1988	Other	Everest University	1767 1767 Pickwick Pl	Orange Park, FL 32003
RPT	49704	07/31/2013	Marquez, Jennifer Cynthia	11/07/1985	Other	Medical Institute Of Palm Beach	4255 North University Road Apt. 101	Sunrise, FL 33351
RPT	49705	07/31/2013	Peace, Brandon Jason	11/25/1991	Cvs Caremark		19Th 425 East 19Th Street Apt 101	Panama City, FL 32405
RPT	49706	07/31/2013	Jackson, Leroy Jr	10/16/1977	Other	Keiser Career College	301 49Th Ave N	St. Petersburg, FL 33703
RPT	49707	07/31/2013	Armstead, Demetrius Shayaer	07/04/1982	Other	Tallahassee Community College	4768 Woodville Hwy Apt 1718	Tallahassee, FL 32305
RPT	49708	07/31/2013	Blaszka, Jaimi	01/11/1980	Cvs Caremark		41 Francis Lane	Palm Coast, FL 32137
RPT	49709	07/31/2013	Allen, Robert William	01/24/1959			6540 Ne 21St Terrace	Fort Lauderdale, FL 33308
RPT	49710	07/31/2013	Gomez, Sergio	02/21/1991			306 Lincoln Rd	South Beach, FL 33139
RPT	49711	08/01/2013	Rosario, Lindsay Marie	01/25/1991	Cvs Caremark		6429 Reef Circle	Tampa, FL 33625
RPT	49712	08/01/2013	Szalanski, Rachael Lynn	11/21/1991	Wal-Mart		3550 South Babcock Street	Melbourne, FL 32901
RPT	49713	08/01/2013	Thompson, Iesha Nicole	11/09/1991	Other	Sanford-Brown Institute Tampa	9501 Williams Rd	Seffner, FL 33584
RPT	49714	08/01/2013	Sheely, Kiwanza Denise	07/13/1988	Other	Fortis Institute	60Th 2915 Nw 60Th Ave Apt. 506	Sunrise, FL 33313
RPT	49715	08/01/2013	Reichard, Susan Marion	08/02/1966	Other	University Of Florida Collge Of Pharmacy	75 Sw 75Th Street Apt E6	Gainesville, FL 32607
RPT	49716	08/01/2013	Reyes, Amaury Ii	01/25/1980	Other	Everest University Tampa	8033 8033 Peterson Rd.	Odessa, FL 33556
RPT	49717	08/01/2013	Sheremet, Mark Leo	11/25/1990	Other	Health Management Associates	3600 Cadbury	Venice, FL 34293
RPT	49718	08/01/2013	Galvez Muente, Jessica M	01/22/1977	Other	Everest Institute	1320 Nw 120Th Street	Miami, FL 33167
RPT	49719	08/01/2013	Patel, Pooja Chandrakant	12/13/1985	Walgreens		4747 Sw College Road	Ocala, FL 34474
RPT	49720	08/02/2013	Spradley, Carla Janretta	08/22/1990		Florida Gulf Coast Univ	347 Sw Blvd	Lake City, FL 32025
RPT	49721	08/02/2013	Salazar, Daniel Elijah	06/17/1991	Wal-Mart		725 N. Tyndall Pwky	Callaway, FL 32404
RPT	49722	08/02/2013	Woodyard-Wilson, Julie Ann	01/02/1990		Anthem College	2613 Georgia Ave	Sanford, FL 32773
RPT	49723	08/02/2013	Martinez, Deyanira Yesmell Deya	02/12/1986	Walgreens		4532 19Th Street Cir W Apt B	Bradenton, FL 34207

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RPT	49724	08/02/2013	Umanzor, Alexis Oneyda	08/07/1961		Florida Education Institute	5344 Nw 30Th Ct	Miami, FL 33142
RPT	49725	08/02/2013	Andrews, Ebony	08/20/1990	Other	Sanford Brown Institute Tampa	609 S. Coronet St.	Plant City, FL 33567
RPT	49726	08/02/2013	Rojas, Jorge A	08/21/1954	Other	University Of Florida	2420 Nw. 36Th Terrace	Gainesville, FL 32605
RPT	49727	08/02/2013	Armenteros, Elena	11/07/1965	Walgreens		4768 Sw 2Nd Ter	Coral Gables, FL 33134
RPT	49728	08/02/2013	Fischer, Tamara Renae	12/20/1990			2899 Forest Ln	Dallas, TX 75234
RPT	49729	08/02/2013	Byron, Scherrell	10/20/1987	Other	Everest University	1719 Singing Palm Dr	Orlando, FL 32712
RPT	49730	08/02/2013	Cannonier, Charles Fernando Jr	06/07/1986	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	49731	08/05/2013	Torres, Rodolfo Adrian	11/30/1977	Walgreens		4053 Crockers Lake Blvd. Apt.2418	Sarasota, FL 34238
RPT	49732	08/05/2013	Washington, Betty Jean	06/07/1954	Walgreens		8325 South Park Circle Suite 200	Orlando, FL 32819
RPT	49733	08/06/2013	Price, Derrick Christopher	05/08/1990			16130 Jog Road	Delray Beach, FL 33484
RPT	49734	08/06/2013	Petersen, Lakia Cierria	04/21/1987			6938 Nw Baroda St	Port Saint Lucie, FL 34983
RPT	49735	08/06/2013	Mercer, Sean Peter	10/24/1989			1001 S. Federal Highway	Boca Raton, FL 33432
RPT	49736	08/06/2013	Kissoon, Devika S	07/15/1974			9600 Park South Ct.	Orlando, FL 32837
RPT	49737	08/06/2013	Presler, Samantha Kerrie	12/14/1986			4297 Oldfield Crossing	Jacksonville, FL 32223
RPT	49738	08/06/2013	Knight, Shandell Nureka	07/05/1978			500 N. Orlando Ave	Winter Park, FL 32789
RPT	49739	08/06/2013	Lusby, Amanda Illene	10/05/1984			12001 Dr Mlk St N Apt 3005	Saint Petersburg, FL 33716
RPT	49740	08/06/2013	Protin, Ashley Blase	02/09/1988			563 N. Franklin Tpk	Ramsey, NJ 07446
RPT	49741	08/06/2013	Whitmarsh, Anne Marie	09/07/1991	Walgreens		1891 Neptune Drive	Englewood, FL 34223
RPT	49742	08/06/2013	Wilson, Eleanor Ann	11/27/1967	Cvs Caremark		46 Watson Road	St. Augusine, FL 32086
RPT	49743	08/06/2013	Filer, Ariel Ciarra	09/03/1992			3350 W Hillsborough Ave #1335	Tampa, FL 33614
RPT	49744	08/06/2013	Forrest, Brittney Nicole	01/10/1995			2839 County Rd 210 West	Jacksonville, FL 32259
RPT	49745	08/06/2013	Pantoja, Priscilla	11/24/1981			17200 Commerce Park Blvd	Tampa, FL 33647

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RPT	49746	08/06/2013	Heyward, Stephanie Deniece	09/09/1981			1400 Trailblazer Drive	Tallahassee, FL 32310
RPT	49747	08/06/2013	Pourbaix, Jacquelyn Nicole	04/16/1981			255 Citrus Tower Blvd #0015	Clermont, FL 34711
RPT	49748	08/06/2013	Reyes, Karem	12/30/1989	Other	Professional Training Centers	15231 Sw 80 St. #305	Miami, FL 33193
RPT	49749	08/06/2013	Pelayo, Lisandra	01/23/1989			8931 Sw 4Th Terrace	Miami, FL 33174
RPT	49750	08/06/2013	Curry, Prince Ii	09/04/1989			2840 David Walker Dr	Eustis, FL 32726
RPT	49751	08/06/2013	Lopez, Keyling E	02/08/1992			14012 S W 8Th St	Miami, FL 33184
RPT	49752	08/06/2013	Algarin, Margie	11/21/1963			500 Eagles Landing Drive	Lakeland, FL 33810
RPT	49753	08/06/2013	Thurmon Bryan Hinds, Claire Michelle	02/01/1987	Walgreens		2240 7Th Ave N	Saint Petersburg, FL 33713
RPT	49754	08/06/2013	Cangiamila, John	08/06/1952			1940 Sw 63 Ave	Gainesville, FL 32608
RPT	49755	08/06/2013	Conzelmann, Brooke Annel	05/12/1988	Other	Cypress Pharmacy Inc.	9371 Cypress Lake Drive Suite 1	Fort Myers, FL 33919
RPT	49756	08/06/2013	Thompson, Yvonne Glendora	03/30/1964		Orange County Public Schools	2726 Castle Oak Ave	Orlando, FL 32808
RPT	49757	08/06/2013	Davis, Christina M	09/02/1983	Other	Ultimate Medical Academy	26638 Glenwood Dr	Wesley Chapel, FL 33544
RPT	49758	08/06/2013	Ellis, Jessica Annette	04/04/1986	Other	Ptcb	686 Glades Road	Boca Raton, FL 33431
RPT	49759	08/06/2013	Ricardo, Ryan Edward	09/04/1976	Other	Everest Institute	2205 Se 24 Pl	Homestead, FL 33035
RPT	49760	08/06/2013	Vilorio, Rojelio Nemecio	02/24/1989	Walgreens		10110 Lyons Rd	Boynton Beach, FL 33473
RPT	49761	08/06/2013	Cameron, Arva Pedra	09/30/1984	Other	Sandford Brown Institute	10401 Deerwood Park Blvd #1	Jacksonville, FL 32256
RPT	49762	08/06/2013	Harvey, Leah Michelle	09/20/1994	Cvs Caremark		37410 Grays Airport Rd	Lady Lake, FL 32159
RPT	49763	08/06/2013	Thomas, Rebecca Victoria	07/31/1994		Henry W. Brewster Technical Center	13287 Arbor Pointe Circle Apt 202	Tampa, FL 33617
RPT	49764	08/06/2013	Amey, Rachel E	11/18/1985	Other	Ultimate Medical Academy	15539 60Th Street	Clearwater, FL 33760
RPT	49765	08/06/2013	Cobb, Asya A'Shaye	01/17/1994	Other	Everest University Jacksonville	866 Dunn Ave	Jacksonville, FL 32218
RPT	49766	08/06/2013	Dunbar, Kayla Marie	03/11/1990			316 N Turkey Pine Loop	Lecanto, FL 34461
RPT	49767	08/06/2013	Williams, Toni	03/01/1976	Cvs Caremark		859791 St Terrace N.	Seminole, FL 33777
RPT	49768	08/06/2013	Braunstein, Sharon C	06/30/1974			7068 Burgess Dr	Lake Worth, FL 33467
RPT	49769	08/06/2013	Rodriguez, Jayne Marie	10/10/1988	Cvs Caremark		8209 Collier Place	Temple Terrace, FL 33637

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RPT	49770	08/06/2013	Holloway, Anthony Marquel	11/09/1991	Other	Everest University Brandon Campus	5302 Ruth Morris Rd	Wimauma, FL 33598
RPT	49771	08/06/2013	Petite Charles, Monique	09/11/1981	Other	Everest University	11484 Johnson Creek Circle	Jacksonville, FL 32218
RPT	49772	08/06/2013	Thomas, Patricia Denise	10/20/1987		Virginia College -Jacksonville	3500 University Blvd North #2801	Jacksonville, FL 32277
RPT	49773	08/06/2013	Trujillo, Leshann Chiloi	11/26/1987	Target Corporation		1200 S Federal Highway	Deerfield Beach, FL 33441
RPT	49774	08/06/2013	Eddy, Samantha Lyn	08/07/1992			319 S. Woodland Blvd.	Deland, FL 32720
RPT	49775	08/06/2013	Godwin, Thomas Mitchell	04/09/1992	Shands At University Of Florida		6406 Nw 37Th Drive	Gainesville, FL 32653
RPT	49776	08/06/2013	Brown, Carolyn	01/06/1956	Walgreens		1215 Dunn Ave #2	Jacksonville, FL 32218
RPT	49777	08/06/2013	Cody, Stacy Camille	08/18/1985	Other	Ultimate Medical Academy	1749 Wade Rd.	Tallahassee, FL 32301
RPT	49778	08/06/2013	Clouse, Lynn Renee	01/16/1985	Other	Ultimate Medical Academy	150 Bonita Dr	Palatka, FL 32177
RPT	49779	08/06/2013	Green, Gina Songe	09/06/1979	Other	Pass Assured	7404 W. Nine Mile Rd	Pensacola, FL 32526
RPT	49780	08/06/2013	Hawkins, Matthew Kyle	04/20/1983	Cvs Caremark		2001 West 86Th Street Clinical Pharmacy	Indianapolis, IN 46260
RPT	49781	08/06/2013	Crespo, Nayla	09/08/1988	Other	Professional Training Centers	4412 West Burke St.	Tampa, FL 33614
RPT	49782	08/06/2013	Head, Deann Lenae	11/18/1991	Other	Everest University	2825 Nw 29Th Dr	Boca Raton, FL 33434
RPT	49783	08/06/2013	Ciliberti, Carmen Thomas	08/04/1992			3972 Town Center Blvd	Orlando, FL 32837
RPT	49784	08/07/2013	Weinreich, Erin	06/24/1993		Florida Health Care Plans	799 Sterling Chase Dr	Port Orange, FL 32128
RPT	49785	08/07/2013	Williams, Lucas Ryan	09/09/1991		Henry W Brewster Technica Center	13000 Bruce B. Downs	Tampa, FL 33612
RPT	49786	08/07/2013	Deitz, Nickolas	12/29/1993	Cvs Caremark		99434 Overseas Hwy	Key Largo, FL 33037
RPT	49787	08/07/2013	Beaty, Amanda Jane	07/10/1986			1015 Camelia St	Atlantic Beach, FL 32233
RPT	49788	08/07/2013	Curry, Kelly Rae	12/26/1967			125 Robinhood Dr	Deland, FL 32724
RPT	49789	08/07/2013	Von Hoven, Tami Marie	10/13/1971	Cvs Caremark		34502 State Road 54	Zephyrhills, FL 33541
RPT	49790	08/07/2013	Alexander, Melissa Louise	07/10/1970			2180 W. 9 Mile Rd	Pensacola, FL 32534
RPT	49791	08/07/2013	Feola, Brittany Marie	02/22/1992			36301 Eastlake Rd	Palm Harbor, FL 34685
RPT	49792	08/07/2013	Amelunke, Terry Lloyd	01/18/1990			9930 50Th St Cir E	Parrish, FL 34219
RPT	49793	08/08/2013	Jacob, Leona	04/21/1993			13800 Pines Blvd	Pembroke Pines, FL 33027

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	49794	08/08/2013	Patel, Shreshthaben Pulin	01/28/1990			9858 Us Hwy 301 S.	Riverview, FL 33578
RPT	49795	08/08/2013	Gutierrez, Dantes Alan	10/07/1988			6050 S. Dixie Hwy	South Miami, FL 33143
RPT	49796	08/08/2013	Gamble, Michelle	08/10/1981			9110 Greenbriar Lane	Port Richey, FL 34668
RPT	49797	08/08/2013	Royo, Claudio Ruben	09/21/1966	Walgreens		11690 Sw 72Nd Street	Miami, FL 33173
RPT	49798	08/08/2013	Bready, Jean	10/20/1966	Other	Southeastern College	6014 Us Highway 19 North Suite 250	New Port Richey, FL 34652
RPT	49799	08/08/2013	Williams, Alisha Latori	09/05/1985	Cvs Caremark		431 St. James Ave	Goose Creek, SC 29445
RPT	49800	08/08/2013	Taylor, Jordan Tyler	07/02/1994	Cvs Caremark		1880 Woodland Circle Apt 203	Vero Beach, FL 32967
RPT	49801	08/08/2013	Castillo, Sharyk	02/06/1985	Other	Everest Institute	12929 Sw 59 Terr	Miami, FL 33183
RPT	49802	08/08/2013	Sgro, Brooke Nicole	06/19/1991		Welldyne Rx	500 Eagles Landing Drive	Lakeland, FL 33810
RPT	49803	08/08/2013	Martinez, Alyssa	07/03/1985	Walgreens		6370 Bayshore Rd	North Fort Myers, FL 33917
RPT	49804	08/08/2013	Ayala-Ramos, Luis Ricardo	06/05/1994	Other	Everest University	13824 Osprey Links Rd Apt. 195	Orlando, FL 32837
RPT	49805	08/08/2013	Ponce, Maria Delosangeles	08/02/1987	Other	Brewster Technical Center	703 River Bay Drive	Tampa, FL 33619
RPT	49806	08/08/2013	Bryan, Meghan Elizabeth	11/15/1990	Wal-Mart		6910 W Waters Ave Apt 1502	Tampa, FL 33634
RPT	49807	08/08/2013	Olds, Brenda Jean	08/11/1964			274 Main Road	Lake Mary, FL 32746
RPT	49808	08/08/2013	Bush, Theodore Alexander	11/04/1992	Other	Mci Institute Of Technology	2329 Center Stone Lane	Riviera Beach, FL 33404
RPT	49809	08/08/2013	Combs, Brandi Lynn	11/22/1978	Other	Ultimate Medical Academy	223 Ne 15Th Ave	Pompano Beach, FL 33060
RPT	49810	08/08/2013	Lemes, Jessica Nicole	09/16/1994			2701 S. Woodland Blvd	Deland, FL 32720
RPT	49811	08/08/2013	Mederos-Alvarez, Aliuska	03/06/1980	Other	Professional Training Centers	150 Se 6Th Ave Apt 38	Homestead, FL 33030
RPT	49812	08/08/2013	Vetaw, Mayshyra	05/23/1993	Other	Pinellas County Job Corps	500 22Nd Street South	St Petersburg, FL 33712
RPT	49813	08/08/2013	Ezeanya, Obiora C	07/24/1989			1819 W Tennessee St	Tallahassee, FL 32304
RPT	49814	08/08/2013	Cadavid, Angela	04/22/1991	Cvs Caremark		2300 N Flamingo Road	Pembroke Pines, FL 33028
RPT	49815	08/08/2013	Kessel, Llelenys	09/12/1971	Other	Rttp100	1 Glen Royal Pwky Apt 1004	Miami, FL 33125
RPT	49816	08/08/2013	Williams, Kerry-Ann	06/11/1986	Wal-Mart		19501 Nw 27 Ave	Miami Gardens, FL 33056

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RPT	49817	08/08/2013	Medina, Samantha Iris Faith	09/29/1991	Other	Ultimate Medical Academy	1707 West Ferris	Tampa, FL 33603
RPT	49818	08/08/2013	Ferrer, Jennifer	10/24/1981	Other	Everest Institute	9722 Sw 166Th Ct	Miami, FL 33196
RPT	49819	08/08/2013	Nanney, Laurel Lea	09/11/1970	Other	Steps Corporation	9330 Sw 183 Terrace	Miami, FL 33157
RPT	49820	08/08/2013	Quijano, Johan	10/30/1991	Other	Everest University	11601 Nw 29Th #4E	Coral Spring, FL 33065
RPT	49821	08/08/2013	Grossman, Kyle Robert	12/27/1990	Cvs Caremark		405 N Ocean Blvd	Pompano Beach, FL 33062
RPT	49822	08/08/2013	Parrish, Brenda Mason	09/14/1951	Other	Everest University	1733 S. Clyde Morris Blve Apt 103	Daytona Beach, FL 32119
RPT	49823	08/08/2013	Jones, Kaitlyn Michelle	10/02/1989	Cvs Caremark		3841 Se 7Th Ave	Cape Coral, FL 33904
RPT	49824	08/08/2013	Michel, Lashonda Trenice	01/25/1989	Other	Everest University	3531 Nw 3Rd St	Lauderhill, FL 33311
RPT	49825	08/08/2013	Pacheco, Maydelin	02/16/1971	Other	Professional Training Centers	13315 Sw 253 Terr	Homestead, FL 33032
RPT	49826	08/08/2013	Calvert, Johana Marquez	03/14/1979	Other	University Of Florida-College Of Pharmacy	6700 Conroy-Windermere Rd Ste140	Orlando, FL 32835
RPT	49827	08/08/2013	Lemons, Barbara Lynn	12/02/1975	Other	Everest University	3915 Darlene Rd.	Middleburg. FL 32068
RPT	49828	08/08/2013	Coble, Nicole Maria	02/23/1986			3792 S. Suncoast Blvd	Homosassa, FL 34448
RPT	49829	08/08/2013	Justice, Krista Lee	10/19/1985	Other	Everest University	2930 Drew St Apt 1410	Clearwater, FL 33759
RPT	49830	08/08/2013	Calderon, Christina	02/08/1993			6545 S E Kanner Hwy	Stuart, FL 34997
RPT	49831	08/08/2013	Jacob, Sajit	09/20/1974	Other	University Of Florida - College Of Pharmacy	15212 Octavia Lane	Odessa, FL 33556
RPT	49832	08/08/2013	Hosinski, James Bryan	10/10/1989			6545 S Kanner Hwy	Stuart, FL 34997
RPT	49833	08/08/2013	Koko, Laura Afi	04/15/1974	Other	Everest University	4719 Chastain Drive	Melbourne, FL 32940
RPT	49834	08/08/2013	Parkhurst, Kristina Nicole	05/15/1993	Other	Everest University	2636 2636 Post Rd.	Melbourne, FL 32935
RPT	49835	08/08/2013	Paelmariano, Jennifer	11/10/1980	Cvs Caremark,Cvs Caremark		4501 4501 Madison Street	Palatka, FL 32177
RPT	49836	08/08/2013	Gainer, Carla Dennette	09/21/1970			4870 South Apopka Vineland Rd	Orlando, FL 32819
RPT	49837	08/08/2013	Santiago, Beatriz Ivette	05/18/1976		Concorde Career Institute	1725 Washington St	Hollywood, FL 33020
RPT	49838	08/08/2013	Vincenzi, Kristin Erin	08/31/1985	Cvs Caremark		615 E 3Rd Avenue	New Smyrna Beach, FL 32169

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RPT	49839	08/08/2013	Hill, Kylene Frances	09/07/1992			11000 N. Military Trail	Palm Beach Gardens, FL 33410
RPT	49840	08/08/2013	Green, Marlan Anthony	03/21/1980			7148 Colony Club Drive	Lake Worth, FL 33463
RPT	49841	08/08/2013	Bonin, Karine Gabrielle	03/13/1992			850 W Sample Road	Pompano Beach, FL 33064
RPT	49842	08/09/2013	Smith, Shari Radonna	03/21/1960			1098 Claude White Rd	Sanford, NC 27332
RPT	49843	08/09/2013	Jackson, Christopher Leigh	07/21/1987	Cvs Caremark		1127 South Sr19	Palatka, FL 32177
RPT	49844	08/09/2013	Obas-Kanes, Rose Carine	08/28/1976	Walgreens		7753 Biltmore Blvd	Miramar, FL 33023
RPT	49845	08/09/2013	Smith, Cory William	01/20/1988	Other	Everest University	342 Coral Dr	Melbourne, FL 32935
RPT	49846	08/09/2013	Mcqueen, Lolita	11/25/1974	Other	Southeastern College	4811 Sw 41St Street Apt 106	Pembroke Park, FL 33023
RPT	49847	08/09/2013	Moller, Diana Mildred	03/20/1977	Cvs Caremark		1806 Ridgewood Ave	Edgewater, FL 32132
RPT	49848	08/09/2013	Lee, Dennis P	03/14/1970	Other	Everest University, Tampa	6423 Moss Way	Tampa, FL 33625
RPT	49849	08/09/2013	Jimenez, Daimarelys	10/19/1973	Other	Professional Training Centers	15461 Sw 156Th Ave	Miami, FL 33187
RPT	49850	08/09/2013	Quigley, Renee Patricia	02/14/1983	Other	Everest University	4163 Oxford Ave.	Jacksonville, FL 32210
RPT	49851	08/09/2013	Jennings, Ayentl Tonye	05/21/1987	Walgreens		2550 2550 N. Hiawassee Rd	Orlando, FL 32818
RPT	49852	08/09/2013	Taylor, Shanika R	12/23/1994	Other	Everest University	306 Cornwallis Court	Kissimmee, FL 34758
RPT	49853	08/09/2013	Porubcan, Laurie Ann	06/19/1963	Walgreens		12130 Us Hwy 41 South Lot 161	Gibsonton, FL 33534
RPT	49854	08/09/2013	Perez Valdespino, Liliet	12/31/1987	Other	Everest Institute	13810 Sw 276 St	Homestead, FL 33032
RPT	49855	08/09/2013	Krollman, Audrey Jean	09/17/1994	Other	Pinellas County Job Corps	500 22Nd Street South	St Petersburg, FL 33707
RPT	49856	08/09/2013	Jimenez-Collazo, Maria Luisa	07/06/1970	Other	University Of Florida - College Of Pharmacy	14102 Colonial Spring Way	Orlando, FL 32826
RPT	49857	08/09/2013	Maggin, Mitchell Justin	11/01/1983	Walgreens		8156 Mystic Harbor Circle	Boynton Beach, FL 33436
RPT	49858	08/09/2013	Chapman, Jutathip Malaena	03/20/1982			825 Beal Pkwy Nw	Fort Walton Beach, FL 32547
RPT	49859	08/09/2013	Patterson, Cynthia Andrea	07/04/1990	Other	Everest Institute	726 Nw 3Rd St	Florida City, FL 33034
RPT	49860	08/09/2013	Loscielle, Jim	01/08/1991	Walgreens		13950 Jog Rd	Delray Beach, FL 33446

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RPT	49861	08/09/2013	Porter, Ryan Daniel	08/11/1993	Cvs Caremark		5331 Maravoss St.	Cocoa, FL 32927
RPT	49862	08/09/2013	Sands, Priscilla Kay	06/25/1994	Publix Super Market, Inc.		2015 Deborah Dr.	Spring Hill, FL 34609
RPT	49863	08/09/2013	Matta, Angelica Marie	12/30/1986	Other	Heritage Institute	21044 Delake Ave.	Port Charlotte, FL 33954
RPT	49864	08/09/2013	Conklin, Christine	10/02/1980	Other	Pharmacy Technician University	3430 Golden Eagle Dr	Land O Lakes, FL 34639
RPT	49865	08/09/2013	Ward, Nanette Marie	06/18/1980	Other	Brewster Technical	7418 Brooklyn Rd	Tampa, FL 33625
RPT	49866	08/09/2013	Shimu, Shawon Shimu	05/01/1992	Other	Heritage Institute	170 170 Brooks Road	North Fort Myers, FL 33917
RPT	49867	08/09/2013	Zubay, Michael Joseph Ii	06/05/1978	Walgreens		11811 143Rd St Unit B	Largo, FL 33774
RPT	49868	08/09/2013	Purvis, Dyanna Ryann	04/01/1983	Cvs Caremark		1208 W. Jefferson Street	Quincy, FL 32351
RPT	49869	08/09/2013	Soliz, Marie Mills	06/13/1977	Other	University Of Florida-College Of Pharmacy	1050 Eastbrook Blvd. 1050 Eastbrook Blvd.	Winter Park, FL 32792
RPT	49870	08/09/2013	Slim, Katie Isabel	06/04/1981	Walgreens		13247 Whitehaven Ln Unit 708	Fort Myers, FL 33966
RPT	49871	08/09/2013	Rigdon, Aleshia Mishael	02/21/1980	Publix Super Market, Inc.		11156 Limerick	Jacksonville, FL 32221
RPT	49872	08/09/2013	Sanchez, Jilene	06/06/1993	Other	Everest Institute	685 Se 37Th Pl	Homestead, FL 33033
RPT	49873	08/09/2013	Guevara, Jorge Alberto	05/07/1991	Other	Concorde Career Institute	8325 Bay Pointe Dr Apt 404N	Tampa, FL 33615
RPT	49874	08/09/2013	Ramos, Mary	08/02/1980	Other	Everest Institute	1461 Ne 169 Street Apt. 128	North Miami Beach, FL 33162
RPT	49875	08/09/2013	Stanaker, Tiffany Anne	01/31/1980	Walgreens		1534 Cape Coral Pkwy	
RPT	49876	08/12/2013	Quinones, Sandra	11/23/1982	Other	South Dade Skill Center	1330 Sw 8Th Ave	Florida City, FL 33034
RPT	49877	08/12/2013	Seguritan, Kimberly Belleza	01/08/1994	Hendry Regional Medical Center		417 W Arcade Ave.	Clewiston, FL 33440
RPT	49878	08/12/2013	Walters, Pauline Isola	04/22/1960	Other	Medical Institute Of Palm Beach;45Th Street Pharmacy	5843 South Bond Drive	West Palm Beach, FL 33415
RPT	49879	08/12/2013	Rybaczuk, Gideon	08/14/1992	Other	Technical Education Center Osceola	1028 L Lake Berkley Dr.	Kissimmee, FL 34746
RPT	49880	08/12/2013	Siwinski, Marilyn	04/15/1981	Other	Heritage Institute;Heritage Institute	5712 Five Acre Road	Plant City, FL 33565
RPT	49881	08/12/2013	Rosier, Nandi Jamila	03/19/1993		Tallahassee Comm College	5652 Braveheart Way	Tallahassee, FL 32317

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RPT	49882	08/12/2013	Sequeira, Jessica Diana	09/25/1982		Everest Institute	10312 Sw 3 St	Miami, FL 33174
RPT	49883	08/12/2013	Wolman, Noah Harris	07/06/1995		Kings Pharmacy	2814 N University Dr	Coral Springs, FL 33065
RPT	49884	08/12/2013	Surface, Crista Nicole	09/13/1984	Walgreens		4239 Memphis Ave	New Port Richey, FL 34652
RPT	49885	08/12/2013	Hassan, Emil Tahmid	08/10/1992			Box 772046	Coral Springs, FL 33077
RPT	49886	08/12/2013	Persaud, Jessica Mathadai	08/28/1993	Cvs Caremark		11711 Southwest 208 Street	Miami, FL 33177
RPT	49887	08/12/2013	Mcnatt, Stephanie Lauren	04/12/1990			16825 E Colonial Drive	Orlando, FL 32820
RPT	49888	08/12/2013	Malanowski, Denise A	05/02/1979			1251 S. Toledo Blade Blvd	North Port, FL 34288
RPT	49889	08/12/2013	Nieves, Myriam Enid	05/26/1995			5142 Vista Lago Drive	Orlando, FL 32811
RPT	49890	08/12/2013	Leonard, Kerry Anne	03/24/1993			12620 Beach Blvd #12	Jacksonville, FL 32246
RPT	49891	08/12/2013	Iglesias, Lisa Daniela	09/10/1994			1590 E Buena Vista Drive	Orlando, FL 32830
RPT	49892	08/12/2013	Martinez, Pura	08/28/1971	Walgreens		4311 Sw 131 Lane	Miramar, FL 33027
RPT	49893	08/12/2013	Jean Francois, Geneau	07/26/1986	Other	Everest University	210 Nw 14Th Ave	Boynton Beach, FL 33435
RPT	49894	08/12/2013	Lalanne, Stanley	03/26/1977	Other	Everest University	396 Wisteria Ct	Deltona, FL 32738
RPT	49895	08/12/2013	Martines, Kristina Marie	07/23/1987			4195 W. Lakemary Blvd	Lake Mary, FL 32746
RPT	49896	08/12/2013	Philogene, Keyonta Kim	08/06/1990	Other	Everest University	4028 45Th Lane	Vero Beach, FL 32967
RPT	49897	08/12/2013	Phan, Paula	04/01/1992			8015 Turkey Lake Rd Ste 300	Orlando, FL 32819
RPT	49898	08/13/2013	Tuite, Donna Marie	09/14/1957			175 S. Barfield	Marco Island, FL 34145
RPT	49899	08/13/2013	Spence, Dinelis Anne	07/08/1978	Walgreens		40079 Hwy 27	Davenport, FL 33859
RPT	49900	08/13/2013	Hodges, Ashley Esther	04/26/1989	Other	Brewster Technical Center	5602 W Knights Griffin Rd	Plant City, FL 33565
RPT	49901	08/13/2013	Dyson, Jessica Arkilah	09/18/1989	Walgreens		6200 Nw 7 Ave	Miami, FL 33150
RPT	49902	08/13/2013	Torres-Corredor, Christine Magdalyn	10/02/1991	Publix Super Market, Inc.		3972 Town Center Blvd	Orlando, FL 32837
RPT	49903	08/13/2013	Costales Santiago, Fabiola Mileska	03/14/1995			2850 Berkshire Circle	Kissimmee, FL 34743
RPT	49904	08/13/2013	Ferguson, Jasmine Alexandria	04/25/1992			700 Ne 6Th Ave	Delray Beach, FL 33483
RPT	49905	08/13/2013	Rendon, Yesenia	08/19/1994			2223 E. Marconi St	Tampa, FL 33605

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RPT	49906	08/13/2013	Canales, Elvin Bonerge	12/18/1991			101 N Main St.	Belle Glade, FL 33430
RPT	49907	08/13/2013	Babcock, Traci Anne	11/10/1987			5945 Us Highway 301 N	Ellenton, FL 34222
RPT	49908	08/13/2013	Bryant, David Augustus	09/07/1990			128 E. Brandon Blvd	Brandon, FL 33511
RPT	49909	08/13/2013	Weaver, Maria F	12/26/1955	Walgreens		1120 N. Tamiami Trail	Nokomis, FL 34275
RPT	49910	08/13/2013	Hassan, Abdullah	08/14/1993			8015 Turkey Lake Rd Ste 300	Orlando, FL 32819
RPT	49911	08/13/2013	Brunson, Quinelle Jacinda Essiah	04/10/1990			5319 E. 18Th Ave	Tampa, FL 33619
RPT	49912	08/13/2013	Elahi, Sumra	04/29/1993			8954 Lantana Road	Lake Worth, FL 33467
RPT	49913	08/13/2013	Fisher, Deborah Ann	05/23/1963			5642 Fish Hawk Crossing Blvd	Lithia, FL 33547
RPT	49914	08/13/2013	Stamper, Holly Marie	08/13/1988	Publix Super Market, Inc.		2040 Shepherd Rd	Mulberry, FL 33860
RPT	49915	08/13/2013	Barcelo, Ailed	07/07/1989			3103 Biscayne Blvd	Miami, FL 33137
RPT	49916	08/13/2013	De La Cruz, Mariko Jordan Denae	01/07/1994			4016 W Wyoming Ave	Tampa, FL 33616
RPT	49917	08/13/2013	Gracia, Paula	08/29/1981			2271 N W 26Th St #6	Miami, FL 33142
RPT	49918	08/13/2013	Bloom, Cynthia Kay	01/21/1972			682 Collier Lake Cir	Sebastian, FL 32958
RPT	49919	08/13/2013	Figueroa, Alexander Ernesto	09/24/1992			72 16Th Ave Sw	Largo, FL 33770
RPT	49920	08/13/2013	Cook, Lloyd Anderson	10/27/1993			2 East Magnolia Avenue	Eustis, FL 32726
RPT	49921	08/13/2013	Chutter, Nikki Shana	07/15/1990			1600 66Th St N	Saint Petersburg, FL 33710
RPT	49922	08/13/2013	Caro, Diana Carolina	04/22/1991			13960 Landstar Blvd	Orlando, FL 32824
RPT	49923	08/13/2013	Simpson, Penny Mcdonald	02/24/1964	Walgreens		100 Nw Park Street	Okeechobee, FL 34972
RPT	49924	08/13/2013	Edwards-Carlisle, Tericka Angelique	03/09/1994			6767 Us Hwy 98 N	Lakeland, FL 33809
RPT	49925	08/13/2013	Mejia, Nachtanapa	08/23/1985	Other	Everest University	2313 Ne 2Nd St #1	Pompano Beach, FL 33062
RPT	49926	08/13/2013	Pekich, Kimi Mae	05/23/1983	Publix Super Market, Inc.		4100 N Wickham Rd Ste 109	Melbourne, FL 32935
RPT	49927	08/13/2013	Price-Sloan, Nicole Renee	12/22/1988	Other	Everest University	1200 Integra Landings Dr Apt 302	Orange City, FL 32763
RPT	49928	08/13/2013	Patail, Bushra	07/05/1988	Cvs Caremark		9462 Edenshire Circle	Orlando, FL 32836
RPT	49929	08/13/2013	Mueller, Brittany Lynn	08/27/1991	Cvs Caremark		4639 W 1St St	Sanford, FL 32771

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RPT	49930	08/13/2013	Martin, Allysha Juliet	07/30/1988	Other	2419	11582 Riverstone Way	Jacksonville, FL 32218
RPT	49931	08/13/2013	Khatami, Mehrshid	06/20/1958	Other	2419-University Of Florida College Of Pharmacy	405 Waymont Ct Suite 101	Lake Mary, FL 32746
RPT	49932	08/13/2013	Mishler, Nicole Elizabeth	09/15/1989	Walgreens		9670 Alice Moore Way	Tallahassee, FL 32309
RPT	49933	08/13/2013	Caraballo, Sanel Oscar	01/14/1984			5351 Spectacular Bid Dr.	Wesley Chapel, FL 33544
RPT	49934	08/14/2013	Pagan, David	06/25/1980	Other	Everest Institute	8750 North Sherman Circle Apt. 106	Miramar, FL 33025
RPT	49935	08/14/2013	Noda, Llipsi Elvia	02/24/1966			Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
RPT	49936	08/14/2013	Nellis, Kayleigh Renae	10/27/1993	Kash N' Karry Food Stores, Inc		5802 5802 14Th St W	Bradenton, FL 34207
RPT	49937	08/14/2013	Ponting, Mallory Scott	08/07/1984			15295 Collier Blvd	Naples, FL 34119
RPT	49938	08/14/2013	Limas, Yadira	07/12/1986	Other	Professional Training Centers	4351 Nw 9Th St #25	Miami, FL 33126
RPT	49939	08/14/2013	Naranjo, Nathalia	07/27/1982	Wal-Mart		5350 Grand Cypress Cir Apt 201	Naples, FL 34109
RPT	49940	08/14/2013	Niblett, Susan	11/06/1988	Wal-Mart		15495 Panama City Beach Pkwy	Panama City Beach, FL 32413
RPT	49941	08/14/2013	Mcduffie, Sylvia	10/10/1960	Other	Ultimate Medical Academy	8653 Mallard Reserve Drive Unit 204	Tampa, FL 33614
RPT	49942	08/14/2013	Lampkin, Tigris	09/02/1974	Other	Ultimate Medical Academy	14408 Hellenic Dr Apt 104	Tampa, FL 33613
RPT	49943	08/14/2013	Almeida, Siboniso	09/23/1968	Other	Ultimate Medical Academy	501 Sussanah Leigh Lane Apt 207	Orlando, FL 32818
RPT	49944	08/14/2013	Thims, Darlene R	03/22/1962	Other	Ultimate Medical Academy	1272 Howland Blvd	Deltona, FL 32738
RPT	49945	08/14/2013	White, Amanda	06/19/1988	Other	Ultimate Medical Academy	2446 57Th St	Sarasota, FL 34243
RPT	49946	08/14/2013	Wiltshire, Ashlee	09/30/1984	Other	Everest University	1036 Eagles Landing	Leesburg, FL 34748
RPT	49947	08/14/2013	Zeng, Fan Rong	05/28/1990	Cvs Caremark		3446 Lowell Ave	Jacksonville, FL 32254
RPT	49948	08/14/2013	Finsted, Brooke Nicole	12/04/1992	Walgreens		1136 Stockbridge Way	West Melbourne, FL 32904
RPT	49949	08/14/2013	Milan, Yenisel	05/02/1989			2507 Nw 16Th St Apt 331	Miami, FL 33125
RPT	49950	08/14/2013	Lewis, Phil Dacosta	12/24/1976			318 W. Colonial Dr	Orlando, FL 32801
RPT	49951	08/14/2013	Mouer, Michelle Lea	12/24/1970	Cvs Caremark		9975 University Pkwy Apt 21	Pensacola, FL 32514
RPT	49952	08/14/2013	Williams-Webb, Shelly	08/28/1983	Cvs Caremark		1591 1591 Lane Ave S Apt 16B 1591 Lane Ave S Apt 16B	Jacksonville, FL 32210

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RPT	49953	08/14/2013	Delosreyes, Maesperanza Lapid	09/05/1979			510 Florida Club Blvd Apt 308	Saint Augustine, FL 32084
RPT	49954	08/14/2013	Bossick, Heather Lynn	05/14/1974	Walgreens		37544 Daliha Terrace	Zephyrhills, FL 33542
RPT	49955	08/14/2013	Alvarez Handy, Alexandra	03/29/1975	Other	Henry Brewster Technical Center	6519 Travis Blvd	Tampa, FL 33610
RPT	49956	08/14/2013	Fernandez, Bertha	10/25/1969	Other	Complete Pharmacy And Medical Solutions, Llc	5829 Nw 158Th Street	Miami Lakes, FL 33014
RPT	49957	08/15/2013	Bell, Tara Lynn	09/16/1990	Other	First Coast Technical College	117 Lone Oak Trail	Palatka, FL 32177
RPT	49958	08/15/2013	Strasdin, Nancy Ann	02/19/1953	Cvs Caremark		6736 Gilman	Garden City, MI 48135
RPT	49959	08/15/2013	Wiangkham, Kornwalee	12/27/1986	Cvs Caremark		5510 Temple Heights Rd	Temple Terrace, FL 33617
RPT	49960	08/15/2013	Driggers, Amanda Lynn	11/09/1990	Cvs Caremark		6011 Shetland Rd	Jacksonville, FL 32277
RPT	49961	08/15/2013	Riley, Kyle Steven	10/09/1990	Cvs Caremark		12550 Eclipse Court	New Port Richey, FL 34654
RPT	49962	08/15/2013	Silva, Yael Esperanza	10/09/1992	Other	Everest Institute	2164 Nw 104Th St Apt# 1	Miamia, FL 33147
RPT	49963	08/15/2013	Farra, Lydia Kaitlyn	03/17/1994	Other	Everest University	1253 Cypress Bend Circle	Melbourne, FL 32934
RPT	49964	08/15/2013	Cywinski, Martha Anne	04/12/1963	Other	Everest University	1113 Garfield Street	Melbourne, FL 32935
RPT	49965	08/15/2013	Valdes, Manuel	09/18/1976		Fortis College	12374 Nw 98 Place	Hialeah Gardens, FL 33018
RPT	49966	08/15/2013	Alderman, Carrie Shal'Wan	02/22/1977	Cvs Caremark		542325 Us Highway 1	Callahan, FL 32011
RPT	49967	08/15/2013	Stiff, Leonard Lewis	08/22/1951	Other	Everest University	341 Mimosa Ave.	Middleburg, FL 32068
RPT	49968	08/15/2013	Carbonell, Caitlyn Brooke	02/03/1995	Caremark Florida Mail Pharmacy		944 Blackberry Ln	Jacksonville, FL 32259
RPT	49969	08/15/2013	Cockrell, Felicia Evette	10/30/1984	Other	Everest University	3841 Kennedy Circle	Cocoa, FL 32926
RPT	49970	08/15/2013	Clark, Takala Chante	05/04/1991	Other	Everest University	3760 Cartee St.	Cocoa, FL 32926
RPT	49971	08/15/2013	Avila, Larissa Michelle	01/05/1991	Publix Super Market, Inc.		5997 Stirling Road	Davie, FL 33024
RPT	49972	08/15/2013	Coomer, Ellen Dawn	02/06/1973	Cvs Caremark		36825 Brook Road	Fruitland Park, FL 34731
RPT	49973	08/15/2013	Sulik, Brandon Michael	12/15/1992	Wal-Mart		1954 Thornhill Rd Apt # 211	Wesley Chapel, FL 33544
RPT	49974	08/15/2013	Holton, Angela Lynn	09/15/1978			7455 State Rd 52	Bayonet Point, FL 34667
RPT	49975	08/15/2013	Rios, Yamiris	04/14/1977	Other	Southeastern College	2855 2855 W 74 Pl	Hialeah, FL 33018

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RPT	49976	08/15/2013	Grigsby, Matthew Tyler	01/24/1986	Cvs Caremark		4684 Highway 90	Marianna, FL 32446
RPT	49977	08/15/2013	Wright, Sharon	03/03/1978	Other	Everest Institute	1430 Ne 170 Street Apt. #325	North Maimi, FL 33161
RPT	49978	08/15/2013	Bailey-Sigler, Tammy Sherrell	07/09/1971	Other	Everest University	2804 Sweet Springs St.	Deltona, FL 32738
RPT	49979	08/15/2013	Heffren, Victor E	01/16/1963	Other	Everest University Brandon Campus	1500 N. Lockwood Ridge Rd Apt 202	Sarasota, FL 34237
RPT	49980	08/15/2013	Butler, Pamela Jean	05/27/1963	Other	Everest University Brandon Campus	6421 Black Dairy Rd Lot 23	Seffner, FL 33584
RPT	49981	08/15/2013	Armstrong, April Alane	08/03/1988	Cvs Caremark		239 Golfpoint Drive	Lake Placid, FL 33852
RPT	49982	08/15/2013	Armbrust, Constance Rose	09/08/1990	Other	Ultimate Medical Academy	8164 Se Croft Circle No. B2	Hobe Sound, FL 33455
RPT	49983	08/15/2013	Anthony, Cheryl Bryant	02/03/1963	Other	Everest University Brandon Campus	518 518 Napa Valley Circle	Valrico, FL 33594
RPT	49984	08/15/2013	Dixon, Nicholas K	12/31/1981	Other	Ultimate Medical Academy	12160 92Nd Avenue	Seminole, FL 33772
RPT	49985	08/15/2013	Fernandez, Angelica Miguel	09/08/1991	Other	Southeastern College	13259 Royal George Ave	Odessa, FL 33556
RPT	49986	08/15/2013	Flexon, Krystal Nichole	08/20/1987	Cvs Caremark		12517 12517 Park Blvd	Seminole, FL 33776
RPT	49987	08/15/2013	Cantu, Juellysia	10/15/1989	Cvs Caremark		15550 San Carlos Blvd.	Fort Myers, FL 33908
RPT	49988	08/15/2013	Crance, Sabrina Kathryn	07/16/1990	Cvs Caremark		15550 San Carlos Blvd	Fort Myers, FL 33908
RPT	49989	08/15/2013	Prieto, Jesus A	02/18/1993	Other	Everest Institute	14230 Sw 161 Pl	Miami, FL 33196
RPT	49990	08/15/2013	Whetstone, April	11/15/1981	Other	Southeastern College	801 S. Federal Hwy. Apt. 103	Lake Worth, FL 33460
RPT	49991	08/15/2013	Charles, Garvey	07/01/1992	Cvs Caremark		19070 South Tamiami Trail	Fort Myers, FL 33908
RPT	49992	08/15/2013	Santana, Zuleida - -	03/04/1972	Other	Everest Institude	1940 Leah Star Rd	Astor, FL 32102
RPT	49993	08/15/2013	Terranova, Ivan Eduardo	08/26/1970	Other	Everest Institute	7070 7070 Nw 177 Street Apt 101	Hialeah, FL 33015
RPT	49994	08/15/2013	Candelario, Jennifer Marie	05/25/1977	Other	Everest University Tampa	5313 Landover Blvd	Springhill, FL 34609
RPT	49995	08/15/2013	Butler, Michael Terell	12/23/1987	Other	Everest University	1016 Granville Ct Upper	St. Peterburg, FL 33761
RPT	49996	08/16/2013	Gil, Jessenia	12/26/1992	Other	Everest Institute	1440 E Mowry Dr. Apt#204	Homestead, FL 33033
RPT	49997	08/16/2013	Alicea, Sarangely	04/03/1991	Walgreens		426 Larkspur Court	Niceville, FL 32578

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RPT	49998	08/16/2013	Amaral, Jessica Lee	11/20/1984	Cypress Pharmacy Inc		9371 Cypress Lake Drive	Fort Myers, FL 33919
RPT	49999	08/16/2013	Garcia, Hector Hugo	04/12/1990			2521 Lightfoot Rd	Wimauma, FL 33598
RPT	50000	08/16/2013	Ferris, Sarah Joanne	08/03/1988	Cvs Caremark		192 Se 4Th St	Satellite Beach, FL 32937
RPT	50001	08/16/2013	Hurtado, Bibiana	11/22/1958	Other	Everest University	6357 Seminole Ter	Margate, FL 33063
RPT	50002	08/16/2013	Crayton, Trinity Anisha	02/22/1991	Other	Everest University	5301 Broken Pine Circle	Orlando, FL 32818
RPT	50003	08/16/2013	Cintra, Yelenis	11/17/1980	Wal-Mart		3035 Hillview St	Sarasota, FL 34239
RPT	50004	08/16/2013	Alleyne, Rudy Martezkeldon	12/18/1983	Walgreens		35344 Sarah Lynn Dr. Apt 202	Dade City, FL 33525
RPT	50005	08/16/2013	Baker, Warren David	12/15/1985	Other	Everest Unversity Brandon Campus	12662 Castle Hill Drive	Tampa, FL 33624
RPT	50006	08/16/2013	D'Angelo, George Francis	09/07/1950	Other	Everest University	287 Autumn Trail	Port Orange, FL 32129
RPT	50007	08/16/2013	Batchelor, Colleen Noelle	05/17/1988	Other	University Of Florida-College Of Pharmacy	Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
RPT	50008	08/16/2013	Del Rosario, Roseanne	07/04/1990	Other	Everest Orange Park	1099 Cactus Cut Road	Middleburg, FL 32068
RPT	50009	08/16/2013	Delzeith, Nycole Christene	02/09/1990	Publix Super Market, Inc.		5565 Pentail Circle	Tampa, FL 33625
RPT	50010	08/16/2013	Rubio, Jennifer	12/30/1990	Other	Everest University	1432 Ne 13Th Ave	Ft Lauderdale, FL 33304
RPT	50011	08/16/2013	Boho, Angela Kaitlyn	01/25/1993	Cvs Caremark		302 East James Lee Boulevard	Crestview, FL 32539
RPT	50012	08/16/2013	Brown, Sarah Elizabeth	04/24/1976	Other	Sanford Brown Institute Tampa	6105 Alice Avenue	Gibsonton, FL 33534
RPT	50013	08/16/2013	Harding, Mussaya Sawangpop	12/06/1985			1198 Gilmore Dr Apt #B	Key West, FL 33040
RPT	50014	08/16/2013	Garcia, Michael A	08/14/1975	Other	Everest University	2524 Spring Harbor Apt 12	Mount Dora, FL 32757
RPT	50015	08/16/2013	Hernandez Cueto, Katia	04/05/1991	Other	University Of Florida	1156 Hancock Creek South Blvd Apt # 103	Cape Coral, FL 33909
RPT	50016	08/16/2013	Garcia, Leyanis	07/08/1983	Cvs Caremark		1836 Sw Leslie Gln	Lake City, FL 32025
RPT	50017	08/16/2013	Das, Timothy John	08/12/1987	Publix Super Market, Inc.		9125 Se Mystic Cove Ter	Hobe Sound, FL 33455
RPT	50018	08/16/2013	Stanley, Mariah Kristen	02/09/1994	Publix Super Market, Inc.		6030 14Th St W.	Bradenton, FL 34207
RPT	50019	08/16/2013	David, Sofia Maria	08/13/1989	Cvs Caremark		344 Benson St	Naples, FL 34113
RPT	50020	08/16/2013	Taher, Hazem	02/24/1981	Walgreens		10914 Scott Mill Road	Jacksonville, FL 32223

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RPT	50021	08/16/2013	Carrera, Jenny Nilda	01/26/1990			2611 Solano Ave #203	Hollywood, FL 33024
RPT	50022	08/16/2013	Solomon, Richard Armando	03/02/1987		Family Care Discount Pharmacy	3633 Cortez Rd W B-9	Bradenton, FL 34210
RPT	50023	08/16/2013	Ramos Sierra, Mayra	09/18/1964			532 East 51 St	Hialeah, FL 33013
RPT	50024	08/16/2013	Waldron, Damion Elias	02/11/1988			1982 Sw Mcallister Ln	Port Saint Lucie, FL 34953
RPT	50025	08/16/2013	Smothers, Torey Jamal	12/16/1985			12230 Sw 210 St.	Miami, FL 33177
RPT	50026	08/16/2013	Alvarez Mora, Yanai	09/26/1978			495 Nw 72Th Ave #309	Miami, FL 33126
RPT	50027	08/16/2013	Chavez-Trejo, Yanelith	09/02/1992			460 Us Hwy 17-92 N	Haines City, FL 33844
RPT	50028	08/16/2013	Salgado, Marco Antonio	12/19/1977		South Miami Pharmacy	6050 S. Dixie Hwy	Miami, FL 33143
RPT	50029	08/16/2013	Henderson, Marisella Cristina	10/15/1973			1236 Costal Creek Ct	Orlando, FL 32828
RPT	50030	08/19/2013	Steedman, Rebecca Delynn	12/15/1992	Cvs Caremark		866 Dunn Avenue	Jacksonville, FL 32218
RPT	50031	08/19/2013	Robinson, Vicki Lynn	07/24/1956	Winn Dixie		625 N Collier	Marco Island, FL 34112
RPT	50032	08/19/2013	Velez, Angeline Christine	02/14/1992			2050 E Osceola Pkwy	Kissimmee, FL 34743
RPT	50033	08/19/2013	Ritz, Sherrie Michelle	11/04/1965		Indian River County School District	14001 State Rd 70 East	Okeechobee, FL 34972
RPT	50034	08/19/2013	Smith, Latoya Mireya	11/05/1986		Henry W. Brewster Technical Center	906 Maydell Ct	Tampa, FL 33619
RPT	50035	08/19/2013	Walton, Kristina Nicole	08/15/1991	Walgreens		1250 Ne Jensen Bch Blvd	Jensen Beach, FL 34957
RPT	50036	08/19/2013	Townsend, Taesu S	07/22/1955	Publix Super Market, Inc.		2125 E County Rd 540 A	Lakeland, FL 33813
RPT	50037	08/19/2013	Wright, Matthew Tyler	03/11/1993	Cvs Caremark		1819 West Tennessee Street	Tallahassee, FL 32304
RPT	50038	08/19/2013	Thomas-Francis, Lileth Jacquline	11/27/1964		Everst University	5560 Arnold Palmer Dr Apt 533	Orlando, FL 32811
RPT	50039	08/19/2013	Rawls, Neshaminy Suphronia	12/05/1990		Tallahassee Comm Coll.	919 Milano Cir Apt 202	Brandon, FL 33511
RPT	50040	08/19/2013	Russo, Alexis Nicole	06/20/1994		Suntree Pharmacy	7640 N Wickham Rd #116	Melbourne, FL 32940
RPT	50041	08/19/2013	Willard, Charles	03/07/1946	Other	South Suburban College	8571 Julian Lane	Naples, FL 34114
RPT	50042	08/19/2013	Workman, Ashley Diana	09/03/1986	Cvs Caremark		2303 South Radcliffe	Bradenton, FL 34207

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RPT	50043	08/19/2013	Byrd, Brittany Danielle	03/30/1989	Cvs Caremark		2677 Old Bainbridge Rd Apt 932-C	Tallahassee, FL 32303
RPT	50044	08/20/2013	Bouza, Yesenia	02/27/1990	Walgreens		2025 Calais Drive Apt 10	Miami Beach, FL 33141
RPT	50045	08/20/2013	Fernandez, Roberto Joel	08/28/1992			2660 E Hwy 50	Clermont, FL 34711
RPT	50046	08/20/2013	Diaz, Joann Denise	04/14/1992			10510 Nw 30Th Ct	Miami, FL 33147
RPT	50047	08/20/2013	Haro, Nicole M	04/13/1986	Walgreens		2295 East Bay Drive	Largo, FL 33771
RPT	50048	08/21/2013	Scarpaci, Samuel Cicero Jr	07/11/1991	Publix Super Market, Inc.		1321 S.Miramar Ave Apt # 6	Indialantic, FL 32903
RPT	50049	08/21/2013	Matilla, Yacenia	08/30/1984	Other	Everest Institute	389 Ludlam Drive	Miami Springs, FL 33166
RPT	50050	08/21/2013	Salom, Richard Patrick	11/10/1982	Walgreens		4210 East St Rd 64	Bradenton, FL 34208
RPT	50051	08/21/2013	Kokoszynski, Josephine Catherine	04/26/1984			9600 Parksouth Ct Ste 100	Orlando, FL 32837
RPT	50052	08/21/2013	Munoz, Eileen Barbara	12/12/1990			16800 Sw 88Th Street	Miami, FL 33196
RPT	50053	08/21/2013	Zolman, Nathan Ryan	02/25/1991	Other	University Of Florida	2461 E. Gulf To Lake Hwy	Inverness, FL 34453
RPT	50054	08/21/2013	Stephen, Ginno	03/22/1988	Cvs Caremark		6170 Lakeland Highlands Road	Lakeland, FL 33812
RPT	50055	08/21/2013	Valentin, Karla Joan	01/18/1989	Cvs Caremark		1300 Sw St. Lucie Blvd	Port St. Lucie, FL 34986
RPT	50056	08/21/2013	Patel, Shivam	03/29/1992	Cvs Caremark		1999 Osceola Parkway	Kissimmee, FL 34743
RPT	50057	08/21/2013	Mahan, Chloe Rose Alexis	12/01/1992			4100 Military Trail	Jupiter, FL 33458
RPT	50058	08/22/2013	Julia, William E	02/18/1970			1458 Nw 97 St	Miami, FL 33147
RPT	50059	08/22/2013	Hong, Jessica	02/27/1992			5007 Nw 45Th Rd Apt 106	Gainesville, FL 32606
RPT	50060	08/22/2013	De Haza, Milly	12/19/1984	Other	Everest Institute	3145 Nw 82Nd Street	Miami, FL 33147
RPT	50061	08/22/2013	Cortez, Adam Michael	03/15/1993	Cvs Caremark		714 Gray Street South	Gulfport, FL 33707
RPT	50062	08/22/2013	Couch, Emily Louise	12/19/1991	Cvs Caremark		5 Garden Street	Titusville, FL 32796
RPT	50063	08/22/2013	Fritz, Ashley Lynn	03/26/1991	Walgreens		5608 Granada Dr Apt 150	Sarasota, FL 34231
RPT	50064	08/22/2013	Brill, Erin Nichole	04/19/1981			733 E Tennessee St	Tallahassee, FL 32308
RPT	50065	08/22/2013	Carter, Jessica Nicole	06/26/1995			9239 Hoenstine Ave	Orlando, FL 32824
RPT	50066	08/22/2013	Miller, Adrienna Sharee	07/07/1991			1337 Hwy 90 W	Defuniak Springs, FL 32433
RPT	50067	08/22/2013	Mcnatt, Sarah Emily	06/19/1994			1921 S. Alafaya Trl	Orlando, FL 32828
RPT	50068	08/22/2013	Dickie, Alex Burton	06/18/1985	Cvs Caremark		3544 Horace Ave	North Port, FL 34286
RPT	50069	08/22/2013	Bowman, Paige Marie	11/18/1993	Cvs Caremark		14411 Palm Beach Blvd.	Fort Myers, FL 33905

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RPT	50070	08/22/2013	Clarke, Reginia	02/24/1992	Cvs Caremark		5502 East Fowler Avenue	Tampa, FL 33617
RPT	50071	08/22/2013	Hails, Marybeth	07/31/1956	Target Corporation;Target Corporation		2340 Highway 77	Panama City, FL 32405
RPT	50072	08/22/2013	Bryant, Brittney	06/19/1990	Other	Everest Institute	645 Ives Dairy Road Apt. 313	Miami, FL 33179
RPT	50073	08/22/2013	Brevard, Sherrick	05/26/1988	Other	Sanford Brown Institute Tampa	2922 E. 20Th Ave	Tampa, FL 33605
RPT	50074	08/22/2013	Amos, Chandra	07/22/1978	Walgreens		10634 Versailles Blvd	Wellington, FL 33449
RPT	50075	08/22/2013	Moody, Brentley Austin	08/21/1995			6371 Park Avenue	Milton, FL 32570
RPT	50076	08/22/2013	Johnson, Lori Lynn	09/07/1972			4717 San Juan Ave	Jacksonville, FL 32210
RPT	50077	08/22/2013	Pate, Coleen Michelle	01/18/1995			6438 Cypress St	Milton, FL 32570
RPT	50078	08/22/2013	Auza, Juan Pablo	01/12/1989	Cvs Caremark		13991 N Cleveland Ave	North Fort Myers, FL 33903
RPT	50079	08/22/2013	Lucier, David Arthur	11/07/1945			1101 8Th Ave W	Palmetto, FL 34221
RPT	50080	08/22/2013	Jackson, Jody Alethia	04/30/1990			12401 Miramar Parkway	Miramar, FL 33027
RPT	50081	08/22/2013	Dardar, Teresa Kay	11/10/1971	Other	2419-University Of Florida-College Of Pharmacy	2407 Southern Links Drive	Fleming Island, FL 32003
RPT	50082	08/22/2013	Diaz-Balcazar, Wendy	08/01/1977	Other	Everest University	9098 Sable Ridge Court	Jacksonville, FL 32244
RPT	50083	08/22/2013	Getchell, Stephen Gregory	12/27/1992	Cvs Caremark		1621 Southwest 13Th Street	Gainesville, FL 32608
RPT	50084	08/22/2013	Williams, Precious S	10/16/1988	Other	Everest University	5412 Galway Dr	Charlotte, NC 28215
RPT	50085	08/22/2013	Cole, Joyce	01/11/1964	Other	Everest Institute	10778 Sw 224 Terr	Miami, FL 33170
RPT	50086	08/22/2013	Roberson, James Curtis Iii	07/15/1990	Cvs Caremark		3501 54Th Avenue South	St. Petersburg, FL 33711
RPT	50087	08/22/2013	Smith, Brittney Nichole	10/02/1990	Cvs Caremark		8700 Us Highway 301 N	Parrish, FL 34219
RPT	50088	08/22/2013	Ragan, Courtney Allane	06/29/1993	Cvs Caremark		611 South Howard Ave.	Tampa, FL 33606
RPT	50089	08/22/2013	Stribling, Jazmyne Marie	05/11/1991	Publix Super Market, Inc.		242 N Orlando Ave	Maitland, FL 32751
RPT	50090	08/23/2013	Gaffar, Tanzim	08/09/1994			6025 Lake Worth Rd	Greenacres, FL 33463
RPT	50091	08/23/2013	Evanoff, Stephanie Ann	09/28/1993			10801 Starkey Rd #200	Seminole, FL 33777
RPT	50092	08/23/2013	Grayford, Dawn Marie	10/03/1993			250 Citrus Tower Blvd	Clermont, FL 34711

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RPT	50093	08/23/2013	Fisher, Danielle Lynn	03/11/1994			280 Sw Port St Lucie Blvd	Port Saint Lucie, FL 34984
RPT	50094	08/23/2013	Boone, Markichia Juaneta	03/29/1989			9824 S Military Trail	Boynton Beach, FL 33436
RPT	50095	08/23/2013	Gerges, Silvia Barsoum	01/30/1976			12689 Challenger Pkwy Ste 100	Orlando, FL 32826
RPT	50096	08/23/2013	Bardwell, Kathryne Lorraine	06/03/1987			741 S Orlando Ave	Winter Park, FL 32789
RPT	50097	08/23/2013	Canola-Flores, Marjorie Viviana	08/29/1992			11936 W Forest Hill Blvd	Wellington, FL 33414
RPT	50098	08/23/2013	Byron, Francina	02/03/1994	Other	Everest Institute	1240 Nw 7Th Ct	Florida City, FL 33034
RPT	50099	08/23/2013	Kelly, Shante Maquitta	01/11/1990	Other	Sanford Brown Institute Tampa	1314 E. Louise Ave	Tampa, FL 33603
RPT	50100	08/23/2013	Parker, Lamichael	06/11/1990	Other	Sanford Brown Institute Tampa	5403 Williams Grant Way Apt 30	Tampa, FL 33610
RPT	50101	08/23/2013	Mcintyre, Peggy Sue	05/20/1963	Other	Everest University	1186 Sherbrook Drive	Deltona, FL 32725
RPT	50102	08/23/2013	Mufleh, Amani Marwan	12/03/1992	Cvs Caremark		11691 11691 Timberwood Rd.	Boca Raton, FL 33428
RPT	50103	08/23/2013	Kellogg, Alyssa Ashley	09/06/1987	Other	University Of Florida-College Of Pharmacy	695 Battersea Drive	Saint Augustine, FL 32095
RPT	50104	08/23/2013	Middleton, Kattie Marie	06/08/1993	Other	2419	544 Bison Circle	Apopka, FL 32712
RPT	50105	08/23/2013	Ibrahim, Rania M	02/06/1980	Other	Ultimate Medical Academy	1625 Gray Bark Drive	Oldsmar, FL 34677
RPT	50106	08/23/2013	Pugh, Faquita Kateria	10/20/1985	Other	Everest University North Campus	273 Springs Colony Circle Apt#238	Altamonte, FL 32714
RPT	50107	08/23/2013	Kravcov, Catherine Ann	03/01/1990	Cvs Caremark		1040 10Th Ave.	Deland, FL 32724
RPT	50108	08/23/2013	Perez Diaz, Liudmila	12/14/1977	Other	Everest Institute	6272 Nw 186 Street Apt. 101	Miami, FL 33015
RPT	50109	08/23/2013	Madison, Brianna	12/31/1991	Other	Ultimate Medical Academy	1909 E Jean Street	Tampa, FL 33610
RPT	50110	08/23/2013	Pantages, Jason	01/17/1990	Walgreens		35553 Us Highway 19 N	Palm Harbor, FL 34684
RPT	50111	08/23/2013	Mcnaney, Kieran Emil	11/22/1984	Cvs Caremark		350 Herons Run Drive Apartment 521	Sarasota, FL 34232
RPT	50112	08/23/2013	Kelly, Kevin Patrick	11/12/1993	Cvs Caremark		8137 124Th St	Seminole, FL 33772
RPT	50113	08/23/2013	Abu-Nasser, Najwa B	01/15/1991	Walgreens		1410 W Virginia Ln	Clearwater, FL 33759
RPT	50114	08/23/2013	Howard, Joshua Louis	06/05/1985	Other	Everest University Jacksonville	3604 Blanding Blvd	Jacksonville, FL 32210

COMPAS DataMart Reporting System
New License Report for 2208 : Registered Pharmacy Technician
7/ 1/2013 - 8/31/2013

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	50115	08/23/2013	Hernandez, Maria De Los Angeles	02/08/1987			10846 Kensigton Park Avenue	Riverview, FL 33578
RPT	50116	08/23/2013	Perry, Carol L	03/28/1966	Other	Rite Aid Pharmacy Technician Training Program	3867 S. Linwood Terrace	Inverness, FL 34452
RPT	50117	08/26/2013	Wilson, Grant Tyler	06/14/1994		Radford M. Locklin Technical Center	5905 Stephanie Drive	Milton, FL 32570
RPT	50118	08/26/2013	Singley, Jesslyn Eliza	03/22/1995		Radford M. Locklin Technical Center	4845 Sidney Lane	Jay, FL 32565
RPT	50119	08/26/2013	Wahlquist, Hyrum Patrick	05/14/1996		Golden Pharmacy	13005 Nw Joe Chason Circle	Bristol, FL 32321
RPT	50120	08/26/2013	Stapp, Heather Nichelle	05/06/1984	Publix Super Market, Inc.		5240 West State Rd 46	Sanford, FL 32771
RPT	50121	08/26/2013	Sanabria Herrera, Ketty	02/09/1991		Florida Education Institute	1750 Nw 27Th Ave Apt 301	Miami, FL 33125
RPT	50122	08/26/2013	Schwartzfisher, Linda Marie	12/07/1950		Barry Univ	3700 Commerce Parkway	Miramar, FL 33025
RPT	50123	08/26/2013	Walker, Brianna	08/20/1991	Cvs Caremark		4550 Lyons Rd	Coconut Creek, FL 33073
RPT	50124	08/26/2013	Wallace, Stephanie Renee	10/18/1983		Lincoln Technical Center	694 Seabrook Ct #202	Altamonte Springs, FL 32714
RPT	50125	08/27/2013	Durham, Charlie	10/13/1961			2280 Robin Hood Rd	Macon, GA 31206
RPT	50126	08/27/2013	Sanchez, Mailen	10/06/1978	Walgreens		998 Sw 67 Ave	Miami, FL 33144
RPT	50127	08/27/2013	Quiles Arroyo, Nydia	10/27/1978	Publix Super Market, Inc.		4402 Curry Ford Rd	Orlando, FL 32812
RPT	50128	08/27/2013	Grossett, Coretta	10/01/1976	Other	Fortis Institute	2701 Sunrise Lakes Dr Apt 311	Sunrise, FL 33322
RPT	50129	08/27/2013	Rodriguez, Yuleisy	06/08/1982	Other	South Dade Skills Center	213 St 9700 Sw 213 St	Miami, FL 33189
RPT	50130	08/27/2013	Sankar, Shennel	10/03/1993	Cvs Caremark		2621 Judge Loop	Kissimmee, FL 34743
RPT	50131	08/27/2013	Watkins, Artravious	08/21/1993	Cvs Caremark		838 Angela Ave Apt E	Rockledge, FL 32955
RPT	50132	08/27/2013	Richardson, Gerren K	11/14/1987	Other	Ultimate Medical Academy	8723 Del Rey Ct	Tampa, FL 33617
RPT	50133	08/28/2013	Kalil, Yamilet	02/19/1975			1668 Sw 11Th St	Miami, FL 33135
RPT	50134	08/28/2013	Shaw, Heather Mary	07/06/1989	Walgreens		790 W. Granada Blvd	Ormond Beach, FL 32174
RPT	50135	08/28/2013	Yancey, Amanda Renee	12/05/1991	Winn Dixie		326 Seminole Trl.	Mulberry, FL 33860
RPT	50136	08/28/2013	Powell, Mache Latronis	03/22/1980			1390 S. Jefferson Street	Monticello, FL 32344
RPT	50137	08/28/2013	Ritchie, Danielle Nicole	11/04/1990	Other	Sanford Brown Institute Tampa	10030 E Wilder Ave.	Tampa, FL 33610

COMPAS DataMart Reporting System
New License Report for 2208 : Registered Pharmacy Technician
7/ 1/2013 - 8/31/2013

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	50138	08/28/2013	Samble, Carina Caitlin	05/10/1992	Publix Super Market, Inc.		2250 S Ferdon Blvd	Crestview, FL 32536
RPT	50139	08/28/2013	Torres, Ashley	09/24/1990	Walgreens		2101 Sadler Rd	Fernandina Beach, FL 32034
RPT	50140	08/28/2013	Lewis, Shandrieka Lashay	04/22/1992			204 Maltese Circle Apt 13	Fern Park, FL 32730
RPT	50141	08/28/2013	Rogers, Melissa Erica	05/06/1987	Walgreens		1800 San Marco Rd	Marco Island, FL 34145
RPT	50142	08/28/2013	Merlino, Anthony John	01/10/1989			4701 S Flamingo Road	Cooper City, FL 33330
RPT	50143	08/28/2013	Roman, Diamond Marie	11/17/1992		Concorde Career Institute	1371 Thomasville Cirlce	Lakeland, FL 33811
RPT	50144	08/28/2013	Suarez, Humberto	10/27/1975	Walgreens		8325 South Park Circle Suite 201	Orlando, FL 32819
RPT	50145	08/28/2013	Taylor, Patience	04/01/1978	Walgreens		3609 Tam Dr	Orlando, FL 32802
RPT	50146	08/28/2013	Saunders, Monica Starr	08/18/1984	Walgreens		8325 South Park Circle Suite 201	Orlando, FL 32819
RPT	50147	08/28/2013	Wilder, Sheena	12/31/1980	Walgreens		1617 Daly Street	Orlando, FL 32808
RPT	50148	08/28/2013	Rockwood, Maritza	02/28/1970	Walgreens		8325 Southpark Circle Suite 201	Orlando, FL 32819
RPT	50149	08/28/2013	Rodriguez, Janet	12/27/1959	Walgreens		8325 South Park Circle Ste 201	Orlando, FL 32819
RPT	50150	08/28/2013	Simons, Brittany Mae	12/21/1987	Walgreens		8325 South Park Circle Ste 201	Orlando, FL 32819
RPT	50151	08/28/2013	Ingram, Amy Porter	03/12/1985			1700 N W 80Th Blvd	Gainesville, FL 32606
RPT	50152	08/28/2013	Kilcoyne, Blake William	04/11/1993			5991 Pine Ridge Rd	Naples, FL 34119
RPT	50153	08/28/2013	Walker, Ronnie L	03/29/1971	Walgreens		8325 South Park Circle Suite 201	Orlando, FL 32819
RPT	50154	08/28/2013	Mccloud, Lynda Marie	02/13/1965			1921 Waldemere St Ste 201	Sarasota, FL 34239
RPT	50155	08/28/2013	Pereyra, Jennifer Stephanie	05/10/1993			5900 W Sample Road Unit 201	Coral Springs, FL 33067
RPT	50156	08/28/2013	Smith, Vivian H	06/09/1955	Walgreens		8325 South Park Circle Suite 201	Orlando, FL 32819
RPT	50157	08/28/2013	Temple, Tricia Marie	03/10/1979	Walgreens		12020 Betty Ann Drive	Orlando, FL 32832
RPT	50158	08/28/2013	Rivera, Jeff Anthony	11/01/1988	Walgreens		8325 South Park Circle Suite 201	Orlando, FL 32819
RPT	50159	08/28/2013	Thomas, Latoya Lynell	07/09/1976	Walgreens		8325 South Park Circle Suite 201	Orlando, FL 32819

COMPAS DataMart Reporting System
New License Report for 2208 : Registered Pharmacy Technician
7/ 1/2013 - 8/31/2013

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	50160	08/28/2013	Soto, Sandra	04/30/1961	Walgreens		8325 South Park Circle Suite 201	Orlando, FL 32819
RPT	50161	08/29/2013	Rodriguez, Yovanna	06/29/1979	Walgreens		8325 South Park Circle Ste 201	Orlando, FL 32819
RPT	50162	08/29/2013	Trask, Larry Kent Jr	09/16/1971	Walgreens		8325 South Park Circle Suite 201	Orlando, FL 32819
RPT	50163	08/29/2013	Washington, Wayne Thomas Ii	05/29/1973	Walgreens		8325 South Park Circle Suite 201	Orlando, FL 32819
RPT	50164	08/29/2013	Williams, Ruth	01/29/1952	Walgreens		8325 South Park Cir Suite 201	Orlando, FL 32819
RPT	50165	08/29/2013	Wood, Jennifer Reshay	12/10/1991	Other	Univ Of Florida;University Of Florida	1116 N. Ferdon Blvd	Crestview, FL 32536
RPT	50166	08/29/2013	Watkins, William Leo	05/15/1986	Cvs Caremark	Express Training Services;	16040 Se 18Th Lane	Ocklawaha, FL 32179
RPT	50167	08/29/2013	Stalker, Mary-Heather Dawn	07/31/1979	Other	Sandfoord Brown	9703 Fox Hollow Rd.	Tampa, FL 33647
RPT	50168	08/29/2013	Quiles, James Luis	04/03/1979		Southwest Florida College	370 Se Mizner Blvd #1604	Boca Raton, FL 33432
RPT	50169	08/29/2013	Nesbitt, Tracy L	06/24/1968	Other	University Of Florida College Of Pharmacy	613 Bowden Rd.	Clewiston, FL 33440
RPT	50170	08/29/2013	Ramirez, Steven Anthony	11/18/1989	Cvs Caremark		550 West Burleigh Boulevard	Tavares, FL 32778
RPT	50171	08/29/2013	Williamson, Amy Ryann	03/02/1991		Oconee Fall Line Technical College	168 S E Kitching Circle	Stuart, FL 34994
RPT	50172	08/29/2013	Lopez, Tanya Lynn	01/01/1977	Other	Mci Institute Of Technology	3132 Grandiflora Dr	Greenacres, FL 33467
RPT	50173	08/29/2013	Henriquez, Hevian E	01/02/1937			12990 Sw 63Rd St Apt 605	Miami, FL 33183
RPT	50174	08/29/2013	Diaz Fernandez, Elizabeth	11/09/1981			1143 Obispo Ave	Miami, FL 33134
RPT	50175	08/29/2013	Cuellar, Julio Cesar	09/30/1974			10229 Nw 9Th St Cir. #109	Miami, FL 33172
RPT	50176	08/29/2013	Gonzalez Lopez, Madays	09/11/1973			21340 Sw 112Th Ave #304	Miami, FL 33189
RPT	50177	08/29/2013	Gonzalez, Martha L	03/31/1964			4460 N W 79Th Ave #1D	Miami, FL 33166
RPT	50178	08/29/2013	Ferraro, Melanie Jean	05/05/1990			1708 N Monroe St	Tallahassee, FL 32303
RPT	50179	08/29/2013	Hernandez, Anna Yeiny	04/11/1991			135 Bradley Place	Palm Beach, FL 33480
RPT	50180	08/30/2013	Colson, Jermaine Dongeur	06/20/1974	Other	Everest University	1128 Ford Street	Tallahassee, FL 32303

COMPAS DataMart Reporting System
New License Report for 2208 : Registered Pharmacy Technician
7/ 1/2013 - 8/31/2013

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	50181	08/30/2013	Koppelmann, Jeffrey L	08/02/1962	Shands At University Of Florida		159 Palm Beach Plantation Blvd.	Royal Palm Beach, FL 33411
RPT	50182	08/30/2013	Kelsey, Khamila Arabia	04/02/1990	Cvs Caremark		9Th 3700 9Th Ave North	Saint Petersburg, FL 33713
RPT	50183	08/30/2013	Levy, Ashley Erin	11/25/1990	Cvs Caremark		2500 51St Street	Gifford, FL 32968
RPT	50184	08/30/2013	Menendez, Sophia	10/10/1991	Publix Super Market, Inc.		15771 Sw 152 Street	Miami, FL 33187
RPT	50185	08/30/2013	Bechar, Heather L	05/25/1989			75 Buxton Lane	Boynton Beach, FL 33426
RPT	50186	08/30/2013	Perkins, O'Brian	03/10/1992	Walgreens		1001 Sw 2Nd Ave	Boca Raton, FL 33432
RPT	50187	08/30/2013	Kidd, Theresa Katelin	08/06/1990	Walgreens		1115 Joel Blvd	Lehigh Acres, FL 33936
RPT	50188	08/30/2013	Marte, Vilma	03/07/1958	Walgreens		8325 South Park Circle Suite 201	Orlando, FL 32819
RPT	50189	08/30/2013	Olivo, Annaliesse Josefina	06/08/1960	Walgreens		8325 South Park Cir Suite 201	Orlando, FL 32819
RPT	50190	08/30/2013	Morales, Abigail Caridad	02/12/1980	Walgreens		8325 South Park Cir Suite 201	Orlando, FL 32819
RPT	50191	08/30/2013	Doxey, Melanie Lynne	10/30/1958			32 Bayberry Branch	Longwood, FL 32707
RPT	50192	08/30/2013	Garcia, William Jr	04/28/1971			34911 Us Hwy 19 N	Palm Harbor, FL 34684

Total Records: **1,065**

Division of
Medical Quality Assurance

MQA

Processed: 9/12/2013 11:24:05AM

COMPAS DataMart Reporting System
New License Report for 2203 : Consultant Pharmacist
7/ 1/2013 - 8/31/2013

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PU	7287	07/03/2013	Glynn, Paul Francis	08/24/1950			2006 Ne 15 Ave	Wilton Manors, FL 33305
PU	7288	07/03/2013	Walczyk, Heather Lynn				2861 Sw 73Rd Way Apt 2013	Davie, FL 33314
PU	7289	07/11/2013	Kohli, Sanjay				12641 Nw 18Th Manor	Pembroke Pines, FL 33028
PU	7290	07/11/2013	Martinez, David Alejandro				14237 Sw 94 Circle Lane	Miami, FL 33186
PU	7291	07/12/2013	Attia, Raed Raafat Naguib				5922 Goleta Circle	Melbourne, FL 32940
PU	7292	07/15/2013	De Young, Paul Andrew				4870 Tallowood Way	Naples, FL 34116
PU	7293	07/15/2013	Mino, Casey Quinn				714 Sw 12Th Ave	Fort Lauderdale, FL 33312
PU	7294	07/22/2013	Smith, Norshawndra Marie				713 Greenleaf Lane	Lake Wales, FL 33853
PU	7295	07/22/2013	Epps, Quovadis Janeene				Box 57868	Jacksonville, FL 32241
PU	7296	07/22/2013	Urieto, Christopher Onosekhale				17803 S W 35Th Court	Miramar, FL 33029
PU	7297	07/22/2013	Lenzi, Lisa Leigh				2800 La Concha Dr	Clearwater, FL 33762
PU	7298	07/22/2013	Colquitt, Charlie Waller				1820 Serpentine Dr So	Saint Petersburg, FL 33712
PU	7299	07/22/2013	Deforte, Nicole Arlene				4124 Country Club Blvd	Cape Coral, FL 33904
PU	7300	07/30/2013	Mcelveen, Derick Jr				11957 Diamond Springs Dr	Jacksonville, FL 32246
PU	7301	07/30/2013	Fortune, Margrette Hardwick				6383 Mallard Trace Dr	Tallahassee, FL 32312
PU	7302	07/30/2013	Mays, Erica Lashea				7965 Preservation Road	Tallahassee, FL 32312
PU	7303	07/31/2013	Lowe, Andra Marie				2869 Lafayette Trace Drive	Saint Cloud, FL 34772
PU	7304	08/06/2013	Meringolo, John Michael				12116 Diamond Springs Dr	Jacksonville, FL 32246
PU	7305	08/06/2013	Hur, Yung W				5411 Bayou Grande Blvd N E	Saint Petersburg, FL 33703
PU	7306	08/08/2013	Ferraro, Robert Peter	05/17/1985			6659 38Th Ln East	Sarasota, FL 34243
PU	7307	08/15/2013	Zapico, Anthony M				809 Burland Circle	Winter Garden, FL 34787
PU	7308	08/15/2013	Vinson, Dorothy Elizabeth				Box 1139	Crystal Beach, FL 34681

COMPAS DataMart Reporting System
New License Report for 2203 : Consultant Pharmacist
7/ 1/2013 - 8/31/2013

Sort Order: Original License Date

Processed: 9/12/2013 11:24:05AM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PU	7309	08/16/2013	Moore, Claudia Christine				3540 Whitehall Dr #102	West Palm Beach, FL 33401
PU	7310	08/23/2013	Wilson, Melissa Roshelle				Box 15349	Tallahassee, FL 32317
PU	7311	08/27/2013	Cummings, Lorie Ann				4610 Bluewater Drive	Panama City, FL 32404
PU	7312	08/28/2013	Xavier, Jean Y				14366 Pompano Pass	Spring Hill, FL 34609
PU	7313	08/28/2013	Botnick, Jeffrey Lawrence				7415 Briella Drive	Boynton Beach, FL 33437
PU	7314	08/28/2013	Gregory, Jennifer Marie				1331 Benevolent St	Maitland, FL 32751
PU	7315	08/28/2013	Coronel, Annette Maria				4400 Nw 113Th Ct	Miami, FL 33178
PU	7316	08/29/2013	Gierbolini-Flores, Mariel				168 Integra Shores Dr Unit 202	Daytona Beach, FL 32117

Total Records: **30**

Division of
Medical Quality Assurance

MQA

Processed: 9/12/2013 11:26:00AM

COMPAS DataMart Reporting System
New License Report for 2204 : Nuclear Pharmacist
7/ 1/2013 - 8/31/2013

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
NP	439	08/21/2013	Adams, Ryan Dale				25 S. Carlen St	Mobile, AL 36606

Total Records: **1**

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
7/ 1/2013 - 8/31/2013

Processed: 9/12/2013 11:27:00AM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	26932	07/01/2013	Ag Ben'S Discount Pharmacy, Inc				10521 Sw 40 St	Miami, FL 33165
PH	26933	07/01/2013	Apex Care Pharmacy, Llc				409 B South Parrott Ave	Okeechobee, FL 34974
PH	26934	07/02/2013	Bond Community Health Center, Inc				2729-8 Municipal Way	Tallahassee, FL 32304
PH	26935	07/02/2013	Bond Community Health Center, Inc				1704 Joe Louis St	Tallahassee, FL 32304
PH	26936	07/03/2013	Wal-Mart Stores East, Lp				445 State Road 13	Fruit Cove, FL 32259
PH	26937	07/03/2013	Rx Express Pharmacy Of Panama City, Inc				540 B E 6Th Street	Panama City, FL 32401
PH	26938	07/03/2013	Flagler'S Drug Store				8216 W Flagler St	Miami, FL 33144
PH	26939	07/03/2013	Lp St. Petersburg Pasadena, Llc				1430 Pasadena Avenue South	South Pasadena, FL 33707
PH	26940	07/09/2013	Shinabery'S Compounding Pharmacy, Plc				1150 E Matthews Ave Ste 103	Jonesboro, AR 72401
PH	26941	07/09/2013	Valley Campus Pharmacy Inc				15211 Vanowen St #301	Van Nuys, CA 91405
PH	26942	07/09/2013	Bond Community Health Center				2634-C Capital Circle Ne Building C	Tallahassee, FL 32308
PH	26943	07/09/2013	Serenity House Detox, Llc				1780 Nw 52 Ave	Lauderhill, FL 33313
PH	26944	07/09/2013	Saluscare, Inc				2450 Prince Street	Fort Myers, FL 33916
PH	26945	07/09/2013	Saluscare,Inc				3763 Evans Avenue	Fort Myers, FL 33901
PH	26946	07/11/2013	Simali Healthcare Llc				1920 Don Wickham Drive Suite #135	Clermont, FL 34711
PH	26947	07/11/2013	South Lake Hospital				2040 Oakley Seaver Drive	Clermont, FL 34711
PH	26948	07/11/2013	Tallahassee Memorial Healthcare, Inc.				1260 Metropolitan Blvd	Tallahassee, FL 32312
PH	26949	07/11/2013	Little Havana Drug Store Inc				1116 Sw 1St Street	Miami, FL 33130
PH	26950	07/11/2013	S & Z Khan, Corp				36600 State Road 54 West	Zephyrhills, FL 33541
PH	26951	07/15/2013	Marley Drug, Inc.				5008 Peters Creek Pkwy	Winston-Salem, NC 27127
PH	26952	07/17/2013	Mohegan Pharmacy				67 Sandy Desert Road	Uncasville, CT 06382

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
7/ 1/2013 - 8/31/2013

Processed: 9/12/2013 11:27:00AM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	26953	07/18/2013	Stonybrook Pharmacy, Llc				13921 S. Plaza	Omaha, NE 68137
PH	26954	07/19/2013	Angel'S Pharmacy I, Inc.				259 E Michigan St	Orlando, FL 32806
PH	26955	07/19/2013	Cleveland Clinic Florida Pharmacy Servic				7857- 59 University Dr. Suite 401-403 Building 4	Parkland, FL 33067
PH	26956	07/19/2013	Geo Care				13619 Southeast Highway 70	Arcadia, FL 34266
PH	26957	07/19/2013	Youth Services International, Inc.				3001 26Th Avenue S.	Saint Petersburg, FL 33712
PH	26958	07/19/2013	Alixa Rx Llc				3100 Northwoods Place Nw Suite F	Norcross, GA 30071
PH	26959	07/22/2013	Alliance Allergy Solutions				1318 20Th Street South Suite 125	Birmingham, AL 35205
PH	26960	07/22/2013	Bond Pharmacy, Inc				132 Fairmont Street Suite B	Clinton, MS 39056
PH	26961	07/22/2013	Vail Valley Pharmacy Llc				105 Edwards Village Blvd Unit G107	Edwards, CO 81632
PH	26962	07/22/2013	Florida Health Care Plan, Inc				2500 West Lake Mary Blvd Suite 109	Lake Mary, FL 32746
PH	26963	07/26/2013	Recovery Resources Enterprises, Inc				461 Venus Drive	Juno Beach, FL 33408
PH	26964	07/26/2013	University Of Florida Board Of Trustees				4740 Nw 39Th Place Suite B	Gainesville, FL 32606
PH	26965	07/26/2013	Pharmacy Discount Service Inc				4894 Nw 7Th Street	Miami, FL 33126
PH	26966	07/26/2013	Sarasota Bay Rehabilitation Center, Llc				2600 Courtland Street	Sarasota, FL 32237
PH	26967	07/29/2013	Wheeler'S Custom Compounding, Inc.				327 Romany Rd.	Lexington, KY 40502
PH	26968	07/29/2013	Genesis Pharmacy Corp				8150 Sw 8Th Street #105	Miami, FL 33144
PH	26969	07/29/2013	Surgcenter Of Orange Park, Llc				1465 Kingsley Ave Suite 1201	Orange Park, FL 32073
PH	26970	07/29/2013	Bird Road Pharmacy & Discount Inc.				7951 Sw 40Th St Suite 102	Miami, FL 33155

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
7/ 1/2013 - 8/31/2013

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	26971	07/29/2013	Imperial Point Pharmacy Center, Inc.				6310 North Federal Hwy	Fort Lauderdale, FL 33308
PH	26972	07/29/2013	Med Care Choice Pharmacy, Inc.				3570 Consumer Street Suite 8	West Palm Beach, FL 33404
PH	26973	07/29/2013	New Era Pharmaceuticals Llc				3350 Nw 53 Street Suite 102-103	Fort Lauderdale, FL 33309
PH	26974	07/30/2013	Avita Drugs Llc				411 Colonial Drive	Baton Rouge, LA 70806
PH	26975	07/30/2013	Youth Services International				8301 South Palm Dr	Pembroke Pines, FL 33025
PH	26976	07/30/2013	Publix Super Markets, Inc				1140 Sw 36Th Avenue	Pompano Beach, FL 33069
PH	26977	07/30/2013	Topical Specialists, Llc				12276 San Jose Blvd Ste 212	Jacksonville, FL 32223
PH	26978	07/30/2013	South Broward Hospital District				3600 Washington Street	Hollywood, FL 33021
PH	26979	07/31/2013	Publix Super Markets, Inc				2438 Laurel Rd East	North Venice, FL 34275
PH	26980	07/31/2013	Watercrest Acquisition I Llc				16650 W. Dixie Hwy	North Miami Beach, FL 33160
PH	26981	07/31/2013	Youth Services International, Inc.				7500 Ricker Road	Jacksonville, FL 32244
PH	26982	08/01/2013	Medarbor Llc				150 Monument Rd Suite 408	Bala Cynwyd, PA 19004
PH	26983	08/02/2013	Lcrx, Llc				8240 E Gelding Drive Suite 115	Scottsdale, AZ 85260
PH	26984	08/02/2013	Strain & Strain Llc				602 C South Morgan	Granbury, TX 76048
PH	26985	08/02/2013	Mathew Management Iv				2864 West Bay Dr	Belleair Bluffs, FL 33770
PH	26986	08/02/2013	Angel'S Touch Pharmacy Discount				4338 Sw 8 Street	Coral Gables, FL 33134
PH	26987	08/05/2013	Walgreen Co				3510 Biscayne Blvd Suite 200	Miami, FL 33137
PH	26988	08/05/2013	Medicure Longwood Inc				420 W State Road 434	Longwood, FL 32750
PH	26989	08/05/2013	Wexford Health Sources				1601 Southwest 187Th Avenue	Miami, FL 331B5
PH	26990	08/05/2013	Wexford Health Sources				19000 Sw 377Th Street	Florida City, FL 33034

COMPAS DataMart Reporting System
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
PH	26991	08/05/2013	Wexford Health Sources				19000 Southwest 377Th Street Suite 200	Florida City, FL 33034
PH	26992	08/05/2013	Anderson Compounding Pharmacy Inc				310 Bluff City Highway	Bristol, TN 37620
PH	26993	08/06/2013	Metcalf'S Discount Pharmacy				3929 Gulfway Dr	Port Arthur, TX 77642
PH	26994	08/06/2013	Transition Pharmacy Llc				4 Neshaminy Interplex Drive Suite 111	Trevose, PA 19053
PH	26995	08/06/2013	Wexford Health Sources				3420 Northeast 168Th Street	Okeechobee, FL 34972
PH	26996	08/07/2013	Aqua Pharma Inc.				2500 W. Flagler St.	Miami, FL 33130
PH	26997	08/07/2013	Navarro Health Services No. 3, Llc				1800 Nw 10Th Avenue Suite 101	Miami, FL 33136
PH	26998	08/07/2013	Wexford Health Sources				13617 Southeast Highway 70	Arcadia, FL 34266
PH	26999	08/08/2013	Merissa Corp				577 Main St	Waltham, MA 02452
PH	27000	08/08/2013	Publix Super Markets, Inc				8101 W Sunrise Blvd	Plantation, FL 33322-5401
PH	27001	08/08/2013	J & K Care Llc				756 N Belcher Road Coachman Plaza	Clearwater, FL 33765
PH	27002	08/08/2013	Wexford Health Sources				13910 Nw 41St Street	Miami, FL 33178
PH	27003	08/08/2013	Wexford Health Sources				14000 Northwest 41St Street	Miami, FL 33178
PH	27004	08/12/2013	Precise Compounding Pharmacy Inc				10810 Washington Blvd Suite C	Culver City, CA 90232
PH	27005	08/14/2013	North Sunflower Medical Center				840 N. Oak Ave	Ruleville, MS 38771
PH	27006	08/14/2013	Best Health Pharmacy Inc				243 Nw 27Th Ave	Fort Lauderdale, FL 33311
PH	27007	08/14/2013	Regional Health Partners, Llc				125 Sw 7Th Street	Williston, FL 32696
PH	27008	08/14/2013	Publix Super Markets, Inc.				1324 Lakeland Hills Blvd Suite 203	Lakeland, FL 33805
PH	27009	08/14/2013	Rush Family Care Inc.				11115 Sw 93Rd Court Road Unit #300	Ocala, FL 34481
PH	27010	08/14/2013	Kash N' Karry Food Stores, Inc				2500 Burnsed Blvd	The Villages, FL 32163

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
7/ 1/2013 - 8/31/2013

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27011	08/14/2013	Wexford Health Sources				33123 Oil Well Road	Punta Gorda, FL 33955
PH	27012	08/14/2013	Rsks Pharmacy Llc				4710 N Habana Ave	Tampa, FL 33614
PH	27013	08/15/2013	Ethical Factor Rx Llc				330 Montage Mountain Road Suite A-11	Moosic, PA 18507
PH	27014	08/16/2013	National Surgical Centers Of America				5365 W Atlantic Ave Suite 501	Delray Beach, FL 33484
PH	27015	08/16/2013	Florida Health Sciences Center				1647 Sun City Center Plaza Suite 104	Sun City Center, FL 33573
PH	27016	08/16/2013	Florida Health Sciences Center				10647 Big Bend Road Suite 212	Riverview, FL 33579
PH	27017	08/16/2013	Compounding Solution Llc				27225 State Rd 56	Wesley Chapel, FL 33544
PH	27018	08/16/2013	Your Pharmacy In Miami Inc				1463 West Flagler St	Miami, FL 33135
PH	27019	08/16/2013	Behavioral Health Of Palm Beaches				106 Blossom Lane	Palm Beach Shores, FL 33408
PH	27020	08/16/2013	G4S Youth Services, Llc				9508 East Columbus Drive	Tampa, FL 33619
PH	27021	08/16/2013	G4S Youth Services, Llc				3930 West Mlk Blvd	Tampa, FL 33614
PH	27022	08/16/2013	Behavioral Health Of Palm Beaches				7859 Lake Worth Road	Lake Worth, FL 33467
PH	27023	08/16/2013	Regency Care Of Blountstown, Llc				16690 S W Chipola Road	Blountstown, FL 32424
PH	27024	08/19/2013	Aids Healthcare Foundation				1164 E. Oakland Park Blvd 3Rd Floor	Oakland Park, FL 33334
PH	27025	08/19/2013	Citrus Health Network, Inc.				8375 South Palm Drive	Pembroke Pines, FL 33025
PH	27026	08/19/2013	Trinity Medical Pharmacy, Llc				9332 State Road 54 Suite 205	New Port Richey, FL 34655
PH	27027	08/19/2013	Wexford Health Sources				6901 State Road 62	Bowling Green, FL 33834
PH	27028	08/19/2013	Americure Rx - Florida Llc				5736 Clark Road	Sarasota, FL 34233
PH	27029	08/21/2013	Wexford Health Sources				1150 Southwest Allapattah Road	Indiantown, FL 34956
PH	27030	08/21/2013	Coram Alternate Site Services, Inc				4334 Brockton Drive Se Suite D	Kentwood, MI 49512

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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
PH	27031	08/21/2013	Operation Par Inc.				1245 Kass Circle	Spring Hill, FL 34606
PH	27032	08/21/2013	One To One Pharmacy Inc				4705 Sw 8 St #1	Coral Gables, FL 33134
PH	27033	08/22/2013	Sphinx Pharmacy Group				1201 Dairy Ashford Ste 114	Houston, TX 77079
PH	27034	08/22/2013	S & P Pharmacy Inc				7108 Envoy Court	Dallas, TX 75247
PH	27035	08/22/2013	Algunas Inc				23299 Ventura Blvd Suite 200	Woodland Hills, CA 91364
PH	27036	08/22/2013	Walgreen Co.				4005 Kilgore Ave	Muncie, IN 47304
PH	27037	08/23/2013	Florida Hospital Home Infusion, Llp				11461 N Us Hwy 301 Suite 105 & 106	Thonotosassa, FL 33592
PH	27038	08/23/2013	Suncoast Community Health Centers, Inc				1729 Lakeland Hills Blvd	Lakeland, FL 33805
PH	27039	08/23/2013	Wal-Mart Stores East, Lp				21151 S Dixie Hwy	Miami, FL 33189
PH	27040	08/23/2013	Reawakening Wellness Center Llc				3600 Red Road 5Th Floor	Miramar, FL 33025
PH	27041	08/23/2013	Clinical Pharmacology Services, Inc				6285 E. Fowler Ave	Tampa, FL 33617
PH	27042	08/23/2013	Northern Rx Llc				2012 E Northwest Hwy	Arlington Heights, IL 60004
PH	27043	08/26/2013	Catholic Hospice, Inc				4725 N Federal Hwy 5Th Floor-North	Fort Lauderdale, FL 33308
PH	27044	08/26/2013	Publix Super Markets, Inc				1180 Royal Palm Beach Blvd	Royal Palm Beach, FL 33411
PH	27045	08/27/2013	Wal-Mart Stores East, Lp				4520 South Semoran Blvd	Orlando, FL 32822
PH	27046	08/27/2013	Skyy Specialty Pharmacy Inc				6802 W. Hillsborough Ave	Tampa, FL 33634
PH	27047	08/28/2013	Inverness Apothecary Trinity Llc				24333 Gordon Terry Pkwy Suite B	Trinity, AL 35673
PH	27048	08/29/2013	M & M Beatty Llc				2112 Belair Rd Suite 11	Fallston, MD 21047
PH	27049	08/29/2013	Custom Made Pharmacy Inc				13322 Riverside Dr	Sherman Oaks, CA 91423
PH	27050	08/29/2013	California Drug Compounding, Llc				6878 Beck Ave	North Hollywood, CA 91605
PH	27051	08/29/2013	R & O Pharmacy, Llc				651 Via Alondra Unit 708 & 709	Camarillo, CA 93012

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27052	08/30/2013	Accredo Health Group, Inc.				6272 Lee Vista Blvd. Suite 100	Orlando, FL 32822

Total Records: **121**

Division of
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COMPAS DataMart Reporting System
Pharmacy Ratio Modifiers Report

Processed: 09/12/2013 11:31:30AM

Modifier Effective Date: 07/01/2013 - 08/31/2013

Prof	Organization Name	DBA Name	Rank	License #	File #	Issue Dte	Modifier Effct Dte	Mod Cde	Lic Status	Mailing Address	Phone	County
2205	305 PHARMACY INC	305 PHARMACY INC	PH	27058	20184	09/09/2013	08/15/2013	3PTR	CLEAR	11398 WEST FLAGLER STREET SUITE 109 MIAMI, FL 33174		Miami-Dade
2205	ACCREDO HEALTH GROUP, INC.		PH	27052	20115	08/30/2013	07/11/2013	3PTR	CLOSED	6272 LEE VISTA BLVD. SUITE 100 ORLANDO, FL 32822		Orange
2205	AIDS HEALTHCARE FOUNDATION	AHF PHARMACY	PH	27024	20089	08/19/2013	08/14/2013	3PTR	CLEAR	45 MELVILLE PARK ROAD MELVILLE, NY 11747		Unknown
2205	AIDS HEALTHCARE FOUNDATION	AHF PHARMACY			20183		08/15/2013	3PTR	APPL IN PROC	45 MELVILLE PARK ROAD MELVILLE, NY 11747		Unknown
2205	BERTYANN CORP.	BEST DISCOUNT & PHARMACY			20195		08/21/2013	3PTR	APPL IN PROC	510 WEST 29 STREET HIALEAH, FL 33012		Miami-Dade
2205	BERTYANN CORP.	BEST DISCOUNT AND PHARMACY			20207		08/26/2013	3PTR	APPL IN PROC	510 WEST 29 STREET HIALEAH, FL 33012		Miami-Dade
2205	BIOSCRIP INFUSION SERVICES, LLC	CAREPOINT PARTNERS			20142		07/22/2013	3PTR	APPL IN PROC	3986 BOULEVARD CENTER DRIVE SUITE 1 JACKSONVILLE, FL 32207		Duval
2205	BIOSCRIP INFUSION SERVICES, LLC	BIOSCRIP INFUSION SERVICES			20143		07/22/2013	3PTR	APPL IN PROC	5912 BRECKENRIDGE PARKWAY SUITE E TAMPA, FL 33610		Hillsborough
2205	CIRCLES OF CARE, INC.		PH	13653	4236	10/18/1995	08/01/2013	3PTR	CLEAR	400 EAST SHERIDAN ROAD MELBOURNE, FL 32901-3184	(321) 984-4900	Brevard
2205	CLEVELAND CLINIC FLORIDA PHARMACY SERVIC	CLEVELAND CLINIC FLORIDA	PH	26955	20104	07/19/2013	07/01/2013	3PTR	CLEAR	2950 CLEVELAND CLINIC BLVD WESTON, FL 33331		Broward
2205	COMPOUNDING SOLUTION LLC	WESLEY CHAPEL COMPOUNDING PHARMACY	PH	27017	20130	08/16/2013	07/16/2013	3PTR	CLEAR	27113 BRUSH CREEK WAY WESLEY CHAPEL, FL 33544		Pasco
2205	CORAL SCRIPT INC				20194		08/21/2013	3PTR	APPL IN PROC	7359 CORAL WAY MIAMI, FL 33155		Miami-Dade
2205	DARJEN INC		PH	27069	20145	09/12/2013	07/26/2013	3PTR	CLEAR	8645 N. MILITARY TRAIL #405-406 PALM BEACH GARDENS, FL 33418		Palm Beach
2205	ERGOGENIC LABS, LLC	ERGOGENIC LABS			20125		07/15/2013	3PTR	APPL IN PROC	1001 YAMATO ROAD #406 BOCA RATON, FL 33431		Palm Beach
2205	EXPRESS SPECIALTY PHARMACY, LLC	EXPRESS SPECIALTY PHARMACY, LLC			20189		08/16/2013	3PTR	APPL IN PROC	4200 S. HENDERSON BLVD TAMPA, FL 33629		Hillsborough
2205	FLORIDA HOSPITAL HOME INFUSION, LLP	FLORIDA HOSPITAL HOME INFUSION, TAMPA DI	PH	27037	19891	08/23/2013	08/20/2013	2PTR	CLEAR	556 Florida Central Parkway Suite 1044 LONGWOOD, FL 32750		Seminole
2205	GOLDENROD PHARMACY LLC				20200		08/23/2013	2PTR	APPL IN PROC	1433 CARING COURT MAITLAND, FL 32751		Orange
2205	GOOD HOMES PHARMACY LLC	GOOD HOMES PHARMACY			20186		08/15/2013	2PTR	APPL IN PROC	9816 CAMBERLEY CIRCLE UNIT 230 ORLANDO, FL 32836		Orange
2205	HILLCREST PROPERTIES VII, INC	HILLCREST PROPERTIES VII	PH	27066	20146	09/10/2013	07/29/2013	3PTR	CLEAR	421 9TH STREET NORTH NAPLES, FL 34102		Collier
2205	IMPERIAL POINT PHARMACY CENTER, INC.		PH	26971	20124	07/29/2013	07/15/2013	3PTR	CLEAR	6278 NORTH FEDERAL HWY #139 FORT LAUDERDALE, FL 33308		Broward
2205	MARIA GROUP L L C	NORTHBAY PHARMACY			20112		07/03/2013	2PTR	APPL IN PROC	15835 BEREA DR ODESSA, FL 33556		Hillsborough
2205	MARTIN MEMORIAL MEDICAL CENTER INC.	TRADITION MEDICAL CENTER			20205		08/26/2013	2PTR	APPL IN PROC	PO BOX 9010 STUART, FL 34994		Martin
2205	MED CARE CHOICE PHARMACY, INC.	MED CARE CHOICE PHARMACY, INC.	PH	26972	20134	07/29/2013	07/19/2013	3PTR	CLEAR	3570 CONSUMER STREET SUITE 8 WEST PALM BEACH, FL 33404		Palm Beach

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COMPAS DataMart Reporting System
Pharmacy Ratio Modifiers Report

Processed: 09/12/2013 11:31:30AM

Modifier Effective Date: 07/01/2013 - 08/31/2013

Prof	Organization Name	DBA Name	Rank	License #	File #	Issue Dte	Modifier Effct Dte	Mod Cde	Lic Status	Mailing Address	Phone	County
2205	MEDS DIRECT RX OF FL, LLC				20227		08/30/2013	3PTR	APPL IN PROC	718 S MILITARY TRAIL DEERFIELD BEACH, FL 33442		Broward
2205	MY FAVORITE PHARMACY LLC.	MY FAVORITE PHARMACY LLC.	PH	27059	20196	09/09/2013	08/23/2013	3PTR	CLEAR	5368 NORTH UNIVERSITY DRIVE LAUDERHILL, FL 33351		Broward
2205	MY PHARMACY OF BIG BEND, LLC.	MY PHARMACY OF BIG BEND	PH	27065	20181	09/10/2013	08/15/2013	2PTR	CLEAR	5002 TARI STREAM WAY BRANDON, FL 33511		Hillsborough
2205	NATIONAL PHARMACY LLC	NATIONAL PHARMACY LLC	PH	27062	19985	09/10/2013	08/26/2013	3PTR	CLEAR	19533 NW 57TH AVE MIAMI, FL 33055		Miami-Dade
2205	NAVARRO HEALTH SERVICES NO. 3, LLC	NAVARRO HEALTH SERVICES LOC 5	PH	26997	20119	08/07/2013	07/11/2013	3PTR	CLEAR	9400 NW 104 STREET MEDLEY, FL 33178		Miami-Dade
2205	NEW ERA PHARMACEUTICALS LLC	NEW ERA SPECIALTY PHARMACY	PH	26973	20135	07/29/2013	07/08/2013	3PTR	CLEAR	3350 NW 53 Street Suite 102-103 FORT LAUDERDALE, FL 33309		Broward
2205	NEW LIFE COMMUNITY PHARMACY INC	NEW LIFE COMMUNITY PHARMACY INC			20180		08/15/2013	2PTR	APPL IN PROC	3032 N W 7TH AVE MIAMI, FL 33127		Miami-Dade
2205	ONE TO ONE PHARMACY INC	ONE TO ONE PHARMACY	PH	27032	20152	08/21/2013	07/30/2013	2PTR	CLEAR	4705 SW 8 ST #1 CORAL GABLES, FL 33134		Miami-Dade
2205	OPTIMUM CARE PHARMACY	OPTIMUM CARE PHARMACY			20208		08/26/2013	2PTR	APPL IN PROC	15 WARREN PL PALM COAST, FL 32164		Flagler
2205	PHARMAKON LLC	DUVAL PHARMACY	PH	24721	17473	06/28/2010	08/13/2013	3PTR	CLEAR	2386 DUNN AVENUE SUITE 117 JACKSONVILLE, FL 32218	(904) 696-8882	Duval
2205	PRESCRIPTIONS PLUS INC	PRESCRIPTIONS PLUS	PH	15876	6395	03/27/1998	07/12/2013	3PTR	CLEAR	3361 FAIRLANE FARMS ROAD WELLINGTON, FL 33414	(561) 795-1636	Palm Beach
2205	PRIME RX LLC	PRIME RX	PH	27056	20133	09/09/2013	07/19/2013	2PTR	CLEAR	10420 N. MCKINLEY DR. TAMPA, FL 33612		Hillsborough
2205	PUBLIX SUPER MARKETS, INC	PUBLIX PHARMACY #0362	PH	27044	20131	08/26/2013	07/16/2013	3PTR	CLEAR	PO BOX 32018 ATTN: BAR/TAX LAKELAND, FL 33802		Polk
2205	PUBLIX SUPER MARKETS, INC	PUBLIX PHARMACY #1450			20212		08/27/2013	3PTR	APPL IN PROC	PO BOX 32018 ATTN: BAR/TAX LAKELAND, FL 33802		Polk
2205	PUBLIX SUPER MARKETS, INC.	PUBLIX PHARMACY #3211	PH	27008	20122	08/14/2013	07/15/2013	3PTR	CLEAR	P O BOX 32018 ATTN: BAR/TAX LAKELAND, FL 33802		Polk
2205	PUBLIX SUPER MARKETS, INC.	PUBLIX SPECIALTY PHARMACY #3212			20177		08/09/2013	3PTR	APPL IN PROC	P O BOX 32018 LAKELAND, FL 33802		Polk
2205	RURAL HEALTH CARE, INC.	AZALEA HEALTH			20147		07/29/2013	3PTR	APPL IN PROC	1305 N ORANGE AVE SUITES 120-123 GREEN COVE SPRINGS, FL 32043		Clay
2205	RUSH FAMILY CARE INC.	RITE CARE PHARMACY	PH	27009	20126	08/14/2013	07/16/2013	2PTR	CLEAR	5070 SW 63RD LOOP OCALA, FL 34474		Marion
2205	S & Z KHAN, CORP	ZEPHYRHILLS PHARMACY	PH	26950	20129	07/11/2013	07/03/2013	3PTR	CLEAR	10212 Garden Alcove Drive TAMPA, FL 33647		Hillsborough
2205	SKYY SPECIALTY PHARMACY INC	BRENT SPECIALTY PHARMACY	PH	27046	20127	08/27/2013	07/16/2013	3PTR	CLEAR	6802 W. HILLSBOROUGH AVE TAMPA, FL 33634		Hillsborough
2205	SOUTH BROWARD HOSPITAL DISTRICT	MEMORIAL HOME INFUSION	PH	26978	20111	07/30/2013	07/08/2013	3PTR	CLEAR	3600 Washington Street HOLLYWOOD, FL 33021		Broward
2205	SOUTHEAST COMPOUNDING PHARMACY LLC	SOUTHEAST COMPOUNDING PHARMACY			20231		08/30/2013	3PTR	APPL IN PROC	3906 CRAGMONT DR TAMPA, FL 33619		Hillsborough
2205	ST PETE COMPOUNDING PHARMACY LLC	ST PETE COMPOUNDING PHARMACY			20116		07/11/2013	3PTR	APPL IN PROC	3434 13TH AVE N SAINT PETERSBURG, FL 33713		Pinellas

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COMPAS DataMart Reporting System
Pharmacy Ratio Modifiers Report

Processed: 09/12/2013 11:31:30AM

Modifier Effective Date: 07/01/2013 - 08/31/2013

Prof	Organization Name	DBA Name	Rank	License #	File #	Issue Dte	Modifier Effct Dte	Mod Cde	Lic Status	Mailing Address	Phone	County
2205	STREAMLINE LLC	STREAMLINE COMPOUNDING PHARMACY			20187		08/16/2013	2PTR	APPL IN PROC	14965 OLD ST. AUGUSTINE RD UNIT # 108 JACKSONVILLE, FL 32258		Duval
2205	TARGET CORPORATION	TARGET STORE T-2843			20201		08/23/2013	3PTR	APPL IN PROC	PO BOX 9471 TPN 0910 MINNEAPOLIS, MN 55403		Unknown
2205	TEN BROECK TAMPA, INC	NORTH TAMPA BEHAVIORAL HEALTH			20223		08/29/2013	3PTR	APPL IN PROC	29910 SR 56 WESLEY CHAPEL, FL 33543		Pasco
2205	WAL-MART STORES EAST, LP	WAL-MART PHARMACY #10-5912	PH	27039	20108	08/23/2013	07/01/2013	3PTR	CLEAR	702 SW 8TH ST BENTONVILLE, AR 72716		Unknown
2205	WALGREEN CO	WALGREENS #15617	PH	26987	19958	08/05/2013	07/22/2013	3PTR	CLEAR	PO BOX 901 DEERFIELD, IL 60015		Unknown
2205	WESTLAND PHARMACY INC	WESTLAND PHARMACY INC	PH	27064	20105	09/10/2013	07/01/2013	3PTR	CLEAR	12963 W. OKEECHOBEE RD #2 HIALEAH, FL 33018		Miami-Dade
2205	WINN DIXIE STORES, INC	WINN-DIXIE PHARMACY #177	PH	12541	3373	09/09/1993	07/25/2013	3PTR	CLEAR	POST OFFICE BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	YOUR PHARMACY IN MIAMI INC	YOUR PHARMACY IN MIAMI	PH	27018	20140	08/16/2013	08/06/2013	3PTR	CLEAR	1463 WEST FLAGLER ST MIAMI, FL 33135		Miami-Dade

Total: 54

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New License Report for 2209 : Pharmacy Technician Training Program

7/ 1/2013 - 8/31/2013

Sort Order: Original License Date

Processed: 9/12/2013 11:30:27AM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RTTP	396	07/02/2013	Superior Pharmacy Of Temple Terrace				5671 E Fowler Ave	Tampa, FL 33617
RTTP	397	07/26/2013	St Mina & Pope Kyrillos				30606 U.S. Hwy 19 N	Palm Harbor, FL 34684
RTTP	398	07/29/2013	Pharmtec, Inc				3900 Colonial Boulevard Suite 2	Fort Myers, FL 33966
RTTP	399	07/29/2013	Metro Rx				4809 E Colonial Dr	Orlando, FL 32803
RTTP	400	08/01/2013	Trust Pharmacy, Llc				36515 Us Hwy 19 N	Palm Harbor, FL 34684
RTTP	401	08/08/2013	Leon Medical Centers				101 Sw 27 Ave	Miami, FL 33135
RTTP	402	08/08/2013	Ford Drug, Inc. Dba Kings Pharmacy				7410 W. Boynton Beach Blvd. #A4	Boynton Beach, FL 33437
RTTP	403	08/08/2013	Ritter'S Towne Pharmacy				120 E New York Ave	Deland, FL 32724
RTTP	404	08/08/2013	Tampa Family Pharmacy				2919 W Swann Ave Suite 101	Tampa, FL 33609
RTTP	405	08/08/2013	Scott'S Pharmacy, Llc				6505 Hwy 29 North	Molino, FL 32577
RTTP	406	08/09/2013	Taylor College				5190 Se 125 St.	Belleview, FL 34420
RTTP	407	08/14/2013	Florida State College At Jacksonville				4501 Capper Road	Jacksonville, FL 32218
RTTP	408	08/19/2013	Wells Pharmacy Network				1210 Sw 33Rd Ave	Ocala, FL 34474
RTTP	409	08/19/2013	R.B. Watson'S Pharmacy, Inc.				16 West Wall Street	Frostproof, FL 33843
RTTP	410	08/29/2013	Suwannee-Hamiltontechnical Center				415 Sw Pinewood Drive	Live Oak, FL 32064
RTTP	411	08/30/2013	Genoa Healthcare Llc.				379 6Th Avenue West	Bradenton, FL 34205

Total Records: **16**

Provider Name	Provider #
DRUG STORE NEWS	50-3802
FLORIDA A&M UNIVERSITY COLLEGE OF PHARMACY AND PHARMACEUTICAL SCIENCES	50-3072
UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY	50-2419
JACKSON MEMORIAL HOSPITAL	50-9806
GANNETT EDUCATION	50-1489
INTERAMERICAN PHARMACISTS ASSOCIATION	50-2601
FLORIDA PHARMACY ASSOCIATION	50-754
FREECE.COM	50-3515
AKH INC. ADVANCING KNOWLEDGE IN HEALTHCARE	50-2560
GANNETT EDUCATION	50-1489
UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY	50-2419
PALMETTO GENERAL HOSPITAL	50-1545
PRIME EDUCATION, INC. (PRIME)	50-1649
AMERICAN SOCIETY OF CONSULTANT PHARMACISTS	50-3997
FLORIDA HOSPITAL HOME INFUSION	50-15680
RXSCHOOL	50-12503
PALM BEACH ATLANTIC GREGORY SCHOOL OF PHARMACY	50-11405
FLORIDA SOCIETY OF HEALTH SYSTEM PHARMACISTS	50-3036
BREVARD COUNTY PHARMACY ASSOCIATION	50-254
PHARMACIST'S LETTER THERAPEUTIC RESEARCH CENTER	50-2973
FLORIDA PHARMACY ASSOCIATION	50-754
THE SOUTH FLORIDA SOCIETY OF NUCLEAR MEDICINE TECHNOLOGISTS	50-7822
JACKSON MEMORIAL HOSPITAL	50-9806
UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY	50-2419
PALM BEACH ATLANTIC GREGORY SCHOOL OF PHARMACY	50-11405
AMERICAN SOCIETY OF CONSULTANT PHARMACISTS	50-3997
NOVA SOUTHEASTERN UNIVERSITY COLLEGE OF PHARMACY	50-2759
FLORIDA PHARMACY ASSOCIATION	50-754
UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY	50-2419

Course Name	Course #	Status
TREATMENT UPDATE FOR THE CARE OF PATIENTS INFECTED WITH HUMAN IMMUNODEFICIENCY VIRUS	20-399525	APPROVED
PREVENTING MEDICATION ERRORS RELATED TO ELECTRONIC SYSTEMS	20-397710	APPROVED
MEDICATION ERRORS: TO ERR IS HUMAN	20-398501	APPROVED
IF IT AINT BROKE, DONT FIX IT: WHY THIS APPROACH TO THE MEDICATION-USE PROCESS IS NOT SAFE FOR PATIENTS	20-399734	APPROVED
VACCINATION FOR PNEUMOCOCCUS, SHINGLES AND INFLUENZA	20-401866	APPROVED
REDUCING AND PREVENTING MEDICATION ERRORS/HIV UPDATE-2013	20-404236	APPROVED
REDUCING MEDICATION ERRORS THROUGH IMPLEMENTING A CONTINUOUS QUALITY IMPROVEMENT PROGRAM	20-406133	APPROVED
MEDICATION ERROR PREVENTION: A GUIDE FOR PHARMACISTS	20-400390	APPROVED
HIV/AIDS 2 HOUR UPDATE FOR KENTUCKY HEALTH PROFESSIONALS	20-306388	APPROVED
PREVENTING MEDICATION ERRORS FOR PHARMACISTS	20-401865	APPROVED
MEDICATION ERRORS: TO ERR IS HUMAN	20-398499	APPROVED
TIME IS BRAIN: GUIDELINES FOR THE EARLY MANAGEMENT OF PATIENT WITH ACUTE ISCHEMIC STROKE	20-399610	APPROVED
CUTTING RISKS: MEDICATION AND MEDICAL ERRORS PREVENTION TO ENSURE PATIENT SAFETY	20-400821	APPROVED
SENIOR CARE CENTRAL FLORIDA 2013	20-404295	APPROVED
OSHA & BIOHAZARDOUS WASTE ANNUAL REVIEW	20-402522	APPROVED
FLORIDA MEDICATION ERROR REDUCTION	20-393736	APPROVED
PRESCRIPTION FOR A MEDICAL ERROR PREVENTION	20-399756	APPROVED
6TH ANNUAL CENTRAL FLORIDA SOCIETY FALL SEMINAR	20-402942	APPROVED
MEDICAL AND MEDICATION ERRORS	20-399592	APPROVED
MEDICATION SAFETY: STRATEGIES FOR PREVENTING MEDICATION ERRORS	20-401847	APPROVED
REGULATORY AND LAW CONFERENCE	20-406120	APPROVED
20TH ANNUAL MEETING OF THE SOUTH FLORIDA SOCIETY OF NUCLEAR MEDICINE TECHNOLOGISTS	20-407314	APPROVED
IF IT AINT BROKE, DONT FIX IT: WHY THIS APPROACH TO THE MEDICATION-USE PROCESS IS NOT SAFE FOR PATIENTS	20-399735	APPROVED
REDUCING MEDICATION ERRORS IN YOUR PRACTICE	20-399679	APPROVED
CLINICAL UPDATES IN HIV THERAPY AND MANAGEMENT	20-400791	APPROVED
SENIOR CARE SOUTH FLORIDA 2013	20-404298	APPROVED
PHYSICAL ASSESSMENT INSTITUTE PATIENT CARE MANAGEMENT	20-400576	APPROVED
HIV/AIDS UPDATE	20-406137	APPROVED
APOLOGY AND MEDICAL/MEDICATION ERRORS	20-398698	APPROVED

Approved Date
8/2/2013
7/12/2013
7/12/2013
8/6/2013
8/9/2013
8/23/2013
8/30/2013
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8/30/2013
8/6/2013
6/30/2013
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Provider Name	Provider #
DRUG STORE NEWS	50-3802
FLORIDA A&M UNIVERSITY COLLEGE OF PHARMACY AND PHARMACEUTICAL SCIENCES	50-3072
UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY	50-2419
JACKSON MEMORIAL HOSPITAL	50-9806
GANNETT EDUCATION	50-1489
INTERAMERICAN PHARMACISTS ASSOCIATION	50-2601
FLORIDA PHARMACY ASSOCIATION	50-754
FREECE.COM	50-3515
AKH INC. ADVANCING KNOWLEDGE IN HEALTHCARE	50-2560
GANNETT EDUCATION	50-1489
UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY	50-2419
PALMETTO GENERAL HOSPITAL	50-1545
PRIME EDUCATION, INC. (PRIME)	50-1649
AMERICAN SOCIETY OF CONSULTANT PHARMACISTS	50-3997
FLORIDA HOSPITAL HOME INFUSION	50-15680
RXSCHOOL	50-12503
PALM BEACH ATLANTIC GREGORY SCHOOL OF PHARMACY	50-11405
FLORIDA SOCIETY OF HEALTH SYSTEM PHARMACISTS	50-3036
BREVARD COUNTY PHARMACY ASSOCIATION	50-254
PHARMACIST'S LETTER THERAPEUTIC RESEARCH CENTER	50-2973
FLORIDA PHARMACY ASSOCIATION	50-754
THE SOUTH FLORIDA SOCIETY OF NUCLEAR MEDICINE TECHNOLOGISTS	50-7822
JACKSON MEMORIAL HOSPITAL	50-9806
UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY	50-2419
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7/12/2013

Individual Name	Title of Course	Hours Offered
Wendy Heck	Social and Behavioral Aspects of Community Health	4 hours of general credit
Wendy Heck	Foundations of Biostatics	4 hours of general credit
Laura Annis	Preceptorship Program for Scientific Association of Novartis in the Disease Area of CIU/CSU	7.25 hours of general credit
Alva Scott Anderson	Current Concepts in Primary Care Cardiology	15 hours of general credit
Mary Alison Anderson	Current Concepts in Primary Care Cardiology	15 hours of general credit
Chen-Chung Wang	Advanced Pharmacy Practice Experience-Chronic Care	20 hours general credit

MEETING MINUTES
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
FULL BOARD MEETING

August 13-14, 2013
Rosen Plaza Hotel
9700 International Drive
Orlando, FL 32819
(407) 996-9700

Board Members:
Albert Garcia, BPharm, MHL, Chair, Miami
Jeffery J. Mesaros, PharmD, Vice-Chair, Tampa
Leo J. "Lee" Fallon, BPharm, PhD, The Villages
Debra B. Glass, BPharm, Tallahassee
Cynthia Griffin, PharmD, Jacksonville
Gavin Meshad, Consumer Member, Sarasota
DeAnn Mullins, BPharm, Lynn Haven
Lorena Risch, Consumer Member, Bradenton
Michele Weizer, PharmD, Boca Raton

Board Staff:
Mark Whitten, Executive Director
Tammy Collins, Program Operations Administrator
Jay Cumbie, Regulatory Specialist II

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

Department of Health Staff:
Yolanda Green, Assistant General Counsel
Matt Witters, Assistant General Counsel

Tuesday, August 13, 2013 – 1:00 p.m.

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

All Members were present.

TAB 1 REPORTS

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

No Information was discussed under the Chair's Report.

B. Executive Director's Report – Mark Whitten

Mark Whitten informed the Board that due to the 1:00 p.m. start time on the first day of the Board meeting, a committee meeting will be moved to the morning session at future Board meetings.

1. Jeff Mesaros – Rules Committee Update

Lynette Norr provided an update from the August 12, 2013 Rules Committee.

Ms. Norr introduced Rule 64B16-30.001 and discussed the changes made.

Motion: by Dr. Weizer, seconded by Dr. Griffin, to approve the changes. Motion carried.

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

Motion: by Dr. Weizer, seconded by Dr. Fallon, that the changes will not raise regulatory costs in excess of $200,000. Motion carried.

Ms. Norr introduced Rule 64B16-28.450 and the proposed language that adds institutional pharmacies to the rule.

Martin Dix approached the Board to state that voting to approve the rule for publication does not eliminate the ability to modify the rule.

Larry Gonzalez approached the Board to echo the thoughts of Mr. Dix and urged the Board to move this rule forward.

Mr. Garcia tabled the vote on this rule until later in order to give the Board members a chance to review the language.

Ms. Norr introduced Rule 64B16-28.605 regarding automated distribution and packaging.

Dr. Mesaros requested that, in the future, all the information that is sent to the Committee members be sent to all Board members for review.

Dr. Mesaros updated the Board members and audience of the discussion from the Rules Committee regarding validity of prescriptions.

Ms. Norr informed the Board of Dr. Weizer's suggestion to review Rule 64B16-28.303 and Rule 64B16-28.301 regarding destruction of controlled substances.

Dr. Weizer provided an overview of the aforementioned rules and discussed the reasons for why the rules need to be reviewed.

Motion: by Dr. Mesaros, seconded by Dr. Weizer, to open rules 64B16-28.303 and 28.301 for review. Motion carried.

Mr. Whitten requested that Mr. Garcia appoint two additional members to the Rules Committee.

Mr. Garcia appointed Dr. Weizer and Dr. Griffin to serve on the Rules Committee.

2. Michele Weizer – Compounding Rules Committee Update

Dr. Weizer provided an update from the Compounding Rules Committee and informed the Board and audience of the issues regarding a non-resident pharmacy in Texas having products recalled that they had shipped to Florida.

Dr. Weizer discussed how USP797 is a clarification of the 2008 USP71 rule that is already in existence.

Dr. Weizer informed the Board and audience that a full copy of USP797 is available for review in the Tallahassee Board office.

Mr. Flynn suggested a workshop for the purpose of going through USP797 line by line and exempting the requirements or guidelines that would have an unnecessary disproportionate negative effect on small business.

Ms. Mullins supported the idea of a noticed workshop to review USP797 to allow organizations such as the FPA to have workgroups prepared. Ms. Mullins also emphasized the importance of our rules being clear and defined as opposed to being just a reference to a chapter

Mr. Garcia proposed the formation of a committee comprised of three Board members and six advisors from the field to work on issues such as adoption of USP797.

Mr. Flynn informed the Board and audience that if said committee is to be formed; only the Board members would have voting rights.

Motion: by Ms. Mullins, seconded by Dr. Mesaros, to form a special committee comprised of three Board members and six advisors. Motion carried.

Motion: by Dr. Griffin, seconded by Ms. Mullins, to have the chair of the compounding committee select the advisors for the special committee. Motion carried.

Mr. Garcia stated that he would like this special committee to have met before the next Board meeting.

Dr. Weizer introduced a letter from Ken Plante regarding office use compounding.

Motion: by Mr. Garcia, seconded by Dr. Weizer, to respond to Mr. Plante reaffirming the Board's commitment to office use compounding. Motion carried.

Mr. Flynn introduced the non-resident draft legislation and explained the edits to Section 465.0156 including the deletion of the language requiring the Florida Board to notify the non-resident Board before taking action.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to approve the proposed language in Section 465.0156 Florida Statutes. Motion carried.

Mr. Flynn then introduced the changes to Section 465.0158 Florida Statutes, which refers to the Sterile Compounding Permit.

Ms. Mullins stated, in regards to patient safety, the importance of non-resident sterile compounding pharmacies having to comply with the same sterile compounding rules as our in-state sterile compounding pharmacies.

Motion: by Ms. Mullins, seconded by Dr. Weizer, to approve the addition of language that states non-resident pharmacy sterile compounding standards must be substantially equivalent or greater to the standards in the state of Florida. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to approve the proposed language in Section 465.0158. Motion carried.

Mr. Flynn introduced the changes to Section 465.017 Florida Statutes that would allow the Department to have the authority to enter into a non-resident pharmacy state and perform an inspection at the cost of the licensee.

Motion: by Dr. Weizer, seconded by Ms. Glass, to approve the proposed language in Section 465.017 Florida Statutes. Motion carried.

Ms. Mullins informed the Board and audience about a statement written by NABP taking a position of support on Senate Bill 959 regarding compounding and requested comment from the rest of the Board members.

Dr. Mesaros commented that Florida, as a whole, didn't have a comparative representation to some of the other Boards, Universities, and Associations that were present at the NABP District III meeting. Dr. Mesaros stated his

belief that the statement made by NABP was not to speak for the Boards that don't agree but the cumulative sentiment at the National meeting, which was of support for Bill.

Ms. Mullins stated her belief that Senate Bill 959 is not good for patient care in the current state it exists.

3. Lee Fallon – Report from FPA Meeting

Dr. Fallon provided a report on his trips to the FPA Annual meeting in Orlando as well as the Southeastern Gathering in Destin, FL.

Dr. Fallon reported that he and Mr. Whitten presented one hundred and twenty eight 50-year pharmacist certificates at the end of the FPA Annual meeting. Dr. Fallon stated that many of the recipients were present.

4. Unlicensed Activity Report

Mr. Whitten provided a report and informed the Board of some updates happening within the ULA program.

15 Minute Break

5. Request for PDM at Multiple Locations – Central Florida Family Health Center, Inc.

Central Florida Family Health Center, Inc. did not have a representative present.

Motion: by Mr. Meshad, seconded by Ms. Glass, to deny the request. Motion carried.

6. Correspondence – Sister Emmanuel Hospital

Carmen Aceves was present on behalf of Sister Emmanuel Hospital.

Ms. Aceves requested guidance from the Board regarding the necessity for her hospital to acquire the new sterile compounding permit despite the fact that her hospital does not have a sterile products room.

Mr. Flynn advised the Board that the Board cannot issue a license to the hospital if the hospital was unable to comply with all the laws and rules regulating sterile compounding.

Mr. Garcia informed the Board that they would now be revisiting the Rules Committee report to discuss Rule 64B16-28.901.

Martin Dix and Harold Cleveland approached the Board to discuss the proposed changes to the rule.

Motion: by Dr. Griffin, seconded by Ms. Glass, to approve proposed changes to Rule 64B16-28.901. Motion carried.

Motion: by Dr. Weizer, seconded by Ms. Glass, that there is no negative impact on small business. Motion carried.

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

C. Attorney General's Report – David Flynn, Assistant Attorney General

1. Rules Report

Mr. Flynn presented the Rules report. Mr. Flynn provided an update to Rule 64B16-28.100 and stated that the rule will be left open the entire time he is with the Board in order to continue to make changes in a more expeditious manner. Mr. Flynn stated that Rules 64B16-26.1031 and Rule 64B16-26.302 have both been adopted.

D. Prosecuting Attorney Report – Yolanda Green, Assistant General Counsel

1. Prosecution Services Report

Yolanda Green introduced herself and presented the Prosecution Services Report.

Ms. Green informed the Board that the probable cause panel (PCP) agendas are now going to have a cap of 55 cases maximum. Ms. Green stated that the cases over the cap of 55 will be heard on the dates that previously have been set aside exclusively for emergency suspension orders (ESO).

Motion: by Dr. Griffin, seconded by Dr. Weizer, to allow PSU to continue prosecuting old cases. Motion carried.

E. Chief Investigative Services Report – Jeanne Clyne

Mr. Whitten presented the Chief Investigative Services Report. Mr. Whitten stated that out of the 684 facilities that responded to the Board survey regarding sterile compounding, 194 stated that they perform only sterile compounding and 490 stated that they perform both sterile and non-sterile compounding. Mr. Whitten also stated that 97.5% of all pharmacy inspections for fiscal 2012-2013 have been completed.

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

A. Ratification of Issued Licenses/Certificates & Staffing Ratios

1. Pharmacist (Licensure) (Client 2201) – 137
2. Pharmacist (Exam Eligibility) (Client 2201) – 498
3. Pharmacist Interns (Client 2202) – 140
4. Registered Pharmacy Technicians (Client 2208) – 951
5. Consultant Pharmacist (Client 2203) – 41
6. Nuclear Pharmacist (Client 2204) – 2
7. Pharmacies/Facilities (Client 2205) – 103
8. Registered Pharmacy Technician Ratios (2:1 or 3:1)- 58
9. Pharmacy Technician Training Program (Client 2209) - 22
10. CE Providers – 14
11. CE Courses - 21
12. CE Individual Requests (Approved) – 0
13. CE Individual Requests (Denied) - 0

Motion: by Dr. Fallon, seconded by Dr. Weizer, to ratify items #1-13. Motion carried.

B. Review and Approval of Minutes

1. June 4-5, 2013

Ms. Mullins requested that two statements from the June meeting be rewritten.

Dr. Mesaros and Dr. Griffin requested that Ms. LuGina Mendez-Harper and Mr. Kyle Parker from the June meeting have the spelling of their names corrected.

Motion: by Dr. Weizer, seconded Dr. Griffin, to approve the minutes with changes. Motion carried.

C. Presentations

1. Board of Pharmacy Website

Allison Stachnik and Charlie Buck introduced the new Board agenda web portal. Ms. Stachnik stated that the new web portal is scheduled to be released in February.

Ms. Stachnik then introduced and provided a walkthrough of the new Florida Board of Pharmacy website.

Public Comments:

Mr. Garcia opened the floor to public comments.

Mr. Fritz Hayes approached the Board to discuss the 2014 Maltagon meeting that will be hosted in Florida. Mr. Hayes recommended contacting a University in regards to preparation for the meeting.

Motion: by Dr. Fallon, seconded by Ms. Glass to **ADJOURN** the meeting at 4:31 p.m. Motion carried.

Wednesday, August 14, 2013 – 9:00 a.m.

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

All members were present except Dr. Jeff Mesaros.

Mr. Garcia informed the audience that the meeting is being recorded and that an audio file will be posted to the website. Mr. Garcia informed the audience of live CE credit available.

Dr. Weizer introduced 64B16-28.450 regarding centralized prescription filling.

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

Motion: by Dr. Weizer, seconded by Ms. Glass, that there is no negative impact on small business. Motion carried.

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

Mr. Garcia introduced Rule 64B16-30.001 to be voted on for reconsideration.

Motion: by Dr. Weizer, seconded by Ms. Glass, to reconsider Rule 64B16-30.001. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Fallon, that there is no negative impact on small business. Motion carried.

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

TAB 3 **DISCIPLINARY CASES – Yolanda Green, Assistant General Counsel**

A. SETTLEMENT AGREEMENT– APPEARANCE REQUIRED CASES

A-1 Yader A Padilla, PSI 14777. Miami, FL
Case No. 2012-17316 PCP: Mullins/Glass/Weizer

Respondent violated:
Count One: Section 465.072(1)(x), F.S. (2010) by failing to report to the Board, or the department if there is no Board, in writing within 30 days after he was convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay fine of $1,000.00. Respondent shall pay costs in the amount of $3,000.00. Respondent must complete a Laws and Rules CE.

Respondent was not present nor represented by counsel.

Motion: by Dr. Griffin, seconded by Ms. Risch, to reject the Settlement Agreement. Motion carried.

Motion: by Dr. Griffin, seconded by Dr. Fallon, to offer a counter settlement for revocation. Motion carried.

A-2 Thomas John Lawley, PS 37816. Boca Raton, FL
Case No. 2013-02530, PCP: Fallon/Griffin

Respondent violated:
Count One: Section 465.016(1)(m), F.S. (2012) by being unable to practice pharmacy with reasonable skill and safety by reason of use of alcohol.
Count Two: Section 456.072(1)(hh), F.S. (2012) when PRN closed his file due to missing tests, refusing to refrain from practice, and testing positive for alcohol.

Terms of Settlement Agreement: Respondent shall by present. Respondent shall pay a fine of $1,000.00. Respondent shall pay costs of $5,000.00. Respondent must be evaluated by PRN and comply with any contract requirements. Respondent will be placed on probation for 5 years to run concurrent with his PRN contract. Respondent may not be prescription department manager for 2 years with his ability to act as prescription department manager be left to the discretion of PRN after the 2 year period.

Respondent was present and sworn in by the court reporter. Respondent was represented by Brian Kahan, Esq.

Penny Ziegler (Professionals Resource Network) was present and stated Mr. Lawley is currently under contract and has been compliant.

Motion: by Mr. Meshad, seconded by Ms. Mullins, to accept the Settlement Agreement. Motion carried.

A-3 G.M.G. Pharmacy and Discount, Inc, PH 26024. Hialeah, FL
Case No. 2012-16158 – PCP Meshad/Weizer

Respondent violated:
Count One: Section 465.023(1)(c), F.S. (2012) through a violation of Rule 64B16-28.109 F.A.C., which establishes that a pharmacy's prescription department shall be securely locked when the prescriptions department is closed.

Count Two: Section 465.023(1)(c), F.S. (2012) by violating Chapter 499, Florida Statutes, through a violation of Section 499.005(28), Florida Statutes (2012), which establishes that it is unlawful for any person to fail to acquire or deliver a pedigree paper as required under Part I of Chapter 499.
Count Three: Section 465.023(1)(c), F.S. (2012) by violating Chapter 499, Florida Statutes, through a violation of Section 499.005(1), Florida Statutes (2012), by holding and/or offering for sale, adulterated drugs.
Count Four: Section 465.023(1)(c), F.S. (2012) by violating Chapter 499(18), Florida Statutes (2012), through a violation of 61N-1.012(1)(a), F.A.C., 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 of other disposition of the product or component.

Terms of Settlement Agreement: Representative of Respondent shall be present. Respondent shall pay a fine of $5,000.00. Respondent shall pay costs of $1,650.11. Respondent shall be placed on two year probationary period requiring semi-annual inspections at Respondent's cost; and mandatory appearance by representative of respondent during the last three months of probation.

Hoiris Manrique (Owner of G.M.G. Pharmacy and Discount, Inc.) was present and sworn in the by the court reporter. Ms. Manrique was not represented by counsel.

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

A-4 Brashear's Vital Care Corp., PH 22730. Lecanto, FL
Case No. 2012-34461 – PCP Meshad/Weizer

Respondent violated
Count One: Section 465.023(1)(c), F.S., (2009, 2010, 2011), by violating Section 465.016(1)(c), F.S. (2009, 2010, 2011).
Count Two: Section 465.023(1)(c), F.S., (2009, 2010, 2011), by violating Section 465.016(1)(s), F.S. (2009, 2010, 2011).
Count Three: Section 465.023(1)(c), F.S., (2011), by violation of Section 456.072(1)(m), F.S., (2011).

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay fine of $1,500.00. Respondent shall pay costs of $1,168.96. Respondent shall be placed on probation for two years including semi-annual inspections at Respondent's cost and an appearance before the Board of Pharmacy during the last three months of probation.

Robert Brashear (President of Brashear's Vital Care Corp.) was present and sworn in by the court reporter. Mr. Brashear was represented by Brian Kahan, Esq.

Motion: by Ms. Mullins, seconded by Dr. Griffin, to accept the Settlement Agreement. Motion carried.

A-5 Alan E. Wingerter, PS 14151. Palatka, FL
Case No. 2012-12447 – PCP Fallon/Risch

Count One: Respondent violated 465.016(1)(r), F.S. (2009-2011) by violating Rule 64B16-26.300(1), F.A.C., which states 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.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay a fine in the amount of $5,000.00. Respondent shall pay costs of $774.16. Respondent shall complete 12 hour Laws and Rules course.

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

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

A-6 Edward B. Beckles, PS 30937. Wesley Chapel, FL
Case No. 2012-11079 – PCP Weizer/Risch

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.

Terms of Settlement Agreement: Respondent shall pay costs not over $921.56. Revocation of License.

Respondent was not present nor represented by counsel.

Motion: Dr. Griffin, seconded by Ms. Glass, to accept the Settlement Agreement. Motion carried

A-7 Robert M. Bojarzin, PS 19647. Ft. Meyers, FL
Case No. 2012-09524 – PCP Mullins/Glass/Fallon/Meshad

Count One: Respondent violated Section 465.015(1)(g), F.S.(2010) 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, except as authorized in Section 465.019(6) or Section 465.025.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay a fine of $500.00. Respondent shall pay costs not over $2,773.05. Respondent shall complete an 8 hour Medication Errors CE.

Case was granted a continuance to the next Board of Pharmacy meeting.

A-8 Cristina Zobeida Prades, PS 47726. Windermere, FL
Case No. 2012-19081 - PCP Griffin/Mesaros

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 of $250.00. Respondent shall pay costs limited to $1,000.52. Respondent shall complete an 8 hour Medication Error CE.

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

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

A-9 Jillian Vanessa Boyett, PS 38445. Orange Park, FL
Case No. 2012-12827 – PCP Mullins/Glass

Count One: Section 465.016(1)(e), F.S., (2010, 2011, 2012) by violating Chapter 499; 21 U.S.C. ss. Known as the Comprehensive Drug Abuse Prevention and Control Act, or Chapter 893 through a violation of Section 893.13(7)(a), F.S., F.S. (2010, 2011, 2012) , by acquiring or obtaining, or attempting to obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.
Count Two: Section 465.016(1)(i), F.S. (2010, 2011, 2012), by compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of professional practice of pharmacy.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay a fine of $5,000.00. Respondent shall pay costs limited to $3,000.00. Respondent shall complete a 12 hour Laws and Rules CE. Respondent must undergo PRN evaluation within 60 days of Final Order and comply with any contract offered. Respondent shall be placed on probation for 5 years.

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

Penny Ziegler (PRN) – stated that respondent has been compliant.

Respondent requested an extension on payment of fees.

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

Motion: by Dr. Griffin, seconded by Dr. Weizer, to accept original Settlement Agreement terms with ability to pay fees over course of probationary period. License cannot be restored until fees are paid. Motion carried.

A-10 Palm Springs General Hospital, PH 2235. Hialeah, FL
Case No. 2013-04842 – PCP Mullins/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 limited to $2,000.00.

Case was granted a continuance to the next Board of Pharmacy meeting.

B. DETERMINATION OF WAIVER

DOW-1 Mary's Pharmacy, Inc., PH 25755. Miami, FL
Case No. 2012-09094 – PCP Risch/Glass

Count One: Respondent violated Section 465.023(1)(c), F.S., by violating Rule 64B16-28.1081, F.A.C., which requires that 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.
Count Two: Respondent violated Section 465.023(1)(c), F.S., by violating Rule 64B16-28.202(3), F.A.C., by failing to notify the Board of Pharmacy in writing as to the effective date of closure and 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.

Motion: by Dr. Weizer, seconded by Dr. Griffin, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Griffin, 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. Griffin, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Griffin, 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 Dr. Fallon, to accept the recommendations of the Department. Motion carried.

DOW-2 Rebecca Jill Thomas, RPT 32912. Jacksonville, FL
Case No. 2012-14117 – PCP Weizer/Risch

Count One: Respondent violated Section 456.072(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.
Count Two: Respondent has 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.

Motion: by Ms. Mullins, seconded by Ms. Glass, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Ms. Mullins, seconded by Ms. Glass, to find that respondent was properly served and has waived the right to a formal hearing. Motion carried.

Motion: by Ms. Mullins, seconded by Ms. Glass, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Ms. Mullins, seconded by Ms. Glass, 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 Ms. Mullins, seconded by Ms. Glass, to accept the recommendations of the Department. Motion carried.

C. VOLUNTARY RELINQUISHMENTS

VR-1, VR-2, and VR-5

Motion: by Dr. Fallon, seconded by Dr. Griffin, to accept the Voluntary Relinquishments (VR-1, VR-2, VR-5). Motion carried.

VR-3, VR-8, VR-10

Motion: by Dr. Weizer, seconded by Ms. Glass, to accept the Voluntary Relinquishments (VR-3, VR-8, VR-10). Motion carried.

VR-1 Nelcia Anne Salmon, PS 28284. Plantation, FL
Case No. 2012-13568 – PCP Weizer/Meshad

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See motion at the beginning of the section.

VR-2 Jose Carlos Morales-Hernandez, PS 26289. Miami, FL
Case No. 2013-03651 – PCP Weizer/Meshad

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See motion at the beginning of the section.

VR-3 Quality Pharmacy, LLC, PH 25560. Tampa, FL
Case No. 2013-07690 – 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 at the beginning of the section.

VR-4 Coral West Pharmacy Inc., PH 14227. Coral Gables, FL
Case No. 2011-09924 – PCP Weizer/Risch

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Motion: by Ms. Glass, seconded by Dr. Griffin, to accept the Voluntary Relinquishment. Motion carried.

VR-5 Weight and Wellness Inc., PH 24846. Plantation, FL
Case No. 2012-13571 – Weizer/Meshad

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See motion at the beginning of the section.

VR-6 Alina De Armas, RPT 4154. Miami, FL
Case No. 2012-06796 – PCP Griffin/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 Ms. Glass, to accept the Voluntary Relinquishment. Motion carried.

VR-7 Marc W. Donegan, PS 31403. Miami Beach, FL
Case No. 2011-09628 – PCP Mullins/Risch

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Pulled by Prosecuting Services Unit.

VR-8 Aldo Patrick Schembari, RPT 43647. Madeira Beach, FL
Case No. 2012-14195 – 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 at beginning of the section.

VR-9 Aldo Patrick Schembari, RPT 43647. Madeira Beach, FL
Case No. 2012-14223 – PCP Mullins/Risch

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Motion: by Ms. Glass, seconded by Dr. Weizer, to accept the Voluntary Relinquishment. Motion carried.

VR-10 Jamie Lynn Mills, RPT 21930. Rockledge, FL
Case No. 2012-14470 – 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 at the beginning of the section.

D. BOARD ACTION BY HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

I-1 Robert M. Poland, PS 19244. Jacksonville Beach, FL
Case No. 2013-00276 – PCP Meshad/Weizer

Count One: 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 all rules adopted under those chapter as they relate to the practice of the profession of pharmacy and sale of prescription drugs.

Motion: by Ms. Mullins, seconded Dr. Griffin, to refer I-1 and I-2 back to probable cause panel. Motion carried.

Mr. Flynn explained to the Board and the audience that I-1 and I-2 have to be referred back to probable because there are no disciplinary guidelines for these particular violations.

I-2 North Beaches Pharmacy Inc., PH 7967. Jacksonville Beach, FL
Case No. 2013-00327 – PCP Weizer/Meshad

Count One: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-27.797, F.A.C., by failing to conform to the standards of practice for compounding sterile preparations.

Motion: **See related motion from I-1.**

I-3 Robert C. Brashear, PS 15856. Inverness, FL
Case No. 2012-10948 – PCP Fallon/Meshad

Count One: Respondent violated Section 465.016(1)(o), F.S. (2008, 2009, 2010, 2011) by 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.
Count Two: Respondent violated Section 465.016(1)(s), F.S. (2008, 2009, 2010, 2011) by dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by Section 465.003(14) F.S. or Section 893.02, F.S. when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.
Count Three: Respondent violated Section 456.072(1)(m), F.S. (2011) by 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.

The Respondent was present and sworn in by the court reporter. The respondent was represented by Brian Kahan, Esq.

Motion: by Ms. Glass, seconded by Dr. Griffin, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Ms. Glass, seconded by Dr. Griffin, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Ms. Glass, seconded by Dr. Griffin, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Ms. Glass, seconded by Dr. Griffin, 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 Ms. Mullins, seconded by Ms. Risch, to reject the recommendations of the Department and impose a $500.00 dollar fine and require Respondent to complete a 12 hour laws and rules CE. Motion carried.

Motion: by Dr. Griffin, seconded by Ms. Glass, to require Respondent to pay fine and costs within 90 days. Motion carried with Ms. Mullins in opposition.

I-4 Dino Jose Antonioni, PS 38504. Miramar, FL

Case No. 2012-14458. PCP – Griffin/Mesaros

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.

I-4 pulled due to issue with notice. Respondent must be notified in Federal prison.

I-5 La Perla Pharmacy, Inc., PH 24200. Miami, FL
Case No. 2012-18263. PCP – Meshad/Weizer

Respondent was not present nor represented by counsel.

Count One: Respondent violated 465.023(1)(c), F.S. (2012) by violating Rule 64B16-28.109 F.A.C.

Motion: by Matt Witters of Prosecuting Services Unit, seconded by Ms. Mullins, to pull the case for further investigation. Motion carried.

I-6 Vinesh C. Darji, PS 32062. Tampa, FL
Case No. 2010-08165. PCP – Fallon/Risch

Count One: Respondent violated Section 465.016(1)(e), F.S. (2012), by violating Chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. ss. 821 et set., known as the Comprehensive Drug Abuse Prevention and Control Act; or Chapter 893.

Respondent was not present nor represented by counsel.

Motion: by Dr. Weizer, seconded by Dr. Griffin, to allow case to be heard as an informal hearing. Motion carried.

Motion: by Ms. Glass, seconded by Dr. Weizer, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Ms. Glass, seconded by Dr. Weizer, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Ms. Glass, seconded by Dr. Weizer, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Ms. 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 of both Pharmacist License and Consultant Pharmacist License (I-7 companion case).

Motion: by Ms. Glass, seconded by Dr. Weizer, to accept the recommendations of the Department. Motion carried.

Motion: by Dr. Weizer, seconded by Ms. Glass, to allow Department withdraw motion to asses costs. Motion carried.

I-7 Vinesh C. Darji, PU 5660. Tampa, FL
Case No. 2010-08164 – PCP Fallon/Risch

Count One: Respondent violated Section 465.016(1)(e), F.S. (2012), by by violating Chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. ss. 821 et set., known as the Comprehensive Drug Abuse Prevention and Control Act; or Chapter 893.

See motion from I-6.

I-8 Tyronda Sanks, RPT 22120. Lauderhill, FL
Case No. 2012-14090 – PCP Mullins/Mesaros

Count One: Respondent violated 465.016(1)(e), F.S. (2011) by violating 893.13(6)(a), F.S. (2011), and Section 893.13(1)(a), F.S. (2012) when she sold the promethazine with codeine syrup.

Respondent was not present nor represented by counsel.

Motion: by Dr. Weizer, seconded by Dr. Griffin, to allow case to be heard as an informal hearing. Motion carried.

Motion: by Ms. Glass, seconded by Dr. Weizer, accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Ms. Glass, seconded by Dr. Weizer, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Ms. Glass, seconded by Dr. Weizer, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Ms. 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. Weizer, seconded by Dr. Fallon, to accept the recommendations of the Department. Motion carried.

Motion: by Dr. Weizer, seconded by Ms. Glass, to allow the Department withdraw motion to assess costs. Motion carried.

I-9 Lloyd Sylvestre Jones, RPT 18104. Miramar, FL
Case No. 2012-16183 – PCP Mullins/Glass

Count One: Section 456.072(1)(o), F.S. (2011), by practicing or offering to practice beyond the scope permitted by law ort accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform.

Count Two: Section 465.016(1)(e), F.S. (2011) through a violation of Chapter 499; 21 U.S.C. ss. 201-392, 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.

Respondent was present and sworn in by the court reporter. Respondent was represented by Lee Pulliam (Qualified Representative).

Motion: by Dr. Weizer, seconded by Dr. Griffin, to allow case to proceed as an informal hearing. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Griffin, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Dr. Weizer, seconded by, Dr. Fallon, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Fallon, 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 Mr. Garcia, seconded by Dr. Fallon, to accept the recommendations of the Department. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to allow Department to withdraw their motion for costs. Motion carried.

TAB 4 APPLICATIONS REQUIRING BOARD REVIEW

A. Examination Applicants

1. Olufeyikemi Awobusuyi, File No. 43898. Melbourne, FL.

Applicant was not present.

Motion: by Dr. Griffin, seconded by Mr. Garcia, to allow applicant to sit for the exam but not issue a license until a PRN evaluation has been completed. Motion failed with Dr. Weizer, Dr. Fallon, Ms. Mullins, and Ms. Risch in opposition.

Motion: by Dr. Weizer, seconded by Dr. Griffin, to allow applicant to sit for the exam but not issue the license until applicant has undergone a PRN evaluation and had that evaluation reviewed by the Board chair. Motion carried.

2. Ryan Richard Hire, File No. 43669. Naples, FL.

Applicant was present and sworn in by the court reporter.

Penny Zeigler (PRN) informed the Board that the applicant has been compliant with his PRN contract.

Motion: by Dr. Griffin, seconded by Mr. Garcia, to allow applicant to sit for the exam. Motion carried.

3. Markus Ville Tiitto, File No. 43573. West Palm Beach, FL.

Applicant was present and sworn in by the court reporter.

Penny Zeigler (PRN) informed the Board that the applicant has been compliant with PRN contract.

Motion: by Dr. Griffin, seconded by Dr. Fallon, to allow applicant to sit for the exam.

4. John Major, File No. 43928. Indian Shores, FL.

Applicant was present and sworn in by the court reporter.

Motion: by Dr. Fallon, seconded by Ms. Mullins, to allow applicant to sit for the exam. License shall not issue until PRN evaluation. If the applicant requires a contract, the decision on license delegated to Board chair.

Bob Parrado approached the Board to discuss a restaurant in the Orlando called "The Pharmacy". Mr. Parrado gave a description of the operation and stated to the Board that he believes their operation is in violation of Florida law and should be looked into further.

B. Endorsement Applicants

1. Cynthia Cruiser, File No. 42614. Narragansett, RI.

Applicant was present and sworn in by the court reporter.

Motion: Dr. Griffin, seconded by Dr. Weizer, to approve the application. Motion carried.

2. Louis P. Sosa, File No. 43580. Ormond Beach, FL.

Applicant was present and sworn in by the court reporter.

Motion: by Dr. Griffin, seconded by Dr. Weizer, to approve the application. Motion carried.

C. Pharmacy Intern Applications.

1. Adam Thomas Gabriel, File No. 19045. Worcester, MA.

Applicant was not present.

Penny Zeigler (PRN) approached the Board to inform them that PRN has the ability to identify and refer people to an evaluator in their home state. Ms. Zeigler stated PRN would vet the evaluator and that the evaluation would be considered a Florida PRN evaluation.

Motion: by Dr. Weizer, seconded by Dr. Griffin, to approve the application pending a PRN evaluation, compliance with PRN for one year, and appearance in front the Board after the year of compliance for a determination to be made. Motion carried.

D. Registered Pharmacy Technician Applications.

1. Torey Jamal Smothers, File No. 50085. Miami, FL.

Applicant was present and sworn in by the court reporter.

Motion: by Dr. Griffin, seconded by Dr. Weizer, to approve the application. Motion carried.

2. Ashley Woof, File No. 49512. Interlachen, FL.

Applicant was present and sworn in by the court reporter.

Motion: by Dr. Griffin, seconded by Ms. Glass, to approve the application. Motion carried.

3. William Ermatinger, File No. 49333. Spring Hill, FL.

Applicant was present and sworn in by the court reporter.

Motion: by Dr. Griffin, seconded by Dr. Weizer, to approve the application. Motion carried.

E. Non-Resident Pharmacy Permit Applications.

1. CarePoint Healthcare, LLC, File No. 19907. Schaumburg, IL.

Bhavesh Patel was present and sworn in by the court reporter.

Motion: by Dr. Griffin, seconded by Dr. Weizer, grant permit with the condition that the applicant will not ship sterile compounded products into the state of Florida. Motion carried.

2. Monroe Clinic Drugs, File No. 20073. Jackson, LA.

Applicant was not present.

Motion: by Dr. Griffin, seconded by Dr. Fallon, to reject the application. Motion carried.

TAB 5 LICENSURE ISSUES

A. Request for Termination of Probation

1. Kenneth S. Ginsburg, PS 25202. Lake Worth, FL.

Petitioner was present and sworn in by the court reporter.

Motion: by Dr. Weizer, seconded by Dr. Griffin, to terminate probation. Motion carried.

B. Request for Reinstatement of License

1. Anita Danna-Grimes, PS 30356. Mobile, AL.

Petitioner was present and sworn in by the court reporter.

Motion: by Ms. Mullins, seconded by Dr. Weizer, to grant reinstatement with conditions that the petitioner can only work at one location, cannot be a prescription department manager, and must be compliant with PRN.

2. Daniel Shack, PS 19555. Delray Beach, FL.

Petitioner was present and sworn in by the court reporter.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to deny the request for reinstatement. Motion carried.

C. Request for Board Appearance.

1. Amy K. Johnson, PS 15668. Gainesville, FL.

Petitioner was present and sworn in by the court reporter. Petitioner was represented by Brian Kahan Esq.

Penny Zeigler (PRN) stated that petitioner has been compliant with all PRN contract requirements.

Motion: by Dr. Weizer, seconded by Dr. Griffin, to terminate PRN contract. Motion carried.

D. Request for Appeal of Application Denial.

1. Ronald Lewis Jackson, File No. 42679. Daphne, AL.

Petitioner was present and sworn in by the court reporter.

Motion: by Dr. Fallon, seconded by Dr. Weizer, to vacate notice of intent to deny. Motion carried.

Motion: by Dr. Weizer, seconded by Ms. Mullins, to approve withdrawal of application. Motion carried.

Public Comments:

Mr. Garcia opened the floor to public comments:

Ms. Mullins spoke about NABP and their support for Senate Bill 959. Ms. Mullins stated the Bill gives the FDA more power and takes away authority from state Boards of Pharmacy.

David Joseph approached the Board to inform them of a proposed language in the House that is related to Senate Bill 959 that is vastly different from the version in the Senate. Mr. Joseph clarified it is not a Bill as of now but is expected to be a Bill once session starts back up.

Motion: by Ms. Mullins, seconded by Mr. Meshad, to have Executive Director Mark Whitten contact Carmen Catizone of NABP and invite him to participate in the Special Compounding Committee to discuss the NABP support of Senate Bill 959. Motion carried.

Motion: by Dr. Fallon, seconded by Dr. Griffin, to adjourn meeting at 2:11p.m. Motion carried.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201202690

PREMIER COMPOUNDING PHARMACY, INC,
RESPONDENT.

NOTICE

TO: PREMIER COMPOUNDING PHARMACY, INC
2000 PGA BLVD SUITE 5507
PALM BEACH GARDENS, FL 33408

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850)-236-6000.

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 9:00a.m. ;therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin C04

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Lucy Schneider, Assistant General Counsel
RE: **Settlement Agreement**
SUBJECT: DOH v. Premier Compounding Pharmacy, Inc.
DOH Case Number: 2012-02690
DATE: August 7, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Premier Compounding Pharmacy, Inc.
Subject's Address of Record:	2000 PGA Blvd Suite #5507 Palm Beach Gardens, FL 33408
Enforcement Address:	2000 PGA Blvd Suite #5507 Palm Beach Gardens, FL 33408
Subject's License No:	23481 **Rank:** PH
Licensure File No:	15528
Initial Licensure Date:	7/14/2008
Board Certification:	No
Required to Appear:	Yes
Current IPN/PRN Contract:	No
Allegation(s):	Section 465.023(1)(c), Florida Statutes (2011) by violating Section 499.005(22), Florida Statutes (2011)
Prior Discipline:	None
Probable Cause Panel:	September 25, 2012; Weizer & Mesaros
Subject's Attorney:	Edwin A. Bayo Grossman, Furlow & Bayo, LLC 2022-2 Raymond Diehl Road Tallahassee, FL 32308
Complainant/Address:	Department Of Health/Investigative Services Unit-West Palm Beach
Materials Submitted:	Memorandum to the Board Settlement Agreement Notice of Scrivener's Error Exhibit A- Administrative Complaint Board Notification Letter

Election of Rights
Cost Summary Report
Defense Attorney/Respondent Documents
Prosecutor's Documents
Supplemental Investigative Report dated
6/19/12, 7/19/12 & 7/26/12
PCP Memo
Final Investigative Report
Exhibits 1-6

LS/bhh/ab

DISCIPLINARY GUIDELINES:

Section 465.023(1)(c), Florida Statutes, through a violation of chapter 499 by operating without a repackaging and/or whole retail pharmacy drug wholesale distributor permit: Utilized closest disciplinary guideline for unpermitted practice - minimum $2,500 fine up to revocation.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

This is a one count administrative complaint alleging Respondent violated Section 465.023(1)(c), Florida Statutes (2011), by violating Chapter 499, Florida Statutes, through a violation of Section 499.005(22), Florida Statutes (2011), which establishes that it is unlawful for any person to fail to obtain a permit or registration, or operate without a valid permit or registration as required by Chapter 499, in this case a prescription drug repackager permit required by Section 499.01(2)(b), Florida Statutes, and/or a retail pharmacy drug wholesale distributor permit required by Section 499.01(2)(f), Florida Statutes.

Mitigating /Aggravating Conditions: None

Terms of Settlement Agreement:

- Appearance
- Fine of $3,000.00
- Costs not to exceed $3,976.92

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. CASE NO. 2012-02690

PREMIER COMPOUNDING 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, Premier Compounding Pharmacy, Inc., was a permitted community pharmacy in the state of Florida, having been issued permit number PH 23481. Respondent's mailing address of record is 2000 PGA Boulevard, Suite 5507, Palm Beach Gardens, Florida 33408.

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's representative 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 **THREE THOUSAND DOLLARS** ($3,000.00). 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. **Payment must be made by cashier's check or money order ONLY.** Personal Checks shall NOT be accepted.

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 **THREE THOUSAND, NINE HUNDRED AND SEVENTY SIX DOLLARS AND NINETY TWO CENTS ($3,976.92**). 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 90 days from the date the Final Order is filed with the Department Clerk. **Payment must be made by cashier's check or money order ONLY.** Personal Checks shall **NOT** be accepted.

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.

6. **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.

7. **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.

8. **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.

9. **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.

10. **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.

11. **Current Addresses**- Respondent shall keep current its mailing address and 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 27th day of DECEMBER, 2012

Premier Compounding Pharmacy, Inc.
CASE NO. 2012-02690

STATE OF Florida

COUNTY OF Palm Beach

Before me personally appeared _____, 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 27 day of December, 2012.

Notary Public
My Commission Expires: 11-8-2015

FAY HUBERT
MY COMMISSION # EE 144926
EXPIRES: November 8, 2015
Bonded Thru Notary Public Underwriters

APPROVED this 3 day of January, 2013.

JOHN H. ARMSTRONG, MD
State Surgeon General and
Secretary of Health

Lucy Schneider
Assistant General Counsel
Florida Department of Health
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No. 0815349
Telephone: (850) 245-4640
Facsimile: (850) 245-4680

Schneider, Lucy

From: Reinhart, Bruce [breinhart@mcdonaldhopkins.com]
Sent: Monday, December 31, 2012 10:32 AM
To: Schneider, Lucy
Subject: Premier Compounding Pharmacy Settlement Agreement
Attachments: BOP settlement agreement (4119945).PDF

Lucy,

Attached is an executed copy of the Settlement Agreement. I will forward the original under separate cover.

Bruce Reinhart

Bruce E. Reinhart
Member

T: 561-472-2970
breinhart@mcdonaldhopkins.com
www.mcdonaldhopkins.com

McDonald Hopkins
A business advisory and advocacy law firm®

Flagler Center Tower
505 South Flagler Drive
Suite 300
West Palm Beach, FL 33401

Chicago • Cleveland • Columbus • Detroit • Miami • West Palm Beach

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

V. **CASE NO. 2012-02690**

PREMIER COMPOUNDING PHARMACY, INC.,

RESPONDENT.
_____/

NOTICE OF SCRIVENER'S ERROR

Petitioner, the Florida Department of Health, by and through its undersigned counsel, hereby files this Notice of Scrivener's Error, and as grounds therefore states: On or about September 27, 2012, Petitioner filed an Administrative Complaint against the pharmacy license of Respondent, Premier Compounding Pharmacy, Inc.

1. Due to a clerical error in paragraph twenty-three (23), it is alleged that Respondent violated Section 465(1)(c), Florida Statutes (2011).

2. Paragraph twenty-three (23) should reflect that Respondent is alleged to have violated Section 465.023(1)(c), Florida Statutes (2011).

3. The correction of this error is of no prejudice to Respondent and makes no substantive change to the Administrative Complaint.

4. This Notice shall take effect upon its filing with the Clerk of the Department.

WHEREFORE, Petitioner requests that the Administrative Complaint filed against the License of Premier Compounding Pharmacy, be amended to reflect the correction detailed above.

Respectfully Submitted,

John H. Armstrong, MD
State Surgeon General and Secretary of Health

Lucy Schneider
Assistant General Counsel
Florida Department of Health
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No.: **0815349**
Telephone: (850) 245-4640
Facsimile: (850) 245-4680

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 12th day of October, 2012, to Premier Compounding Pharmacy, Inc., 2000 PGA Boulevard, Suite 5507, Palm Beach Gardens, Florida 33408.

Lucy Schneider
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO.: 2012-02690**

PREMIER COMPOUNDING PHARMACY, INC.,

RESPONDENT.

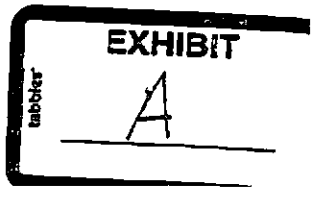
_____/

ADMINISTRATIVE COMPLAINT

Petitioner, the Florida Department of Health (Petitioner), by and through the undersigned counsel, hereby files this Administrative Complaint before the Board of Pharmacy against Respondent, Premier Compounding Pharmacy, Inc. (Respondent), and in support thereof would state:

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 retail pharmacy permitted as a community pharmacy within the state of Florida, having been issued permit number PH 23481.



3. Respondent's address of record is 2000 PGA Boulevard, Suite 5507, Palm Beach Gardens, Florida 33408.

4. North County Surgicenter (NCS) is an outpatient surgical center located at 4000 Burns Road, Palm Beach Gardens, Florida 33410. NCS possesses a Type B Modified Class II Institutional pharmacy permit within the State of Florida, having been issued permit number PH 12060.

5. On or about November 3, 2011, NCS shipped twenty (20) packages of 5ml vials of Fentanyl to Respondent.

6. Respondent repackaged the twenty (20) packages of 5 ml vials of Fentanyl received from NCS, into fifty (50) packages of 2 ml vials of Fentanyl, that were shipped back to NCS on or about November 6, 2011.

7. Fentanyl is a prescription drug according to Section 499.003, Florida Statutes, and a Schedule II controlled substance under Chapter 893, Florida Statutes.

8. Section 499.003(49), Florida Statutes (2011), defines "repackage" to include repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

9. Section 499.01(2)(b), Florida Statutes (2011), establishes that a prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

10. Respondent sold or transferred the Fentanyl directly to NCS. Such sale or transfer was not patient-specific. Therefore, the drugs were not being dispensed to NCS as the patient's agent, but were being sold or transferred as a wholesale distribution.

11. Section 499.003(54), Florida Statutes (2011), defines "wholesale distribution" as distribution of prescription drugs to persons other than a consumer or patient.

12. Section 499.01(2)(f), Florida Statutes (2011) establishes that a retail pharmacy drug wholesale distributor permit is required for any retail pharmacy engaged in wholesale distribution of prescription drugs in this state.

13. Respondent was operating as a prescription drug repackager without possessing a prescription drug repackaging permit, and/or Respondent was operating as a retail pharmacy drug wholesale distributor without possessing a retail pharmacy drug wholesale distributor permit.

14. On or about November 17, 2011, NCS shipped thirty (30) packages of 5ml vials of Fentanyl to Respondent.

15. Respondent repackaged the thirty (30) packages of 5 ml vials of Fentanyl received from NCS, into seventy-five (75) packages of 2 ml vials of Fentanyl, that were shipped back to NCS on or about November 17, 2011.

16. As set forth above, Respondent was operating as a prescription drug repackager without possessing a prescription drug repackaging permit, and/or Respondent was operating as a retail pharmacy drug wholesale distributor without possessing a retail pharmacy drug wholesale distributor permit.

17. On or about December 20, 2011, NCS shipped thirty (30) packages of 5ml vials of Fentanyl to Respondent.

18. Respondent repackaged the thirty (30) packages of 5 ml vials of Fentanyl received from NCS, into seventy-five (75) packages of 2 ml vials of Fentanyl, that were shipped back to NCS on or about December 22, 2011.

19. As set forth above, Respondent was operating as a prescription drug repackager without possessing a prescription drug repackaging permit, and/or Respondent was operating as a retail pharmacy drug wholesale distributor without possessing a retail pharmacy drug wholesale distributor permit.

20. On or about April 10, 2012, NCS shipped four (4) packages of 50 mcg/ml vials of Fentanyl to Respondent.

21. Respondent repackaged the four (4) packages of 50 mcg/ml vials of Fentanyl received from NCS, into one hundred (100) packages of 25 mcg/ml vials of Fentanyl, that were shipped back to NCS on or about April 10, 2012.

22. As set forth above, Respondent was operating as a prescription drug repackager without possessing a prescription drug repackaging permit, and/or Respondent was operating as a retail pharmacy drug wholesale distributor without possessing a retail pharmacy drug wholesale distributor permit.

23. Section 465(1)(c), Florida Statutes (2011), 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 499, Florida Statutes.

24. Section 499.005(22), Florida Statutes (2011), provides that it is unlawful for a person to fail to obtain a permit or registration, or operate without a valid permit when a permit or registration is required by this part for that activity.

25. As set forth above, Respondent operated as a prescription drug repackager and/or retail pharmacy drug wholesale distributor without the possessing the required permits.

26. Based upon the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2011), by violating Chapter 499, Florida Statutes, through a violation of Section 499.005(22), Florida Statutes (2011), which establishes that it is unlawful for any person to fail to obtain a permit or registration, or operate without a valid permit or registration as required by Chapter 499, in this case a prescription drug repackager permit and/or a retail pharmacy drug wholesale distributor permit.

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 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 27th **day of** September, **2012.**

JOHN H. ARMSTRONG, MD
State Surgeon General and Secretary of Health

Lucy Schneider, 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. 0815349

/LS
PCP: September 25, 2012
PCP Members: Weiger AND Mesa Ros.

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.

August 7, 2013

Edwin A. Bayo, Esquire
Grossman, Furlow & Bayo, LLC
2022-2 Raymond Diehl Road
Tallahassee, FL 32308

Re: DOH vs. Premier Compounding Pharmacy, Inc.
DOH Case Number: 2012-02690

Dear Mr. Bayo:

The Settlement Agreement previously entered into by the parties in the case is presently being scheduled to be heard at the next regularly scheduled meeting of the Board. 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,

Lucy Schneider
Assistant General Counsel

LS/ab

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: 201202690

Subject's Name: PREMIER COMPOUNDING PHARMACY, INC

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	2.00	$115.25
Investigation:	23.00	$1,407.44
Legal:	20.50	$2,103.35
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	45.50	$3,626.04
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$3,626.04

-$2,103.35 Minus Legal fees

$1,522.69

August 7, 2013

Edwin A. Bayo, Esquire
Grossman, Furlow & Bayo, LLC
2022-2 Raymond Diehl Road
Tallahassee, FL 32308

Re: DOH vs. Premier Compounding Pharmacy, Inc.
DOH Case Number: 2012-02690

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Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Lucy Schneider
Assistant General Counsel

LS/ab

McDonald Hopkins
A business advisory and advocacy law firm®

Direct Dial: 561.472.2970
E-mail: breinhart@mcdonaldhopkins.com

McDonald Hopkins LLC
505 South Flagler Drive
Suite 300
West Palm Beach, FL 33401

P 1.561.472.2121
F 1.561.472.2122

October 24, 2012

By facsimile to (850) 245-4683

Lucy Schneider
Assistant General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin C65
Tallahassee, Florida 32399-3265

Re: Premier Compounding Pharmacy, Case No. 2012-02690

Dear Ms. Schneider:

Thank you for taking the time to chat with me on Monday. I look forward to working with you. This letter will confirm that McDonald Hopkins LLC will be representing Premier Compounding Pharmacy in the above-cited matter. I will be the primary point of contact.

Enclosed is an executed Election of Rights form indicating that we would like to pursue further settlement discussions in advance of an informal hearing before the Board of Pharmacy. To allow sufficient time for thorough and meaningful settlement discussions, we ask that this matter be placed on the agenda for the Board's meeting in February 2013.

Please contact me at 561-472-2970 or at breinhart@mcdonaldhopkins.com if you have any questions.

Sincerely,

Bruce E. Reinhart

ELECTION OF RIGHTS

DOH v. Premier Compounding Pharmacy, Inc. Case No. 2012-02690

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. X 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:

_____

_____

2012 OCT 29 AM 10: 05
PRACTITIONER REGULATION
LEGAL

In addition to the above selection, I also elect the following:

( ) ~~I accept the terms of the Settlement Agreement, have signed and am returning the Settlement Agreement or~~ I am interested in settling this case.

( ) I do not wish to continue practicing, have signed and returned the voluntary relinquishment of licensure 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.)

_____
Respondent's Name
Address: 2000 PGA Blvd., Ste 5507
Palm Beach Gardens, FL 33408
Lic. No. PH 23481
Phone No. (561) 691-4991
Fax No. (561) 691-4998

STATE OF FLORIDA
COUNTY OF Palm Beach

Before me, personally appeared Tracy Christian whose identity is known to me or by _____ (type of identification) and who, acknowledges that his/her signature appears above. Sworn to or affirmed by Affiant before me this 24th day of October 2012

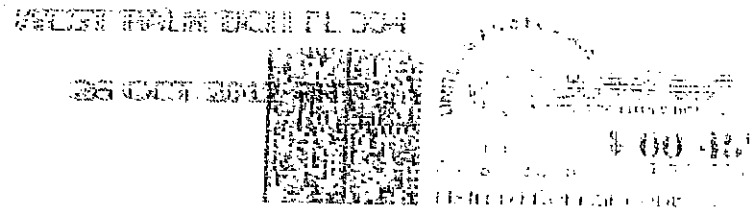
_____ 5/20/2014
Notary Public-State of Florida My Commission Expires

KAYLA M. CAVALLARO
MY COMMISSION # DD994281
EXPIRES: May 20, 2014
FL Notary Discount Assoc. Co.

_____
Type or Print Name

PLEASE MAIL AND/OR FAX COMPLETED FORM TO: Lucy Schneider, 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) 245-4683; TDD 1-800-955-8771.

McDonald Hopkins
A business advisory and advocacy law firm®
McDonald Hopkins LLC
505 South Flagler Drive
Suite 300
West Palm Beach, FL 33401



Lucy Schneider
Assistant General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin C65
Tallahassee, Florida 32399-3265

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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.

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Premier Compounding Pharmacy, Inc.**
Case Number: 2012-02690

MEMBERS: **Michele Weizer and Jeffrey Mesaros**

DATE OF PCP: September 25, 2012 **AGENDA ITEM:** A-07

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 (2011), by violating Chapter 499, Florida Statutes, through a violation of 499.005(22), Florida Statutes (2011), which establishes that it is unlawful for any person to fail to obtain a permit or registration, or operate without a valid permit or registration as required by Chapter 499, in this case a prescription drug repackager permit and/or a retail pharmacy whole drug wholesale distributor permit.

____ 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** _____

10/1/12

Chair, Probable Cause Panel
Board of Pharmacy

Date

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: West Palm Beach	Date of Case: 2/23/12	Case Number: 2012 - 02690

Subject:	Source:
PREMIER COMPOUNDING PHARMACY, INC 2000 PGA Blvd, Suite 5507 Palm Beach Gardens, FL 33408 O: (561) 691-4991	**DOH / ISU / West Palm Beach** 900 S. US Highway 1, Suite 207 Jupiter, FL 33477 O: (561) 743-4715

Prefix:	License #:	Profession:	Board:	Report Date:
PH	23481	Pharmacy	Pharmacy	5/29/12

Period of Investigation:	Type of Report:
03/07/12 – 5/29/12	FINAL

Possible Violations: F.S. 465.023(1)(c); 465.016(1)(e)(r); 456.072 (1)(j)(o); 893.03; FAC 64B16-28.110: non-compliance with the "Florida Drug and Cosmetic Act"; violating any provision of this chapter or chapter 456; aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice a profession contrary to this chapter; 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; and, failure of a licensee to take action in correcting the violation(s) within 15 days after notice may result in the institution of regular disciplinary proceedings.

Synopsis: This investigation is predicated upon receipt of an internally generated complaint (EX 1) submitted by the DOH as a result of a routine community pharmacy inspection (#105763) and a compounding inspection on 1/24/12 at PREMIER COMPOUNDING PHARMACY, INC (PREMIER) located in Palm Beach Gardens, FL. It is alleged that during the course of the routine inspection, violations were identified, as noted in the inspection reports (EX 4) including but not limited to: transferring drugs from PREMIER to NORTH COUNTY SURGI-CENTER, including incomplete DEA 222 forms; outdated stock on shelves due to inaccurate inventory/computer entries resulting in incorrect labeling of sub-compounded drugs that appear as expired; and, performing "centralized prescription filling" where PREMIER sends prescriptions to another pharmacy to be filled with their label, the filled prescription is sent back to PREMIER, relabeled and dispensed.

PREMIER'S owner was notified of the investigation in a letter dated 3/7/12 (EX 2) with a copy of the case summary and the DOH's inspection #105763.

A check of the Department computer records revealed that PREMIER COMPOUNDING PHARMACY, INC is currently licensed as a COMMUNITY PHARMACY.

There is no patient involvement; therefore a patient notification letter was not required.

PREMIER COMPOUNDING PHARMACY is **not known to be currently represented by an attorney.**

On 4/9/12, TRACY CHRISTIAN, R.Ph submitted a written response (EX 6) with supporting documents indicating it is her opinion that PREMIER is in compliance.

RECEIVED LEGAL 12 MAY 30 PM 1:42

Related Case(s): PS 2012-02762

Investigator/Date:	Approved By/Date:
5/29/12	5/29/12
JACQUELINE MANNING, Investigator WI101	CHRISTOPHER FERGUSON, Investigations Supervisor

Distribution: HQ/ISU

Received
Investigative Services
MAY 30 2012
DOH/MQA
Tallahassee HQ

TABLE OF CONTENTS

ALL RECORDS PERTAINING TO THE PHARMACY INSPECTION INCLUDED IN THIS FILE HAVE BEEN FORWARDED TO PSU FOR COPYING AND INCLUDING IN THE INVESTIGATIVE REPORT FOR RELATED CASE **PS 2012-02762.**

*** EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES.**

INVESTIGATIVE DETAILS

On 3/6/12 and subsequent dates, this investigator met with DOH Inspector NINA SAXON, WI 86, to discuss community pharmacy inspection #95178 (EX1) which SAXON performed on 1/23/12 and which generated this complaint. SAXON found the following:

- PREMIER is acting as a wholesaler and is repackaging medications they receive from NORTH COUNTY SURGI-CENTER, which purchases large packages of, but not limited to, Fentanyl in vials of 5ml, for example. These vials are sent to PREMIER who re-packages the Fentanyl in 2ml syringes to control waste. However, neither NORTH COUNTY nor PREMIER hold wholesaler permits; the transfer of the medication is not recorded in DEA 222 forms; PREMIER is not recording the re-packaging procedure and there are no records of traceability maintained at PREMIER.

- Multiple outdated compounds in stock were found in active stock. PREMIER claims the medication was not expired due to a computer generated error. Errors were found on labeling on manual sub-formula compounded drugs and that the computer generated labels were using bar-coded information from the label already in the computer. Staff is correcting the manual worksheet, but not updating the computer and the expired date on the bar-code label. PREMIER indicated they are addressing the issue and a new computer dedicated to the compounding of sterile preparations and bar-code function is forthcoming. It was noted that until the computer generated error is corrected, the expired dates on compounded stock remains incorrect. PREMIER does not know when the computer will be in place.

- PREMIER is performing what they call "centralized prescription filling". It was observed that PREMIER receives prescriptions including for HCG, a compounded hormone primarily used in weight loss; a doctor calls/faxes a prescription to PREMIER, PREMIER transfers the order by fax to KRS PHARMACY. KRS fills the prescription with a KRS label and then sends the filled prescription to PREMIER. PREMIER re-labels the prescription vial with PREMIER's label and dispenses the prescription as the filling pharmacy.

On 5/21/12, a re-inspection was performed at PREMIER with Inspector SAXON, this investigator, along with DOH Investigator, ROB SEIMETZ. Noted during the re-inspection were the following continued violations, with all copies obtained with pictures documented in (EX 5). TRACY CHRISTIAN, R.Ph was present during the re-inspection.

- Medication labels and outdated stock, including compounds were still found in active stock. Additional outdated stock was found during the re-inspection.

- The medication label errors discovered during the initial inspection were to be corrected once the new computer system was in place, per CHRISTIAN's response (EX 6). The computer has been installed and in use, however the labels have not been corrected with the proper bar-coded information. On 5/21/12, CHRISTIAN advised this would be corrected immediately.

- During the re-inspection, it was noted that employees utilizing the new computer are not entering their names at the time of sign-in, causing entries to be under the previous logged in user's name. The user name error potentially affects formula worksheets and all prescription documentation, if not corrected at sign-in. CHRISTIAN indicated immediate attention would be given to computer accuracy training.

- The DEA 222 forms inspected appeared to be completed adequately. CHRISTIAN was advised to have the receiver of the medications to sign for the receipt within the body of the form since the purchaser is not always the receiver.

- It was noted on the DEA 222 forms inspected that PREMIER continues to re-package Fentanyl for surgi-centers. CHRISTIAN indicated on 5/21/12 she has also diluted and repackaged Fentanyl at an institution's request, copies were provided. PREMIER's repackaging use to be in small vials; CHRISTIAN indicated syringes are preferable and most commonly requested. CHRISTIAN indicated it is her understanding that a Pharmacy wholesale permit is not required for "repackaging." CHRISTIAN's opinion is that she is compliant if the repackaging is for "institutional use".

- PREMIER also compounds Avastin 25 mg/ml 0.05ml injectable which is repackaged at 0.05ml into 30G insulin syringes. CHRISTIAN indicated it is held at PREMIER and filled as needed.

- CHRISTIAN indicated PREMIER accepted HCG (Human Chorionic Gonadotropin) prescriptions along with other hormone treatment prescriptions. PREMIER does not carry HCG and has to forward the requests to GBTRX in Boca Raton, FL. In the past, PREMIER would receive the filled prescription and dispense with PREMIER's label. CHRISTIAN indicated she discontinued this practice recently and no longer accepted prescriptions for HCG; a communication was sent to referring physicians that as a service to physicians and patients, PREMIER would continue to forward the HCG prescriptions to GBTRX, a pharmacy in Boca Raton, FL; however the filled prescription would be dispensed directly from GBTRX to the patient.

- There were various licensed registered pharmacy technicians present during the inspection, including JENNIFER DIVELY, a technical student in training who was working under CHRISTIAN's direct supervision. DIVELY was advised to email her credentials and transcript to the Board of Pharmacy.

- CHRISTIAN advised that PREMIER keeps a perpetual inventory of controlled substances II and III's. It was also observed that there was currently an overage in stock of six-Oxycodone 15 mg pills; CHRISTIAN was not aware of this. She advised she does not actively participate in the inventory process. It was suggested that she could strengthen the controls in place by signing-off at some interval of the inventory process.

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit 1 contains copies of the completed community pharmacy inspection 105763 on PREMIER COMPOUNDING PHARMACY, INC on 1/24/12. Included are SAXON's complaint forms and remarks.

Exhibit 3 are SAXON's work sheets and copies of various supports she obtained during the routine inspection on 1/24/12 including but not limited to, DEA 222 forms, a biennial inventory dated 1/10/11; and prescription logs for the period 11/1/11 – 1/24/12. Included is a copy of a Central Fill Pharmacy Contract between Premier Compounding and KRS Global Biotechnology dated 6/14/10.

Exhibit 4 includes three previous pharmacy inspections performed by DOH Inspector NINA SAXON at Premier Compounding, with TRACY CHRISTIAN R. Ph. Inspection # 95178 dated 1/4/11. In addition to a few administrative non-compliance findings, SAXON noted records were not separated by drug class; that a controlled substance biennial inventory had not been performed; and that DEA 222 forms had not been completed correctly; CQI meetings were not documented as required and a disclosure statement was missing from the daily sign in log.

A routine pharmacy inspection #84663 was attempted on 9/10/09 by SAXON, with TRACY CHRISTIAN, R.Ph. present, however SAXON noted required records were missing and the inspection was failed. A re-inspection was performed on 9/21/09 and documented on the same inspection # 84663. Among general administrative findings noted, the dispensing logs were found to be incomplete, inconsistent and not printed daily, and that records were not separated by drug class as required.

PREMIER's New Pharmacy Inspection #77743 dated 7/10/08 indicated Premier passed with minor operational findings: phone rolled over to a personal cell and P&P needed to be printed.

Exhibit 5 includes copies of PREMIER's re-inspection on 5/21/12, with copies of samples and pictures taken during the inspection, including communications from PREMIER to physicians regarding HCG prescriptions, copies of formula worksheets, copies of logs for Fentanyl prescription orders dispensed; Control II and III perpetual inventories, copies of DEA 222 forms; pictures of expired medications and compounds.

STATEMENT OF INSPECTOR NINA SAXON (SOURCE)
DOH / ISU / West Palm Beach
900 S. US Highway 1, Suite 207
Jupiter, FL 33477
O: (561) 743-4715

On 3/6/12 and subsequent dates, this investigator met with DOH Inspector NINA SAXON, WI 86, to discuss routine community pharmacy inspection #95178 (EX1) performed on 1/23/12, which generated this complaint. All communications, including the subsequent re-inspection (EX 5) done on 5/21/12 with SAXON, are detailed within the INVESTIGATIVE DETAILS section.

STATEMENT OF TRACY L. CHRISTIAN, R.Ph. (WITNESS)
18169 Woodside Trail
Jupiter, FL 33458
O: (561) 691-4991

On 3/21/12, CHRISTIAN provided a written statement (EX 6). On 4/18/12 and subsequent dates, she spoke with this investigator, and details of the re-inspection are in the INVESTIGATIVE DETAILS section; in a combination of all communications, she essentially stated:

- She is the PDM and President at PREMIER COMPOUNDING PHARMACY, INC since it opened in 2008.

- She admitted "some blank spaces" had been found on "some DEA 222 forms" as noted by SAXON during the inspection. CHRISTIAN indicated the pharmacists at Premier "are more comfortable ordering Control II substances online, therefore they are unfamiliar with the manual/hard copy form".

- She denied Premier is not signing in and out received Fentanyl. CHRISTIAN indicated there are DEA 222 forms receiving (EX 6) Schedule II and IIIs and other DEA 222s showing Schedule II and IIIs leaving Premier, She submitted copies of forms involving North County Surgi-Center.

Investigator's notes: Copies submitted by CHRISTIAN (EX 6) are not identical to those submitted by SAXON (EX 4).

- She denied Premier is not recording the re-packaging procedure. She indicated Premier has formula worksheets for each compounding manipulation performed which outlines the process for each item. Examples are in (EX 6).

- CHRISTIAN disagrees that there are no records of traceability at the facility.

- CHRISTIAN indicated in her written response dated 3/21/12 (EX 6) that the expired medications found in the pharmacy's sterile compounding area are not expired, but are labeled as such due to a computer issue and corrections are made manually. This will be corrected within two weeks of the response when a new computer and server are installed.

- The re-inspection (EX 5) done on 5/21/12 showed evidence that expired medications and compounds are still in active stock.

- CHRISTIAN denied PREMIER is working out of scope of a community pharmacy without a wholesaler license. CHRISTIAN indicated that according to Rule 64B16-28.450 she is filling prescriptions under centralized prescription rules and not acting as a wholesaler. Samples of orders were obtained during the re-inspection (EX 5).

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 HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

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

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201216677

CODY FAY BALLANCE,
RESPONDENT.

NOTICE

TO: CODY FAY BALLANCE
100 4TH AVE SOUTH #228
ST PETERSBURG, FL 33701

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850)-236-6000.

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 9:00a.m. ; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 –

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-16677**

CODY FAY BALLANCE, 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, Cody Fay Ballance, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 46832.

2. Respondent's mailing address of record is 100 Fourth Avenue South, # 228, Saint Petersburg, Florida 33701.

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 **FIVE HUNDRED DOLLARS ($500.00)**. 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. **Payment must be made by cashier's check or money order ONLY.** Personal Checks shall **NOT** be accepted.

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 TWELVE DOLLARS and SIXTY-TWO CENTS ($2,012.62).** 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. **Payment must be made by cashier's check or money order ONLY.** Personal Checks shall **NOT** be accepted.

4. **CE Course-** Respondent shall successfully complete a Continuing Education Course on the subject of Quality Related Events (QRE) 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.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 16 day of July, 2013.

Cody Fay Ballance, R.Ph.
CASE NO. 2012-16677

STATE OF Florida

COUNTY OF Pinellas

Before me personally appeared Cody Fay Ballance, R.Ph., whose identity is known to me or by Florida Driver License (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 16 day of July, 2013.

Notary Public
My Commission Expires:

MICHELLE A. COLEMAN
Notary Public - State of Florida
My Comm. Expires Oct 30, 2015
Commission # EE 134978
Bonded Through National Notary Assn.

APPROVED this 25th day of July, 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: 850.245.4640
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. 2012-16677

CODY FAY BALLANCE, 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, Cody Fay Balance, 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 46832.

EXHIBIT
A

3. Respondent's address of record is 100 Fourth Avenue South, #228, Saint Petersburg, Florida 33701.

4. On or about October 29, 2012, a prescription for Nitrofurantoin was ordered for Patient M.M.

5. On or about October 29, 2012, Respondent furnished prescription number 1058581-02524 for Patient M.M. The medication furnished was Gabapentin.

6. 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 constitutes grounds for disciplinary action by the Board of Pharmacy.

7. Respondent furnished upon prescription an ingredient or article different from the ingredient or article prescribed by furnishing Gabapentin for Patient M.M. instead of the prescribed Nitrofurantoin.

8. Based on the foregoing, 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.

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 20th **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
Fla. Bar No. 0780420
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444, ext. 8104
Facsimile: (850) 245-4683
Email: Mary_Miller2@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Amy L Carey
DATE 6-21-13

PCP: June 20, 2013
PCP Members: Risch + Nasaros

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.

August 26, 2013

Michael Schwartz, Esquire
410 North Gadsden Street
Tallahassee, FL 32301

Re: DOH vs. Cody Fay Balance, R.Ph.
DOH Case Number: 2012-16677

Dear Mr. Schwartz:

I am in receipt of the settlement agreement executed by your client on July 16, 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

ELECTION OF RIGHTS

DOH v. Cody Fay Balance, R.Ph. Case No. 2012-16677

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 Agreement, have signed and am returning the Settlement Agreement or I am interested in settling this case.

( ) I do not wish to continue practicing, have signed and returned the voluntary relinquishment of licensure 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.)

Cody Ballance Cody Fay Ballance
Respondent's Name

Address: [redacted]

Lic. No. [redacted]

Phone No. [redacted]

Fax No. _____

STATE OF FLORIDA
COUNTY OF Pinellas

Before me, personally appeared Cody Ballance, whose identity is known to me or by Florida Driver License (type of identification) and who, acknowledges that his/her signature appears above. Sworn to or affirmed by Affiant before me this 16 day of July 2013.

Notary Public-State of Florida

My Commission Expires Oct. 30. 2015

Michelle A Coleman
Type or Print Name

PLEASE MAIL AND/OR FAX COMPLETED FORM TO: Mary S. Miller, 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) 245-4683; TDD 1-800-955-8771.

MICHELLE A. COLEMAN
Notary Public - State of Florida
My Comm. Expires Oct 30, 2015
Commission # EE 134978
Bonded Through National Notary Assn.

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Search	Complaint/Case Number: 201216677	MAIN	HELP

Complaint Cost Summary

Complaint Number: 201216677

Subject's Name: BALLANCE, CODY FAY

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**2.30**	**$126.28**
Investigation:	**8.70**	**$556.62**
Legal:	**3.10**	**$329.72**
Compliance:	**0.00**	**$0.00**
	**********	**********
Sub Total:	**14.10**	**$1,012.62**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$1,012.62**

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Cody Fay Ballance, R.Ph. (MSM)**
Case Number: 2012-16677

MEMBERS: **Gavin ~~Meshad and~~ Michele Weizer** Mesars / Rusch

DATE OF PCP: **June 20, 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 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)

___ Upon **reconsideration**, dismiss

___ **other**

2013 JUL -5 PM 3:24

6/20/13

Chair, Probable Cause Panel
Board of ~~Pharmacy~~

Date

MICHAEL I. SCHWARTZ
Attorney at Law
410 N. Gadsden Street
Tallahassee, Florida 32301
Phone: (850) 224-1088
Fax: (850) 224-0085

February 8, 2013

VIA FAX ONLY – 727/552-1157

Mr. Ron Dilworth
Investigative Services – DOH
525 Mirror Lake Drive North
Suite 310A
St. Petersburg, FL 33701

Re: Cody Balance – Case No. 2012-16677 (Companion to 2012-17685

Dear Mr. Dilworth:

Please be advised that above-noted case has just been referred to me by Walgreens for representation. As such, please consider this as the response to the initial complaint letter dated December 7, 2012, as well as my notice of appearance as counsel. Further, all requests for information should be submitted through my office.

Further, pursuant to Section 456.073(10), *Florida Statutes*, I am requesting copies of the completed investigative files. After receipt and review of the requested information, a determination will be made (within 20 days of receipt of the investigative file) as to the filing of any additional response prior to the matter going to the Probable Cause Panel for consideration.

Another notice of appearance should be filed in a companion case once Walgreens refers the case to me. In the meantime, should you have any questions regarding this matter, please feel free to contact me.

Sincerely,

Michael I. Schwartz

Cc: Thomas Isbon, Walgreens
Patty Zagami, Walgreens
Cody Balance, RPH

Pls confirm receipt

7196 9008 9111 8826 4705

TO:

456 CA
Cassandra/Miller
Date Mailed 4/5/2013
2012-16677

SENDER:

REFERENCE:
Ballance, Cody

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 4705

3. Service Type CERTIFIED MAIL™

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Michael Schwartz, Esquire
410 N. Gadsden Street
Tallahassee, FL 32301

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? ☐ Yes
If YES, enter delivery address below: ☐ No

Reference Information

456 CA 2012-16677
Cassandra/Miller

Ballance
68

PS Form 3811, January 2005 Domestic Return Receipt

April 5, 2013

Certified Article Number
7196 9008 9111 8826 4705
SENDERS RECORD

Michael Schwartz, Esquire
410 N. Gadsden Street
Tallahassee, FL 32301

Re: Complaint No. 2012-16677
Respondent: Cody Fay Ballance, R.Ph.

Dear Mr. Schwartz:

Pursuant to section 456.073(10), Florida Statutes, you requested a copy of the Department's investigative file prior to the submission of this matter to the probable cause panel. 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.

Upon receipt of this form, and a determination by the Department to recommend that an Administrative Complaint be filed, a copy of the investigative file, including any expert witness report or patient record, will be forwarded to you for review. Our office will not make duplicates of any x-rays contained within the investigative file unless specifically requested to do so. You will have twenty (20) days from the date of mailing to file your response with the Department, unless an extension is granted by the attorney handling this matter.

However, please note that the Department is only required to provide a copy of the investigative file after the investigation has been completed and only if the Department is recommending an

Administrative Complaint. A copy of the file will not be provided if the Department recommends closure of the complaint.

If you have any questions, please give me a call at (850) 245-4444 ext. 8104.

Respectfully,

Mary S. Miller
Assistant General Counsel

MSM/cmn

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 on behalf of Cody Fay Ballance, R.Ph.

_____
Michael Schwartz, Esquire

Acknowledgement of and
Agreement to Maintain Patient Confidentiality

I, Michael Schwartz, represent, 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 9th day of April, 2013 on behalf of Cody Fay Ballance, R.Ph.

Michael Schwartz, Esquire

April 19, 2013

Certified Article Number
7196 9008 9111 8827 2731
SENDERS RECORD

Michael Schwartz, Esquire
410 N. Gadsden Street
Tallahassee, FL 32301

Re: Complaint No. 2012-16677
Respondent: Cody Fay Balance, R.Ph.

Dear Mr. Schwartz:

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.

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 8104.

Respectfully,

Mary S. Miller
Assistant General Counsel

MSM/cmn

Enclosures: Invoice # MQPR13-561
Investigative File # 2012-16677

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

INVESTIGATIVE REPORT

Office:	Date of Case:	Case Number:
St. Petersburg	11/30/2012	PS2012-16677

Subject:	Source:
CODY FAY BALLANCE, R.PH. 100TH 4TH Ave S, #228 St. Petersburg, FL 33701 (219) 671-1180	**R.M. (Patient's Husband)**

Prefix:	License No.	Profession:	Board:	Report Date:
PS	46832	Pharmacist	Pharmacy	02/08/2013

Period of Investigation:	Type of Report:
12/07/2012 – 02/08/2013	FINAL

Alleged Violation: F.S. 456.072(1)(dd), 465.016(g)(r)(t); F.A.C 64B16-30.001(2)(g): violating any provision of this chapter, the applicable practice act, or any rules adopted pursuant thereto, furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy, violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto, failing to consult with the prescribing physician or the patient.

Synopsis: This investigation is predicated upon receipt of a complaint and attachments (Exh. 1) from RM, which alleges that on 10/29/2012, at WALGREENS PHARMACY (PH11527), located at 337 75th Ave., St Petersburg, FL 33706, a misfill occurred when fourteen capsules of 100mg Gabapentin were dispensed to MM, a 78 y/o female, instead of the prescribed fourteen capsules of 100mg Nitrofurantoin. BALANCE was identified as the dispensing pharmacist.

A notification letter dated 12/07/2012 (EXH. 2) was provided to BALLANCE with a copy of the Case Summary and attachments at her listed address.

MM was notified by letter on 12/08/2012 (EXH. 3).

Subject is represented by Attorney MICHAEL SCHWARTZ, 850/884-1088, 410 N. Gadsden St, 32301. ATTORNEY requested a copy of the final investigative file (EXH. 4)

SCHWARTZ has indicated that a response will be provided within 20 days of receipt of this investigative file.

Related Cases: PS2012-17685

Investigator/Date:	Approved By/Date:
2/08/13	Marlene Toledo 2/8/13
Ron Dilworth, II, Investigation Specialist II (PI-33)	Matthew Knispel, Investigation Supervisor (PI-39)

Distribution: HDQTRS/ISU

for Matthew Knispel

TABLE OF CONTENTS

* **CONTAINS INFORMATION WHICH IDENTIFY THE PATIENT BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(A) FLORIDA STATUTES.**

** **HOSPITAL RECORDS – THESE RECORDS ARE SEALED PURSUANT TO SECTION 456.057(10)(A) FLORIDA STATUTES AND NO COPIES ARE RETAINED IN THE AREA 5 INVESTIGATIVE OFFICE.**

INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit 1 is a copy of the Case Summary and Attachments. Included in those documents was a written statement from the source and emergency department discharge form.

In the statement, R.M. wrote that M.M. was dispensed Gabapentin, which is used an anti-seizure medication. M.M. later realized that she was prescribed Nitrofurantoin, which is given to treat urinary tract infections.

The discharge form from PALMS OFPASADENA HOSPITAL, dated 10/28/2012, indicated that M.M. was diagnosed with a urinary tract infection (UTI). The emergency room physician prescribed 100mg Nitrofurantoin tablets.

Exhibit 5 is a subpoena, dated 12/11/2012, for the patient records of M.M., from Palms of Pasadena Hospital, prior to her discharge on 10/28/2012.

On 01/14/2013, documents requested by subpoena were received (**Exh. 6**). The record included all medical documentation for M.M. while admitted at Palms of Pasadena Hospital on 10/28/2012 to the completion of data entry of her emergency room visit on 10/29/2012.

The record indicated that M.M. arrived in the emergency room on 10/28/2012 with a chief complaint of a "possible bladder infection" (pg. 53). After testing, M.M. was diagnosed with a Urinary Tract Infection (UTI). Dr KAIVON MADINI prescribed "Nitrofurantoin Tablet 100mg" for that diagnosis (pg.73).

A note in the Emergency Department Visit Record indicated that M.M. contacted the hospital and informed them that she had received Gabapentin, not Nitrofurantoin, which was filled at Walgreens. The note also stated, "PT JUST CALLED BACK AND TOLD ME IT WAS WALGREENS THAT MADE THE ERROR" (pg. 87).

On 01/10/2013, this investigator went to Walgreen Company located at 337 75th Ave., St. Petersburg, FL 33706 to gather information pertaining to this complaint (**Exh. 7**). Information collected included a patient profile, the last non-confidential CQI after the incident, staff on duty during the alleged incident, a copy of the prescription filled, and number of prescriptions filled.

The patient profile, of M.M., indicated that M.M. was dispensed 14 tablets of 100Mg Gabapentin and 14 tablets of 100Mg Nitrofurantoin on 10/29/2012. The most recent CQI, conducted after the alleged incident, did address the issue of misfills (pg. 98). The prescription, initially filled, was clearly typed and stated the following Sig: Nitrofurantoin Tablet 100MG 1 tab POBID 7 days #14(fourteen). There were 106 prescriptions filled at that location on 10/29/2012. The only personnel in the pharmacy at the time of fill were CODY FAY BALLENCE, R.PH. and MYKEL CHANEL THOMAS, R.PT. The Pharmacy Department Manager indicated that the original container of medication was discarded.

Exhibit 8 contains the Confidential Index.

1) INFORMATION FROM R.M., Patient's Husband - Source

In a face-to-face interview conducted at the complainant's home on 01/07/2013, R.M. gave a statement that mirrored his written statement, submitted at the time of complaint (pgs. 7-8). R.M. stated that he had nothing more to add.

2) INTERVIEW OF M.M., Patient - WITNESS

In a face-to-face interview conducted at the patient's home on 01/07/2013, M.M. stated that she took one tab of the Gabapentin before reading the information pamphlet attached to the medication. After reading the information packet, M.M. discontinued use of the medication and contacted the hospital and the pharmacy immediately.

The dispensing pharmacist was still on duty, and apologized to M.M. once he was aware of the mistake. M.M. stated that a refund for the medication was given to her, as well as, a $50 gift card to Walgreens. M.M. gave the Gabapentin back to the pharmacist and received the correct medication at that time.

This investigator asked M.M. if she experienced any adverse side effects or went back to the hospital, for exam, as a result of taking the medication. M.M. stated that she did not experience any effects from taking the Gabapentin, but she would like to ensure that this does not happen to her or anyone else in the future.

3) INTERVIEW OF MICHAEL SCHWARTZ, PA on behalf of BALLANCE - SUBJECT

On 01/02/2013, SCHARTZ indicated, via letter, that he will be representing BALLANCE in this matter (Exh. 4). SCHWARTZ also stated that he may submit a response to the allegations within 20 days of receipt of the investigative report.

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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. 201300163

FLORIDA SOLUTIONS PHARMACY,
RESPONDENT.

NOTICE

TO: FLORIDA SOLUTIONS PHARMACY
1057 W 29 STREET
HIALEAH, FL 33012

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850)-236-6000.

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 9:00a.m. ;therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 –

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Kristal Beharry, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Florida Solutions Pharmacy
DOH Case Number 2013-00163
DATE: August 2, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Florida Solutions Pharmacy
Subject's Address of Record:	260 Westward Drive, Suite 101 Miami Springs, FL 33166
Enforcement Address:	260 Westward Drive, Suite 101 Miami Springs, FL 33166
Subject's License No:	21697 **Rank:** PH
Licensure File No:	14064
Initial Licensure Date:	12/7/2005
Board Certification:	None
Required to Appear:	Yes
Current IPN/PRN Contract:	None
Allegation(s):	Section 465.023(1)(c), F.S. (2012)
Prior Discipline:	None
Probable Cause Panel:	Mesaros & Risch June 20, 2013
Subject's Attorney:	Pro Se
Complainant/Address:	Department of Health/Investigative Services Unit-Miami

Materials Submitted:

Memorandum to the Board
Settlement Agreement
Administrative Complaint
Board Notification Letter
Election of Rights
Cost Summary Report
PCP Memo
Final Investigative Report with Exhibits 1 - 4

GUIDELINES:
Section 465.023(1)(c), F.S. – **$1,500 fine up to $3,000 fine and (1) year probation**

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

This is a one count administrative complaint alleging that Respondent, or any affiliated person, partner, officer, director, or agent of Respondent, has violated Section 465.023(1)(c), Florida Statutes (2012), by violating Rules 64B16-28.102, 64B16-27.300, 64B16-28.830(2), and 64B16-28.118, Florida Administrative Code, and/or Sections 893.07(1)(a), and 465.016(1)(l), Florida Statutes (2012), during an inspection.

On or about January 30, 2013, a Department inspector conducted a routine inspection and noted several deficiencies, including no current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format, no CQI Policy and Procedures and proof of quarterly meetings, no controlled substance inventory taken on a biennial basis and available for inspection, and appropriate records of returned/unused unit dose medicinal drugs were not maintained or available.

Terms of Settlement:

-Appearance at Board meeting required
-Administrative fine of $4,000
-Costs not to exceed $2,000
-Probation for (1) year, including quarterly inspections at Respondent's cost, corrective action plan, mandatory appearance before the Board during the last (3) months of probation
-Immediate correction of deficiencies noted in Administrative Complaint

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-00163**

FLORIDA SOLUTIONS PHARMACY,

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, Florida Solutions Pharmacy, was a licensed pharmacy in the state of Florida, having been issued license number PH 21697. Respondent's mailing address of record is 260 Westward Drive, Suite 101, Miami Springs, Florida 33166.

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 **FOUR THOUSAND DOLLARS ($4,000).** 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 120 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 DOLLARS ($2,000)**. 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 quarterly inspections to ensure compliance with the laws and rules at Respondent's physical location at Respondent's cost.

b. The Respondent shall submit a corrective action plan aimed at demonstrating compliance with all deficiencies

noted within the Administrative Complaint to the Florida Board of Pharmacy for approval within ninety (90) days of the filing of the Final Order incorporating this Settlement Agreement.

c. 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 22 day of July, 2013

FLORIDA SOLUTIONS PHARMACY
CASE NO. 2013-00163

STATE OF FLORIDA

COUNTY OF MIAMI-DADE

Before me personally appeared Eugenio Delgado, 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 22 day of July, 2013.

Notary Public State of Florida
Elora Sakal
My Commission EE107462
Expires 06/28/2015

Notary Public
My Commission Expires: 06-28-15

APPROVED this 27th day of August, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

K. Beharry

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

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. CASE NO. 2013-00163

FLORIDA SOLUTIONS PHARMACY,

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, Florida Solutions Pharmacy, 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 21697.

EXHIBIT
tabbies
A

3. Respondent's address of record is 260 Westward Drive, Suite 101, Miami Springs, Florida 33166.

4. On or about January 30, 2013, a Department inspector conducted a routine inspection of Respondent at 260 Westward Drive, Suite 101, Miami Springs, Florida 33166.

5. On or about January 30, 2013, the Department inspector noted the following deficiencies:

a. No current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format as required by Rule 64B16-28.102, Florida Administrative Code;

b. No CQI Policy and Procedures and proof of quarterly meetings as required by Rule 64B16-27.300, Florida Administrative Code;

c. No controlled substance inventory taken on a biennial basis and available for inspection as required by Section 893.07(1)(a), Florida Statutes; and/or

d. Appropriate records of returned/unused unit dose medicinal drugs were not maintained/available as required by Rules 64B16-28.830(2), 64B16-28.118,

Florida Administrative Code, and Section 465.016(1)(l), Florida Statutes (2012).

6. Rule 64B16-28.102, Florida Administrative Code, provides that the prescription department of each pharmacy shall have a current pharmacy reference compendium 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 is acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

7. Rule 64B16-27.300, Florida Administrative Code, provides that each pharmacy shall establish a Continuous Quality Improvement Program which shall be described in the pharmacy's policy and procedure manual. Rule 64B16-27.300, Florida Administrative Code, also provides that the pharmacy's policy and procedure manual shall contain 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.

8. Section 893.07(1)(a), Florida Statutes (2012), requires that a complete and accurate record of all stocks of controlled substances on hand be inventoried on a biennial basis.

9. Rule 64B16-28.830(2), Florida Administrative Code, provides that a special closed system pharmacy shall be under the supervision of a prescription department manager who is responsible for maintaining all drug records and following other rules as relate to the practice of pharmacy.

10. Rule 64B16-28.118, Florida Administrative Code, provides that 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.

11. Section 465.016(1)(l), Florida Statutes (2012), provides that each pharmacist shall maintain appropriate records for any unused or returned medicinal drugs.

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, 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.

13. As set forth above in paragraph 5, on or about January 30, 2013, Respondent, or any affiliated person, partner, officer, director, or agent of Respondent, violated multiple rules of the Board of Pharmacy, requirements of Chapter 893, Florida Statutes (2012), and/or Chapter 465, Florida Statutes (2012).

14. 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 Rules 64B16-28.102, 64B16-27.300, 64B16-28.830(2), and 64B16-28.118, Florida Administrative Code, and/or Sections 893.07(1)(a), and 465.016(1)(l), Florida Statutes (2012), during an inspection.

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 21st **day of** June, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and Secretary of Health

K. Beharry

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) 245-4640
Facsimile: (850) 245-4683

PCP: 06/20/13
PCP Members: Mesaros + Risch

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Amy L. Canary
DATE 6-21-13

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.

August 27, 2013

Florida Solutions Pharmacy
260 Westward Drive
Miami Springs, FL

Re: DOH vs. Florida Solutions Pharmacy
DOH Case Number: 2013-00163

Dear Mr. Delgado:

I am in receipt of the settlement agreement executed by you on July 23, 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 Nursing, scheduled for October 9, 2013, at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408. You will receive official notification from the Florida Board of Nursing 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,

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: 201300163

Subject's Name: FLORIDA SOLUTIONS PHARMACY

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	1.00	$54.90
Investigation:	8.60	$550.22
Legal:	4.80	$510.51
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	14.40	$1,115.63
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,115.63

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Florida Solutions Pharmacy (KB)**
Case Number: 2013-00163

MEMBERS: **Gavin ~~Meshad and Michele~~ Weizer** Mesaros Ruck

DATE OF PCP: **June 20, 2013** **AGENDA ITEM: A-13**

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 Rules 64B16-28.102, 64B16-27.300, 64B16-28.830(2), and 64B16-28.118, Florida Administrative Code, and/or Section 893.07(1)(a), and 465.016(1)(l), 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**

2013 JUL 5 PM 12:24

6/20/13

Chair, Probable Cause Panel Date
Board of Pharmacy

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201306313

SCOTT EDWARD KIERENIA,
RESPONDENT.

NOTICE

TO: SCOTT EDWARD KIERENIA
2156 TILLMAN AVE
WINTER GARDEN, FL 34787

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850)-236-6000.

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 9:00a.m. ; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

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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.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

V. **CASE NO. 2013-06313**

SCOTT EDWARD KIERENIA, 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, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Scott Edward Kierenia, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 47160. Respondent's mailing address of record is 2156 Tillman Avenue, Winter Garden, Florida 34787.

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 ($1000)**. 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 **thirty (30) days** from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

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.

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 August, 2013.

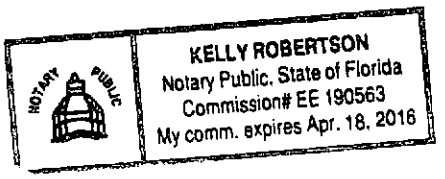
SCOTT EDWARD KIERENIA, R.PH.
CASE NO. 2013-06313

STATE OF Florida

COUNTY OF Orange

Before me personally appeared Scott Kierenia RPh, whose identity is known to me or by FL DL (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 23 day of August, 2013.



Kelly Robertson
Notary Public
My Commission Expires: Apr. 18, 2016

APPROVED this 27 day of August, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Jodi-Ann V. Johnson
Assistant General Counsel

Counsel for Petitioner
Jodi-Ann V. Johnson
Florida Bar No. 0073525
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

/JVJ

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-06313**

SCOTT EDWARD KIERENIA, R.PH.,

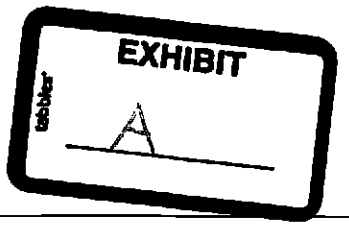
RESPONDENT.
_____/

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, Scott Edward Kierenia, 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 47160.



3. Respondent's address of record is 2156 Tillman Avenue, Winter Garden, Florida 34787.

4. On or about March 29, 2013, a prescription for Cymbalta 30 mg was ordered for Patient JO.

5. On or about March 29, 2013, Respondent dispensed Cymbalta 60 mg to Patient JO.

6. 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 constitutes grounds for disciplinary action by the Board of Pharmacy.

7. Respondent furnished upon prescription an ingredient or article different from the ingredient or article prescribed by furnishing Cymbalta 60 mg for Patient JO instead of the prescribed Cymbalta 30 mg.

8. 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 30th **day of** July, **2013**.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Jodi-Ann V. Johnson
Assistant General Counsel
Fla. Bar No. 0073525
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: Jodi-Ann_Johnson@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE JUL 30 2013

/JVJ

PCP: July 30, 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.

August 29, 2013

VIA US MAIL

Scott Edward Kierenia, R.Ph.
2156 Tillman Avenue
Winter Garden, Florida 34787

Re: DOH vs. Scott Edward Kierenia, R.Ph.
DOH Case Number: 2013-06313

Dear Mr. Kierenia:

I am in receipt of the Settlement Agreement executed by you on August 23, 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 **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 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

Jodi-Ann V. Johnson
Assistant General Counsel

JAVJ/pb

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Complaint Cost Summary

Complaint Number: 201306313

Subject's Name: KIERENIA, SCOTT EDWARD

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.90	$49.41
Investigation:	14.60	$934.09
Legal:	1.60	$170.18
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	17.10	$1,153.68
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,153.68

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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: **Scott Edward Kierenia, R.Ph.** (JVJ)
Case Number: 2013-06313

MEMBERS: **Michele Weizer, PharmD and Gavin Meshad**

DATE OF PCP: ~~May~~ **May 30, 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 465.016(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)

___ Upon **reconsideration**, dismiss

___ **other**

Michele Weizer PharmD, BCPS 7/30/13
Chair, Probable Cause Panel Date
Board of Pharmacy

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201303899

MONIKA MARIE GIRGIS,
RESPONDENT.

NOTICE

TO: MONIKA MARIE GIRGIS
165 BLUFF VIEW DRIVE
BELLEAIR BLUFFS, FL 33770

AND: ALLEN GROSSMAN
2022-2 RAYMOND DIEHL ROAD
GROSSMAN, FURLOW, & BAYO', L.L.C.
TALLAHASSEE, FL 32308

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850)-236-6000.

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 9:00a.m. ;therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

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

Dr Mark Whitten

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

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Monika Marie Girgis, R.Ph.
DOH Case Number 2013-03899
DATE: August 28, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Monika Marie Girgis, R.Ph.
Subject's Address of Record:	165 Bluff View Drive Belleair Bluffs, FL 33770
Enforcement Address:	165 Bluff View Drive Belleair Bluffs, FL 33770
Subject's License No:	38789 **Rank:** PS
Licensure File No:	29783
Initial Licensure Date:	6/17/2004
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No

Allegation(s):	**Count I:** Section 456.072(1)(k), F.S. (2011, 2012), by violating Section 456.072(1)(m), F.S. (2011, 2012), by 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 **Count II:** Section 465.016(1)(e), F.S. (2011, 2012), by violating 893.013(7)(a)(9), F.S. by acquiring or obtaining, or attempting to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge
Prior Discipline:	None
Probable Cause Panel:	June 20, 2013 Mesaros & Risch
Subject's Attorney:	Allen Grossman 2022-2 Raymond Diehl Road Grossman, Furlow, & Bayo', L.L.C. Tallahassee, FL 32308
Complainant/Address:	Department Of Health/ISU St. Petersburg
Materials Submitted:	Memorandum to the Board Election of Rights Settlement Agreement Exhibit A – Administrative Complaint Board Notification Letter Defense Documents PCP Memorandum Final Investigative Report Exhibits 1 thru 11

GUIDELINES:
Count I: From a $10,000 fine and two years probation up to revocation and a $10,000 fine and one year suspension.
Count II: From a $5,000 fine and two years probation up to revocation.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

This is a two count administrative complaint which alleges that the Respondent admittedly created fake prescriptions for a controlled substance and admittedly obtained possession of the substance in question.

Terms of Settlement:

- Appearance
- $2,500 Fine
  - Costs limited to $2,500
  - Laws and Rules (12 hours) within one year of Final Order
- PRN evaluation within sixty days of Final Order and treatment if necessary.
- Two years probation.

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

V. **CASE NO. 2013-03899**

MONIKA MARIE GIRGIS, 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, MONIKA MARIE GIRGIS, R.Ph., was a licensed registered pharmacist in the state of Florida, having been issued license number PS 38789. Respondent's mailing address of record is 165 Bluff View Drive, Belleair Bluffs, Florida 33770.

STIPULATED LAW

1. Respondent admits that they are subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent neither admits nor denies the factual allegations contained in the Administrative Complaint.

PROPOSED DISPOSITION

1. **Appearance**- Respondent, MONIKA MARIE GIRGIS, 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 FIVE HUNDRED DOLLARS ($2,500).** 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 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 and Treatment-** Respondent shall undergo an evaluation facilitated by the Professional Resources Network (PRN) within sixty (60) days of the filing of the Final Order accepting and incorporating this Settlement Agreement. If the results of the evaluation deem treatment appropriate, Respondent shall comply with any and all recommendations of the PRN advocacy contract.

6. **PROBATION-** Respondent shall be placed on **TWO (2) YEARS** probation which will run concurrent with any PRN monitoring. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. Respondent 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 employed; 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;

b. Respondent shall ensure that her 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;

c. Respondent shall not function as a prescription department manager in any Florida permitted pharmacy during the entire term of her probation;

d. Respondent shall comply with any and all recommendations from PRN; and

e. Respondent shall make a mandatory appearance before the Board of Pharmacy during her 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.

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 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 21 day of July, 2013.

MONIKA MARIE GIRGIS, R.Ph.
Case 2013-03899

STATE OF Florida }
}
COUNTY OF Pinellas }

Before me personally appeared MONIKA MARIE GIRGIS, R.Ph., whose identity is known to me or by Driver License (type of identification), and who, under oath, acknowledges that her signature appears above. Sworn to and subscribed before me this 21 day of July, 2013.

MICHAEL ADAMS
MY COMMISSION # DD 973449
EXPIRES: April 2, 2014
Bonded Thru Budget Notary Services

Notary Public
My Commission Expires: 7/21/13

APPROVED this 28 day of August, 2013.

John H. Armstrong, MD
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

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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

August 29, 2013

VIA US MAIL

Allen Grossman, Esquire
2022-2 Raymond Diehl Road
Grossman, Furlow & Bayo, L.L.C.
Tallahassee, Florida 32308

Re: DOH vs. Monika Marie Girgis, R.Ph.
DOH Case Number: 2013-03899

Dear Mr. Grossman:

I am in receipt of the settlement agreement executed by your client on July 12, 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 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,

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

Complaint Cost Summary

Complaint Number: 201303899

Subject's Name: GIRGIS, MONIKA MARIE

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.50	$82.35
Investigation:	20.10	$1,285.99
Legal:	3.90	$414.81
Compliance:	0.05	$1.61
	**********	**********
Sub Total:	25.55	$1,784.76
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,784.76

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

Monika Marie Girgis, R.Ph. (MGW)

RE: **Case Number: 2013-03899**

MEMBERS: **Gavin Meshad and Michele Weizer** MESHAD/Risch

DATE OF PCP: **June 20, 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 465.016(1)(r), Florida Statutes (2011, 2012), by violating Section 456.072(1)(m), Florida Statutes (2011, 2012);

Section 465.016(1)(e), Florida Statutes (2011, 2012), by violation of Section 893.013(7)(a)(9), 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)
c)

___ Upon **reconsideration**, dismiss

___ **other** _____

2013 JUN -5 PM 2:23

6/20/13

Chair, Probable Cause Panel — Date
Board of Pharmacy

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201301123

ADORYS MARTINEZ FLORES,
RESPONDENT.

NOTICE

TO: ADORYS MARTINEZ FLORES
10235 SW 24 ST C-149
MIAMI, FL 33165

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850)-236-6000.

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 9:00a.m. ;therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
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: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Christopher A. Jurich, Assistant General Counsel CJ 8/28/13 ORC
RE: Settlement Agreement
SUBJECT: DOH v. Adorys Martinez Flores, R.Ph.
DOH Case Number 2013-01123
DATE: August 28, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Adorys Martinez Flores, R.Ph.
Subject's Address of Record:	10235 S.W. 24 St C-149 Miami, FL 33165
Enforcement Address:	3898 S.W. 133 Place Miami, FL 33175
Subject's License No:	48533 **Rank:** PS
Licensure File No:	37722
Initial Licensure Date:	11/2/2011
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No
Allegation(s):	Section 465.016(1)(r), F.S. (2012), by violating 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 all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.
Prior Discipline:	None

Probable Cause Panel: June 20, 2013
Mesaros & Risch

Subject's Attorney: Javier Talamo
7600 W. 20th Avenue, Suite 213
Hialeah, FL 33016

Complainant/Address: Department Of Health/ISU Miami

Materials Submitted: Memorandum to the Board
Settlement Agreement
Exhibit A – Administrative Complaint
Board Notification Letter
Election of Rights
Cost Summary
PCP Memorandum
Final Investigative Report
Exhibits 1 thru 7

CAJ/crl

GUIDELINES:
Minimum: $500 fine and 12 hour Laws & Rules Course or MPJE, up to Maximum: Revocation.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

This a one count Administrative Complaint which alleges that the Respondent, who was the prescription department manager for the pharmacy Permittee, Las Mercedes Drug Store, Inc., during two inspections by the Department on January 9, 2013, and February 27, 2013, which revealed that the Permittee could not retrieve prescription drug pedigrees for audited medications. As the prescription department manager, the Respondent failed to ensure the Permittee's compliance with all rules as they relate to the profession of pharmacy.

Terms of Settlement:

- Appearance
- $1000 Administrative Fine payable within 30 days
- Costs limited to $1,263.12 payable within 90 days
- Continuing education course - 12 hours of Laws and Rules completed within 1 year

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-01123**

ADORYS MARTINEZ FLORES, 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, Adorys Martinez Flores, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 48533. Respondent's mailing address of record is 10235 Southwest 24 Street C-149, Miami, Florida 33165.

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 **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 **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 **ONE THOUSAND TWO HUNDRED SIXTY THREE DOLLARS AND TWELVE CENTS ($1,263.12)**. 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** consisting of **TWELVE (12) 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.

5. **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.

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 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 12 day of August, 2013.

Adorys Martinez Flores, R.Ph.
Case No. 2013-01123

STATE OF Florida

COUNTY OF Miami-Dade

Before me personally appeared Adorys, 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 12th day of August, 2013.

Notary Public
My Commission Expires:

YESSENIA LINARES
MY COMMISSION # EE 120216
EXPIRES: November 13, 2015
Bonded Thru Budget Notary Services

APPROVED this 15th day of August, 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. 2013-01123**

ADORYS MARTINEZ FLORES, R.Ph.,

RESPONDENT.

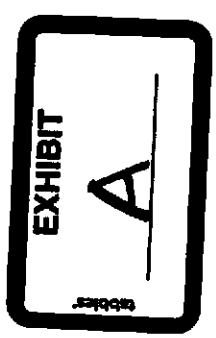
_____/

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, Adorys Martinez Flores, 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 48533.



3. Respondent's address of record is 3898 SW 133 Place, Miami, Florida 33175.

4. At all times material to this Administrative Complaint, Respondent was the prescription department manager (PDM) of Las Mercedes Drug Store, Inc. (the Permittee), which is a permitted community pharmacy within the state of Florida having permit number PH 25947.

5. On or about January 9, 2013, a Department of Health (Department) inspector conducted an inspection of the Permittee at 7209 SW Coral Way, Miami, Florida 33155, and observed the following deficiency:

a. Pedigrees not retrievable as required by Rule 64F-12.012(3)(a)2., (d), Florida Administrative Code.

6. On or about February 27, 2013, the Department inspector conducted an inspection of the Permittee at 7209 SW Coral Way, Miami, Florida 33155, and observed the following deficiency:

a. Pedigrees not retrievable as required by Rule 64F-12.012(3)(a)2., (d), Florida Administrative Code.

7. 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.

8. Section 465.022(11)(a), Florida Statutes (2012), states that "[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."

9. As the PDM, Respondent was responsible for ensuring the Permittee complied with Rule 61N-1.012(3)(a)2., (d), Florida Administrative Code, (formerly Rule 64F-12.012(3)(a)2., (d), F.A.C.), which provides that a copy of the pedigree paper must be maintained by each wholesaler preparing a pedigree paper and by each recipient.

10. As noted by the deficiencies set forth above, Respondent failed to ensure the Permittee's compliance with the rules adopted by the Board of Pharmacy.

11. Based on the foregoing, Respondent has 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, 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 20th **day of** June **, 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 #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444 ext. 8174
Facsimile: (850) 245-4683
Email: christopher_jurich@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUN 20 2013

/CAJ
PCP: June 20, 2013
PCP Members: Mesaros, J. & Risch, L.

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:
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

August 29, 2013

VIA US MAIL

Javier Talamo, Esq.
7600 W. 20th Avenue, Suite #213
Kravitz, Talamo, Leyton, L.L.P.
Hialeah, Florida 33016

Re: DOH v. Adorys Martinez Flores, R.Ph.
DOH Case Number: 2013-01123

Dear Mr. Talamo:

I am in receipt of the settlement agreement executed by your client on August 12, 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 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,

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

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: 201301123

Subject's Name: MARTINEZ FLORES, ADORYS

	***** Cost to Date *****	
	Hours	Costs
Complaint:	0.80	$43.92
Investigation:	15.30	$978.90
Legal:	6.60	$701.97
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	22.70	$1,724.79
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,724.79

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Adorys Martinez Flores, R.Ph., (CAJ)**
Case Number: 2013-01123

MEMBERS: **Gavin Meshad and ~~Michele~~ Weizer** Mesaros/Rasch

DATE OF PCP: **June 20, 2013** **AGENDA ITEM: A-10**

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 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**

6/20/13

Chair, Probable Cause Panel Date
Board ~~of Pharmacy~~

2013 JUN -5 PM 2:24

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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 # _____

Insp # _____

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
Las Mercedes Drug Store, Inc	25947	2/27/2013
DOING BUSINESS AS	DEA NUMBER FL3648663	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 7209 SW Coral Way	TELEPHONE # (786)518-2793 EXT.	
CITY Miami	COUNTY 23	STATE/ZIP 33155
		PRESCRIPTION DEPARTMENT MANAGER LICENSE #

PRESCRIPTION DEPARTMENT HOURS							
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9:00A	9:00A	9:00A	9:00A	9:00A	Closed	Closed
Close	5:00P	5:00P	5:00P	5:00P	5:00P	Closed	Closed

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Adorys Martinez flores, PS 48533
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
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 do not apply at this time.
Wholesaler is ANDA, SMITH, and Verticale Wholesale.
#10 No expired medication at this time.
#22 Reviewed daily log for Jan and Feb. 2013.
#25 Verified pharmacy is reporting to PDMP every seven days by reviewing PDMP report.
#30 No invoices produced for the purchase of approximately 3 bottles of Crestor 20mg #90. Approximately 390 were dispensed and only 1 invoice showing 90 were purchased during the period of January 1, 2013 until February 27, 2013. Owner advises he might have the invoice at this accountant.

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.

CONFIDENTIAL

PRINT NAME OF RECIPIENT Adorys Martinez flores, PS 48533

Institutional Representative

02-27-2013
Date

Investigator/Sr. Pharmacist Signature

ID mi200

INV 359 Revised 12/12, 5/12, 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

EXHIBIT 3

: 00017

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 Las Mercedes Drug Store, Inc		PERMIT NUMBER 25947		DATE OF INSPECTION 2/27/2013
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER/ CONSULTANT PHARMACIST
STREET ADDRESS 7209 SW Coral Way		TELEPHONE # (786)518-2793	EXT.	
CITY Miami	COUNTY MIAMI-DADE	STATE/ZIP 33155		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.	[X]

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

Investigator/Sr. Pharmacist sign here also

02-27-2013
Date

Investigator/Sr. Pharmacist Signature

ID mi200

INV 373 Revised 06/12, 01/07 Replaces 12/02

00018

PENN FOSTER
CAREER SCHOOL

Yanurys Tait

Student #: 21577146

Log on at: www.PennFoster.edu

PENNFOSTER
CAREER SCHOOL

Israel Libera

Student #: 21755214

Log on at: www.PennFoster.edu

Speak with an Admissions Counselor
1-800-275-4410

2010 Graduate Survey

94.5% Achieved Goals

97.2% Would Recommend to a Friend

98.6% Satisfied with Studies

Enroll Today...Start Today!

When you enroll with Penn Foster you're able to start your studies almost immediately. Once you receive your confirming email with your student I.D. number, you can log into the Penn Foster student web site and begin your program.

Get more information today, contact us or enroll online and you could be working on your first lesson – and toward a new career – in a matter of minutes!

Pharmacy Technician

Program Overview

You could be a Pharmacy Technician in as little as one year! Learn at home with Penn Foster Career School and you'll get the support you need while learning at your own pace.

You'll get the training you need to work closely with pharmacists in providing medication and health care products to patients. Whether you'll work for a retail pharmacy, local druggist, grocery store, or hospital, you'll be an important part of a rewarding profession.

Our Pharmacy Technician training program provides you the skills you need to succeed and even offers a Pharmacy Technician Certification Exam Review.

As a Pharmacy Technician, you'll need to know medical terminology, managing and updating patient records, and office procedures. The Penn Foster Career School program can help you learn these skills and many more affordably, quickly and conveniently.

Your courses include:

- Receive prescriptions from doctors and hospitals.
- Prepare prescriptions for patients.
- Verify insurance and prescription information.
- Assist the pharmacist with everyday duties.

Flexible, Convenient, Self-Paced!
There is no going to class, no need to rearrange schedules. You choose the right time and place to complete your coursework. And you work at your own pace. There's no one to rush you or hold you back.

While you'll work independently, you won't be alone. Expert instructors and support staff — dedicated to helping you complete your coursework — are just a phone call or an email away.

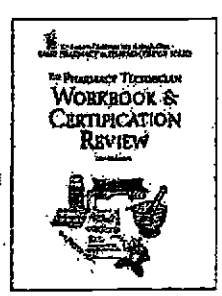
Last day!

ENROLL NOW

REQUEST INFORMATION

Respected and Accredited
You'll earn your Pharmacy Technician Career Diploma from Regionally and Nationally Accredited Penn Foster Career School. Over 13 million students have enrolled in our training programs, making Penn Foster one of the world's largest and most respected distance learning institutions.

Certification Eligibility
Graduates of the Penn Foster Pharmacy Technician Program are automatically eligible to take the *PTCB (Pharmacy Technician Certification Board)* examination. You will also receive the Pharmacy Technician Workbook and Certification Review. This workbook is the only Pharmacy Technician workbook officially endorsed by the American Pharmacists Association (APhA).



State Requirements
State boards may impose a variety of different requirements. These requirements vary from state to state. (The states of Florida, Indiana, Louisiana, Maryland, Minnesota, Nevada, North Dakota, South Carolina, Utah, Virginia, and Washington will not consider the training received in this program adequate to fulfill pharmacy technician credentialing requirements. You should contact the State Board of Pharmacy to obtain the requirements applicable to pharmacy technicians in your state.)

Contact Penn Foster Today.
We'll send you FREE information – with absolutely no obligation! Find out more about Penn Foster's Pharmacy Technician training that includes:

- All the books, lessons, equipment, and learning aids you need
- Work experience option
- Unlimited, toll-free instructional support
- Access to student services by website, phone, and mail

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 # 18955

Insp # 113395

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
LAS MERCEDES DRUG STORE INC				2/10/2012
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
LAS MERCEDES DRUG STORE INC				KAMAR OLAWALE MUSTAPHA
STREET ADDRESS		TELEPHONE #	EXT.	
7209 SW CORAL WAY		786-704-3382		
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
MIAMI	23	33155		37331

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1.	
Open	10 AM	10 AM	10 AM	10 AM	10 AM	CLOSED	CLOSED	2.	
Close	6 PM	6 PM	6 PM	6 PM	6 PM	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. [64B16-27.410, 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: All N/A responses are due to this being an initial inspection for this facility to obtain a community pharmacy permit. This inspector has reviewed all that is applicable to this inspection and found the facility to be in compliance at this time. The facility is ready to obtain a permit.

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. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Isreal Libera (owner)

Institutional Representative

02-10-2012
Date

Investigator/Sr. Pharmacist Signature

ID mi204

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

EXHIBIT 4

00022

Application License Cash Exams Inspection Enforcement Utilities Window Help

64 Department of Health MQA rsuarez 03/05/2013

Find Inspections (in11)

Fed Tax # 454216367 LAS MERCEDES DRUG STORE INC

File # 18955 Pharmacy

License # 25947 CLEAR

Indv/Org # 8573711

License Type 2205

Inspection #

Appl #

Expires 02/28/2015

Find

New Insp

Clear

Inspection #	Location	Type	Start Date	End Date	Complaint #	Status	Disposition	Result
121726	7209 SW CORAL W	R				Open	RQST	Unknown
120557	7209 SW CORAL W	2	02/27/13	02/27/13		Closed	CMPT	Failed
113723	7209 SW CORAL W	R	01/09/13	01/09/13		Closed	CMPT	Failed
113395	7209 SW CORAL W	N	02/10/12	02/10/12		Closed	CMPT	Pass

Work

View

Application

Exit

FLORIDA DEPARTMENT OF STATE
DIVISION OF CORPORATIONS

Detail by Entity Name

Florida Profit Corporation

LAS MERCEDES DRUG STORE, INC

This detail screen does not contain information about the 2013 Annual Report.

Click the 'Search Now' button to determine if the 2013 Annual Report has been filed.

Search Now

Filing Information

Document Number	P12000002746
FEI/EIN Number	NONE
Date Filed	01/09/2012
State	FL
Status	ACTIVE
Effective Date	01/09/2012
Last Event	AMENDMENT
Event Date Filed	06/14/2012
Event Effective Date	NONE

Principal Address

7209 SW CORAL WAY
MIAMI FL 33155

Mailing Address

7209 SW CORAL WAY
MIAMI FL 33155

Registered Agent Name & Address

LIBERA, ISRAEL
7209 SW CORAL WAY
MIAMI FL 33155 US

CONFIDENTIAL

Officer/Director Detail

Name & Address

Title P

LIBERA, ISRAEL

EXHIBIT 5

7209 SW CORAL WAY
MIAMI FL 33155

Title VTD

CORDOVI, MICHEL
7209 SW CORAL WAY
MIAMI FL 33155

Annual Reports

No Annual Reports Filed

Document Images

06/14/2012 -- Amendment View image in PDF format

01/09/2012 -- Domestic Profit View image in PDF format

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LAS MERCEDES DRUG STORE, INC

Certificate of Status	0
Certified Copy	0
Page Count	05
Estimated Charge	$35.00

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JUN 14 2012
T. ROBERTS

: 00025

FILED
12 JUN 14 PM 2:50
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

H12000158966

Articles of Amendment
to
Articles of Incorporation
of

LAS MERCEDES DRUG STORE, INC

(Name of Corporation as currently filed with the Florida Dept. of State)

P12000002746

(Document Number of Corporation (if known))

Pursuant to the provisions of section 607.1006, Florida Statutes, this ***Florida Profit Corporation*** adopts the following amendment(s) to its Articles of Incorporation:

A. If amending name, enter the new name of the corporation:

_____ *The new name must be distinguishable and contain the word "corporation," "company," or "incorporated" or the abbreviation "Corp.," "Inc.," or Co.," or the designation "Corp," "Inc," or "Co". A professional corporation name must contain the word "chartered," "professional association," or the abbreviation "P.A."*

B. Enter new principal office address, if applicable:
(Principal office address MUST BE A STREET ADDRESS)

_____

_____

_____

C. Enter new mailing address, if applicable:
(Mailing address MAY BE A POST OFFICE BOX)

_____

_____

_____

D. If amending the registered agent and/or registered office address in Florida, enter the name of the new registered agent and/or the new registered office address.

Name of New Registered Agent _____

_____
(Florida street address)

New Registered Office Address: _____, Florida _____
(City) *(Zip Code)*

New Registered Agent's Signature, if changing Registered Agent:
I hereby accept the appointment as registered agent. I am familiar with and accept the obligations of the position.

_____
Signature of New Registered Agent, if changing

H12000158966

H12000156966

If amending the Officers and/or Directors, enter the title and name of each officer/director being removed and title, name, and address of each Officer and/or Director being added:
(Attach additional sheets, if necessary)

Please note the officer/director title by the first letter of the office title:
P = President; V= Vice President; T= Treasurer; S= Secretary; D= Director; TR= Trustee; C = Chairman or Clerk; CEO = Chief Executive Officer; CFO = Chief Financial Officer. If an officer/director holds more than one title, list the first letter of each office held. President, Treasurer, Director would be PTD.

Changes should be noted in the following manner. Currently John Doe is listed as the PST and Mike Jones is listed as the V. There is a change, Mike Jones, leaves the corporation. Sally Smith is named the V and S. These should be noted as John Doe, PT as a Change, Mike Jones, V as Removed, and Sally Smith, SV as an Add.

Example:

X	Change	PT	John Doe
X	Remove	V	Mike Jones
X	Add	SV	Sally Smith

Type of Action (Check One)	Title	Name	Address
1) ___ Change X Add ___ Remove	VTD	MICHEL CORDOVI	7209 SW CORAL WAY MIAMI, FLORIDA 33155
2) ___ Change ___ Add ___ Remove			
3) ___ Change ___ Add ___ Remove			
4) ___ Change ___ Add ___ Remove			
5) ___ Change ___ Add ___ Remove			
6) ___ Change ___ Add ___ Remove			

H12000156966

H12000158966

E. If amending or adding additional Articles, enter change(s) here:
(attach additional sheets, if necessary). (Be specific)

F. If an amendment provides for an exchange, reclassification, or cancellation of issued shares, provisions for implementing the amendment if not contained in the amendment itself:
(If not applicable, indicate N/A)

H12000158966

H12000158966

The date of each amendment(s) adoption: 6-14-12

Effective date if applicable: _____
(no more than 90 days after amendment file date)

Adoption of Amendment(s) (CHECK ONE)

☒ The amendment(s) was/were adopted by the shareholders. The number of votes cast for the amendment(s) by the shareholders was/were sufficient for approval.

☐ The amendment(s) was/were approved by the shareholders through voting groups. *The following statement must be separately provided for each voting group entitled to vote separately on the amendment(s):*

"The number of votes cast for the amendment(s) was/were sufficient for approval

by _____"
(voting group)

☐ The amendment(s) was/were adopted by the board of directors without shareholder action and shareholder action was not required.

☐ The amendment(s) was/were adopted by the incorporators without shareholder action and shareholder action was not required.

Dated 6-14-12

Signature _____
(By a director, president or other officer – if directors or officers have not been selected, by an incorporator – if in the hands of a receiver, trustee, or other court appointed fiduciary by that fiduciary)

ISRAEL LIBERA
(Typed or printed name of person signing)

PRESIDENT
(Title of person signing)

H12000158966

: 00030

Electronic Articles of Incorporation For

LAS MERCEDES DRUG STORE, INC

P12000002746
FILED
January 09, 2012
Sec. Of State
jshivers

The undersigned incorporator, for the purpose of forming a Florida profit corporation, hereby adopts the following Articles of Incorporation:

Article I

The name of the corporation is:

LAS MERCEDES DRUG STORE, INC

Article II

The principal place of business address:

7209 SW CORAL WAY
MIAMI, FL. 33155

The mailing address of the corporation is:

7209 SW CORAL WAY
MIAMI, FL. 33155

Article III

The purpose for which this corporation is organized is:

ANY AND ALL LAWFUL BUSINESS.

Article IV

The number of shares the corporation is authorized to issue is:

100

Article V

The name and Florida street address of the registered agent is:

ISRAEL LIBERA
7209 SW CORAL WAY
MIAMI, FL. 33155

I certify that I am familiar with and accept the responsibilities of registered agent.

Registered Agent Signature: ISRAEL LIBERA

P12000002746
FILED
January 09, 2012
Sec. Of State
jshivers

Article VI

The name and address of the incorporator is:

ISRAEL LIBERA
7209 SW CORAL WAY

MIAMI FL 33155

Electronic Signature of Incorporator: ISRAEL LIBERA

I am the incorporator submitting these Articles of Incorporation and affirm that the facts stated herein are true. I am aware that false information submitted in a document to the Department of State constitutes a third degree felony as provided for in s.817.155, F.S. I understand the requirement to file an annual report between January 1st and May 1st in the calendar year following formation of this corporation and every year thereafter to maintain "active" status.

Article VII

The initial officer(s) and/or director(s) of the corporation is/are:

Title: P
ISRAEL LIBERA
7209 SW CORAL WAY
MIAMI, FL. 33155

Article VIII

The effective date for this corporation shall be:

01/09/2012

FLORIDA DEPARTMENT OF STATE
DIVISION OF CORPORATIONS

Detail by Entity Name

Florida Profit Corporation

LAS MERCEDES DRUG STORE, INC

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Filing Information

Document Number	P12000002746
FEI/EIN Number	NONE
Date Filed	01/09/2012
State	FL
Status	ACTIVE
Effective Date	01/09/2012
Last Event	AMENDMENT
Event Date Filed	06/14/2012
Event Effective Date	NONE

Principal Address

7209 SW CORAL WAY
MIAMI FL 33155

Mailing Address

7209 SW CORAL WAY
MIAMI FL 33155

Registered Agent Name & Address

LIBERA, ISRAEL
7209 SW CORAL WAY
MIAMI FL 33155 US

Officer/Director Detail

Name & Address

Title P

LIBERA, ISRAEL

7209 SW CORAL WAY
MIAMI FL 33155

Title VTD

CORDOVI, MICHEL
7209 SW CORAL WAY
MIAMI FL 33155

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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
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201216397

JESSICA DANIELLE BRAMBLE,
RESPONDENT.

NOTICE

TO: JESSICA DANIELLE BRAMBLE
22393 OCEANSIDE AVE
PORT CHARLOTTE, FL 33952

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850)-236-6000.

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 9:00a.m. ;therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
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: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Jessica Danielle Bramble, R.P.T.
DOH Case Number 2012-16397
DATE: August 28, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Jessica Danielle Bramble
Subject's Address of Record:	22393 Oceanside Ave Port Charlotte, FL 33952
Enforcement Address:	22393 Oceanside Ave Port Charlotte, FL 33952
Subject's License No:	24357 **Rank:** RPT
Licensure File No:	26148
Initial Licensure Date:	12/31/2009
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No

Allegation(s):	**Count I:** Section 465.016(1)(e), F.S. (2011), by admitting to a violation of Section 893.13(7)(a)(9), F.S. **Count II:** Section 465.016(1)(e), F.S. (2011), by violating Section 499.005(4), F.S. (2011), by admittingly substituting hydromorphone with sterile water and returning it to the Pyxis machine
Prior Discipline:	None
Probable Cause Panel:	January 31, 2013 Fallon & Risch
Subject's Attorney:	Pro Se
Complainant/Address:	Lee Memorial Health System Post Office Box 2218 Laureen Harris, System Counsel Ft Myers, FL 33902
Materials Submitted:	Memorandum to the Board Settlement Agreement Exhibit A – Administrative Complaint Board Notification Letter Election of Rights Cost Summary PCP Memorandum Final Investigative Report Exhibits 1 thru 9

GUIDELINES:
Count I: From a $5,000 fine and two years probation up to revocation.
Count II: From $1,000 fine up revocation.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

After an investigation, the Respondent admitted to accessing various pyxis machines without a legitimate reason to do so and removing hydromorphone and replacing it with sterile water.

Terms of Settlement:

- Appearance
- Costs limited to $2,784.33
- Revocation

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

V. **CASE NO. 2012-16397**

JESSICA DANIELLE BRAMBLE, 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, Jessica Danielle Bramble, R.P.T., was a licensed registered pharmacy technician in the state of Florida, having been issued license number RPT 24357. Respondent's mailing address of record is 22393 Oceanside Avenue, Port Charlotte, Florida 33952.

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. **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 EIGHTY-FOUR DOLLARS AND THIRTY-THREE CENTS**

($2,784.33). 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.

3. The license of **JESSICA DANIELLE BRAMBLE, R.P.T.**, is revoked. Within 30 days the Respondent shall return her/his license to DOH-Compliance Management Unit, 4052 Bald Cypress Way, Tallahassee, Florida 32399-3276, Attention: Pharmacy Compliance Officer, or shall surrender the license to an investigator of the Department of Health. The Respondent's employer shall immediately be informed of the revocation in writing from the Respondent with a copy to DOH-Compliance Management Unit, 4052 Bald Cypress Way, Tallahassee, Florida 32399-3276, Attention: Pharmacy Compliance Officer.

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.

6. **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.

7. **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.

8. **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.

9. **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.

10. **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.

11. **Current Addresses**- Respondent shall keep current his/her mailing address and his/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 06 day of March, 2013

Jessica Bramble

JESSICA DANIELLE BRAMBLE, R.P.T.
CASE NO. 2012-16397

STATE OF Florida

COUNTY OF Sarasota

Before me personally appeared Jessica Bramble R.P.T., whose identity is known to me or by ~~Jessica Bramble~~ FL DL (type of identification), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 6 day of March, 2013. VP

VERONICA A. PALUMBO
Notary Public, State of Florida
Commission# EE 25039
My comm. expires Sept. 9, 2014

Notary Public
My Commission Expires:

APPROVED this 29 day of August, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel

Counsel for Petitioner
Matthew G. Witters
Florida Bar No. 091245
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: 850.245.4640
Fax: 850.245.4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

V. **CASE NO. 2012-16397**

JESSICA DANIELLE BRAMBLE, R.P.T.,

RESPONDENT.

ADMINISTRATIVE COMPLAINT

Petitioner Department of Health, by and through its undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, Jessica Danielle Bramble, 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 Order, Respondent was a licenses registered pharmacy technician (RPT) operating within the State of Florida, pursuant to Chapter 465, Florida Statutes, holding permit number RPT 24357.

EXHIBIT A

3. Respondent's address of record is 22393 Oceanside Avenue, Port Charlotte, Florida 33952.

4. At all time material to this complaint, Respondent was employed as a RPT at Health Park Medical Center (HPMC) located in Lee County, Florida.

5. HPMC utilizes the Pyxis automated medication dispensing system ("Pyxis"). Pyxis is a locked cart that contains controlled substances and is accessed through the use of a computer. Each time a nurse removes a controlled substance from the Pyxis cart, he or she must identify the patient for whom the medication is intended. If the dose available in the Pyxis cart is greater than the dose designated by the physician, the nurse must discard the excess in the presence of a witness and document doing so in the Pyxis computer. This is done to accurately account for controlled substances removed and to assure proper billing of the patient for nursing care provided. To accurately record care rendered to the patient, all medications administered must be documented in the patient's record.

6. Additionally, HPMC's Pyxis system included a biometric scanner which required fingerprint confirmation for each entry into the system.

7. HPMC utilizes the DSX access control system. The DSX access control system maintains record of each access via a secured electronic database requiring a unique identifier for each use.

8. On or about January 22, 2012, Respondent was witnessed by HPMC staff entering multiple medication rooms on multiple floors at HPMC.

9. On or about January 23, 2012, an investigation was initiated by HPMC into the Respondent's actions and entries into the Pyxis medication system.

10. As a result of this investigation, HPMC was able to obtain records which showed that the Respondent entered medication rooms and accessed Pyxis machines when she had no legitimate reason to do so.

11. On or about February 1, 2012, Respondent participated in a recorded telephonic interview with HPMC staff.

12. During the course of this interview, Respondent admitted to accessing various Pyxis machines at HPMC without a legitimate reason to do so, and removing hydromorphone.

13. Hydromorphone is prescribed to treat pain. According to Section 893.03(2), Florida Statutes, hydromorphone 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, and abuse of hydromorphone may lead to severe psychological or physical dependence.

14. Additionally, Respondent admitted to substituting the hydromorphone with sterile water and returning it to the Pyxis machine.

15. Section 499.006(8)(b), Florida Statutes (2011), provides that a drug is adulterated if any substance has been substituted wholly or in part.

COUNT ONE

16. Petitioner realleges and incorporates paragraphs one (1) through fifteen (15), as if fully set forth herein.

17. Section 465.016(1)(e), Florida Statutes (2011), provides that a registered pharmacy technician can be disciplined, including suspension, for violating a provision of Chapter 893, Florida Statutes.

18. Section 893.13(7)(a)(9), Florida Statutes, prohibits a person from acquiring or obtaining, or attempting to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.

19. Respondent violated Section 465.016(1)(e), Florida Statutes (2010), by violating Section 893.13(7)(a)(9), Florida Statutes, by obtaining

hydromorphone, a controlled substance by fraudulent means, as admitted during her recorded interview with a HPMC staff.

20. Based on the foregoing, Respondent has violated Section 465.016(1)(e), Florida Statutes (2011), by admitting to a violation of Section 893.13(7)(a)(9), Florida Statutes.

COUNT TWO

21. Petitioner realleges and incorporates paragraphs one (1) through fifteen (15), as if fully set forth herein.

22. Section 465.016(1)(e), Florida Statutes (2011), provides that a registered pharmacy technician can be disciplined, including suspension, for violating a provision of Chapter 499, Florida Statutes.

22. Section 499.006(8)(b), Florida Statutes (2011), provides that a drug is adulterated if any substance has been substituted wholly or in part

23. Section 499.005(4), Florida Statutes (2011), provides that 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 is grounds for disciplinary action.

24. Respondent admitted to substituting hydromophone with sterile water and returning it to the Pyxis machine at HPMC.

25. Based on the foregoing, Respondent violated Section 465.016(1)(e), Florida Statutes (2011), by violating Section 499.005(4), Florida Statutes (2011), by admittedly substituting hydromorphone with sterile water and returning it to the Pyxis machine.

WHEREFORE, the Petitioner respectfully requests that the Board of Nursing 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 31 **day of** January **, 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) 245-4640
Facsimile: (850) 245-4683
Email: matthew_witters@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JAN 31 2013

PCP: 01-31-13
PCP Members: Fallon & 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.

August 29, 2013

VIA US MAIL

Jessica Danielle Bramble, R.P.T.
22393 Oceanside Avenue
Port Charlotte, Florida 33952

Re: DOH vs. Jessica Danielle Bramble, R.P.T.
DOH Case Number: 2012-16397

Dear Ms. Bramble:

I am in receipt of the settlement agreement executed by you on March 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 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 at 850-245-4444, ext. 8172.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

cc: file

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Complaint Cost Summary

Complaint Number: 201216397

Subject's Name: BRAMBLE, JESSICA DANIELLE

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.50	$27.45
Investigation:	16.40	$1,010.78
Legal:	7.80	$829.59
Compliance:	0.05	$1.61
	**********	**********
Sub Total:	24.75	$1,869.43
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,869.43

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Jessica Danielle Bramble, R.P.T.**
Case Number: 2012-16397

MEMBERS: **Leo Fallon and Lorena Risch**

DATE OF PCP: **January 31, 2013** **AGENDA ITEM: A-12**

This matter came before the Probable Cause Panel on tbe 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 (2001), by admitting to a violation of Section 893.13(7)(a)(9), Florida Statutes (2011), by admitting to a violation of Section 893.13(7)(a)(9), Florida Statutes.

Section 465.016(1)(e), Florida Statutes (2011), by violating Section 499.005(4), Florida Statutes (2011), by admittedly substituting bydromorphone with sterile water and returning it to the Pyxis machine.

___ 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 Fallon 1/31/2013

Chair, Probable Cause Panel Date
Board of Pharmacy

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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.—

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307687

HEALTHY CHOICE PHARMACY, INC,
RESPONDENT.

NOTICE

TO: HEALTHY CHOICE PHARMACY, INC
1343 FOUR SEASONS BLVD
TAMPA, FL 33613

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is not required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
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: Mark Whitten, Executive Director, Board of Pharmacy

FROM: Ana M. Gargollo-McDonald, Assistant General Counsel

RE: **Voluntary Relinquishment**

SUBJECT: DOH v. Healthy Choice Pharmacy, Inc., PH
DOH Case Number: 2013-07687

DATE: July 17, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Healthy Choice Pharmacy, Inc., PH
Subject's Address of Record:	1343 Four Seasons Blvd. Tampa, FL 33613
Enforcement Address:	1343 Four Seasons Blvd. Tampa, FL 33613
Subject's License No:	25637 **Rank:** PH
Licensure File No:	18501
Initial Licensure Date:	8/25/2011
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No

Allegation(s):	Violated Section 456.072(1)(dd), Florida Statutes (2012), also by violating Rule 64B16-28.202(a)(b), Florida Administrative Code
Prior Discipline:	None
Probable Cause Panel:	Waived
Subject's Attorney:	Pro Se
Complainant/Address:	Department Of Health/Investigative Services Unit-Tampa
Materials Submitted:	Memorandum to the Board Motion For Voluntary Relinquishment of License Voluntary Relinquishment (filed) Board Notification Letter Final Investigative Report Exhibits 1-9

AMD/bhh

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-07687**

HEALTHY CHOICE PHARMACY, INC.,

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 **June 27, 2013**, a Complaint was filed with the Department of Health, alleging that Respondent violated provisions of Chapter 456 and/or Chapter 464, 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.

Respectfully Submitted,

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

ANA M. GARGOLLO-MCDONALD
Assistant General Counsel
Fla. Bar No. **0008907**
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**@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 15th day of July, 2013, to: **HEALTHY CHOICE PHARMACY, INC., 1343 FOUR SEASONS BOULEVARD, TAMPA, FLORIDA 33613**.

ANA M. GARGOLLO-MCDONALD
Assistant General Counsel

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Amy Carraway
DATE 7-5-13

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. DOH Case No. 2013-07687

Healthy Choice Pharmacy, Inc., Pharmacy
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent Healthy Choice Pharmacy, Inc., Pharmacy, license No. 25637, 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 Data Bank as disciplinary action. Licensing authorities in other states may impose discipline in their jurisdiction based on discipline taken in Florida.

2. Respondent agrees to never reapply for licensure as a Pharmacy in the State of Florida.

EXHIBIT#
2

3. Respondent agrees to voluntarily cease practicing pharmacy 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. 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.

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 26th day of June, 2013.

Healthy Choice Pharmacy, Inc.

STATE OF Florida
COUNTY OF Hillsborough

Before me, personally appeared Robert S. Ivastro, whose identity is known to me or who produced Florida Drivers License (type of identification) and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 26th day of June, 2013.

NOTARY PUBLIC

My Commission Expires:

SCOTT M. MARTIN
Commission # EE 115226
Expires July 25, 2015
Bonded Thru Troy Fain Insurance 800-385-7019

SCOTT M. MARTIN
Commission # EE 115226
Expires July 25, 2015
Bonded Thru Troy Fain Insurance 800-385-7019

July 18, 2013

VIA U.S. MAIL

HEALTHY CHOICE PHARMACY, INC.
1343 FOUR SEASONS BLVD.
TAMPA, FLORIDA 33613,

Re: DOH vs. HEALTHY CHOICE PHARMACY, INC. PH.
DOH Case Number: 2013-07687

Dear SIR/MADAM:

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 your Florida **Pharmacy** 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 850-245-4640. 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 October 9, 2013, at the Wyndham Bay Point Resort, 4114 Jan Coley Drive, Panama City, Florida 32408**. You are not required to attend the meeting.

Sincerely,

ANA M. GARGOLLO-MCDONALD
Assistant General Counsel

AMD/bhh

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: TAMPA	Date of Case: 05/14/13	Case Number: 201307687
Subject: **HEALTHY CHOICE PHARMACY, INC.** 1343 Four Seasons Blvd Tampa, FL 33613 813-644-7199	Source: **DOH / ISU / TAMPA**	

Prefix:	License #:	Profession:	Board:	Report Date:
PH	25637	Pharmacy	Pharmacy	06/27/13

Period of Investigation: 05/29/13 to 06/27/13	Type of Report: FINAL

Alleged Violation: F.S. 456.072(1)(k)(dd); F.S. 465.016(1)(r); 465.023(1)(c); RULE 64B16-28.202(3)(a)(b) F.A.C.: Failing to perform...; Violating any provision...; Violated any of the requirements...; In the event of closure of a pharmacy, the permittee shall notify the Board.....

Synopsis: This report is predicated upon a Case Summary, (Exhibit #1), based upon a complaint from the Tampa Investigative Services Unit. On 02/14/13, Investigator JOSEPH DeGREGORIO attempted to perform a routine pharmacy inspection at HEALTHY CHOICE PHARMACY, INC. with the primary business address located at 8315 Sheldon Rd., Tampa, FL. According to Investigator DeGREGORIO, the location was vacant with no signs posted. HEALTHY CHOICE PHARMACY, INC. did not notify the Board of Pharmacy of the closure of the facility.

On 05/29/13, Investigator SCOTT MARTIN notified HEALTHY CHOICE PHARMACY, INC. of the investigation by letter, (Exhibit #2), dated 05/29/13 to the address of record and was provided a copy of the Case Summary, Complaint, and a Voluntary Relinquishment of License Form.

A check of the DOH computer licensure records revealed that HEALTHY CHOICE PHARMACY, INC. is licensed as a pharmacy. The current license expired on 02/28/13 and is in a delinquent status.

The patient notification was not utilized since no patients were identified.

The source notification letter was not utilized since the complainant is the Department of Health.

HEALTHY CHOICE PHARMACY, INC is not currently represented by an attorney.

On 06/26/13, ROBERT SILVESTRO, owner of HEALTHY CHOICE PHARMACY, INC., met with Investigator MARTIN at the Tampa ISU office and signed the Voluntary Relinquishment of License Form.

Related Case(s): None

Investigator/Date: Scott M. Martin 6/27/13 Scott M. Martin TI-149 Investigation Specialist II	Approved By/Date: 6-27-13 Babette S. Agett TI-115 Investigation Supervisor Babette S Agett

Distribution: HQ/ISU

TABLE OF CONTENTS

***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 #1 is the Case Summary.

Exhibit #2 is the Notification Letter sent on 05/29/13 to the following addresses obtained in the COMPAS database and Florida Corporation Website.

- 1343 Four Seasons Blvd., Tampa, FL 33613
- 8315 Sheldon Rd., Tampa, FL 33615

Exhibit #3 is the Florida Corporation information regarding ownership of HEALTHY CHOICE PHARMACY, INC.

Exhibit #4 is a copy of the most recent Pharmacy Inspection Report dated 02/14/13

Exhibit #5 includes the photographs (two) of HEALTHY CHOICE PHARMACY, INC. location. These photographs were taken by Investigator SCOTT MARTIN on 05/30/13.

Exhibit #6 is one CD of the photographs.

Exhibit #7 is the Evidence Control Form. One CD of the photographs has been entered into evidence in the Tampa ISU office.

Exhibit #8 is the Voluntary Relinquishment form signed by SILVESTRO on 06/26/13.

Exhibit #9 is the e-mail message sent to DANNY HERNANDEZ, PSU Deputy General Counsel, along with a scanned copy of the Voluntary Relinquishment.

Interview of ROBERT S. SILVESTRO - Owner of HEALTHY CHOICE PHARMACY, INC. (Witness)
1343 Four Seasons Blvd.
Tampa, FL 33613
813-644-7199

On 06/21/13, Investigator SCOTT MARTIN interviewed ROBERT S. SILVESTRO, owner of HEALTHY CHOICE PHARMACY, INC., via telephone. SILVESTRO stated he applied for a pharmacy license for HEALTHY CHOICE PHARMACY, INC. and had every intention of opening for business. A PHARMACIST was hired to obtain licensure. SILVESTRO signed a lease for business space at 8315 Sheldon RD, Tampa, FL. The leased space was built out to accommodate the pharmacy and signage was installed to identify the pharmacy's location. He contacted the DEA on 05/08/12 and withdrew his pharmacy permit application. SILVESTRO stated he ran out of money waiting for the DEA permit approval.

On 06/26/13, SILVESTRO met with Investigator Martin at the Tampa ISU office and signed a Voluntary Relinquishment form (Exhibit #8). SILVESTRO was identified by his Florida Driver's License.

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FLORIDA DEPARTMENT OF STATE
DIVISION OF CORPORATIONS

Sunbiz

Events **No Name History**

Entity Name Search

Search

Return to Search Results

Detail by Entity Name

Florida Profit Corporation

HEALTHY CHOICE PHARMACY, INC.

Filing Information

Document Number	P10000031934
FEI/EIN Number	272339296
Date Filed	04/13/2010
State or Country	FL
Status	INACTIVE
Effective Date	04/13/2010
Last Event	VOLUNTARY DISSOLUTION
Event Date Filed	04/23/2012
Event Effective Date	NONE

Principal Address

8315 SHELDON RD
TAMPA, FL 33615

Changed: 04/28/2011

Mailing Address

1343 FOUR SEASONS BLVD
TAMPA, FL 33613

Changed: 04/28/2011

Registered Agent Name & Address

SILVESTRO, ROBERT SP
1343 FOUR SEASONS BLVD
TAMPA, FL 33613

Address Changed: 04/28/2011

Officer/Director Detail

Name & Address

EXHIBIT# 3

Title P

19

SILVESTRO, ROBERT S
1343 FOUR SEASONS BLVD
TAMPA, FL 33613

Annual Reports

Report Year	Filed Date
2011	04/28/2011

Document Images

04/23/2012 -- VOLUNTARY DISSOLUTION	View image in PDF format
04/28/2011 -- ANNUAL REPORT	View image in PDF format
04/13/2010 -- Domestic Profit	View image in PDF format

Events **No Name History**

Entity Name Search
Search

Return to Search Results

19

FILED
Apr 23, 2012
Secretary of State

ARTICLES OF DISSOLUTION

Pursuant to section 607.1401, Florida Statutes, this Florida corporation submits the following Articles of Dissolution:

FIRST: The name of the corporation as currently filed with the Florida Department of State:

HEALTHY CHOICE PHARMACY, INC.

SECOND: The document number of the corporation: P10000031934

THIRD: The file date of the articles of incorporation: April 13, 2010

FOURTH: None of the corporation's shares have been issued.

The corporation has not commenced business.

FIFTH: No debt of the corporation remains unpaid.

SIXTH: The net assets of the corporation remaining after winding up have been distributed to the shareholders, if shares were issued.

SEVENTH: A majority of the incorporators authorized the dissolution.

I submit this document and affirm that the facts stated herein are true. I am aware that any false information submitted in a document to the Department of State constitutes a third degree felony as provided for in section 817.155, Florida Statutes.

Signature: ROBERT SILVESTRO PRESIDENT

Electronic Signature of Signing Officer, Director, Incorporator or Authorized Representative

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE ☐ CHANGE LOC ☐ NEW ☐ CURRENTLY NOT OPERATING ☒ CHANGE OWNER ☐

File # 18501

Insp # 110884

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT	PERMIT NUMBER		DATE OF INSPECTION
HEALTHY CHOICE PHARMACY, INC	25637		2/14/2013
DOING BUSINESS AS HEALTHY CHOICE PHARMACY, INC	DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 8315 SHELDON RD	TELEPHONE # 813-644-7199	EXT.	
CITY TAMPA	COUNTY 39	STATE/ZIP 33615	PRESCRIPTION DEPARTMENT MANAGER LICENSE #

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.]	☒		
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.]	☒		
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.]	☒		
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.] [64B16-28.116, F.A.C.]	☒		
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]	☒		
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.]	☒		
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.]	☒		

* Note: If establishment is engaged in sterile compounding, a separate inspection form should be completed.

Remarks:

To date this pharmacy has not commenced operations. Permit is set to expire 02-28-13.

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 Not Operating

NOT OPERATING

Institutional Representative

02-14-2013

Date

EXHIBIT# 4

Investigator's/Pharmacist Signature

ID ti117

INV 359 Revised 12/12, 5/12, 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

21

HEALTHY CHOICE
PHARMACY
8315
30/05/2013

HEALTHY CHOICE
PHARMACY
8315
COMING SOON
HealthyChoiceRX
P:813-644-7199
F:813-644-7299
Hours of Operation:
Mon. - Fri. - 10am-6pm
Saturday - 10am-2pm
Sunday - Closed
30/05/2013

EXHIBIT#
5

Complaint Number: PH 2013-07687

Patient : N/A

Subject: HEALTHY CHOICE PHARMACY

Investigator: Scott Martin, ISII

CD: One (1) CD - photographs

Exhibit # 6

Page: 23

1 of 1


HEALTHY CHOICE
PHARMACY
8315
COMING SOON
HealthyChoiceRX
P:813-644-7199
F:813-644-7299
Hours of Operation:
Mon - Fri - 10am-6pm
Saturday - 10am-2pm
Sunday - Closed
8131609208


HEALTHY CHOICE
PHARMACY
8315
COMING SOON
P:813-644-7199
F:813-644-7299
8317
PHONE UNLOCK
PHONE REPAIR
BILL PAYMENT
30/05/2013

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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.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v.

DOH Case No. 2013-07687

Healthy Choice Pharmacy, Inc., Pharmacy
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent Healthy Choice Pharmacy, Inc., Pharmacy, license No. 25637, 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 Data Bank as disciplinary action. Licensing authorities in other states may impose discipline in their jurisdiction based on discipline taken in Florida.

2. Respondent agrees to never reapply for licensure as a Pharmacy in the State of Florida.

EXHIBIT# 8

3. Respondent agrees to voluntarily cease practicing pharmacy 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. 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.

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 26th day of June, 2013.

Healthy Choice Pharmacy, Inc.

STATE OF Florida
COUNTY OF Hillsborough

Before me, personally appeared Robert S. Ivestro, whose identity is known to me or who produced Florida Drivers License (type of identification) and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 26th day of June, 2013.

NOTARY PUBLIC

My Commission Expires:

SCOTT M. MARTIN
Commission # EE 115226
Expires July 25, 2015
Bonded Thru Troy Fain Insurance 800-385-7019

SCOTT M. MARTIN
Commission # EE 115226
Expires July 25, 2015
Bonded Thru Troy Fain Insurance 800-385-7019

Agett, Babette

To: Hernandez, Daniel
Cc: Martin, Scott M.
Subject: VR - 2013-07687
Attachments: VR - 2013-07687.pdf

Dan - attached, please find a Voluntary Relinquishment for case #: 2013-07687 / Healthy Choice Pharmacy, Inc. This case involved a pharmacy that had been abandoned without proper notification to the Board so that the license could be closed. The owner opted to sign the VR.

I was advised to send it to you. Thank you. Babette Agett / Tampa ISU.

Babette Smith Agett, R.N.
Investigation Supervisor
DOH / MQA / ISU / Tampa
6800 N. Dale Mabry Hwy; Ste. 220
Tampa FL 33614
813-873-4798; Fax: 813-871-7421

CONFIDENTIAL

EXHIBIT# 9

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307692

DRM ENTERPRISES, INC.,
RESPONDENT.

NOTICE

TO: DRM ENTERPRISES, INC.
P.O. BOX 2969
LAKELAND, FL 33806

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is not required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Michael Lawrence, Jr., Assistant General Counsel MJL
RE: Voluntary Relinquishment
SUBJECT: DOH v. DRM Enterprises, Inc.
DOH Case Number 2013-07692
DATE: July 16, 2013 AB

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	DRM Enterprises, Inc.
Subject's Address of Record:	P.O. Box 2969 Lakeland, FL 33806
Enforcement Address:	P.O. Box 2969 Lakeland, FL 33806
Subject's License No:	16061 **Rank:** PH
Licensure File No:	6578
Initial Licensure Date:	7/1/1998
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	456.072(1)(k)(dd), FS 465.016(1)(r), FS 465.023(1)(c), FS; 64B16-28.202(3)(a)(b), FAC
Prior Discipline:	None
Probable Cause Panel:	waived
Subject's Attorney:	A S Weekley 1635 North Tampa St #100 Tampa, FL 33602
Complainant/Address:	Department Of Health/Investigative Services Unit-Tampa
Materials Submitted:	Memorandum to the Board Motion for Final Order Voluntary Relinquishment Notification Letter Final Investigative Report with Exhibits 1-10

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. CASE NO. 2013-07692

DRM ENTERPRISES, INC.
Respondent.
_____/

MOTION FOR FINAL ORDER
BASED UPON A VOLUNTARY RELINQUISHMENT OF LICENSE

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. On or about May 14, 2013, a Uniform Consumer Complaint was filed with the Department of Health, alleging that the Subject violated the provisions of Chapter 456 or Chapter 465, Florida Statutes.

2. In lieu of undergoing further disciplinary proceedings, the Respondent returned an executed Voluntary Relinquishment of his/her license.

3. 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 Uniform Consumer Complaint.

WHEREFORE the parties respectfully request the Board of Pharmacy enter a Final Order incorporating the terms of the Voluntary Relinquishment of Licensure.

Respectfully Submitted,

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) 245-4444 x8199
Facsimile: (850) 245-4683
Email: michael_lawrence@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. certified mail this 18th day of July, 2013, to A.S. Weekley, 1635 North Tampa St #100, Tampa, FL 33602 and P.O. Box 2969, Lakeland, FL 33806.

Michael G. Lawrence, Jr.
Assistant General Counsel

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUL 16 2013

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. DOH Case No. 2013-07692

DRM Enterprises, Inc., Pharmacy
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent DRM Enterprises, Inc., Pharmacy, license No. 16061, 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 Data Bank as disciplinary action. Licensing authorities in other states may impose discipline in their jurisdiction based on discipline taken in Florida.

2. Respondent agrees to never reapply for licensure as a Pharmacy in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy 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. 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.

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 1st day of July, 2013.

DRM Enterprises, Inc.

STATE OF FL
COUNTY OF DESOTO

Before me, personally appeared Duane Russell McKeown, whose identity is known to me or who produced FL DL (type of identification) and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 1st day of July, 2013.

NOTARY PUBLIC

My Commission Expires: 11/23/2013

Notary Public State of Florida
Margie T Bergens
My Commission DD925487
Expires 11/23/2013

July 18, 2013

A.S. Weekley
1635 N. Tampa St #100
Tampa, FL 33602

Re: DOH vs. DRM Enterprises, Inc.
DOH Case Number: 2013-07692

Dear Mr. Weekley:

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 their license, pursuant to Section 456.072(1)(f), Florida Statutes;
- he/she would never reapply for licensure as a Pharmacy in the State of Florida; and
- Voluntarily relinquishing his/her Florida pharmacy license may have an effect on pharmacy licenses they may hold in other states.

If this is not what you or your client 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 client's request for Voluntary Relinquishment of License at their next regularly scheduled meeting. You are not required to attend the meeting.

Sincerely,

Michael S. Lawrence, Jr.
Assistant General Counsel

ML/ab

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: TAMPA	Date of Case: 05/14/13	Case Number: 201307692
Subject: **DRM ENTERPRISES, INC.** P.O. BOX 2969 Lakeland FL 33806	Source: **DOH / ISU / TAMPA**	

Prefix:	License #	Profession:	Board:	Report Date:
PH	16061	Pharmacy	Pharmacy	07/08/13

Period of Investigation: 05/29/13 to 07/08/13	Type of Report: FINAL

Alleged Violation: F.S. 456.072(1)(k)(dd); F.S. 465.016(1)(r); 465.023(1)(c); RULE 64B16-28.202(3)(a)(b) F.A.C.: Failing to perform...; Violating any provision...; Violated any of the requirements...; In the event of closure of a pharmacy, the permittee shall notify the Board.....

Synopsis: This report is predicated upon a Case Summary, (Exhibit #1), based upon a complaint from the Tampa Investigative Services Unit. On 11/02/12, Investigator JOSEPH DeGREGORIO attempted to perform a routine pharmacy inspection at DRM ENTERPRISES, INC. / D.B.A. MARTIN DRUG at the physical address of 437 S. Central Avenue in Lakeland, Florida. According to Investigator DeGREGORIO, the location is vacant with no forwarding address or contact phone number. DRM ENTERPRISES, INC. / D.B.A. MARTIN DRUG did not notify the Board of Pharmacy of the closure of the facility.

DRM ENTERPRISES, INC. / D.B.A. MARTIN DRUG was notified of the investigation by letter, (Exhibit #2), dated 05/29/13 to the address of record and was provided a copy of the Case Summary and complaint.

A check of the DOH computer licensure records revealed that DRM ENTERPRISES, INC. is licensed as a pharmacy. The current license expired on 02/28/13 and is in a delinquent status.

The patient notification was not utilized since no patients were identified.

The source notification letter was not utilized since the complainant is the Department of Health.

DRM ENTERPRISES, INC. / D.B.A. MARTIN DRUG is represented by A.S. WEEKLEY of Weekley/Schulte/Valdes, Attorneys at Law; 1635 North Tampa Street, Suite 100, Tampa, FL, 33602; 813-221-1154 (Exhibit #8). WEEKLEY requested a copy of the investigative report.

On 07/03/13, Investigator MARTIN received the signed Voluntary Relinquishment of License Form from DUANE McKOWN, owner of DRM ENTERPRISES, INC. (Exhibit #9).

Related Case(s): None

Investigator/Date: Scott M. Martin 7/8/13 Scott M. Martin TI-149 Investigation Specialist II	Approved By/Date: 7-08-13 Babette S. Agett TI-115 Investigation Supervisor Babette S Agett

Distribution: HQ/ISU

Received
Investigative Services

JUL 10 2013

DOH/ISU
Tallahassee, FL

RECEIVED-LEGAL
13 JUL 10 PM 3:12

INV FORM 300, created 07/02

TABLE OF CONTENTS

***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 #1 is the Case Summary

Exhibit #2 is the Subject Notification Letter and Voluntary Relinquishment of License Form sent out to the following addresses obtained in the COMPAS database and Florida Corporation Website.

- P.O. Box 2969 Lakeland, FL 33806
- P.O. Box 429 Placida, FL 33946
- P.O. Box 402 Placida, FL 33946
- 4200 South Florida Ave. Lakeland, FL 33813
- 437 South Central Ave. Lakeland, FL 33815

Exhibit #3 is the Florida Corporation information regarding ownership of DRM ENTERPRISES, INC.

Exhibit #4 is the current pharmacy inspection report dated 11/02/12.

Exhibit #5 includes three (3) photographs of the vacant pharmacy business located at 437 S. Central Ave. in Lakeland, FL. These photographs were taken by Investigator SCOTT MARTIN on 05/30/13.

Exhibit #6 is one (1) CD containing three (3) digital photographs.

Exhibit #7 is the Evidence Control Form. One CD of the photographs has been entered into evidence in the Tampa ISU office.

Exhibit #8 is the Letter of Representation from A.S. WEEKLEY, Attorney, dated 06/19/13.

Exhibit #9 is the Voluntary Relinquishment of License Form received 07/03/13.

Exhibit #10 is the E-mail message sent to YOLANDA GREEN, Attorney for PSU.

Interview of KAREN MCKOWN - Owner of People's Pharmacy (Witness)
People's Pharmacy
4977 US Hwy 98 North
Lakeland, FL 33809
863-858-4444

On 05/30/13, Investigator SCOTT MARTIN interviewed KAREN MCKOWN at 437 S. Central Ave. in Lakeland, FL. K. McKOWN said the owner of DRM ENTERPRISES, INC. is DUANE McKOWN, her ex-husband. K. McKOWN resigned from her position as President of DRM ENTERPRISES, INC. on 05/25/12 (Exhibit 3). K. McKOWN is no longer associated with DRM ENTERPRISES, INC.

Interview of DUANE McKOWN – Owner of DRM ENTERPRISES, INC. (Witness)

DUANE McKOWN
P.O. Box 402
Placida, FL 33946
863-712-4011

On 05/30/13, Investigator SCOTT MARTIN interviewed DUANE McKOWN. D. McKOWN is the owner of DRM ENTERPRISES, INC. D. McKOWN said he is currently a licensed pharmacist and no longer owns any pharmacy business since his divorce from KAREN McKOWN. D. McKOWN said he did not notify the Florida Division of Corporations or the Board of Pharmacy of DRM ENTERPRISES' dissolution. D. McKOWN said he would consider the Voluntary Relinquishment of License Form that he received from the Tampa ISU office.

On 07/03/13, Investigator MARTIN received the signed Voluntary Relinquishment of License Form from D. McKOWN.

Investigator's Note:

A Letter of Representation was received from D. McKOWN'S attorney, A.S. WEEKLEY, on 06/19/13. WEEKLEY needed clarification that D. McKOWN'S pharmacist license would not be affected if a Voluntary Relinquishment of License Form was signed for DRM ENTERPRISES, INC. WEEKLEY was provided information explaining the scope of this investigation was limited to the DRM ENTERPRISES, INC. pharmacy license.

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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.

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FLORIDA DEPARTMENT OF STATE
DIVISION OF CORPORATIONS

Sunbiz

No Events No Name History

Entity Name Search
Search

Return to Search Results

Detail by Entity Name

Florida Profit Corporation

DRM ENTERPRISES, INC.

Filing Information

Document Number	S34597
FEI/EIN Number	593054487
Date Filed	02/27/1991
State or Country	FL
Status	ACTIVE

Principal Address

437 SOUTH CENTRAL AVE
LAKELAND, FL 33815

Changed: 04/16/2007

Mailing Address

PO BOX 2969
LAKELAND, FL 33806-2969

Changed: 04/29/2009

Registered Agent Name & Address

GUARD, JR., PIERCE J
4200 SOUTH FLORIDA AVENUE
LAKELAND, FL 33813

Name Changed: 12/22/2009

Address Changed: 12/22/2009

Officer/Director Detail

NONE

Annual Reports

Report Year	Filed Date
2010	01/05/2010
2011	06/14/2011
2012	04/25/2012

Document Images

EXHIBIT# 3

20

05/25/2012 -- Off/Dir Resignation	View image in PDF format
04/25/2012 -- ANNUAL REPORT	View image in PDF format
06/14/2011 -- ANNUAL REPORT	View image in PDF format
01/05/2010 -- ANNUAL REPORT	View image in PDF format
12/22/2009 -- ANNUAL REPORT	View image in PDF format
04/29/2009 -- ANNUAL REPORT	View image in PDF format
04/07/2008 -- ANNUAL REPORT	View image in PDF format
04/16/2007 -- ANNUAL REPORT	View image in PDF format
04/20/2006 -- ANNUAL REPORT	View image in PDF format
04/14/2005 -- ANNUAL REPORT	View image in PDF format
04/08/2004 -- ANNUAL REPORT	View image in PDF format
04/11/2003 -- ANNUAL REPORT	View image in PDF format
04/22/2002 -- ANNUAL REPORT	View image in PDF format
04/12/2001 -- ANNUAL REPORT	View image in PDF format
04/17/2000 -- ANNUAL REPORT	View image in PDF format
04/15/1999 -- ANNUAL REPORT	View image in PDF format
04/24/1998 -- ANNUAL REPORT	View image in PDF format
04/17/1997 -- ANNUAL REPORT	View image in PDF format
04/30/1996 -- ANNUAL REPORT	View image in PDF format
04/13/1995 -- ANNUAL REPORT	View image in PDF format

No Events **No Name History**

Entity Name Search

Search

Return to Search Results

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2012 FOR PROFIT CORPORATION ANNUAL REPORT

FILED
Apr 25, 2012
Secretary of State

DOCUMENT# S34597

Entity Name: DRM ENTERPRISES, INC.

Current Principal Place of Business:

437 SOUTH CENTRAL AVE
LAKELAND, FL 33815 US

New Principal Place of Business:

Current Mailing Address:

PO BOX 2969
LAKELAND, FL 338062969 US

New Mailing Address:

FEI Number: 59-3054487 **FEI Number Applied For ( )** **FEI Number Not Applicable ( )** **Certificate of Status Desired ( )**

Name and Address of Current Registered Agent:

GUARD, JR., PIERCE J
4200 SOUTH FLORIDA AVENUE
LAKELAND, FL 33813 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: P/D
Name: MCKOWN, KAREN
Address: 6744 CRESCENT WOODS CIR
City-St-Zip: LAKELAND, FL 33813 US

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: KAREN MCKOWN P 04/25/2012

Electronic Signature of Signing Officer or Director — Date

22

S34597

(Requestor's Name)

(Address)

(Address)

(City/State/Zip/Phone #)

☐ PICK-UP ☐ WAIT ☐ MAIL

(Business Entity Name)

(Document Number)

Certified Copies _____ Certificates of Status _____

Special Instructions to Filing Officer:

Office Use Only

200235122112

Resignation of Officer

05/25/12--01020--013 **35.00

FILED
2012 MAY 25 PM 12:23
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

5/29/12

23

FILED

2012 MAY 25 PM 12:23

SECRETARY OF STATE
TALLAHASSEE, FLORIDA

OFFICER / DIRECTOR RESIGNATION FOR A CORPORATION

I. Karen McKown, hereby resign as President (Title)

of DRM Enterprises, Inc (Name of Corporation)

S34597 (Document Number, if known), a corporation organized under the laws of the State of Florida.

Karen McKown
(Signature of resigning officer/director)

FILING FEE IS $35.00

Make checks payable to Florida Department of State and mail to:

Amendment Section
Division of Corporations
P.O. Box 6327
Tallahassee, Florida 32314

24

COVER LETTER

TO: Amendment Section
Division of Corporations

SUBJECT: DRM, Enterprises
(Name of Corporation)

DOCUMENT NUMBER: S34597

The enclosed Resignation of Registered Agent for a Corporation and fee are submitted for filing.

Please return all correspondence concerning this matter to the following:

Duane R McKown
(Name of Person)

DRM Enterprises
(Name of Firm/Company)

P.O. Box 429
(Address)

Placida, FL 33946
(City/State and Zip Code)

For further information concerning this matter, please call:

Pierce J Guard, Jr at (863) 619-7338
(Name of Person) (Area Code & Daytime Telephone Number)

Enclosed is a check made payable to the Florida Department of State for $87.50 for an active corporation or $35.00 for an administratively dissolved, voluntarily dissolved or withdrawn corporation.

Street Address:
Amendment Section
Division of Corporations
Clifton Building
2661 Executive Center Circle
Tallahassee, FL 32301

Mailing Address:
Amendment Section
Division of Corporations
Post Office Box 6327
Tallahassee, FL 32314

CR2E046 (04/12)

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH
WWW.DOH.STATE.FL.US

File # 6578
Insp # 108125

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
DRM ENTERPRISES, INC.		16061		11/2/2012
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
MARTIN DRUGS				
STREET ADDRESS		TELEPHONE #	EXT.	
437 S. CENTRAL AVENUE				
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
LAKELAND	63	33815		

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.]		☒		
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.]		☒		
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.]		☒		
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: This pharmacy is closed and the building is closed. Most of the equipment and furnishings have been removed. According to Gerald Amyot, a pharmacist who worked part time at Martin Drugs stated the pharmacy closed in February 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 N/A

N/A
Institutional Representative

11-02-2012
Date

Investigator/Sr. Pharmacist Signature

ID ti122

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

EXHIBIT# 4

26


MARTIN DRUG
437 CENTRAL AVE.
HOME HEALTHCARE
CENTER
GOOD
NEIGHBOR
PHARMACY
30/05/2013


437
CENTRAL AVE
Protection One
30/05/2013

EXHIBIT#
5


GOOD NEIGHBOR PHARMACY
MARTIN DRUG
30/05/2013

Complaint Number: PH 2013-07692

Patient : N/A

Subject: DRM ENTERPRISES, INC.

Investigator: Scott Martin, ISII

CD: One (1) CD – Digital Photographs

Exhibit # 6

Page: 29

1 of 2


MARTIN DRUG
437 CENTRAL AVE.
HOME HEALTHCARE
CENTER
GOOD NEIGHBOR PHARMACY
30/05/2013


437
CENTRAL AVE
MONITORED
SECURITY SYSTEM BY
Protection One
(800) GET-HELP
30/05/2013


GOOD NEIGHBOR PHARMACY
MARTIN DRUG
Protection One
30/05/2013

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

HEALTH

Vision: To be the **Healthiest State** in the Nation

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

EVIDENCE CONTROL FORM

Case Number 2013-07692 Office Property Receipt Number 144 C Date/Time 7/8/13 12 50 p

Owners Name n/a Phone:

Address:

Obtained By Scott Martin. ISII Phone 813-871-7425

Address: 6800 N. Dale Mabry Hwy, Ste. 220; Tampa, FL 33614

Item #	Quantity	Description
1- 1 (one) CD	1 (one)	Compact Disc containing 3 (three) photographs of abandoned
2-		pharmacy
3-		
4-		
5-		
6-		

I hereby acknowledge that the above list represents all property impounded by me in the official performance of my duty as an Investigator for the Department of Health.

Scott Martin
Investigator's Signature

CHAIN OF CUSTODY					
Item#	RELEASED BY	Date/Time	RECEIVED BY	Date/Time	PURPOSE OF CHANGE OF CUSTODY
1	Signature: Scott Martin Name: Scott Martin		Signature: Babette Agot Name: Babette Agot	7/8/13	Storage of Evidence
2	Signature: Name:		Signature: Name:		
3	Signature: Name:		Signature: Name:		
4	Signature: Name:		Signature: Name:		
5	Signature: Name:		Signature: Name:		
6	Signature: Name:		Signature: Name:		

Final Disposition

Returned To
Item 1 2 3 4 5 6

Received By Date

Address Phone

City State Zip

Destroyed By
Item 1 2 3 4 5 6

Name Date

Witness

Remarks

EXHIBIT#
7

INV FORM 342. Created 10/02

30

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.

PAUL M. WEEKLEY
CHRISTOPHER J. SCHULTE
JODY M. VALDES
J. TRAVIS GODWIN

WEEKLEY | SCHULTE | VALDES
ATTORNEYS AT LAW

JESSICA D. DARDEAU
MEGAN B. MAZZONE
MARSHALL D. SCHRAP
A.S. "GUS" WEEKLEY, JR., M.D.

July 3, 2013

VIA FACSIMILE – 813-871-7421
VIA U.S. MAIL

Mr. Scott M. Martin
Investigator Specialist II
Florida Department of Health
6800 N. Dale Mabry Hwy., Suite 220
Tampa, Fl. 33614

Re: DRM Enterprises, Inc.
Pharmacy License No 16061
Case Number: 2013-07692

Dear Mr. Martin:

Enclosed please find the Voluntary Relinquishment of Pharmacy License No. 16061 for DRM Enterprises, Inc. It has been executed by Duane Russell McKown. This is submitted on behalf of Mr. McKown after our telephone understanding that it will have no effect on Mr. McKown's Pharmacist License.

Thank you for your cooperation in this matter and please be assured of ours in reciprocity

If you have any questions, please feel free to contact me.

Sincerely,

A.S. Weekley, Jr., M.D.
E-Mail: gus.weekley@wsvlegal.com

ASW:np

Enclosure

cc: DRM Enterprises, Inc. d/b/a Wilson Drug
Duane McKown

EXHIBIT# 9

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. DOH Case No. 2013-07692

DRM Enterprises, Inc., Pharmacy
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent DRM Enterprises, Inc., Pharmacy, license No. 16061, 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 Data Bank as disciplinary action. Licensing authorities in other states may impose discipline in their jurisdiction based on discipline taken in Florida.

2. Respondent agrees to never reapply for licensure as a Pharmacy in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy 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. 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.

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 1ST day of July, 2013.

DRM Enterprises, Inc.

STATE OF FL
COUNTY OF DESOTO

Before me, personally appeared Duane Russell McKown, whose identity is known to me or who produced FL DL - M250-176 57-130.9 (type of identification) and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 1st day of July, 2013.

Margie T Bergens
NOTARY PUBLIC

My Commission Expires: 11/23/2013

Notary Public State of Florida
Margie T Bergens
My Commission DD925487
Expires 11/23/2013

PAUL M. WEEKLEY
CHRISTOPHER J. SCHULTE
JODY M. VALDES
J. TRAVIS GODWIN

WEEKLEY | SCHULTE | VALDES

ATTORNEYS AT LAW

JESSICA D. DARENEAU
MEGAN B. MAZZONE
MARSHALL D. SCHAAP
A.S. "GUS" WEEKLEY, JR., M.D.

July 3, 2013

VIA FACSIMILE – 813-871-7421
VIA U.S. MAIL

Mr. Scott M. Martin
Investigator Specialist II
Florida Department of Health
6800 N. Dale Mabry Hwy., Suite 220
Tampa, FL 33614

Re: DRM Enterprises, Inc.
Pharmacy License No 16061
Case Number: 2013-07692

Dear Mr. Martin:

Enclosed please find the Voluntary Relinquishment of Pharmacy License No. 16061 for DRM Enterprises, Inc. It has been executed by Duane Russeu McKown. This is submitted on behalf of Mr. McKown after our telephone understanding that it will have no effect on Mr. McKown's Pharmacist License.

Thank you for your cooperation in this matter and please be assured of ours in reciprocity

If you have any questions, please feel free to contact me.

Sincerely,

A.S. Weekley, Jr., M.D.
E-Mail: gus.weekley@wsvlegal.com

ASW:np

Enclosure

cc: DRM Enterprises, Inc. d/b/a Wilson Drug
Duane McKown

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. DOH Case No. 2013-07692

DRM Enterprises, Inc., Pharmacy
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent DRM Enterprises, Inc., Pharmacy, license No. 16061, 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 Data Bank as disciplinary action. Licensing authorities in other states may impose discipline in their jurisdiction based on discipline taken in Florida.

2. Respondent agrees to never reapply for licensure as a Pharmacy in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy 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. 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.

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 1st day of July, 2013.

DRM Enterprises, Inc.

STATE OF FL
COUNTY OF DESOTO

Before me, personally appeared DUANE RUSSELL MCKAWN, whose identity is known to me or who produced FL DL - M250-176 57-130.9 (type of identification) and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 1st day of July, 2013.

NOTARY PUBLIC

My Commission Expires: 11/23/2013

Notary Public State of Florida
Margie T Bergens
My Commission DD925487
Expires 11/23/2013

Agett, Babette

To: Green, Yolonda

Cc: Martin, Scott M.

Subject: Voluntary Relinquishment

Yolando - please see attached Voluntary Relinquishment for case #: 2013-07692 / DRM Enterprises. This was an abandoned pharmacy. The owner finally agreed to sign the VR. If you have any questions, please do not hesitate to contact Scott Martin, the investigator, at 813-871-7425. Thank you.

Babette Smith Agett, R.N.
Investigation Supervisor
DOH / MQA / ISU / Tampa
6800 N. Dale Mabry Hwy; Ste. 220
Tampa FL 33614
813-673-4798; Fax: 813-871-7421

EXHIBIT# 10

Florida
HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

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

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201215204

JOSHUA STEPHEN EZZO,
RESPONDENT.

NOTICE

TO: JOSHUA STEPHEN EZZO
532 BLAIRMORE BLVD
ORANGE PARK, FL 32073

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is not required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000..

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitker
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Judson Searcy, General Counsel JS
RE: Voluntary Relinquishment
SUBJECT: DOH v. Joshua Stephen Ezzo, RPT
DOH Case Number 2012-15204
DATE: July 16, 2013 AB

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Joshua Stephen Ezzo
Subject's Address of Record:	532 Blairmore Blvd Orange Park, FL 32073
Enforcement Address:	532 Blairmore Blvd Orange Park, FL 32073
Subject's License No:	32450 **Rank:** RPT
Licensure File No:	33194
Initial Licensure Date:	7/20/2010
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	456.072(1)(x), FS (2012)
Prior Discipline:	None
Probable Cause Panel:	March 28, 2013; Weizer & Meshad
Subject's Attorney:	Pro Se
Complainant/Address:	Department Of Health/Office Of General Counsel
Materials Submitted:	Memorandum to the Board Voluntary Relinquishment Administrative Complaint Notification Letter Election of Rights Probable Cause Memorandum Final Investigative Report with Exhibits 1-2

DISCIPLINARY GUIDELINES:

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Bridget Coates
DATE: 7-12-13

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v.

DOH Case No. 2012-15204

JOSHUA STEPHEN EZZO, R.P.T.,
Respondent.

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, Joshua Stephen Ezzo, R.P.T., license No. 32450, hereby voluntarily relinquishes Respondent's license to practice 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 license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for licensure 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 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. 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 11 day of July, 2013.

Joshua Stephen Ezzo, R.P.T.

STATE OF FLORIDA
COUNTY OF: Clay

Before me, personally appeared Joshua S. Ezzo, whose identity is known to me by FLDL (type of identification) and who, under oath, acknowledges that his signature appears above. Sworn to and subscribed before me this 11 day of July, 2013.

NOTARY PUBLIC

My Commission Expires:

TOM P. TAN
Commission # DD 973949
Expires April 15, 2016

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-15204**

JOSHUA STEPHEN EZZO, R.P.T.,

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, Joshua Stephen Ezzo, 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 Complaint, Respondent was a registered pharmacy technician within the state of Florida, having been issued license number RPT 32450.

3. Respondent's address of record is 532 Blairmore Boulevard, Orange Park, Florida 32073.

4. On or about June 21, 2012, in the Circuit Court of the Fourth Judicial Circuit, in and for Clay County, Florida, in case number 2012-CF-000938, Respondent pled guilty to one count of Grand Theft and one count of Dealing in Stolen Property.

5. Respondent failed to timely report, in writing, the above-referenced pleas to the Board of Pharmacy.

6. Section 456.072(1)(x), Florida Statutes (2012), provides 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.

7. Respondent failed to timely report to the board in writing the pleas in the above-referenced criminal case in paragraph four within thirty (30) days after his pleas were entered by the court.

8. Based on the foregoing, Respondent violated Section 456.072(1)(x), Florida Statutes (2012), 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.

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, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and Secretary of Health

JUDSON SEARCY
Assistant General Counsel
Fla. Bar No. 0098772
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: judson_searcy@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE MAR 28 2013

PCP: 3-28-13
PCP Members: Weize + 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.

July 16, 2013

Joshua S Ezzo
532 Blairmore Blvd
Orange Park, FL 32073

Re: DOH vs. Joshua Stephen Ezzo, RPT
DOH Case Number: 2012-15204

Dear Mr. Ezzo:

I am in receipt of the settlement agreement executed by you on July 11, 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,

Judson Searcy
Assistant General Counsel

JS/ab

ELECTION OF RIGHTS

DOH v. Joshua Stephen Ezzo, RPT Case No. 2012-15214

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. DSE 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 Agreement, have signed and am returning the Settlement Agreement or I am interested in settling this case.

X I do not wish to continue practicing, have signed and returned the voluntary relinquishment of licensure 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.)

Joshua Stephen Ezzo
Respondent's Name
Address:

Lic. No.

Phone

Fax No.

STATE OF FLORIDA
COUNTY OF Clay

Before me, personally appeared Joshua S. Ezzo whose identity is known to me or by

FL DL (type of identification) and who, acknowledges that his/her signature appears above. Sworn to or affirmed by Affiant before me this 11 day of July 2013.

Notary Public-State of Florida

Tom Tan
Type or Print Name

My Commission Expires 4/16/14

TOM P. TAN
Commission # DD 973949
Expires April 16, 2014
Bonded Thru Troy Fain Insurance 800-385-7019

PLEASE MAIL AND/OR FAX COMPLETED FORM TO: Judson Searcy, 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) 245-4683; TDD 1-800-955-8771.

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Joshua Stephen Ezzo, RPT.**
Case Number: 2012-15204

MEMBERS: **Gavin Meshad and Michele Weizer**
DATE OF PCP: **March 28, 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)(x), 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** _____

Michele Weizer PharmD, BCPS 3/28/13
Chair, Probable Cause Panel Date
Board of Pharmacy

FLORIDA DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: CONSUMER SERVICES	Date of Complaint: October 22, 2012	Case Number: 2012-15204

Subject: **JOSHUA STEPHEN EZZO, RPT** 532 Blairmore Blvd Orange Park, FL 32073 (904) 469-9201	Source: **DEPARTMENT OF HEALTH** **OFFICE OF GENERAL COUNSEL** 4052 Bald Cypress Way Tallahassee, FL 32399

Prefix: RPT 2208	License #: 32450	Profession: Registered Pharmacy Technician	Board: Pharmacy	Report Date: January 11, 2013

Period of Investigation: 10/22/12-01/11/13	Type of Report: FINAL

Alleged Violation: s. 456.072(1)(dd): Violating any provision of this chapter, the applicable practice act, or any rules adopted, s. 465.016(1)(f), FS: Having been convicted or found guilty, regardless... 465.016(1)(o), FS: Failing to report to the department any licensee under chapter... 465.016(1)(r), FS: Violating any provision of this chapter or chapter 456...

Synopsis: This investigation is predicated on the receipt of information from Department of Health/Office of General Counsel (Ex. #1, Case Summary and attachments) which alleges EZZO failed to report a criminal conviction. Certified court documents received from Clay County Clerk of Court show that EZZO entered a plea of guilty to the offense of Grand Theft (s. 812.014, FS) and Dealing in Stolen Property (s. 812.019, FS) on 06/21/12. EZZO failed to report this conviction within 30 days (Ex. # 1, Case Summary and attachments).

EZZO was notified of this complaint by regular mail dated 10/22/12 (Ex. # 2). Forwarded with this letter were copies of the Case Summary and complaint (Ex. # 1).On 12/19/12 a Subject notification letter was mailed certified to his address of record (Domestic Return Receipt/Green card returned on 12/26/12 signed by EZZO) and Accurint address: 198 Arora Blvd, #2208, Orange Park, FL 32073-3287 (Domestic Return receipt/Green card returned on 12/26/12 signed by Subject).

DOH computer information query conducted 01/11/13 revealed EZZO is duly licensed to practice as a Registered Pharmacy Technician in the State of Florida and that his license is in CLEAR/ACTIVE status.

No patient(s) were identified, thus patient notification was not required.

EZZO does not appear to be represented by counsel as of the date of this report.

EZZO has not responded to this investigator, in writing, as of the date of this report.

Related Case:

Investigator/Date: Antoinette Carter (HA115) 01/11/13 Investigation Specialist II	Approved By/Date: Caroline Anderson Shane Walters OMC Manager I 1/11/13

Distribution: Legal/Consumer Services Unit

TABLE OF CONTENTS

INVESTIGATIVE DETAILS

SUMMARY OF RECORDS

Exhibit #1 is a Case Summary, complaint and documents from Clay County Clerk of Court. Certified court documents received from Clay County Clerk of Court show that EZZO entered a plea of guilty to the offense of Grand Theft (s. 812.014, FS) and Dealing in Stolen Property (s. 812.019, FS) on 06/21/12. EZZO failed to report this conviction within 30 days (Ex. # 1, Case Summary and attachments).

STATEMENT OF DEPARTMENT OF HEALTH/Office of General Counsel-- Source

Address of Record: 4052 Bald Cypress Way
Tallahassee, FL 32399

No additional information was received from the Source.

STATEMENT OF JOSHUA STEPHEN EZZO, RPT-- Subject

Address of Record: 532 Blairmore Blvd
Orange Park, FL 32073
(904) 469-9201

EZZO has not responded to this investigator, in writing, as of the date of this report.

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. 201310982

MALISSA SUE BENDER,
RESPONDENT.

NOTICE

TO: MALISSA SUE BENDER
181 SW PALM DRIVE APT. 202
PORT ST. LUCIE, FL 34986

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is not required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

For Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Michael Lawrence, Jr., Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. Malissa Sue Bender, R.P.T.
DOH Case Number 2013-10982
DATE: August 1, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Malissa Sue Bender
Subject's Address of Record:	181 SW Palm Drive, Apt 202 Port St Lucie, FL 34986
Enforcement Address:	181 SW Palm Drive, Apt 202 Port St. Lucie, FL 34986
Subject's Additional Address:	231 SW Palm Dr, Apt 108 Port St Lucie, FL 34986
Subject's License No:	37251 **Rank:** RPT
Licensure File No:	38283
Initial Licensure Date:	4/4/2011
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	456.072(1)(z)(dd), FS 465.016(1)(d)2.(e)(i)(m), FS
Prior Discipline:	None
Probable Cause Panel:	Waived
Subject's Attorney:	Pro Se
Complainant/Address:	Department Of Health/Consumer Services Unit 4052 Bald Cypress Way, Bin C-75 Tallahassee, FL 32399
Materials Submitted:	Memorandum to the Board Motion For Final Order Voluntary Relinquishment Notification Letter

Final Investigative Report with Exhibits 1-3

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,
v. CASE NO. 2013-10982

MALISSA SUE BENDER, R.P.T.,
Respondent.
_____/

MOTION FOR FINAL ORDER
BASED UPON A VOLUNTARY RELINQUISHMENT OF LICENSE

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. On or about July 15, 2013, a Uniform Consumer Complaint was filed with the Department of Health, alleging that the Subject violated the provisions of Chapter 456 or Chapter 465, Florida Statutes.

2. In lieu of undergoing further disciplinary proceedings, the Respondent returned an executed Voluntary Relinquishment of his/her license.

3. 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 Uniform Consumer Complaint.

WHEREFORE the parties respectfully request the Board of Pharmacy enter a Final Order incorporating the terms of the Voluntary Relinquishment of Licensure.

Respectfully Submitted,

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) 245-4444 x8199
Facsimile: (850) 245-4683
Email: michael_lawrence@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. certified mail this 2nd day of August, 2013, to Malissa Bender, 231 SW Palm Drive, Apt 108, Port St Lucie, FL 34986.

Michael G. Lawrence, Jr.
Assistant General Counsel

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE AUG 0 1 2013

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. DOH Case Number: 2013- 10982

MALISSA SUE BENDER, RPT
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent MALISSA SUE BENDER, license number RPT 37251, hereby voluntarily relinquishes Respondent's license to practice as a Registered 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 license pursuant to section 456.072 (1) (f), Florida Statutes.

2. Respondent agrees to never reapply for licensure as a Registered Pharmacy Technician in the State of Florida.

3. Respondent agrees to voluntarily cease practicing as a Registered Pharmacy Technician immediately upon executing the Voluntary Relinquishment.

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 case, 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 case become public record and remain public record and that information is immediately accessible to the public, pursuant to 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 22nd day of July, 2013.

MALISSA SUE BENDER

STATE OF FL
COUNTY OF ST LUCIE

NVDL(CDC)

Before me, personally appeared MALISSA SUE BENDER, whose identity is known to me by Mal Bal MALISSA BENDER type of identification) and who, under oath, acknowledges that her signature appears above. Sworn to and subscribed before me this 22 day of July 22, 2013.

NOTARY PUBLIC

My Commission Expires:

AMY SENIOR
Commission # EE 198446
Expires May 23, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

August 1, 2013

Malissa Bender
231 SW Palm Dr #108
Port St Lucie, FL 34986

Re: DOH vs. Malissa Sue Bender, R.P.T.
DOH Case Number: 2013-10982

Dear. Ms. Bender:

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;
- 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,

Michael G. Lawrence, Jr.
Assistant General Counsel

ML/ab

STATE OF FLORIDA

DEPARTMENT OF HEALTH
INVESTIGATIVE REPORT

Office: West Palm Beach		Date of Case: 7/15/13		Case Number: 2013-10982
Subject: **MALISSA SUE BENDER, RPT** 181 SW Palm Dr., Apt. 202* Port Saint Lucie, FL 34986 (772) 626-3014		Source: **DEPT. OF HEALTH/CONSUMER SERVICES UNIT (CSU)**		
Prefix: RPT	License #: 37251	Profession: Registered Pharmacy Technician	Board: Pharmacy	Report Date: 7/23/2013
Period of Investigation: 7/22/13 – 7/23/13		Type of Report: SUPPLEMENTAL		

Alleged Violation: F.S. 456.072(1)(z)(dd); 465.016(1)(d)2.(e)(i)(m)-Failure to perform any statutory/legal obligation; Impaired from alcohol/drugs/other; Prescription/dispensing outside professional practice; Violating any provision/rule

Synopsis: This SUPPLEMENTAL report is predicated upon receipt of the Voluntary Relinquishment form executed by BENDER on 7/22/13 (EX# S-1).

Additionally on 7/22/13, CVS Regional Loss Prevention Manager ADALBERT MARTINEZ was interviewed by Investigator SENIOR via telephone (954-649-2452), essentially confirming the details reported in the police report are accurate. On 6/7/13 a patient's prescription was filled for 30 Oxycodone pills. On 7/10/13 when the patient presented to pick up that prescription, the pills could not be found. There was no eye witness or surveillance footage available. MARTINEZ' internal investigation entailed his review of staffing schedules for the date the prescription was filled (6/7/13). He intended on interviewing all staff present that day. BENDER happened to be the first person MARTINEZ interviewed. BENDER admitted to taking the filled patient's prescription. BENDER detailed that she had a neighbor who had recently been diagnosed with cancer and BENDER wanted to help her find pain relief. On 6/7/13 BENDER saw the opportunity and removed the vial of filled Oxycodone (30 count) from the "waiting bin" area of the pharmacy. BENDER placed the vial in her pocket, went home and reportedly gave the neighbor the vial.

During questioning, MARTINEZ asked BENDER if there were any other missing medications they should know about. BENDER then further admitted that around 6/20/13 she took an entire stock bottle of 120 count Hydrocodone from the shelf, placed it in her pocket, and took it home, again reportedly for the neighbor. MARTINEZ confirmed that the pharmacy had not been aware of the missing bottle of Hydrocodone at that point. Along with the Pharmacy Supervisor, an inventory of Hydrocodone was conducted and a great deal of Hydrocodone was confirmed missing. This led to the further investigation and arrest of a second Pharmacy Technician. MARTINEZ provided a copy of BENDER's written statement regarding the above details, as well as a Promissory Note completed by BENDER, and medication pricing documents (EX#S-4).

EXHIBITS

S-1 Voluntary Relinquishment form executed by BENDER 7/22/13 .....p.2-3,
S-2 BENDER's wallet RPT license, obtained at time of VR (7/22/13).....p.4
S-3 Copy of email to appropriate counsel/DOH personnel, dated 7/23/13.....p.5
S-4 BENDER's written statement and additional documentation, provided by CVS....p.6-13

*BENDER advises her current address is: 231 SW Palm Dr., Apt 108, Port St. Lucie, FL 34986

Related Cases: 2013-10988

Investigator/Date: 7/23/13
AMY SENIOR, INVESTIGATOR, WI-89

Approved By/Date:
MICHELLE MILLER, INV. MANAGER, WI-102

Distribution: HQ/ISU

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. DOH Case Number: 2013- 10982

MALISSA SUE BENDER, RPT

Respondent.

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent MALISSA SUE BENDER, license number RPT 37251, hereby voluntarily relinquishes Respondent's license to practice as a Registered 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 license pursuant to section 456.072 (1) (f), Florida Statutes.

2. Respondent agrees to never reapply for licensure as a Registered Pharmacy Technician in the State of Florida.

3. Respondent agrees to voluntarily cease practicing as a Registered Pharmacy Technician immediately upon executing the Voluntary Relinquishment.

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 case, 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

EXHIBIT # S-1
p 2

waiver, Respondent understands that the record and case become public record and remain public record and that information is immediately accessible to the public, pursuant to 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 22nd day of July, 2013.

MALISSA SUE BENDER

STATE OF FL
COUNTY OF ST LUCIE

Before me, personally appeared MALISSA SUE BENDER, whose identity is known to me by NYDL (DOC) 854-938-367 (type of identification) and who, under oath, acknowledges that her signature appears above. Sworn to and subscribed before me this 22 day of July 22, 2013.

NOTARY PUBLIC

My Commission Expires:

AMY SENIOR
Commission # EE 198446
Expires May 23, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

2.3

envelope
contents:

one (1) walled sized

DOH issued

RPT license card

(RPT 37251)

EXHIBIT # S-2

p. 4

Senior, Amy
From: Senior, Amy
Sent: Tuesday, July 23, 2013 9:52 AM
To: Green, Yolonda; Friedberg, Jenifer
Cc: Miller, Michelle; Ferguson, Christopher K; Summer, Bonnie
Subject: VR

Attachments: vr-07232013094200.pdf

Please find attached executed VR
RE: 2013-10982

vr-0723201309420
0.pdf (91 KB)

Amy Senior, CPM
Medical Quality Assurance Investigator
Department of Health
Division of Medical Quality Assurance
Investigative Services Unit
900 S. US Highway One, Suite 207
Jupiter, FL 33477
Direct# (561) 741-4583
Fax # (561) 741-4581

EXHIBIT # 83

p5

CVS0305-01 Employee Maintenance 07/10/13
Ver. 1.15 08:57 AM

Emp Number 0937266 Name MALISSA BENDER Record Status A

Title Code	350020	SSN	
Title Desc	PHARMACY TECHNICIAN	Address	1956 EMBER ST
Home Dept #	89	City	PORT ST.LUCIE
Dept Description	PHARMACY	State	FL
Ft/Pt	FT	Zip	34953-
Date Ft/Pt	09/04/2011	Birth Date	02/24/1984
Date of Hire	01/19/2011	Current Status	A
Rate Effective	01/06/2013		
Next Review	02/17/2014		
Service Date	02/17/2010	LOCAL INFORMATION:	
		Home Phone	(772) 626-3014
ELIGIBILITY:		Work Phone	
Vacation Hours	(38.0)	Schedule Name	
Holiday (Y)	Sick (Y)	Locker Number	EWMS Home Store
Funeral (Y)	Jury (Y)	Valid Initials	Pay/Union Code No Union
		Alternative Week Overtime Hours:YES	0.5

ESC EXIT F1 UPDAT F5 CLEAR F6 MENU F9 MGRS F10 HELP F12 KEYS

Time=08:58 Current Window=3 Number of Windows=4 SYSTEM MESSAGE AVAILABLE

EXHIBIT # S-4

p6

STATEMENT

I, Malissa Bender (Please Print), hereby make this statement voluntarily to CVS/pharmacy and to Albert Martinez on July 10 at 2013 11:19 AM Store # 5157.

I understand that I am making this statement of my own free will without any threat, promise, or coercion.

Address: 231 SW Palm Dr. Apt 108 Port St Lucie FL 34986

Phone: 772-626-3014 DOB: 2/24/84 AGE: 29

Q= Question by: Albert Martinez

A= Answer by: Malissa Bender

Q. What is your current title and length of service at CVS/pharmacy?

A. Pharmacy Technician 3 years

Q. Malissa, today we discussed some losses that you caused CVS is this correct?

A. yes

Q. Please explain in detail what happened?

A- There was the first time when I took oxycodone for a neighbor I took the drug from the waiting bin. Another time I took a bottle of hydrocodone 10/325 as well from the shelf and put it in my pocket. Both of these incidents I took the medication for a neighbor and have since lost contact with that person. I know it was the wrong thing to do and was not compensated in any way for my actions.

I offer this statement voluntarily, and state that it is true, to the best of my knowledge. I have not been threatened, coerced, or promised leniency by any agent of CVS/pharmacy to compel me to submit this statement.

SIGNED: Malissa Bender DATE: 7/10/13 TIME: 11:26 Am

WITNESS: [signature] DATE: 7/10/13 TIME: 11:26 am

WITNESS: [signature] DATE: 7/10/13 TIME: 11:51 am

STATEMENT

Q. When did you take these drugs from CVS #5157?
A. Oxycodone was about 3 weeks ago I think and the hydrocodone was around June 28th sometime the last week of June.

Q. How much of each drug did you take and/or remove from the pharmacy?
A. hydrocodone 100 oxycodone 15

Q. Did you have permission and/or authorization to remove these drugs from CVS #5157?
A. No

Q. How did you remove the drugs from the pharmacy?
A. The oxycodone I removed from the bag and bottle and put in my pocket. The hydrocodone I took the bottle and put it in my pocket (it was a stock bottle the original bottle

Q. Did you ever pay for these drugs?
A. No

I offer this statement voluntarily, and state that it is true, to the best of my knowledge. I have not been threatened, coerced, or promised leniency by any agent of CVS/pharmacy to compel me to submit this statement.

SIGNED: [signature] DATE: 7/10/13 TIME: 11:34 AM

WITNESS: [signature] DATE: 7/10/13 TIME: 11:37 am

WITNESS: [signature] DATE: 7/16/13 TIME: 11:51 am

STATEMENT

Q. Are you responsible for any other drug losses before CVS #5175 that we have not yet discussed?
A. No

Q. What is the total loss you caused CVS by your actions?
A. $446.18

Q. Are you willing to pay CVS back for these losses?
A. yes

Q. Have you been truthful during this conversation and statement today?
A. yes

Q Have you been treated fairly by me today during this process?
A. yes

I offer this statement voluntarily, and state that it is true, to the best of my knowledge. I have not been threatened, coerced, or promised lenlency by any agent of CVS/pharmacy to compel me to submit this statement.

SIGNED: [signature] DATE: 7/10/13 TIME: 11:46 AM

WITNESS: [signature] DATE: 7/10/13 TIME: 11:46 am

WITNESS: J N Bowers DATE: 7/10/13 TIME: 11:57 am

9

STATEMENT

Q. Do you understand your actions violated the law and CVS policy?

A. Yes

Q. Is there anything else you want to say?

A. Im sorry for my actions and regret any negatives outcomes and hardships it has caused CVS and its employees.

— end of statement —

I offer this statement voluntarily, and state that it is true, to the best of my knowledge. I have not been threatened, coerced, or promised leniency by any agent of CVS/pharmacy to compel me to submit this statement.

SIGNED: [signature] DATE: 7/10/13 TIME: 11:49 AM

WITNESS: [signature] DATE: 7/10/13 TIME: 11:49 am

WITNESS: [signature] DATE: 7/10/13 TIME: 11:51 am

Promissory Note

Store: 6157
Date: 7-10-2013

I, Malissa Bender (Please Print), have acknowledged the unauthorized conversion of certain property of CVS, Inc., in a statement dated 7/10/13 and signed by me. I agree to make full restitution as set out below, or as ordered by a court of law, to CVS, Inc.

I agree to make restitution in the amount of $ Four hundred forty six and 18/100 (Printed Amount) | $ 446.18

Default in the payment of any installment when due, either in whole or part, at the option of CVS, Inc., shall cause the whole sum to become due and payable at once without notice. Failure to exercise this option shall not constitute a waiver of the right to exercise the same in the event of any subsequent default.

Upon default, I agree to pay all amounts due and owing pursuant to this Promissory Note, plus the cost and suit and reasonable attorney's fees.

The rights and remedies hereby given shall not affect other rights and remedies which CVS may have against the undersigned, nor shall CVS acceptance hereof, or any payment or payments hereunder, affect such other rights or remedies.

This note is not given in exchange for any promise, express or implied, regarding either the status of my employment or any other action the company may take, either civil or criminal, and is entered into by me voluntarily, without duress, and with my full knowledge and consent as to the terms herein.

In the event any portion of this promissory note shall be determined to be void for any reason, the remaining provisions of this note shall remain valid and enforceable.

Witness

Signature

Witness

7/10/13
Date

11

Price Quote

wks01:Alt-F2 - CHAIN : Wed, 10 Jul 2013 11:40:27 AM

1. Drug Name	OXYCODONE HCL 15 MG TABLET	00603-4991-21 100EA AB QUALITEST
2. Patient Type	CASH	
3. Drug Quantity	20	
4. Drug Unit Cost	0.76	
5. Price	18.39	
6. Patient Pay Amount	18.39	
7. Equivalent Drug	OXYCODONE HCL 15 MG TABLET	43063-0219-10 10EA ZA PD-RX PHARM
8. Price	89.19	
9. Price Difference	-70.80	

7/10/13

Select a function and press <Enter>

Change Line (#), Price Calculation For a Specific Quantity (Q999.99), Price Calculation For a Specific Dollar Amount ($$99.99), Exit (X)

Patient	Prescriber	Drug	Third Party	Profile	Radar Store	Clinical	Refill	Help	Credentials	Store Info	Adj Status
F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12

JUL-10-2013 WED 01:01 PM CVS 5157 FAX:772 343 0608 P.007

Price Quote

wks01:Alt-F2 – CHAIN : Wed, 10 Jul 2013 11:39:27 AM

1.	Drug Name	HYDROCODON-ACETAMINOPHN 10-325	00406-0367-01 100EA AA MALLINCKRODT PH
2.	Patient Type	CASH	
3.	Drug Quantity	100	
4.	Drug Unit Cost	0.70	
5.	Price	77.99	
6.	Patient Pay Amount	77.99	
7.	Equivalent Drug	HYDROCODON-ACETAMINOPHN 10-325	55289-0737-06 6EA ZA PD-RX PHARM
8.	Price	406.99	
9.	Price Difference	-329.00	

7/10/13

Select a function and press <Enter>

Change Line (#), Price Calculation For a Specific Quantity (Q999.99), Price Calculation For a Specific Dollar Amount ($99.99), Exit (X)

Patient	Prescriber	Drug	Third Party	Profile	Radar Store	Clinical	Refill	Help	Credentials	Store Info	Adj Status
F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12

STATE OF FLORIDA

DEPARTMENT OF HEALTH
INVESTIGATIVE REPORT

Office: West Palm Beach		Date of Case: 7/15/13		Case Number: 2013-10982
Subject: **MALISSA SUE BENDER, RPT** 181 SW Palm Dr., Apt. 202* Port Saint Lucie, FL 34986 (772) 626-3014			Source: **DEPT. OF HEALTH/CONSUMER SERVICES UNIT (CSU)**	
Prefix: RPT	License #: 37251	Profession: Registered Pharmacy Technician	Board: Pharmacy	Report Date: 7/17/2013
Period of Investigation: 7/17/13 – 7/17/13			Type of Report: FINAL	

Alleged Violation: F.S. 456.072(1)(z)(dd); 465.016(1)(d)2.(e)(i)(m)-Failure to perform any statutory/legal obligation; Impaired from alcohol/drugs/other; Prescription/dispensing outside professional practice; Violating any provision/rule

Synopsis: This investigation is predicated upon receipt of an internally-generated complaint (EX#1) from DOH's CSU indicating internet news media reported BENDER was arrested 7/10/13 in Port Saint Lucie for grand theft of controlled substances. BENDER allegedly admitted to stealing Oxycodone and Hydrocodone from her employer: CVS Pharmacy, located in Saint Lucie West.

BENDER was notified of this investigation via telephone and certified letter dated 7/17/13 (EX#2) and was provided a copy of the Case Summary, complaint, and a voluntary relinquishment form.

Per DOH licensure database records, BENDER is a licensed Registered Pharmacy Technician.

There is no direct patient involvement, thus patient notification is unnecessary.

BENDER is not known to be currently represented by an attorney in this DOH matter.

In a telephonic statement, BENDER admitted to the essence of the allegation, although clarified that she only stole a hand fill of Hydrocodone and did not take the Oxycodone as the media has reported. BENDER will consider voluntarily relinquishing her license, possibly in the near future.

*BENDER advises her current address is: 231 SW Palm Dr., Apt 108, Port St. Lucie, FL 34986

Related Cases: 2013-10988

Investigator/Date:	Approved By/Date:
Amy Senior 7/17/13	Michelle Miller 7/17/13
AMY SENIOR, INVESTIGATOR, WI-89	MICHELLE MILLER, INV. MANAGER, WI-102

Distribution: HQ/ISU

TABLE OF CONTENTS

***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

DOH CSU reviewed an internet news report from palmbeachpost.com (EX#1) advising BENDER, while employed at CVS Pharmacy in Saint Lucie West, admitted to taking a patient's prescription of 30 Oxycodone pills. BENDER reportedly also admitted that two weeks prior she stole a stock bottle of Hydrocodone. BENDER was reportedly arrested by Port Saint Lucie Police Department on 7/10/13. Police reports confirm she was charged with two counts of theft of a controlled substance. BENDER reportedly stated she stole the medications for an ailing neighbor; however the neighbor reportedly moved away with no further contact info provided by BENDER.

SUMMARY OF RECORD

EX#3 is the police report from Port Saint Lucie Police Department (PD agency case# 13-11934) advising on 7/10/13 CVS staffer reported a missing prescription filled on/around 6/7/13 for 30 Oxycodone. The prescription was filled, but when the customer came to pick it up, it was missing and never found. CVS loss prevention department did an investigation. There were no witnesses or surveillance footage available. CVS Loss Prevention Manager ADALBERT MARTINEZ narrowed down the time frame of when the prescription went missing and narrowed down to two employees that would have been around at that time. Upon interviewing one of the employees: BENDER, she admitted to taking the prescription. BENDER gave MARTINEZ a written statement explaining that she stole the prescription. BENDER further admitted to taking a stock bottle of Hydrocodone about two weeks ago; which had not been known to CVS until BENDER's admission.

When PSL PD made contact with BENDER, she said she stole prescription medication from the pharmacy. BENDER admitted to taking the prescription that was filled for the customer and also took a bottle of Hydrocodone from the pharmacy shelf about two weeks ago. BENDER states the pills are all now gone and she is unable to get them back. BENDER states she gave the pills to a neighbor and did not receive any compensation for them. BENDER claims the neighbor had cancer and could not afford the pain pills. The neighbor asked BENDER to get the pills for her. BENDER would not provide any information on the neighbor, claiming the neighbor moved away about a week ago.

INVESTIGATOR'S NOTE:

Attempts were made to contact/interview/obtain statements from any CVS staffer who may have been witnessed to or familiar with the investigation of this matter. Contact with CVS store Pharmacist BRAD WHEELER, RPH lead to being referred to NICOLE POWERS, District Pharmacy Supervisor (401-665-8017). WHEELER stated he was advised to not make any statements about the matter. POWERS was unable to provide needed details and referred this investigator to ADALBERT MARTINEZ, Regional Loss Prevention Manager (954-649-2452). Messages left for MARTINEZ have not yet been returned. If/when additional information is received from CVS it will be relayed to DOH's PSU in a supplemental report.

INTERVIEW OF MALISSA SUE BENDER, RPT-SUBJECT

Current address:
231 SW Palm Dr., Apt 108
Port Saint Lucie, FL 34986
(772) 626-3014

On 7/17/13 BENDER was interviewed by Investigator SENIOR via telephone, essentially stating:

- BENDER confirms that approximately one month ago, she moved from her address of record to the above-indicated address. She was advised of her obligation to update same with the Board.

- BENDER admits that the general essence of the news report (EX#1) is true; but they do not have the exact details correct.

- BENDER admits while employed at CVS Pharmacy as a Pharmacy Technician, she did steal a handful of Hydrocodone pills. BENDER states there is no truth that she stole Oxycodone pills as reported. She is aware that a patient came in to the pharmacy to pick up their Oxycodone prescription and it was missing; however she had nothing to do with that.

- BENDER states the reason she stole the Hydrocodone was that someone she knew from being a pharmacy customer could not afford their medication; so BENDER stole some pills for that person.

- BENDER denies stealing pills for her personal use or to sell the pills. BENDER denies having any substance abuse problem and does not require any treatment or evaluation for same.

- BENDER states she will likely strongly consider voluntarily relinquishing her license. Once she receives and reviews the complaint and VR documents, she will re contact this investigator to discuss further.

- BENDER states she has not entered any plea in the corresponding criminal court matter; and there is no trial date set as of yet.

CONFIDENTIAL INDEX TO PATIENT'S NAME IS EXHIBIT#4

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. 201300800

DEBORAH LOUISE CHENOWETH,
RESPONDENT.

NOTICE

TO: DEBORAH LOUISE CHENOWETH
17363 MEADOW LAKE CIRCLE
FORT MYERS, FL 33967

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is not required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Michael Lawrence, Jr., Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. Deborah Louise Chenoweth, R.Ph.
DOH Case Number 2013-00800
DATE: August 1, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Deborah Louise Chenoweth
Subject's Address of Record:	17363 Meadow Lake Circle Fort Myers, FL 33967
Enforcement Address:	17363 Meadow Lake Circle Fort Myers, FL 33967
Subject's License No:	43436 **Rank:** PS
Licensure File No:	34370
Initial Licensure Date:	3/25/2008
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	465.016(1)(h), FS (2010)
Prior Discipline:	None
Probable Cause Panel:	June 27, 2013; Fallon & Glass
Subject's Attorney:	Pro Se
Complainant/Address:	Anonymous
Materials Submitted:	Memorandum to the Board Voluntary Relinquishment Administrative Complaint Notice of Scrivener's Error Notification Letter Election of Rights Probable Cause Panel Memorandum Final Investigative Report with Exhibits 1-3

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. CASE NO. 2013-00800

DEBORAH LOUISE CHENOWETH, R.Ph.,

RESPONDENT.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent Deborah Louise Chenoweth, R.Ph., license No. 43436, hereby voluntarily relinquishes Respondent's license to 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.

2. Respondent agrees to never reapply for licensure as a pharmacist in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy 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. 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 22nd day of July, 2013.

Deborah L Cheroweth

Deborah Louise Cheroweth, R.Ph.

STATE OF FLORIDA
COUNTY OF: Lee

Before me, personally appeared Deborah Louise Cheroweth, whose identity is known to me by Knows personally (type of identification) and who, under oath, acknowledges that his signature appears above. Sworn to and subscribed before me this 22nd day of July, 2013.

NOTARY PUBLIC

My Commission Expires:

KAREN LAWRENCE
MY COMMISSION # EE 866214
EXPIRES: March 17, 2017
Bonded Thru Notary Public Underwriters

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-00800**

DEBORAH LOUISE CHENOWETH, 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, Deborah Louise Chenoweth, 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 43436.

3. Respondent's address of record is 17363 Meadow Lake Circle, Fort Myers, Florida 33967.

4. The Arizona State Board of Pharmacy is the regulatory agency of the practice of pharmacy in the State of Arizona.

5. Respondent's Arizona pharmacy license was license number S010764.

6. On or about September 10, 2010, the Arizona State Board of Pharmacy issued Board Order No. 10-00-71-PHR.

7. The Arizona State Board of Pharmacy issued Board Order No. 10-00-71-PHR due to Respondent's violation of A.R.S. § 32-1901.01(B)(2), for violating a formal order, terms of probation, a consent agreement or a stipulation issued or entered into by the Board or its executive director.

8. Violating a Board Order in Florida would constitute a violation of Section 465.016(1)(n), Florida Statutes.

9. Board Order No. 10-00-71-PHR revoked Respondent's Arizona pharmacy license.

10. Section 465.016(1)(h), Florida Statutes (2010), provides that having been disciplined by a regulatory agency in another state for any

offense that would constitute a violation of this chapter constitutes grounds for disciplinary action.

11. Respondent was disciplined by a regulatory agency in another state for an offense that would constitute a violation of Chapter 465, Florida Statutes, by having Respondent's Arizona pharmacy license revoked by the Arizona State Board of Pharmacy in Board Order No. 10-00-71-PHR.

12. Based on the foregoing, Respondent violated Section 465.016(1)(n), Florida Statutes (2010), by violating an order of the board or department previously entered in a disciplinary hearing.

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 27th **day of** June, **2013**.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Judith A. Johnson for
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) 245-4444, extension 8199
Facsimile: (850) 245-4683
Email: michael_lawrence@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE JUN 27 2013

/MGL

PCP: 6.27.2013
PCP Members: Fallon and 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.

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE JUL 0 3 2013

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-00800**

DEBORAH LOUISE CHENOWETH, 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 June 27, 2013, Petitioner filed an Administrative Complaint against Respondent alleging violations of Section 465.016(1)(n), Florida Statutes (2010).

2. Due to a clerical error, paragraph twelve (12) of the Administrative Complaint states, "Based on the foregoing, Respondent violated Section 465.016(1)(n), Florida Statutes (2010), by violating an

order of the board or department previously entered in a disciplinary hearing."

3. The correct reference should have stated, "Based on the foregoing, Respondent violated Section 465.016(1)(h), Florida Statutes (2010), by having been disciplined by a regulatory agency in another state for any offense that would constitute a violation of this chapter."

4. The Administrative Complaint is to properly reflect the correct statute number and statutory language.

5. The correction of this error is of no prejudice to Respondent and makes no substantive change to the Administrative Complaint.

6. This Notice shall take effect upon its filing with the Clerk of the Department.

WHEREFORE, Petitioner requests that the Administrative Complaint be amended to reflect the correction as detailed above.

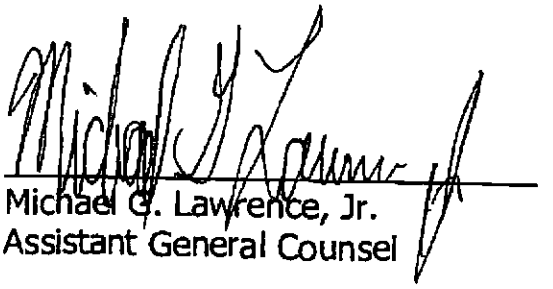
Respectfully submitted'

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) 245-4444, extension 8199
Facsimile: (850) 245-4683
Email: michael_lawrence@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 3rd day of July, 2013, to Deborah Louise Chenoweth, 17363 Meadow Lake Circle, Fort Myers, Florida 33967.



Michael G. Lawrence, Jr.
Assistant General Counsel

MGL

July 31, 2013

Deborah Chenoweth
17363 Meadow Lake Circle
Ft Myers, FL 33967

Re: DOH vs. Deborah Louise Chenoweth, R.Ph.
DOH Case Number: 2013-00800

Dear. Ms. Chenoweth:

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;
- 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 x8199. 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,

Michael G. Lawrence, Jr.
Assistant General Counsel

ML/ab

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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.

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Deborah Louise Chenoweth, R.Ph. (MGL)**
Case Number: 2013-00800

MEMBERS: **Lee Fallon and Debra Glass**

DATE OF PCP: **June 27, 2013** **AGENDA ITEM: A-2**

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)(n), Florida Statutes (2010);

____ 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 Date
Board of Pharmacy

HEALTH

INVESTIGATIVE REPORT

Office: CONSUMER SERVICES	Date of Complaint: February 18, 2013	Case Number: PS 2013-00800

Subject: **DEBORAH LOUISE CHENOWETH** **17363 Meadow Lake Circle** **Fort Myers, FL 33967** **239-985-2239**	Source: **Anonymous**

Prefix: PS	License # : 43436	Profession: Pharmacist	Board: Pharmacy	Report Date: 04/18/2013

Period of Investigation: 03/13/2013 through 04/18/2013	Type of Report: FINAL

Alleged Violation: SS. 456.072(1)(f)(dd) and 465.016(1)(h)(r), F.S. License disciplined by other state; Violate statute/rule

Synopsis: This investigation is predicated on the receipt of an anonymous complaint concerning CHENOWETH's discipline and revocation by the Arizona Board of Pharmacy. CHENOWETH's Arizona license was placed on probation in 2002 for diverting controlled substances. This discipline was reported to the Florida Board of Pharmacy at the time of licensure. CHENOWETH was again disciplined by the Arizona Board of Pharmacy in 2008 for writing a new prescription for herself, and refilling two other prescriptions without authorization from her doctor. CHENOWETH's Arizona license was revoked on 09/20/2010. (EXHIBIT #1)

CHENOWETH was notified of this complaint by letter, dated 03/13/2013. The notification was sent to the mailing address of record. Forwarded with this letter were copies of the Case Summary and the initiating documents. (EXHIBIT #2)

DOH licensure information was viewed on 04/18/2013. It reflects CHENOWETH is duly licensed to practice as a Pharmacist in the State of Florida with Clear, Active status.

No patient involvement, thus patient notification not required.

CHENOWETH is not known to be represented by counsel in this matter as of the date of this report.

CHENOWETH responded to notification of this complaint via letter, received on 04/08/2013. (Exhibit #3)

Related Case:

Investigator/Date: Anita M. Hill (HA23) 04/18/2013	Approved By/Date: Nicole Singleton, OMC Manager for Shane Walters APR 18 2013

Distribution: Prosecution Services Unit/Consumer Services Unit

TABLE OF CONTENTS

INVESTIGATIVE DETAILS

INTERVIEW/STATEMENT OF ANONYMOUS COMPLAINANT - Source

Address of Record:

On 01/10/2013, Investigator Hill received an anonymous complaint questioning why CHENOWETH is practicing pharmacy in Florida, and whether CHENOWETH has reported her Arizona discipline and revocation to Florida. CHENOWETH's Arizona license was placed on probation in 2002 for diverting controlled substances. This discipline was reported to the Florida Board of Pharmacy at the time of licensure. CHENOWETH was again disciplined by the Arizona Board of Pharmacy in 2008 for writing a new prescription for herself, and refilling two other prescriptions without authorization from her doctor. CHENOWETH's Arizona license was revoked on 09/20/2010. (EXHIBIT #1)

INTERVIEW/STATEMENT OF DEBORAH LOUISE CHENOWETH - Subject

Address of Record: **17363 Meadow Lake Circle**
Fort Myers, FL 33967
239-985-2239

CHENOWETH responded to notification of this complaint via letter, received on 04/08/2013. CHENOWETH states her Arizona license was on probation when she applied licensure in Florida, and she was placed on one year probation by the Florida Board of Pharmacy when she obtained her Florida license. CHENOWETH states her probation in Arizona was not for diverting controlled substances, it was a result of her self-reporting to a group similar to PRN in June 2001. CHENOWETH states she hired an attorney in 2002 after having problems with the group, and the Arizona probation followed. CHENOWETH states she was at the end of her probation when she moved to Florida in 2007. CHENOWETH states she had no intention of working or living in Arizona again, so she didn't feel the need to respond. CHENOWETH returned to Arizona in 2007 to work until her Florida license was approved. In November 2007, while working as a floating pharmacist at Walgreens in Tucson, AZ, CHENOWETH contacted her physician in Florida and requested two refills and a new prescription for Amoxicillin. CHENOWETH admits that she took the medication out of the pharmacy expecting them to be approved, but the prescriptions were denied after she left the store. CHENOWETH reports that she billed her insurance company for the medications, but she has paid restitution. CHENOWETH states her Arizona license was revoked for failure to pay the civil penalty, which she was unable to pay due to financial hardships. CHENOWETH states she wasn't aware of her requirement to report her Arizona license revocation to the Florida Board of Pharmacy. CHENOWETH further states she knew that she would never return to Arizona so the license revocation wasn't an issue for her. CHENOWETH reports that she hasn't worked as a pharmacist since September 2012.

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Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

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

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307691

WILSON DRUG,
RESPONDENT.

NOTICE

TO: WILSON DRUG
4977 US HWY 98 NORTH
LAKELAND, FL 33809

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is not required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Kristal Beharry, Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. DRM Enterprises, Inc. d/b/a Wilson Drug
DOH Case Number 2013-07691
DATE: July 16, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	DRM Enterprises, Inc. d/b/a Wilson Drug
Subject's Address of Record:	4977 US Hwy. 98 North Lakeland, FL 33809
Enforcement Address:	4977 US Hwy. 98 North Lakeland, FL 33809
Subject's License No:	18748 **Rank:** PH
Licensure File No:	10881
Initial Licensure Date:	9/3/2002
Board Certification:	None
Required to Appear:	No
Current IPN/PRN Contract:	None
Allegation(s):	Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.202(3), F.A.C.
Prior Discipline:	None
Probable Cause Panel:	None
Subject's Attorney:	A.S. Weekley, Esquire Weekley/Schulte/Valdes 1635 North Tampa St. #100 Tampa, FL 33602 813-221-1154 Telephone
Complainant/Address:	Department of Health/Investigative Services Unit-Tampa

Materials Submitted:

Memorandum to the Board
Motion for Voluntary Relinquishment of License
Voluntary Relinquishment (filed)
Notification Letter
Final Investigative report with Exhibits 1-10

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

CASE NO. 2013-07691

v.

DRM Enterprises, Inc. d/b/a Wilson Drug,
Respondent.
_____/

MOTION FOR FINAL ORDER
BASED UPON A VOLUNTARY RELINQUISHMENT OF LICENSE

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. On or about May 14, 2013, a Uniform Consumer Complaint was filed with the Department of Health, alleging that the Subject violated the provisions of Chapter 464 or Chapter 456, Florida Statutes.

2. In lieu of undergoing further disciplinary proceedings, the Respondent returned an executed Voluntary Relinquishment of his/her license.

3. 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 Uniform Consumer Complaint.

WHEREFORE the parties respectfully request the Board of Pharmacy enter a Final Order incorporating the terms of the Voluntary Relinquishment of Licensure.

Respectfully submitted,

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Kristal Beharry
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
(850) 245-4444 telephone
(850) 245-4683 facsimile
Florida Bar No. 0078070

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 27th day of August, 2013, to A.S. Weekley, Weekley/Schulte/Valdes, 1635 North Tampa Street, Suite 100, Tampa, FL 33602.

K. Beharry

Kristal Beharry
Assistant General Counsel

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUL 16 2013

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v.

DOH Case No. 2013-07691

DRM Enterprises, Inc./DBA Wilson Drug, Pharmacy
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent DRM Enterprises, Inc./DBA Wilson Drug, Pharmacy, license No. 18748, 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 Data Bank as disciplinary action. Licensing authorities in other states may impose discipline in their jurisdiction based on discipline taken in Florida.

2. Respondent agrees to never reapply for licensure as a Pharmacy in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy 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. 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.

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 1st day of July, 2013.

DRM Enterprises, Inc.

STATE OF FL
COUNTY OF DESOTO

Before me, personally appeared DUANE RUSSELL McKOWN, whose identity is known to me or who produced FL DL _____ _____ (type of identification) and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 1st day of July, 2013.

NOTARY PUBLIC

My Commission Expires: 11/23/2013

Notary Public State of Florida
Margie F Bergens
My Commission DD925487
Expires 11/23/2013

August 27, 2013

A.S. Weekley, Esquire
Weekley/Schulte/Valdes
Attorneys at Law
1635 North Tampa Street, Suite 100
Tampa, FL 33602

Re: DOH vs. DRM Enterprises, Inc. d/b/a Wilson Drug Pharmacy
DOH Case Number: 2013-07691

Dear Mr. Weekley:

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 client's license, pursuant to Section 456.072(1)(f), Florida Statutes;
- Voluntarily relinquishing a Florida profession license may have an effect on profession 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. 8218. 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 October 9, 2013, at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408. You are not required to attend the meeting.

Sincerely,

K. Beharry

Kristal Beharry
Assistant General Counsel

KBcmn

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: TAMPA	Date of Case: 05/14/13			Case Number: 201307691
Subject: **WILSON DRUG** 4977 U.S. Hwy 98 North Lakeland FL 33809 863-858-4444		Source: **DOH / ISU / TAMPA**		
Prefix: PH	License # 18748	Profession: Pharmacy	Board: Pharmacy	Report Date: 07/08/13
Period of Investigation: 05/29/13 to 07/08/13		Type of Report: FINAL		

Alleged Violation: F.S. 456.072(1)(k)(dd); F.S. 465.016(1)(r); 465.023(1)(c); RULE 64B16-28.202(3)(a)(b) F.A.C.: Failing to perform...; Violating any provision...; Violated any of the requirements...; In the event of closure of a pharmacy, the permittee shall notify the Board.....

Synopsis: This report is predicated upon a Case Summary, (Exhibit #1), based upon a complaint from the Tampa Investigative Services Unit. On 12/12/12, Investigator JOSEPH DeGREGORIO attempted to perform a routine pharmacy inspection at WILSON DRUG at the address of record. According to Investigator DeGREGORIO, the location is now occupied by a new pharmacy; People's Pharmacy. WILSON DRUG did not notify the Board of Pharmacy of the closure of the facility.

WILSON DRUG was notified of the investigation by letter, (Exhibit #2), dated 05/29/13 to the address of record and was provided a copy of the Case Summary and complaint.

A check of the DOH computer licensure records revealed that WILSON DRUG is licensed as a pharmacy. The current license expired on 02/28/13 and is in a delinquent status.

The patient notification letter was not utilized since no patients were identified.

The source notification letter was not utilized since the complainant is the Department of Health.

WILSON DRUG is represented by A.S. WEEKLEY of Weekley/Schulte/Valdes, Attorneys at Law; 1635 North Tampa Street, Suite 100, Tampa, FL, 33602; 813-221-1154 (Exhibit #8). WEEKLEY requested a copy of the investigative report.

On 07/03/13, Investigator MARTIN received the signed Voluntary Relinquishment of License Form from DUANE McKOWN, owner of WILSON DRUG (Exhibit #9).

Related Case(s): None

Investigator/Date: Scott M. Martin 7/8/13 Scott M. Martin TI-149 Investigation Specialist II	Approved By/Date: 7-8-13 Babette S. Agett TI-115 Investigation Supervisor Babette S Agett

Distribution: HQ/ISU

TABLE OF CONTENTS

***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 #1 is the Case Summary

Exhibit #2 is the Subject Notification Letter and Voluntary Relinquishment of License Form sent out to the following addresses obtained in the COMPAS database and Florida Corporation Website.

- P.O. Box 429 Placida, FL 33946
- P.O. Box 402 Placida, FL 33946
- 4200 South Florida Ave. Lakeland, FL 33813
- 4977 US Hwy 98 North Lakeland, FL 33809
- 437 South Central Ave. Lakeland, FL 33815

Exhibit #3 is the Florida Corporation information regarding ownership of DRM ENTERPRISES, INC./D.B.A. WILSON DRUG.

Exhibit #4 is the most current pharmacy inspection report dated 12/12/12. .

Exhibit #5 includes the photographs of the business now located at 4977 Hwy 98 North in Lakeland, FL. (PEOPLE'S PHARMACY). These photographs were taken by Investigator SCOTT MARTIN on 05/30/13.

Exhibit #6 is one (1) CD containing three (3) digital photographs.

Exhibit #7 is the Evidence Control Form. One CD of the photographs has been entered into evidence in the Tampa ISU office.

Exhibit #8 is the Letter of Representation from A.S. WEEKLEY, Attorney, dated 06/19/13.

Exhibit #9 is the Voluntary Relinquishment of License Form received 07/03/13.

Exhibit #10 is the E-mail message sent to YOLANDA GREEN, Attorney for PSU.

Interview of KAREN MCKOWN - Owner of People's Pharmacy (Witness)
People's Pharmacy
4977 US Hwy 98 North
Lakeland, FL 33809
863-858-4444

On 05/30/13, Investigator SCOTT MARTIN interviewed KAREN MCKOWN at 437 S. Central Ave. in Lakeland, FL. K. McKOWN is the owner of PEOPLE'S PHARMACY that is currently located in the business space vacated by WILSON DRUG. K. McKOWN said the owner of WILSON DRUG, DUANE McKOWN, is her ex-husband. K. McKOWN resigned from her position as President of DRM ENTERPRISES, INC./D.B.A. WILSON DRUG on 05/25/12 (Exhibit 3). K. McKOWN is no longer associated with Wilson Drug.

Interview of DUANE McKOWN – Owner of WILSON DRUG (Witness)

DUANE McKOWN
P.O. Box 402
Placida, FL 33946
863-712-4011

On 05/30/13, Investigator SCOTT MARTIN interviewed DUANE McKOWN. D. McKOWN is the owner of WILSON DRUG. D. McKOWN said he is currently a licensed pharmacist and no longer owns any pharmacy business since his divorce from KAREN McKOWN. D. McKOWN said he did not notify the Florida Division of Corporations or the Board of Pharmacy of WILSON DRUG'S dissolution. D. McKOWN said he would consider the Voluntary Relinquishment of License Form that he received from the Tampa ISU office.

On 07/03/13, Investigator MARTIN received the signed Voluntary Relinquishment of License Form from D. McKOWN.

Investigator's Note:

A Letter of Representation was received from D. McKOWN'S attorney, A.S. WEEKLEY, on 06/20/13. WEEKLEY needed clarification that D. McKOWN'S pharmacist license would not be affected if a Voluntary Relinquishment of License Form was signed for WILSON DRUG. WEEKLEY was provided information explaining the scope of this investigation was limited to the WILSON DRUG pharmacy license.

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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.

FLORIDA DEPARTMENT OF STATE
DIVISION OF CORPORATIONS

Sunbiz

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Detail by Entity Name

Florida Profit Corporation

DRM ENTERPRISES, INC.

Filing Information

Document Number	S34597
FEI/EIN Number	593054487
Date Filed	02/27/1991
State or Country	FL
Status	ACTIVE

Principal Address

437 SOUTH CENTRAL AVE
LAKELAND, FL 33815

Changed: 04/16/2007

Mailing Address

PO BOX 2969
LAKELAND, FL 33806-2969

Changed: 04/29/2009

Registered Agent Name & Address

GUARD, JR., PIERCE J
4200 SOUTH FLORIDA AVENUE
LAKELAND, FL 33813

Name Changed: 12/22/2009

Address Changed: 12/22/2009

Officer/Director Detail

NONE

Annual Reports

Report Year	Filed Date
2010	01/05/2010
2011	06/14/2011
2012	04/25/2012

Document Images

CONFIDENTIAL EXHIBIT# 3

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No Events No Name History

Entity Name Search

Search

Return to Search Results

2012 FOR PROFIT CORPORATION ANNUAL REPORT

FILED
Apr 25, 2012
Secretary of State

DOCUMENT# S34597

Entity Name: DRM ENTERPRISES, INC.

Current Principal Place of Business:

437 SOUTH CENTRAL AVE
LAKELAND, FL 33815 US

New Principal Place of Business:

Current Mailing Address:

PO BOX 2969
LAKELAND, FL 338062969 US

New Mailing Address:

FEI Number: 59-3054487 **FEI Number Applied For ( )** **FEI Number Not Applicable ( )** **Certificate of Status Desired ( )**

Name and Address of Current Registered Agent:

GUARD, JR., PIERCE J
4200 SOUTH FLORIDA AVENUE
LAKELAND, FL 33813 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: P/D
Name: MCKOWN, KAREN
Address: 6744 CRESCENT WOODS CIR
City-St-Zip: LAKELAND, FL 33813 US

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: KAREN MCKOWN P 04/25/2012

Electronic Signature of Signing Officer or Director — Date

S34597

(Requestor's Name)

(Address)

(Address)

(City/State/Zip/Phone #)

☐ PICK-UP ☐ WAIT ☐ MAIL

(Business Entity Name)

(Document Number)

Certified Copies _____ Certificates of Status _____

Special Instructions to Filing Officer:

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Resignation of Officer

05/25/12--01020--013 **35.00

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2012 MAY 25 PM 12:23
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

5/29/12

24

FILED

2012 MAY 25 PM 12:23

SECRETARY OF STATE
TALLAHASSEE, FLORIDA

OFFICER / DIRECTOR RESIGNATION FOR A CORPORATION

I, Karen McKown, hereby resign as President
(Title)

of DRM Enterprises, Inc
(Name of Corporation)

S34597
(Document Number, if known), a corporation organized under the laws of the State of Florida.

Karen McKown
(Signature of resigning officer/director)

FILING FEE IS $35.00

Make checks payable to Florida Department of State and mail to:

Amendment Section
Division of Corporations
P.O. Box 6327
Tallahassee, Florida 32314

25

COVER LETTER

TO: Amendment Section
Division of Corporations

SUBJECT: DRM, Enterprises
(Name of Corporation)

DOCUMENT NUMBER: S34597

The enclosed Resignation of Registered Agent for a Corporation and fee are submitted for filing.

Please return all correspondence concerning this matter to the following:

Duane R McKown
(Name of Person)

DRM Enterprises
(Name of Firm/Company)

P.O. Box 429
(Address)

Placida, FL 33946
(City/State and Zip Code)

For further information concerning this matter, please call:

Pierce J Guard, Jr at (863) 619-7338
(Name of Person) (Area Code & Daytime Telephone Number)

Enclosed is a check made payable to the Florida Department of State for $87.50 for an active corporation or $35.00 for an administratively dissolved, voluntarily dissolved or withdrawn corporation.

Street Address:
Amendment Section
Division of Corporations
Clifton Building
2661 Executive Center Circle
Tallahassee, FL 32301

Mailing Address:
Amendment Section
Division of Corporations
Post Office Box 6327
Tallahassee, FL 32314

CR2E046 (04/12)

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE ☐ CHANGE LOC ☐ NEW ☐ CURRENTLY NOT OPERATING ☒ CHANGE OWNER ☐

File # 10881

Insp # 108141

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
DRM ENTERPRISES INC		18748		12/12/2012
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
WILSON DRUG				
STREET ADDRESS		TELEPHONE #	EXT.	KENNETH W FUQUA
4977 US HWY 98 NORTH		(863) 683-2807		
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
LAKELAND	63	33809		11329

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday		
Open								1.	
Close								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.]	☒	☐	☐
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.]	☒	☐	☐
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.]	☒	☐	☐
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:

This pharmacy has not been operational since 05-18-12 when the location was taken over by PH 26163. The PDM listed here is the PDM for PH 21163

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 Not Operating

Not operating

Institutional Representative

12-12-2012

Date

Investigator/Sr. Pharmacist Signature

ID ti117

INV 359 Revised 5/12, 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

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EXHIBIT# 4

27

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE ☐ CHANGE LOC ☐ NEW ☐ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☒

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

File # 19148

Insp # 115186

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
PEOPLE'S PHARMACY, INC				5/14/2012
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 4977 HWY 98 NORTH		TELEPHONE # 863-858-4444	EXT.	KENNETH W FUQUA
CITY LAKELAND	COUNTY 63	STATE/ZIP 33809		PRESCRIPTION DEPARTMENT MANAGER LICENSE # 11329

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1.	
Open	9A						N/A	2.	
Close	6P					2P	N/A	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.]		☐	☒	☐
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.]		☐	☒	☐
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:

This is a Change of Ownership inspection. The Change of Ownership inspection has been completed and passed.

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 Karen McKown, Office Manager

Karen McKown

Institutional Representative

05-14-2012

Date

Investigator/Sr. Pharmacist Signature

ID ti117

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

28

30/05/2013

30/05/2013

EXHIBIT#
5

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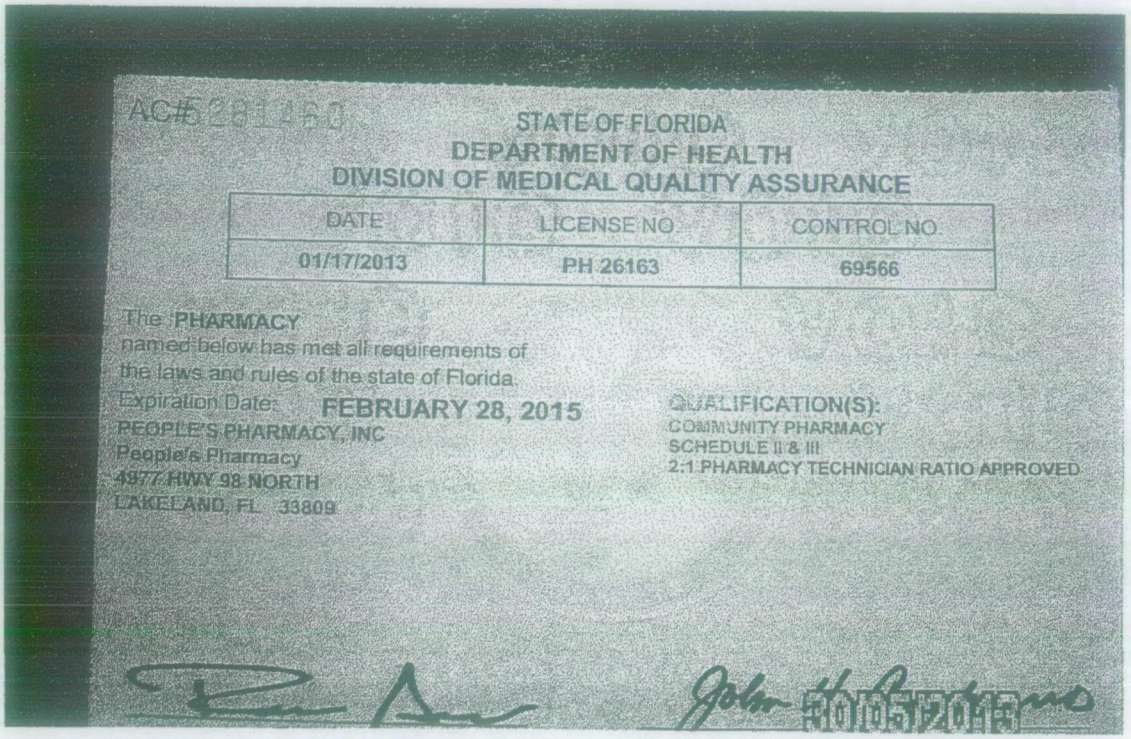

AC#5281460

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
01/17/2013	PH 26163	69566

The PHARMACY
named below has met all requirements of
the laws and rules of the state of Florida.
Expiration Date: FEBRUARY 28, 2015
PEOPLE'S PHARMACY, INC
People's Pharmacy
4977 HWY 98 NORTH
LAKELAND, FL 33809

QUALIFICATION(S):
COMMUNITY PHARMACY
SCHEDULE II & III
2:1 PHARMACY TECHNICIAN RATIO APPROVED

John H. Armstrong, M.D.
01/24/2013

20202013


OPEN
people's
30/05/2013

AC# [illegible]

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
01/17/2013	PH 26163	69566

The PHARMACY named below has met all requirements of the laws and rules of the state of Florida.

Expiration Date: FEBRUARY 28, 2015

PEOPLE'S PHARMACY, INC
People's Pharmacy
4977 HWY 98 NORTH
LAKELAND, FL 33809

QUALIFICATION(S):
COMMUNITY PHARMACY
SCHEDULE II & III
2:1 PHARMACY TECHNICIAN RATIO APPROVED

Rick Scott
GOVERNOR

John H. Armstrong, MD, FACS
STATE SURGEON GENERAL

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

EVIDENCE CONTROL FORM

Case Number 2013-07691 Office Property Receipt Number 143C Date/Time 7/8/13 12 50 p

Owners Name n/a Phone:

Address:

Obtained By Scott Martin, ISII Phone 813-871-7425

Address: 6800 N. Dale Mabry Hwy. Ste. 220; Tampa, FL 33614

Item #	Quantity	Description
1- 1 (one) CD	1 (one)	Compact Disc containing 3 (three) photographs of abandoned
2-		pharmacy
3-		
4-		
5-		
6-		

I hereby acknowledge that the above list represents all property impounded by me in the official performance of my duty as an Investigator for the Department of Health.

Scott Martin
Investigator's Signature

CHAIN OF CUSTODY				
Item#	RELEASED BY Date/Time		RECEIVED BY Date/Time	PURPOSE OF CHANGE OF CUSTODY
1	Signature: Scott Martin Name: Scott Martin		Signature: Babette Agott 7/8/13 Name: Babette Agott	Storage of Evidence
2	Signature: Name:		Signature: Name:	
3	Signature: Name:		Signature: Name:	
4	Signature: Name:		Signature: Name:	
5	Signature: Name:		Signature: Name:	
6	Signature: Name:		Signature: Name:	

Final Disposition

Returned To
Item 1 2 3 4 5 6

Received By Date

Address Phone

City State Zip

Destroyed By
Item 1 2 3 4 5 6

Name Date

Witness

Remarks

EXHIBIT# 7

INV FORM 342, Created 10/02

CONFIDENTIAL

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.

PAUL M. WEEKLEY
CHRISTOPHER J. SCHULTE
JODY M. VALDES
J. TRAVIS GODWIN

WEEKLEY | SCHULTE | VALDES
ATTORNEYS AT LAW

JESSICA D. DARIENEAU
MEGAN B. MAZZONE
MARSHALL D. SCHWAB
A.S. "GUS" WEEKLEY, JR., M.D.

July 3, 2013

VIA FACSIMILE – 813-871-7421
VIA U.S. MAIL

Mr. Scott M. Martin
Investigator Specialist II
Florida Department of Health
6800 N. Dale Mabry Hwy., Suite 220
Tampa, FL 33614

Re: Wilson Drug
Pharmacy License 18748
Case Number: 2013-07691

Dear Mr. Martin:

Enclosed please find the Voluntary Relinquishment of Pharmacy License No. 18748 for Wilson Drug. It has been executed by Duane Russell McKown. This is submitted on behalf of Mr. McKown after our telephone understanding that it will have no effect on Mr. McKown's Pharmacist License.

Thank you for your cooperation in this matter and please be assured of ours in reciprocity.

If you have any questions, please feel free to contact me.

Sincerely,

A.S. Weekley, Jr., M.D.
E-Mail: gus.weekley@wsvlegal.com

ASW:np

Enclosure

cc: DRM Enterprises, Inc. d/b/a Wilson Drug
Duane McKown

EXHIBIT# 9

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. DOH Case No. 2013-07691

DRM Enterprises, Inc./DBA Wilson Drug, Pharmacy
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent DRM Enterprises, Inc./DBA Wilson Drug, Pharmacy, license No. 18748, 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 Data Bank as disciplinary action. Licensing authorities in other states may impose discipline in their jurisdiction based on discipline taken in Florida.

2. Respondent agrees to never reapply for licensure as a Pharmacy in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy 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. 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.

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 1st day of July, 2013.

DRM Enterprises, Inc.

STATE OF FL
COUNTY OF DESOTO

Before me, personally appeared DUANE RUSSELL McKOWN, whose identity is known to me or who produced FL DL - _____ (type of identification) and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 1st day of July, 2013.

NOTARY PUBLIC

My Commission Expires: 11/23/2013

Notary Public State of Florida
Margie T Bergens
My Commission DD925487
Expires 11/23/2013

PAUL M. WEEKLEY
CHRISTOPHER J. SCHULTE
JODY M. VALDES
J. TRAVIS GODWIN

WEEKLEY | SCHULTE | VALDES

ATTORNEYS AT LAW

JESSICA D. DARENEAU
MEGAN B. MAZZONE
MARSHALL D. SCHAAP
A.S. "GUS" WEEKLEY, JR., M.D.

July 3, 2013

VIA FACSIMILE – 813-871-7421
VIA U.S. MAIL

Mr. Scott M. Martin
Investigator Specialist II
Florida Department of Health
6800 N. Dale Mabry Hwy., Suite 220
Tampa, FL 33614

Re: Wilson Drug
Pharmacy License 18748
Case Number: 2013-07691

Dear Mr. Martin:

Enclosed please find the Voluntary Relinquishment of Pharmacy License No. 18748 for Wilson Drug. It has been executed by Duane Russeu McKown. This is submitted on behalf of Mr. McKown after our telephone understanding that it will have no effect on Mr. McKown's Pharmacist License.

Thank you for your cooperation in this matter and please be assured of ours in reciprocity

If you have any questions, please feel free to contact me.

Sincerely,

A.S. Weekley, Jr., M.D.
E-Mail: gus.weekley@wsvlegal.com

ASW:np

Enclosure

cc: DRM Enterprises, Inc. d/b/a Wilson Drug
Duane McKown

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. DOH Case No. 2013-07691

DRM Enterprises, Inc./DBA Wilson Drug, Pharmacy
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent DRM Enterprises, Inc./DBA Wilson Drug, Pharmacy, license No. 18748, 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 Data Bank as disciplinary action. Licensing authorities in other states may impose discipline in their jurisdiction based on discipline taken in Florida.

2. Respondent agrees to never reapply for licensure as a Pharmacy in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy 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. 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.

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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.

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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 1st day of July, 2013.

DRM Enterprises, Inc.

STATE OF FL
COUNTY OF DESOTO

Before me, personally appeared DUANE RUSSELL MCKOWN, whose identity is known to me or who produced FL DL - (type of identification) and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 1st day of July, 2013.

NOTARY PUBLIC

My Commission Expires: 11/23/2013

Notary Public State of Florida
Margie T Bergens
My Commission DD925487
Expires 11/23/2013

Agett, Babette

To: Green, Yolonda
Cc: Martin, Scott M.
Subject: Voluntary Relinquishment
Attachments: VR - 2013-07691.pdf

Yolando - please see attached Voluntary Relinquishment for case #: 2013-07691 / Wilson Drugs. This was an abandoned pharmacy. The owner finally agreed to sign the VR. If you have any questions, please do not hesitate to contact Scott Martin, the investigator, at 813-871-7425. Thank you.

Babette Smith Agett, R.N.
Investigation Supervisor
DOH / MQA / ISU / Tampa
6800 N. Dale Mabry Hwy; Ste. 220
Tampa FL 33614
813-873-4798; Fax: 813-871-7421

CONFIDENTIAL EXHIBIT# 10 CONFIDENTIAL

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. 201305212

ERIC HAMILTON CAIRNS,
RESPONDENT.

NOTICE

TO: ERIC HAMILTON CAIRNS
2472 DEN ST
ST. AUGUSTINE, FL 32092

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is not required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitton
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

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

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel MW CRC
RE: Voluntary Relinquishment
SUBJECT: DOH v. Eric Hamilton Cairns, R.Ph.
DOH Case Number 2013-05212
DATE: August 28, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Eric Hamilton Cairns
Subject's Address of Record:	2472 Den Street St. Augustine, FL 32092
Enforcement Address:	2472 Den Street St. Augustine, FL 32092
Subject's License No:	34472 **Rank:** PS
Licensure File No:	23481
Initial Licensure Date:	10/1/1999
Board Certification:	No
Required to Appear:	No
Current PRN Contract:	No
Allegation(s):	Relinquished license prior to PCP
Prior Discipline:	None
Probable Cause Panel:	Relinquished license prior to PCP
Subject's Attorney:	Pro Se
Complainant/Address:	Department Of Health/ISU Jacksonville

Allegation(s):	Section 465.016(1)(e), F.S. (2010, 2011, 2012) by violating Chapter 499; 21 U.S.C. ss. 301-392, known as the Comprehensive Drug Abuse Prevention and Control Act, or Chapter 893 through a violation of Section 893.13(7)(a), F.S. (2010, 2011, 2012), by acquiring or obtaining, or attempting to obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.
Prior Discipline:	None
Probable Cause Panel:	None
Subject's Attorney:	Pro Se
Complainant/Address:	Department Of Health/ISU Jacksonville
Materials Submitted:	Memorandum to the Board Motion for Final Order Voluntary Relinquishment – filed Board Notification Letter Supplemental Investigation Final Investigative Report Exhibits 1 thru 6

MGW/crl

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

CASE NO. 2013-05212

V.

Eric H. Cairns, R.Ph.,

Respondent.
_____/

MOTION FOR FINAL ORDER
BASED UPON A VOLUNTARY RELINQUISHMENT OF LICENSE

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. On or about **March 29, 2013**, a Uniform Consumer Complaint was filed with the Department of Health, alleging that the Subject violated the provisions of Chapter 456 or Chapter 465, Florida Statutes.

2. In lieu of undergoing further disciplinary proceedings, the Respondent returned an executed Voluntary Relinquishment of his/her license.

3. 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 **Uniform Consumer Complaint**.

WHEREFORE, the parties respectfully request the Board Pharmacy of enter a Final Order incorporating the terms of the Voluntary Relinquishment of Licensure.

Respectfully Submitted,

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@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 29 day of August, 2013, to: Eric Hamilton Cairns, 2472 Den Street, St. Augustine, Florida 32092.

Matthew G. Witters
Assistant General Counsel

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE AUG 09 2013

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. DOH Case Number 2013-05212

ERIC H. CAIRNS, R.PH.,

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, Eric H. Cairns, R.Ph, license number 34472, 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.

2. Respondent agrees to never reapply for licensure as a Pharmacist in the State of Florida.

3. 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,

EXHIBIT A EXHIBIT # 5-1 PAGE # 2

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.

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. 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.

6. 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 29 day of July, 2013.

Eric H. Cairns, R.Ph.
Case No. 2013-05212

STATE OF FLORIDA
COUNTY OF:

Before me, personally appeared Eric H. Cairns, whose identity is known to me by personal knowledge (type of identification) and who, under oath, acknowledges that her signature appears above. Sworn to and subscribed before me this 29 day of July, 2013.

My Commission Expires:

NOTARY PUBLIC

STEPHEN D. KAYSER
Commission # EE 027906
Expires November 1, 2014

August 29, 2013

VIA U.S. MAIL

Eric Hamilton Cairns
2472 Den Street
St. Augustine, Florida 32092

Re: DOH vs. Eric Hamilton Cairns, R.Ph.
DOH Case Number: 2013-05212

Dear Mr. Cairns:

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 Registered Pharmacy Technician license may have an effect on Registered Pharmacy Technician 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 October 9, 2013 at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, Florida 32408. You are not required to attend the meeting.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Jacksonville	Date of Case: 03/29/13	Case Number: 201305212

Subject: **ERIC H. CAIRNS, RPH**
2472 Den Street
St. Augustine, FL 32092
H (904) 757-7726

Source: **DOH/ISU JACKSONVILLE**
1912 Hamilton Street, Unit 104
Jacksonville, FL 32210
W (904) 381-6022

Prefix: 2201	License #: 34472	Profession: Pharmacist	Board: Pharmacy	Report Date: 07/29/13

Period of Investigation: 07/25/13 – 07/29/13

Type of Report: SUPPLEMENTAL - 1

Alleged Violation: F.S. 465.016 (1)(d)2.3.(e)(i)(m)(r) "The following acts..." "Being unfit..." "The misuse..." "Any abnormal..." "Violating chapter 499..." "Compounding, dispensing..." "Being unable to practice..." "Violating any provision..." F.S. 456.072 (1)(a)(m)(z) "Making misleading..." "Making deceptive..." "Being unable to practice..." F.S. 893.02 "The following words..."

Synopsis:

This supplemental investigation is predicated upon receipt of a telephone call from FDLE Special Agent G. DANDELAKE on 07/25/13 asking this Investigator if a voluntary relinquishment could be drafted for CAIRNS as part of a criminal case plea agreement. On 07/25/13 this Investigator left a voicemail message as well as sent an email to SHAFFER CLARIDGE, ESQ./PSU asking him to please draft a voluntary relinquishment for CAIRNS. On the afternoon of 07/29/13 CLARIDGE sent this Investigator an email containing a copy of the voluntary relinquishment, and this Investigator forwarded a copy of the relinquishment to DANDELAKE. On 07/29/13 this Investigator along with DANDELAKE traveled to the Duval County Courthouse where this Investigator executed the voluntary relinquishment on CAIRNS pharmacy license in front of CAIRNS, his attorney and the presiding judge. This Investigator was not able to collect CAIRNS' wall and/or wallet licenses due to CAIRNS having resided in a mental health facility since 05/13. On 07/29/13 this Investigator scanned and emailed a copy of the executed voluntary relinquishment to CLARIDGE. CAIRNS plead guilty to Trafficking in Illegal Drugs 4 grams to less than 14 grams of Hydrocodone, was adjudged guilty, given 10 years of probation, has to successfully complete the Hanley Centers Secured Residential Treatment Program, and has to voluntarily relinquish his Florida pharmacist license as well as never seek to reinstate his pharmacist license through the Florida Department of Health.

EXHIBITS:

S-1 Voluntary Relinquishment (pgs. 2-3)

RECEIVED-LEGAL
13 JUL 31 PM 4:50

Related Case: None

Investigator/Date:

Stephen D. Kayser
MQA Investigator (J1-88) 07/29/13

Approved By/Date:

Charles C. Coats, III
District Investigation Manager 7-30-13

Distribution: HQ/ISU

Received
Investigative Services
JUL 31 2013
DOH/MQA
Tallahassee HQ

INV Form 300 7/02

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. DOH Case Number 2013-05212

ERIC H. CAIRNS, R.PH.,

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, Eric H. Cairns, R.Ph, license number 34472, 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.

2. Respondent agrees to never reapply for licensure as a Pharmacist in the State of Florida.

3. 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.

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.

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DATED this 29 day of July, 2013.

Eric H. Cairns, R.Ph.
Case No. 2013-05212

STATE OF FLORIDA
COUNTY OF:

Before me, personally appeared Eric H. Cairns, whose identity is known to me by personal knowledge (type of identification) and who, under oath, acknowledges that her signature appears above. Sworn to and subscribed before me this 29 day of July, 2013.

My Commission Expires:

NOTARY PUBLIC

STEPHEN D. KAYSER
Commission # EE 027906
Expires November 1, 2014

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **DOH Case Number 2013-05212**

ERIC H. CAIRNS, R.PH.,

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, Eric H. Cairns, R.Ph, license number 34472, hereby voluntarily relinquishes Respondent's license to practice pharmacy in the State of Florida and states as follows:

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EXHIBIT A

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DATED this 29 day of July, 2013.

Eric H. Cairns, R.Ph.
Case No. 2013-05212

STATE OF FLORIDA
COUNTY OF:

Before me, personally appeared Eric H. Cairns, whose identity is known to me by Personal Knowledge (type of identification) and who, under oath, acknowledges that her signature appears above. Sworn to and subscribed before me this 29 day of July, 2013.

My Commission Expires:

NOTARY PUBLIC

STEPHEN D. KAYSER
Commission # EE 027906
Expires November 1, 2014
Bonded Thru Troy Fain Insurance 800-385-7019

Shannon, Denise

From: Claridge, Shaffer R
Sent: Wednesday, May 01, 2013 10:33 AM
To: Shannon, Denise
Subject: FW:

R. Shaffer Claridge, 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. 8166

From: Claridge, Shaffer R
Sent: Wednesday, May 01, 2013 10:33 AM
To: Kayser, Stephen
Subject: RE:

Stephen,

Find out if you can get access to him, and if so find out if he is being evaluated by anybody at River Point. If so, see if he will authorize a release of those evaluations. He had previously indicated willingness to voluntarily relinquish his license. We had wanted the OCE to determine whether or not he is mentally competent to voluntarily relinquish. Thanks,

Shaffer

R. Shaffer Claridge, 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. 8166

From: Kayser, Stephen
Sent: Wednesday, May 01, 2013 7:06 AM
To: Claridge, Shaffer R
Subject:

Mr. Claridge,

Eric Caims is currently located at River Point Behavioral Health (as a condition of his bail agreement he had to go straight into an inpatient mental health facility) which costs roughly $10,000 a month. I am not even sure I am allowed to have access to him, and if I did I'm not sure he would be allowed to leave to get evaluated by another individual/facility. How would you like me to proceed?

Stephen

Stephen D. Kayser
Medical Malpractice Investigator
Florida Department of Health
Investigative Services Jacksonville
1912 Hamilton Street, Unit 104
Jacksonville, FL 32210
Phone (904) 381-6030
Fax (904) 381-6050

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **DOH Case Number 2013-05212**

ERIC H. CAIRNS, R.PH.,

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

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DATED this _____ day of _____, 2013.

_____

STATE OF FLORIDA
COUNTY OF:

Eric H. Cairns, R.Ph.
Case No. 2013-05212

Before me, personally appeared _____, whose identity is known to me by _____ (type of identification) and who, under oath, acknowledges that her signature appears above. Sworn to and subscribed before me this _____ day of _____, 2013.

_____

My Commission Expires:

NOTARY PUBLIC

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Jacksonville	Date of Case: 03/29/13	Case Number: 201305212

Subject: **ERIC H. CAIRNS, RPH** 2472 Den Street St. Augustine, FL 32092 H (904) 940-1408	Source: **DOH/ISU JACKSONVILLE** 1912 Hamilton Street, Unit 104 Jacksonville, FL 32210 W (904) 381-6022

Prefix: 2201	License #: 34472	Profession: Pharmacist	Board: Pharmacy	Report Date: 04/16/13

Period of Investigation: 04/01/13 - 04/16/13	Type of Report: FINAL

Alleged Violation: F.S. 465.016 (1)(d)2.3.(e)(i)(m)(r) "The following acts…" "Being unfit…" "The misuse…" "Any abnormal…" "Violating chapter 499…" "Compounding, dispensing…" "Being unable to practice…" "Violating any provision…" F.S. 456.072 (1)(a)(m)(z) "Making misleading…" "Making deceptive…" "Being unable to practice…" F.S. 893.02 "The following words…"

Synopsis:

This investigation is predicated upon receipt of a complaint submitted by DOH/ISU JACKSONVILLE in regard to ERIC H. CAIRNS, RPH alleging on 03/27/13 CAIRNS was arrested by FDLE and charged with: two counts of theft of a controlled substance; possession of a schedule III or IV with intent to sale/manufacture/deliver; and traffic in opium or derivative 4 grams to under 30 kilograms. On 03/24/13 CAIRNS called the St. Johns County Sheriff's Office and confessed to stealing/diverting numerous controlled prescription drugs from Target Pharmacy located at 9525 Crosshill Blvd., Jacksonville, FL 32222 while he was employed there as a pharmacist, (Exhibit 1).

The Subject of this investigation was notified of the investigation by letter dated 04/01/13 and was provided with a copy of the Department of Health's Case Summary and a copy of the originating documents submitted by DOH/ISU JACKSONVILLE, (Exhibit 2).

A check of DOH computer records revealed CAIRNS is currently licensed as a Pharmacist. CAIRNS' first license was obtained on 10/01/99.

No Patient Notification was necessary in this case.

CAIRNS, at the time of this Investigation is not known to be represented by legal counsel.

RECEIVED-LEGAL
13 APR 17 PM 3:00

***** CONTINUED ON NEXT PAGE *****

Related Case: None

Investigator/Date:	Approved By/Date:
Stephen D. Kayser Medical Malpractice Investigator (JI-88) 04/16/13	Charles C. Coats, III District Investigation Manager

Distribution: HQ/ISU

INV Form 300 7/02

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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.**

SYNOPSIS CONTINUATION

CAIRNS, has been transferred back and forth between a lockdown mental facility and the Duval County Jail (where he is also on lockdown). On 04/01/13 this Investigator traveled to CAIRNS' place of residence listed above and hand delivered the Notification letter to CAIRNS' wife and informed her to have CAIRNS call this Investigator if he had any questions. On 04/03/13 this Investigator traveled to the Duval County Jail, made contact with CAIRNS and let him read the Notification letter (he is in solitary confinement and was not allowed to have the letter in his cell). A copy of the Notification letter was left with a correctional officer with instructions to place it with CAIRNS' possessions.

INVESTIGATIVE DETAILS

Summary of Exhibits/Records/Documents

Exhibit 1 is a Case Summary and attachments. The attachments include the following:

- Department of Health Healthcare Practitioner Complaint form dated 03/28/13.
- Jacksonville Sheriff's Office arrest and booking report 2013208317 dated 03/27/13.
- Copy of an email received on 03/28/13 from Special Agent G. DANDELAKE of the FDLE regarding CAIRNS arrest.
- Copy of an arrest warrant in FDLE case JA-18-0217 indicating the following bonds to be placed with each charge: $5,003 for grand theft of a controlled substance; $5,003 for grand theft of a controlled substance; $10,003 for possession with intent to sell, manufacture or deliver a controlled substance defined by F.S. 893.13 (1)(a)(2); and $50,003 for trafficking in Hydrocodone greater than 28 grams.
- Copy of an affidavit for arrest warrant for CAIRNS dated 03/27/13.

Exhibit 3 is a copy of a St. John's County Sheriff's Office Offense Report dated 03/24/13 indicating they responded to CAIRNS' residence in reference to suspicious circumstances, and CAIRNS informed them for the past two years he had been stealing prescription medications from Target pharmacy located at 9525 Crosshill Drive, Jacksonville, FL 32222 while he was the pharmacy manager received on 04/03/13 via hand delivery from FDLE. CAIRNS admitted to recently stealing: Alprazolam 1mg 500 count, Alprazolam 2mg 500 count, 3 bottles of testosterone, Zolpiden 10mg 500 count (two bottles), Hydrocodone 10/500mg 500 count (two bottles) and Oxycodone ER 80mg count 11 (expired medication). CAIRNS further stated that he had taken the aforementioned medications and buried them in his parent's front yard in Windamere, FL. Included with the offense report is a copy of a sworn affidavit dated 03/24/13 written by CAIRNS admitting to stealing the drugs from Target pharmacy.

Exhibit 4 is a copy of a Jacksonville Sheriff's Office (JSO) field investigation report dated 03/27/13 in which JSO patrol officer R.J. REEVES met with CAIRNS at the Target pharmacy where CAIRNS was a pharmacist,received on 04/03/13 via hand delivery from FDLE. CAIRNS again admitted that he had been stealing drugs from the Target pharmacy and that he felt Target was on to him so he wanted to "come clean about his activities." CAIRNS then began to make statements of having suicidal ideations and threats to possibly harm himself, and out of concern for CAIRNS' safety and the safety of others CAIRNS was taken into protective custody under the provisions of the "Baker Act" and transported to the Mental Health Center of Jacksonville.

Exhibit 5 is a copy of a JSO field investigation report dated 03/30/13 in which patrol officer T.L. TERRELL responded to a call from FDLE regarding an individual who was parked in the law enforcement parking lot of the FDLE Jacksonville Communications Center who indicated he had an explosive device under the driver's seat of his vehicle received on 04/03/13 via hand delivery from FDLE. Nothing out of the ordinary was discovered under the driver's seat of the vehicle or anywhere else in the vehicle. The vehicle belonged to CAIRNS and CAIRNS was the driver of the vehicle and when asked why he was there, CAIRNS responded he was trying to get in touch with the FDLE agent to meet with DANDELAKE. CAIRNS indicated he had been arrested on 03/27/13 for stealing

prescription medication from a Target pharmacy where he worked and that he had been seen at mental health clinics before. CAIRNS was again transported to the Mental Health Center of Jacksonville under the provisions of the Baker Act and placed into protective custody for his and others safety.

Exhibit 6 is a copy of a FDLE arrest and booking report dated 04/01/13 indicating DANDELAKE was contacted by CAIRNS on the morning of 03/30/13 and stated that he believed he was being watched and followed, received on 04/03/13 via hand delivery from FDLE. Later that morning CAIRNS arrived at the FDLE Operations Center and informed law enforcement officers that he had an explosive device in his vehicle. CAIRNS was subsequently placed in the Mental Health Clinic of Jacksonville under the Baker Act provision and was released into the custody of FDLE and placed in the Duval County Jail under the charge: Bomb, false report about planting bomb or explosive.

INVESTIGATOR'S NOTE

On 04/03/13 this Investigator sent a copy of FDLE'S video interview of CAIRNS directly to JENIFER FRIEDBERG/PSU for her review. As of the writing of this report this Investigator has not been able to secure another copy of the video interview. Once another copy has been obtained by this Investigator it will be forwarded to the Legal Department in the form of a supplemental report.

INTERVIEW OF DANIEL KREPS, RPH (Witness)

Pharmacist
Target Pharmacy
9525 Crosshill Blvd.
Jacksonville, FL 32222
W (904) 248-4367

On 04/08/13 this Investigator interviewed KREPS via telephone at his place of employment listed above. KREPS essentially stated:

- He worked with CAIRNS for about three and a half years at Target Pharmacy, but he worked an opposite shift and only saw him a few hours each month.
- He cannot say whether CAIRNS' behavior was different, but the technicians who worked with CAIRNS seemed to think something was different.
- He noticed more of a negative attitude change in CAIRNS over the past few months regarding work and work activities.
- A pharmacy technician reported to him that she saw CAIRNS take a prescription bottle from the counter and place it in his pocket.
- The pharmacy technician could not tell what kind of medication was in the bottle, but the next day a patient came to pick up a prescription for Norco 10/325mg 120 count, and the prescription could not be located in the will call bin or anywhere else and had not been signed for.

KREPS had no additional information to add at this time.

INTERVIEW OF KEARA THOMAS, RPT (Witness)

Registered Pharmacy Technician
Target Pharmacy
9525 Crosshill Blvd.
Jacksonville, FL 32222
W (904) 248-4367

On 04/08/13 this Investigator interviewed THOMAS via telephone at her place of employment listed above. THOMAS essentially stated:

- She worked with CAIRNS for approximately two and a half years.
- On one particular instance she remembers seeing CAIRNS take a prescription bottle and place it in his pocket, but she could not see what medication was in the bottle.
- The next day a patient came to pick up their prescription (Hydrocodone 10/325mg count 120) and the prescription was not in the will call bin and could not be found and she had to print another label and refill the prescription.
- She remembers filling the original prescription for Hydrocodone 10/325mg count 120 for that patient the day CAIRNS placed a prescription bottle in his pocket.
- There were other instances where there have been pills (she is not sure of what type) in clear plastic Target bags (used for when a label is too small to be placed on the box/container) in the back of the pharmacy.
- She is not sure why the bags were in the back of the pharmacy in CAIRNS' box because there is no need for any medications to be back there.
- She noticed significant changes in CAIRNS' behavior over the past few months.
- CAIRNS was usually happy, open and talkative with her and other staff members at Target.
- Within the past few months CAIRNS became very angry, short and agitated and directing his agitation at her.
- CAIRNS would tell her things like "your attitude is wearing thin with me."
- Then CAIRNS' behavior would change and he would be very apologetic and offer to buy her lunch to make up for it.
- During one conversation with CAIRNS, he asked her if the camera angles had been changed, and she replied (jokingly) that she did not know and asked "why, do you have something to hide?"
- CAIRNS behavior then started to become very paranoid.
- CAIRNS stated to her "If I go down I'm taking everyone in this store down with me."
- CAIRNS then shut down and said very little about anything to anyone.
- She has never seen CAIRNS act the way he did the past few months.

THOMAS had no additional information to add at this time.

INTERVIEW OF JOE COSTELLO (Witness)

Store Manager
Target
9525 Crosshill Blvd.
Jacksonville, FL 32222
W (904) 248-4366

On 04/08/13 this Investigator interviewed COSTELLO via telephone at his place of employment listed above. COSTELLO essentially stated:

- He was on vacation when CAIRNS turned himself in to St. Johns County Sheriff's Office, and when he came back there was a string of emails regarding CAIRNS asking about taking a leave of absence.
- He received a phone call from the store that CAIRNS had turned himself into authorities.
- He had noticed some behavioral changes with CAIRNS over the past few months, and an in-house investigation was started but he was not part of that investigation.
- He does not believe that the investigation turned up anything or action would have been taken.
- CAIRNS had no disciplinary problems and had worked at that particular Target pharmacy for approximately 5 to 6 years.
- CAIRNS was terminated from Target pharmacy.
- He is not sure if an inventory check has been performed to get a count of what was allegedly taken by CAIRNS.

COSTELLO had no additional information to add at this time.

INTERVIEW OF SUSAN SALEEB, RPH (Witness)

District Pharmacy Manager
Target Pharmacy
2402 Ridgemoor Drive
Orlando, FL 32828
C (321) 262-4241

On 04/08/13 this Investigator interviewed SALEEB via telephone at her place of employment listed above. SALEEB essentially stated:

- She was on maternity leave from 12/13/12 through 03/11/13, and when she came back from leave she had noticed that CAIRNS' behavior had changed.
- There was an employee in the pharmacy that noticed some suspicious behavior from CAIRNS.
- At that point they started to monitor CAIRNS via video, but were unable to find anything of use.
- Starting on 03/19/13 she started to get a string of emails from CAIRNS about him asking how to go about requesting/taking a leave of absence.
- She responded to the first couple of emails telling him where to access certain forms, but the emails started getting progressively stranger.

- She was advised not to respond to the latter emails, and the last email she received was on 03/24/13.
- On 03/24/13 CAIRNS turned himself into authorities and admitted to stealing drugs from the Target pharmacy.
- She has not had any correspondence with CAIRNS since he sent the last email on 03/24/13.
- CAIRNS was the pharmacy manager and had no disciplinary problems/write ups that she is aware of.
- Even though she is the District Pharmacy Manager, CAIRNS as a pharmacy manager reports directly to the store manager.

SALEEB had no additional information to add at this time.

INTERVIEW OF BILL CORFIELD (Witness)

Special Investigations Team Leader
Target
4750 Millenia Plaza Way
Orlando, FL 32839
C (904) 534-3696

On 04/03/13 this Investigator interviewed CORFIELD via telephone at his place of employment listed above. CORFIELD essentially stated:

- His investigation kicked off with a pharmacy technician that came forward to say that she saw CAIRNS take a prescription bottle of medication that had been filled for a patient.
- The patient came in the next day to pick up the prescription and the prescription was not there and another had to be filled for the patient.
- When CAIRNS was confronted about the missing prescription and about him possibly taking the prescription CAIRNS responded "I don't know."
- Leading up to that incident the Target pharmacy staff indicated CAIRNS' behavior had changed over the past few months.
- Because of CAIRNS' alleged theft of the prescription and suspicious behavior, he reviewed video of the pharmacy a week prior to the theft as well as a week after the theft, but nothing was on the video regarding the theft or any other actions that led them to suspect theft.
- The staff did a cursory inventory of all CII'S and CIII'S and nothing was amiss.

CORFIELD had no additional information to add at this time.

STATEMENT OF ERIC H. CAIRNS, RPH (Subject)

2472 Den Street
St. Augustine, FL 32092
H (904) 584-2363

On 04/03/13 this Investigator reviewed a video interrogation/interview of CAIRNS by FDLE. CAIRNS essentially stated:

- He called SJCSO on 03/24/13 and deputies were sent to his house.
- He admitted to the officers that he had been stealing drugs from Target pharmacy for three years.
- He worked for approximately eleven and a half years as a pharmacist with Target.
- It started out with him taking expired medications that people brought back to the store.
- The expired medications are placed in an "expired bin" and then the drugs are either destroyed or sent back to the manufacturer.
- Then he progressed to stealing drugs from the shelves (Target inventory).
- He took a lot of Hydrocodone stock bottles 10/500mg count 500.
- He knew where the camera angles were in the pharmacy and in the store at Target and knew how to stay out of their paths.
- Testosterone and syringes were also something that he stole from the pharmacy.
- He began injecting himself with testosterone and even injected himself at least one time while on duty at Target pharmacy.
- He buried at least 500 Alprazolam 2mg tablets, 500 Alprazolam 1mg tablets, 1000 Hydrocodone 10/500mg tablets, a couple of vials of testosterone 30mg, an unknown quantity of Doxycyclene, an unknown quantity of Omeprazole, 11 tablets of Oxycontin 80mg as well as syringes.
- He and his wife also flushed an unknown number of medications down the toilet at their house.
- Testosterone cream and androgel (and pump) were also taken from Target pharmacy by him.
- Sometime in late 02/13 he had a large cardboard box that he filled with stock bottles of Hydrocodone, Alprazolam, testosterone/syringes and other drugs, and he placed another empty box on top of the box full of drugs and walked out of Target.
- He was able to take stock bottles of medication because Target wanted a monetary inventory of roughly $500,000, and because that particular Target was growing so fast they were holding over a $500,000 inventory which allowed him to take inventory to make the numbers come down.
- He started diverting Zopildem 10mg stock bottles and was taking about one tablet a night.
- The jump from non-controlled medications to controlled medications was made because of pain in his head, feet and knees.
- He has falsified call in prescriptions for controlled drugs, but only to benefit the patient or make it easier for the patient.
- Shortly before the time when he confessed he received a phone call from a Target and had a bad feeling about the call, and then he received an email from a "big wig" at Target.
- His partner was acting kind of weird, asking him questions and giving him contradicting statements.
- He began at that point to feel that Target might be onto his diversion.

- He denies taking Methadone even though there was a documented shortage in the pharmacy.
- He placed a 500 count stock bottle of Hydrocodone in the back of the pharmacy and informed SABRINA WALSH, RPT that he had placed the medication back there for her to do whatever she wanted to with them.
- The reason he called SJCSO is because he thought Target was on to him and that he was going to be terminated.

CAIRNS had no additional information to add at this time.

On 04/03/13 this Investigator along with FDLE AGT. DANDELAKE traveled to the Duval County Jail to speak with CAIRNS. CAIRNS essentially stated:

- The information contained in the Case Summary and Healthcare Practitioner Complaint Form seemed pretty accurate and "cut and dry."
- He indicated that he was not too worried at this point about his pharmacy license because he had bigger problems he was facing.

CAIRNS had no additional information to add at this time.

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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
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201301267

BROTHERS PHARMACY AND DISCOUNT, LLC,
RESPONDENT.

NOTICE

TO: BROTHERS PHARMACY AND DISCOUNT, LLC
1001 SW 27 AVE
MIAMI, FL 33135

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. The Respondent is not required to be present at this meeting. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Kristal Beharry, Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. Brothers Pharmacy and Discount, LLC
DOH Case Number 2013-01267
DATE: August 23, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Brothers Pharmacy and Discount, LLC
Subject's Address of Record:	1001 SW 27th Avenue Miami, FL 33135
Enforcement Address:	1001 SW 27th Avenue Miami, FL 33135
Subject's License No:	23338 **Rank:** PH
Licensure File No:	15864
Initial Licensure Date:	4/22/2008
Board Certification:	None
Required to Appear:	No
Current IPN/PRN Contract:	None
Allegation(s):	Section 465.023(1)(c) by violating Rule 64B16-28.202(3)(a)
Prior Discipline:	None
Probable Cause Panel:	None
Subject's Attorney:	Arturo Yero, Esquire Law Offices of Arturo Yero, P.A. 782 NW Lejune Road, Suite #350 Miami, FL 33126 305-444-0884 Telephone
Complainant/Address:	Department of Health/Investigative Services

Materials Submitted:

Memorandum to the Board
Motion for Voluntary Relinquishment of License
Voluntary Relinquishment (filed)
Notification of Letter
Final Investigative report with Exhibits 1-5

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

CASE NO. 2013-01267

v.

BROTHERS PHARMACY AND DISCOUNT, LLC,
Respondent.
_____/

MOTION FOR FINAL ORDER
BASED UPON A VOLUNTARY RELINQUISHMENT OF LICENSE

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. On or about January 16, 2013, a Uniform Consumer Complaint was filed with the Department of Health, alleging that the Subject violated the provisions of Chapter 464 or Chapter 456, Florida Statutes.

2. In lieu of undergoing further disciplinary proceedings, the Respondent returned an executed Voluntary Relinquishment of his/her license.

3. 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 Uniform Consumer Complaint.

WHEREFORE the parties respectfully request the Board of Pharmacy enter a Final Order incorporating the terms of the Voluntary Relinquishment of Licensure.

Respectfully submitted,

John H. Armstrong, MD
State Surgeon General and Secretary of Health

fw Casey d. Cowan

Kristal Beharry
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
(850) 245-4444 telephone
(850) 245-4683 facsimile
Florida Bar No. 0078070

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 30th day of August, 2013, to Arturo Yero, Esquire, Law Offices of Arturo Yero, P.A., 782 Le Jeune Road, Suite 350, Miami, FL 33126.

Casey L Cowan

By: Kristal Bellarry
Assistant General Counsel

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE AUG 14 2013

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v.

DOH Case No. 2013-01267

BROTHERS PHARMACY AND DISCOUNT, LLC
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent BROTHERS PHARMACY AND DISCOUNT, LLC, license number PH 23338, by and through its owner/officer, hereby voluntarily relinquishes Respondent's license to operate as a community 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, 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 and its owner/officer agree to never reapply for licensure as a community pharmacy in the State of Florida.

3. Respondent, by and through its owner/officer, agrees to voluntarily cease operating as a community pharmacy immediately upon executing this Voluntary Relinquishment. Respondent, by and through its owner/officer, further agrees to refrain from operating as a community 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, by and through its owner/officer, 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, 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, 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, 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, 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, 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 13 day of August, 2013

BROTHERS PHARMACY AND DISCOUNT, LLC
By and through its owner/officer Jorge Tejeda
(print name)

STATE OF FLORIDA
COUNTY OF:
Before me personally appeared Jorge Tejeda, whose identity is known to me by Florida Driver's License (type of identification) and who, under oath, acknowledges that his signature appears above. Sworn to and subscribed before me this 12 day of August, 2013

NOTARY PUBLIC

My Commission Expires:

NOTARY PUBLIC STATE OF FLORIDA
ARTURO YERO
MY COMMISSION # EE 062618
EXPIRES: March 31, 2015
Bonded Thru Budget Notary Services

August 30, 2013

Arturo Yero, Esquire
Law Offices of Arturo Yero, P.A.
782 Le Jeune Road, Suite 350
Miami, FL 33126

Re: DOH vs. Brothers Pharmacy and Discount, LLC
DOH Case Number: 2013-01267

Dear Mr. Yero:

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 their license, pursuant to Section 456.072(1)(f), Florida Statutes;
- he/she would never reapply for licensure as a Profession in the State of Florida; and
- voluntarily relinquishing his/her Florida Profession license may have an effect on Profession licenses they may hold in other states.

If this is not what your client understood, please contact me as soon as possible to discuss, at 850-245-4444 ext. 8218. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your client's request for Voluntary Relinquishment of License at their next regularly scheduled meeting. Your client is not required to attend the meeting.

Sincerely,

Casey LCowan

for Kristal Beharry
Assistant General Counsel

KB/cmn

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: MIAMI XI	Date of Case: 1/16/2013	Case Number: PH 2013-01267
Subject: **BROTHERS PHARMACY** 1001 SW 27th Avenue Miami, FL 33135 (305)281-8642	Source: **DOH/ISU**	

Prefix:2205	License #:23338	Profession: Pharmacy	Board: Pharmacy	Report Date:4/1/13

Period of Investigation:1/28/13-4/1/13	Type of Report: FINAL REPORT

Possible violation of SS. 456.072(1)(k)(dd); 465.016(1)(r), F.S.; Rules 64B16-27.1001; 64B16-28.1081; 64B16-28.202; 64B16-28.203, F.A.C. Violate Statutes/Rules; Fail to perform legal responsibilities

Synopsis:

This investigation is predicated upon receipt of a uniform complaint form completed by DOH/ISU which indicates a failed pharmacy inspection at BROTHERS PHARMACY AND DISCOUNT PH#23338(Exhibit #1). On 1/7/13 a routine inspection was attempted at BROTHERS PHARMACY AND DISCOUNT (PH 23338), located at 1002 SW 27th Ave, Miami, FL 33135. The pharmacy appears to have been abandoned. The Inspector was unable to verify if any drugs remained on premise. The DOH database reflected that a closure had not been reported.

BROTHERS was notified of the investigation by letter, dated 1/28/13 (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 that BROTHERS is currently licensed as a community pharmacy. The pharmacy license is currently listed as delinquent.

No patients were identified thus no notification was necessary

BROTHERS is represented by an attorney, ARTURO YERO, 782 NW LeJune Road Suite #350 Miami, FL 33126, (305)444-0884.

BROTHERS written response was received on 2/20/13

Related Case(s): 2013-01268

Investigator/Date: April 1, 2013 Neil Downs Investigator MI-207	Approved By/Date: April 1, 2013 Carided Rodriguez Supervisor

Distribution: HQ/ISU

TABLE OF CONTENTS

***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES**

INVESTIGATIVE DETAILS

On 3/11/13 this investigator received a call from subject attorney ARTURO YERO who advised that BROTHERS may relinquish license. As of date of this report no relinquishment of license has been received from BROTHERS.

Pharmacy license #23338 is currently delinquent in DOH database as of 2/28/13.

Pictures of closed pharmacy location included in exhibit #1.

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit #1 contains the Case Summary and initiating documents.

Exhibit #2 Copy of Subject Notification letter, dated 1/28/13

Exhibit #3 Copy of letter of representation/statement from BROTHERS PHARMACY

Exhibit #4 Copy of last three pharmacy inspections for BROTHERS PHARMACY

Exhibit #5 Copy of FDLE search warrant and related information received from FDLE for BROTHERS PHARMACY

INTERVIEW OF CHARLES BUFFALINO, SUPERVISORY AGENT, FDLE (WITNESS)
Miami Regional Operations Center
1030 NW 111th Avenue
Miami, Florida 33172
(305)470-5500

On 2/19/13 this investigator was able to speak with Agent BUFFALINO via telephone. BUFFALINO confirmed that BROTHERS PHARMACY was no longer operating. BUFFALINO stated that pharmacy owner and pharmacy department manager were arrested back in November of 2012 and he would provide a copy of FDLE warrants to this investigator. He did not have any additional information to add at this time.

Investigator Note: On 3/6/13 this investigator received a copy of FDLE arrest and search warrants for BROTHERS PHARMACY from BUFFALINO (Exhibit #5)

STATEMENT OF BROTHERS PHARMACY (SUBJECT)
1001 SW 27th Avenue
Miami, FL 33135
(305)281-18642

On 2/20/13 this investigator received a written statement from BROTHERS through attorney ARTURO YERO. The statement briefly states that pharmacy is no longer operating at location 1001 SW 27th Avenue Miami, FL 33135 since 1/1/13. He states that the pharmacy followed procedure set forth by the FLORIDA BOARD OF PHARMACY. The full statement is avaible in exhibit #4.

Investigator Note: A copy of closure notification letter to the board of pharmacy was attached to statement.

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

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ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 15864
Insp # 113346

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
BROTHERS PHARMACY AND DISCOUNT, LLC		23338		1/11/2013
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 1001 SW 27 AVE		TELEPHONE # 305-642-1800	EXT.	WILLIAM T WALKER
CITY MIAMI	COUNTY 23	STATE/ZIP 33135		PRESCRIPTION DEPARTMENT MANAGER LICENSE # 27392

PRESCRIPTION DEPARTMENT HOURS							
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	5pm	5pm	5pm	5pm	5pm	2pm	closed

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
31	Preparation time does not exceed 1 hour when preparing, and administration 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: Inspector Maldonado (mi185) visited facility on 1/7/2013 to conduct a routine pharmacy inspection and upon arrival found pharmacy to be vacant/abandoned. Inspector looked inside and facility seems to be completely empty. Inspector also called the pharmacy at 305-642-1800 and the voicemail is full.

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 Not Available

N/A
Institutional Representative

01-11-2013
Date

CMC
Investigator/Sr. Pharmacist Signature

ID mi185

INV 359 Revised 12/12, 5/12, 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

EXHIBIT 4

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

File # 15864
Insp # 106037

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
BROTHERS PHARMACY AND DISCOUNT, LLC		23338		1/24/2012
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
		FB0852358		
STREET ADDRESS		TELEPHONE #	EXT.	WILLIAM T WALKER
1001 SW 27 AVE		305-308-8456		
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
MIAMI	23	33135		

PRESCRIPTION DEPARTMENT HOURS							
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9 AM	9 AM	9 AM	9 AM	9 AM	9 AM	CLOSED
Close	5 PM	5 PM	5 PM	5 PM	5 PM	2 PM	CLOSED

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. [64B16-27.410, 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: Most current CQI was completed on 01/2012. Most current inventory was completed on 11/12/2011. The facility buys medication from the following whole sellers: Cardinal Health, Quest, Top RX. I have reviewed all that is applicable to this inspection and have found the facility to be in compliance at this time. Inspector received a copy of a 6 month dispensing log of control 2 substances (6 months). I have reviewed the inspection with the PS prior to signing.

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 William Walker (PDM)

William Walker
Institutional Representative

01-24-2012
Date

Investigator/Sr. Pharmacist Signature

ID mi204

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
INVESTIGATIVE SERVICES
WWW.DOH.STATE.FL.US

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
[illegible]	[illegible]		[illegible]
DOING BUSINESS AS	TELEPHONE NUMBER	EXTENSION	
STREET ADDRESS: [illegible]	CITY: [illegible]	COUNTY: [illegible]	STATE: [illegible] ZIP: [illegible]
DEA NUMBER: [illegible]		EXPIRATION DATE	
PRESCRIPTION DEPARTMENT MANAGER NAME: [illegible]	PDM NOTIFICATION DATE	LICENSE NUMBER: [illegible]	
VENDOR WHOLESALER PHARMACY	VENDOR LICENSE NUMBER		
REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE NUMBER		
1 RPT [illegible]			
2 RPT [illegible]			
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.] [64B16-28.1035 F.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.] [64B16-28.1191, F.A.C.]		✓	
10.	CQI Policy and Procedures and quarterly meetings. [64B16-27.300, F.A.C.] [766.101, F.S.] [illegible]		✓	
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, F.S.]		✓	
14.	All controlled substance prescriptions contain information required [893.04(1)(c), F.S.] [illegible]		✓	
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), 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: [illegible]

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] Signature of Pharmacist — Date [illegible] — [signature] Investigator or Pharmacist Signature ID Number

[signature] Print Name

INV 339 Revised [illegible] Replaces [illegible] — White Copy Field — Yellow Copy Headquarters — Pink Copy [illegible]

: 00017

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

FLORIDA DEPARTMENT OF HEALTH
WWW.DOH.STATE.FL.US

ADDITIONAL REMARKS

4052 Bald Cypress Way, BIN # C70 ◦ Tallahassee, FL 32399-3270

Facility Name	Inspection Number	Date of Inspection
Brothers Pharmacy	Ph 23338	1/20/2011
Doing Business as	File Number	License #
Street address		Telephone #
1001 SW 1 Avenue		

City	County	State	Zip
Miami	Dade	Fl	33135

REMARKS: #2 one of the technician is not properly identified. Pharmacy buys controls from PBA: Health, and from Cardinal Health.
#17 DEA222 Form was not signed by PDM. Inspector asked PDM to please sign it.
#16 Controlled Inventory was completed on 10/7/2009.
#5 N/A no interns at this time.
#18 Pharmacy is safe at this time since the Pharmacist/PDM is on site.
Pharmacy is within compliance at this time. Inspector have educated the PDM and [illegible] the inspection [illegible] signing.
Inspector obtained copies of dispensing log for controlled II's that were dispensed within the last two months before the pharmacy starting ordering controlled II's two months ago.
#2 Pharmacy tech is [illegible] the [illegible].

I have read and acknowledge the receipt of this supplemental inspection report, and do affirm that the information given is true and correct to the best of my knowledge.

[signature] 1-20-11
Signature of Owner or Licensee — Date

[signature]
Inspector signature/ID Number — Date 1/20/11

INV 416 Created 07/03

White Copy: Field   Yellow Copy: Headquarters   Pink Copy: Licensee

STATE OF FLORIDA
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE - ISU/DDC PROGRAM

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US/MQA/DDC

ADDITIONAL REMARKS

CORPORATE NAME BROTHERS PHARMACY AND DISCOUNT, LLC	INSPECTION NUMBER 105385	TYPE OF PERMIT 2205	DATE OF INSPECTION 1/19/2011
DOING BUSINESS AS	FILE NUMBER 15884	LICENSE # 23338	
STREET ADDRESS 1001 SW 27 AVE		TELEPHONE # 305-308-8456	EXT #
CITY MIAMI	COUNTY MIAMI-DADE	STATE/ZIP 33135	

Remarks:
A re-inspection was completed on 1/20/2010. please refer to manual re-inspection due to tablet issues.

;

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.

PRINT NAME OF RECIPIENT N/A

N/A
Institutional Representative

01-19-2011
Date

Drug Agent/Inspector Signature

ID mi187

INV 416 Revised 01/07 Replaces 07/03

: 00019

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
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201117660

IHAB S. BARSOUM,
RESPONDENT.

NOTICE

TO: IHAB S. BARSOUM
14937 BRUCE B DOWNS BLVD
SUITE 204
TAMPA, FL 33613

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Michael Lawrence, Jr., Assistant General Counsel
RE: Determination of Waiver
SUBJECT: DOH v. Ihab S. Barsoum, P.S.
DOH Case Number 2011-17660
DATE: August 12, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Ihab S. Barsoum
Subject's Address of Record:	14937 Bruce B Downs Blvd, Suite 204 Tampa, FL 33613
Enforcement Address:	14937 Bruce B Downs Blvd, Suite 204 Tampa, FL 33613
Subject's Additional Addresses:	17303 Ladera Estates Blvd. Lutz, FL 33548 Federal Correctional Institution 2225 Haley Barbour Parkway Yazoo City, MS 39194
Subject's License No:	30945 **Rank:** PS
Licensure File No:	19958
Initial Licensure Date:	11/8/1995
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Ct 1: 456.072(1)(c), FS (2012) Ct 2: 456.072(1)(x), FS (2012)
Prior Discipline:	None
Probable Cause Panel:	February 28, 2013; Glass & Mullins
Subject's Attorney:	Pro Se
Complainant/Address:	Department Of Health/Consumer Services Unit
Materials Submitted:	Memorandum to the Board Motion for Determination of Waiver Exhibit A – Administrative Complaint

Exhibit B – Certified Mail Receipt
Exhibit C – Affidavit of Diligent Search
Exhibit D – Board Affidavit
Exhibit E – Clerk's Affidavit
Motion to Assess Costs with
Exhibit A – Affidavit of Fees & Costs Expended
Exhibit 1 – Cost Summary
Exhibit 2 – Itemized Cost
Probable Cause Memorandum
Emergency Suspension Order
Affidavit of Diligent Search
Certified Mail Receipt
Administrative Weekly
Final Investigative Report with Exhibits 1-5

Disciplinary Guidelines:
COUNT I - 456.072(1)(c), Florida Statutes (2012):
First Offense: Misdemeanor: $1,000 fine up to $5,000 fine and one year suspension; Felony: $3,000 fine and one year probation to Revocation

COUNT II – 456.072(1)(x), Florida Statutes (2012):
First Offense: $1,000 fine to $2,500 fine and one (1) year suspension

PRELIMINARY CASE REMARKS: DETERMINATION OF WAIVER

This is a two-count administrative complaint alleging Respondent violated Section 456.072(1)(c), Florida Statutes (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; and Section 456.072(1)(x), Florida Statutes (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. 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.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. **CASE NO. 2011-17660**

IHAB S. BARSOUM, R.Ph.,
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 February 28, 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 March 6, 2013 (7196 9008 9111 1491 3912). A signed

green receipt card was 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 July 11, 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,

Michael G. Lawrence, Jr.
Assistant General Counsel
Florida Bar No. 0011265
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444 x8199
Facsimile: (850) 245-4683
Email:michael_lawrence@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 furnished via U.S. mail this 20th day of August, 2013, to Ihab Barsoum, FCI #55623-018, 2225 Haley Barbour Parkway, Yazoo City, MS 39194; 17303 Ladera Estates Blvd., Lutz, FL 33548; 14937 Bruce B. Downs Blvd., Suite 204, Tampa, FL 33613.

Michael G. Lawrence, Jr.
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2011-17660**

IHAB S. BARSOUM, 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, Ihab S. Barsoum, 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 Administrative Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 30945.

EXHIBIT
tabbies
A

3. Respondent's address of record is 14937 Bruce B. Downs Boulevard, Suite 204, Tampa, Florida, 33613.

4. Respondent's current address is believed to be 17303 Ladera Estates Boulevard, Lutz, Florida 33548.

5. On or about August 21, 2012, in the United States District Court, Middle District of Florida, Tampa Division, in case number 8:11-CR-548-T-33MAP, Respondent was found guilty by a jury on six counts: one count of conspiracy to knowingly and intentionally dispense and distribute, and cause to be dispensed and distributed, quantities of Oxycodone, a Schedule II Controlled Substance, not for a legitimate medical purpose and not in the usual course of professional practice, a felony, in violation of 21 U.S.C. § 846; and five counts of knowingly and intentionally acting outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance, a felony, in violation of 21 U.S.C. § 841(a)(1).

6. Respondent failed to report being found guilty of the crimes referenced in paragraph five (5) to the Board of Pharmacy in writing within thirty (30) days of the date he was found guilty on or about August 21, 2012.

COUNT ONE

7. Petitioner realleges and incorporates paragraphs one (1) through six (6), as if fully set forth herein.

8. Section 456.072(1)(c), Florida Statutes (2012), 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.

9. 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).

10. On or about August 21, 2012, in the United States District Court, Middle District of Florida, Tampa Division, in case number 8:11-CR-548-T-33MAP, Respondent was found guilty by a jury of one or more of the following crimes that relate to the practice of, or the ability to practice, pharmacy:

a. One count of conspiracy to knowingly and intentionally dispense and distribute, and cause to be dispensed and distributed, quantities of Oxycodone, a Schedule II

Controlled Substance, not for a legitimate medical purpose and not in the usual course of professional practice, a felony, in violation of 21 U.S.C. § 846;

b. Five counts of knowingly and intentionally acting outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance, a felony, in violation of 21 U.S.C. § 841(a)(1).

11. Based on the foregoing, Respondent violated Section 456.072(1)(c), Florida Statutes (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

12. Petitioner realleges and incorporates paragraphs one (1) through six (6), as if fully set forth herein.

13. Section 456.072(1)(x), Florida Statutes (2012), provides that failing to report to the board, or the department if there is no board, in writing within thirty (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 disciplinary action.

14. 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).

15. Respondent failed to report being found guilty of the crimes referenced in paragraph five (5) to the Board of Pharmacy in writing within thirty (30) days of the date he was found guilty on or about August 21, 2012.

16. Based on the foregoing, Respondent violated Section 456.072(1)(x), Florida Statutes (2012), by failing to report to the board in writing within thirty (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.

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** February, **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) 245-4444, extension 8199
Facsimile: (850) 245-4683
Email: michael_lawrence@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE FEB 28 2013

/MGL

PCP: February 28, 2013
PCP Members: Glass & Mullins

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 1491 3912

TO:

I.S. Barsoum
2011-17660
ab – Stip Pk
Sent 3/6/13

SENDER:

REFERENCE:

Ihab S. Barsoum
17303 Ladera Estates Blvd.
Lutz, FL 33548

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 1491 3912

3. Service Type **CERTIFIED MAIL™**

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Ihab S. Barsoum
17303 Ladera Estates Blvd.
Lutz, FL 33548
Case No. 2011-17660
Stip Pk – Sent 3/6/13

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly): GIHAN BARSOUM
B. Date of Delivery: 3/9/13

C. Signature: X A. B
☐ Agent ☐ Addressee

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

lawrence

PS Form 3811, January 2005 Domestic Return Receipt

EXHIBIT
tabbies
B

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

Department of Health
Petitioner

vs

Case No. 2011-17660

Ihab S. Barsoum, R.Ph.
Respondent

2013 JUL 12

COMES NOW, the affiant, who first being duly swom, deposes and states:

1) Affiant is a/an Deputy Sheriff employed by Yazoo County Sheriff Dept, State of MS.

2) That on (date) 7/11/13, Affiant made a diligent effort to locate Respondent, to serve __X__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:

✓ Affiant made personal service on Respondent or on some person over the age of 15 residing at (address) 2225 Haley Barbour Parkway Yazoo, MS 39194 on (date) 7/11/13.

_____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent provided to me by the DOH Prosecution Services Unit; (b) 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: _____.

John V Johnson
Affiant Signature

State of MS County of YAZOO

Before me, personally appeared Affiant, whose identity is known to me by JOHN JOHNSON (ID type) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed before me this 11th day of July, 2013.

Pamela Dortch, D.C.
Signature of Notary Public
My Commission Expires: March 11, 2016
Pamela Dortch, D.C.
Printed Name of Notary Public

STATE OF MISSISSIPPI NOTARY PUBLIC ID # 101630 PAMELA DORTCH Commission Expires March 11, 2016 YAZOO COUNTY

EXHIBIT C

Affidavit of Non-Receipt

I, Mark Whitten, hereby certify in my official capacity as custodian for the Board's licensure files that the Board of Pharmacy as of August 16, 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **Ihab S. Barsoum, R.Ph.; 2011-17660,** which would affect the Subject's substantial interests or rights.

Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Mark Whitten, 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 16 day of August, 2013.

HELAINE ROBISON
MY COMMISSION # EE 136625
EXPIRES: November 17, 2015
Bonded Thru Notary Public Underwriters

Notary Public
My commission expires:

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 **Ihab S. Barsoum, R.Ph.; 2011-17660**, 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 12th day of August, 2013.

Angela Barton
Notary Public

My Commission Expires:

ANGELA BARTON
NOTARY PUBLIC - STATE OF FLORIDA
COMMISSION # DD922154
EXPIRES 9/1/2013
BONDED THRU 1-888-NOTARY1

EXHIBIT
E

PRACTITIONER REGULATION
LEGAL
2013 AUG -2 PM 12:50

7/20/13

Michael G. Lawrence Jr.
Assistant General Counsel
Prosecution Service Unit
4052 Bald Cypress Way Bin-65
Tallahassee, FL. 32399-3265

Re: Case Name: IHAB S. BARSOUM, RPh.
Case No.: 2011-17660.

Please accept this letter regarding the case mentioned above

Unfortunately, we do not have notary public available on site. The come once a month and they do not notify us except for a few days in advance.

I would like to inform you that we are in appeal for the case regarding the charge that were mention in the letter sent to me in Yazoo FCC law.

After consulting with with my attorney I was advised to notify you in writing that I am contesting the charge and still claim my innocence. While I was in Pinellas County Jail I was visited by a representative from the board of pharmacy. I had informed him of my intention to appeal my case, and prove my innocence.

If you are in need of any further information you can contact me at Yazoo FCC or my attorney at

Mark Obrien
511 West Bay Street Suite 330
Tampa FL 33606
813-228-6988 office
866 202-5964 fax

Thank You for your Time

Ihab Barsoum

August 20, 2013

Ihab S. Barsoum
17303 Ladera Estates Blvd.
Lutz, FL 33548

Ihab S. Barsoum
FCI #55623-018
2225 Haley Barbour Parkway
Yazoo, City, MS 39194

Re: **Case Name:** **Ihab S. Barsoum, R.Ph.**
Case Number: **2011-17660**

Dear Mr. Barsoum:

I am in receipt of your letter dated July 20, 2013. I contacted Mark O'Brien, Esq., and he indicated he is only representing you regarding your criminal appeal and is not representing you in this matter.

Although you are appealing your criminal conviction, the completion of relevant appellate remedies does not preclude the Department from prosecuting your pharmacy license and submitting your case to the Board of Pharmacy for discipline. In Rife v. Dep't of Prof'l Reg., 638 So. 2d 542, 543 (Fla. 2d DCA 1994), the court allowed discipline based on action against appellant's license in another state even though appellate proceedings were still pending.

You were served with an administrative complaint via personal service on June 11, 2013. You failed to dispute the allegations of fact contained within the administrative complaint and failed to submit a response within twenty-one days of service of the administrative complaint, so your case will be heard by the Board of Pharmacy as a Motion for Determination of Waiver and for Final Order by Hearing Not Involving Disputed Issues of Material Fact. You will receive notice of the meeting at a future time.

Sincerely yours,

Michael G. Lawrence, Jr.
Assistant General Counsel

MGL

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. CASE NO. 2011-17660

IHAB S. BARSOUM, 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 $1,749.48, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.10	$62.56
Investigation:	16.30	$1,026.71
Legal:	6.20	$658.60
Compliance:	0.05	$1.61
Sub Total:	23.65	$1,749.48
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,749.48

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $1,090.88 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 $1,090.88 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 $1,090.88.

DATED this 20th day of August, 2013.

Respectfully submitted,

Michael G. Lawrence, Jr.
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar #0011265
(850) 245-4444 x8199 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 20th day of August, 2013, to Ihab S. Barsoum, FCI #55623-018, 2225 Haley Barbour Parkway, Yazoo City, MS 39194; Ihab S. Barsoum, 17303 Ladera Estates Blvd., Lutz, FL 33548; Ihab S. Barsoum, 14937 Bruce B. Downs Blvd., Suite 204, Tampa, FL 33613.

Michael G. Lawrence, Jr.
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.

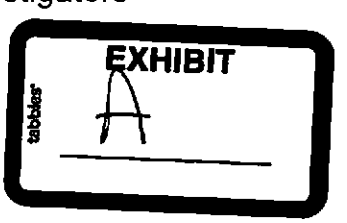
4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2011-17660** (Department of Health v. **IHAB S. BARSOUM**) are **ONE THOUSAND SEVEN HUNDRED FORTY-NINE DOLLARS AND FORTY-EIGHT CENTS ($1,749.48).**

6) The costs for DOH case number(s) **2011-17660** (Department of Health v. **IHAB S. BARSOUM**) 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) **2011-17660** (Department of Health v. **IHAB S. BARSOUM**) 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



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 13th day of August, 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: 201117660

Subject's Name: BARSOUM, IHAB S

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.10	$62.56
Investigation:	16.30	$1,026.71
Legal:	6.20	$658.60
Compliance:	0.05	$1.61
	**********	**********
Sub Total:	23.65	$1,749.48
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,749.48

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201117660

Report Date 08/13/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
COMPLIANCE MANAGEMENT UNIT						
HA17	0.10	$57.62	$5.76	11/15/2011	1	ROUTINE ADMINISTRATIVE DUTIES
HC27	0.05	$32.13	$1.61	02/14/2013	125	LICENSE STATUS CHANGE
Sub Total	**0.15**		**$7.37**			
CONSUMER SERVICES UNIT						
HA107	0.70	$57.62	$40.33	11/01/2011	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HA05	0.30	$54.90	$16.47	02/06/2013	25	REVIEW CASE FILE
Sub Total	**1.00**		**$56.80**			
INVESTIGATIVE SERVICES UNIT						
TI123	0.50	$61.19	$30.60	01/31/2012	7	PRELIMINARY INVESTIGATION
TI141	1.20	$61.19	$73.43	05/17/2012	7	PRELIMINARY INVESTIGATION
TI141	0.60	$61.19	$36.71	05/17/2012	58	TRAVEL TIME
TI123	1.00	$61.19	$61.19	07/10/2012	7	PRELIMINARY INVESTIGATION
TI123	1.50	$61.19	$91.79	09/27/2012	7	PRELIMINARY INVESTIGATION
TI123	1.00	$61.19	$61.19	11/21/2012	4	ROUTINE INVESTIGATIVE WORK
TI123	2.00	$63.98	$127.96	11/29/2012	4	ROUTINE INVESTIGATIVE WORK
TI123	1.00	$63.98	$63.98	11/29/2012	58	TRAVEL TIME
TI123	0.20	$63.98	$12.80	12/12/2012	4	ROUTINE INVESTIGATIVE WORK
TI123	0.20	$63.98	$12.80	01/10/2013	4	ROUTINE INVESTIGATIVE WORK
TI123	2.00	$63.98	$127.96	02/06/2013	58	TRAVEL TIME
TI123	1.00	$63.98	$63.98	02/06/2013	4	ROUTINE INVESTIGATIVE WORK
TI123	1.50	$63.98	$95.97	02/06/2013	76	REPORT PREPARATION
TI123	1.00	$63.98	$63.98	02/14/2013	6	SUPPLEMENTAL INVESTIGATION
TI123	1.60	$63.98	$102.37	06/28/2013	6	SUPPLEMENTAL INVESTIGATION

EXHIBIT
2

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201117660

Report Date 08/13/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
Sub Total	16.30		$1,026.71			
PROSECUTION SERVICES UNIT						
HLL83B	0.10	$102.41	$10.24	11/02/2011	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL83B	0.10	$102.41	$10.24	11/02/2011	115	CONTACT WITH INVESTIGATORS
HLL38B	0.60	$106.35	$63.81	02/07/2013	25	REVIEW CASE FILE
HLL38B	0.50	$106.35	$53.18	02/07/2013	81	ESO/ERO
HLL96B	0.40	$106.35	$42.54	02/14/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL96B	0.30	$106.35	$31.91	02/14/2013	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFF
HLL96B	1.00	$106.35	$106.35	02/14/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL96B	0.50	$106.35	$53.18	02/15/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL96B	0.20	$106.35	$21.27	02/19/2013	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFF
HLL96B	0.20	$106.35	$21.27	02/19/2013	60	MISCELLANEOUS
HLL38B	0.40	$106.35	$42.54	02/19/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL38B	0.20	$106.35	$21.27	02/25/2013	89	PROBABLE CAUSE PREPARATION
HLL38B	0.10	$106.35	$10.64	02/28/2013	68	SIGNING CLOSING ORDERS, ADMINISTRATIVE COMPLAINTS AND REASONAB
HLL38B	0.40	$106.35	$42.54	03/06/2013	79	STIPULATION
HLL38B	0.40	$106.35	$42.54	03/11/2013	25	REVIEW CASE FILE
HLL36B	0.20	$106.35	$21.27	03/25/2013	25	REVIEW CASE FILE
HLL38B	0.40	$106.35	$42.54	07/01/2013	25	REVIEW CASE FILE
HLL38B	0.20	$106.35	$21.27	08/02/2013	25	REVIEW CASE FILE
Sub Total	6.20		$658.60			

Total Cost **$1,749.48**

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201117660

Report Date 08/13/2013

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: 08/13/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

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. Ihab S. Barsoum, RPh.**
DOH Case Number 2011-17660

MEMBERS: Debra B. Glass, BPharm, and DeAnn Mullins, BPharm

DATE OF PCP: February 28, 2013 **AGENDA ITEM: A2(JS)**

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 456.072(1)(x), 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** _____

9-5-13

Chair, Probable Cause Panel Date
Board of Pharmacy

Final Order No. DOH-13-0243-ESO-MQA
FILED DATE: FEB 14 2013
Department of Health
By: [signature]
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the License of
Ihab S. Barsoum, R.Ph.
License No. PS 30945
Case Number: 2011-17660

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 Ihab S. Barsoum, R.Ph., to practice as a pharmacist in the State of Florida. Mr. Barsoum holds license number PS 30945. His address of record is 14937 Bruce B. Downs Boulevard, Suite 204, Tampa, Florida, 33613. Mr. Barsoum's current address is believed to be 17303 Ladera Estates Boulevard, Lutz, Florida 33548. The following Findings of Fact and Conclusions of Law support the emergency suspension of Mr. Barsoum's license to practice as a pharmacist.

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). Section 456.074(1), Florida Statutes (2012), authorizes the Department to summarily suspend Mr.

Barsoum's license to practice as a pharmacist.

2. At all times material to this Order, Mr. Barsoum was licensed to practice as a pharmacist in the State of Florida pursuant to Chapter 465, Florida Statutes (2012).

3. On or about August 21, 2012, in the United States District Court, Middle District of Florida, Tampa Division, in case number 8:11-CR-548-T-33MAP, Respondent was found guilty by a jury on six counts: one count of conspiracy to knowingly and intentionally dispense and distribute, and cause to be dispensed and distributed, quantities of Oxycodone, a Schedule II Controlled Substance, not for a legitimate medical purpose and not in the usual course of professional practice, a felony, in violation of 21 U.S.C. § 846; and five counts of knowingly and intentionally acting outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance, a felony, in violation of 21 U.S.C. § 841(a)(1).

4. Section 456.074(1), Florida Statutes (2012), provides that the department *shall* issue an emergency order suspending the license of any person licensed under chapter 465, Florida Statutes, who is convicted or

found guilty, regardless of adjudication, of a felony under 21 U.S.C. §§ 801-970.

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 456.074(1), Florida Statutes (2012), and Chapter 465, Florida Statutes (2012), as set forth above.

2. The Department is mandated to summarily suspend Mr. Barsoum's license to practice as a pharmacist in accordance with Section 456.074(1), Florida Statutes (2012).

WHEREFORE, in accordance with Section 456.074(1), Florida Statutes (2012), it is ORDERED THAT:

1. The license of Ihab S. Barsoum, R.Ph., license number 30945, is immediately suspended.

2. A proceeding seeking formal suspension or discipline of the license of Ihab S. Barsoum, R.Ph., to practice as a pharmacist will be promptly instituted and acted upon in compliance with Section 120.569, Florida Statutes (2012).

DONE and ORDERED this 13th day of February, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

PREPARED BY:
Michael G. Lawrence, Jr.
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Florida Bar Number 0011265
(850) 245 - 4444 Telephone
(850) 245 - 4683 Facsimile

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.

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

Department of Health
Petitioner

vs

Case No. 2011-17660

Ihab S. Barsoum, R.Ph.
Respondent

2013 JUL 22

COMES NOW, the affiant, who first being duly swom, deposes and states:

1) Affiant is a/an Deputy Sheriff employed by Yazoo County Sheriff Dept. State of MS.

2) That on (date) 7/11/13, Affiant made a diligent effort to locate Respondent, to serve __X__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:

✓ Affiant made personal service on Respondent or on some person over the age of 1S residing at (address) 2225 Haley Barbour Parkway Yazoo, MS 39194 on (date) 7/11/13.

_____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent provided to me by the DOH Prosecution Services Unit; (b) 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: _____

John V Johnson
Affiant Signature

State of MS County of YAZOO

Before me, personally appeared Affiant, whose identity is known to me by John Johnson (ID type) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed before me this 19th day of July, 2013.

Pamela Dortch, D.C.
Signature of Notary Public
My Commission Expires: March 11, 2016
Pamela Dortch, D.C.
Printed Name of Notary Public

STATE OF MISSISSIPPI NOTARY PUBLIC ID # 101630 PAMELA DORTCH Commission Expires March 11, 2016 YAZOO COUNTY

7196 9008 9111 4171 6548

TO:

Ihab S. Barsoum, RPh
14937 Bruce B Downs
Blvd, Suite 204
Tampa, FL 33613
ESO : 11-17660 2/18/13

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

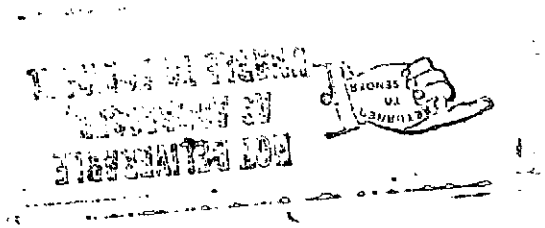
DEPARTMENT OF
ALTH

ition Services Unit
ald Cypress Way, Bin #C65
see, Florida 32399-3265

7196 9008 9111 4171 6548

FIRST CLASS

UNITED STATES POSTAGE
PITNEY BOWES
02 1A $ 06.77°
0004371978 FEB 19 2013
MAILED FROM ZIPCODE 32301



Ihab S. Barsoum, R.Ph.
14937 Bruce B. Downs Blvd., Suite 204
Tampa, FL 33613

Michael

NIXIE 336133409-1N 02/28/13

RETURN TO SENDER
UNABLE TO FORWARD
UNABLE TO FORWARD
RETURN TO SENDER

Pope, Berita

From: Pope, Berita
Sent: Monday, February 18, 2013 3:09 PM
To: zzzz Feedback, MQA_PSU_Operations
Subject: ESO FAW Barsoum

Attachments: ESO FAW Barsoum.doc

ESO FAW
Barsoum.doc (51 KB

Berita Pope
Regulatory Supervisor / Consultant
Emergency Action Unit
Department of Health, Prosecution Services
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Tele.: 850-245-4444 ext. 8196
Fax: 850-245-4662
Berita_Pope@doh.state.fl.us
www.doh.state.fl.us/mqa

Mission: Promote, protect and improve the health of all people in Florida.
Vision: A healthier future for the people of Florida.

Florida HEALTH

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

MEMORANDUM

TO: Florida Administrative Weekly, Liz Cloud

FROM: Berita Pope, Regulatory Supervisor / Consultant BP

RE: Ihab S. Barsoum, R.Ph., License # PS 3094S (FAW # 12663367)

CASE NO: 2011-17660

DATE: February 18, 2013

Attached please find notice of the issuance of an Emergency Suspension Order for notice in the next issue of the Florida Administrative Weekly.

On February 14, 2013, the State Surgeon General issued an Order of Emergency Suspension Order with regard to the license of Ihab S. Barsoum, R.Ph., License #PS3094S. 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 4S6.073(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.

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
FAX: 850/245-4662

www.floridashealth.com
TWITTER: HealthyFLA
FACEBOOK: FLDepartmentofHealth
YOUTUBE: fldoh

Florida HEALTH

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

Florida Department of Health
Office of the General Counsel
Prosecution Services Unit
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February 18, 2013

Certified Article Number
7196 9008 9111 4171 6548
SENDERS RECORD

Ihab S. Barsoum, R.Ph.
14937 Bruce B. Downs Blvd. Suite 204
Tampa, FL 33613

RE: Department of Health vs. Ihab S. Barsoum, R.Ph.
Case Number: 2011-17660

Dear Ihab Rarsoum:

Enclosed please find an Order of Emergency Suspension of License filed February 14, 2013, against your license to practice as a registered pharmacist in the State of Florida. You should immediately cease the practice as a registered pharmacist according to the enclosed Order of Emergency Suspension of License.

If you have any questions, please do not hesitate to contact Michael Lawrence, Jr., Assistant General Counsel at (850) 245-4444.

Sincerely,

Berita Pope

Berita Pope
Regulatory Supervisor / Consultant
Prosecution Services Unit

/bp
Enclosure

** Transmit Conf.Report **

P.1 Feb 18 2013 05:20pm

Fax/Phone Number	Mode	Start	Time	Page	Result	Note
99216847	Normal	18:05:20pm	0'31"	1	* O K	

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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

February 18, 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. Ihab S. Barsoum, R.Ph
Case Number: 2011-17660

Dear Judge Cohen:

This letter is to advise you that the Department has issued an Emergency Suspension Order concerning the license of Ihab S. Barsoum, R.Ph. to practice as a registered 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 Michael Lawrence, Jr., Assistant General Counsel at (850) 245-4444.

/bp

Sincerely,

Berita Pope

Berita Pope
Regulatory Supervisor / Consultant
Prosecution Services Unit

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
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Florida HEALTH

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in Florida through
integrated state, county,
& community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

February 18, 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. Ihab S. Barsoum, R.Ph
Case Number: 2011-17660

Dear Judge Cohen:

This letter is to advise you that the Department has issued an Emergency Suspension Order concerning the license of Ihab S. Barsoum, R.Ph. to practice as a registered 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 Michael Lawrence, Jr., Assistant General Counsel at (850) 245-4444.

/bp

Sincerely,

Berita Pope

Berita Pope
Regulatory Supervisor / Consultant
Prosecution Services Unit

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
FAX: 850/245-4662

www.floridashealth.com
TWITTER: HealthyFLA
FACEBOOK: FLDepartmentofHealth
YOUTUBE: fldoh

Apellaniz, Melba

From: Apellaniz, Melba
Sent: Thursday, February 14, 2013 12:15 PM
To: DL MQA Inv Serv Priority Mail Area6 (TI) Tampa
Subject: Hand Service ESO 11-17660/Barsoum
Attachments: Supp.Req.11-17660.Barsoum.2.14.13..doc; DOH 13-0243 ESO 201117660-1.PDF

Good Afternoon,

Attached please find a request to hand service ESO for case 2011-17660, Ihab S. Barsoum, R.Ph.

<<...>> <<...>>

Thanks,

Melba L. Apellániz, RSII
Assistant to: Daniel Hernandez, DGC
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. 8223

Mission: To protect, promote, and improve the health of all people in Florida through integrated state, county, & community efforts.

Vision: To be the **Healthiest State** in the Nation

Values: ICARE

I innovation: We search for creative solutions and manage resources wisely.
C collaboration: We use teamwork to achieve common goals & solve problems.
A accountability: We perform with integrity & respect.
R responsiveness: We achieve our mission by serving our customers & engaging our partners.
E excellence: We promote quality outcomes through learning & continuous performance improvement.

Purpose: To protect the public through health care licensure, enforcement and information.

Focus: To be the nation's leader in quality health care regulation.

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

FROM: Melba L. Apellaniz, RSII for Michael Lawrence, Jr., Esq.	TO: ISU Babette Agett
Date: 2/14/2013	TO: CSU
Phone #: (850) 245-4640 Ext. 8223	CC: Victor R. Troupe

Case Number: 2011-17660 Board: **Pharmacy**
Subject: **Ihab S. Barsoum, R.Ph.** HL Code:**hll46a** Status: **90**
Requested Completion Date: ASAP

(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 ESO/ERO. Thanks.

*The following additional information is needed for each service request:

Last Known Address: 17303 Ladera Estates Blvd., Lutz, Florida 33548; Last Known Name & Phone Number: Ihab S. Barsoum, R.Ph.; Unknown; 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

Final Order No. DOH-13-0243-ESO-MQA
FILED DATE FEB 1 4 2013
Department of Health
By: Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the License of
Ihab S. Barsoum, R.Ph.
License No. PS 30945
Case Number: 2011-17660

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 Ihab S. Barsoum, R.Ph., to practice as a pharmacist in the State of Florida. Mr. Barsoum holds license number PS 30945. His address of record is 14937 Bruce B. Downs Boulevard, Suite 204, Tampa, Florida, 33613. Mr. Barsoum's current address is believed to be 17303 Ladera Estates Boulevard, Lutz, Florida 33548. The following Findings of Fact and Conclusions of Law support the emergency suspension of Mr. Barsoum's license to practice as a pharmacist.

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). Section 456.074(1), Florida Statutes (2012), authorizes the Department to summarily suspend Mr.

Barsoum's license to practice as a pharmacist.

2. At all times material to this Order, Mr. Barsoum was licensed to practice as a pharmacist in the State of Florida pursuant to Chapter 465, Florida Statutes (2012).

3. On or about August 21, 2012, in the United States District Court, Middle District of Florida, Tampa Division, in case number 8:11-CR-548-T-33MAP, Respondent was found guilty by a jury on six counts: one count of conspiracy to knowingly and intentionally dispense and distribute, and cause to be dispensed and distributed, quantities of Oxycodone, a Schedule II Controlled Substance, not for a legitimate medical purpose and not in the usual course of professional practice, a felony, in violation of 21 U.S.C. § 846; and five counts of knowingly and intentionally acting outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance, a felony, in violation of 21 U.S.C. § 841(a)(1).

4. Section 456.074(1), Florida Statutes (2012), provides that the department *shall* issue an emergency order suspending the license of any person licensed under chapter 465, Florida Statutes, who is convicted or

found guilty, regardless of adjudication, of a felony under 21 U.S.C. §§ 801-970.

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 456.074(1), Florida Statutes (2012), and Chapter 465, Florida Statutes (2012), as set forth above.

2. The Department is mandated to summarily suspend Mr. Barsoum's license to practice as a pharmacist in accordance with Section 456.074(1), Florida Statutes (2012).

WHEREFORE, in accordance with Section 456.074(1), Florida Statutes (2012), it is ORDERED THAT:

1. The license of Ihab S. Barsoum, R.Ph., license number 30945, is immediately suspended.

2. A proceeding seeking formal suspension or discipline of the license of Ihab S. Barsoum, R.Ph., to practice as a pharmacist will be promptly instituted and acted upon in compliance with Section 120.569, Florida Statutes (2012).

DONE and ORDERED this 13th day of February, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

PREPARED BY:
Michael G. Lawrence, Jr.
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Florida Bar Number 0011265
(850) 245 - 4444 Telephone
(850) 245 - 4683 Facsimile

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.

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area VI Tampa	Date of Case: 11-20-12	Case Number: 2011-17660
Subject: **IHAB S. BARSOUM, R.PH.** 17303 Ladera Estates Boulevard Lutz, Florida 33548* Telephone: Unknown	Source: **Department Of Health / Consumer Services Unit**	

Prefix:	License #:	Profession:	Board:	Report Date:
PS	30945	Pharmacist	Pharmacy	02-07-13

Period of Investigation: 11-21-13 through 02-07-13	Type of Report: FINAL

Alleged Violation: F.S. 465.016(1)(e)(f)(i)(r)(s), F.S. 499-893, U.S.C. ss. 301-392, or 21 U.S.C. ss. 821 et seq; (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,... (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 or chapter 456, or any rules adopted pursuant thereto... (s) Dispensing any medicinal drug based upon a communication that purports to be a prescription...

Synopsis: This investigation is predicated upon receipt of a Case Summary, Exhibit #1, based upon complaint from Department Of Health / Consumer Services Unit. On 10-28-11, a press release from Sunshine State News reported BARSOUM (PS 30945) was charged with conspiracy to distribute prescription drugs such as Oxycodone. Court documents from the U.S. District Court Tampa provided by ISU state that BARSOUM pled guilty on August 21, 2012 to 6 counts of dispensing Oxycodone not for a legitimate medical purpose and not in the usual course of professional practice.

BARSOUM was notified of the investigation by letter dated 11-21-13 (Exhibit #2) at 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 BARSOUM is currently licensed as a pharmacist.

The patient notification letter was not sent since there was no direct patient involvement.

BARSOUM is not represented by an attorney.

BARSOUM has not responded to the allegations, however on 02-06-13, Investigator TROUPE met with BARSOUM and requested he sign a Voluntary Relinquishment. BARSOUM declined to sign Voluntary Relinquishment.

*New address given to TROUPE by BARSOUM.

Related Case(s):

Investigator/Date: 02-07-13 Victor R. Troupe	Approved By/Date: 2-07-13
Medical Malpractice Investigator, TI-123	Babette S. Agett, TI – 115
	Investigation Supervisor Babette S. Agett

Distribution: HQ/ISU

Received
Investigative Services
FEB 08 2013
DOH/MQA
Tallahassee HQ

Page 1

TABLE OF CONTENTS

***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 #1 is the Case Summary with attached article titled "U.S. Attorney General announces arrest of 9 area doctors, 2 pharmacists on prescription drug charges". Article documents in summary: "...The pharmacist arrested are IHAB S. BARSOUM, 40 of Pasco County... ...The roundup is part of "Pill Nation II," a Drug Enforcement Administration initiative..."

Exhibit #3 is Voluntary Relinquishment of License form of BARSOUM for pharmacist license PS 30945. On Wednesday, February 06, 2013 Investigator TROUPE went to Pinellas County Jail; 14400 49th Street North; Clearwater, Florida and presented BARSOUM with Voluntary Relinquishment of Licensure form. BARSOUM declined to sign Voluntary Relinquishment of licensure form and indicated to this investigator that he will get in contact with his attorney prior to making any decision. BARSOUM indicated to this investigator that his address of record for all correspondence related to this case to be mailed to 17303 Ladera Estates Boulevard; Lutz, Florida 33548. This investigator then handed Voluntary Relinquishment of Licensure form to correctional officier who then presented to BARSOUM.

Exhibit #4 are documents obtained from United States District Court Middle District Of Florida Tampa Division: Documents consist of:

- Superseding Indictment:
  - Count One – "...From an unknown date, but no later than 2007, and continuing through in or about July 2011, in the Middle District of Florida and elsewhere, the defendant, IHAB "STEVE" BARSOUM, did knowingly and intentionally conspire with other persons, both known and unknown to the Grand Jury, to knowingly and intentionally dispense and distribute, and cause to be dispensed and distributed, quantities of Oxycodone, a Schedule II Controlled Substance, not for a legitimate medical purpose and not in the usual course of professional practice..."
  - Count Two – "...On or about January 24, 2011, in the Middle District of Florida, the defendant, IHAB "STEVE" BARSOUM, did knowingly and intentionally act outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance..."
  - Count Three – "...On or about February 2, 2011, in the Middle District of Florida, the defendant, IHAB "STEVE" BARSOUM, did knowingly and intentionally act outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance..."
  - Count Four – "...On or about March 7, 2011, in the Middle District of Florida, the defendant, IHAB "STEVE" BARSOUM, did knowingly and intentionally act outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance..."
  - Count Five – "...On or about April 13, 2011, in the Middle District of Florida, the defendant, IHAB "STEVE" BARSOUM, did knowingly and intentionally act outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance..."
  - Count Six – "...On or about June 23, 2011, in the Middle District of Florida, the defendant, IHAB "STEVE" BARSOUM, did knowingly and intentionally act outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance..."
  - Forfeiture of ...Defendant's DEA Registration Number FT0131386...Defendant's Florida Licensure Number PS30945..."
- Verdict form. Form indicates the verdict of guilty for counts 1-6.

concurrently...Upon release from imprisonment, the defendant shall be on supervised release for a term of thirty-six (36) months as to counts one through six. All such terms to run concurrently (pages 25-30).

Exhibit #5 is Department of Health Investigative Services Community Pharmacy Inspections for dated 09-28-12. Form indicates S & S Pharmacy as currently not operating.

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

DEPARTMENT OF HEALTH,
Petitioner,

v. DOH Case No. 2011-17660

IHAB S. BARSOUM, R.Ph.
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent IHAB S. BARSOUM, R.Ph., license No. PS30945, 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 disciplinary action. Licensing authorities in other states may impose discipline in their jurisdiction based on discipline taken in Florida.

2. Respondent agrees to never reapply for licensure as a pharmacist in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from

EXHIBIT# 3

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. 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 _____ day of _____, 2013.

_____
IHAB S. BARSOUM

STATE OF FLORIDA
COUNTY OF:

Before me, personally appeared Ihab S. Barsoum, 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:

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v.

IHAB "STEVE" BARSOUM

CASE NO. 8:11-CR-548-T-33MAP
21 U.S.C. § 846
21 U.S.C. § 841(a)(1)
21 U.S.C. § 853 (Forfeiture)

SUPERSEDING INDICTMENT

The Grand Jury charges:

COUNT ONE

From an unknown date, but no later than 2007, and continuing through in or about July 2011, in the Middle District of Florida and elsewhere, the defendant,

IHAB "STEVE" BARSOUM,

did knowingly and intentionally conspire with other persons, both known and unknown to the Grand Jury, to knowingly and intentionally dispense and distribute, and cause to be dispensed and distributed, quantities of Oxycodone, a Schedule II Controlled Substance, not for a legitimate medical purpose and not in the usual course of professional practice, contrary to Title 21, United States Code, Sections 841(a)(1) and 841(b)(1)(C).

All in violation of Title 21, United States Code, Section 846.

EXHIBIT#
4

: 00615

COUNT TWO

On or about January 24, 2011, in the Middle District of Florida, the defendant,

IHAB "STEVE" BARSOUM,

did knowingly and intentionally act outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance.

All in violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(1)(C).

COUNT THREE

On or about February 2, 2011, in the Middle District of Florida, the defendant,

IHAB "STEVE" BARSOUM,

did knowingly and intentionally act outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance.

All in violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(1)(C).

COUNT FOUR

On or about March 7, 2011, in the Middle District of Florida, the defendant,

IHAB "STEVE" BARSOUM,

did knowingly and intentionally act outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled

Substance.

All in violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(1)(C).

COUNT FIVE

On or about April 13, 2011, in the Middle District of Florida, the defendant,

IHAB "STEVE" BARSOUM,

did knowingly and intentionally act outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance.

All in violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(1)(C).

COUNT SIX

On or about June 23, 2011, in the Middle District of Florida, the defendant,

IHAB "STEVE" BARSOUM,

did knowingly and intentionally act outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance.

All in violation of Title 21, United States Code, Sections 841(a)(1) and 841(b)(1)(C).

FORFEITURE

1. The allegations contained in Counts One through Six of this Indictment

are hereby realleged and incorporated by reference for the purpose of alleging forfeitures, pursuant to the provisions of Title 21, United States Code, Section 853.

2. From his engagement in any or all of the violations alleged in Counts One through Six of the Indictment, punishable by imprisonment for more than one year, defendant,

IHAB "STEVE" BARSOUM,

shall forfeit to the United States, pursuant to Title 21, United States Code, Sections 853(a)(1) and (2), all of his right, title and interest in:

a. property constituting and derived from any proceeds defendant obtained, directly or indirectly, as a result of such violations; and,

b. property used and intended to be used in any manner or part to commit or to facilitate the commission of such violations.

3. The specific property to be forfeited includes, but is not limited to:

a . Defendant's DEA Registration Number FT0131386

b. 2005 BMW, VIN # WBAEK73495B326752

c. 2008 BMW, VIN # WBANU53538CT13324

d. Defendant's Florida Pharmacist License Number PS30945

4. If any of the property described above as being subject to forfeiture, as a result of any act or omission of the defendant:

a. cannot be located upon the exercise of due diligence;

b. has been transferred, sold to or deposited with a third person;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or,

e. has been commingled with other property which cannot be subdivided without difficulty;

the United States will seek, pursuant to Title 21, United States Code, Section 853(p), forfeiture of any other property of said defendant up to the value of the forfeitable property.

A TRUE BILL,

Foreperson

ROBERT E. O'NEILL
United States Attorney

By: _____
SHAUNA S. HALE
Assistant United States Attorney

By: _____
(For) JOSEPH K. RUDDY
Assistant United States Attorney
Chief, Narcotics Section

FORM OBD-34
APR 1991

No. 8:11-CR-548-T-33MAP

UNITED STATES DISTRICT COURT

Middle District of Florida
Tampa Division

THE UNITED STATES OF AMERICA

vs.

IHAB "STEVE" BARSOUM

SUPERSEDING INDICTMENT

Violations:

21 U.S.C. § 846
21 U.S.C. § 841(a)(1)

A true bill,

Foreperson

Filed in open court this 5th day

of July 2012.

Clerk

Bail $_____

FILED
2012 JUL -5 PM 12:06
CLERK, U.S. DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA, FLORIDA

GPO 863 525

58828

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v. CASE NO. 8:11-CR-548-T-33MAP

IHAB STEVE BARSOUM

_____/

VERDICT FORM

1. **Count One of the Superseding Indictment**

As to the offense of conspiracy to knowingly and intentionally dispense and distribute, and cause to be dispensed and distributed, quantities of Oxycodone, a Schedule II Controlled Substance, not for a legitimate medical purpose and not in the usual course of professional practice, in violation of 21 U.S.C. § 846,

We, the Jury, find the defendant, **Ihab "Steve" Barsoum:**

Guilty Y Not Guilty _____

2. **Count Two of the Superseding Indictment**

As to the offense of knowingly and intentionally acting outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance, in violation of 21 U.S.C. § 841(a)(1),

We, the Jury, find the defendant, **Ihab "Steve" Barsoum**:

Guilty X Not Guilty _____

3. **Count Three of the Superseding Indictment**

As to the offense of knowingly and intentionally acting outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance, in violation of 21 U.S.C. § 841(a)(1),

We, the Jury, find the defendant, **Ihab "Steve" Barsoum**:

Guilty X Not Guilty _____

4. **Count Four of the Superseding Indictment**

As to the offense of knowingly and intentionally acting outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance, in violation of 21 U.S.C. § 841(a)(1),

We, the Jury, find the defendant, **Ihab "Steve" Barsoum**:

Guilty X Not Guilty _____

5. **Count Five of the Superseding Indictment**

As to the offense of knowingly and intentionally acting outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance, in violation of 21 U.S.C. § 841(a)(1),

We, the Jury, find the defendant, **Ihab "Steve" Barsoum**:

Guilty X Not Guilty _____

6. **Count Six of the Superseding Indictment**

As to the offense of knowingly and intentionally acting outside the course of professional practice by distributing, and causing to be distributed, Oxycodone, a Schedule II Controlled Substance, in violation of 21 U.S.C. § 841(a)(1),

We, the Jury, find the defendant, **Ihab "Steve" Barsoum:**

Guilty X Not Guilty _____

SO SAY WE ALL, this 21st day of August 2012.

FOREPERSON

AO 245B (Rev 06/05) Sheet 1 - Judgment in a Criminal Case

UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

JUDGMENT IN A CRIMINAL CASE

CASE NUMBER: 8:11-cr-548-T-33MAP
USM NUMBER: 55623-018

vs.

IHAB "STEVE" BARSOUM

Defendant's Attorney: Todd Foster. Ret.

THE DEFENDANT:

X was found guilty on count(s) ONE through SIX of the Superseding Indictment after a plea of not guilty.

TITLE & SECTION	NATURE OF OFFENSE	OFFENSE ENDED	COUNT
21 U.S.C. §§841(a)(1), 846 and 841(b)(1)(C)	Conspiracy to Dispense and Distribute Oxycodone Not for a Legitimate Professional Practice	July 2011	ONE
21 U.S.C. §§841(a)(1) and 841(B)(1)(C)	Distribution of Oxycodone Outside the Course of Professional Practice	January 24, 2011	TWO
21 U.S.C. §§841(a)(1) and 841(B)(1)(C)	Distribution of Oxycodone Outside the Course of Professional Practice	February 2, 2011	THREE
21 U.S.C. §§841(a)(1) and 841(B)(1)(C)	Distribution of Oxycodone Outside the Course of Professional Practice	March 7, 2011	FOUR
21 U.S.C. §§841(a)(1) and 841(B)(1)(C)	Distribution of Oxycodone Outside the Course of Professional Practice	April 13, 2011	FIVE
21 U.S.C. §§841(a)(1) and 841(B)(1)(C)	Distribution of Oxycodone Outside the Course of Professional Practice	June 23, 2011	SIX

The defendant is sentenced as provided in pages 2 through 6 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

Continued on next page

IT IS FURTHER ORDERED that the defendant must 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 must notify the court and United States Attorney of any material change in economic circumstances.

Date of Imposition of Sentence: February 4, 2013

VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE

DATE: February 5, 2013

AO 245B (Rev 06/05) Sheet 2 - Imprisonment (Judgment in a Criminal Case)

Defendant: IHAB "STEVE" BARSOUM Judgment - Page 3 of 6
Case No.: 8:11-cr-548-T-33MAP

IMPRISONMENT

The defendant is hereby committed to the custody of the United States Bureau of Prisons to be imprisoned for a term of **TWO HUNDRED FOUR (204) MONTHS** as to Counts ONE through SIX. All such terms to run concurrently.

_X_ The Court makes the following ***recommendations*** to the Bureau of Prisons:

1) Confinement at FCI Coleman LOW or another LOW facility in Florida.

_X_ The defendant is remanded to the custody of the United States Marshal.
__ The defendant shall surrender to the United States Marshal for this district.

__ at __ a.m./p.m. on __.
__ as notified by the United States Marshal.

__ The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons.

__ before 2 p.m. on __.
__ as notified by the United States Marshal.
__ as notified by the Probation or Pretrial Services Office.

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 United States Marshal

SUPERVISED RELEASE

Upon release from imprisonment, the defendant shall be on supervised release for a term of **THIRTY-SIX (36) MONTHS** as to Counts ONE through SIX. All such terms to run concurrently.

The defendant must report to the probation office in the district to which the defendant is released within 72 hours of release from the custody of the Bureau of Prisons.

The defendant shall not commit another federal, state, or local crime. Based on the probation officer's determination that additional drug urinalysis is necessary, the Court authorizes random drug testing not to exceed 104 tests per year. The defendant shall not illegally possess a controlled substance. The defendant shall refrain from any unlawful use of a controlled substance.

The defendant shall submit to one drug test within 15 days of release from imprisonment and at least two periodic drug tests thereafter, as determined by the court.

X The mandatory drug testing provisions of the Violent Crime Control Act are imposed. The court orders the defendant to submit to random drug testing not to exceed 104 tests per year.

X The defendant shall not possess a firearm, destructive device, or any other dangerous weapon.

X The defendant shall cooperate in the collection of DNA as directed by the probation officer.

If this judgment imposes a fine or restitution it is a condition of supervised release that the defendant pay in accordance with the Schedule of Payments sheet of this judgment.

The defendant must comply with the standard conditions that have been adopted by this court as well as with any 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 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 of the probation officer;

11) the defendant shall notify the probation officer within seventy-two 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; and

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.

AO 245B (Rev 06/05) Sheet 5 - Criminal Monetary Penalties (Judgment in a Criminal Case)

Defendant: IHAB "STEVE" BARSOUM
Case No.: 8:11-cr-548-T-33MAP

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	Fine	Total Restitution
Totals:	$600.00	Waived	N/A

___ The determination of restitution is deferred until ____. An *Amended Judgment in a Criminal Case* (AO 245C) will be entered after such determination.

___ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. 3664(i), all non-federal victims must be paid before the United States.

Name of Payee	Total Loss*	Restitution Ordered	Priority or Percentage
Totals:	$___	$___	

_ Restitution amount ordered pursuant to plea agreement $ _____.

_ The defendant must pay interest on a fine or restitution of more than $2,500, unless the restitution or fine 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 Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

_ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

  _ the interest requirement is waived for the ___ fine ___ restitution.

  _ the interest requirement for the ___ fine ___ restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for the offenses committed on or after September 13, 1994, but before April 23, 1996.

Defendant: IHAB "STEVE" BARSOUM
Case No.: 8:11-cr-548-T-33MAP

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties are due as follows:

A. X Lump sum payment of $600.00 due immediately, balance due

___ not later than _____, or

___ in accordance ___ C, ___ D, ___ E or ___ F below; or

B. ___ Payment to begin immediately (may be combined with ___ C, ___ D, or ___ F below); or

C. ___ Payment in equal _____ (e.g., weekly, monthly, quarterly) installments of $ _____ over a period of _____ (e.g., months or years), to commence _____ days (e.g., 30 or 60 days) after the date of this judgment; or

D. ___ Payment in equal _____(e.g., weekly, monthly, quarterly) installments of $ _____ over a period of _____, (e.g., months or years) to commence _____ (e.g. 30 or 60 days) after release from imprisonment to a term of supervision; or

E. ___ Payment during the term of supervised release will commence within ___ (e.g., 30 or 60 days) after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time, or

F. ___ Special instructions regarding the payment of criminal monetary penalties:

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

_ Joint and Several

Defendant and Co-Defendant Names and Case Numbers (including defendant number), Total Amount, Joint and Several Amount, and corresponding payee, if appropriate:

_ The defendant shall pay the cost of prosecution.

_ The defendant shall pay the following court cost(s):

X The defendant shall forfeit the defendant's interest in the following property to the United States: The Court Orders that the defendant forfeit to the United States immediately and voluntarily any and all assets previously identified in the Indictment, that are subject to forfeiture. The specific property to be forfeited includes, but is not limited to: (a) defendant's DEA Registration Number FT0131386; (b) 2005 BMW, VIN# WBAEK73495B326752; and (c) 2008 BMW, VIN# WBANU53538CT13324.

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH
WWW.DOH.STATE.FL.US

File # 14936
Insp # 104676

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
S & S PHARMACY INC		22447		9/27/2012
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
PLATINUM PHARMACY & COMPOUND				
STREET ADDRESS		TELEPHONE #	EXT.	IHAB S. BARSOUM
14937 BRUCE B. DOWNS BLVD # 204		(813) 866-5000		
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
TAMPA	39	33613		30945

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.]				☒
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.]	☒			
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.]	☒			
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.] [64B16-28.116, 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: The pharmacy is not open. There is brown paper over all of the windows and a sign stating "pharmacy department closed" is on the door. There is a sign on the door which has the name of the pharmacy, which has the hours of operation scratched off. The telephone number listed on the sign, (813) 866-5000, is a non-working number. There is no sign or information posted which tells patients where they can obtain their prescription records.

According to an employee next to the pharmacy location, the pharmacist was arrested and on 09-26-12, people came in and moved everything out of the pharmacy, including taking all of the shelves and cabinets out.

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. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT N/A

N/A
Institutional Representative

09-28-2012
Date

Investigator/Sr. Pharmacist Signature

ID ti122

EXHIBIT# 5

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
INVESTIGATIVE SERVICES
COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH
WWW.DOH.STATE.FL.US

File # 14936
Insp # 101242

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	DATE OF INSPECTION
S & S PHARMACY INC	22447	11/24/2010
DOING BUSINESS AS	DEA NUMBER	PRESCRIPTION DEPARTMENT MANAGER
TRINITY PHARMACY	FT0131386	
STREET ADDRESS	TELEPHONE # / EXT.	IHAB S. BARSOUM
9945 TRINITY BLVD	813-766-9955	
CITY / COUNTY	STATE/ZIP	PRESCRIPTION DEPARTMENT MANAGER LICENSE #
NEW PORT RICHEY / 61	34655	30945

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.]		☒	☐
2	Board of Pharmacy notified in writing of current Rx department manager. [465.018.F.S.]		☒	☐
3	Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]		☒	☐
4	Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]		☒	☐
5	Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]		☒	☐
6	Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]		☒	☐
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.]		☒	☐
8	Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]		☒	☐
9	Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.		☒	☐
10	Generic drug sign displayed. [465.025(7),F.S.]		☒	☐
11	Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]		☒	☐
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.]*		☒	☐
13	Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]		☒	☐
14	Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]		☒	☐
15	Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]		☒	☐
16	Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]		☒	☐
17	Prescription department has drug refrigeration storage. [64B16-28.104.F.A.C.]		☒	☐
18	Prescription department clean and safe. [64B16-28.105,F.A.C.]		☒	☐
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.]		☒	☐
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.]		☒	☐
21	Medication property labeled [64B16-27.101,F.A.C.]		☒	☐
22	All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]		☒	☐
23	CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]		☒	☐
24	Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]		☒	☐
25	"Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]		☒	☐

	SATISFACTORY	N/A	YES	NO
26	All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2.F.A.C.]		☒	☐
27	Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]		☒	☐
28	Complete pharmacy prescription records. [64B16-28.140,F.A.C.]		☒	☐
29	Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]		☒	☐
30	Controlled substance records readily retrievable. [893.07,F.S.]		☒	☐
31	Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]		☒	☐
32	Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]		☒	☐
33	Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]		☒	☐
34	Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]		☒	☐
35	All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]		☒	☐
36	Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]		☒	☐
37	Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]		☒	☐
38	Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]		☒	☐
39	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]		☒	☐
40	DEA 222 order forms properly completed. [893.07(2),F.S.]		☒	☐
41	Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07.F.S] [64B16-28.140,F.A.C.]*		☒	☐
42	Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b).F.S.]		☒	☐
43	Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]		☒	☐
44	Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *		☒	☐
45	Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *		☒	☐
46	Compounding records properly maintained [64B16-28.140(4),F.A.C.] *		☒	☐
47	Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *		☒	☐

Questions with (*) may be answered n/a (not applicable).

Remarks: All questions are N/A.
This pharmacy will be changing locations to 14937 Bruce B Downs Blvd. Tampa FL 33613.

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 CHANGE OF LOCATION

N/A
Institutional Representative

11-24-2010
Date

N/A
Investigator/Sr. Pharmacist Signature

ID ti117

INV 359 Revised 01/07 Replaces 12/02

2110 First Street, Suite 3-137
Fort Myers, Florida 33901
239/461-2200
239/461-2219 (fax)

207 NW 2nd Street
Room 118
Ocala, Florida 34475
352/629-0053
352/671-6743 (Fax)

U.S. Department of Justice
United States Attorney
Middle District of Florida

Main Office
400 North Tampa Street, Suite 3200
Tampa, Florida 33602
813/274-6000
813/274-6358 (Fax)

300 N. Hogan Street, Room 700
Jacksonville, Florida 32202
904/301-6300
904/301-6310 (Fax)

501 West Church Street, Suite 300
Orlando, Florida 32805
407/648-7500
407/648-7643 (Fax)

Reply to: **Tampa**

October 31, 2012

Florida Department of Health
Attn: Office of the General Counsel
4052 Bald Cypress Way, Bin #C-65
Tallahassee, Florida 32399

Re: Pharmacist License No. PS30945
United States v. Ihab "Steve" Barsoum
Case No. 8:11-cr-548-T-33MAP

Dear Sir/Maam:

On October 31, 2012, the Honorable Virginia M. Hernandez Covington, United States District Judge, Middle District of Florida, Tampa Division, entered the attached Preliminary Order of Forfeiture divesting defendant Ihab S. Barsoum, of his right, title, and interest in his Florida pharmacist license # PS0945. On August 21, 2012, a jury found Ihab S. Barsoum, guilty on Counts One through Six of his Superseding Indictment. Barsoum's sentencing is currently scheduled for November 12, 2012.

Should you have any questions regarding the foregoing, please call me at (813) 274-6036.

Sincerely,

ROBERT E. O'NEILL
United States Attorney

By: for
JAMES A. MUENCH
Assistant United States Attorney

Enclosures

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA

v. Case No. 8:11-cr-548-T-33MAP

IHAB "STEVE" BARSOUM

PRELIMINARY ORDER OF FORFEITURE

THIS CAUSE comes before the Court upon the United States' Motion for a Preliminary Order of Forfeiture, pursuant to 21 U.S.C. § 853 and Federal Rule of Criminal Procedure 32.2(b)(2), which, at sentencing, shall become a final order of forfeiture as to defendant Ihab Steve Barsoum's right, title, and interest in his Pharmacist License Number PS30945.

Following the Jury's Verdict finding the defendant guilty of the Oxycodone violations charged in Counts One through Six of the Superseding Indictment, the Court found, by a preponderance of the evidence, that the defendant's pharmacist license shall be forfeited to the United States. Thus, the United States has established the requisite *nexus* between the property and the offenses of conviction.

Accordingly, it is hereby

ORDERED that for good cause shown, said motion of the United States is GRANTED.

It is FURTHER ORDERED that, pursuant to the provisions of 21 U.S.C. § 853(a) and Rule 32.2(b)(2), Federal Rules of Criminal Procedure, all right, title

and interest of defendant Ihab Steve Barsoum in his pharmacist license number PS30945 are hereby FORFEITED to the United States of America for disposition according to law.

The Court retains jurisdiction to entertain any third party claims that may be asserted in these proceedings, and to enter any further order necessary for the forfeiture and disposition of such property.

ORDERED in Tampa, Florida, on October 31, 2012.

Virginia M. Hernandez Covington

VIRGINIA M. HERNANDEZ COVINGTON
UNITED STATES DISTRICT JUDGE

U.S. Department of Justice
United States Attorneys Office
Middle District of Florida
400 N. Tampa Street, Suite 3200
Tampa, Florida 33602

Official Business

TAMPA FL 335
SAINT PETERSBURG FL
31 OCT 2012 PM 9 L

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10/31/2012

Florida Department of Health
Office of the General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265

32399326599

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201300708

GOOD SIGHT PHARMACY, INC,
RESPONDENT.

NOTICE

TO: GOOD SIGHT PHARMACY, INC
5554 SW 8TH STREET
CORAL GABLES, FL 33134

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850)-236-6000.

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 9:00a.m. ;therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Vernisha Foster, Assistant General Counsel
RE: Determination of Waiver
SUBJECT: DOH v. Good Sight Pharmacy, Inc
DOH Case Number 2013-00708
DATE: August 14, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Good Sight Pharmacy, Inc
Subject's Address of Record:	5554 SW 8th Street Coral Gables, Florida 33134
Enforcement Address:	5554 SW 8th Street Coral Gables, Florida 33134
Subject's License No:	25104 **Rank:** PH
Licensure File No:	17932
Initial Licensure Date:	12/3/2010
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Section 465.023(1)(c), F.S.(2012) through a violation of Rule 64B16-28.202(3), F.A.C.
Prior Discipline:	None
Probable Cause Panel:	March 28, 2013 Gavin Meshad and Michele Weizer
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
Exhibit A - Affidavit of fees and costs expended
Exhibit 1 – Complaint Cost Summary
Exhibit 2 – Itemized Cost by Complaint
Supplemental Report dated 06/17/2013
PCP Memo
Final Investigative Report
Exhibits 1-2

Disciplinary Guidelines: $1,500 fine up to revocation

PRELIMINARY CASE REMARKS:

On or about May 23, 2012, a Department inspector attempted to conduct an inspection at Respondent's address of record. Upon arriving to Respondent's address of record, it was discovered that Capital Pharmacy Discount was operating at that address. Respondent had not reported a closure.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-00708**

GOOD SIGHT PHARMACY, 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 May 28, 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: April 13, 2013 (7196 9111 5773 2310). 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 June 17, 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 July 1, 2013 and appearing consecutively on July 8, 15, 22, 2013. Petitioner received proof of publication on July 26, 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 and 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.

Respectfully Submitted,

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, FL 32399-3265
Florida Bar #0092743
(850) 245-4444 telephone
(850) 245-4683 facsimile
Email:vernisha_foster@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 28 day of August, 2013, to: Good Sight Pharmacy, Inc., 5554 Southwest 8th Street, Coral Gables, Florida 33134.

Vernisha Foster
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. CASE NO. 2013-00708

GOOD SIGHT PHARMACY, INC.,

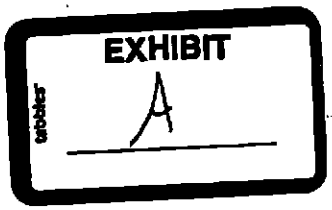
RESPONDENT.

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, Good Sight 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 community pharmacy within the state of Florida, having been issued permit number PH 25104.



3. Respondent's address of record is 5554 Southwest 8th Street, Coral Gables, Florida 33134.

4. On or about May 23, 2012, a Department inspector attempted to conduct an inspection of Respondent at 5554 Southwest 8th Street, Coral Gables, Florida 33134.

5. On or about May 23, 2012, the Department's inspector found Capitol Pharmacy Discount operating at Respondent's address of record.

6. As of January 10, 2013, Respondent had not reported a closure of the pharmacy.

7. 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.

8. 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, and 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.

9. Respondent failed to do one or more of the following:

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.

10. Section 465.023(1)(c), Florida Statutes (2011), 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 64B16-28.202(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, and 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.

12. Respondent failed to follow the pharmacy closure requirements as set forth in Rule 64B16-28.202(3), Florida Administrative Code, by failing to do one or more of the following:

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.

13. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2011), by violating 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, and 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.

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

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 MAR 28 2013

/VF
PCP: March 28, 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.

CERTIFIED MAIL™

FLORIDA DEPARTMENT OF HEALTH

Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, Florida 32399-3265

7196 9008 9111 5773 2310

UNITED STATES POSTAGE
PRIORITY MAIL
02 1A $ 07.17°
0004371978 APR 09 2013
MAILED FROM ZIPCODE 32301

NIXIE 331341407-1N 05/29/13

RETURN TO SENDER
UNABLE TO FORWARD
UNABLE TO FORWARD
RETURN TO SENDER

2013 JUN -4 PM 12:42

EXHIBIT 8

7196 9008 9111 5773 2310

TO:

STIP PACK
Pauline/Foster
Date Mailed 4/9/2013
2013-00327

SENDER:

REFERENCE:

Good Sight Pharmacy
5554 Southwest 8th Street
Coral Gables, Florida 33134

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 5773 2310

3. Service Type **CERTIFIED MAIL™**

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Good Sight Pharmacy
5554 Southwest 8th Street
Coral Gables, Florida 33134

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? ☐ Yes
If YES, enter delivery address below: ☐ No

Reference Information

STIP PACK 2013-00327
Pauline/Foster

PS Form 3811, January 2005 Domestic Return Receipt

Track & Confirm

GET EMAIL UPDATES PRINT DETAILS

YOUR LABEL NUMBER	SERVICE	STATUS OF YOUR ITEM	DATE & TIME	LOCATION	FEATURES
71969008911157732310		Notice Left	April 13, 2013, 11:26 am	MIAMI, FL 33134	Certified Mail™
		Arrival at Unit	April 13, 2013, 7:47 am	MIAMI, FL 33134	
		Depart USPS Sort Facility	April 13, 2013	OPA LOCKA, FL 33054	
		Processed through USPS Sort Facility	April 12, 2013, 7:02 pm	OPA LOCKA, FL 33054	
		Depart USPS Sort Facility	April 12, 2013	OPA LOCKA, FL 33054	
		Processed through USPS Sort Facility	April 11, 2013, 3:46 pm	OPA LOCKA, FL 33054	
		Depart USPS Sort Facility	April 9, 2013	TALLAHASSEE, FL 32301	
		Processed through USPS Sort Facility	April 9, 2013, 10:55 pm	TALLAHASSEE, FL 32301	

Check on Another Item

What's your label (or receipt) number?

Find

FLORIDA DEPARTMENT OF
HEALTH

Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, Florida 32399-3265

PRACTITIONER REGULATION
LEGAL

2013 MAY 10 PM 1:42

CERTIFIED MAIL

7196 9008 9111 5773 2327

UNITED STATES POSTAGE
PITNEY BOWES
02 1A $ 07.17⁰
0004371978 APR 09 2013
MAILED FROM ZIPCODE 32301

Vernisha

RETURN TO SENDER
UNCLAIMED

Jexy Perez
9551 Fountainbleau Boulevard
Apartment 312
Miami, Florida 33172

N/F
4/19/13

Track & Confirm

GET EMAIL UPDATES PRINT DETAILS

YOUR LABEL NUMBER	SERVICE	STATUS OF YOUR ITEM	DATE & TIME	LOCATION	FEATURES
71969008911157732327		Delivered	May 10, 2013, 11:42 am	TALLAHASSEE, FL 32399	Certified Mail™
		Available for Pickup	May 9, 2013, 8:11 am	TALLAHASSEE, FL 32399	
		Depart USPS Sort Facility	May 7, 2013	TALLAHASSEE, FL 32301	
		Processed through USPS Sort Facility	May 7, 2013, 7:29 pm	TALLAHASSEE, FL 32301	
		Unclaimed	April 27, 2013, 3:34 pm	MIAMI, FL 33172	
		Notice Left	April 13, 2013, 3:38 pm	MIAMI, FL 33172	
		Processed through USPS Sort Facility	April 13, 2013, 7:31 am	OPA LOCKA, FL 33054	
		Depart USPS Sort Facility	April 13, 2013	OPA LOCKA, FL 33054	
		Processed through USPS Sort Facility	April 12, 2013, 4:55 pm	OPA LOCKA, FL 33054	
		Depart USPS Sort Facility	April 12, 2013	OPA LOCKA, FL 33054	
		Processed through USPS Sort Facility	April 11, 2013, 3:46 pm	OPA LOCKA, FL 33054	
		Depart USPS Sort Facility	April 9, 2013	TALLAHASSEE, FL 32301	
		Processed through USPS Sort Facility	April 9, 2013, 10:55 pm	TALLAHASSEE, FL 32301	

Check on Another Item

What's your label (or receipt) number?

Find

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

DEPARTMENT OF HEALTH
Petitioner

vs

Case No. 201300708

GOOD SIGHT PHARMACY INC
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 05/20/13and 06/10/13 AND 06/17/13 Affiant made a diligent effort to locate Respondent, to serve ESO/ERO and related papers.

3) Check applicable answer below:

___Affiant made personal service on Respondent at Respondent's usual place of abode

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) Accurint (d) Division of Drivers, Licenses; _____

Sunday Adesina
Affiant

State Of Florida County Of MIAMI-DADE

Before me, personally appeared Sunday Adesina whose identity is known to me by Personal knowledge (type of identification) and who, acknowledges that his/her signature appears above.

Swom to or affirmed by Affiant before me this 17th day of June 20 13

Notary Public-State of Florida

Jeneice Mayers
Type or Print Name

My Commission Expires

JENEICE MAYERS
Commission # EE 018845
Expires August 19, 2014
Bonded Thru Troy Fain Insurance 800-385-7019

EXHIBIT
tabbies
C

5

A FREE AND INDEPENDENT NEW ER VOICE

COMMUNITY NEWSPAPERS

PUBLISHED MONDAY
MIAMI, MIAMI-DADE, FLORIDA

RECEIVED-LEGAL

13 JUL 26 AM 8:04

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
GOOD SIGHT PHARMACY, INC.
CASE NO. 2013-00708

in the XXXXX Court, was published in said newspaper in the issue of

07/01, 07/08, 07/15, 07/22/2013

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 Georgia K. Tait

Sworn to and subscribed before me this

22ND day of JULY 2013.

JESUS TOLEDO

(Print or type or stamp commissioned name of Notary Public)

JESUS C. TOLEDO
Notary Public - State of Florida
My Comm. Expires Apr 10, 2017
Commission # EE 876555
Bonded Through National Notary Assn.

(SEAL)

My Commission Expires: _____

Personally known X

NOTICE OF ACTION

BEFORE THE BOARD OF PHARMACY

IN RE: The license to practice pharmacy of

Good Sight Pharmacy, Inc.
6554 Southwest 8th Street
Coral Gables, Florida 33134
&
9951 Fontainebleau Blvd.
Apartment 312
Miami, Florida 33172

CASE NO.: 2013-00708
LICENSE NO.: PH 25104

The Department of Health has filed an Administrative Complaint against you, a copy of which may be obtained by contacting, Vernisha Foster, 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 March 27, 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) 245-4444, 1-800-955-8771 (TDD) or 1-800-955-8770(V), via Florida Relay Service.

07/01, 07/08, 07/15, 07/22/2013

Community Newspapers
6796 S.W. 62nd Avenue
South Miami, Florida 33143
305-669-7355 Ext. 228 • Fax: 305-662-6980

EXHIBIT
tabbies
D

I, Mark Whitten, hereby certify in my official capacity as custodian for the Board of Pharmacy licensure files that the Board of Pharmacy as of August 16, 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **Good Sight Pharmacy, INC., CASE NUMBER 2013-00708** which would affect the Subject's substantial interests or rights.

Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Mark Whitten, whose identity is known to me personal (type of identification) and who, under, oath, acknowledges that his/her signature appears above.

Sworn to and subscribed this 16 day of August, 2013.

HELAINE ROBISON
MY COMMISSION # EE 138625
EXPIRES: November 17, 2015
Bonded Thru Notary Public Underwriters

Notary Public

EXHIBIT
number 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, Good Sight Pharmacy, INC., Case Number 2013-00708**, 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 14th day of August, 2013.

Angela Barton

Notary Public

My Commission Expires:

ANGELA BARTON
NOTARY PUBLIC - STATE OF FLORIDA
COMMISSION # DD922154
EXPIRES 9/1/2013
BONDED THRU 1-888-NOTARY

EXHIBIT
tabbies
F

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-00708**

GOOD SIGHT PHARMACY, INC.,

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 $703.11, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	Costs
Complaint:	0.40	$10.75
Investigation:	7.60	$458.38
Legal:	2.20	$233.98
Compliance:	0.00	0.00
Sub Total:	10.20	$703.11
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$703.11

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $479.13 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 $479.13 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 $479.13.

DATED this 27 day of August, 2013.

Respectfully Submitted,

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, FL 32399-3265
Florida Bar # 0092743
(850) 245-4444 telephone
(850) 245-4683 facsimile
Email:vernisha_foster@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 28 day of August, 2013, to: Good Sight Pharmacy, Inc., 5554 Southwest 8th Street, Coral Gables, Florida 33134.

Vernisha Foster
Assistant General Counsel

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 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 21 day of August, 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

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) **2013-00708** (Department of Health v. **GOOD SIGHT PHARMACY, INC., PHARMACY**) are **SEVEN HUNDRED THREE DOLLARS AND ELEVEN CENTS ($703.11).**

6) The costs for DOH case numbers **2013-00708** (Department of Health v. **GOOD SIGHT PHARMACY, INC., PHARMACY**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case numbers **2013-00708** (Department of Health v. **GOOD SIGHT PHARMACY, INC., 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 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 21 day of August, 2013, by Shane Walters, who is personally known to me.

Notary Signature

Antoinette Carter

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

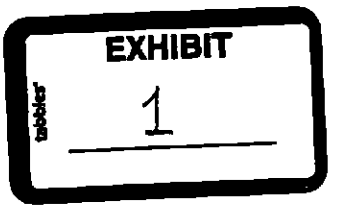
ANTOINETTE F. CARTER
MY COMMISSION EXPIRES
September 26, 2015
#EE 132192
Bonded thru
Troy Fain Insurance
NOTARY PUBLIC, STATE OF FLORIDA

Complaint Cost Summary

Complaint Number: 201300708

Subject's Name: GOOD SIGHT PHARMACY, INC

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.40	$10.75
Investigation:	7.60	$458.38
Legal:	2.20	$233.98
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	10.20	$703.11
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$703.11



Division of
Medical Quality Assurance

MQA

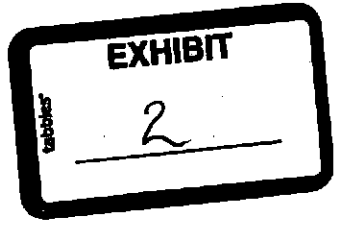
*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201300708

Report Date 08/20/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA132	0.10	$54.90	$5.49	01/11/2013	25	REVIEW CASE FILE
HA166	0.30	$17.53	$5.26	02/18/2013	25	REVIEW CASE FILE
HA166	0.60	$17.53	$10.52	02/18/2013	76	REPORT PREPARATION
Sub Total	**1.00**		**$21.27**			
INVESTIGATIVE SERVICES UNIT						
MI211	1.40	$63.98	$89.57	05/15/2013	6	SUPPLEMENTAL INVESTIGATION
MI28	0.40	$63.98	$25.59	05/15/2013	4	ROUTINE INVESTIGATIVE WORK
MI211	0.50	$63.98	$31.99	05/16/2013	6	SUPPLEMENTAL INVESTIGATION
MI211	0.60	$63.98	$38.39	05/20/2013	6	SUPPLEMENTAL INVESTIGATION
MI211	1.50	$63.98	$95.97	06/10/2013	58	TRAVEL TIME
MI211	1.00	$63.98	$63.98	06/10/2013	6	SUPPLEMENTAL INVESTIGATION
MI211	1.60	$63.98	$102.37	06/17/2013	6	SUPPLEMENTAL INVESTIGATION
Sub Total	**7.00**		**$447.86**			
PROSECUTION SERVICES UNIT						
HLL92A	0.20	$106.35	$21.27	03/05/2013	25	REVIEW CASE FILE
HLL92A	0.40	$106.35	$42.54	03/05/2013	46	LEGAL RESEARCH
HLL92A	0.60	$106.35	$63.81	03/05/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL92A	0.20	$106.35	$21.27	03/05/2013	29	REVIEW ADMINISTRATIVE COMPLAINT
HLL92A	0.10	$106.35	$10.64	03/05/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL92A	0.70	$106.35	$74.45	04/01/2013	79	STIPULATION
Sub Total	**2.20**		**$233.98**			



*** C O N F I D E N T I A L ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201300708

Report Date 08/20/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
Total Cost			**$703.11**			

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 08/20/2013

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: 05/13/13	Case Number: PH-201300708

Subject: **GOOD SIGHT PHARMACY INC** 5554 SW 8TH STREET MIAMI FL 33134 305-767-8631	Source: **DEPARTMENT OF HEALTH** Prosecution Service Unit 4052 Bald Cypress Way Tallahassee, Florida 32399

Prefix: 2205	License #:25104	Profession: Pharmacy	Board: Pharmacy	Report Date:06/17/13

Period of Investigation:05/13/13-06/17/13	Type of Report: Supplemental 1

Alleged Violation: See final report

Synopsis: This supplemental report is predicated upon the receipt of request to hand serve Administrative complaint, election of right and stipulation received from attorney PAULINE BENNETT on behalf of attorney VERNISHA FOSTER of prosecution service unit to the subject and or registered agent of GOOD SIGHT PHARMACY INC.

S1. Copy Of Florida Department Of State Division Of Corporations print out showing registration agent for GOOD SIGHT PHARMACY INC.....pg 2-4

S2. Copy of due diligent search completed by this investigator.....pg.5

Investigators Note:
This investigator presented to the address of record and possible contacts obtained through DOH database to serve the Administrative complaint on 06/10/13 but the subject could not be reached either through the address of record or telephones numbers .

RECEIVED-LEGAL
13 JUN 20 AM 8:18

Investigator/Date: 06/17/12 **Sunday Adesina Investigator MI-211** **Medical Quality Assurance Investigator**	**Approved By/Date 06/17/13** **Caridad Rodriguez** **Investigator Supervisor**

Received
Investigative Services
JUN 19 2013

Distribution: HQ/ISU

DOH/MQA
Tallahassee HQ

P11000078765

06/07/2011 04:25 #0765 P.001/003

Florida Department of State
Division of Corporations
Electronic Filing Cover Sheet

Note: Please print this page and use it as a cover sheet. Type the fax audit number (shown below) on the top and bottom of all pages of the document.

(((H11000190932 3)))

H11000190932ABC

Note: DO NOT hit the REFRESH/RELOAD button on your browser from this page. Doing so will generate another cover sheet.

RECEIVED
11 JUL 27 PM 2:59
SECRETARY OF STATE
TALLAHASSEE, FLORIDA

To:
Division of Corporations
Fax Number : (850)617-6381

From:
Account Name : LAZARUS CORPORATE FILING SERVICE, INC.
Account Number : I20000000019
Phone : (305)552-5973
Fax Number : (305)220-1440

Enter the email address for this business entity to be used for future annual report mailings. Enter only one email address please.

Email Address: _____

FILED
11 JUL 27 AM 9:23
SECRETARY OF STATE
DIVISION OF CORPORATIONS

FLORIDA PROFIT/NON PROFIT CORPORATION
D&D GENERAL INVESTMENTS, INC.

Certificate of Status	0
Certified Copy	1
Page Count	03
Estimated Charge	$78.75

Electronic Filing Menu Corporate Filing Menu Help

PS 7/28/11

1 of 1

7/27/2011 2:55 PM

S. N

SECRETARY OF STATE
DIVISION OF CORPORATIONS

H11000190932 11 JUL 27 AM 9:23

ARTICLES OF INCORPORATION

The undersigned Incorporator(s), for the purpose of forming a corporation under the Florida Business Corporation Act, hereby adopt(s) the following Articles of Incorporation.

ARTICLE I – NAME

The **name** of the corporation shall be:

D&D GENERAL INVESTMENTS, INC

ARTICLE II – PRINCIPAL OFFICE

The principal place of **business** and **mailing** of this corporation shall be:

9551 Fontainebleau Blvd #318.
Miami, FL 33172.

ARTICLE III – SHARES

The number of shares of stock that this corporation is authorized to have outstanding at any one time is:

100.

ARTICLES IV - INITIAL REGISTERED AGENT AND STREET ADDRESS

The **name** and **address** of the initial registered agent is:

Jely Perez.
9551 Fontainebleau Blvd #318.
Miami, FL 33172.

H11000190932

3

H11000190932

ARTICLE V – INCORPORATOR

The name and address of the incorporator to these Articles of Incorporation is:

Jeny Perez.
9551 Fontainebleau Blvd # 318.
Miami, FL 33172.

The undersigned incorporator has executed these Articles of Incorporation this _____ day of _____ 20_____.

_____
Signature

ARTICLE VI- DIRECTOR (S)

The name(s) and street address (es) of the director(s) to these Articles of Incorporation is (are):

Jeny Perez (P)

CERTIFICATE OF DESIGNATION OF REGISTERED AGENT /REGISTERED OFFICE

Having been named as Registered Agent and to accept service of process for the above stated corporation at place designated in this certificate, 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 related to the proper and complete performance of my duties, and I am familiar with and accept the obligations of my position as Registered Agent.

_____
Registered Agent Signature

H11000190932

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

DEPARTMENT OF HEALTH
Petitioner

vs

Case No. 201300708

GOOD SIGHT PHARMACY INC
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 05/20/13and 06/10/13 AND 06/17/13 Affiant made a diligent effort to locate Respondent, to serve ESO/ERO and related papers.

3) Check applicable answer below:

__Affiant made personal service on Respondent at Respondent's usual place of abode

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) Accurint (d) Division of Drivers, Licenses; _____

Sunday Adesina
Affiant

State Of Florida County Of MIAMI-DADE

Before me, personally appeared Sunday Adesina 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 17th day of June 20 13

Notary Public-State of Florida

Jeneice Mayers
Type or Print Name

My Commission Expires

JENEICE MAYERS
Commission # EE 018845
Expires August 19, 2014
Bonded Thru Troy Fain Insurance 800-385-7019

VF

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Good Sight Pharmacy, Inc.**
Case Number: 2013-00708

MEMBERS: **Gavin Meshad and Michele Weizer**

DATE OF PCP: **March 28, 2013** **AGENDA ITEM: A-17**

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 (2011), 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** _____

Michele Weizer PharmD, BCPS 3/28/13
Chair, Probable Cause Panel Date
Board of Pharmacy

FLORIDA DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office:	Date of Complaint:	Case Number:
CONSUMER SERVICES	January 10, 2013	PH 2013-00708

Subject: **GOOD SIGHT PHARMACY, INC.** 5554 SW 8th Street Coral Gables, FL 33134	Source: **DEPARTMENT OF HEALTH** **INVESTIGATION SERVICES UNIT- MIAMI**

Prefix:	License #:	Profession:	Board:	Report Date:
2205	25104	Pharmacy	Pharmacy	February 18, 2013

Period of Investigation:	Type of Report:
January 16- February 18, 2013	FINAL

Alleged Violation: § Possible violation of ss 465.016(1)(r), 465.023(1)(c) F.S.; Rule 64B16-28.202(1)(2)(3)(a)(b)(4)(a)(b)(5), 64B16-28.203(1)(2)(3)(4)(5)(6), 64B16-28.1081, F.A.C.

Synopsis: This investigation is predicated on the receipt of a complaint from the Florida Department of Health, INVESTIGATIVE SERVICES UNIT- MIAMI (ISU-MIAMI) received on January 10, 2013 to the effect that GOOD SIGHT is no longer operating at the address of record and no closure has been reported. There is now a different pharmacy operating at this address, Capitol Pharmacy Discount, causing the Investigator to be unable to determine if drugs were left in GOOD SIGHT. (Ex. 1)

GOOD SIGHT was notified by mail on January 16, 2013, letter being mailed to the address of record and including the initiating document and a copy of the complaint. (Ex. 2)

A check of the Florida Department of Health's licensure information reveals the GOOD SIGHT is licensed as a Pharmacy with status of Clear.

Patient notification is not required because there is no patient involvement.

GOOD SIGHT is not known to be represented by counsel at this time.

GOOD SIGHT has not responded to the notification letter as of February 18, 2013. If a response is received it will be forwarded to the Prosecution Services Unit.

Related Case: None

Investigator/Date:	Approved By/Date:
Laurie Weitbrecht Feb. 18, 2013	Shane Walters FEB 18 2013

Distribution: Legal/Consumer Services Unit

TABLE OF CONTENTS

INVESTIGATIVE DETAILS

SUMMARY OF RECORDS

Exhibit 1 includes a copy of the May 23, 2012 Inspection Report documenting that GOOD SIGHT was not in operation at the address of record as of inspection date. It is noted that Capitol Pharmacy Discount was operational at this address. No pharmacy closure has been received and the Investigator was unable to determine if GOOD SIGHT left any drugs. Also included are licensure documents showing the listed PDM, Olusola Omotunde Jolaogun PS 35040, dropped as of May 31,2011.
(Ex. 1)

INTERVIEW/STATEMENT OF DEPARTMENT OF HEALTH(Complainant)

No further information received from complainant.

INTERVIEW/STATEMENT OF GOOD SIGHT PHARMACY(Subject)

No response received from GOOD SIGHT to date.

Address of Record

5554 SW 8th Street
Coral Gables, FL 33134

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. 201216942

GEORGE ADRIAZOLA,
RESPONDENT.

NOTICE

TO: GEORGE ADRIAZOLA
13282 NW 1 TERR
MIAMI, FL 33182

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850)-236-6000.

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 9:00a.m. ;therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Kristal Beharry, Assistant General Counsel
RE: Determination of Waiver
SUBJECT: DOH v. George Adriazola, RPT
DOH Case Number 2012-16942
DATE: August 23, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	George Adriazola, RPT
Subject's Address of Record:	13282 NW 1st Terrace Miami, FL 33182
Enforcement Address:	13282 NW 1st Terrace Miami, FL 33182
Subject's License No:	39191 **Rank:** RPT
Licensure File No:	38758
Initial Licensure Date:	8/24/2011
Board Certification:	None
Required to Appear:	No
Current IPN/PRN Contract:	None
Allegation(s):	Count 1: Section 456.072(1)(c), F.S. (2012) Count 2: Section 456.072(1)(x), F.S. (2012)
Prior Discipline:	None
Probable Cause Panel:	March 28, 2013 Meshad and Weizer
Subject's Attorney:	Pro Se
Complainant/Address:	Department of Health/Consumer Services Unit
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 – Board Affidavit

Exhibit E – Clerk Affidavit
Motion to Assess Costs
Exhibit A – Affidavit of Fees and Costs Expended
Exhibit 1 – Complaint Cost Summary
Exhibit 2 – Itemized Cost by Complaint
Supplemental Investigative Report 6/12/13
PCP Memo
Final Investigative Report with Exhibits 1 - 2

Disciplinary Guidelines:

Count I: Section 456.072(1)(c), Florida Statutes (2012): $3,000 fine and one (1) year probation up to Revocation

Count II: Section 456.072(1)(x), Florida Statutes (2012): $1,000 fine up to Revocation

PRELIMINARY CASE REMARKS: INFORMAL HEARING

This is a two count Administrative Complaint alleging violations of Section 456.072(1)(c), Florida Statutes (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, pharmacy; and Section 456.072(1)(x), Florida Statutes (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.

On or about September 18, 2012, in the Circuit Court of the Eleventh Judicial Circuit in and for Miami-Dade County, Florida, Respondent entered a plea of guilty to one count of unlawful possession of a prescription drug with intent to sell, a third-degree felony in violation of Section 499.03, Florida Statutes. Respondent did not report his plea to the Board in writing within 30 days.

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. 2012-16942**

GEORGE ADRIAZOLA, RPT,

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 March 28, 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: April 5, 2013 (7196 9008 9111 8827 2533). 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 completed on June 6, 2013. The affidavit of personal service is attached as Petitioner's Exhibit C.

4. 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.

5. 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.

6. 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 D & E.

7. 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.

8. 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) 245-4444 ext. 8218
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 21st day of August, 2013, to: George Adriazola, 13282 NW 1st Terrace, Miami, FL 33182.

K. Beharry

Kristal Beharry
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-16942**

GEORGE ADRIAZOLA, RPT,

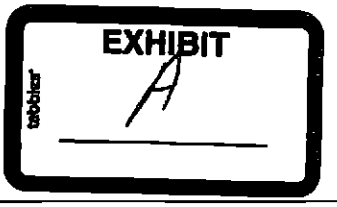
RESPONDENT.
_____/

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, George Adriazola, RPT, 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 within the state of Florida, having been issued license number RPT 39191.



3. Respondent's address of record is 13282 Northwest 1 Terrace, Miami, Florida 33182.

4. On or about September 18, 2012, in the Circuit Court of the Eleventh Judicial Circuit in and for Miami-Dade County, Florida, in case number F12-004270, Respondent entered a plea of guilty to one count of unlawful possession of a prescription drug with intent to sell, a third-degree felony in violation of Section 499.03, Florida Statutes.

5. Respondent failed to timely report, in writing, the plea described above in paragraph (4) to the Board of Pharmacy.

COUNT I

6. Petitioner realleges and incorporates paragraphs one (1) through five (5) as if fully set forth herein.

7. Section 456.072(1)(c), Florida Statutes (2012), 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, pharmacy constitutes grounds for disciplinary action.

8. Unlawful possession of a prescription drug with intent is to sell is a crime that relates to the practice of pharmacy or to the ability to practice pharmacy.

9. As set forth above, Respondent pled guilty to one count of unlawful possession of a prescription drug with intent to sell, a third degree felony, in violation of Section 499.03, Florida Statutes, in the Circuit Court in and for Miami-Dade County, Florida.

10. Based on the foregoing, Respondent violated Section 456.072(1)(c), Florida Statutes (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, pharmacy.

COUNT II

11. Petitioner realleges and incorporates paragraphs one (1) through five (5) as if fully set forth herein.

12. Section 456.072(1)(x), Florida Statutes (2012), provides that 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.

13. Respondent failed to timely report to the board, in writing, the plea described in paragraph four within thirty (30) days after entering the plea.

14. Based on the foregoing, Respondent violated Section 456.072(1)(x), Florida Statutes (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.

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

K. Beharry

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) 245-4640
Facsimile: (850) 245-4683

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE MAR 28 2013

/KB
PCP: 03/28/13
PCP Members: Meshad & 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.

7196 9008 9111 8827 2533

TO:

Stip Pack
Cassandra/Beharry
Date Mailed 4/5/2013
2012-16942

SENDER:

REFERENCE:

Adriazola, George

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

Track & Confirm

You entered: 71969008911188272533

[redacted]

Your item was returned to the sender on May 18, 2013 at 5:03 pm in MIAMI, FL 33184 because it was not claimed by the addressee. Additional information for this item is stored in files offline.

You may request that the additional information be retrieved from the archives, and that we send you an e-mail when this retrieval is complete. Requests to retrieve additional information are generally processed momentarily.

I would like to receive notification on this request

Restore

Find Another Item

What's your label (or receipt) number?

Find

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

DEPARTMENT OF HEALTH
Petitioner

vs

Case No. RPT 2012-16942

GEORGE ADRIAZOLA, RPT
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 06/06/13, Affiant made a diligent effort to locate Respondent, to serve Administrative Complaint, Election of Rights and Stipulation 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) 06/06/13.

_____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 Dade

Before me, personally appeared Jeneice Mayers 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 12th day of June 2013

Notary Public-State of Florida

Sunday Adesina
Type or Print Name

My Commission Expires

SUNDAY A. ADESINA
Commission # EE 838210
Expires September 25, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

Florida Department of Health
Division of Medical Quality Assurance · Bureau of Enforcement
8350 NW 52nd Terrace, Suite 400 • Doral, FL 33166-7709
PHONE: (305) 470-5805 • FAX: (305) 499-2090

EXHIBIT
tabbies
C

I, Mark Whitten, hereby certify in my official capacity as custodian for the Board of Pharmacy's licensure files that the Board of Pharmacy as of August 23, 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: George Adriazola, R.PT., CASE NUMBER: 2012-16942** which would affect the Subject's substantial interests or rights.

Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Mark Whitten, whose identity is known to me personal (type of identification) and who, under, oath, acknowledges that his/her signature appears above.

Sworn to and subscribed this 23 day of August, 2013.

Notary Public

HELAINE ROBISON
MY COMMISSION # EE 138625
EXPIRES: November 17, 2015
Bonded Thru Notary Public Underwriters

EXHIBIT
D

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: George Adriazola, RPT, Case No.: 2012-16942**, 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.

Swom to and subscribed before me this 23rd day of August, 2013.

Angela Barton

Notary Public

My Commission Expires:

ANGELA BARTON
NOTARY PUBLIC - STATE OF FLORIDA
COMMISSION # DD922154
EXPIRES 9/1/2013
BONDED THRU 1-888-NOTARY

STATE OF FLORIDA
DEPARTMENT OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-16942**

GEORGE ADRIAZOLA, RPT,

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 $2,364.07, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**1.50**	**$82.35**
Investigation:	**23.80**	**$1,514.36**
Legal:	**7.20**	**$765.75**
Compliance:	**0.05**	**1.61**
Sub Total:	**32.55**	**$2,364.07**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$2,364.07**

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $1,598.32 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 $1,598.32 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 $1,598.32.

DATED this 27th day of August, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

K. Beharry

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 ext. 8218
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 foregoing Motion to Assess Costs has been provided by U.S. Mail this 27th day of August, 2013, to: George Adriazola, 13282 NW 1st Terrace, Miami, FL 33182.

K. Beharry

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) **2012-16942** (Department of Health v. **GEORGE ADRIAZOLA, RPT**) are **TWO THOUSAND THREE HUNDRED SIXTY-FOUR DOLLARS AND SEVEN CENTS ($2,364.07).**

6) The costs for DOH case numbers **2012-16942** (Department of Health v. **GEORGE ADRIAZOLA, RPT**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case numbers **2012-16942** (Department of Health v. **GEORGE ADRIAZOLA, RPT**) 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 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 26th day of August, 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

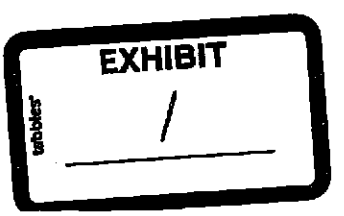
Stamp Commissioned Name of Notary Public:

Complaint Cost Summary

Complaint Number: 201216942

Subject's Name: ADRIAZOLA, GEORGE

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.50	$82.35
Investigation:	23.80	$1,514.36
Legal:	7.20	$765.75
Compliance:	0.05	$1.61
	**********	**********
Sub Total:	32.55	$2,364.07
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$2,364.07



Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216942

Report Date 08/26/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
COMPLIANCE MANAGEMENT UNIT						
HC27	0.05	$32.13	$1.61	01/02/2013	137	PRIORITY DOWNGRADES/UPGRADES
Sub Total	**0.05**		**$1.61**			
CONSUMER SERVICES UNIT						
HA23	0.60	$54.90	$32.94	11/16/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HA23	0.10	$54.90	$5.49	11/20/2012	35	TELEPHONE CALLS
HA23	0.80	$54.90	$43.92	12/04/2012	144	CSU INVESTIGATIVE WORK
Sub Total	**1.50**		**$82.35**			
INVESTIGATIVE SERVICES UNIT						
MI209	2.00	$61.19	$122.38	11/29/2012	4	ROUTINE INVESTIGATIVE WORK
MI209	1.00	$61.19	$61.19	11/29/2012	76	REPORT PREPARATION
MI196	4.00	$63.98	$255.92	12/05/2012	4	ROUTINE INVESTIGATIVE WORK
MI211	1.00	$63.98	$63.98	12/11/2012	6	SUPPLEMENTAL INVESTIGATION
MI211	1.00	$63.98	$63.98	12/11/2012	58	TRAVEL TIME
MI196	1.00	$63.98	$63.98	12/11/2012	58	TRAVEL TIME
MI196	1.00	$63.98	$63.98	12/11/2012	4	ROUTINE INVESTIGATIVE WORK
MI28	0.60	$63.98	$38.39	12/12/2012	4	ROUTINE INVESTIGATIVE WORK
MI196	8.00	$63.98	$511.84	12/12/2012	76	REPORT PREPARATION
MI196	1.50	$63.98	$95.97	06/03/2013	58	TRAVEL TIME
MI196	0.20	$63.98	$12.80	06/03/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
MI196	0.80	$63.98	$51.18	06/06/2013	58	TRAVEL TIME
MI196	0.20	$63.98	$12.80	06/06/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
MI196	1.50	$63.98	$95.97	06/12/2013	76	REPORT PREPARATION
Sub Total	**23.80**		**$1,514.36**			

EXHIBIT
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Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216942

Report Date 08/26/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
PROSECUTION SERVICES UNIT						
HLL70B	0.60	$106.35	$63.81	12/07/2012	25	REVIEW CASE FILE
HLL70B	0.70	$106.35	$74.45	12/07/2012	46	LEGAL RESEARCH
HLL70B	0.10	$106.35	$10.64	12/07/2012	35	TELEPHONE CALLS
HLL70B	0.10	$106.35	$10.64	12/12/2012	35	TELEPHONE CALLS
HLL70B	1.20	$106.35	$127.62	12/19/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL70B	0.40	$106.35	$42.54	12/19/2012	26	PREPARE OR REVISE MEMORANDUM
HLL70B	1.80	$106.35	$191.43	12/27/2012	26	PREPARE OR REVISE MEMORANDUM
HLL90A	0.30	$106.35	$31.91	01/03/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL90A	0.70	$106.35	$74.45	01/16/2013	25	REVIEW CASE FILE
HLL90A	1.00	$106.35	$106.35	01/16/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL90A	0.30	$106.35	$31.91	04/05/2013	90	POST PROBABLE CAUSE PROCESSING
Sub Total	7.20		**$765.75**			

Total Cost	**$2,364.07**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 08/26/2013

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: 12/03/2012	Case Number: RPT 2012-16942
Subject: **GEORGE ADRIAZOLA** 13282 NW 1st Terr Miami, FL 33182 (786) 246-4108 (C)	Source: **DOH/CONSUMER SERVICES UNIT**	

Prefix:	License #:	Profession:	Board:	Report Date:
2208	39191	Registered Pharmacy Technician	Pharmacy	06/12/13

Period of Investigation: 05/24/13 – 06/12/13	Type of Report: SUPPLEMENTAL - 1

Alleged Violation: SEE FINAL REPORT

Synopsis: This Supplemental Report is predicated upon receipt of a Supplemental request from CASSANDRA NICHOLSON, Assistant for General Counsel, KRISTAL BEHARRY from the Department of Health Prosecution Services Unit to hand-serve Administrative Complaint, Election of Rights and Stipulation to GEORGE ADRIAZOLA last known address, 13282 NW 1st Terrace, Miami, FL 33182.

RECEIVED-LEGAL
13 JUN 18 AM 11:49

INVESTIGATOR NOTE:
On 06/06/13 at approximately 11:17 am, this Investigator presented to the last known physical address for GEORGE ADRIAZOLA, 13282 NW 1st Terrace, Miami, FL 33182 after reviewing Accurint Data and hand-served Administrative Complaint, which includes Settlement Agreement, Election of Rights and Stipulation to GEORGE ADRIAZOLA, RPT (Identity confirmed against ADRIAZOLA's Florida State drivers license).

Exhibits(s):
S1 – Affidavit of Service or Diligent Search, (p. 2)

Related Case(s): NONE

Received
Investigative Services
JUN 17 2013
DOH/MQA
Tallahassee HQ

Investigator/Date: June 12, 2013	Approved By/Date: June 12, 2013
Jeneice Mayers, Investigation Specialist II	Caridad Rodriguez, Investigator Supervisor

Distribution: HQ/ISU

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

DEPARTMENT OF HEALTH
Petitioner

vs

Case No. RPT 2012-16942

GEORGE ADRIAZOLA, RPT
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 06/06/13, Affiant made a diligent effort to locate Respondent, to serve Administrative Complaint, Election of Rights and Stipulation 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) 06/06/13.

_____ 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 Dade

Before me, personally appeared Jeneice MAyers 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 12th day of June 2013

Notary Public-State of Florida

Type or Print Name

My Commission Expires:

SUNDAY A. ADESINA
Commission # EE 838210
Expires September 25, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **George Adriazola, RPT**
Case Number: 2012-16942

MEMBERS: **Gavin Meshad and Michele Weizer**

DATE OF PCP: **March 28, 2013** **AGENDA ITEM: A-2**

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)(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)
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 XI	Date of Case: 12/03/2012	Case Number: RPT 2012-16942

Subject:	Source:
GEORGE ADRIAZOLA 13282 NW 1 Terr Miami, FL 33182 (786) 246-4108 (C)	**DOH/CONSUMER SERVICES UNIT**

Prefix:	License #:	Profession:	Board:	Report Date:
2208	39191	Registered Pharmacy Technician	Pharmacy	12/13/12

Period of Investigation: 12/04/12 – 12/13/12	Type of Report: PRIORITY - 1

Possible Violation of SS. 456.072 (1)(c)(k)(x)(z)(dd) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken: Being convicted or found guilty of, or entering a plea...; Failing to perform any statutory or legal obligation placed upon...; Failing to report to the board, or the department if there is no board, in writing...; Being unable to practice with reasonable skill and safety to patients ...; Violating any provision of this chapter, the applicable practice act, or any rules...; F.S.; 465.016(1)(d) 1., 2., (e)(f)(j)(m)(r) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2): Being unfit or incompetent to practice pharmacy by reason of: Habitual intoxication. The misuse or abuse of any medicinal drug appearing in any schedule set forth in chapter 893. Violating chapter 499; 21 U.S.C. ss...; Having been convicted or found guilty, regardless of adjudication, in a court...; Making or filing a report or record which the licensee knows to be false, intentionally...; Being unable to practice pharmacy with reasonable skill...; Violating any provision of this chapter or chapter 456, or any...;

Synopsis: This investigation is predicated upon receipt of Case Summary and Initiating Documents (Exhibit #1), submitted by DOH/CONSUMER SERVICES UNIT. DOH/CONSUMER SERVICES UNIT stated that they received internally generated complaint stating GEORGE ADRIAZOLA was convicted of Possess Cont. Sub. w/o Presc. (S.499.03 (3), F.S.) in Miami-Dade County, FL. Court documents obtained from Miami-Dade County Clerk of Court stated ADRIAZOLA entered a guilty plea to the charge Prescr/New/Drug/Possess w/Intent to Sell/Deliver (S.499.03 (3), F.S.) and was adjudicated guilty on 09/18/12. This conviction resulted from ADRIAZOLA stealing Alprazolam 2mg from his place of employment, CVS Pharmacy, located at 3695 West Flagler St., Miami, FL. Additionally, ADRIAZOLA was arrested for Possession of Marijuana (S. 893.13 (6) (b), F.S.) on 04/30/11 and 07/27/11 in Miami-Dade County, FL. CCIS indicates adjudication was withheld on these charges; however Miami-Dade Clerk of Court was unable to produce disposition documents.

ADRIAZOLA was notified of the investigation by Subject Notification Letter, dated 12/04/12 (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 GEORGE ADRIAZOLA has a clear and active Registered Pharmacy Technician License, which will expire on 12/31/12.

No patient(s) were identified, thus patient notification was not required.

ADRIAZOLA is not represented by an attorney at this time.

Although multiple attempts were done by this Investigator to contact GEORGE ADRIAZOLA, as of date of this Investigative Report ADRIAZOLA has not responded to the allegation.

Related Case(s): NONE

Investigator/Date: December 13, 2012
Jeneice Mayers
Jeneice Mayers, Investigation Specialist II

Approved By/Date: December 13, 2012
Edward Thompson, Investigator Manager

Received
Investigative Services
DEC 17 2012

Distribution: HQ/ISU

DOH/MQA
Tallahassee, FL

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

DOH INVESTIGATIVE REPORT CASE NUMBER: RPT 2012-16942

TABLE OF CONTENTS

INVESTIGATIVE DETAILS

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit 1: Contains Case summary and Attachment which contains the following documentation:
- Certified Court Documents

Exhibit 2: Contains a copy of the Subject Notification Letter, dated 12/04/12

INTERVIEW OF GEORGE MULERO, MIAMI MMI INVESTIGATOR – (Witness)
DOH/MIAMI INVESTIGATIVE SERVICES
8350 NW 52nd Terrace, Ste 400
Miami, FL 33166
(305) 470-5894 (W)

On 11/06/12, this Investigator interviewed Medical Malpractice Investigator GEORGE MULERO at the Miami ISU office. MULERO initially stated the following: On 11/29/12, he visited Miami-Dade Criminal Court Building for the purpose of obtaining Certified Criminal History/background relative to GEORGE ADRIAZOLA. MULERO also stated that the record reveals that ADRIAZOLA was arrested at his place of employment CVS Pharmacy 3695 West Flagler St, Miami, FL for committing Retail Theft of a medication known as ALPROZOLAN 2mg and also arrested on 04/30/11, as well as 07/27/11 for Possession of Marijuana. MULERO insinuated to this Investigator that no Disposition was found relative to these charges and that he obtain all the Certified Copies of Arrest Records and Disposition for GEORGE ADEIAZOLA.

INTERVIEW OF JULIANA MILLON, ATTORNEY FOR THE STATE ATTORNEY'S OFFICE – (Witness)
Employment Address:
MIAMI-DADE STATE ATTORNEY'S OFFICE
1350 N.W. 12th Avenue
Miami, FL 33136
(305) 547-0100 (W)

On 12/12/12, Medical Malpractice Investigator NEIL DOWNS contacted JULIANA MILLON to conduct an interview and also requested documentation from there state case. MILLON stated to MMI, DOWNS that our office already received all of the CERTIFIED COURT DOCUMENTS and Disposition for GEORGE ADRIAZOLA and also stated to DOWNS that ADRIAZOLA plea guilty and was placed on probation for one year.

INTERVIEW OF JOSELYN MAYMI, PHARMACIST (LICENSE #47426) – (Witness)
Employment Address:
CVS Pharmacy
3695 West Flagler Street
Miami, FL 33135
(305) 643-9304 (W)

On 12/11/12, this Investigator and Miami Medical Malpractice Investigator, SUNDAY ADESINA presented to CVS Pharmacy PH 20603 located at 3695 West Flagler Street, Miami, FL 33135 and conducted an interview with PDM, JOSELYN MAYMI. MAYMI stated the following: She was present the day RPT, GEORGE ADRIAZOLA was arrested. MAYMI stated that ADRIAZOLA was placing high orders on ALPROZOLAM 2mg and Loss Control Department conducted an audit on ALPROZOLAM 2mg between 09/11 – 02/12 and found out that 85 bottles of ALPROZOLAM 2MG was missing. MAYMI also stated that her Store Manager, HECTOR REGUERO confronted ADRIAZOLA on 02/20/12, because on the previous day ADRIAZOLA order 8 bottles of ALPRAZOLAM and only one bottle of ALPROZOLAM 2mg was placed on the self. MAYMI further stated that ADRIAZOLA was taken to the back room of the pharmacy and admitted to her Store Manager, HECTOR REGUERO that he stole the 7 bottle of ALPRAZOLAM 2mg. ADRIAZOLA was later arrested for retail theft/possession of drugs without Prescription.

INTERVIEW OF HECTOR REGUERO, CVS STORE MANAGER – (Witness)
Employment Address:
CVS Pharmacy
3695 West Flagler Street
Miami, FL 33135
(305) 643-9304 (W)

On 12/11/12, this Investigator and Miami Medical Malpractice Investigator, SUNDAY ADESINA presented to CVS Pharmacy PH 20603 located at 3695 West Flagler Street, Miami, FL 33135 and conducted an interview with CVS Store Manager, HECTOR REGUERO. In summary, REGUERO stated to this Investigator that after an inventory was conducted between 09/11 – 02/12 by his Loss Prevention Department he found out that 85 bottles of ALPROZOLAM 2mg were missing and further review indicated that GEORGE ADRIAZOLA was placing high order on ALPROZOLAM 2mg. REGUERO also stated that around 02/12 GEORGE ADRIAZOLA order 8 bottle of ALPROZOLAM 2mg, but only one bottle was placed on the self. REGUERO stated that on 02/20/12 he asked GEORGE ADRIAZOLA what happen to the medication ALPROZOLAM 2mg that he order. REGUERO further stated that GEORGE ADRIAZOLA was taken to the back of the

Pharmacy Department where he verbally admitted that he stole the medication ALPROZOLAM 2mg. REGUERO stated that he contacted Miami-Dade Police Department and GEORGE ADRIAZOLA was arrested for retail theft/possession of drugs w/o Prescription.

INVESTIGATOR NOTE:

On 12/11/12at approximately 11:00 am, this Investigator and SUNDAY ADESINA, Miami Medical Malpractice Investigator presented to the last known physical address for GEORGE ADRIAZOLA, 13282 NW 1 Terr, Miami, FL 33182 and 2110 SW 151st PL, Miami, FL 33185 per Accurint Data. Upon arrival of address 2110 SW 151st PL, Miami, FL 33185 a man came out and stated that he is the owner of the house and no one by the name of ADRIAZOLA lived there. This Investigator also presented to 13282 NW 1 Terr, Miami, FL 33182 and no one was present, so I placed my Business Card in the mailbox.

On 12/12/12, this Investigator called ADRIAZOLA at telephone number (786) 246-4108 number was disconnected. This Investigator also conducted an Accurint Search on ADRIAZOLA and the Finder Report listed ADRIAZOLA current address as 13282 NW 1 Terr, Miami, FL 33182, which this is the one listed in DOH database. In addition, this Investigator mailed a copy of the Subject Notification Letter and Attached Documents to the current address via US Mail (Exhibit #20, to the same address as the one listed in the DOH records. As of 12/13/12, ADRIAZOLA has not responded to the allegations after several attempts via US Mail.

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

Scroll down to see the available pages or advance to the next document if all pages have been removed.

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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.

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. 201218551

SPEED II PHARMACY INC,
RESPONDENT.

NOTICE

TO: SPEED II PHARMACY INC
2900 W 12TH AVE STE 4
HIALEAH, FL 33012

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

Per Mark Whitten

Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel MGW CRU
RE: Determination of Waiver
SUBJECT: DOH v. Speed II Pharmacy, Inc.
DOH Case Number 2012-18551
DATE: August 28, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Speed II Pharmacy, Inc.
Subject's Address of Record:	2900 West 12th Avenue Suite 4 Hialeah, FL 33012
Enforcement Address:	2900 West 12th Avenue Suite 4 Hialeah, FL 33012
Subject's License No:	26049 **Rank:** PH
Licensure File No:	19075
Initial Licensure Date:	4/4/2012
Board Certification:	No
Required to Appear:	No
Current PRN Contract:	No

Allegation(s):	**Count I:** Section 465.023(1)(c), F.S. (2012), by violating Section 465.022(10), F.S. (2012), 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, and/or by violating Section 465.022(11), F.S. (2012), a permittee must notify the department of the identity of prescription department manager within 10 days after employment **Count II:** Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.1081, F.A.C., which requires that 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.
Prior Discipline:	None
Probable Cause Panel:	March 28, 2013 Meshad & Weizer
Subject's Attorney:	Pro Se
Complainant/Address:	Department Of Health/ISU 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 – Board Affidavit Exhibit D – Clerk Affidavit Motion to Assess Costs

Exhibit A – Affidavit of Fees and Costs Expended
Exhibit 1 – Complaint Cost Summary
Exhibit 2 – Itemized cost by Complaint
PCP Memorandum
Final Investigative Report
Exhibits 1 thru 6

GUIDELINES:
Count I: Fine based length of time from notifying Board, $500 per month up to $7,500.
Count II: From a $500 fine and a twelve hour laws and rules course up to $2,000 fine and one year probation.

PRELIMINARY CASE REMARKS: DETERMINATION OF WAIVER

This is a two count Administrative Complaint which alleges that On or about November 19, 2012 DE ceased being the Respondent's PDM. Respondent failed to notify the Department of the change of PDM and/or the identity of the PDM.

Additionally, on or about December 11, 2012 a Department inspector found the Respondent to be closed during posted business hours.

MGW/crl

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-18551**

Speed II 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 herright 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 March 28, 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 or about April 18, 2013 Certified Mail Number 7196 9008 9111 8826 3944. A signed green receipt card was returned. A copy of the certified mail receipt is attached 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 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 C and D.

4. 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.

5. 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.

6. 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.

7. The Department has determined that there are no material facts in dispute and has concluded that Respondent has waived her right to elect the method of resolution.

8. 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 October 9, 2013 at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, Florida 32408.

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.

Respectfully submitted,

John H. Armstrong, MD
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@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 furnished via U.S. mail to: Speed II Pharmacy, Inc., 2900 West 12th Avenue, Suite 4, Hialeah, Florida 33012 this 29 day of August, 2013.

Matthew G. Witters
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-18551**

SPEED II PHARMACY, INC.,

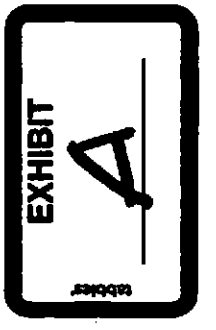
RESPONDENT.
_____/

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, Speed II 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 Complaint, Respondent was a permitted community pharmacy within the state of Florida, having been issued permit number PH 26049.



3. Respondent's address of record is 2900 W. 12th Avenue, Suite 4, Hialeah, Florida 33012.

4. On or about November 19, 2012, D.E., a pharmacist ceased being the prescription department manager (PDM) of record for the Respondent.

5. Pharmacy permittees are required to have a PDM of record to ensure the pharmacy's compliance with the laws and rules related to the practice of the profession of pharmacy and the sale of prescription drugs.

6. From on or about November 19, 2012, to on or about December 18, 2012, Respondent did not notify the Department of a change of PDM of record and/or failed to notify the Department of the identity of the PDM of record.

7. On or about December 11, 2012, a Department inspector attempted to conduct and inspection of the Respondent at 2900 W. 12th Avenue, Suite 4, Hialeah, Florida 33012.

8. On or about December 11, 2012, the Department's inspector found the Respondent's prescription department to be closed during posted operational hours.

COUNT ONE

9. Petitioner realleges and incorporates paragraphs one (1) through eight (8) as if fully set forth herein.

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. Section 465.022(10), Florida Statutes (2012), provides that 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.

12. Section 465.022(11), Florida Statutes (2012), provides that a permittee must notify the department of the identity of the prescription department manager within 10 days after employment.

13. As set forth above, from on or about November 19, 2013, to on or about December 18, 2012, Respondent did not notify the Department of

a change of PDM of record and/or failed to notify the Department of the identity of the PDM of record.

14. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating Section 465.022(10), Florida Statutes (2012), 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, and/or by violating Section 465.022(11), Florida Statutes (2012), a permittee must notify the department of the identity of the prescription department manager within 10 days after employment.

COUT TWO

15. Petitioner realleges and incorporates paragraphs one (1) through eight (8) as if fully set forth herein.

16. 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.

17. Rule 64B16-28.1081, Florida Administrative Code, provides, in pertinent part, that 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.

18. As set forth above, Respondent's prescription department was not open on December 11, 2012 when a Department inspector attempted to perform and inspection and therefore, was not open the minimum forty (40) hours per week.

19. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-28.1081, Florida Administrative Code, which requires that 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.

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 28 **day of** March **, 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) 245-4640
Facsimile: (850) 245-4683
Email: matthew_witters@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.

7196 9008 9111 8826 3944

TO:

SENDER: Christine

REFERENCE: Stip Pack

PS Form 3800, January 2005

RETURN RECEIPT SERVICE		
	Postage	
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

SPEED II PHARMACY
2900 W 12TH AVE
STE 4
HIALEAH FL 33012

USPS®
Receipt for Certified Mail™
No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

4-4-13

2. Article Number

7196 9008 9111 8826 3944

3. Service Type **CERTIFIED MAIL™**

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly) | B. Date of Delivery

C. Signature

x [signature] ☐ Agent ☐ Addressee

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

APR 18 AM 9:17

PRACTITIONER LICENSURE

SPEED II PHARMACY
2900 W 12TH AVE
STE 4
HIALEAH FL 33012

PS Form 3811, January 2005 Domestic Return Receipt

7196 9008 9111 8826 3944

TO:

SENDER: Christine

REFERENCE: Stip Pack

PS Form 3800, January 2005

RETURN RECEIPT SERVICE	Postage	
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

SPEED II PHARMACY
2900 W 12TH AVE
STE 4
HIALEAH FL 33012

USPS®
Receipt for Certified Mail™
No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

4-4-13

2. Article Number

7196 9008 9111 8826 3944

3. Service Type **CERTIFIED MAIL™**

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly) | B. Date of Delivery

C. Signature

x [signature] ☐ Agent ☐ Addressee

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

PRACTITIONER REGISTRATION
2013 APR 18 AM 9:17

SPEED II PHARMACY
2900 W 12TH AVE
STE 4
HIALEAH FL 33012

PS Form 3811, January 2005 Domestic Return Receipt

EXHIBIT B

I, Mark Whitten, hereby certify in my official capacity as custodian for the Board of Pharmacy, licensure files that the Board of Pharmacy as of May 13, 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **SPEED II PHARMACY, INC., CASE NUMBER 2012-18551**, which would affect the Subject's substantial interests or rights.

Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Mark Whitten, 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 13TH day of May, 2013.

LORRAINE GAIL CURRY
MY COMMISSION # EE 97887
EXPIRES: May 26, 2015
Bonded Thru Notary Public Underwriters

Lorraine Gail Curry
Notary Public

EXHIBIT 3

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 **SPEED II PHARMACY, INC. CASE NUMBER 2012-18551**, which would affect the Respondent's substantial interests or rights.

Custodian of Record
Department Clerk's Office

Before me, personally appeared Amy Carraway, 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 10 day of May, 2013.

LAWANDA M BELL
MY COMMISSION # EE187051
EXPIRES May 09, 2016
(407) 398-0153 FloridaNotaryService.com

Lawanda Bell
Notary Public

My Commission Expires:

EXHIBIT D

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-18551**

Speed II 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 $1,085.43 based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**0.40**	**$21.96**
Investigation:	**12.30**	**$786.95**
Legal:	**2.60**	**$276.52**
Compliance:	**0.00**	**$0.00**
Sub Total:	**15.30**	**$1,085.43**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$1,085.43**

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $808.91 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 $808.91 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 $808.91.

DATED this 28 day of August, 2013.

Respectfully Submitted,

John H. Armstrong, MD, FACS
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@doh.state.fl.us

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 29 day of August, 2013, to: Speed II Pharmacy, Inc., 2900 West 12th Avenue, Suite 4, Hialeah, Florida 33012.

Matthew G. Witters
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 **2012-18551** (Department of Health v. **SPEED II PHARMACY, INC.**) are **ONE THOUSAND EIGHTY-FIVE DOLLARS AND FORTY-THREE CENTS ($1,085.43).**

6) The costs for DOH case numbers **2012-18551** (Department of Health v. **SPEED II 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 numbers **2012-18551** (Department of Health v. **SPEED II 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

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 13 day of May, 2013, by Shane Walters, who is personally known to me.

Notary Signature

Antoinette Carter

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

Complaint Cost Summary

Complaint Number: 201218551

Subject's Name: SPEED II PHARMACY INC

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**0.40**	**$21.96**
Investigation:	**12.30**	**$786.95**
Legal:	**2.60**	**$276.52**
Compliance:	**0.00**	**$0.00**
	**********	**********
Sub Total:	**15.30**	**$1,085.43**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$1,085.43**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201218551

Report Date 05/13/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA136	0.40	$54.90	$21.96	12/20/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
Sub Total	**0.40**		**$21.96**			
INVESTIGATIVE SERVICES UNIT						
MI211	2.00	$63.98	$127.96	12/27/2012	4	ROUTINE INVESTIGATIVE WORK
MI211	2.30	$63.98	$147.15	01/03/2013	58	TRAVEL TIME
MI211	2.00	$63.98	$127.96	01/04/2013	4	ROUTINE INVESTIGATIVE WORK
MI211	1.00	$63.98	$63.98	01/15/2013	4	ROUTINE INVESTIGATIVE WORK
MI211	1.50	$63.98	$95.97	01/16/2013	4	ROUTINE INVESTIGATIVE WORK
MI211	2.00	$63.98	$127.96	01/18/2013	4	ROUTINE INVESTIGATIVE WORK
MI211	1.50	$63.98	$95.97	01/28/2013	76	REPORT PREPARATION
Sub Total	**12.30**		**$786.95**			
PROSECUTION SERVICES UNIT						
HLL90B	0.60	$106.35	$63.81	02/13/2013	25	REVIEW CASE FILE
HLL90B	0.60	$106.35	$63.81	02/13/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL90B	0.20	$106.35	$21.27	02/18/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL90B	0.20	$106.35	$21.27	02/18/2013	89	PROBABLE CAUSE PREPARATION
HLL90B	0.20	$106.35	$21.27	03/26/2013	89	PROBABLE CAUSE PREPARATION
HLL90B	0.10	$106.35	$10.64	03/28/2013	63	PRESENTATION OF CASES TO PROBABLE CAUSE PANEL
HLL90B	0.30	$106.35	$31.91	03/28/2013	79	STIPULATION
HLL90B	0.20	$106.35	$21.27	03/29/2013	79	STIPULATION
HLL90B	0.20	$106.35	$21.27	04/04/2013	90	POST PROBABLE CAUSE PROCESSING
Sub Total	**2.60**		**$276.52**			

EXHIBIT
tables
2

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201218551

Report Date 05/13/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description

Total Cost	**$1,085.43**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 05/13/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Speed II Pharmacy, Inc.**
Case Number: 2012-18551

MEMBERS: **Gavin Meshad and Michele Weizer**

DATE OF PCP: **March 28, 2013** **AGENDA ITEM: A-6**

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;

Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-28.1081, 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**

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 XI	Date of Case:12/18/12			Case Number: PH 2012-18551
Subject: **SPEED II PHARMACY INC** 2900 W 12TH AVENUE STE 4 HIALEAH,FL 33012 786-310-7845			Source: **DEPARTMENT OF HEALTH**	
Prefix:2205	License#:26049	Profession: Pharmacy	Board: Pharmacy	Report Date:01/29/13
Period of Investigation:12/27/12-01/29/13		Type of Report: Final		

Alleged Violation: Possible Violation of S.S.456.072 (1)(k)(dd), 465.016 (r), 465.023(1)(c), F.S., and Rules 64B16-28.102(4), 64B16-28.1081, 64B16-28.109, F.A.C. Failure to maintain proper Pharmacy establishment, Failure to perform legal obligation.

Synopsis: This investigation is predicated upon the receipt of a Case Summary and Initiating Documents from Department of Health Pharmacy Inspector CHANIRA MALDONADO-CANATE. On 12/10/2012 during a routine pharmacy inspection of SPEED II PHARMACY INC (Schedule II & III Community Pharmacy # 26049 located at 2900 W 12th Ave, Suite 4 in Hialeah) revealed a pharmacist was not on duty at this pharmacy which was closed during posted hours, did not meet 40 hour requirement, and was deemed unsafe on account of unlicensed staff with access to medications in an unlocked pharmacy department. PS # 17484 was the PDM of record until 11/27/2012.

SPEED II PHARMACY INC was notified of the investigation by letter, dated 12/27/12 (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 SPEED II PHARMACY INC is a licensed pharmacy with a clear and active status.

There is no patient identify in this case, thus patient notification was not required.

SPEED II PHARMACY INC is not represented by an attorney at the time of this report.

SPEED II PHARMACY INC denied all the allegations in a statement (Exhibit #6), received by this investigator on 01/22/13

Related Case(s): None

Investigator/Date: 01/29/13 **Sunday Adesina M.211** **Medical Malpractice Investigator**	Approved By/Date: 01/29/13 **Caridad Rodriguez** **Investigator Supervisor**

Distribution: HQ/ISU

TABLE OF CONTENTS

***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 Case Summary and attachments from initiating documents

EXHIBIT#2 Copy of Subject Notification letter, dated 12/27/12

EXHIBIT#3 Copy of Florida Department of state Division of corporation listing DE LA TORRE GUIDO as the owner of the Pharmacy

EXHIBIT#4 Copy of pictures taken by this investigator on 01/3/13 during a re-inspection visit, the picture revealed a closed pharmacy and the notice that was placed on the entrance for customers notification on closing status and period
EXHIBIT#5 Copy of e- mail correspondence between SPEED II PHARMACY INC owner and this investigator on 01/04/13

EXHIBIT#6 Copy of SPEED II PHARMACY INC statement received on 01/22/13 by this investigator

INTERVIEW OF PHARMACY INSPECTOR MALDONADO-CANATE –SOURCE
Employment:
8359 NW 2ND Terrace,
Doral, FL 33166.
305-470-5800

On 12/31/12 this investigator interviewed Pharmacy Inspector CHANIRA MALDONADO-CANATE at Miami ISU office located at 8359 NW 2ND Terrace, Doral FL 33166. Inspector CHANIRA MALDONADO-CANATE stated that on 12/10/12 she attempted to perform a routine inspection at SPEED II PAHRMACY located at 2900 W 12 TH Avenue. Hialeah, Fl 33012 when she observed that the prescription department was not locked and there was no pharmacist present during her visit. She also stated that two employees were observed in the pharmacy prescription area without any identification and the pharmacy was also closed during posted operation hours. Inspector CHANIRA MALDONADO-CANATE stated that there was no PDM of record at the time of inspection. The record revealed that the last PDM was taken off the record on 11/27/12 and the pharmacy had not updated the new PDM with the board.

STATEMENT OF SPEED II PHARMACY INC LIC # (26049) -SUBJECT

Address:
2900 W 12TH AVENUE STE 4
HIALEAH, FL 33012
786-310-7845

A written statement was received from the owner of SPEED II PHARMACY INC (Exhbit#6) on 01/22/13. On December 10, 2012 a routine inspection of SPEED II PHARMACY INC was not done since the pharmacy manager was not present. The employee present was GLADYS SANTOS (front clerk) and VIVIAN MARTINEZ Pharmacist Intern (PS/24934).According to the Pharmacist Intern (PS/24934) the inspector came to conduct the annual Inspection, the prescription department door was closed but not locked because the lock was broken. The lock was fixed next day. The drugs inside the prescription department was only generic, no controls (Attach a copy of the drugs) Since April 5, 2012 SPEED II PHARMACY INC received the Florida Board of Pharmacy, DEA License on October 15, 2012 and the Medicare Part D Insurance November 15, 2012. This pharmacy has never dispensed any prescription. The PDM Pharmacy Manager was canceled without the knowledge of GUIDO DE LA TORRE.

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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The Pharmacy Will be Closed
from December 21, 2012 till
January 7th 2012 Due to
Holidays
Sorry for the Inconvenience
and Thank You, Management
EXHIBIT 4
CONFIDENTIAL


PHARMACY
PH: 786-310-7845
* HEALTH & BEAUTY
* ARTICULOS PARA EL HOGAR
* EQUIPOS MEDICOS
* PERFUMES
* COSMETICOS
* FANTASIA FINA
GREEN MOUNTAIN COFFEE
Lottery
Uniformes - Accesorios Clinicos


D II PHARMACY
PH: 786-310-7845
* HEALTH & BEAUTY
* ARTICULOS PARA EL HOGAR
* EQUIPOS MEDICOS
* PERFUMES
* COSMETICOS
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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. 201213596

RYAN DANIEL RODRIGUEZ,
RESPONDENT.

NOTICE

TO: RYAN DANIEL RODRIGUEZ
11179 PEERLESS LANE
JACKSONVILLE, FL 32246

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Mark Whitten, Executive Director; Board of Pharmacy
FROM: Thomas J. Morton, Assistant General Counsel
RE: Motion for Determination of Waiver
SUBJECT: DOH v. Ryan Daniel Rodriguez, R.P.T.
DOH Case Numbers 2012-13596 and 2012-13608
DATE: August 29, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 8-9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Ryan Daniel Rodriguez, R.P.T.
Subject's Address of Record:	11179 Peerless Lane Jacksonville, FL 32246 (904) 945-9059 Telephone
Enforcement Address:	11179 Peerless Lane Jacksonville, FL 32246
Subject's License No:	5867 **Rank:** RPT
Licensure File No:	6742
Initial Licensure Date:	11/4/2009
Board Certification:	None
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Section 465.016(1)(e), Florida Statutes (2011-2012) Section 456.072(1)(c), Florida Statutes (2012)
Prior Discipline:	None
Probable Cause Panel:	DeAnn M. Mullins and Debra B. Glass
Subject's Attorney:	Pro Se

Complainant/Address: Department Of Health/ISU-Jacksonville

Materials Submitted:
Memorandum to the Board
Motion for Determination of Waiver
Administrative Complaint
Copy of Returned Envelope
Affidavit of Service
Affidavits of Non-Receipt - Board Office
Affidavits of Non-Receipt - Agency Clerk's Office
PCP Memo
DOH Case Number 2012-13596
Supplemental Investigative Report dated 10-8-12,
With Exhibit S-1
Final Investigative Report with Exhibits 1-8
DOH Case Number 2012-13608
Final Investigative Report with Exhibits 1-2
Other Required Documents

Disciplinary Guidelines:

COUNT I - Section 465.016(1)(e), Florida Statutes (2011-2012):
Minimum - $2,500 fine and one (1) year probation.
Maximum - Revocation

COUNT II - Section 456.072(1)(c), Florida Statutes (2012):
Minimum – One (1) year suspension, two (2) year probation and $5,000 fine
Maximum - Revocation

PRELIMINARY CASE REMARKS: DETERMINATION OF WAIVER

This is a two count Administrative Complaint alleging Respondent violated the following Florida Statutes. The first count alleges Respondent violated Section 465.016(1)(e), Florida Statutes (2011-2012), when he stole and possessed hydrocodone and/or alprazolam from Walgreens, which he did not obtain lawfully or pursuant to a valid prescription or order, in violation of Section 893.13(6)(a), Florida Statutes (2012). The second count alleges Respondent violated Section 456.072(1)(c), Florida Statutes (2012), when he plead guilty to unlawful possession of a controlled substance, a third degree felony.

On February 14, 2013, an Order of Emergency Suspension of License ("ESO") was filed, suspending Respondent's license to practice as a registered pharmacy technician in the State of Florida. On February 19, 2013, a copy of the ESO was mailed to Respondent at his address of record in Jacksonville, Florida, via certified mail. This package was delivered to Respondent on February 23, 2013.

On February 28, 2013, an Administrative Complaint was filed against Respondent's license. On March 1, 2013, a letter enclosing the Administrative Complaint, Election of Rights, Explanation of Rights and Voluntary Relinquishment of License form was sent to Respondent at his address of record, via certified mail. The package was returned as "Unclaimed."

On May 14, 2013, a letter enclosing the Administrative Complaint, Election of Rights, Explanation of Rights and Voluntary Relinquishment of License form were personally served on Respondent's mother, Nadine Rodriguez, at Respondent's address of record and residence.

Respondent has not filed, with either the Department 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.

RECOMMENDATION OF THE DEPARTMENT

- Revocation.
- Costs.

CONSIDERATIONS SUPPORTING THE DEPARTMENT'S RECOMMENDATION

- Respondent has only been practicing since 11/4/09.
- The recommendation is consistent with the disciplinary guidelines.

TJM/tgc

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v.

CASE NOS. 2012-13596 & 2012-13608

RYAN D. RODRIGUEZ, 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 his 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 February 28, 2013. A copy of said Administrative Complaint is attached hereto as Petitioner's Exhibit A.

2. Copies of the Administrative Complaint, Explanation of Rights, Election of Rights, and Voluntary Relinquishment of License forms were sent to Respondent, via certified U.S. mail delivery, on March 1, 2013, (article number 7196 9008 9111 8828 2020), to 11179 Peerless Lane, Jacksonville, Florida 32246, Respondent's address of record. The documents were returned by the U.S. Postal Service as "UNCLAIMED." A copy of said returned envelope is attached hereto as Petitioner's Exhibit B.

3. Copies of the Administrative Complaint, Explanation of Rights, Election of Rights, and Voluntary Relinquishment of License forms were hand-served to Respondent's mother, Nadine Rodriguez, on May 14, 2013, at 11179 Peerless Lane, Jacksonville, Florida 32246, Respondent's address of record and residence. A copy of said Affidavit of Service is attached hereto 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 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 receives 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 both his address of record that a copy of the investigative file in this case shall be furnished to the Board of Pharmacy to establish a prima facie case regarding the violations as set forth in the Administrative Complaint.

8. The Petitioner has determined that there are no material facts in dispute and has concluded that Respondent has waived his right to elect the method of resolution.

9. The Petitioner 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 October 8-9, 2013, in Panama City, Florida.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy find that Respondent has waived his 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, 465, and 893, Florida Statutes, as alleged in the Administrative Complaint, impose discipline in accordance with the disciplinary guidelines, and enter a Final Order.

Respectfully submitted this 29th day of August, 2013.

Thomas J. Morton
Assistant General Counsel
Florida Bar Number 013771
Florida Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
(P) 850-245-4444
(F) 850-245-4684
(E) Thomas_morton@doh.state.fl.us

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished via U.S. Certified Mail on this 29th, day of August, 2013 to Ryan D. Rodriguez, R.P.T., 11179 Peerless Lane, Jacksonville, Florida 32246.

Certified Article Number
7196 9008 9111 9327 5130
SENDERS RECORD

Thomas J. Morton
Assistant General Counsel

TJM/tgc

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

V. **CASE NOS. 2012-13596**
2012-13608

RYAN DANIEL RODRIGUEZ, 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, Ryan Daniel Rodriguez, 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 Complaint, Respondent was a registered pharmacy technician within the state of Florida, having been issued registration number RPT 5867.

EXHIBIT
tabbies
A

3. Respondent's address of record is 11179 Peerless Lane, Jacksonville, Florida 32246.

4. At all times material to this Complaint, Respondent was registered to practice as a pharmacy technician in the State of Florida, pursuant to Chapter 465, Florida Statutes.

5. On multiple occasions between on or about January 2012, and on or about September 2012, Respondent stole hydrocodone and/or alprazolam from Walgreen's while working as a pharmacy technician.

6. Hydrocodone is commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes, 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.

7. Alprazolam is prescribed to treat anxiety. According to Section 893.03(4), Florida Statutes, alprazolam 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 alprazolam may lead to limited physical or psychological dependence relative to the substances in Schedule III.

8. On or about September 10, 2012, Respondent was arrested and charged with trafficking in opium or any derivative and theft of a controlled substance, in connection with his theft while employed as a pharmacy technician with Walgreen's.

9. On or about October 24, 2012, in the Circuit Court of the Fourth Judicial Circuit in and for Duval County, Florida, in case number 16-2012-CF-008994, Respondent entered a plea of guilty to unlawful possession of a controlled substance, a third degree felony, in violation of Section 893.13(6)(a), Florida Statutes (2012).

10. Section 465.014(8), Florida Statutes (2011-2012), subjects a registered pharmacy technician to discipline for committing an act that constitutes grounds for discipline as set forth in Section 456.072(1), or Chapter 465, Florida Statutes (2011-2012).

COUNT ONE

11. Petitioner realleges and incorporates by reference the allegations in paragraphs one (1) through ten (10) as if fully set forth herein.

12. Section 465.016(1)(e), Florida Statutes (2011-2012), subjects a licensee to discipline for violating the provisions of Chapter 893, Florida Statutes (2011-2012).

13. Section 893.13(6)(a), Florida Statutes (2011-2012), provides, in part:

> 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.

14. Respondent stole, and possessed, hydrocodone and/or alprazolam from Walgreen's, which he did not obtain lawfully or pursuant to a valid prescription or order.

15. Based on the foregoing, Respondent violated Section 465.016(1)(e), Florida Statutes (2011-2012), when he stole, and possessed, hydrocodone and/or alprazolam from Walgreen's, which he did not obtain lawfully or pursuant to a valid prescription or order, in violation of Section 893.13(6)(a), Florida Statutes (2012).

COUNT TWO

16. Petitioner realleges and incorporates by reference the allegations in paragraphs one (1) through ten (10) as if fully set forth herein.

17. Section 456.072(1)(c), Florida Statutes (2012), subjects a licensee to discipline for entering a plea of guilty to a crime which relates to the practice, or the ability to practice, a licensee's profession.

18. Respondent pled guilty to unlawful possession of a controlled substance, which stemmed from his theft of hydrocodone and/or alprazolam while employed as a pharmacy technician with Walgreen's, and which relates to Respondent's practice, or ability to practice, as a pharmacy technician.

19. Based on the foregoing, Respondent violated Section 456.072(1)(c), Florida Statutes, (2012), when he pled guilty to unlawful possession of a controlled substance.

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 28th day of February, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Thomas J. Morton
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar # 13771
Phone - (850) 245-4444 x 8212
Fax - (850) 245-4684
thomas_morton@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Angel Sanders
DATE: 2-28-13

PCP: February 28, 2013
PCP Members: DeAnn M. Mullins, BPharm and Debra B. 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.

FLORIDA DEPARTMENT OF
HEALTH

Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, Florida 32399-3265

7196 9008 9111 8828 2020

EXHIBIT B

RETURNED TO SENDER

- ☐ MOVED, LEFT NO ADDRESS
- ☐ FORWARDING ORDER EXPIRED
- ☐ ATTEMPTED - NOT KNOWN
- ☐ UNCLAIMED ☐ REFUSED
- ☐ NO SUCH STREET
- ☐ NO SUCH NUMBER
- ☐ INSUFFICIENT ADDRESS

Ryan D. Rodriguez, R.P.T.
11179 Peerless Lane
Jacksonville, Florida 32246

2013 APR 30 PM 2:20

PETITIONER'S EXHIBIT

c

Thank you for using Return Receipt Service

RETURN RECEIPT REQUESTED
USPS® MAIL CARRIER
DETACH ALONG PERFORATION

2. Article Number

7196 9008 9111 8828 2020

3. Service Type CERTIFIED MAIL™

Restricted Delivery? *(Extra Fee)* ☐ Yes

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? ☐ Yes
If YES, enter delivery address below: ☐ No

RETURNED TO SENDER

- ☐ MOVED, LEFT NO ADDRESS
- ☐ FORWARDING ORDER EXPIRED
- ☐ ATTEMPTED - NOT KNOWN
- ☐ UNCLAIMED ☐ REFUSED
- ☐ NO SUCH STREET
- ☐ NO SUCH NUMBER
- ☐ INSUFFICIENT ADDRESS

LN 2/9

TJ Morton; 3-1-13; Rodriguez 12-13596 & 12-13608; AC, EOR, ExpOR, VR

PS Form 3811, January 2005 Domestic Return Receipt

Thank you for using Return Receipt Service

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

Department of Health
Petitioner

vs

Case No. 201213608
201213596

Ryan D. Rodriguez, RPT
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 05/14/13, Affiant made a diligent effort to locate Respondent, to serve X 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:

X Affiant made personal service on Respondent's mother NADINE RODRIGUEZ at their address of record 11179 Peerless Lane, Jacksonville, FL 32246.

_____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 Stephen Kayser 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 20th day of May 20 13.

Notary Public-State of Florida

My Commission Expires

Paul D Kloko

Type or Print Name

EXHIBIT
tabbies
C

PAUL D. KLOKO
Commission # EE 194782
Expires May 2, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

I, Mark Whitten, hereby certify in my official capacity as custodian for the Board of Pharmacy, licensure files that the Board of Pharmacy as of August 27, 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **Ryan D. Rodriguez, R.P.T.; Case Numbers 2012-13596 and 2012-13608**, which would affect the Subject's substantial interests or rights.

Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Mark Whitten, 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 27th day of August, 2013.

Notary Public

LORRAINE GAIL CURRY
MY COMMISSION # EE 97887
EXPIRES: May 28, 2015
Bonded Thru Notary Public Underwriters

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 **Ryan D. Rodriguez, R.P.T.; Case Numbers 2012-13596 and 2012-13608**, which would affect the Respondent's substantial interests or rights.

Angel Sanders
Custodian of Record
Department Agency Clerk's Office

STATE OF FLORIDA
COUNTY OF Leon

Before me, personally appeared Angel Sanders, whose identity is personally known to me or known to me by PK (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 26th day of August, 2013.

Angela Barton
Notary Public

My Commission Expires:

ANGELA BARTON
NOTARY PUBLIC - STATE OF FLORIDA
COMMISSION # DD922154
EXPIRES 9/1/2013
BONDED THRU 1-888-NOTARY1

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. Ryan D. Rodriguez, RPT**
DOH Case Number 2012-13608 & 2012-13596

MEMBERS: Debra B. Glass, BPharm, and DeAnn Mullins, BPharm

DATE OF PCP: February 28, 2013 **AGENDA ITEM: A4(TJM)**

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:

Count I: Section 465.016(1)(e), Florida Statutes (2011-2012), in violation of Section 893.13(6)(a), Florida Statutes (2012)

Count II: Section 456.072(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)
c)

____ Upon **reconsideration**, dismiss

____ **Other** _____

3-4-13

Chair, Probable Cause Panel
Board of Pharmacy

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.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NOS. 2012-13596**
2012-13608

RYAN DANIEL RODRIGUEZ, R.P.T.,

Respondent.
_____/

MOTION TO ASSESS COSTS
IN ACCORDANCE WITH SECTION 456.072(4)

The Department of Health, by and through counsel, moves the Board of Pharmacy for entry of a Final Order assessing costs against Respondent for the investigation and prosecution of these cases 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 actions and will enter a Final Order.

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 affidavits (Exhibits A and B), the investigation and prosecution of these cases has resulted in costs in the total amount of $2,661.05, based on the following itemized statement of costs:

a. Total costs for Complaints $248.63
b. Total costs for Investigations $1,474.33
c. Total costs for Legal $933.15
d. Total costs for Compliance $4.94
e. Total costs for expenses $0.00

4. The attached affidavit reflects the Department's costs for attorney time in these cases as $933.15 (Exhibit C). The cost of obtaining an affidavit from an outside attorney will be greater than $933.15. Therefore, the Department is not seeking costs for attorney time in these cases.

5. Should 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 objections are made, Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavits attached as Exhibits A and B, and any timely-filed written objections.

6. Petitioner requests that the Board grant this motion and assess costs in the amount of $1,727.90 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 (2012).

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against Respondent in the amount of $1,727.90.

DATED this 29th day of August, 2013.

Respectfully submitted,

Thomas J. Morton
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar # 0013771
(850) 245-4444 Phone
(850) 245-4684 FAX

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Amended Motion to Assess Costs has been provided to Respondent, Ryan Daniel Rodriguez, R.P.T., at 11179 Peerless Lane, Jacksonville, Florida 32246, by U.S. Certified Mail this 29th day of August, 2013.

Certified Article Number
7196 9008 9111 9327 5017
SENDERS RECORD

Thomas J. Morton
Assistant General Counsel

TJM/tgc

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.

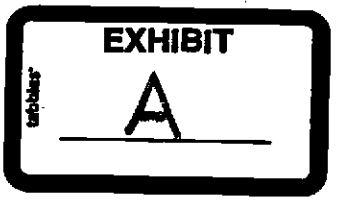
4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number **2012-13596** (Department of Health v. **Ryan D. Rodriguez, R.P.T.**) are **ONE THOUSAND FIVE HUNDRED NINETY-THREE DOLLARS AND SIXTEEN CENTS ($1,593.16).**

6) The costs for DOH case number **2012-13596** (Department of Health v. **Ryan D. Rodriguez, 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 number **2012-13596** (Department of Health v. **Ryan D. Rodriguez, 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



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 29 day of August 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: 201213596

Subject's Name: RODRIGUEZ, RYAN DANIEL

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.00	$57.62
Investigation:	16.60	$1,017.18
Legal:	5.00	$518.36
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	22.60	$1,593.16
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,593.16

EXHIBIT
tabbies
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Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201213596

Report Date 08/29/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA107	1.00	$57.62	$57.62	09/13/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
Sub Total	**1.00**		**$57.62**			
INVESTIGATIVE SERVICES UNIT						
JI91	0.50	$61.19	$30.60	09/17/2012	4	ROUTINE INVESTIGATIVE WORK
JI91	1.30	$61.19	$79.55	09/17/2012	58	TRAVEL TIME
JI91	0.80	$61.19	$48.95	09/17/2012	76	REPORT PREPARATION
JI91	0.30	$61.19	$18.36	09/18/2012	4	ROUTINE INVESTIGATIVE WORK
JI91	0.50	$61.19	$30.60	09/18/2012	76	REPORT PREPARATION
JI91	0.30	$61.19	$18.36	09/19/2012	76	REPORT PREPARATION
JI91	0.30	$61.19	$18.36	09/19/2012	4	ROUTINE INVESTIGATIVE WORK
JI91	0.30	$61.19	$18.36	09/20/2012	76	REPORT PREPARATION
JI91	0.30	$61.19	$18.36	09/20/2012	4	ROUTINE INVESTIGATIVE WORK
JI91	0.20	$61.19	$12.24	09/21/2012	4	ROUTINE INVESTIGATIVE WORK
JI91	0.40	$61.19	$24.48	09/24/2012	4	ROUTINE INVESTIGATIVE WORK
JI91	0.70	$61.19	$42.83	09/25/2012	4	ROUTINE INVESTIGATIVE WORK
JI91	0.80	$61.19	$48.95	09/25/2012	76	REPORT PREPARATION
JI91	0.40	$61.19	$24.48	09/25/2012	76	REPORT PREPARATION
JI91	3.00	$61.19	$183.57	09/26/2012	4	ROUTINE INVESTIGATIVE WORK
JI91	0.70	$61.19	$42.83	09/26/2012	76	REPORT PREPARATION
JI91	0.90	$61.19	$55.07	09/27/2012	4	ROUTINE INVESTIGATIVE WORK
JI91	1.20	$61.19	$73.43	09/27/2012	76	REPORT PREPARATION
JI91	0.90	$61.19	$55.07	09/28/2012	76	REPORT PREPARATION
JI91	0.70	$61.19	$42.83	09/28/2012	4	ROUTINE INVESTIGATIVE WORK
JI91	0.90	$61.19	$55.07	10/08/2012	76	REPORT PREPARATION
JI91	0.30	$61.19	$18.36	10/25/2012	4	ROUTINE INVESTIGATIVE WORK
JI91	0.40	$61.19	$24.48	10/31/2012	4	ROUTINE INVESTIGATIVE WORK
JI88	0.50	$63.98	$31.99	05/20/2013	6	SUPPLEMENTAL INVESTIGATION

EXHIBIT 2

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201213596

Report Date 08/29/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
Sub Total	**16.60**		**$1,017.18**			
PROSECUTION SERVICES UNIT						
HLL94A	0.10	$102.41	$10.24	09/18/2012	37	REVIEW LETTER
HLL94A	0.10	$102.41	$10.24	09/18/2012	36	PREPARATION OR REVISION OF LETTER
HLL70B	0.40	$102.41	$40.96	09/25/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL70B	2.20	$102.41	$225.30	10/04/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL70B	0.60	$102.41	$61.45	10/05/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL70B	0.50	$106.35	$53.18	10/16/2012	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFF
HLL70B	0.80	$106.35	$85.08	02/20/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL70B	0.30	$106.35	$31.91	08/27/2013	91	BOARD MEETING PREPARATION
Sub Total	**5.00**		**$518.36**			

Total Cost	**$1,593.16**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 08/29/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NOS. 2012-13596**
2012-13608

RYAN DANIEL RODRIGUEZ, R.P.T.,

Respondent.
_____/

MOTION TO ASSESS COSTS
IN ACCORDANCE WITH SECTION 456.072(4)

The Department of Health, by and through counsel, moves the Board of Pharmacy for entry of a Final Order assessing costs against Respondent for the investigation and prosecution of these cases 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 actions and will enter a Final Order.

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 affidavits (Exhibits A and B), the investigation and prosecution of these cases has resulted in costs in the total amount of $2,661.05, based on the following itemized statement of costs:

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b. Total costs for Investigations $1,474.33
c. Total costs for Legal $933.15
d. Total costs for Compliance $4.94
e. Total costs for expenses $0.00

4. The attached affidavit reflects the Department's costs for attorney time in these cases as $933.15 (Exhibit C). The cost of obtaining an affidavit from an outside attorney will be greater than $933.15. Therefore, the Department is not seeking costs for attorney time in these cases.

5. Should 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 objections are made, Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavits attached as Exhibits A and B, and any timely-filed written objections.

6. Petitioner requests that the Board grant this motion and assess costs in the amount of $1,727.90 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 (2012).

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against Respondent in the amount of $1,727.90.

DATED this 29th day of August, 2013.

Respectfully submitted,

Thomas J. Morton
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar # 0013771
(850) 245-4444 Phone
(850) 245-4684 FAX

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Amended Motion to Assess Costs has been provided to Respondent, Ryan Daniel Rodriguez, R.P.T., at 11179 Peerless Lane, Jacksonville, Florida 32246, by U.S. Certified Mail this 29th day of August, 2013.

Certified Article Number
7196 9008 9111 9327 5017
SENDERS RECORD

Thomas J. Morton
Assistant General Counsel

TJM/tgc

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.

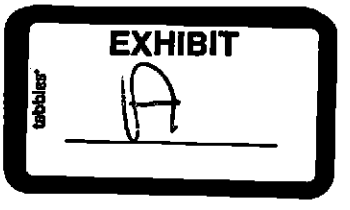
4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number **2012-13608** (Department of Health v. **Ryan D. Rodriguez, R.P.T.**) are **ONE THOUSAND NINETY-NINE DOLLARS AND EIGHTY CENTS ($1,099.80).**

6) The costs for DOH case number **2012-13608** (Department of Health v. **Ryan D. Rodriguez, 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 number **2012-13608** (Department of Health v. **Ryan D. Rodriguez, 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



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 29 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: 201213608

Subject's Name: RODRIGUEZ, RYAN DANIEL

	***** Cost to Date *****	
	Hours	Costs
Complaint:	3.40	$191.01
Investigation:	7.50	$457.15
Legal:	4.20	$446.70
Compliance:	0.15	$4.94
	**********	**********
Sub Total:	15.25	$1,099.80
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,099.80

EXHIBIT
tabbies 1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201213608

Report Date 08/29/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
COMPLIANCE MANAGEMENT UNIT						
HC08	0.10	$33.33	$3.33	02/14/2013	119	REVIEWING FO/CITATIONS & TERM INPUT
HC27	0.05	$32.13	$1.61	02/28/2013	138	COMPLAINT DELETIONS/CORRECTIONS/UPDATES
Sub Total	**0.15**		**$4.94**			
CONSUMER SERVICES UNIT						
HA107	1.00	$57.62	$57.62	09/13/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HA107	0.60	$57.62	$34.57	10/17/2012	25	REVIEW CASE FILE
HA107	0.60	$54.90	$32.94	11/01/2012	25	REVIEW CASE FILE
HA107	1.20	$54.90	$65.88	12/06/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HA107	2.00	$54.90	$109.80	12/12/2012	77	PREPARATION OF DESK INVESTIGATION SYNOPSIS
HA107	0.50	$54.90	$27.45	12/13/2012	77	PREPARATION OF DESK INVESTIGATION SYNOPSIS
Sub Total	**5.90**		**$328.26**			
INVESTIGATIVE SERVICES UNIT						
JI88	1.00	$63.98	$63.98	02/20/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
JI88	1.00	$63.98	$63.98	02/25/2013	6	SUPPLEMENTAL INVESTIGATION
JI88	0.50	$63.98	$31.99	02/26/2013	6	SUPPLEMENTAL INVESTIGATION
JI88	1.50	$63.98	$95.97	05/13/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
JI88	1.00	$63.98	$63.98	05/14/2013	6	SUPPLEMENTAL INVESTIGATION
Sub Total	**5.00**		**$319.90**			
PROSECUTION SERVICES UNIT						
HLL70B	0.50	$106.35	$53.18	12/20/2012	81	ESO/ERO
HLL70B	0.50	$106.35	$53.18	12/21/2012	81	ESO/ERO
HLL70B	0.10	$106.35	$10.64	12/26/2012	37	REVIEW LETTER

EXHIBIT 2

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201213608

Report Date 08/29/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
HLL70B	0.20	$106.35	$21.27	12/27/2012	36	PREPARATION OR REVISION OF LETTER
HLL83B	0.20	$106.35	$21.27	02/12/2013	81	ESO/ERO
HLL70B	1.20	$106.35	$127.62	02/12/2013	81	ESO/ERO
HLL70B	0.80	$106.35	$85.08	02/20/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL70B	0.30	$106.35	$31.91	02/27/2013	89	PROBABLE CAUSE PREPARATION
HLL70B	0.30	$106.35	$31.91	02/28/2013	63	PRESENTATION OF CASES TO PROBABLE CAUSE PANEL
HLL70B	0.10	$106.35	$10.64	03/01/2013	90	POST PROBABLE CAUSE PROCESSING
Sub Total	*4.20*		**$446.70**			

Total Cost	**$1,099.80**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 08/29/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

Final Order No. DOH-13-0267-ESO -MQA
FILED DATE: FEB 14 2013
Department of Health
By: [signature]
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the Registration of
Ryan Daniel Rodriguez, RPT
License No.: RPT 5867
Case No.: 2012-13608

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 Ryan D. Rodriguez, RPT ("Mr. Rodriquez"), to practice as a registered pharmacy technician in the State of Florida. Mr. Rodriguez holds license number RPT 5867 and his mailing address of record is 11179 Peerless Lane, Jacksonville, Florida 32246. The following Findings of Fact and Conclusions of Law support the emergency suspension of Mr. Rodriguez's license to practice as a registered 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 Mr. Rodriguez's license to practice as a registered

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, Mr. Rodriguez was licensed to practice as a registered pharmacy technician pursuant to Chapter 465, Florida Statutes (2012).

3. On or about October 24, 2012, in the Circuit Court of the Fourth Judicial Circuit in and for Duval County, Florida, in case number 16-2012-CF-008994, Mr. Rodriguez entered a plea of guilty to unlawful possession of a controlled substance, a third degree felony, in violation of Section 893.13(6)(a), Florida Statutes (2012).

4. Section 456.074(1), Florida Statutes (2012), 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 felony under Chapter 893, Florida Statutes, regardless of adjudication.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General concludes as follows:

1. The Department of Health has jurisdiction pursuant to Sections 20.43, and 456.074(1), Florida Statutes (2012).

2. The Department must suspend Mr. Rodriguez's license to practice as a registered pharmacy technician in accordance with Section 456.074(1), Florida Statutes (2012).

3. This summary procedure is fair under the circumstances to adequately protect the public.

WHEREFORE, in accordance with Section 456.074(1), Florida Statues, it is ORDERED THAT:

1. The license of Ryan D. Rodriguez, RPT, license number RPT 5867, is immediately suspended.

2. A proceeding seeking formal suspension or discipline of the license of Mr. Rodriguez to practice as a registered pharmacy technician will be promptly instituted and acted upon in compliance with Section 120.569, Florida Statutes (2012).

DONE and ORDERED this 14th day of February, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

PREPARED BY:
Thomas J. Morton
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar # 13771
(850) 245-4444 x 8212 phone
(850) 245-4662 fax
thomas_morton@doh.state.fl.us

In Re: The Emergency Suspension of the License of
Ryan D. Rodriguez, RPT
License Number: RPT 5867
Case Number: 2012-13608

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 one copy of a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, with the Department of Health and a second copy of the Petition accompanied by a filing fee prescribed by law with the District Court of Appeal within thirty (30) days of the date this Order is filed.

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

Department of Health
Petitioner

vs

Case No. 201213608

Ryan D. Rodriguez, RPT
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 02/20/13, 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 mother NADINE RODRIGUEZ at their address of record 11179 Peerless Lane, Jacksonville, FL 32246.

_____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.); and others: _____

Affiant

State Of Florida
County Of Duval

Before me, personally appeared Stephen Kayser whose identity is known to me by personal knowledge (type of identification) and who, acknowledges that his/her signature appears above.

Swom to or affirmed by Affiant before me this 25th day of February 20 13.

Notary Public-State of Florida

My Commission Expires

Amy L Dennis
Type or Print Name

AMY L. DENNIS
Commission # DD 873183
Expires March 23, 2013
Bonded Thru Troy Fain Insurance 800-385-7019

EXHIBIT #S-2 PAGE # 8

Track & Confirm

GET EMAIL UPDATES PRINT DETAILS

YOUR LABEL NUMBER	SERVICE	STATUS OF YOUR ITEM	DATE & TIME	LOCATION	FEATURES
71969008911188281900		Delivered	February 23, 2013, 11:05 am	JACKSONVILLE, FL 32246	Certified Mail™ Return Receipt Electronic
		Depart USPS Sort Facility	February 22, 2013	JACKSONVILLE, FL 32203	
		Processed through USPS Sort Facility	February 22, 2013, 5:12 am	JACKSONVILLE, FL 32203	

Check on Another Item

What's your label (or receipt) number?

2. Article Number

7196 9008 9111 8828 1900

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly) B. Date of Delivery 2-23-13

C. Signature X ☐ Agent ☐ Addressee

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type CERTIFIED MAIL™

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Ryan Daniel Rodriquez, RPT
11179 Peerless Lane
Jacksonville, FL 32246

ESO : 12-13608 2/19/13 T. Morton

PS Form 3811, January 2005 Domestic Return Receipt

MEMORANDUM

TO: Florida Administrative Weekly, Liz Cloud

FROM: Berita Pope, Regulatory Supervisor / Consultant

RE: Ryan Daniel Rodriguez, RPT., License # RPT 5867 (FAW # 12668411)

CASE NO: 2012-13608

DATE: February 19, 2013

Attached please find notice of the issuance of an Emergency Suspension of License for notice in the next issue of the Florida Administrative Weekly.

On February 14, 2013, the State Surgeon General issued an Order of Emergency Suspension of License with regard to the license of Ryan Daniel Rodriquez, License # RPT 5867 This Emergency Suspension of License 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: Jacksonville	Date of Case: 9/13/12	Case Number: RPT 2012-13596

Subject:

RYAN DANIEL RODRIGUEZ, REGISTERED PHARMACY TECHNICIAN

11179 Peerless Lane

Jacksonville, Fl 32246

H (904) 945-9059

Source:

DEPARTMENT OF HEALTH/ INVESTIGATIVE SERVICES UNIT - JACKSONVILLE

Prefix: RPT	License #: 5867	Profession: Registered Pharmacy Technician	Board: Pharmacy	Report Date: 9/28/12

Period of Investigation: 9/17/12 – 9/28/12

Type of Report: FINAL

Alleged Violation: F.S. 456.072(1)(a)(m)(z)(dd) "The following acts..." "Making misleading, deceptive..." "Making deceptive, untrue, or fraudulent representations..." "Being unable to practice with reasonable..." "Violating any provision of this chapter..." F.S. 465.016(1)(d)2.3.(i)(m)(r) "The following acts..." "Being unfit or incompetent..." "The misuse or abuse of any medicinal drug..." "Any abnormal physical or mental condition..." "Compounding, dispensing, or distributing a legend drug..." "Being unable to practice pharmacy with reasonable skill..." "Violating any provision of this chapter..."

Synopsis: This investigation is predicated upon an internal complaint from the DEPARTMENT OF HEALTH INVESTIGATIVE SERVICES UNIT - JACKSONVILLE in regard to RYAN RODRIGUEZ, a Registered Pharmacy Technician at Walgreens alleging that on 9/10/12 RODRIGUEZ was arrested by the Jacksonville Sheriff's Office on one count of Trafficking in Opium or Derivative and a second count of Theft of Any Amount of Controlled Substance. Through an investigation by the Jacksonville Sheriff's Office it also became known that RODRIGUEZ was involved in diversion of narcotics from four different Walgreen's stores. RODRIGUEZ admitted that he had taken controlled substances for over a year from Walgreen's stores and was ultimately terminated, (Exhibit 1).

RODRIGUEZ was notified of the investigation by a letter hand-served by this Investigator on 9/17/12 to his address of record. RODRIGUEZ was provided a copy of the Case Summary and attachments, (Exhibit 2).

A search of the DOH licensure database reveals RODRIGUEZ is currently licensed as a Registered Pharmacy Technician. RODRIGUEZ'S license is currently Clear/Active. RODRIGUEZ first obtained his license on 11/04/09.

A patient advisement letter was not necessary as this case does not involve patient care.

RODRIGUEZ is not known to be represented by an attorney with this matter.

RODRIGUEZ in a telephone conversation with this Investigator on 9/26/12 indicated that he wishes to keep his Registered Pharmacy Technician license, and will be responding to the Board by way of a written response in the near future. Any information and/or interviews conducted subsequent to the completion of this final report will be forwarded in the form of a supplemental report.

Related Case: None

Investigator/Date:

Todd P. McCormick
Investigation Specialist II (JI-91) 9/28/12

Approved By/Date:

Wendy Fo
Investigator Supervisor (JI-7

Distribution: HQ/ISU

INV Form 300 7/02

TABLE OF CONTENTS

***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. In addition to the Case Summary, additional records were provided. Through review of these records this Investigator noted:

- A copy of a Healthcare Practitioner Complaint Form
- A copy of a Jacksonville Sheriff's Office Arrest and Booking Report, (Incident Number 667762) which indicates that the Jacksonville Sheriff's Office was contacted by RICHARD MCGOWAN, a Walgreen's Loss Prevention Officer who advised that RODRIGUEZ has been stealing Hydrocodone and Xanax from various Walgreen's stores that he had been working in Duval county. Investigation revealed that RODRIGUEZ had been stealing controlled substances from the following Walgreen's pharmacies located at: 6006 Beach Boulevard, 14450 Beach Boulevard, 10899 Baymeadows Road, and 406 Atlantic Boulevard. On 7/08/12, MCGOWAN interviewed RODRIGUEZ at the Walgreen's located at 6006 Beach Boulevard, at which point RODRIGUEZ admitted that he had been taking both controlled substances from the listed pharmacies for the past year. RODRIGUEZ also admitted this information to the Jacksonville Sheriff's Office. RODRIGUEZ further indicated that he was addicted to the Hydrocodone, which was why he was taking the medications. Walgreens suffered a total loss of 2,500 Hydrocodone tablets, and 800 Xanax tablets which totaled over $1900. The amount of Hydrocodone taken well exceeded the trafficking amount of four grams. RODRIGUEZ completed a written statement.

Exhibit 3 is a copy of Subpoena A 0074296 issued to Walgreens for a copy of evidence of alleged medication diversion.

Exhibit 4 is a copy of Administrative Paperwork from Walgreens received via UPS on 9/26/12. A copy of a completed Walgreen's Certification of Records form is included. Through review of the Administrative Paperwork this Investigator noted:

- A copy of RICHARD MCGOWAN'S, (Walgreen's Loss Prevention Officer) Case Inquiry Report, (Case Number 1241763) which indicates that at a Walgreens store, located at 6006 Beach Boulevard in Jacksonville, Fl, RODRIGUEZ admitted to stealing 1,310 Hydrocodone 10-325 tablets, 1,310 Hydrocodone 10-500 tablets, and 400 Alprazolam 2mg tablets, which is valued at $1,995.52 for over "the past 8 months". The investigation was predicated on noticing suspicious negative adjustments at several stores while reviewing the "LPxRx" reports. The suspects were narrowed down to RODRIGUEZ, who worked as a floater technician at the stores which were experiencing the shortages. RODRIGUEZ was interviewed and provided a full written admission for the theft of drugs. RODRIGUEZ was arrested and is pending prosecution. During the investigation, MCGOWAN noticed suspicious negative adjustments for Hydrocodone 10-325, Hydrocodone 10-500, and Alprazolam 2mg during the month of 4/12. MCGOWAN noticed these suspicious negative adjustments for stores # 4281 (14405 Beach Boulevard Jacksonville, Fl), #4310 (406 Atlantic Boulevard Neptune Beach, Fl), # 4327 (6006 Beach Boulevard Jacksonville, Fl). A further 52-week history on these drugs provided further confirmation of the suspicious activity. RODRIGUEZ was identified as a floater technician working at these stores during the time of the suspicious negative adjustments. On 9/08/12, MCGOWAN was alerted by store #4310 (406 Atlantic Boulevard Neptune Beach, Fl) that Alprazolam 2mg were missing during a narcotic count. RODRIGUEZ had been working as a floater at this store at the time of the suspicious negative adjustment. RODRIGUEZ was interviewed at the office in store # 4327, (6006 Beach Boulevard Jacksonville, Fl) and stated that he stole the drugs during the delete process. RODRIGUEZ further stated that he took Hydrocodone/Alprazolam prescriptions from the bins, put the stolen pills into his pocket and discarded the vials into the "DPI" box.

RODRIGUEZ maintained that he stole the drugs due to a back injury that he had suffered in high school, and agreed to provide Walgreens full restitution in the amount of $1,995.52.

- A copy of RODRIGUEZ'S voluntary written statement dated 9/10/12 in which he indicates that he had been addicted "off and on" to Hydrocodone for about a year. He did not have any medical coverage to go to a doctor, so he "decided to take some from the certain pharmacies" that he was working at. At times RODRIGUEZ would take a prescription of 40-60 tablets a day, and at other times he took more. RODRIGUEZ admits to taking narcotics from the following stores: 05788, (10899 Baymeadows Road Jacksonville, Fl), #4281, (14405 Beach Boulevard Jacksonville, Fl) # 4310, (406 Atlantic Boulevard Neptune Beach, Fl), and #4327, (6006 Beach Boulevard Jacksonville, Fl). RODRIGUEZ further admitted to taking the pills from the pharmacies by "doing the deletes", and putting the empty bottles into the "DPI" box.
- A copy of RODRIGUEZ'S Time Card Entries form which cover the time period of 9/01/11 through 6/28/12. This Investigator noted RODRIGUEZ was working in Walgreens stores # 4281 (14405 Beach Boulevard Jacksonville, Fl), #4310 (406 Atlantic Boulevard Neptune Beach, Fl), # 4327 (6006 Beach Boulevard Jacksonville, Fl) during the 4/12 time period. In addition this Investigator noted that on 4/09/12 RODRIGUEZ worked at store #4310 (406 Atlantic Boulevard Neptune Beach, Fl) location.
- A copy of "Pharmacy 52 Week WIC Activity" Reports for the following Walgreens stores: # 4281 (14405 Beach Boulevard Jacksonville, Fl), #4310 (406 Atlantic Boulevard Neptune Beach, Fl), # 4327 (6006 Beach Boulevard Jacksonville, Fl) and #5788 (10899 Baymeadows Road Jacksonville, Fl). Through review of the reports this Investigator noted negative adjustments of stores # 4281 (14405 Beach Boulevard Jacksonville, Fl), #4310 (406 Atlantic Boulevard Neptune Beach, Fl), # 4327 (6006 Beach Boulevard Jacksonville, Fl) involving Hydrocodone 10-325 tablets, Hydrocodone 10-500 tablets during the 4/12 time period.

Exhibit 5 is a copy of Administrative Paperwork from Walgreens received via email on 9/26/12. This Investigator placed the information onto a CD format. Through review of the Administrative Paperwork this Investigator noted corresponding Narcotic Dispensing Reports, (additional information) for the time period of 9/10/11 through 9/10/12 for each of the four Walgreen's store locations: # 4281 (14405 Beach Boulevard Jacksonville, Fl), #4310 (406 Atlantic Boulevard Neptune Beach, Fl), # 4327 (6006 Beach Boulevard Jacksonville, Fl) and #5788 (10899 Baymeadows Road Jacksonville, Fl).

INVESTIGATOR'S NOTE:
Through speaking with the Walgreen's Legal Department on 9/25/12 this Investigator was advised that RODRIGUEZ has been terminated, however there is no actual termination form in which can be produced.

Exhibit 6 is a copy of RODRIGUEZ'S Sworn Statement provided to the Jacksonville Sheriff's Office received from the Assistant State Attorney's Office via facsimile on 9/28/12. Through review of RODRIGUEZ'S Sworn Statement this Investigator noted that RODRIGUEZ indicated that he has been addicted to Hydrocodone for about a year. RODRIGUEZ did not have any medical coverage to see a doctor, so he decided to take some from the "certain pharmacies" that he was working at. RODRIGUEZ "started taking them about a year ago, but was able to get off of them for a short period of time and stop". RODRIGUEZ tried to stop consuming the pills, but has been unable to. RODRIGUEZ wants to get off, but he can not because every time he tries to get off the pills, he suffers from withdrawals.

Exhibit 7 is a copy of an IPN/DOH Investigator Communication Form this Investigator faxed to PRN for current PRN activity of RODRIGUEZ on 9/17/12.

Exhibit 8 is a copy of an IPN/DOH Investigator Communication Form response received via facsimile from PRN on 9/18/12. Through review of this response form this Investigator noted that RODRIGUEZ was not reported to, nor did RODRIGUEZ contact PRN in reference to this case.

INTERVIEW OF RICHARD MCGOWAN (WITNESS)

Loss Prevention Officer
Walgreens
800 Southpoint Parkway
Jacksonville, Fl 32216
W (904) 296-1043
C (904) 487-1827

On 9/18/12 this Investigator interviewed MCGOWAN via telephone from his place of employment listed above. MCGOWAN essentially stated:

- MCGOWAN, a Loss Prevention Manager had observed "negative adjustments" on pharmacy reports.
- Due to the reports of narcotic shortages an investigation was commenced.
- RODRIGUEZ became the "common denominator" during the investigation, as he was a floater, and had worked at the various Walgreen's pharmacies that reported "negative adjustments".
- RODRIGUEZ was interviewed by MCGOWAN, at which time he admitted to the theft of Hydrocodone and Xanax.
- RODRIGUEZ further admitted that he had given some pills to friends, as well as used the pills for his own personal consumption.
- There are no known witnesses to RODRIGUEZ'S narcotic activity.
- The different pharmacists that worked with RODRIGUEZ did not observe anything and would have no additional information other than what is printed out in the pharmacy reports.
- RODRIGUEZ has been terminated from his position.
- MCGOWAN had no additional information other than what he has provided in his report, (Exhibit 4).

MCGOWAN had no additional information to add at this time.

INTERVIEW OF BRADLEY BODIFORD (WITNESS)

Assistant State Attorney
Office of the State Attorney
220 East Bay Street
Jacksonville, Fl 32202
W (904) 630-2379

On 9/28/12 this Investigator interviewed BODIFORD via telephone from his place of employment listed above. BODIFORD essentially stated:

- RODRIGUEZ will be formally charged on one count of Theft of a Controlled Substance, and a second count of Possession of a Controlled Substance during his arraignment which is scheduled to be held on 10/03/12.

- RODRIGUEZ has had a clean criminal record leading up to this incident.
- BODIFORD will be releasing RODRIGUEZ'S sworn statement that he made to the Jacksonville Sheriff's Office to this Investigator, (Exhibit 6).

BODIFORD had no additional information to add at this time.

INVESTIGATOR'S NOTE:
On 9/17/12, this Investigator hand served a Subject Notification Letter and Voluntary Relinquishment of License paperwork to RODRIGUEZ'S address of record. On 9/26/12, this Investigator followed up with a telephone call to RODRIGUEZ'S residence. RODRIGUEZ informed this Investigator that he wished to keep his Registered Pharmacy Technician license, and would be providing a written response as to the allegations in the near future. As of this date, this Investigator has not received a response. Any information and/or interviews conducted subsequent to the completion of this final report will be forwarded in the form of a supplemental report.

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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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

INVESTIGATIVE REPORT

Office:	Date of Complaint:	Case Number:
CONSUMER SERVICES	December 6, 2012	201213608

Subject:	Source:
RYAN DANIEL RODRIGUEZ, RPT 11179 Peerless Lane Jacksonville, FL 32246 (904) 945-9059	**DEPARTMENT OF HEALTH**

Prefix:	License # :	Profession:	Board:	Report Date:
RPT	5867	Registered Pharmacy Technician	Pharmacy	12/12//12

Period of Investigation:	Type of Report:
12/10/12 through 12/12/12	FINAL

Alleged Violation: § 456.072(1)(c)(dd); 465.016(1)(f)(r),FS; 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 DEPARTMENT OF HEALTH alleging RODRIGUEZ was convicted on 10/24/12 in Duval County for Theft of Controlled Substance [812.014(2)(c), FS] and Possession of Controlled Substance [893.13(6)(a), FS]. Court Documents indicate RODRIGUEZ was Adjudicated Guilty Withheld and placed on Probation. (EXHIBIT #1)

RODRIGUEZ was notified of this complaint by letter, dated 12/10/12. 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 reviewed on 12/12/12. It reflects RODRIGUEZ is duly licensed to practice as a Registered Pharmacy Technician in the State of Florida under Clear / Active status.

No patient(s) was/were identified, thus patient notification was not required.

RODRIGUEZ does not appear to be represented by counsel in this matter as of the date of this report.

RODRIGUEZ has not responded as of this date.

Related Case:

Investigator/Date:	Approved By/Date:
Leo Paulson (HA107) 12/12/12	Shane Walters, OMC Manager DEC 13 2012

Distribution: Prosecution Services Unit/Consumer Services Unit

TABLE OF CONTENTS

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 the Duval County Court stating on 10/24/12 RODRIGUEZ was Adjudicated Guilty Withheld and put on Probation.

INTERVIEW/STATEMENT OF DEPARTMENT OF HEALTH- Source

RODRIGUEZ was convicted on 10/24/12 in Duval County for Theft of Controlled Substance [812.014(2)(c), FS] and Possession of Controlled Substance [893.13(6)(a), FS]. Court Documents indicate RODRIGUEZ was Adjudicated Guilty Withheld and placed on Probation.

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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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 October 9, 2013, commencing at 9:00a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
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: Mark Whitten, 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: August 16, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** 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
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

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

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

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, **2013.**

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

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

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
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

*** 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
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

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**			

Time Tracking System
Itemized Cost by Complaint

Complaint 201019143

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

ELECTION OF RIGHTS

Case Name: James M. Maister, R.Ph. **Case No. 2010-18143**

PLEASE SELECT ONLY 1 OF THE 3 OPTIONS (19143)

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. A **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 Agreement, have signed and am returning the Settlement Agreement **or** I am interested in settling this case.

( ) I do not wish to continue practicing and have signed and returned the Voluntary Relinquishment of licensure form.

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.) James Maister

Respondent's signature

Address: _____

[!] CONFIDENTIAL

Lic. No. _____

Phone No. _____

Fax No. _____

STATE OF FLORIDA
COUNTY OF Pinellas

Before me personally appeared James Maister whose identity is known to be by _____ (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 May, 2013

Notary Public
My Commission Expires: 1-13-2017

MICHAEL HEATH
NOTARY PUBLIC
STATE OF FLORIDA
Comm# EE884725
Expires 1/13/2017

PLEASE MAIL AND/OR FAX COMPLETED FORM TO: Casey L. Cowan, Assistant General Counsel, DOH, Prosecution Services Unit, 4052 Bald Cypress Way, Bin C-65, Tallahassee, Florida 32399-3265. Telephone Number: (850) 245-4444; FAX (850) 245-4683- TDD 1-800-955-8771.

2013 MAY 13 AM 9:52

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

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.

RECEIVED-LEGAL
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	Approved By/Date: 4-18-13
Victor R. Troupe Medical Malpractice Investigator, TI-123	Babette S. Agett, TI – 115 Investigation Supervisor

Distribution: HQ/ISU

Received
Investigative Services
APR 19 2013
DOH/MQA
Tallahassee HQ

Page 1

FLORIDA DEPARTMENT OF HEALTH

Consumer Services ULA

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# SI 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

32399226599

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: 2201	License #: 34202	Profession: Pharmacist	Board: Pharmacy	Report Date: 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.

RECEIVED - LEGAL
10 OCT 29 PM 2:27

Related Case(s): 2010-19119

Investigator/Date: 10-28-10 Victor R. Troupe	Approved By/Date: 10-28-10
Medical Malpractice Investigator, TI-123	Babette S. Agett, TI – 115
	Investigation Supervisor Babette S Agett

Distribution: HQ/ISU

Received
Investigative Services

OCT 29 2010

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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 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.

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

RECEIVED
OCT 08 2010
By

Name: Department Of Health
Address:
Home Phone:

REPORTED INFORMATION

Receive Date: 10/05/2010
Responsible Party: ha107
Classification Code:

Source Code: 5
Status Code: 10
Incident Date: 09/30/2010

Form Code: 1
Priority: 1

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

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REPORT EXHIBIT 1

2010-19119

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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Charlie Crist
Governor

FLORIDA DEPARTMENT OF HEALTH

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

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FLORIDA DEPARTMENT OF HEALTH

Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., MPH
State Surgeon General

Received
OCT 07 2010
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Jacksonville IS

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Name: James M Maister
Address: 4810 DIAMONDS PALM LOOP
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Home Phone:

SOURCE OF INFORMATION

Name: Department Of Health
Address:
Home Phone:

RECEIVED
OCT 08 2010
By

REPORTED INFORMATION

Receive Date: 10/05/2010
Responsible Party: ha107
Classification Code:

Source Code: 5
Status Code: 10
Incident Date: 09/30/2010

Form Code: 1
Priority: 1

Patient Name:

Possible Code(s): 33

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Leo Paulson

1

4052 Bald Cypress Way, Bin C-75 ♦ Tallahassee, FL 32399-3265 ♦ 850-245-4339 Voice ♦ 850-488-0796 Fax

00013

2010-1919

Nc

St. Petersburg Times
tampabay.com

October 1, 2010

Wesley Chapel pharmacist accused of fraud

Times staff

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St. Petersburg Times

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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.

CERTIFIED DOCUMENT

COMPLAINT #: 2010 - 19143

PATIENT:

SUBJECT: JAMES M. MAISTER, R.Ph

INVESTIGATOR: Victor R. Troupe

**** CERTIFIED DOCUMENT – DO NOT WRITE ON IT**

EXHIBIT#: 14

Page 170-172

Five of Six

PAT FRANK
CLERK OF THE CIRCUIT COURT
HILLSBOROUGH COUNTY, FLORIDA

[ ] IN THE CIRCUIT COURT [✓] IN THE COUNTY COURT
OF THE THIRTEENTH JUDICIAL CIRCUIT IN AND FOR HILLSBOROUGH COUNTY, FLORIDA

DIVISION: [ ] FELONY [✓] MISDEMEANOR [ ] CIVIL INFRACTION

CLERK'S CERTIFICATE OF DISPOSITION

DEFENDANT'S NAME: Maister, James Matthew

DATE OF BIRTH: 09/07/1965 SOCIAL SECURITY #: XXXX-XX-XXXX

CASE NUMBER: 99-CM-024577 DIVISION: F OFFENSE DATE: 09/06/1999

VIOLATION/CHARGE/ORDINANCE: F.S. Battery (Domestic Violence)

COURT DISPOSITION

Judge: Pomponio Disposition Date: 03/08/2000 Count #: 1

Plea: [ ] guilty [ ] not guilty [ ] nolo-contendere → * No plea entered

Finding: [ ] guilty [ ] not guilty

[ ] Adjudication of guilty [ ] Adjudication withheld [ ] Dismissed [✓] Nolle-Prosequi [ ] Not guilty

[ ] Other: _____

[ ] SENTENCE: _____

_____

OTHER DISPOSITION

[ ] State Attorney - No file Letter of Release

[ ] Admitted Civil infraction by payment of civil penalty (Florida Statute/County Ordinance/Municipal Ordinance)

[✓] Criminal Arrest Affidavit or te charging document is no longer available in accordance with the retention Requirements as set forth in the "Rules of Judicial Administration 2.075.

This is to certify that the information listed above is true and correct.

Witness my Hand and Official Seal the 15 day of October, 2010.

PAT FRANK
CLERK OF CIRCUIT COURT

By: Deputy Clerk

SEAL

COCR1674(Rev.01-13-05)

PAT FRANK
CLERK OF THE CIRCUIT COURT
HILLSBOROUGH COUNTY, FLORIDA

[ ] IN THE CIRCUIT COURT [✓] IN THE COUNTY COURT
OF THE THIRTEENTH JUDICIAL CIRCUIT IN AND FOR HILLSBOROUGH COUNTY, FLORIDA

DIVISION: [ ] FELONY [✓] MISDEMEANOR [ ] CIVIL INFRACTION

CLERK'S CERTIFICATE OF DISPOSITION

DEFENDANT'S NAME: Maister, James Matthew

DATE OF BIRTH: 09/07/1905 SOCIAL SECURITY #: XXXX-XX-XXXX

CASE NUMBER: 99-CM-02575 DIVISION: C OFFENSE DATE: 03/06/1999

VIOLATION/CHARGE/ORDINANCE: FS/ Obt. prop. for worthless check

COURT DISPOSITION

Judge: Ober Disposition Date: 06/12/2000 Count #: 2

Plea: [ ] guilty [ ] not guilty [✓] nolo-contendere

Finding: [ ] guilty [ ] not guilty

[ ] Adjudication of guilty [✓] Adjudication withheld [ ] Dismissed [ ] Nolle-Prosequi [ ] Not guilty

[ ] Other: _____

[✓] SENTENCE: 6/12/2000 CC suspended, dep. closed.

OTHER DISPOSITION

[ ] State Attorney - No file Letter of Release

[ ] Admitted Civil infraction by payment of civil penalty (Florida Statute/County Ordinance/Municipal Ordinance)

[✓] Criminal Arrest Affidavit or te charging document is no longer available in accordance with the retention Requirements as set forth in the "Rules of Judicial Administration 2.075.

This is to certify that the information listed above is true and correct.

Witness my Hand and Official Seal the 15 day of October, 2010

PAT FRANK
CLERK OF CIRCUIT COURT

By: Dulce G. Magallones
Deputy Clerk

SEAL

COCR1674(Rev.01-13-05)

PAT FRANK
CLERK OF THE CIRCUIT COURT
HILLSBOROUGH COUNTY, FLORIDA

[ ] IN THE CIRCUIT COURT [✓] IN THE COUNTY COURT
OF THE THIRTEENTH JUDICIAL CIRCUIT IN AND FOR HILLSBOROUGH COUNTY, FLORIDA

DIVISION: [ ] FELONY [✓] MISDEMEANOR [ ] CIVIL INFRACTION

CLERK'S CERTIFICATE OF DISPOSITION

DEFENDANT'S NAME: Maister, James Matthew

DATE OF BIRTH: 09/07/1965 SOCIAL SECURITY #: XXXX-XX-XXXX

CASE NUMBER: 00-CM-006684 DIVISION: C OFFENSE DATE: 03/03/1999

VIOLATION/CHARGE/ORDINANCE: F3/ Obt. prop. for worthless check

COURT DISPOSITION

Judge: Ober Disposition Date: 05/11/2000 Count #: 1

Plea: [ ] guilty [✓] not guilty [ ] nolo-contendere

Finding: [ ] guilty [ ] not guilty

[ ] Adjudication of guilty [ ] Adjudication withheld [ ] Dismissed [✓] Nolle-Prosequi [ ] Not guilty

[ ] Other: _____

[ ] SENTENCE: _____

_____

OTHER DISPOSITION

[ ] State Attorney - No file Letter of Release

[ ] Admitted Civil infraction by payment of civil penalty (Florida Statute/County Ordinance/Municipal Ordinance)

[✓] Criminal Arrest Affidavit or te charging document is no longer available in accordance with the retention Requirements as set forth in the "Rules of Judicial Administration 2.075.

This is to certify that the information listed above is true and correct.

Witness my Hand and Official Seal the 15 day of October, 20 10

PAT FRANK
CLERK OF CIRCUIT COURT

By: Rose A. Magdalenes
Deputy Clerk

SEAL

COCR1674(Rev.01-13-05)

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.

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

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IN THE CIRCUIT/COUNTY COURT OF THE SIXTH JUDICIAL CIRCUIT
OF THE STATE OF FLORIDA IN AND FOR PASCO COUNTY

9901120MMAES

STATE OF FLORIDA

V. BATTERY DV, 1oM

JAMES MATTHEW MAISTER
SPN 00318670

NO INFORMATION

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.

Dated this 9 day of April, 1999.

BERNIE McCABE, State Attorney
Sixth Judicial Circuit of Florida

Philip O. Van Allen
Assistant State Attorney

NI-3

STATE OF FLORIDA, COUNTY OF PASCO
THIS IS TO CERTIFY THAT THE FOREGOING IS A TRUE AND CORRECT COPY OF THE DOCUMENT ON FILE OR OF PUBLIC RECORD IN THIS OFFICE
WITNESS MY HAND AND OFFICIAL SEAL THIS
15th DAY OF October 2010
PAULA S. O'NEIL, CLERK & COMPTROLLER
BY _____ DEPUTY CLERK

APR 15 '99
BOOK 87 PAGE 1195

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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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. 201214458

DINO JOSE ANTONIONI,
RESPONDENT.

NOTICE

TO: DINO JOSE ANTONIONI
15115 SW 54TH ST
THE RESERVE AT HUNGTINTON
MIRAMAR, FL 33027

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

For Mark Witten
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Kristal Beharry, Assistant General Counsel
RE: **Hearing - No Disputed Material Facts**
SUBJECT: DOH v. Dino Jose Antonioni, R.Ph.
DOH Case Number 2012-14458
DATE: August 27, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013**, meeting of the board. The following information is provided in this regard.

Subject:	Dino Jose Antonioni, R.Ph.
Subject's Address of Record:	15115 SW 54th Street Miramar, FL 33027
Enforcement Address:	15115 SW 54th Street Miramar, FL 33027
Additional Address:	Dino Jose Antonioni, Register #14930-111 CI D. Ray James Correctional Institution P.O. Box 2000 Folkston, GA 31537
Subject's License No:	38504 **Rank:** PS
Licensure File No:	29137
Initial Licensure Date:	3/1/2004
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Section 456.072(1)(c), F.S. (2012)
Prior Discipline:	None
Probable Cause Panel:	Griffin & Mesaros April 25, 2013
Subject's Attorney:	Pro Se
Complainant/Address:	Dino J. Antonioni (Self Report)
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
Exhibit 1
Exhibit 2
Board Notification Letters
Election of Rights
Prosecutor Document
Supplemental Investigative Report with Exhibits 4/17/13
Emergency Suspension Order with Attachments
Final Investigative Report with Exhibits 1 – 5

DISCIPLINARY GUIDELINES:
Section 456.072(1)(c), F.S.—

- Felony: $3,000 fine and one (1) year probation up to revocation

PRELIMINARY CASE REMARKS: INFORMAL HEARING

This is a one count Administrative Complaint alleging a violation of Section 456.072(1)(c), Florida Statutes (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, pharmacy.

On or about March 27, 2013, in the United States District Court, Northern District of California, Respondent entered a plea of guilty to one count of conspiracy with intent to distribute Schedule III or IV controlled substances, a felony, in violation of 21 U.S.C. 846. Conspiracy with intent to distribute Schedule III or IV controlled substances is a crime that relates to the practice of pharmacy or the ability to practice pharmacy.

Respondent returned an Election of Rights electing an informal hearing.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-14458**

DINO JOSE ANTONIONI, R.Ph.,

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 registered pharmacist, thereby affecting the Respondent's substantial interests.

2. On or about April 29, 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 registered pharmacist.

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
State Surgeon General and Secretary of Health

Kristal Beharry
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Florida Bar No. **0078070**
Telephone: (850) 245-4444 ext. 8218
Facsimile: (850) 245-4683

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 June, 2013, to: **DINO JOSE ANTONIONI, 15115 Southwest 54th Street, Miramar, FL 33027** and **DINO JOSE ANTONIONI, REGISTER #14930-111, CI D. RAY JAMES, CORRECTIONAL INSTITUTION, P.O. BOX 2000, FOLKSTON, GA 31537.**

Kristal Beharry
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-14458**

DINO JOSE ANTONIONI, 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, Dino Jose Antonioni, 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 Administrative Complaint, Respondent was a pharmacist within the state of Florida, having been issued license number PS 38504.

3. Respondent's address of record is 15115 Southwest 54th Street, Miramar, Florida 33027.

4. At all times material to this Administrative Complaint, Respondent was licensed to practice as a pharmacist in the State of Florida pursuant to Chapter 465, Florida Statutes (2012).

5. On or about August 31, 2010, in the United States District Court, Northern District of California, an indictment was filed alleging that Respondent conspired to distribute more than forty-eight million dollars worth of controlled substances outside the scope of professional practice between in or about January 2006, and March 2008. Respondent was subsequently arrested in or about September 2010.

6. On or about December 7, 2010, in the United States District Court, Northern District of California, a superseding indictment was filed charging Respondent with one count of conspiracy to distribute Schedule III and IV controlled substances in violation of 21 U.S.C. 846; one count of attempted possession with intent to distribute and distribution of Schedule III and IV controlled substances in violation 21 U.S.C. ss. 846, 841(a)(1), (b)(1)(D) & (b)(2); one count of conspiracy to launder money in violation

of 18 U.S.C. 1956(h) & (a)(2)(A); and one count of international money laundering in violation of 18 U.S.C. 1956(a)(2)(A).

7. On or about March 27, 2013, in the United States District Court, Northern District of California, in case number CR-10-00642-011, Respondent entered a plea of guilty to one count of conspiracy with intent to distribute Schedule III or IV controlled substances, a felony, in violation of 21 U.S.C. 846.

8. Section 456.072(1)(c), Florida Statutes (2012), 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, pharmacy constitutes grounds for disciplinary action.

9. Conspiracy with intent to distribute Schedule III or IV controlled substances is a crime that relates to the practice of pharmacy or the ability to practice pharmacy.

10. As set forth above, Respondent entered a plea of guilty to one count of conspiracy with intent to distribute Schedule III or IV controlled substances, a felony, in violation of 21 U.S.C. 846, in the United States District Court, Northern District of California.

11. Based on the foregoing, Respondent violated Section 456.072(1)(c), Florida Statutes (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, 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 deems appropriate.

SIGNED this 25th **day of** April, **2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

K. Beharry

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 APR 25 2013

/KB
PCP: 04/25/13
PCP Members: Griffin 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. 2012-14458**

DINO JOSE ANTONIONI, 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 $2247.56, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**2.70**	**$155.56**
Investigation:	**20.00**	**$1235.57**
Legal:	**8.00**	**$851.60**
Compliance:	**0.15**	**4.83**
Sub Total:	**30.85**	**$2247.56**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$2247.56**

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $1,395.96 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 $1,395.96 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 $1,395.96.

DATED this 4th day of June, 2013.

Respectfully Submitted,

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

K. Beharry

Kristal Beharry
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Florida Bar No. **0078070**
Telephone: (850) 245-4444 ext. 8218
Facsimile: (850) 245-4683

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 4th day of June, 2013, to: **DINO JOSE ANTONIONI, 15115 Southwest 54th Street, Miramar, FL 33027** and **DINO JOSE ANTONIONI, REGISTER #14930-111, CI D. RAY JAMES, CORRECTIONAL INSTITUTION, P.O. BOX 2000, FOLKSTON, GA 31537.**

K. Beharry

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.

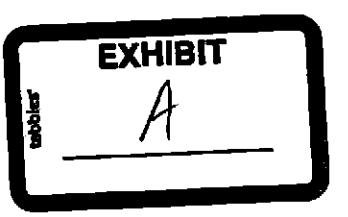
4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2012-14458** (Department of Health v. **DINO JOSE ANTONIONI, R. Ph.**) are **TWO THOUSAND TWO HUNDRED FORTY-SEVEN DOLLARS AND FIFTY-SIX CENTS ($2, 247.56).**

6) The costs for DOH case numbers **2012-14458** (Department of Health v. **DINO JOSE ANTONIONI, 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 **2012-14458** (Department of Health v. **DINO JOSE ANTONIONI, 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



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 15th day of May, 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: 201214458

Subject's Name: ANTONIONI, DINO JOSE

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	2.70	$155.56
Investigation:	20.00	$1,235.57
Legal:	8.00	$851.60
Compliance:	0.15	$4.83
	**********	**********
Sub Total:	30.85	$2,247.56
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$2,247.56

EXHIBIT

tabbies

/

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201214458

Report Date 05/15/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
COMPLIANCE MANAGEMENT UNIT						
HC27	0.05	$32.13	$1.61	10/29/2012	137	PRIORITY DOWNGRADES/UPGRADES
HC27	0.05	$32.13	$1.61	04/08/2013	137	PRIORITY DOWNGRADES/UPGRADES
HC27	0.05	$32.13	$1.61	04/15/2013	125	LICENSE STATUS CHANGE
Sub Total	**0.15**		**$4.83**			
CONSUMER SERVICES UNIT						
HA136	1.00	$57.62	$57.62	10/01/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HA136	0.20	$57.62	$11.52	10/01/2012	25	REVIEW CASE FILE
HA136	0.70	$57.62	$40.33	10/02/2012	25	REVIEW CASE FILE
HA136	0.50	$57.62	$28.81	10/03/2012	25	REVIEW CASE FILE
HA136	0.10	$57.62	$5.76	10/16/2012	144	CSU INVESTIGATIVE WORK
HA136	0.20	$57.62	$11.52	10/16/2012	144	CSU INVESTIGATIVE WORK
Sub Total	**2.70**		**$155.56**			
INVESTIGATIVE SERVICES UNIT						
LI98	0.30	$61.19	$18.36	10/08/2012	4	ROUTINE INVESTIGATIVE WORK
LI98	0.20	$61.19	$12.24	10/08/2012	4	ROUTINE INVESTIGATIVE WORK
LI98	1.10	$61.19	$67.31	10/08/2012	58	TRAVEL TIME
LI92	1.50	$61.19	$91.79	10/08/2012	4	ROUTINE INVESTIGATIVE WORK
LI92	0.50	$61.19	$30.60	10/08/2012	76	REPORT PREPARATION
LI92	1.50	$61.19	$91.79	10/10/2012	4	ROUTINE INVESTIGATIVE WORK
LI92	4.50	$61.19	$275.36	10/10/2012	76	REPORT PREPARATION
LI92	1.00	$61.19	$61.19	10/11/2012	4	ROUTINE INVESTIGATIVE WORK
LI92	0.50	$61.19	$30.60	10/11/2012	76	REPORT PREPARATION
LI92	0.70	$61.19	$42.83	10/12/2012	76	REPORT PREPARATION
LI92	0.50	$61.19	$30.60	10/15/2012	76	REPORT PREPARATION

EXHIBIT
tabbies 2

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
LI92	0.50	$61.19	$30.60	10/15/2012	4	ROUTINE INVESTIGATIVE WORK
LI92	2.50	$61.19	$152.98	10/16/2012	76	REPORT PREPARATION
LI92	0.50	$61.19	$30.60	10/17/2012	76	REPORT PREPARATION
LI92	0.50	$63.98	$31.99	01/10/2013	6	SUPPLEMENTAL INVESTIGATION
LI75	2.50	$63.98	$159.95	04/17/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
LI75	1.20	$63.98	$76.78	04/17/2013	76	REPORT PREPARATION
Sub Total	**20.00**		**$1,235.57**			

PROSECUTION SERVICES UNIT

HLL5A	0.60	$102.41	$61.45	10/04/2012	25	REVIEW CASE FILE
HLL91B	0.60	$111.56	$66.94	10/04/2012	25	REVIEW CASE FILE
HLL91B	0.40	$106.35	$42.54	10/24/2012	25	REVIEW CASE FILE
HLL91B	0.20	$106.35	$21.27	10/24/2012	70	CONFERENCES WITH LAWYERS
HLL91B	0.30	$106.35	$31.91	10/25/2012	26	PREPARE OR REVISE MEMORANDUM
HLL90A	0.40	$106.35	$42.54	10/30/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL90A	0.20	$106.35	$21.27	12/05/2012	60	MISCELLANEOUS
HLL90A	0.20	$106.35	$21.27	01/16/2013	60	MISCELLANEOUS
HLL90A	0.20	$106.35	$21.27	03/07/2013	60	MISCELLANEOUS
HLL90A	0.20	$106.35	$21.27	03/29/2013	60	MISCELLANEOUS
HLL90A	0.30	$106.35	$31.91	04/04/2013	25	REVIEW CASE FILE
HLL90A	0.70	$106.35	$74.45	04/05/2013	25	REVIEW CASE FILE
HLL90A	0.20	$106.35	$21.27	04/05/2013	26	PREPARE OR REVISE MEMORANDUM
HLL90A	1.50	$106.35	$159.53	04/05/2013	81	ESO/ERO
HLL90B	0.40	$106.35	$42.54	04/05/2013	70	CONFERENCES WITH LAWYERS
HLL90A	0.20	$106.35	$21.27	04/10/2013	81	ESO/ERO
HLL90A	0.30	$106.35	$31.91	04/16/2013	25	REVIEW CASE FILE
HLL90A	1.10	$106.35	$116.99	04/16/2013	81	ESO/ERO
Sub Total	**8.00**		**$851.60**			

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201214458

Report Date 05/15/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
Total Cost			**$2,247.56**			

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 05/15/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

June 4, 2013

VIA U. S. MAIL

Dino Jose Antonioni
15115 Southwest 54th Street
Miramar, FL 33027

Re: DOH vs. Dino Jose Antonioni, R.Ph.
DOH Case Number: 2012-14458

Dear Mr. Antonioni:

I am in receipt of your election of rights requesting a hearing not involving disputed issues of material fact, executed by you on May 14, 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 August 14, 2013, at the Rosen Plaza Hotel, 9700 International Drive, Orlando, Florida 32819. 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,

K. Beharry

Kristal Beharry
Assistant General Counsel

KB/cmn

June 4, 2013

VIA U.S. MAIL

Dino Jose Antonioni, Register # 14930-111
CI D. Ray James
Correctional Institution
P.O. Box 2000
Folkston, GA 31537

Re: DOH vs. Dino Jose Antonioni, R.Ph.
DOH Case Number: 2012-14458

Dear Mr. Antonioni:

I am in receipt of your election of rights requesting a hearing not involving disputed issues of material fact, executed by you on May 14, 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.

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Sincerely,

K. Beharry

Kristal Beharry
Assistant General Counsel

KB/cmn

August 28, 2013

VIA U.S. MAIL

Dino Jose Antonioni, Register # 14930-111
CI D. Ray James
Correctional Institution
P.O. Box 2000
Folkston, GA 31537

Re: DOH vs. Dino Jose Antonioni, R.Ph.
DOH Case Number: 2012-14458

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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, FL 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,

K. Beharry

Kristal Beharry
Assistant General Counsel

KB/cmn

August 28, 2013

VIA U.S. MAIL

Dino Jose Antonioni
15115 SW 54th Street
Miramar, FL 33027

Re: DOH vs. Dino Jose Antonioni, R.Ph.
DOH Case Number: 2012-14458

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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.

Inmate Locator

- About the Inmate Locator
- Visiting - General Info
  - Visiting Hours
  - Who Can Visit?
  - Background Checks
  - Business Visits
  - Special Circumstances
  - Visiting Room Procedures
  - Conjugal Visits
- Locate Inmates Released Before 1982
- Who is a "Federal" Inmate?

Related Documents

Inmate Locator - Locate Federal inmates from 1982 to present

Name	Register #	Age-Race-Sex	Release Date Actual or Projected	Location
1. DINO JOSE ANTONIONI	14930-111	45-White-M	02-26-2014	D. RAY JAMES CORR FACL CI

Results 1 - 1 of 1

New Search FAQs Privacy

United States District Court
Northern District of California

UNITED STATES OF AMERICA
v.
DINO JOSE ANTONIONI

JUDGMENT IN A CRIMINAL CASE

USDC Case Number: CR-10-00642-011 CRB
BOP Case Number: DCAN310CR000642-011
USM Number: None
Defendant's Attorney: Michael Shephard

THE DEFENDANT:

[x] pleaded guilty to count: Ten of the Superseding Indictment.
[ ] pleaded nolo contendere to count(s) ___ which was accepted by the court.
[ ] was found guilty on count(s) ___ after a plea of not guilty.

The defendant is adjudicated guilty of these offense(s):

Title & Section	Nature of Offense	Offense Ended	Count
21 U.S.C. § 846	Conspiracy with Intent to Distribute Schedule III or IV Controlled Substances	2008	Ten

The defendant is sentenced as provided in pages 2 through 7 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

[ ] The defendant has been found not guilty on count(s) ___.

[x] All other counts are dismissed on the motion of the United States.

IT IS ORDERED that the defendant must 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 must notify the court and United States attorney of any material changes in economic circumstances.

March 27, 2013
Date of Imposition of Judgment

Signature of Judicial Officer

Honorable Charles R. Breyer, Senior U. S. District Judge
Name & Title of Judicial Officer

March 28, 2013
Date

CONFIDENTIAL

DEFENDANT: DINO JOSE ANTONIONI
CASE NUMBER: CR-10-00642-011 CRB

IMPRISONMENT

The defendant is hereby committed to the custody of the United States Bureau of Prisons to be imprisoned for a total term of nine (9) months .

[x] The Court makes the following recommendations to the Bureau of Prisons: that the defendant be designated to a facility near Miami, Florida to facilitate visitation with his family.

[ ] The defendant is remanded to the custody of the United States Marshal. The appearance bond is hereby exonerated.

[ ] The defendant shall surrender to the United States Marshal for this district.

[ ] at ___ [] am [] pm on ___.
[ ] as notified by the United States Marshal.

The appearance bond shall be deemed exonerated upon the surrender of the defendant.

[x] The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

[x] before 2:00 pm on May 28, 2013 (60 days).
[x] as notified by the United States Marshal.
[ ] as notified by the Probation or Pretrial Services Office.

The appearance bond shall be deemed exonerated upon the surrender of the defendant.

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 United States Marshal

DEFENDANT: DINO JOSE ANTONIONI
CASE NUMBER: CR-10-00642-011 CRB

SUPERVISED RELEASE

Upon release from imprisonment, the defendant shall be on supervised release for a term of three (3) years .

The defendant must report to the probation office in the district to which the defendant is released within 72 hours of release from the custody of the Bureau of Prisons.

The defendant shall not commit another federal, state or local crime.

The defendant shall not unlawfully possess a controlled substance. The defendant shall refrain from any unlawful use of a controlled substance. The defendant shall submit to one drug test within 15 days of release from imprisonment and two periodic drug tests thereafter.

[x] The above drug testing condition is suspended based on the court's determination that the defendant poses a low risk of future substance abuse. (Check if applicable.)

[x] The defendant shall not possess a firearm, ammunition, destructive device, or any other dangerous weapon. (Check if applicable.)

[x] The defendant shall cooperate in the collection of DNA as directed by the probation officer. (Check if applicable.)

[ ] The defendant shall register with the state sex offender registration agency in the state where the defendant resides, works, or is a student, as directed by the probation officer. (Check if applicable.)

[ ] The defendant shall participate in an approved program for domestic violence. (Check if applicable.)

If this judgment imposes a fine or restitution, it is a condition of supervised release that the defendant pay in accordance with the Schedule of Payments sheet of this judgment.

The defendant must comply with the standard conditions that have been adopted by this court as well as with any additional conditions in this judgment.

STANDARD CONDITIONS

1) The defendant shall not leave the judicial district without 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 dependants 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 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 of the probation officer;
11) The defendant shall notify the probation officer within seventy-two 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; and
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.

SPECIAL CONDITIONS OF SUPERVISION

1. The defendant shall pay any special assessment that is imposed by this judgment and that remains unpaid at the commencement of the term of supervised release.

2. The defendant shall make an application to register as a drug offender pursuant to state law.

3. The defendant shall submit his person, residence, office, vehicle, or any property under his control to a search. Such a search shall be conducted by a United States Probation Officer or any federal, state, or local law enforcement officer at any time with or without cause. Failure to submit to such a search may be grounds for revocation; the defendant shall warn any residents that the premises may be subject to searches.

4. The defendant shall comply with the rules and regulations of the U.S. Immigration and Customs Enforcement and, if deported, not reenter the United States without the express consent of the Secretary of the Department of Homeland Security. Upon any reentry into the United States during the period of court ordered supervision, the defendant shall report to the nearest U.S. Probation Office within 72 hours.

5. The defendant shall participate in the Location Monitoring Program as directed by the probation officer for a period of nine (9)months, and be monitored by electronic monitoring. Location monitoring shall be utilized to verify his or her compliance with home detention while on the program. The defendant is restricted to his or her residence at all times except for employment, education, religious services, medical appointments, substance abuse or mental health treatment, attorney visits, court appearances, court-ordered obligations. or other activities pre-approved by the probation officer. The cost will be determined by the probation officer at the time of enrollment in the program.

DEFENDANT: DINO JOSE ANTONIONI
CASE NUMBER: CR-10-00642-011 CRB

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	Fine	Restitution
Totals:	$ 100	N/A	N/A

[ ] The determination of restitution is deferred until _. An *Amended Judgment in a Criminal Case* (AO 245C) will be entered after such determination.

[ ] The defendant shall make restitution (including community restitution) to the following payees in the amount listed below. The defendant shall make all payments directly to the U.S. District Court Clerk's Office who will disburse payments to the payee.

If the defendant makes a partial payment, each payee shall receive an approximately proportional payment unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss*	Restitution Ordered	Priority or Percentage
Totals:	$ _	$ _	

[ ] Restitution amount ordered pursuant to plea agreement $ _

[ ] The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine 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 Sheet 6, may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

[ ] The court determined that the defendant does not have the ability to pay interest, and it is ordered that:

[ ] the interest requirement is waived for the [ ] fine [ ] restitution.

[ ] the interest requirement for the [ ] fine [ ] restitution is modified as follows:

* Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT: DINO JOSE ANTONIONI
CASE NUMBER: CR-10-00642-011 CRB

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties are due as follows:

A [x] Lump sum payment of $100 due immediately, balance due
[ ] not later than ____, or
[ ] in accordance with ( ) C, ( ) D, ( ) E, ( ) F (x) G or ( ) H below; or

B [ ] Payment to begin immediately (may be combined with ( ) C, ( ) D, or ( ) F below); or

C [ ] Payment in equal (e.g. weekly, monthly, quarterly) installments of $ _ over a period of __ (e.g., months or years), to commence _ (e.g., 30 or 60 days) after the date of this judgment; or

D [ ] Payment in equal (e.g. weekly, monthly, quarterly) installments of $ _ over a period of __ (e.g., months or years), to commence _ (e.g., 30 or 60 days) after release from imprisonment to a term of supervision; or

E [ ] Payment during the term of supervised release will commence within (e,g, 30 or 60 days) after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

F [ ] Special instructions regarding the payment of criminal monetary penalties:

G. [x] In Custody special instructions: Payment of criminal monetary penalties is due during imprisonment at the rate of not less than $25.00 per quarter and payment shall be through the Bureau of Prisons Inmate Financial Responsibility Program. Criminal monetary payments shall be made to the Clerk of U.S. District Court, 450 Golden Gate Ave., Box 36060, San Francisco, CA 94102

H. [ ] Out of Custody special instructions: It is further ordered that the defendant shall pay to the United States a special assessment of $ and a fine of $ which shall be due immediately. If incarcerated, payment of criminal monetary payment is due during imprisonment and payment shall be through the Bureau of Prisons Inmate Financial Responsibility Program. Criminal monetary payments shall be made to the Clerk of U.S. District Court, 450 Golden Gate Ave., Box 36060, San Francisco, CA 94102.

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

[ ] Joint and Several

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

DEFENDANT: DINO JOSE ANTONIONI
CASE NUMBER: CR-10-00642-011 CRB

Defendant and co-defendant Names	Case Numbers (including defendant number)	Total Amount	Joint and Several Amount	Corresponding Payee (if appropriate)

[ ] The defendant shall pay the cost of prosecution.

[ ] The defendant shall pay the following court cost(s):

[x] The defendant shall forfeit the defendant's interest in the following property to the United States: Money Judgment in the amount of $300,000.

[ ] The Court gives notice that this case involves other defendants who may be held jointly and severally liable for payment of all or part of the restitution ordered herein and may order such payment in the future, **but such future orders do not affect this defendant's responsibility for the full amount of the restitution ordered.**

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) penalties, and (8) costs, including cost of prosecution and court costs.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Fort Lauderdale	Date of Case: 10/03/2012	Case Number: PS 2012-14458

Subject:	Source:
DINO JOSE ANTONIONI, RPh 1S11S Southwest S4th Street Miramar, Florida 33027 (9S4) 397-1881	**DINO JOSE ANTONIONI, RPh** 1S11S Southwest S4th Street Miramar, Florida 33027 (9S4) 397-1881

Prefix:	License #:	Profession:	Board:	Report Date:
PS	38S04	Pharmacist	Pharmacy	4/17/2013

Period of Investigation:	Type of Report:
04/16/2013 - 4/17/2013	SUPPLEMENTAL #1

Alleged Violation: SEE FINAL REPORT

Synopsis:

This SUPPLEMENTAL was predicated upon a PSU Request from Department of Health Assistant General Counsel KRISTAL BEHARRY, requesting service of Emergency Suspension Order on ANTONIONI.

On April 17, 2013, this Investigator served the Emergency Suspension Order to ANTONIONI by leaving a copy to his wife at his home address.

RECEIVED-LEGAL
13 APR 22 AM 8:39

Related Case: N/A

Investigator/Date: 4/17/2013	Approved By/Date: 4/17/2013
ENRIQUE T. TORRES, **Medical Malpractice Investigator LI-75**	Received Investigative Services APR 19 2013 **LUIS NIEVES,** **Investigative Supervisor LI-101**

Distribution: HQ/ISU

DOH/MQA

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

FROM: Melba L. Apellaniz, RSII for Kristal Beharry, Esq.	TO: Patricia Callahan
Date: 4/16/2013	TO: CSU
Phone #: (850) 245-4640 Ext. 8223	CC: Yvanne Gustave

Case Number: 2012-14458 Board: **Pharmacy**
Subject: **Dino José Antonioni, R.Ph.** HL Code:**hll46a** Status: **90**
Requested Completion Date: ASAP

(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 ESO/ERO. Thanks.

*The following additional information is needed for each service request:

Last Known Address: 15115 SW 54th Street, The Reserve At Huntington, Miramar, FL 33027; Last Known Name & Phone Number: Dino José Antonioni, R.Ph.; (954) 397-1881; 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
13 APR 22 AM 8:39

TABLE OF CONTENTS

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

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Requested Completion Date: ASAP

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☐ Additional Information Requested (**Activity Code 145**)

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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
APR 22 AM 8:39

INV FORM 376, Revised 1/12. 10/11, 6/10, 06/09, 4/09, 11/08 Created 4/05

EXHIBIT #51-1

Final Order No. DOH-13-0674-ESD -MQA
FILED DATE APR 15 2013
Department of Health
By: Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the License of
Dino Jose Antonioni, R.Ph.
License No.: PS 38504
Case No.: 2012-14458

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 Dino Jose Antonioni, R.Ph., to practice as a pharmacist in the State of Florida. Mr. Antonioni holds license number PS 38504. His address of record is 15115 Southwest 54th Street, Miramar, Florida 33027. The following Findings of Fact and Conclusions of Law support the emergency suspension of Mr. Antonioni's license to practice as a pharmacist.

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). Section 456.074(1), Florida Statutes (2012), authorizes the Department to summarily suspend Mr. Antonioni's license to practice as a pharmacist.

2. At all times material to this Order, Mr. Antonioni was licensed to practice as a pharmacist in the State of Florida pursuant to Chapter 465, Florida Statutes (2012).

3. On or about August 31, 2010, in the United States District Court, Northern District of California, an indictment was filed alleging that Mr. Antonioni conspired to distribute more than forty-eight million dollars worth of controlled substances outside the scope of professional practice between in or about January 2006, and March 2008. Mr. Antonioni was subsequently arrested in or about September 2010.

4. On or about December 7, 2010, in the United States District Court, Northern District of California, a superseding indictment was filed charging Mr. Antonioni with one count of conspiracy to distribute Schedule III and IV controlled substances in violation of 21 U.S.C. 846; one count of attempted possession with intent to distribute and distribution of Schedule III and IV controlled substances in violation 21 U.S.C. ss. 846, 841(a)(1), (b)(1)(D) & (b)(2); one count of conspiracy to launder money in violation of 18 U.S.C. 1956(h) & (a)(2)(A); and one count of international money laundering in violation of 18 U.S.C. 1956(a)(2)(A).

5. On or about March 27, 2013, in the United States District Court, Northern District of California, in case number CR-10-00642-011, Mr. Antonioni entered a plea of guilty to one count of conspiracy with intent to distribute Schedule III or IV controlled substances, a felony, in violation of 21 U.S.C. 846.

6. The Department did not learn of the above referenced plea until on or about April 5, 2013.

7. Section 456.074(1), Florida Statutes (2012), provides that the Department *shall* issue an emergency order suspending the license of any person licensed under Chapter 465, Florida Statutes, who pleads guilty to a felony under 21 U.S.C. ss. 801-970, 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 (2012), and Chapter 465, Florida Statutes (2012).

2. The Department is mandated to summarily suspend Mr. Antonioni's license to practice as a pharmacist in accordance with Section 456.074(1), Florida Statutes (2012).

WHEREFORE, in accordance with Section 456.074(1), Florida Statutes (2012), it is ORDERED THAT:

1. The license of Dino Jose Antonioni, R.Ph., license number PS 38504, is immediately suspended.

2. A proceeding seeking formal suspension or discipline of the license of Dino Jose Antonioni, R.Ph., to practice as a pharmacist will be promptly instituted and acted upon in compliance with Section 120.569, Florida Statutes (2012).

DONE and ORDERED this 15th day of April, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

PREPARED BY:
Kristal Beharry
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. 0078070

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Section 120.68, Florida Statutes (2012), 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.

9

AFFIDAVIT OF SERVICE

DEPARTMENT OF HEALTH

vs. CASE No.: PS 2012-14458

DINO JOSE ANTONIONI, RPh

COMES NOW, the Affiant, who first being duly swom, deposes and states:

1) Affiant is an Investigator employed by the Department of Health, State of Florida.

2) That on April 17, 2013, Affiant served __ Administrative Complaint and related papers; ____Order compelling examination(s); ____Subpoena(s); ____Final order; ____Notice to cease and desist; **_X_ ESO and related papers** ___ Citation (check appropriate block)

3) (Check applicable answer)

_X_ Affiant made personal service on Mrs. Antonioni on behalf of Respondent at his home address of 15115 Southwest 54th Street, Miramar, Florida 33027.

____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: _____

Enrique T.Torres, MMI – Affiant

STATE OF FLORIDA }
COUNTY OF BROWARD }

Before me, personally appeared **Enrique T. Torres** whose identity is personally known to me and who, acknowledges that his signature appears above.

Sworn to or affirmed by Affiant before me this 17th day of April, 2013.

Notary Public-State of Florida

Ivy A. Lewis

Type or Print Name

IVA ALDENE LEWIS
My Commission Expires
Commission # EE 071535
Expires March 7, 2015
Bonded Thru Troy Fain Insurance 800-385-7019

April 16, 2013

Certified Article Number
7196 9008 9111 8827 8535
SENDERS RECORD

Dino Jose Antonioni, R.Ph.
15115 SW 54th Street
The Reserve At Hungtinton
Miramar, FL 33027

RE: Department of Health vs. Dino Jose Antonioni, R.Ph.
Case Number: 2012-14458

Dear Mr. Antonioni:

Enclosed please find an Order of Emergency **Suspension** of License filed April 15, 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 Kristal Beharry, Assistant General Counsel at (850) 245-4444.

Sincerely,

Melba L. Apellaniz
Regulatory Specialist II
Prosecution Services Unit

7196 9008 9111 8827 8535

TO:

Dino J. Antonioni, R.Ph.
15115 SW 54th St.
The Reserve At Huntington
Miramar, FL 33027

SENDER:

REFERENCE: ESO
2012-14458

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

4/16/2013

2. Article Number

7196 9008 9111 8827 8535

3. Service Type **CERTIFIED MAIL™**

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Dino J. Antonioni, R.Ph.
15115 SW 54th St.
The Reserve At Huntington
Miramar, FL 33027

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly)

B. Date of Delivery 4/18/13

C. Signature

X

☐ Agent
☐ Addressee

D. Is delivery address different from item 1?
If YES, enter delivery address below:

☐ Yes
☐ No

APR 18 2013 9:04 AM

Antonioni
12-14458 4/16/2013
Beharry

PS Form 3811, January 2005 Domestic Return Receipt

Apellaniz, Melba

From: FL-Rules@dos.state.fl.us
Sent: Tuesday, April 16, 2013 9:02 AM
To: Apellaniz, Melba
Subject: Submit Notice in FAR

You have successfully submitted a notice for publication in the Florida Administrative Register on 4/16/2013 9:01:53 AM.

Department: Department of Health
Organization: Board of Pharmacy
Notice type: Miscellaneous
Issue: 39/75

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=12890056

You may contact the Florida Administrative Register office at (850)245-6270 for additional information.

@ItsWorkingFL: https://twitter.com/ItsWorkingFL The Department of State is leading the commemoration of Florida's 500th anniversary in 2013. For more information, please go to www.fla500.com.
The Department of State is committed to excellence. Please take our Customer Satisfaction Survey: http://survey.dos.state.fl.us/index.aspx?email=fl.rules@dos.myflorida.com

MEMORANDUM

TO:	Florida Administrative Register, Liz Cloud
FROM:	Melba L. Apellaniz, Regulatory Specialist II
RE:	Dino Jose Antonioni, R.Ph., License # PS 38504
CASE NO:	2012-14458
DATE:	April 16, 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 April 15, 2013, the State Surgeon General issued an Order of Emergency Suspension Order with regard to the license of Dino Jose Antonioni, R.Ph., License # PS 38504. 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.

#12890056

** Transmit Conf. Report **

P. 1

Apr 16 2013 09:05am

Fax/Phone Number	Mode	Start	Time	Page	Result	Note
99216847	Normal	16:09:04am	0'29"	1	* O K	

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

April 16, 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. Dino Jose Antonioni, R.Ph.
Case Number: 2012-14458

Dear Judge Cohen:

This letter is to advise you that the Department has issued an Emergency Suspension Order concerning the license of **Dino Jose Antonioni** 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 Kristal Beharry, Assistant General Counsel at (850) 245-4444.

Sincerely,

Melba L. Apellaniz
Regulatory Specialist II
Prosecution Services Unit

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

April 16, 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. Dino Jose Antonioni, R.Ph.
Case Number: 2012-14458

Dear Judge Cohen:

This letter is to advise you that the Department has issued an Emergency Suspension Order concerning the license of **Dino Jose Antonioni** 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 Kristal Beharry, Assistant General Counsel at (850) 245-4444.

Sincerely,

Melba L. Apellaniz
Regulatory Specialist II
Prosecution Services Unit

Apellaniz, Melba

From: Apellaniz, Melba
Sent: Tuesday, April 16, 2013 8:51 AM
To: DL MQA Inv Serv Priority Mail Area10 (LI) Ft. Lauderdale
Subject: Hand Service ESO 12-14458/Antonioni
Attachments: Supp.Req.12-14458.Antonioni.4.16.13.doc; DOH 13-0674 ESO 201214458-1.PDF

Good Morning,

Attached please find a request to hand service ESO for case 2012-14458, Dino José Antonioni, R.Ph.

<<...>> <<...>>

Thanks,

Melba L. Apellániz, RSII
Assistant to: Daniel Hernandez, DGC
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. 8223

Mission: To protect, promote, and improve the health of all people in Florida through integrated state, county, & community efforts.

Vision: To be the **Healthiest State** in the Nation

Values: ICARE

I innovation: We search for creative solutions and manage resources wisely.
C collaboration: We use teamwork to achieve common goals & solve problems.
A accountability: We perform with integrity & respect.
R responsiveness: We achieve our mission by serving our customers & engaging our partners.
E excellence: We promote quality outcomes through learning & continuous performance improvement.

Purpose: To protect the public through health care licensure, enforcement and information.

Focus: To be the nation's leader in quality health care regulation.

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

FROM: Melba L. Apellaniz, RSII for Kristal Beharry, Esq.	TO: Patricia Callahan
Date: 4/16/2013	TO: CSU
Phone #: (850) 245-4640 Ext. 8223	CC: Yvanne Gustave

Case Number: 2012-14458 Board: **Pharmacy**
Subject: **Dino José Antonioni, R.Ph.** HL Code:**hll46a** Status: **90**
Requested Completion Date: ASAP

(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 ESO/ERO. Thanks.

*The following additional information is needed for each service request:

Last Known Address: 15115 SW 54th Street, The Reserve At Huntington, Miramar, FL 33027; Last Known Name & Phone Number: Dino José Antonioni, R.Ph.; (954) 397-1881; 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)

Final Order No. DOH-13-0674-ESD -MQA
FILED DATE APR 15 2013
Department of Health
By: Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the License of
Dino Jose Antonioni, R.Ph.
License No.: PS 38504
Case No.: 2012-14458

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 Dino Jose Antonioni, R.Ph., to practice as a pharmacist in the State of Florida. Mr. Antonioni holds license number PS 38504. His address of record is 15115 Southwest 54th Street, Miramar, Florida 33027. The following Findings of Fact and Conclusions of Law support the emergency suspension of Mr. Antonioni's license to practice as a pharmacist.

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). Section 456.074(1), Florida Statutes (2012), authorizes the Department to summarily suspend Mr. Antonioni's license to practice as a pharmacist.

2. At all times material to this Order, Mr. Antonioni was licensed to practice as a pharmacist in the State of Florida pursuant to Chapter 465, Florida Statutes (2012).

3. On or about August 31, 2010, in the United States District Court, Northern District of California, an indictment was filed alleging that Mr. Antonioni conspired to distribute more than forty-eight million dollars worth of controlled substances outside the scope of professional practice between in or about January 2006, and March 2008. Mr. Antonioni was subsequently arrested in or about September 2010.

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5. On or about March 27, 2013, in the United States District Court, Northern District of California, in case number CR-10-00642-011, Mr. Antonioni entered a plea of guilty to one count of conspiracy with intent to distribute Schedule III or IV controlled substances, a felony, in violation of 21 U.S.C. 846.

6. The Department did not learn of the above referenced plea until on or about April 5, 2013.

7. Section 456.074(1), Florida Statutes (2012), provides that the Department *shall* issue an emergency order suspending the license of any person licensed under Chapter 465, Florida Statutes, who pleads guilty to a felony under 21 U.S.C. ss. 801-970, 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 (2012), and Chapter 465, Florida Statutes (2012).

2. The Department is mandated to summarily suspend Mr. Antonioni's license to practice as a pharmacist in accordance with Section 456.074(1), Florida Statutes (2012).

WHEREFORE, in accordance with Section 456.074(1), Florida Statutes (2012), it is ORDERED THAT:

1. The license of Dino Jose Antonioni, R.Ph., license number PS 38504, is immediately suspended.

2. A proceeding seeking formal suspension or discipline of the license of Dino Jose Antonioni, R.Ph., to practice as a pharmacist will be promptly instituted and acted upon in compliance with Section 120.569, Florida Statutes (2012).

DONE and ORDERED this 15th day of April, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

PREPARED BY:
Kristal Beharry
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. 0078070

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Section 120.68, Florida Statutes (2012), 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.

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. Dino Jose Antonioni, R.Ph.**
DOH Case Number 2012-14458

MEMBERS: Jeffrey J. Mesaros, R.Ph & Cynthia R. Griffin, PharmD

DATE OF PCP: April 25, 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 465.072(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)
c)

____ Upon **reconsideration**, dismiss

____ **Other** _____

Cynthia R Griffin PharmD 4/25/13
Chair, Probable Cause Panel Date
Board of Pharmacy

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
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201216863

ERIC JASEN GAINES II,
RESPONDENT.

NOTICE

TO: ERIC JASEN GAINES II
7 LILAC LN
CRAWFORDVILLE, FL 32327

AND: R. TIMOTHY JANSEN
1206 NORTH DUVAL STREET
TALLAHASSEE, FL 32303

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m. therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

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

for Mark Whitten

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

MEMORANDUM

TO: Mark Whitten, Executive Director, Board of Pharmacy
FROM : Louise Wilhite-St. Laurent, Deputy General Counsel
RE: Informal Hearing
SUBJECT: DOH v. Eric Jansen Gaines, II, RPT
DOH Case Number 2012-16863
DATE: August 28, 2013

Enclosed you will find materials in the above-referenced case to be placed on the **October 8-9, 2013**, agenda for final agency action for the meeting of the board. The following information is provided in this regard.

Subject:	Eric Jansen Gaines, II, RPT
Subject's Address of Record:	7 Lilac Lane Crawfordville, FL 32327 850-566-4001 Telephone
Enforcement Address:	7 Lilac Lane Crawfordville, FL 32327
Subject's License No:	45259 **Rank:** RPT
Licensure File No:	47149
Initial Licensure Date:	10/31/2012
Board Certification:	None
Required to Appear:	No
Current IPN/PRN Contract:	None
Allegation(s):	Count I: Section 465.016(1)(e), Florida Statues (2012), by violating Section 893.13(6)(a) or (7)(a), Florida Statutes (2012) Count II: Section 456.072(1)(c), Florida Statutes (2012)

Prior Discipline: 11/15/12, (2012-16868, duplicative of Count II, closing order issued)

Probable Cause Panel: Jeffery J. Mesa PharmD, and Lorena M. Risch
PCP: June 20, 2013

Subject's Attorney: Pro Se

Complainant/Address: Department Of Health/CSU

Materials Submitted:
Memorandum to the Board
Motion for Final Order
Administrative Complaint
Election of Rights
Supplemental Investigative Report III dated 5/15/13 with Exhibits S-1 through S-2
Supplemental Investigative Report II dated 4/18/13 with Exhibits S-1 through S-3
Supplemental Investigative Report I dated with Exhibit S-1
Final Investigative Report with Exhibits 1-4
Other Required Document
Order Compelling an Examination
Emergency Suspension Order
Election of Rights
Motion to Assess Costs with attachments
Notification Letter to Respondent

DISCIPLINARY GUIDELINES:
Section 465.016(1)(e), Florida Statues (2012), by violating Section 893.13, Florida Statutes (2012): Minimum - $5,000.00 fine and 2 years probation to Maximum – Revocation.

Section 456.072(1)(c), Florida Statutes (2012), for a misdemeanor conviction related to the practice: Minimum - $1,000.00 fine to Maximum – Revocation.

PRELIMINARY CASE REMARKS: INFORMAL HEARING

- **FACTS:** Respondent stole upwards of 1,115 pills of controlled substances from his employer, Publix Pharmacy. Respondent admitted to ingesting some of the substances (Respondent was observed ingesting liquid hydrocodone on surveillance camera in the pharmacy), and bartering or giving away other drugs that he stole from the pharmacy. Deputies recovered approximately 400 pills from Respondent's home. Respondent was charged with a felony in Wakulla county and petit theft in Leon County. The Wakulla county charges were dropped and the Respondent plead nolo contendere to the misdemeanor count of petit theft on March 11, 2013 and adjudication was withheld.
  - An Emergency Suspension Order was issued by the Department on June 4, 2013.
  - An Administrative Complaint was filed on June 20, 2013.
  - Respondent returned an Election of Rights dated July 8, 2013, electing an informal hearing.

RECOMMENDATION OF THE DEPARTMENT

- The Department recommends revocation of the Respondent's license to practice as a registered pharmacy technician and the imposition of costs incurred by the Department in investigating and prosecuting this case through the date of the entry of the final order.

CONSIDERATIONS SUPPORTING THE DEPARTMENT'S RECOMMENDATION

- The Department makes the revocation recommendation because of the egregiousness of the Respondent's conduct in this case. The Respondent was first licensed in October 2012, and immediately began stealing large amounts of Schedule II controlled substances from his employer. The Respondent did not possess any of the required judgment for individuals working with controlled substances. Respondent blatantly stole medications from his employer, consumed them (even doing so while working), bartered the substances for food or just gave them away. Respondent should have been aware of the serious effects these drugs can have on people, but he had no regard for the damage his actions could cause to himself, his employer, or the people to whom he was providing the drugs. Furthermore, Respondent received extremely minimal punishment for his felony crimes, and the

probation conditions imposed fell short of addressing any of the real issues that led to Respondent's theft of the drugs.

Should the Board of Pharmacy not wish to revoke Respondent's license, the Department recommends that the only acceptable discipline alternative would be a $5,000 fine, imposition of all costs incurred by the Department in investigating and prosecuting the case, a one-year suspension, a period of four years probation, and a PRN evaluation with the requirement to follow PRN's recommendations.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-16863**

ERIC JASEN GAINES, II, R.P.T.,

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 **Registered Pharmacy Technician** thereby affecting the Respondent's substantial interests.

2. On or about June 20, 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 **Registered Pharmacy Technician**.

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

Louise Wilhite-St. Laurent
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Florida Bar No. 0091244
Telephone: (850) 245-4444, ext.8331
Facsimile: (850) 245-4662
Email: Louise_StLaurent@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 27 day of August, 2013, to: Eric Jansen Gaines, II, RPT, 7 Lilac Lane, Crawfordville, Florida 32327.

Louise Wilhite-St. Laurent
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO.: 2012-16863**

ERIC JASEN GAINES, II, R.P.T.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health ("Petitioner" or "Department"), files this Administrative Complaint against the Respondent, ERIC JASEN GAINES, II, R.P.T. ("Respondent"), and states:

1. Petitioner is the state agency charged with regulating pharmacists, pursuant to Chapters 20, 456 and 465, Florida Statutes (2012).

2. At all times material to this Administrative Complaint, Respondent was a registered pharmacy technician, pursuant to Chapter 465, Florida Statutes (2012), having been issued license number RPT 45259.

3. Respondent's address of record is 7 Lilac Lane, Crawfordville, Florida 32327.

4. At all times material to this Administrative Complaint, Respondent worked as a registered pharmacy technician at Publix Pharmacy located at 5032 Capital Circle Southwest, Suite 1, Tallahassee, Florida 32305.

5. On or about October 26, 2012, a Publix Loss Prevention Officer received a tip from an anonymous Publix customer that a pharmacy employee named "Eric" was selling stolen prescription medications from the store.

6. The Loss Prevention Officer determined that the Pharmacy was missing the following amounts of medications from its inventory: 115 tablets of Xanax 0.5 mg; 168 tablets of alprazolam 0.5 mg; 12 tablets of temazepam 30 mg; 158 tablets of hydrocodone/APAP 5/500 mg; 86 tablets of hydrocodone/APAP 7.5/3.25 mg; and 65 tablets of hydrocodone/APAP 10/325 mg; 99 tablets of hydrocodone/APAP 10/500 mg.

7. Alprazolam, also known by the brand name Xanax, is prescribed to treat anxiety. According to Section 893.03(4), Florida Statutes (2012), alprazolam 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 alprazolam may lead to limited physical or psychological dependence relative to the substances in Schedule III.

8. Temazepam is prescribed to treat insomnia. According to Section 893.03(4), Florida Statutes (2012), temazepam 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 temazepam may lead to limited physical or psychological dependence relative to the substances in Schedule III.

9. Hydrocodone/APAP, also known by the brand name Vicodin, contains hydrocodone and acetaminophen, or Tylenol and is prescribed to treat pain. According to Section 893.03(3), Florida Statutes (2012), 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. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

10. On or about November 2, 2012, Publix pharmacy surveillance cameras were repositioned for additional monitoring.

11. The video surveillance taken on November 3, 2012, showed Respondent dumping prescription pills from multiple bottles into his hand and placing the medications into the pocket of his work jacket.

12. The pharmacy manager conducted a targeted drug count before Respondent's shift on November 3, 2012, and recounted after Respondent's shift.

13. The targeted drug count revealed a shortage of the following medications after Respondent's shift: 194 pills of alprazolam 0.5 mg; 200 pills of alprazolam 1 mg; 4 pills of alprazolam 2 mg; 115 pills of hydrocodone/APAP 5/325 mg; 71 pills of hydrocodone/APAP 5/500 mg; and 29 pills of hydrocodone/APAP 10/500 mg.

14. The video surveillance from November 3, 2012, also showed Respondent consuming liquid hydrocodone in the back of the pharmacy during his shift.

15. On or about November 5, 2012, deputies with the Wakulla County Sheriff's Office Narcotics Unit conducted a search of Respondent's home located at 7 Lilac Lane, Crawfordville, Florida.

16. During the search of Respondent's home, 198 tablets of alprazolam 1 mg, 192 tablets of alprazolam 0.5 mg, 20 tablets of acetaminophen/hydrocodone, and 2 Ambien tablets were seized.

17. Ambien is the brand name for the drug zolpidem, prescribed to treat insomnia. According to Title 21, Section 1308.14, Code of Federal Regulations, zolpidem is a Schedule IV controlled substance. Zolpidem can cause dependence and is subject to abuse.

18. On or about November 5, 2012, Respondent admitted stealing Vicodin, Xanax, Tramadol and Percocet on approximately 10 to 15 occasions from August 2012 to November 2012 to a Publix Loss Prevention Officer. Respondent admitted stealing approximately 1,115 pills from the Publix Pharmacy during that time period.

19. Tramadol, commonly known by the brand name Ultram, is an opioid class medication prescribed to treat pain. Tramadol is a legend drug, but not a controlled substance. Tramadol, like all opioid-class drugs, can affect mental alertness, is subject to abuse, and can be habit forming.

20. Percocet is a brand name for oxycodone/APAP, which contains oxycodone and acetaminophen or Tylenol. 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.

21. On or about November 5, 2012, Respondent admitted to a Publix Loss Prevention Officer that he consumed some of the stolen pills and sold or gave away others.

22. On or about November 5, 2012, Respondent admitted to a Leon County Sheriff's Deputy that he provided the stolen pills to friends and acquaintances.

23. On or about November 5, 2012, Respondent admitted to a Wakulla County Sheriff's Deputy that he traded the stolen pills for food at a local restaurant and also consumed some of the stolen pills.

24. On or about November 12, 2012, a Leon County Judge issued an arrest warrant for the Respondent in Leon County Case Number 2012MM4910 for the charge of petit theft, a first degree misdemeanor, resulting from the Respondent's theft of medications from Publix Pharmacy.

25. On or about March 11, 2013, the Respondent entered a plea of nolo contendere to the charge of petit theft in Leon County Case Number 2012MM4910. The Leon County Court judge withheld adjudication, placed

the Respondent on six months of probation with the possibility of early termination and required the Respondent to complete a theft class and pay $550.00 in restitution to Publix.

COUNT I

26. Petitioner realleges and incorporates paragraphs 1 through 25 as if fully set forth herein.

27. Section 465.016(1)(e), Florida Statutes (2012), subjects registered pharmacy technicians to discipline for violating Chapter 893, Florida Statutes.

28. Chapter 893.13, Florida Statutes (2012), 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:
> 1. Distribute or dispense a controlled substance in violation of this chapter....
> [or]
> 9. Acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by

misrepresentation, fraud, forgery, deception or subterfuge.

29. Respondent violated Section 465.016(1)(e), Florida Statutes (2012), in one or more of the following ways:

a. By possessing alprazolam, or Xanax, in violation of Chapter 893.13(6)(a), Florida Statutes (2012);

b. By possessing temazepam in violation of Chapter 893.13(6)(a), Florida Statutes (2012);

c. By possessing hydrocodone/APAP in violation of Chapter 893.13(6)(a), Florida Statutes (2012);

d. By possessing oxycodone/APAP, or Percocet, in violation of Chapter 893.13(6)(a), Florida Statutes (2012);

e. By distributing or dispensing alprazolam, or Xanax, in violation of Chapter 893.13(7)(a)(1), Florida Statutes (2012);

f. By distributing or dispensing temazepam in violation of Chapter 893.13(7)(a)(1), Florida Statutes (2012);

g. By distributing or dispensing hydrocodone/APAP in violation of Chapter 893.13(7)(a)(1), Florida Statutes (2012);

h. By distributing or dispensing oxycodone/APAP, or Percocet, in violation of Chapter 893.13(7)(a)(1), Florida Statutes (2012);

i. By acquiring possession of alprazolam, or Xanax, by misrepresentation, fraud, forgery, deception or subterfuge in violation of Chapter 893.13(7)(a)(9), Florida Statutes (2012);

j. By acquiring possession of temazepam by misrepresentation, fraud, forgery, deception or subterfuge in violation of Chapter 893.13(7)(a)(9), Florida Statutes (2012);

k. By acquiring possession of hydrocodone/APAP by misrepresentation, fraud, forgery, deception or subterfuge in violation of Chapter 893.13(7)(a)(9), Florida Statutes (2012); and/or

l. By acquiring possession of oxycodone/APAP, or Percocet, by misrepresentation, fraud, forgery, deception or subterfuge in violation of Chapter 893.13(7)(a)(9), Florida Statutes (2012).

30. Based on the foregoing, Respondent has violated Section 465.016(1)(e), Florida Statutes (2012), by violating Chapter 893, Florida Statutes (2012).

COUNT II

31. Petitioner realleges and incorporates paragraphs 1 through 25 as if fully set forth herein.

32. Section 456.072(1)(c), Florida Statutes (2012), subjects registered pharmacy technicians to discipline for "[b]eing 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."

33. Respondent violated Section 456.072(1)(c), Florida Statutes (2012), by entering a plea of nolo contendere to the charge of Petit Theft, arising from the Respondent's theft of the pills from his employer, in Leon County Case Number 2012MM4910.

34. The charge of Petit Theft, under the facts of this case, relates to the practice of, or the ability to practice, Respondent's profession.

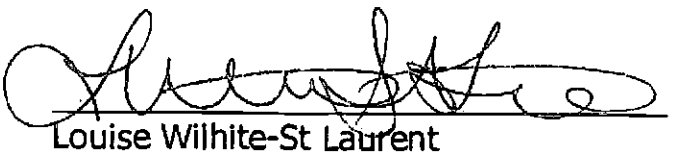
35. Based on the foregoing, Respondent has violated Section 456.072(1)(c), Florida Statutes (2012), by being convicted of or entering a plea of nolo contendere to a crime in any jurisdiction which relates to the practice of, or the ability to practice, Respondent's profession.

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 20th day of June, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health



Louise Wilhite-St Laurent
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Florida Bar Number 0091244
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4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
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Email: Louise_StLaurent@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE JUN 20 2013

PCP: June 20, 2013

PCP Members: Jeffrey J. Mesaros, PharmD
Lorena M. Risch

DOH V. ERIC JASEN GAINES, II, R.P.T.; Case No. 2012-16863

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 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.

CONFIDENTIAL AND EXEMPT MATERIALS

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STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Tallahassee	Date of Case: 11/15/2012	Case Number: 2012-16863

Subject:	Source:
ERIC JASEN GAINES, II 7 Lilac Lane Crawfordville, Florida 32327 (850) 566-4001	**DOH/CSU** ( )

Prefix:	License #:	Profession:	Board:	Report Date:
RPT 2208	45259	Registered Pharmacy Technician	Pharmacy	03/12/2013

Period of Investigation:	Type of Report:
03/12/2013	SUPPLEMENTAL

Alleged Violation: Section 465.016(1)(d), F.S. - Being unfit or incompetent to practice pharmacy...; Section 465.016(1)(e), F.S. - 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; Section 465.016(1)(i), F.S. - Compounding, dispensing, or distributing a legend drug...; Section 465.016(1)(m), F.S. - Being unable to practice pharmacy with reasonable skill and safety...; Section 465.016(1)(r), F.S. - Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto; Section 456.072(1)(z), F.S. - 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...; Section 456.072(1)(dd), F.S. – Violating any provision of this chapter, the applicable practice act, or any rules adopted pursuant thereto; Section 893.13(1)(a), F.S. - Except as authorized by this chapter and chapter 499, it is unlawful for any person...; Section 893.13(6)(a), F.S. - It is unlawful for any person to be in actual or constructive possession of a controlled substance...; Section 893.13(7)(a), F.S. - A person may not....

Synopsis: This supplemental investigation is predicated upon receipt of a letter of representation of GAINES from Attorney R. TIMOTHY JANSEN.

JANSEN'S contact information is Jansen & Davis, PA, 1206 North Duval Street, Tallahassee, Florida 32303, (850) 224-1440.

EXHIBITS:

S1 - Letter of representation of GAINES submitted by Attorney JANSEN (pages 2-3).

RECEIVED-LEGAL
13 MAR 18 AM 8:56

Related Complaint(s): N/A

Investigator/Date:	Approved By/Date:
03/12/2013	3/12/13
J. Lauren Kennedy, Investigator, CI-45	Jim Cooksey, Investigation Manager

Distribution: HQ/ISU

Received
MAR 15 2013
DOH/MQA
Tallahassee HQ

JANSEN & DAVIS, P.A.

Attorneys and Counselors at Law

R. Timothy Jansen

1206 N. Duval Street
Tallahassee, Florida 32303

Telephone (850) 224-1440
Facsimile (850) 224-0381
www.jansenlawoffice.com

Ryan R. Davis

February 28, 2013

Ms. Lauren Kennedy
Investigator
Florida Department of Health
4052 Bald Cypress Way, Bin C-70
Tallahassee, FL 32399-1701

RE: Eric Gaines II, 2012-16863

Dear Ms. Kennedy:

Please be advised that our firm is representing Mr. Gaines in the administrative matter described in the attached letter from you dated November 16, 2012. Upon receipt of this letter, please contact me to discuss this matter further.

Thank you for your attention to this matter. I look forward to speaking to you soon.

Sincerely,

For [signature] 86047
FL. Bar

R. Timothy Jansen

Enclosure

November 16, 2012

CONFIDENTIAL TO:
Eric Jasen Gaines, II
7 Lilac Lane
Crawfordville, Florida 32327

Case Number: 2012-16863

Dear Mr. Gaines:

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. 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 promote, protect and improve the health of all people in Florida. If you have any questions, please call me at (850) 413-0850.

Sincerely,

J. Lauren Kennedy
Investigator

Enclosures

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: **Department of Health, Prosecution Services Unit**

FROM: **Chair, Probable Cause Panel; Florida Board of Pharmacy**

RE: **Eric Jasen Gaines, R.P.T.**
Case Number 2012-16863

MEMBERS: **Jeffrey J. Mesaros, PharmD. and Lorena Risch**

DATE OF PCP: **June 20, 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:

Count I: **Section 465.016(1)(e), Florida Statutes (2012), by violating Chapter 893, Florida Statutes (2012)**
Count II: **Section 456.072(1)(c), Florida Statutes (2012)**

_____ Probable Cause was **not** found

_____ In lieu of probable cause, issue **Letter of Guidance**

_____ Case requires **Expert review**

_____ Case Needs **further investigation**
a)
b)
c)

_____ Upon **reconsideration, dismiss**

_____ **Other** _____

_____
Chair, Probable Cause Panel
Date
Board of Pharmacy

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Tallahassee	Date of Case: 11/15/2012	Case Number: 2012-16863

Subject:	Source:
ERIC JASEN GAINES, II 7 Lilac Lane Crawfordville, Florida 32327 (850) 566-4001	**DOH/CSU** ( )

Prefix:	License #:	Profession:	Board:	Report Date:
RPT 2208	45259	Registered Pharmacy Technician	Pharmacy	11/20/2012

Period of Investigation:	Type of Report:
11/16/2012 - 11/20/2012	FINAL

Alleged Violation: Section 465.016(1)(d), F.S. - Being unfit or incompetent to practice pharmacy...; Section 465.016(1)(e), F.S. - 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; Section 465.016(1)(i), F.S. - Compounding, dispensing, or distributing a legend drug...; Section 465.016(1)(m), F.S. - Being unable to practice pharmacy with reasonable skill and safety...; Section 465.016(1)(r), F.S. - Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto; Section 456.072(1)(z), F.S. - 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...; Section 456.072(1)(dd), F.S. – Violating any provision of this chapter, the applicable practice act, or any rules adopted pursuant thereto; Section 893.13(1)(a), F.S. - Except as authorized by this chapter and chapter 499, it is unlawful for any person...; Section 893.13(6)(a), F.S. - It is unlawful for any person to be in actual or constructive possession of a controlled substance...; Section 893.13(7)(a), F.S. - A person may not....

Synopsis: This investigation is predicated upon source information (Case Summary and attachments, Exhibit #1), submitted by DOH/CSU stating GAINES was arrested on 11/09/2012 in Wakulla County, Florida, on drug trafficking charges after law enforcement conducted a search of GAINES' residence and discovered prescription medication that was stolen from a Tallahassee Publix pharmacy. GAINES was charged with drug trafficking of more than 14 grams but less than 28 grams and possession of a Schedule III or IV narcotics with intent to sell. The total amount of seized pills included 390 generic Xanax pills which weighed 50.5 grams and 20 Hydrocodone pills weighing 15.3 grams. Two additional Ambien pills were also seized. Arrest warrants are pending in Leon County, Florida, as GAINES faces additional charges.

GAINES was notified of this investigation by letter, dated 11/16/2012, and was provided a copy of the Case Summary and originating complaint (Exhibit #2). GAINES was also notified telephonically on 11/16/2012.

A search of DOH licensure records reveals GAINES is currently a registered pharmacy technician, with a license status of clear, active, and an expiration date of 12/31/2014.

Patient Notification was not required in this investigation.

GAINES has stated he is represented by attorney; however, no letter of representation has been received.

GAINES has not responded to the allegation(s).

Related Complaint(s): N/A

Investigator/Date:	Approved By/Date:
J. Lauren Kennedy, Investigator, OI-45 11/20/2012	Jim Cooksey, Investigation Manager 11/20/12

Received
Investigative Services
NOV 21 2012

Distribution: HQ/ISU

DOH/MQA
Tallahassee HQ

TABLE OF CONTENTS

***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(8), FLORIDA STATUTES**

****These records are sealed pursuant to Section 456.057(8), Florida Statutes and copies of same are not maintained in the Tallahassee Investigative Services office**

INVESTIGATIVE DETAILS

SUMMARY OF RECORDS

Exhibit #3 consists of a copy of court documents from the LEON COUNTY CLERK OF COURTS. The documents include a copy of the Complaint (11/12/2012), Probable Cause Affidavit (11/06/2012), and Warrant for Arrest (11/14/2012) for the charge of Petit Theft. According to the documents, GAINES admitted to the allegations.

Exhibit #4 consists of a copy of court documents from the WAKULLA COUNTY CLERK OF COURTS. The documents show GAINES was arrested in Wakulla County on 11/09/2012 and charged with possession of Schedule 4 narcotic with intent to sale and Trafficking in Illegal Drugs. According to the documents, GAINES admitted to the allegations.

INTERVIEW OF ERIC JASEN GAINES (subject)

Employment:

None reported

Residence:

7 Lilac Lane
Crawfordville, Florida 32327
(850) 566-4001

KENNEDY contacted GAINES telephonically on 11/16/2012 and notified GAINES of this investigation. GAINES scheduled an interview with KENNEDY for 2:30 pm on 11/19/2012.

On 11/19/2012 KENNEDY received a telephone call from GAINES. GAINES stated he has retained an attorney, who has advised GAINES not to speak to KENNEDY. KENNEDY advised GAINES to have his attorney fax a letter of representation to KENNEDY. No letter of representation has been received as of 11/20/2012.

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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STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: The Order Compelling Examination of
Eric Jasen Gaines, II, R.P.T.
Registration Number RPT 45259
Case Number 2012-16863

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 456, 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

Leslie Parsons, D.O.
329 N. Broad Street
Thomasville, GA 31792
(229) 403-1512
ON
Wednesday, July 31, 2013 @ 1:00 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 465.016(1)(m) or 456.072(1)(z), 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 Sections 465.016(1)(m) or 456.072(1)(z), 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, Eric Gaines, II, R.P.T. (Mr. Gaines), was registered pharmacy technician within the state of Florida, having been issued registration number RPT 45259, pursuant to Chapter 465, Florida Statutes (2012).

2. On or about October 26, 2012, Publix Loss Prevention Officer, Mr. B.H., received a tip from a Publix customer reporting that someone in the Publix Pharmacy, located at 5032 Capital Circle SW, Tallahassee, Florida, was selling stolen prescription medications from the store.

3. On or about November 2, 2012, the cameras within the pharmacy were repositioned to allow additional monitoring of the events occurring within the pharmacy.

4. The video surveillance taken on November 3, 2012, showed Mr. Gaines dumping prescription pills from multiple bottles into his hand and placing

the medications into the pocket of his work jacket. The pharmacy manager conducted a targeted drug count before Mr. Gaines began work on November 3, 2012, and recounted after Mr. Gaines's shift. The drug count revealed a shortage in the following medications: alprazolam 0.5mg (194 pills taken); alprazolam 1mg (200 pills taken); alprazolam 2mg (4 pills taken); hydrocodone/APAP 5/325mg (115 pills taken); hydrocodone/APAP 5/500mg (71 pills taken); hydrocodone/APAP 10/500mg (29 pills taken).

5. Alprazolam, also known by the brand name Xanax, is prescribed to treat anxiety. According to Section 893.03(4), Florida Statutes (2012), alprazolam 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 alprazolam may lead to limited physical or psychological dependence relative to the substances in Schedule III.

6. Hydrocodone/APAP, also known by the brand name Vicodin, contains hydrocodone and acetaminophen, or Tylenol and is prescribed to treat pain. According to Section 893.03(3), Florida Statutes (2012), 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. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

7. The video surveillance of November 3, 2012, also showed Mr. Gaines consuming liquid hydrocodone in the back of the pharmacy during his shift.

8. On or about November 5, 2012, Mr. B.H. conducted an interview of Mr. Gaines in the presence of the store manager, Ms. J.C. During the interview, Mr. Gaines admitted to stealing various controlled substances, including Vicodin, Xanax, Tramadol and Percocet, on approximately 10 to 15 occasions during the months of August through November, 2012. Mr. Gaines admitted to stealing approximately 1,115 pills from the pharmacy during that time. In a written statement, Mr. Gaines admitted to consuming some of the pills as well as selling or giving away others.

9. Tramadol, commonly known by the brand name Ultram, is an opioid class medication prescribed to treat pain. Tramadol is a legend drug, but not a controlled substance. Tramadol, like all opioid-class drugs, can affect mental alertness, is subject to abuse, and can be habit forming.

10. Percocet is a brand name for oxycodone/APAP, which contains

oxycodone and acetaminophen or Tylenol. 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.

11. Mr. Gaines informed Mr. B.H. and Deputy S.E., a Leon County Sheriff's Deputy, that he also possessed additional stolen medication at his home in Crawfordville, Florida.

12. On or about November 5, 2012, deputies with the Wakulla County Sheriff's Office Narcotics Unit conducted a search of Mr. Gaines's home. The deputies observed and seized 198 tablets of Alprazolam 1mg, 192 tablets of Alprazolam 0.5mg, 20 tablets of acetaminophen/hydrocodone (unknown dosage levels), and 2 Ambien tablets that Mr. Gaines kept behind his headboard. Deputies also observed unused syringes that Mr. Gaines kept in his bathroom.

13. Ambien is the brand name for the drug zolpidem, prescribed to treat insomnia. According to Title 21, Section 1308.14, Code of Federal Regulations, zolpidem is a Schedule IV controlled substance. Zolpidem can cause dependence and is subject to abuse.

14. Mr. Gaines admitted to Deputy J.P., a deputy with the Wakulla

County Sheriff's Office, that he ingested some of the stolen medications and he traded other medications for food at a local restaurant. Mr. Gaines told Deputy J.P. that giving medications to other people made him feel "cooler."

15. On or about November 5, 2012, Publix terminated Mr. Gaines from employment as a registered pharmacy technician due to the theft of medications from the pharmacy.

16. Section 456.072(1)(z), Florida Statutes (2012), states, in pertinent part, "[t]he following acts constitute grounds for which... disciplinary action[]... may be taken: [b]eing 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."

17. Section 456.072(1)(z), Florida Statutes (2012), also states, "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. Mr. Gaines admitted to consuming multiple controlled substances that he stole from his employer. He was also observed on surveillance video consuming controlled substances in the workplace while on duty as a registered pharmacy technician. Mr. Gaines's behavior indicates that he is experiencing at least some level of drug dependence, or impaired judgment as a result of drug dependence, and may be potentially dangerous if he continues to work in the field of pharmacy where he will necessarily be exposed to multiple controlled substances.

3. Therefore, the State Surgeon General, through his undersigned designee, concludes that probable cause exists to believe Mr. Gaines 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. Gaines is necessary to protect the public and ensure that he is able to practice pharmacy 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 Section 456.072(1)(z), Florida Statutes (2012), should be enforced.

DONE and ORDERED by the Department of Health on this 29th 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:
Louise Wilhite-St Laurent
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Florida bar Number 0091244
(850) 245 – 4444 ext. 8331 Telephone
(850) 245 – 4662 Facsimile

Final Order No. DOH-13-1014-ESO -MQA
FILED DATE JUN 0 4 2013
Department of Health
By [signature]
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the Registration of
Eric Jasen Gaines, II, R.P.T.
Registration Number RPT 45259
Case Number 2012-16863

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 Eric Jasen Gaines, R.P.T., to practice as a registered pharmacy technician in the State of Florida. Mr. Gaines holds registration number RPT 45259. His address of record is 7 Lilac Lane, Crawfordville, Florida 32327. The following Findings of Fact and Conclusions of Law support the emergency suspension of Mr. Gaines's registration to practice as a registered 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 (2012). Section 456.073(8), Florida Statutes (2012), authorizes the State Surgeon General to summarily suspend Mr. Gaines's registration to practice as a registered 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, Mr. Gaines was a registered pharmacy technician in the State of Florida, pursuant to Chapter 465, Florida Statutes (2012), and worked as a registered pharmacy technician at Publix Pharmacy located at 5032 Capital Circle Southwest, Suite 1, Tallahassee, Florida 32305.

3. On or about October 26, 2012, B.H., a Publix Loss Prevention Officer, received a tip from a Publix customer that a pharmacy employee named "Eric" was selling stolen prescription medications from the store.

4. After receiving this information, B.H. ran a report for the pharmacy location where Mr. Gaines worked to determine if any medications were missing. The report revealed the following discrepancies: Xanax 0.5mg was short by 115 tablets; alprazolam 0.5mg was short by 168 tablets; temazepam 30mg was short by 12 tablets; hydrocodone/APAP 5/500mg was short by 158 tablets; hydrocodone/APAP 7.5/3.25mg was short by 86 tablets; hydrocodone/APAP 10/325mg was short by 65 tablets; and hydrocodone/APAP 10/500mg was short by 99 tablets.

5. Alprazolam, also known by the brand name Xanax, is prescribed to treat anxiety. According to Section 893.03(4), Florida Statutes (2012), alprazolam 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 alprazolam may lead to limited physical or psychological dependence relative to the substances in Schedule III.

6. Temazepam is prescribed to treat insomnia. According to Section 893.03(4), Florida Statutes (2012), temazepam 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 temazepam may lead to limited physical or psychological dependence relative to the substances in Schedule III.

7. Hydrocodone/APAP, also known by the brand name Vicodin, contains hydrocodone and acetaminophen, or Tylenol and is prescribed to treat pain. According to Section 893.03(3), Florida Statutes (2012), 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. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

8. On or about November 2, 2012, Publix pharmacy surveillance cameras were repositioned for additional monitoring.

9. The video surveillance taken on November 3, 2012, showed Mr. Gaines dumping prescription pills from multiple bottles into his hand and placing the medications into the pocket of his work jacket. The pharmacy manager conducted a targeted drug count before Mr. Gaines began work on November 3, 2012, and recounted after Mr. Gaines's shift. The drug count revealed a shortage of the following medications: 194 pills of alprazolam 0.5mg; 200 pills of alprazolam 1mg; 4 pills of alprazolam 2mg; 115 pills of hydrocodone/APAP 5/325mg; 71 pills of hydrocodone/APAP 5/500mg; and 29 pills of hydrocodone/APAP 10/500mg.

10. The video surveillance from November 3, 2012, also showed Mr. Gaines consuming liquid hydrocodone in the back of the pharmacy during his shift.

11. On or about November 5, 2012, B.H. conducted an interview of Mr. Gaines in the presence of J.C., the store manager. During the

interview, Mr. Gaines admitted to stealing various controlled substances, including Vicodin, Xanax, Tramadol, and Percocet on approximately 10 to 15 occasions from August 2012 to November 2012. Mr. Gaines admitted to stealing approximately 1,115 pills from the pharmacy during that time. In a written statement, Mr. Gaines admitted to consuming some of the pills as well as selling or giving away others.

12. Tramadol, commonly known by the brand name Ultram, is an opioid class medication prescribed to treat pain. Tramadol is a legend drug, but not a controlled substance. Tramadol, like all opioid-class drugs, can affect mental alertness, is subject to abuse, and can be habit forming.

13. Percocet is a brand name for oxycodone/APAP, which contains oxycodone and acetaminophen or Tylenol. 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.

14. On or about November 5, 2012, S.E., a Leon County Sheriff's Deputy, interviewed Mr. Gaines. Mr. Gaines informed S.E. that once he began providing stolen pills to friends and acquaintances, it made Mr.

Gaines feel good that people wanted something from him.

15. Mr. Gaines also informed B.H. and S.E. that he possessed additional stolen medication at his home in Crawfordville, Florida.

16. On or about November 5, 2012, deputies with the Wakulla County Sheriff's Office Narcotics Unit conducted a search of Mr. Gaines's home. The deputies observed and seized 198 tablets of Alprazolam 1mg, 192 tablets of Alprazolam 0.5mg, 20 tablets of acetaminophen/hydrocodone of unknown dosage levels, and 2 Ambien tablets. Mr. Gaines kept all of the seized medications behind his headboard. Deputies also observed unused syringes that Mr. Gaines kept in his bathroom.

17. Ambien is the brand name for the drug zolpidem, prescribed to treat insomnia. According to Title 21, Section 1308.14, Code of Federal Regulations, zolpidem is a Schedule IV controlled substance. Zolpidem can cause dependence and is subject to abuse.

18. Mr. Gaines admitted to J.P., a deputy with the Wakulla County Sheriff's Office, that he ingested some of the stolen medications himself and traded other medications for food at a local restaurant. Mr. Gaines told J.P. that supplying pills to his friends made him feel "cooler."

19. On or about November 5, 2012, Publix terminated Mr. Gaines from employment as a registered pharmacy technician due to the theft of medications from the pharmacy.

20. Mr. Gaines entered a plea to theft charges on or about March 11, 2013, and was placed on probation for a period of six months.

21. In the course of practicing pharmacy, registered pharmacy technicians assist the pharmacist 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

22. Mr. Gaines's behavior in stealing over 1,100 prescription medication tablets for personal use over a three-month period, his use of the stolen drugs to benefit friends and acquaintances, his actual consumption of controlled substances while working in the pharmacy, and his motive for his actions clearly demonstrate that he is lacking the in judgment and moral character needed to practice as a registered pharmacy

technician.

23. As a result of his employment as a registered pharmacy technician, Mr. Gaines was aware that prescription medications and controlled substances may only be dispensed to patients with prescriptions who need the medications for a legitimate health reason. Despite this, Mr. Gaines illegally dispensed and distributed controlled substances to his friends, acquaintances and himself while knowing that no legitimate medical reason existed for the dispensing of the substances.

24. Mr. Gaines's lack of good judgment and moral character, his use of non-prescribed controlled substances while working, his illegal distribution of stolen controlled substances to individuals without a medical necessity, and his disregard for the laws and rules governing the practice of pharmacy in the State of Florida represent a significant likelihood that Mr. Gaines will cause harm to the general public. This probability constitutes an immediate serious danger to the health, safety, and welfare of the citizens of the State of Florida. Restricting Mr. Gaines's registration would not adequately protect the public because the very nature of practicing as a registered pharmacy technician puts Mr. Gaines in contact with legend drugs and controlled substances, which creates the risk for

further theft and distribution of the controlled substances. As a result, nothing short of the immediate suspension of Mr. Gaines'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 (2012), and Chapter 465, Florida Statutes (2012), as set forth above.

2. Section 465.016(1)(i), Florida Statutes (2012), subjects registered pharmacy technicians to discipline, including suspension as specified in Section 456.072(2), Florida Statutes (2012), for "[c]ompounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy."

3. Mr. Gaines violated Section 465.016(1)(i) by:

a. Dispensing or distributing alprazolam, or Xanax, to himself,

and/or to friends or acquaintances, outside of the practice of pharmacy;

b. Dispensing or distributing hydrocodone/APAP, or Vicodin, to himself, and/or to friends or acquaintances, outside of the practice of pharmacy;

c. Dispensing or distributing tramadol to himself and/or to friends or acquaintances, outside of the practice of pharmacy;

d. Dispensing or distributing oxycodone/APAP to himself and/or to friends or acquaintances, outside of the practice of pharmacy; and/or

e. Dispensing or distributing Ambien to himself and/or to friends or acquaintances, outside of the practice of pharmacy.

4. Section 120.60(6), Florida Statutes (2012), 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.

5. Mr. Gaines'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 (2012), it is

ORDERED THAT:

1. The registration of Eric Jasen Gaines, II, registration number RPT 45259, is immediately suspended.

2. A proceeding seeking formal discipline of the registration of Mr. Gaines 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 (2012).

DONE and ORDERED this 3rd day of June, 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.

STATE OF FLORIDA
Department of Health
ELECTION OF RIGHTS

DOH v. **Eric Jasen Gaines, II, R.P.T.** DOH Case Number **2012-16863**

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 licensure 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)

Eric Jasen Gaines II

Address: [redacted]

Lic. No. [redacted]

Phone No. [redacted]

FAX No. [redacted]

E-Mail [redacted]

STATE OF FLORIDA
COUNTY OF Leon

Before me, personally appeared Eric Jasen Gaines II, whose identity is known to me or by _____ (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 8th day of July, 2013.

Notary Public-State of Florida

My Commission Expires:

Fran P. Rowls
Type or Print Name

FRAN P. ROWLS
MY COMMISSION # EE 146909
EXPIRES: December 27, 2015
Bonded Thru Budget Notary Services

PLEASE MAIL AND/OR FAX COMPLETED FORM TO: Louise Wilhite-St. Laurent, Assistant General Counsel, DOH, Prosecution Services Unit, 4052 Bald Cypress Way, Bin C-65, Tallahassee, Florida 32399-3265. Telephone Number: (850) 245-4444, ext. 8331; FAX (850) 245-[illegible]62; TDD 1-800-955-8771

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-16863**

ERIC JASEN GAINES, II, RPT,

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 (2003). 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 (2003),[1] states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or after July 1, 2001,

[1] Ch. 2003-416, § 19, Laws of Fla., effective September 15, 2003, amended Section 456.072(4), Florida Statutes (2003), to include the underlined language.

> 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. . . . (emphasis added)

3. The investigation and prosecution of this case has resulted in costs in the total amount of $6,072.92, based on the following itemized statement of costs:

a. Total costs for Complaints $82.35
b. Total costs for Investigations $1,515.75
c. Total costs for Legal $2,052.68
d. Total costs for expenses $2,422.14

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $6,072.92, 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 $6,072.92 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 (2003).

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $6,072.92.

DATED this 27th day of August, 2013.

Respectfully submitted,

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

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 27th day of August, 2013 to Eric Jasen Gaines, II, RPT, 7 Lilac Lane, Crawfordville, Florida 32327.

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) **2012-16863** (Department of Health v. **Eric Jasen Gaines, II, R.P.T.**) are **SIX THOUSAND SEVENTY-TWO DOLLARS AND NINETY-TWO CENTS ($6,072.92).**

6) The costs for DOH case numbers **2012-16863** (Department of Health v. **Eric Jasen Gaines, II, 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 **2012-16863** (Department of Health v. **Eric Jasen Gaines, II, RPT**) 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

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 26th day of August, 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: 201216863

Subject's Name: GAINES, ERIC JASEN II

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.50	$82.35
Investigation:	23.90	$1,515.75
Legal:	19.30	$2,052.68
Compliance:	0.10	$3.33
	**********	**********
Sub Total:	44.80	$3,654.11
Expenses to Date:		$2,418.81
Prior Amount:		$0.00
Total Costs to Date:		$6,072.92

EXHIBIT
tabbies
1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216863

Report Date 08/26/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
COMPLIANCE MANAGEMENT UNIT						
HC08	0.10	$33.33	$3.33	06/04/2013	119	REVIEWING FO/CITATIONS & TERM INPUT
Sub Total	**0.10**		**$3.33**			
CONSUMER SERVICES UNIT						
HA132	0.90	$54.90	$49.41	11/15/2012	25	REVIEW CASE FILE
HA23	0.10	$54.90	$5.49	11/16/2012	144	CSU INVESTIGATIVE WORK
HA132	0.30	$54.90	$16.47	04/12/2013	35	TELEPHONE CALLS
HA132	0.20	$54.90	$10.98	06/07/2013	35	TELEPHONE CALLS
Sub Total	**1.50**		**$82.35**			
INVESTIGATIVE SERVICES UNIT						
CI45	1.20	$61.19	$73.43	11/16/2012	4	ROUTINE INVESTIGATIVE WORK
CI45	1.10	$61.19	$67.31	11/16/2012	76	REPORT PREPARATION
CI56	0.50	$61.19	$30.60	11/16/2012	58	TRAVEL TIME
CI56	0.10	$61.19	$6.12	11/16/2012	1	ROUTINE ADMINISTRATIVE DUTIES
CI45	0.20	$61.19	$12.24	11/19/2012	4	ROUTINE INVESTIGATIVE WORK
CI45	0.40	$61.19	$24.48	11/19/2012	76	REPORT PREPARATION
CI45	1.30	$61.19	$79.55	11/20/2012	76	REPORT PREPARATION
CI45	1.20	$63.98	$76.78	12/10/2012	6	SUPPLEMENTAL INVESTIGATION
CI45	0.90	$63.98	$57.58	01/02/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.10	$63.98	$6.40	01/08/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.80	$63.98	$51.18	01/16/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.90	$63.98	$57.58	01/23/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	1.20	$63.98	$76.78	01/24/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.10	$63.98	$6.40	01/31/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.40	$63.98	$25.59	02/11/2013	6	SUPPLEMENTAL INVESTIGATION

EXHIBIT
exhibit 2

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CI45	0.10	$63.98	$6.40	02/18/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.40	$63.98	$25.59	02/21/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.40	$63.98	$25.59	02/21/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.10	$63.98	$6.40	03/07/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	1.30	$63.98	$83.17	03/12/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.10	$63.98	$6.40	03/28/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.20	$63.98	$12.80	04/03/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.70	$63.98	$44.79	04/04/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.70	$63.98	$44.79	04/17/2013	6	SUPPLEMENTAL INVESTIGATION
CI52	0.20	$63.98	$12.80	04/17/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	2.30	$63.98	$147.15	04/18/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.20	$63.98	$12.80	04/22/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.40	$63.98	$25.59	05/09/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.80	$63.98	$51.18	05/13/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.40	$63.98	$25.59	05/15/2013	6	SUPPLEMENTAL INVESTIGATION
CI55	0.20	$63.98	$12.80	05/15/2013	1	ROUTINE ADMINISTRATIVE DUTIES
CI45	1.90	$63.98	$121.56	06/07/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	0.40	$63.98	$25.59	07/22/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	1.30	$63.98	$83.17	08/08/2013	6	SUPPLEMENTAL INVESTIGATION
CI45	1.40	$63.98	$89.57	08/09/2013	6	SUPPLEMENTAL INVESTIGATION
Sub Total	**23.90**		**$1,515.75**			

PROSECUTION SERVICES UNIT

HLL5A	0.20	$106.35	$21.27	11/19/2012	25	REVIEW CASE FILE
HLL91B	0.10	$106.35	$10.64	11/20/2012	25	REVIEW CASE FILE
HLL91B	0.30	$106.35	$31.91	11/27/2012	25	REVIEW CASE FILE
HLL91B	0.10	$106.35	$10.64	11/27/2012	103	REVIEW SUPPLEMENTAL REPORT
HLL91B	0.10	$106.35	$10.64	12/04/2012	60	MISCELLANEOUS
HLL91B	0.10	$106.35	$10.64	01/08/2013	25	REVIEW CASE FILE
HLL91B	0.20	$106.35	$21.27	03/07/2013	115	CONTACT WITH INVESTIGATORS
HLL91B	0.10	$106.35	$10.64	03/19/2013	103	REVIEW SUPPLEMENTAL REPORT

Time Tracking System
Itemized Cost by Complaint

Complaint 201216863

Report Date 08/26/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
HLL91B	0.20	$106.35	$21.27	03/28/2013	115	CONTACT WITH INVESTIGATORS
HLL91B	0.10	$106.35	$10.64	04/08/2013	35	TELEPHONE CALLS
HLL91B	0.10	$106.35	$10.64	04/08/2013	70	CONFERENCES WITH LAWYERS
HLL91B	0.10	$106.35	$10.64	04/18/2013	115	CONTACT WITH INVESTIGATORS
HLL91B	0.10	$106.35	$10.64	04/22/2013	115	CONTACT WITH INVESTIGATORS
HLL91B	0.10	$106.35	$10.64	04/29/2013	103	REVIEW SUPPLEMENTAL REPORT
HLL91B	0.10	$106.35	$10.64	05/15/2013	115	CONTACT WITH INVESTIGATORS
HLL91B	0.10	$106.35	$10.64	05/17/2013	103	REVIEW SUPPLEMENTAL REPORT
HLL91B	0.20	$106.35	$21.27	05/17/2013	26	PREPARE OR REVISE MEMORANDUM
HLL91B	0.10	$106.35	$10.64	05/17/2013	103	REVIEW SUPPLEMENTAL REPORT
HLL91B	0.20	$106.35	$21.27	05/17/2013	26	PREPARE OR REVISE MEMORANDUM
HLL101B	1.30	$106.35	$138.26	05/21/2013	25	REVIEW CASE FILE
HLL101B	2.00	$106.35	$212.70	05/21/2013	40	PREPARATION OF OR REVISION OF A PLEADING
HLL101B	4.00	$106.35	$425.40	05/21/2013	81	ESO/ERO
HLL101B	0.30	$106.35	$31.91	05/24/2013	40	PREPARATION OF OR REVISION OF A PLEADING
HLL101B	0.30	$106.35	$31.91	05/24/2013	40	PREPARATION OF OR REVISION OF A PLEADING
HLL101B	0.30	$106.35	$31.91	05/29/2013	81	ESO/ERO
HLL101B	0.80	$106.35	$85.08	06/04/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL101B	0.40	$106.35	$42.54	06/05/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL101B	0.10	$106.35	$10.64	06/06/2013	89	PROBABLE CAUSE PREPARATION
HLL101B	0.10	$106.35	$10.64	06/10/2013	35	TELEPHONE CALLS
HLL101B	0.50	$106.35	$53.18	06/11/2013	89	PROBABLE CAUSE PREPARATION
HLL101B	0.30	$106.35	$31.91	06/13/2013	63	PRESENTATION OF CASES TO PROBABLE CAUSE PANEL
HLL101B	2.00	$106.35	$212.70	06/13/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL101B	0.30	$106.35	$31.91	06/13/2013	63	PRESENTATION OF CASES TO PROBABLE CAUSE PANEL
HLL101B	2.00	$106.35	$212.70	06/13/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL101B	0.40	$106.35	$42.54	06/20/2013	89	PROBABLE CAUSE PREPARATION
HLL101B	0.20	$106.35	$21.27	06/20/2013	63	PRESENTATION OF CASES TO PROBABLE CAUSE PANEL
HLL101B	0.40	$106.35	$42.54	06/20/2013	89	PROBABLE CAUSE PREPARATION
HLL101B	0.20	$106.35	$21.27	06/20/2013	63	PRESENTATION OF CASES TO PROBABLE CAUSE PANEL
HLL101B	0.50	$106.35	$53.18	08/14/2013	91	BOARD MEETING PREPARATION
HLL101B	0.30	$106.35	$31.91	08/15/2013	91	BOARD MEETING PREPARATION

Time Tracking System
Itemized Cost by Complaint

Complaint 201216863

Report Date 08/26/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
Sub Total	**19.30**		**$2,052.68**			

Total Cost	**$3,654.11**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint 201216863

Report Date: 08/26/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description
PROSECUTION SERVICES UNIT				
HLL96B	07/31/2013	$2,400.00	131747	PHYSICIAN SERVICES (OPS)
HLL101B	06/18/2013	$18.81	133100	LEGAL & OFFICIAL ADVERTISEMENTS
	SubTotal	**$2,418.81**		
	Total Expenses	**$2,418.81**		

August 27, 2013

Eric Jansen Gaines, II, R.P.T.
7 Lilac Lane
Crawfordville, Florida 32327

Re: DOH vs. Eric Jansen Gaines, II, R.P.T.
DOH Case Number: 2012-16863

Dear Mr. Gaines:

I am in receipt of your election of rights requesting a hearing not involving disputed issues of material fact executed by you on July 8, 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 for this case to be presented at the next regularly scheduled meeting of the Florida Board of Pharmacy.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Louise Wilhite-St. Laurent.
Assistant General Counsel

John H. Armstrong, MD
Surgeon General and Secretary of Health

LSL/mla
Enclosures

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201301501

LAMONTE GEORGE HAMBRICK,
RESPONDENT.

NOTICE

TO: LAMONTE GEORGE HAMBRICK
PO BOX 151572
TAMPA, FL 33684

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on October 9, 2013, commencing at 9:00a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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 9:00a.m.; therefore, it is imperative that you arrive promptly at 9:00a.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 18th day of September, 2013.

for Mark Whitten
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: Mark Whitten, Executive Director, Board of Pharmacy
FROM: Lauren Leikam, General Counsel
RE: **Hearing - No Disputed Material Facts**
SUBJECT: DOH v. Lamonte George Hambrick, R.P.T.
DOH Case Number: 2013-01501
DATE: August 19, 2013

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **October 9, 2013** meeting of the board. The following information is provided in this regard.

Subject:	Lamonte George Hambrick, R.P.T.
Subject's Address of Record:	P.O. Box 151572 Tampa, FL 33684
Enforcement Address:	Hardee Work Camp DC#: T79719 6901 State Road 62 Bowling Green, Florida 33834
Subject's License No:	8527 **Rank:** R.P.T.
Licensure File No:	899
Initial Licensure Date:	11/17/2009
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Ct. 1: Violated Section 456.072(1)(c), F.S. (2012) Ct. 2: Violated Section 456.072(1)(x), F.S. (2012)
Prior Discipline:	None
Probable Cause Panel:	March 8, 2013 Weiser & Meshad
Subject's Attorney:	Pro Se

Complainant/Address: Department Of Health/Bureau Of Operations

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
Exhibit 1- Complaint Cost Summary
Exhibit 2- Itemized Cost by Complaint
Board Notification Letter
Election of Rights
Defense Attorney/Respondent Documents
Prosecutor's Documents
PCP Memo
Emergency Suspension Order (entire packet)
Affidavit of Diligent Search
Certified Mail Receipt
Administrative Weekly
Final Investigative Report
Exhibits 1-2

LAL/bhh

DISCIPLINARY GUIDELINES:

Section 456.072(1)(c), Florida Statutes (2012): 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.

Minimum: Misdemeanor- $1,000.00 fine/ Felony- $3,000 fine and one (1) year probation
Maximum: Misdemeanor- Revocation /Felony–Revocation

Section 456.072(1)(x), Florida Statutes (2012): 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.

Minimum: $1,000.00 fine

Maximum: Revocation

PRELIMINARY CASE REMARKS: INFORMAL HEARING

This is a two count administrative complaint alleging Respondent violated Section 456.072(1)(c), Florida Statutes (2012), and Section 456.072(1)(x), Florida Statutes (2012). On or about October 31, 2012, Respondent entered a plea of guilty to one (1) count of trafficking in illegal drugs twenty-eight (28) grams to twenty (20), kilograms, a first degree felony, in violation of Section 893.135(1)(c)(1)(c), Florida Statutes (2012); and one (1) count of grand theft, a third degree felony, in violation of Section 812.014(2)(c)(2), Florida Statutes (2012). Respondent failed to report his pleas to the department or board within thirty days from the date Respondent entered the pleas.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-01501**

LAMONTE GEORGE HAMBRICK, R.P.T.,

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 **Registered Pharmacy Technician**, thereby affecting the Respondent's substantial interests.

2. On or about April 10th, 2013, Petitioner served Respondent with the Administrative Complaint via Certified Mail at the Hardee Work Camp, DC#T79719, 6901 State Road 62, Bowling Green, Florida 33834, and P.O. Box 15152, Tampa, Florida 33684, at the 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 **Registered Pharmacy Technician**.

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
State Surgeon General and Secretary of Health

LAUREN A. LEIKAM
Assistant General Counsel
Florida Bar No.: **0887700**
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Telephone (850) 245-4444
Facsimile (850) 245-4683
Email: lauren_leikam@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 furnished via U.S. mail to: **LAMONTE GEORGE HAMBRICK, R.P.T., of POST OFFICE BOX 151572 TAMPA, FLORIDA 33684, and THE HARDEE WORK CAMP, DC#T79719, 6901 STATE ROAD 62, BOWLING GREEN, FLORIDA 33834** on, this 30th day of August, 2013.

LAUREN A. LEIKAM
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-01501**

LAMONTE GEORGE HAMBRICK, 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, Lamonte George Hambrick, 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 Complaint, Respondent was a registered pharmacy technician within the State of Florida, having been issued license number RPT 8527.

3. Respondent's address of record is P.O. Box 151572, Tampa, Florida 33684.

4. On or about October 31, 2012, in the Circuit Court of the Thirteenth Judicial Circuit in and for Hillsborough County, Florida, in case number 12-CF-007394, Respondent entered a plea of guilty to one (1) count of trafficking in illegal drugs twenty-eight (28) grams to twenty (20) kilograms, a first degree felony, in violation of Section 893.135(1)(c)1.c., Florida Statutes (2012); and one (1) count of grand theft, a third degree felony, in violation of Section 812.014(2)(c)2., Florida Statutes (2012).

5. Respondent failed to report the above referenced pleas to the Board of Pharmacy within thirty (30) days after the date Respondent entered the pleas.

COUNT I

6. Petitioner realleges and incorporates paragraphs one (1) through five (5) as if fully set forth herein.

7. Section 456.072(1)(c), Florida Statutes (2012), 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 discipline.

8. As set forth above, on or about October 31, 2012, Respondent entered a plea of guilty to one (1) count of trafficking in illegal drugs twenty-eight (28) grams to twenty (20) kilograms, in violation of Section 893.135(1)(c)1.c., Florida Statutes (2012); and one (1) count of grand theft, in violation of Section 812.014(2)(c)2., Florida Statutes (2012); which are crimes that relate to the practice of the licensee's profession as a registered pharmacy technician.

9. Based on the foregoing, Respondent violated Section 456.072(1)(c), Florida Statutes (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 II

10. Petitioner realleges and incorporates paragraphs one (1) through five (5) as if fully set forth herein.

11. Section 456.072(1)(x), Florida Statutes (2012), provides 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.

12. As set forth above, Respondent failed to timely report to the board in writing his pleas of guilt in the above-referenced criminal case within thirty (30) days after date Respondent entered the pleas.

13. Based on the foregoing, Respondent violated Section 456.072(1)(x), Florida Statutes (2012), 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.

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 8th **day of** March, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and Secretary of Health

Lauren A. Leikam
Assistant General Counsel
Fla. Bar No. 0088700
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

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE MAR 08 2013

/LAL
PCP: 3/8/13
PCP Members: WEIZER/MESHAD

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO.: 2013-01501**

LAMONTE GEORGE HAMBRICK, 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. 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 $1,125.96, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**0.80**	**$43.92**
Investigation:	**9.30**	**$589.57**
Legal:	**4.60**	**$489.25**
Compliance:	**0.10**	**3.22**
Sub Total:	**14.80**	**$1,125.96**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$1,125.96**

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $636.71 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 $636.71 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 $636.71.

DATED this 30th day of August, 2013

Respectfully Submitted,

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

LAUREN A. LEIKAM
Assistant General Counsel
Florida Bar No. **0887700**
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email:lauren_leikam@doh.stat.fl.us

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 to: **LAMONTE GEORGE HAMBRICK, POST OFFICE BOX 151572, TAMPA, FLORIDA 33684, and THE HARDEE WORK CAMP, DC#T79719, 6901 STATE ROAD 62, BOWLING GREEN, FLORIDA 33834,** on this 30th day of August, 2013.

LAUREN A. LEIKAM
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) **2013-01501** (Department of Health v. **LAMONTE GEORGE HAMBRICK, R.P.T.**) are **ONE THOUSAND ONE HUNDRED TWENTY-FIVE DOLLARS AND NINETY-SIX CENTS ($1,125.96).**

6) The costs for DOH case numbers **2013-01501** (Department of Health v. **LAMONTE GEORGE HAMBRICK, 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 **2013-01501** (Department of Health v. **LAMONTE GEORGE HAMBRICK, R.P.T.**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

EXHIBIT
tabbies
A

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 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 13 day of May, 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: 201301501

Subject's Name: HAMBRICK, LAMONTE GEORGE

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.80	$43.92
Investigation:	9.30	$589.57
Legal:	4.60	$489.25
Compliance:	0.10	$3.22
	**********	**********
Sub Total:	14.80	$1,125.96
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,125.96

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201301501

Report Date 05/10/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
COMPLIANCE MANAGEMENT UNIT						
HC27	0.05	$32.13	$1.61	02/11/2013	137	PRIORITY DOWNGRADES/UPGRADES
HC27	0.05	$32.13	$1.61	02/20/2013	125	LICENSE STATUS CHANGE
Sub Total	**0.10**		**$3.22**			
CONSUMER SERVICES UNIT						
HA23	0.80	$54.90	$43.92	01/31/2013	144	CSU INVESTIGATIVE WORK
HA23	0.60	$54.90	$32.94	02/04/2013	76	REPORT PREPARATION
Sub Total	**1.40**		**$76.86**			
INVESTIGATIVE SERVICES UNIT						
TI128	0.50	$63.98	$31.99	01/24/2013	58	TRAVEL TIME
TI128	1.50	$63.98	$95.97	01/24/2013	4	ROUTINE INVESTIGATIVE WORK
TI128	1.20	$63.98	$76.78	01/25/2013	4	ROUTINE INVESTIGATIVE WORK
TI128	0.50	$63.98	$31.99	01/25/2013	58	TRAVEL TIME
TI123	1.00	$63.98	$63.98	02/20/2013	6	SUPPLEMENTAL INVESTIGATION
TI123	4.00	$63.98	$255.92	02/22/2013	6	SUPPLEMENTAL INVESTIGATION
Sub Total	**8.70**		**$556.63**			
PROSECUTION SERVICES UNIT						
HLL97A	0.40	$106.35	$42.54	02/12/2013	25	REVIEW CASE FILE
HLL97A	1.10	$106.35	$116.99	02/12/2013	81	ESO/ERO
HLL97A	0.30	$106.35	$31.91	02/12/2013	46	LEGAL RESEARCH
HLL97A	0.20	$106.35	$21.27	02/13/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL97A	1.20	$106.35	$127.62	02/22/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL97A	0.10	$106.35	$10.64	02/25/2013	46	LEGAL RESEARCH

tabbies

EXHIBIT 2

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 05/10/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

August 30, 2013

VIA U. S. MAIL

LAMONTE GEORGE HAMBRICK
HARDEE WORK CAMP, DC#T79719
6901 STATE ROAD 62
BOWLING GREEN, FLORIDA 33834

Re: DOH vs. LAMONTE GEORGE HAMBRICK, R.P.T.
DOH Case Number: 2013-01501

Dear Mr. HAMBRICK:

I am in receipt of your election of rights requesting a hearing not involving disputed issues of material fact executed by you on **April 2, 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,

LAUREN A. LEIKAM
Assistant General Counsel

LAL/bhh

August 30, 2013

VIA U. S. MAIL

LAMONTE GEORGE HAMBRICK
POST OFFICE BOX 151572
TAMPA, FLORIDA 33684

Re: DOH vs. LAMONTE GEORGE HAMBRICK, R.P.T.
DOH Case Number: 2013-01501

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Sincerely,

LAUREN A. LEIKAM
Assistant General Counsel

LAL/bhh

August 30, 2013

VIA U. S. MAIL

LAMONTE GEORGE HAMBRICK
HARDEE WORK CAMP, DC#T79719
6901 STATE ROAD 62
BOWLING GREEN, FLORIDA 33834

Re: DOH vs. LAMONTE GEORGE HAMBRICK, R.P.T.
DOH Case Number: 2013-01501

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Sincerely,

LAUREN A. LEIKAM
Assistant General Counsel

LAL/bhh

August 30, 2013

VIA U. S. MAIL

LAMONTE GEORGE HAMBRICK
POST OFFICE BOX 151572
TAMPA, FLORIDA 33684

Re: DOH vs. LAMONTE GEORGE HAMBRICK, R.P.T.
DOH Case Number: 2013-01501

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Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

LAUREN A. LEIKAM
Assistant General Counsel

LAL/bhh

ELECTION OF RIGHTS
Case Name: Lamonte George Hambrick, RPT Case No. 2013-01501
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 Agreement, have signed and am returning the Settlement Agreement **or** I am interested in settling this case.

( ) I do not wish to continue practicing and have signed and returned the Voluntary Relinquishment of licensure form.

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.)

_____
Respondent's signature

Address: _____

Lic. No. _____

Phone No. _____

Fax No. _____

2013 MAR 32 AM 9:

PRACTITIONER REGULATION LEGAL

STATE OF FLORIDA
COUNTY OF Hardee

Before me personally appeared Hambrick Lamonte whose identity is known to be by Inmate ID (type of identification), and who under oath, acknowledges that his/her signature appears above. Sworn to and subscribed by Respondent before me this 22 day of March, 2013.

_____
Notary Public
My Commission Expires:

RONALD K. BARNES
MY COMMISSION # EE 166266
EXPIRES: March 30, 2016
Bonded Thru Budget Notary Services

PLEASE MAIL AND/OR FAX COMPLETED FORM TO: Lauren A. Leikam, Assistant General Counsel, DOH, Prosecution Services Unit, 4052 Bald Cypress Way, Bin C-65, Tallahassee, Florida 32399-3265. Telephone Number: (850) 245-4444, ext. 8150; FAX (850) 245-4683- TDD 1-800-955-8771.

Lamarte Hambrick - T79714
Hardee Work Camp
6899 State Road 62
Bowling Green, FL 33834

USA
Justice
FOREVER

Lauren A. LeiKam, Assistant General Counsel, DOH
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-8771

32399870 17

PROVIDED TO OKEECHOBEE
CORRECTIONAL INSTITUTION
ON 7-1-13 KD FOR MAILING
INMATE LEGAL MAIL

2013 JUL -5 AM 10:47

DOH Case No: 2013-01501 7/1/13

Dear Ms. Leikam,

Last month I received your letter stating that an informal hearing on my case is scheduled on August 14, 2013. My question to you is: Is it possible for me to attend this informal hearing even though I am incarcerated? If not, can a telephonic hearing be scheduled so I can at least be a part of the hearing? I stated to you before in a previous letter that my current case is pending review on appeal with the 2nd District Court of Appeal. My case number with them is: 2D13-1708. You can check the status of my case with them at their website: www.2dca.org. I was wondering if a final order or decision on my case could be postponed until a decision is made on my appeal? Also, is it still possible for me to voluntarily relinquish my license? If so, please let me know at your earliest possible convenience. Anything you can do would be greatly appreciated. I await to hear back from you as soon as possible.

Sincerely,
Lamonte Hambrick
#

Lamonte Hambrick-i 11719
Hardee Work Camp
6899 State Road 62
Bowling Green, FL 33834

MAILED FROM
HARDEE
CORRECTIONAL

Hasler
07/02/2013
US POSTAGE

FIRST-CLASS
Liberty
FOREVER
$00.00

ZIP 33834
011D1162578

Lauren Lei Kam
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399

32399837017

Case No: 2013-01501 April 17, 2013

Dear Ms. LeiKam,

I am writing you to inform you that I received the settlement agreement and I am rejecting it. The reason why is because I am appealing my case, and it is currently pending review from the 2nd District Court of Appeal. If you would like to check into it, the case no is: 2D13-1708. If possible, I would like to postpone an informal hearing with the Board of Pharmacy until my appeal is honored and resolved. Please let me know if this is satisfactory with you at your earliest convenience. Thank you kindly.

Sincerely,
Lemonte Hambrick
#Z

PROVIDED TO HARDEE CORRECTIONAL INSTITUTION FOR MAILING ON 4-17-13 BY INMATE LEGAL MAIL (SW)

2013 APR 22 AM 9:26

Lamonte Hambrick - T79719
Hardee Work Camp
6899 State Road 62
Bowling Green, FL 33834

U.S. POSTAGE
34102
FOREVER
03-13
08259836
APC
FE0093800105546 0625

Lauren A. Leikam
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399

32399$7017

Certified Article Number
7196 9008 9111 8827 3189
SENDERS RECORD

August 7, 2013,

Lamonte George Hambrick, R.P.T.
Hardee Work Camp
DC #: T79719
6901 State Road 62
Bowling Green, Florida 33834

Re: **Department of Health v. Lamonte George Hambrick, R.P.T.**
Complaint Number: 2013-01501

Dear Mr. Hambrick:

I received your letter dated July 1, 2013, requesting a postponement of your case before the Board of Pharmacy. I also understand Assistant General Counsel Casey Cowan responded to your request, and second request for a continuance was directed to the Board of Pharmacy. Again, the Board of Pharmacy does not allow telephonic appearance, and will not postpone this case indefinitely pending the outcome of your criminal appeal. However, the Board of Pharmacy has agreed to postpone your case until the October 2013 Board of Pharmacy meeting so that you may make arrangements to be present. You will receive a separate notice regarding the October 2013 Board of Pharmacy meeting. In the future, please direct any request for continuances directly to the Board of Pharmacy. As a prosecutor for the Department of Health, I do not have the authority to grant continuances, or change the time a hearing is scheduled to be heard.

Thank you for your attention to this matter. Please feel free to contact me at 850-245-4444 extension 8150 if you have any questions.

Sincerely,

Lauren A. Leikam
Assistant General Counsel

7196 9008 9111 8827 3189

TO:

Postponement Letter
Blondell/Leikam
Date Mailed 8/8/2013
2013-01501

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

Lamonte George Hambrick, R.P.T.
Hardee Work Camp
DC #: T79719
6901 State Road 62
Bowling Green, Florida 33834

Certified Article Number
7196 9008 9111 9326 6336
SENDERS RECORD

July 8, 2013

Lamonte George Hambrick, R.P.T.
Hardee Work Camp
DC #: T79719
6901 State Road 62
Bowling Green, Florida 33834

Re: **Department of Health v. Lamonte George Hambrick, R.P.T.**
Complaint Number: 2013-01501

Dear Mr. Hambrick:

I received the letter you sent to Ms. Leikam on July 1, 2013. Ms. Leikam is currently out of the office and I am responding on her behalf. In your letter, you indicated that you would like to attend the August Board of Pharmacy hearing via telephone and requested to postpone the case until a decision is made on your criminal appeal. Unfortunately, the Board of Pharmacy does not allow telephonic appearance and the Department is unwilling to postpone this case until a decision is made on your criminal appeal. If you would like to continue this case until the October Board of Pharmacy meeting, you will have to submit a request to the Board of Pharmacy.

You indicated in your letter that you are interested in relinquishing your license. If you would like to voluntarily relinquish your license, please sign and notarize the Voluntary Relinquishment of License included with this letter. If we do not receive the signed voluntary relinquishment form by August 5, 2013, your case will proceed to the Board of Pharmacy meeting as an informal hearing.

If you any questions, please contact me at the address below or via telephone at (850) 245-4444, extension 8103. Ms. Leikam is expected to return to the office on July 15, 2013, and she can be reached at extension 8150.

Sincerely,

Casey L. Cowan

Casey L. Cowan
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **Case No. 2013-01501**

LAMONTE GEORGE HAMBRICK, R.P.T

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, LAMONTE GEORGE HAMBRICK, license number **8527,** hereby voluntarily relinquishes Respondent's license as a registered 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 case. 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. Licensing authorities in other states may impose discipline in their jurisdiction based on discipline taken in Florida.

2. Respondent agrees to never reapply for licensure as a registered pharmacy technician in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy 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. 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 this case. 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.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review, 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 case.

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.

SIGNED this ____ day of _____, 2013.

_____
LAMONTE GEORGE HAMBRICK, R.P.T.

STATE OF FLORIDA
COUNTY OF _____

Before me personally appeared _____ whose identity is known to be by _____ (type of identification), and who under oath, acknowledges that his/her signature appears above. Sworn to and subscribed by Respondent before me this ____ day of _____, 2013.

_____
Notary Public
My Commission Expires:

7196 9008 9111 9326 6336

TO:

VR-Letter
Blondell/Leikam
Date Mailed 7/8/2013
2013-01501

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

Lamonte George Hambrick, R.P.T.
Hardee Work Camp
DC #: T79719
6901 State Road 62
Bowling Green, Florida 33834

2. Article Number

7196 9008 9111 9326 6336

3. Service Type **CERTIFIED MAIL™**

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Lamonte George Hambrick, R.P.T.
Hardee Work Camp
DC #: T79719
6901 State Road 62
Bowling Green, Florida 33834

VR-Letter/2013-01501
Blondell/Leikam

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly) B. Date of Delivery 7-10-13

C. Signature X ☐ Agent ☐ Addressee

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

Reference Information

JUL 2013 BOWLING GREEN FL 33834

PS Form 3811, January 2005 Domestic Return Receipt

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. Lamonte G. Hambrick, R.P.T.**
DOH Case Number 2013-01501

MEMBERS: Michele Weizer, PharmD, and Gavin W. Meshad

DATE OF PCP: **March 08, 2013** **AGENDA ITEM: A-1(LL)**

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:

Count I: **Section 456.072(1)(c), Florida Statutes (2012)**
Count II: **Section 456.072(1)(xx), 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** _____

Michele Weizer, PharmD, BCPS 3/8/2013
Chair, Probable Cause Panel Date
Board of Pharmacy

February 21, 2013

Certified Article Number
7196 9008 9111 5772 5923
SENDERS RECORD

Lamonte George Hambrick, RPT
P.O. Box 151572
Tampa, FL 33684

RE: Department of Health vs. Lamonte George Hambrick, R.P.T.
RE: Case Number: 2013-01501

Dear Mr. Hambrick:

Enclosed please find an Order of Emergency Suspension of License filed February 20, 2013, against your license 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 License.

If you have any questions, please do not hesitate to contact Lauren Leikam, Assistant General Counsel at (850) 245 4444.

Sincerely,

Melba L. Apellaniz
Regulatory Specialist II
Prosecution Services Unit

/mla
Enclosure

** Transmit Conf.Report **

P.1 Feb 21 2013 11:04am

Fax/Phone Number	Mode	Start	Time	Page	Result	Note
99216847	Normal	21:11:03am	0'29"	1	* O K	

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

February 21, 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. Lamonte George Hambrick, R.P.T.
RE: Case Number: 2013-01501

Dear Judge Cohen:

This letter is to advise you that the Department has issued an Emergency Suspension Order concerning the license of **Lamonte George Hambrick** 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 Lauren Leikam, Assistant General Counsel at (850) 245 4444.

Sincerely,

Melba L. Apellaniz
Regulatory Specialist II
Prosecution Services Unit

/mla

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
PHONE: 850/245-4444 • FAX 850/245-4662

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

February 21, 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. Lamonte George Hambrick, R.P.T.
RE: Case Number: 2013-01501

Dear Judge Cohen:

This letter is to advise you that the Department has issued an Emergency Suspension Order concerning the license of **Lamonte George Hambrick** 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,

Melba L. Apellaniz
Regulatory Specialist II
Prosecution Services Unit

/mla

Apellaniz, Melba

From: Apellaniz, Melba
Sent: Wednesday, February 20, 2013 3:06 PM
To: DL MQA Inv Serv Priority Mail Area6 (TI) Tampa
Subject: Hand Service ESO 13-01501/Hambrick
Attachments: Supp.Req.13-01501.Hambrick.2.20.13.doc; Inv.Report.13-01501.Hambrick.2.20.13.pdf; DOH 13-0287 ESO 201301501-1.PDF

Good Afternoon,

Attached please find a request to hand service ESO for case 2013-01501, Lamonte George Hambrick, R.P.T.

<<...>> <<...>> <<...>>

Thanks,

Melba L. Apellániz, RSII
Assistant to: Daniel Hernandez, DGC
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. 8223

Mission: To protect, promote, and improve the health of all people in Florida through integrated state, county, & community efforts.

Vision: To be the **Healthiest State** in the Nation

Values: ICARE

I innovation: We search for creative solutions and manage resources wisely.
C collaboration: We use teamwork to achieve common goals & solve problems.
A accountability: We perform with integrity & respect.
R responsiveness: We achieve our mission by serving our customers & engaging our partners.
E excellence: We promote quality outcomes through learning & continuous performance improvement.

Purpose: To protect the public through health care licensure, enforcement and information.

Focus: To be the nation's leader in quality health care regulation.

Final Order No. DOH-13-0287-ESO-MQA
FILED DATE: FEB 20 2013
Department of Health
By: [signature]
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the License of
Lamonte George Hambrick, R.P.T.
License No.: RPT 8527
Case No.: 2013-01501

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 Lamonte George Hambrick, R.P.T., to practice as a registered pharmacy technician in the State of Florida. Mr. Hambrick holds license number RPT 8527. His address of record is P.O. Box 151572, Tampa, Florida 33684. The following Findings of Fact and Conclusions of Law support the emergency suspension of Mr. Hambrick's license to practice as a registered pharmacy technician.

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). Section 456.074(1), Florida Statutes (2012), authorizes the Department to summarily suspend Mr. Hambrick's license to practice as a registered pharmacy technician.

2. At all times material to this Order, Mr. Hambrick was licensed to practice as a registered pharmacy technician in the State of Florida pursuant to Chapter 465, Florida Statutes (2012).

3. On or about May 15, 2012, the Hillsborough County Sheriff's Office arrested Mr. Hambrick for trafficking in illegal drugs twenty-eight (28) grams to twenty (20) kilograms in violation of Section 893.135(1)(c)1.c., Florida Statutes (2012), and grand theft in violation of Section 812.014(2)(c)2., Florida Statutes (2012).

4. On or about October 31, 2012, in the Circuit Court of the Thirteenth Judicial Circuit in and for Hillsborough County, Florida, in case number 12-CF-007394, Mr. Hambrick entered a plea of guilty to one (1) count of trafficking in illegal drugs twenty-eight (28) grams to twenty (20) kilograms, a first degree felony, in violation of Section 893.135(1)(c)1.c., Florida Statutes (2012); and one (1) count of grand theft, a third degree felony, in violation of Section 812.014(2)(c)2., Florida Statutes (2012).

5. The Department did not learn of the above referenced pleas until on or about January 23, 2013.

6. Section 456.074(1), Florida Statutes (2012), provides that the Department *shall* issue an emergency order suspending the license of any

person licensed under Chapter 465, Florida Statutes (2012), who pleads guilty to a felony under Chapter 893, Florida Statutes, 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 (2012), and Chapter 465, Florida Statutes (2012).

2. The Department is mandated to summarily suspend Mr. Hambrick's license to practice as a registered pharmacy technician in accordance with Section 456.074(1), Florida Statutes (2012).

WHEREFORE, in accordance with Section 456.074(1), Florida Statutes (2012), it is ORDERED THAT:

1. The license of Lamonte George Hambrick, R.P.T., license number RPT 8527, is immediately suspended.

2. A proceeding seeking formal suspension or discipline of the license of Lamonte George Hambrick, R.P.T., to practice as a registered

pharmacy technician will be promptly instituted and acted upon in compliance with Section 120.569, Florida Statutes (2012).

DONE and ORDERED this 19th day of February, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

PREPARED BY:
Lauren A. Leikam
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Florida Bar No. 0088700
(850)245-4640 Telephone
(850)245-4683 Facsimile

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.

AFFIDAVIT OF SERVICE

DEPARTMENT OF HEALTH
Petitioner

vs

Case No. 2013-01501

LAMONTE GEORGE HAMBRICK, RPT
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 February 20, 2013 through February 22, 2013, 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) February 22, 2013 LAMONTE GEORGE HAMBRICK, RPT. was hand served Order of Emergency Suspension of License, related papers and Voluntary Relinquishment of License at Hardee Work Camp correctional facility located at 6901 State Road 62; Bowling Green, Florida. Identification was verified by facility correctional officer.

___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) Division of Drivers Licenses; and Accurint Search.

Affiant

State Of Florida
County Of Hillsborough

Before me, personally appeared Terrence Dawkins 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 22nd day of February 2013.

Notary Public-State of Florida

My Commission Expires

Type or Print Name

7196 9008 9111 5772 5923

TO:

Lamonte G. Hambrick, RPT
P.O. Box 151572
Tampa, FL 33684

SENDER: ESO

REFERENCE: 2013-01501

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

2/21/2013

2. Article Number

7196 9008 9111 5772 5923

3. Service Type **CERTIFIED MAIL™**

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:

Lamonte G. Hambrick, RPT
P.O. Box 151572
Tampa, FL 33684

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly) Cynthia Anderso

B. Date of Delivery MAR - 4 2013

C. Signature X Cynthia Anderson ☐ Agent ☐ Addressee

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

NAPLES FL 34104

Hambrick
2013-01501 2/21/2013
Leikam

PS Form 3811, January 2005 Domestic Return Receipt

Apellaniz, Melba

From: FL-Rules@dos.state.fl.us
Sent: Thursday, February 21, 2013 11:16 AM
To: Apellaniz, Melba
Subject: Submit Notice in FAR

You have successfully submitted a notice for publication in the Florida Administrative Register on 2/21/2013 11:15:37 AM.

Department: Department of Health
Organization: Board of Pharmacy
Notice type: Miscellaneous
Issue: 39/37

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=12675977

You may contact the Florida Administrative Register office at (850)245-6270 for additional information.

Florida is headed in the right direction! View Florida's Jobs Growth Chart: http://www.flgov.com/photoview/jobcreationchart.jpg
The Department of State is leading the commemoration of Florida's 500th anniversary in 2013. For more information, please go to www.fla500.com.
The Department of State is committed to excellence. Please take our Customer Satisfaction Survey: http://survey.dos.state.fl.us/index.aspx?email=fl.rules@dos.myflorida.com

MEMORANDUM

TO: Florida Administrative Weekly, Liz Cloud

FROM: Melba L. Apellaniz, Regulatory Specialist II

RE: Lamonte George Hambrick, R.P.T. License # RPT 8527
CASE NO(S): 2013-01501

DATE: February 21, 2013

Attached please find notice of the issuance of an Emergency Suspension Order for notice in the next issue of the Florida Administrative Weekly.

On February 20, 2013, State Surgeon General issued an Order of Emergency Suspension Order with regard to the license of Lamonte George Hambrick, R.P.T. License # RPT 8527. 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.

#12675977

FLORIDA DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office:	Date of Complaint:	Case Number:
CONSUMER SERVICES	01/30/2013	RPT 2013-01501

Subject:	Source:
LAMONTE GEORGE HAMBRICK, RPT PO BOX 151572 Tampa, FL 33684 239-293-0650	**DEPARTMENT OF HEALTH** **Bureau of Operations**

Prefix:	License # :	Profession:	Board:	Report Date:
RPT	8527	Registered Pharmacy Technician	Pharmacy	02/04/2013

Period of Investigation:	Type of Report:
01/31/2013 through 02/04/2013	FINAL

Alleged Violation: SS. 456.0635(3)(a), 456.072(1)(c)(k)(x)(dd) and 465.016(1)(e)(f)(r), F.S.; Conviction as defined in 456.0635; Convicted of a crime related to the practice; Failure to perform statutory/legal obligation; Violate statute/rule

Synopsis: This investigation is predicated on the receipt of an internally generated complaint with an attached spreadsheet stating a report from CCIS indicating HAMBRICK has 893 convictions which have not been reported/addressed. Court documents received from the Hillsborough County Clerk of Court revealed HAMBRICK entered a guilty plea and was adjudicated guilty on charges of Trafficking in Illegal Drugs 28 gram to 30 Kil (S. 893.135(1)(c)(1)(c), F.S.) and Grand Theft Third Degree $5,000-$10,000 (S. 812.014(2)(c)2., F.S. on 10/31/2012. (EXHIBIT #1)

HAMBRICK was notified of this complaint by certified letter, dated 01/31/2013. The notification was sent to the mailing address of record. Forwarded with this letter were copies of the Case Summary and the initiating documents. (EXHIBIT #2)

DOH licensure information viewed on 02/04/2013 reflects HAMBRICK is duly licensed to practice as a Registered Pharmacy Technician in the State of Florida with a Delinquent, Active Status.

No patient involvement, thus patient notification not required.

HAMBRICK does not appear to be represented by counsel in this matter as of the date of this report.

HAMBRICK has not responded to notification of this complaint as of the date of this report. (EXHIBIT #4)

Related Case:

Investigator/Date:	Approved By/Date:
Anita M. Hill (HA23) 02/04/2013	Nicole Singleton, OMC Manager 2/4/13

Distribution: Prosecution Services Unit/Consumer Services Unit

TABLE OF CONTENTS

INVESTIGATIVE DETAILS

INTERVIEW/STATEMENT OF DEPARTMENT OF HEALTH – Source

Address of Record: **Bureau of Operations**

On 01/23/2013, Investigator Hill received an internally generated complaint with an attached spreadsheet stating a report from CCIS indicating HAMBRICK has 893 convictions which have not been reported/addressed. Court documents received from the Hillsborough County Clerk of Court revealed HAMBRICK entered a guilty plea and was adjudicated guilty on charges of Trafficking in Illegal Drugs 28 gram to 30 Kil (S. 893.135(1)(c)(1)(c), F.S.) and Grand Theft Third Degree $5,000-$10,000 (S. 812.014(2)(c)2., F.S. on 10/31/2012. (EXHIBIT #1)

INTERVIEW/STATEMENT OF LAMONTE GEORGE HAMBRICK, RPT - Subject

Address of Record: **PO BOX 151572**
Tampa, FL 33684
239-293-0650

HAMBRICK has not responded to notification of this complaint as of the date of this report.

Investigator's Note: Any response received from HAMBRICK will be forwarded to this file upon receipt.

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.

January 31, 2013

CONFIDENTIAL
Lamonte George Hambrick, RPT
Post Office Box 151572
Tampa, FL 33684

Complaint #: 201301501

Dear Mr. Hambrick:

The Consumer Services Unit has received the enclosed complaint against you. We reviewed the complaint or report and determined that the Pharmacy Practice 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,

Anita M. Hill

Anita M. Hill
Government Analyst I

AMH/tb
Enclosure
CERTIFIED MAIL: 7011 2970 0003 6945 2037

7011 2970 0003 6945 2037

U.S. Postal Service™
CERTIFIED MAIL™ RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

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OFFICIAL USE

Postage	$
Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postag	

Postmark Here

Sent To: CONFIDENTIAL
Street, Apt. N: Lamonte George Hambrick, RPT
or PO Box No: Post Office Box 151572
City, State, Zi: Tampa, FL 33684
201301501 ha 23

PS Form 3800, August 2006 — See Reverse for Instructions

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:

NFIDENTIAL
monte George Hambrick, RPT
ost Office Box 151572
ampa, FL 33684
01301501 ha 23

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X Rev. L. L. Hambrick ☐ Agent ☐ Addressee

B. Received by *(Printed Name)* C. Date of Delivery

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) 7011 2970 0003 6945 2037

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

REPORT
EXHIBIT# 2
PAGE# 21

September 18, 2013

Joseph Thomas Brown
6826 Hatteras Drive
Lake Worth, FL 33467

RE: Application for Licensure by Examination

Dear Mr. Brown:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida 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.

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CONFIDENTIAL AND EXEMPT MATERIALS

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Florida HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.doh.state.fl.us/mqa/pharmacy

07/01/2013 295.00
ID: 15724 Type: F
BT: 3000075
VL: 913000269

FC 44114

ITEM #2 –PHARMACIST EXAMINATION APPLICATION FOR U.S. AND PUERTO RICO GRADUATES
FEE: $295.00

2201-15724

Please print or type legibly.

1. Biographical data				
Last name: Brown	First name: Joseph	Middle name: Thomas		
Street address (ML – Mailing Address): 6826 Hatteras DR.	City: Lake Worth	State: FL.	Zip: 33467	
Work address (PL – Practice Location):	City:	State:	Zip:	
Home phone number: 561-800-6408	Business phone number:	E-mail address: JoeTBrown@BellSouth.net		
Date of birth: 8-30-64	Place of birth: Passaic, New Jersey			

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

4. Name of University, College or School of Pharmacy attended

Nova Southeastern University - College of Pharmacy

5. Date of graduation	6. Type of degree earned	7. Have you ever been licensed as an Intern in Florida?
June 1991	B.S. Pharmacy	Yes ✓ No _____ Intern License number: _____

RECEIVED
JUN 25 2013
Licensing and Auditing Services

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 ____ Date of transfer: ____ No ✓	Yes ____ Date of exam: 1991 No ✓

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 ✓ No ____

11. Have you ever applied to take the Florida Pharmacist Examination? If yes, please indicate the date.

Yes ✓ No ____ Date ____

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
18 years	Eckerd Drugs		Pharmacy Manager	Full Time
	See Attached Supplemental Responses			

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
Florida	PS26675	8/21/1991

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 ✓

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 ✓ 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 ✓ No _____
21. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No ✓
22. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No ✓
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 ✓ 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 _____ N/A
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 ✓
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 ✓
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 ✓
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 ✓
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 _____ N/A
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 ✓
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 _____ N/A
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 ✓
28a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No _____ N/A
28b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____ N/A
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 ✓ (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 ✓ 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 _____

NOTE: Please check to be sure that you have answered all of the questions above.

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SOUTHEASTERN UNIVERSITY OF THE HEALTH SCIENCES

COLLEGE OF PHARMACY

College of Osteopathic Medicine
College of Optometry

June 6, 1991

The Florida Board of Pharmacy
130 N. Monroe
Tallahassee, FL 32301

Dear Board:

This letter is written to certify that Joseph T. Brown, Internship Certificate numbered 7219, has completed the following college-supervised rotations and internship (at Eckerd drugs) in fulfillment of the Florida Internship requirements.

Internship:	550
Hospital Ext.:	320
Community Ext.:	320
Ambulatory:	160
Drug Information:	160
Geriatric:	167
Internal Medicine:	160
Elective A:	0
Elective B:	0
Elective C:	0
Elective D:	0
TOTAL HOURS:	1837

Please accept a total of 1837 hours toward fulfillment of this candidate's internship hours.

Sincerely,

Carmen Aceves-Blumenthal, B.S. Pharm., M.S.
Asst. Professor in Pharmacy Practice
Director of Experiential Education

cc: P. Magalian

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Joseph Thomas Brown

7770 Springfield Lake Dr., Lake Worth, FL 33467
Home: (561) 800-6408 - Cell: (561) 800-6408 : joetbrown@bellsouth.net

Professional Summary

Pharmacist with over twenty years of retail experience in the state of Florida. Dedicated to patient knowledge and understanding of medication therapy. Established positive relationships with medical professionals, healthcare organizations, insurance representatives, wholesalers and patients.

Professional Experience

Pharmacy Manager/owner
January 2001 to May 2011
Express RX - Greenacres, FL
Created a new pharmacy, with a module based on a greater emphasis on pharmacist to patient education and satisfaction with the pharmacy profession. Created a web based live weekly internet program describing the benefits of using a small drugstore compared to the chains. Worked along side AM talk show host Dick Farrell in West Palm Beach discussing new medications on the market, taking phone calls from listeners, and also promoting independent pharmacies. Was a preceptor and adviser for Keiser College in Lake Worth, teaching pharmacy technician students the retail side of their profession. I also was a preceptor for Palm Beach Atlantic College of pharmacy and worked with many of their students.
My pharmacy was a runner up for Small Business of the Year in 2004 by Northwood University in West Palm Beach.
I also was one of the first to implement the Flavorx system in 2001 for flavoring liquid medication for kids, and the compounding of certain canine anti seizure medications. I partnered with Transaction Data to develop a patient friendly prescription processing system.
I worked with Ameriscource Bergen's Good Neighbor Pharmacy filming thirty second television spots on the local CBS station for breast cancer awareness, the promotion of GNP and its affiliates, and the dangers of drug interactions. Pharmacy of the year by Good Neighbor Pharmacy in 2009.
Within two years my pharmacy tripled in sales and prescription volume.

Pharmacy Manager
September 1991 to January 1999
Eckerd Drug - Greenacres, FL
Communicated directly with doctors via telephone, fax, and email. Responsible for pharmacist and employee schedules, payroll, and inventory at a twenty-four hour pharmacy. Worked directly with district supervisors in coordinating staff meetings, speaking engagements and customer relations. Developed and implemented the compounding and distribution of progesterone suppositories with my night pharmacist. Was placed in the District Manager training program and frequently traveled with supervisors to other stores in an effort to increase productivity and customer satisfaction. Won a customer service award with the company.

Education and Training

Bachelor of Science : Pharmacy, 1991
Nova Southeastern University College of Pharmacy - Davie, FL, USA

Associate of Science : Pre-pharmacy, 1988
Miami-Dade College - Miami, FL, USA

Community Service

Yearly health fairs, Express RX, 2001-2011
Answered phone questions about drug interactions, CBS T.V., 2006-2009
Provided flu vaccinations, 2006-2011
Adjunct teacher, Keiser College, 2003-2011
Adviser for the Fountains community health fair organizations, Lake Worth 2005-2011
Lake Worth Chamber of Commerce, 2001-2011

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Final Order No. DOH-11-1243-ESO-MQA
FILED DATE: 6-2-2011
Department of Health
By: Melissa Nolen
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the License of
JOSEPH BROWN, RPH
License No.: PS 26675
Case Nos.: 2011-08871

ORDER OF EMERGENCY SUSPENSION OF LICENSE

The State Surgeon General, ORDERS the emergency suspension of the license of Joseph Brown, RPH, to practice as a pharmacist in the State of Florida. Mr. Brown holds license number PS 26675. His address of record is 6826 Hatteras Drive, Lake Worth, Florida 33467. The following Findings of Fact and Conclusions of Law support the emergency suspension of Mr. Brown's License to practice as a pharmacist.

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. Section 456.073(8), Florida Statutes (2010), authorizes the State Surgeon General to summarily suspend Mr. Brown's license to practice as a pharmacist in

the State of Florida, in accordance with Section 120.60(6), Florida Statutes (2010).

2. At all times material to this Order, Mr. Brown was licensed to practice as a pharmacist, in the State of Florida, pursuant to Chapter 465, Florida Statutes.

3. On or about May 25, 2011, Respondent, Mr. Brown, was the subject of a traffic stop, during which he gave consent to police to search his car and his person. During said search, Mr. Brown was found to be in possession of ten Hydrocodone/APAP 10/325mg pills and four pills of the prescription drug Ambien.

4. Mr. Brown was arrested by the Palm Beach Sheriff's Office and charged with a violation of Section 893.13(6)(a), Florida Statutes (2010), for possession of hydrocodone, a schedule III substance, without a prescription.

5. Mr. Brown was booked into the Palm Beach County Jail at 11:44 pm on Wednesday, May 25, 2011, and was released on a $6,000 bond at 7:05 pm on Thursday, May 26, 2011.

6. After being advised of his Miranda Rights, Mr. Brown admitted the following to police officers:

a) that he has a substance abuse problem,

b) that the pills found in his vehicle were taken directly out of his pharmacy's stock,

c) that he did not have a lawful prescription for these substances,

d) that he was personally using 10-20 Ambien and Hydrocodone tablets daily, and

e) that he has been selling schedule III and IV substances to established pharmacy customers without a prescription.

7. Hydrocodone/APAP contains hydrocodone and acetaminophen (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. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

8. Ambien is the brand name for the drug zolpidem, prescribed to treat insomnia. According to Title 21, Section 1308.14, Code of Federal Regulations, zolpidem is a Schedule IV controlled substance. Zolpidem can cause dependence and is subject to abuse.

9. Section 465.016(1)(e), Florida Statutes, provides that a pharmacist can be disciplined, including suspension, for violating a provision of Chapter 893, Florida Statutes.

10. Mr. Brown violated Section 465.016(1)(e), Florida Statutes (2010), by violation of 893.13(6)(a), Florida Statutes (2010), by possessing hydrocodone/APAP, a controlled substance, without a prescription, as admitted in his written statement.

11. Section 120.60(6), Florida Statutes, authorizes the Department to summarily suspend a pharmacist's license if the Department finds that the pharmacist presents an immediate serious danger to the public health, safety, or welfare.

12. In the course of their work, pharmacists have access to medications, including controlled substances, which have a high likelihood for abuse and harm. They must prepare such drugs in a manner that is safe and effective for the patient. Even medications

that are not generally considered dangerous may kill or severely harm a patient if that patient is allergic to an ingredient or is taking another medication that may adversely interact with the prescribed medication.

13. Controlled substances are *controlled* by state and federal law because they carry a risk of addiction and, if used in any way other than as prescribed by a doctor, the risk of overdose and other harmful health effects, in addition to the harm presented by their misuse while engaged in dangerous activities, such as operating a motor vehicle. By diverting controlled substances from a regulated pharmacy setting into the illicit drug trade, Mr. Brown's actions contribute to the widespread problem of prescription drugs being abused in the State of Florida.

14. Mr. Brown's intentional diversion of controlled substances evidences a lack of professional judgment and moral character which creates the potential for future diversion if the licensee is allowed to continue in the occupation of pharmacist. Further, his admission that he personally has been abusing controlled substances without a prescription further elevates the risk that he would continue diverting controlled substances. The continued licensure of Mr. Brown

constitutes an immediate serious danger to the health, safety, or welfare of the citizens of the State of Florida. Nothing short of the immediate suspension of Mr. Brown's license will ensure the protection of the public from this danger.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General concludes as follows:

1. The Department has jurisdiction pursuant to Sections 20.43 and 456.073(8), Florida Statutes (2010) and Chapter 465, Florida Statutes.

2. Mr. Brown violated Section 465.016(1)(e), Florida Statutes (2010), by violation of Section 893.13(6)(a), Florida Statutes (2010).

WHEREFORE, in accordance with Section 120.60(6), Florida Statutes (2010), it is ORDERED THAT:

1. The license of JOSEPH BROWN, RPH, License number PS 26675, is immediately suspended.

2. A proceeding seeking formal suspension or discipline of the license of JOSEPH BROWN, RPH, to practice as a pharmacist will be

promptly instituted and acted upon in compliance with Section 120.569, Florida Statutes.

DONE and ORDERED this 2 day of June, 2011.

H. Frank Farmer, Jr., M.D., Ph.D.
State Surgeon General

PREPARED BY:
David C. Bibb
Florida Bar No. 190330
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(850) 245 – 4640 Telephone
(850) 245 – 4682 Facsimile

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.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

vs. CASE NO. 2011-08871

JOSEPH BROWN, 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, JOSEPH BROWN, 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 26675.

3. Respondent's address of record is 6826 Hatteras Drive, Lake Worth, Florida 33467.

4. On or about May 25, 2011, Respondent, Mr. Brown, was the subject of a traffic stop, during which he gave consent to police to search his car and his person. During said search, Mr. Brown was found to be in possession of ten Hydrocodone/APAP 10/325mg pills and four pills of the prescription drug Ambien.

5. Mr. Brown was arrested by the Palm Beach Sheriff's Office and charged with a violation of Section 893.13(6)(a), Florida Statutes (2010), for possession of hydrocodone, a schedule III substance, without a prescription.

6. Mr. Brown was booked into the Palm Beach County Jail at 11:44 pm on Wednesday, May 25, 2011, and was released on a $6,000 bond at 7:05 pm on Thursday, May 26, 2011.

7. After being advised of his Miranda Rights, Mr. Brown admitted the following to police officers:

a. that he has a substance abuse problem,

b. that the pills found in his vehicle were taken directly out of his pharmacy's stock,

c. that he did not have a lawful prescription for these substances,

d. that he was personally using 10-20 Ambien and Hydrocodone tablets daily, and

e. that he has been selling schedule III and IV substances to established pharmacy customers without a prescription.

8. Hydrocodone/APAP contains hydrocodone and acetaminophen (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. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

COUNT I – Violation of Chapter 893

9. Petitioner reasserts the allegations of paragraphs 1 through 8 of this complaint as if set out herein at length.

10. Section 465.016(1)(e), Florida Statutes, provides that a pharmacist can be disciplined, including suspension, for violating a provision of Chapter 893, Florida Statutes.

11. On or about May 25, 2011, Mr. Brown was in possession of hydrocodone/APAP, a controlled substance, without a prescription, as admitted in his written statement.

12. Mr. Brown violated Section 465.016(1)(e), Florida Statutes (2010), by violation of 893.13(6)(a), Florida Statutes (2010), by possessing hydrocodone/APAP, a controlled substance, without a prescription.

COUNT II – Dispensing or Distribution Drugs
Outside the Professional Practice of Pharmacy

13. Petitioner reasserts the allegations of paragraphs 1 through 8 of this complaint as if set out herein at length.

14. Section 465.016(1)(i), Florida Statutes (2010), provides that a pharmacist can be disciplined, including suspension, for compounding dispensing, or distributing a legend drug, including any controlled substance, other than in the professional practice of pharmacy.

15. As demonstrated by his possession of Hydrocodone and Ambien without a prescription and as admitted in his statement to police, both on May 25, 2011, Respondent improperly diverted legend drugs, including controlled substances, from his pharmacy stocks without a prescription, and gave those to drugs himself and to others.

16. Respondent violated Section 4655.016(1)(i), Florida Statutes (2010), by distributing legend drugs, including controlled substances, 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 24 day of June, 2011.

H. Frank Farmer, Jr., M.D., Ph.D.
State Surgeon General

David C. Bibb
Assistant General Counsel
Florida Bar No. 190330
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
850.245.4640
850.245.4682 fax

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Sandra Soto
DATE: 6/27/2011

PCP Date: 22 JUN 11
PCP Members: SALEM & WEIZER

DOH v. JOSEPH BROWN, RPH, CASE NO. 2011-08871

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. 2011-08871**

JOSEPH BROWN, 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, JOSEPH BROWN, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 26675. Respondent's mailing address of record is 6826 Hateras Drive, Lake Worth, Florida 33467.

2. Respondent was charged by an Administrative Complaints, 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.

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, JOSEPH BROWN, 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 of **THREE THOUSAND FIVE HUNDRED TWENTY-NINE DOLLARS AND FIFTY-ONE CENTS** ($3,529.51). 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 four (4) years from the date the Final Order is filed with the Department Clerk.

3. **Evaluation and Treatment-** Respondent shall enter and successfully participate in a Professional Resource Network (PRN) contract.

4. **Probation-** Upon reinstatement of licensure, Respondent shall be placed on a minimum of four (4) 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. Respondent 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;

d. 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;

e. Respondent shall comply with any and all recommendations from PRN; and

f. Respondent shall make a mandatory appearance before the Board of Pharmacy during his last year of probation.

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 25 day of April, 2012.

JOSEPH BROWN, R.PH.
Case 2011-08871

STATE OF Florida }
}
COUNTY OF Palm Beach }

Before me personally appeared JOSEPH BROWN, R.PH., whose identity is known to me or by personally Known (type of identification), and who, under oath, acknowledges that hissignature appears above. Sworn to and subscribed before me this 25th day of April, 2012.

NOTARY PUBLIC-STATE OF FLORIDA
Dawn L. Strolla
Commission # DD822691
Expires: SEP. 14, 2012
BONDED THRU ATLANTIC BONDING CO., INC.

Notary Public
My Commission Expires:

APPROVED this 30th 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

Final Order No. DOH-12-1205-S-MQA
FILED DATE JUN 28 2012
Department of Health
By _____
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
Petitioner,

vs.

CASE NO.: 2011-08871
LICENSE NO.: PS 26675

JOSEPH T. BROWN, R.PH.,
Respondent.

_____/

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 6, 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) As authorized by the Settlement Agreement the Board finds that the costs of investigation and prosecution are $3,529.51.

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 Joseph T. Brown, R.Ph. at 6826 Hatteras Drive, Lake Worth, Florida 33467; 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 28th day of June, 2012.

Angel Sanders

Deputy Agency Clerk

7011 2970 0003 1594 0205

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE APR 12 2013

NOTICE OF AGENCY ACTION
DENIAL OF LICENSE RENEWAL

April 12, 2013

Joseph T Brown
6826 Hatteras Drive
Lake Worth, FL 33467

RE: Application for Pharmacist License No. 26675

Dear Mr. Brown:

This letter is notification that your application for renewal of Pharmacist license no. 26675 is denied.

On or about May 21, 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: 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 12th day of April, 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 Joseph T Brown 6826 Hatteras Drive Lake Worth, FL 33467 and by interoffice mail to Janine B. Myrick, Senipr Attorney, and the Bureau of Operations, Florida Department of Health this 12th day of April, 2013.

Angel Sanders
Deputy Agency Clerk

7012 1010 0002 2383 3773

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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Rick Scott
Governor

FLORIDA DEPARTMENT OF HEALTH

John H. Armstrong, M.D.
State Surgeon General

June 28, 2012

Mr. Joseph T. Brown
6826 Hatteras Drive
Lake Worth, FL 33467

Compliance Reference Number: 201108871

Dear Mr. Brown:

Your licensing Board has imposed specific obligations in the above-referenced Final Order. Attached are information sheets to assist you in complying with these requirements.

All terms must be completed on or before the specified due dates. Additional disciplinary action may be taken against your license if the requirements are not received by the due date.

Please reference the case number listed above on all correspondence forwarded to this office pertaining to this case. Your Compliance Officer may change during your monitoring because of staff changes and workload distribution. If you wish to return to active practice after your obligations have been met, you must continue to timely renew your license.

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 between counties. If you have any questions, please contact me at (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:	201108871
Respondent Name:	Joseph T Brown
Final Order Date:	6/28/2012
Today's Date:	6/28/2012

Licensee:	Joseph T Brown	**Profession:**	2201 : Pharmacist
Mailing Address:	6826 Hatteras Drive Lake Worth, FL 33467	**File Nbr:**	15724
		License Nbr:	26675
		License Status:	Probation
Attorney:	Corey Strolla	**Address:**	2247 Palm Beach Lakes Boulevard Suite 107 West Palm Beach, FL 33409
		Phone:	561-802-8987
Monitor:	None on Record		
Supervisor:	None on Record		
Appeal:	N		

Discipline Imposed:	Start Date	End Date	Comments
Emergency Suspension	06/02/2011	06/27/2012	
Probation	06/28/2012		

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
PRN Evaluation		08/03/2012		
PRN Contract	07/28/2012			
Respondent Report	09/28/2012			
Supervisor's Report	09/28/2012			
Respondent Report	12/28/2012			
Supervisor's Report	12/28/2012			
Respondent Report	03/28/2013			
Supervisor's Report	03/28/2013			
Respondent Report	06/28/2013			
Supervisor's Report	06/28/2013			
Respondent Report	09/28/2013			
Supervisor's Report	09/28/2013			
Respondent Report	12/28/2013			
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Supervisor's Report	12/28/2014			
Respondent Report	03/28/2015			
Supervisor's Report	03/28/2015			
Respondent Report	06/28/2015			
Supervisor's Report	06/28/2015			
Respondent Report	09/28/2015			
Supervisor's Report	09/28/2015			
Respondent Report	12/28/2015			
Supervisor's Report	12/28/2015			
Respondent Report	03/28/2016			
Supervisor's Report	03/28/2016			
Costs	06/28/2016		3,529.51	0.00
Respondent Report	06/28/2016			
Supervisor's Report	06/28/2016			
Miscellaneous				
Miscellaneous				
Appearances				

COMPLIANCE MANAGEMENT UNIT
FINE/COSTS INVOICE

Respondent:	**Joseph T. Brown**		
Profession-License Number:	**2201 Pharmacist** **26675**	**Indv/Org #**	**5013340**
File Number:	**15724**	**Case Number:**	**201108871**

Administrative Costs:	**$ 3,529.51**	**Due Date: June 28, 2016**
TOTAL:	**$ 3,529.51**	

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."

BOARD OF PHARMACY
SUPERVISOR'S QUARTERLY REPORT

Please print or write legibly.

Respondent's Name:			
Respondent's License Number:		Case Number:	
Address:	City	State	Zip
Telephone Number			
Monitor:			
Address:	City	State	Zip
Telephone Number			
Quarter (3 months)	From:	To:	

Brief statement of why Respondent is on probation:

Description of current practice (type and composition) and location:

Brief statement of compliance with probationary terms:

Brief statement of licensee's relationship with supervising person:

_____

_____

_____

Detail any problems which may have arisen with licensee

_____

_____

_____

_____

_____

Signature: _____ Date: _____

Mailing Address: Department of Health, Compliance Management Unit
4052 Bald Cypress Way, Bin C76 • Tallahassee, FL 32399
Fax: (850) 488-0796

BOARD OF PHARMACY
RESPONDENT'S QUARTERLY REPORT

Please print or write legibly.

Respondent's Name:			
Respondent's License Number:		Case Number:	
Address:	_____ _____ City State Zip		
Telephone Number			
Monitor:			
Address:	_____ _____ _____ _____ City State Zip		
Telephone Number			
Quarter (3 months)	From: To:		

Brief statement of why Respondent is on probation:

_____

_____

_____

_____

Description of current practice and location:

_____

_____

_____

_____

Brief statement of compliance with probationary terms:

_____

_____

_____

_____

Brief statement of licensee's relationship with supervising person:

_____

_____

_____

Detail any problems which may have arisen with licensee

_____

_____

_____

_____

_____

Signature: _____ Date: _____

Mailing Address: Department of Health, Compliance Management Unit
4052 Bald Cypress Way, Bin C76 • Tallahassee, FL 32399
Fax: (850) 488-0796

BOARD OF PHARMACY
RESPONDENT'S QUARTERLY REPORT

Please print or write legibly.

Respondent's Name:			
Respondent's License Number:		Case Number:	
Address:	_____ _____ City State Zip		
Telephone Number			
Reporting Period	From: To:		

Please initial

_____ According to the terms of my final order, I am required to notify the Department of Health of my employment status as a Pharmacist. I am not employed as a Pharmacist.

Signature: _____ Date: _____

Mailing Address: Department of Health, Compliance Management Unit
4052 Bald Cypress Way, Bin C76 • Tallahassee, FL 32399
Fax: (850) 488-0796

20110880/

Nelson, Sondra

From: Nelson, Sondra
Sent: Monday, October 15, 2012 8:58 AM
To: 'Joseph Brown'
Subject: RE: Resondant report

Hi Mr. Brown,

Sorry, I was out of the office on Friday. Your fax has been received. Thank you.

From: Joseph Brown [mailto:joetbrown@bellsouth.net]
Sent: Friday, October 12, 2012 1:24 PM
To: Nelson, Sondra
Subject: Re: Resondant report

Hi Sondra, I just wanted to make sure you received the fax this morning. Thanks again,
Joseph Brown.

From: "Sondra_Nelson@doh.state.fl.us" <Sondra_Nelson@doh.state.fl.us>
To: joetbrown@bellsouth.net
Sent: Thu, October 11, 2012 5:02:47 PM
Subject: RE: Resondant report

You're welcome. Yes, please send me a copy of the PRN letter. You can email it to me or fax it to 850-488-0796. Thank you.

From: Joseph Brown [mailto:joetbrown@bellsouth.net]
Sent: Thursday, October 11, 2012 4:43 PM
To: Nelson, Sondra
Subject: Re: Resondant report

Thank you for the email. I have been with PRN since September of 2011. Do you need a copy of the contract from them?

Joseph T. Brown PS26675

From: "Sondra_Nelson@doh.state.fl.us" <Sondra_Nelson@doh.state.fl.us>
To: joetbrown@bellsouth.net
Sent: Tue, October 9, 2012 3:57:08 PM
Subject: RE: Resondant report

Hi Mr. Brown,

I'm sorry I haven't responded sooner but I've been out of the office. I've attached the information packet that was sent to you June 28, 2012. I have also requested that the Board office give you a call regarding licensure renewal but they are currently out of the office at a Pharmacy Board meeting so it will be later in the week when they are able to call you. Please let me know if you have any questions. Thanks.

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From: Joseph Brown [mailto:joetbrown@bellsouth.net]
Sent: Friday, October 05, 2012 1:11 PM
To: Nelson, Sondra
Subject: Resondant report

Hi Sondra, this is to confirm that I am unemployed as of today, and waiting to hear how to renew my

Nelson, Sondra

From: Joseph Brown [joetbrown@bellsouth.net]
Sent: Thursday, October 11, 2012 8:55 PM
To: Nelson, Sondra
Subject: Re: Resondant report

Hi Sondra, I also wanted to tell you if there were any questions feel free to contact Delena Torrence at PRN, she is my case manager. The phone number is 1-800-888-8776 Et. 216. Her email is delena@flprn.org.

Again, thanks for you help.

Joseph T. Brown PH26675.

From: "Sondra_Nelson@doh.state.fl.us" <Sondra_Nelson@doh.state.fl.us>
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Joseph T. Brown PS26675

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Subject: RE: Resondant report

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From: Joseph Brown [mailto:joetbrown@bellsouth.net]

Nelson, Sondra

From: Joseph Brown [joetbrown@bellsouth.net]
Sent: Thursday, October 11, 2012 8:37 PM
To: Nelson, Sondra
Subject: Re: Resondant report

I will fax it Friday, thank you.

Joseph T. Brown PS26675

From: "Sondra_Nelson@doh.state.fl.us" <Sondra_Nelson@doh.state.fl.us>
To: joetbrown@bellsouth.net
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Sent: Friday, October 05, 2012 1:11 PM
To: Nelson, Sondra
Subject: Resondant report

Hi Sondra, this is to confirm that I am unemployed as of today, and waiting to hear how to renew my Pharmacist license. I did receive my
board order in the mail, but not the information packet. You can email me at
Joetbrown@bellsouth.net.
Thank you for your help,

Joseph T. Brown, PS26675.

CONFIDENTIAL AND EXEMPT MATERIALS

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September 18, 2013

Arlen Trevor Harter
1270 Boston Lane
Bradenton, FL 34212

RE: Application for Licensure by Examination

Dear Mr. Harter:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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2201

F-43350

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.doh.state.fl.us/mqa/pharmacy

05/14/2013 295.00
ID: 43350 Type: F
BT: 3020824
VL: 912061182

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		
Harter	Arlen	Trevor		
Street address (ML – Mailing Address)	City	State	Zip	
1270 Boston Lane	Bradenton	Fl	34212	
Work address (PL – Practice Location)	City	State	Zip	
1270 Boston Lane	Bradenton	Fl	34212	
Home phone number	Business phone number	E-mail address		
941-725-0752	941-725-0752	atharter@gmail.com		
Date of birth	Place of birth			
11/16/1981	Manatee Memorial Hospital, Bradenton Fl			

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

University of Florida

5. Date of graduation	6. Type of degree earned	7. Have you ever been licensed as an intern in Florida?
May 7, 2013	Doctor of Pharmacy	Yes ✓ No _____ Intern License number: PSI27595

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 _____ Date of transfer: _____ No ✓	Yes _____ Date of exam: _____ No ✓

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 ✓ No _____

11. Have you ever applied to take the Florida Pharmacist Examination? If yes, please indicate the date.

Yes _____ No ✓ Date _____

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

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

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 ✓

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 ✓ 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 ✓ No _____
21. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No ✓
22. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No ✓
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 _____ 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 _____
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 _____
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 _____
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 ✓
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 ✓
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 ✓
28a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ 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 ✓ _____ (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 _____ 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.

Arlen Hartsee
Applicant Signature

May 7, 2013
Date

NOTE: Please check to be sure that you have answered all of the questions above.

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STATE OF FLORIDA
BOARD OF PHARMACY

IN RE: THE APPLICATION OF

ARLEN HARTER
_____/

2208/10326

NOTICE OF INTENT TO APPROVE LICENSE WITH CONDITIONS

This matter appeared before the Board of Pharmacy at a duly-noticed public meeting held on February 10, 2010, in Jacksonville, Florida, for consideration of an application for a license 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 a license as a Registered Pharmacy Technician is conditionally approved with the following conditions and restrictions on licensure:

1. The applicant shall obtain an evaluation from the Professionals' Resource Network (PRN) and comply with any recommendation made by PRN.

2. If PRN does not recommend a contract, then the license shall issue unencumbered, upon notification of same to the Chair of the Board.

3. If PRN recommends a contract, then the license shall issue upon PRN's notification to the Chair of the Board that the applicant is in compliance with a recommended contract and the applicant is able to practice with reasonable skill and safety.

4. The Board delegates the authority to assess compliance with this Notice and authorizes issuance of the license when its Chair finds the applicant has met the above listed condition.

5. The Board proposes these restrictions for the following reasons:

a. The applicant has three convictions for DUI and has been treated to alcohol addiction.

b. Pursuant to Section 465.016(1)(d) the Board may deny an application is the applicant is 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.

c. Pursuant to Section 456.072(1)(z), Florida Statutes (2009), the Board may deny a license if the applicant is unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals or other type of material, or as a result of any mental or physical condition.

d. Pursuant to Section 456.072(2), Florida Statutes (2009), the Board is authorized to deny a license application or issue a license with conditions or restrictions for any violations under Section 456.072(2) or the Florida Pharmacy Act.

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 15 day of March, 2010.

BOARD OF PHARMACY

Rebecca Poston

Rebecca Poston, BPharm
Executive Director *for*
Michele Weizer, PharmD, 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.

NOTICE OF RIGHT TO JUDICIAL REVIEW

SHOULD THIS NOTICE BECOME FINAL AGENCY ACTION, A PARTY WHO IS ADVERSELY AFFECTED BY THE ORDER IS ENTITLED TO JUDICIAL REVIEW, 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

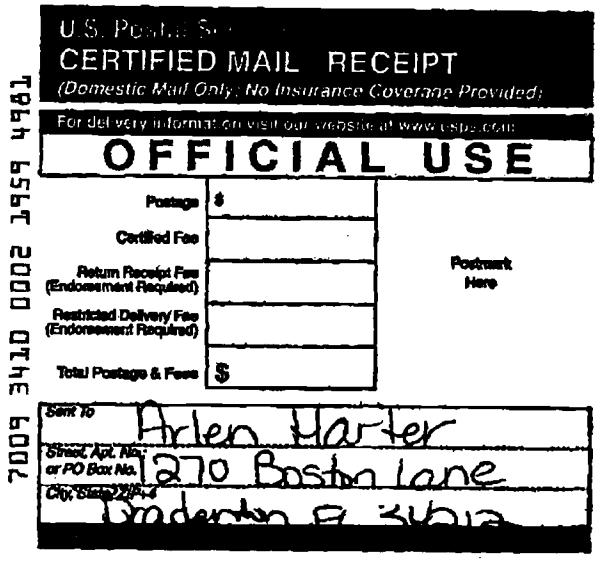
OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by Certified Mail to Arlen Harter at 1270 Boston Lane, Bradenton, Florida 34212; by interoffice mail to Allison Dudley, Assistant Attorney General, Office of the Attorney General, PL-01, The Capitol, Tallahassee, Florida 32399-1050; this 17th day of March, 2010.

Angela Baxter

Deputy Agency Clerk



Final Order No. DOH-08-1639-FOL-MQA
FILED DATE - 7-16-08
Department of Health
By: Rachel Bolin
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

vs.

DOH Case No.: 2007-37871
License No.: PSI 15661

ARLEN T. HARTER, PSI,

Respondent.
_____/

FINAL ORDER

THIS MATTER came before the Board of Pharmacy (hereinafter "the Board") at a duly noticed public meeting on June 11, 2008, in Orlando, Florida for a hearing not involving disputed issues of material fact pursuant to Respondent's completion of an Election of Rights form requesting a hearing pursuant to Sections 120.569 and 120.57(2), Florida Statutes. Petitioner filed an Administrative Complaint seeking disciplinary action against Respondent's license to practice as a pharmacy intern. A copy of the Administrative Complaint is attached to and made a part of this Final Order.

Petitioner was represented by Billie Jo Owens, Assistant General Counsel, with the Department of Health. Respondent was neither present nor represented by counsel.

The prosecuting attorney offered the investigative file into evidence to prove the facts as alleged in the Administrative Complaint. The investigative file was received into evidence and the Board finds that the uncontested facts adequately support the allegations. After a complete review of the record in this matter, including consideration of the Administrative Complaint, any written evidence or testimony, and any mitigating

or aggravating circumstances, the Board makes the following findings and conclusions:

FINDINGS OF FACT

1. The allegations of fact set forth in the Administrative Complaint are approved, adopted, and incorporated herein by reference as the findings of fact by the Board.

2. There is competent, substantial evidence to support the Board's findings and conclusions.

CONCLUSIONS OF LAW

1. The conclusions of law alleged and set forth in the Administrative Complaint are approved and adopted and incorporated herein by reference as the conclusions of law of the Board.

2. The violations set forth in the Administrative Complaint warrant disciplinary action by the Board.

3. Based upon the Findings of Fact, the Board concludes that the licensee violated Section 456.072(1)(hh), Florida Statutes, and Section 465.016(1)(m), Florida Statutes.

The Board is empowered by Sections 465.016(2) and 456.072(2), Florida Statutes, to impose a penalty against the licensee. Therefore, it is **ORDERED** that:

Respondent's intern registration is hereby **REVOKED**. If Respondent re-enrolls in pharmacy school, Respondent shall be allowed to submit an application for intern registration.

RULING ON MOTION TO ASSESS COSTS

The Board reviewed Petitioner's Motion to Assess Costs. Respondent did not file any objections to Petitioner's Motion. Petitioner's Motion is granted and the Board imposes the costs associated with this case in the amount of **two thousand one hundred ninety-two dollars and sixty-three cents ($2,192.63)**, to be paid within **thirty-six (36) months** of the filing date of this Final Order.

COMPLIANCE ADDRESS

Payment of the costs shall be made to: Department of Health, Compliance Management Unit, Post Office Box 6320, Tallahassee, Florida 32314-6320, attn: Board of Pharmacy Compliance Officer.

This order shall become effective upon filing with the Clerk of the Department of Health.

DONE AND ORDERED this 15 day of July, 2008.

BOARD OF PHARMACY

Rebecca R. Poston

Rebecca R. Poston, R.Ph., Executive Director
on behalf of Albert Garcia, R.Ph., CHAIR

NOTICE OF RIGHT TO JUDICIAL REVIEW

A PARTY WHO IS ADVERSELY AFFECTED BY THIS FINAL ORDER IS ENTITLED TO JUDICIAL REVIEW PURSUANT TO SECTION 120.68, FLORIDA STATUTES. REVIEW PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF A 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 APPEAL, 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 THE FILING DATE OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by **U.S. Mail** to: **Arlen Harter,** 1270 Boston Lane, Bradenton, Florida 34212; and by interoffice mail to **Deborah Bartholow Loucks**, Assistant Attorney General, Office of the 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 July 16, _____, 2008.

Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2007-37871**

ARLEN T. HARTER, PSI,

RESPONDENT.
_____/

2-4-08

ADMINISTRATIVE COMPLAINT

Petitioner Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent Arlen T. Harter, PSI, 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 pharmacy intern within the state of Florida, having been issued license number PSI 15661.

3. Respondent's address of record is 1270 Boston Lane, Bradenton, Florida 34202.

4. The Florida Professionals Resource Network ("PRN"), is the impaired practitioners program for the Board of Pharmacy, pursuant to Section 456.076, Florida Statutes. PRN is an independent program that monitors the evaluation, care, and treatment of impaired healthcare professionals. PRN oversees random drug screens and provides for the exchange of information between treatment providers and the Department for the protection of the public. Raymond M. Pomm, M.D., a Board-certified psychiatrist and addictionologist, is the Medical Director of PRN and is charged with responsibility for the oversight of the program and documentation of compliance and noncompliance with PRN monitoring contracts.

5. Respondent was a third year pharmacy student at the University of Florida in August 2005; he was initially registered as a Pharmacist Intern on or about November 7, 2002.

6. On or about August 30, 2005, Respondent was brought to the Emergency Room at North Florida Regional Medical Center by the

Gainesville Police Department presenting significant symptoms of withdrawal from alcohol including nausea, vomiting, and auditory hallucinations.

7. Respondent was transferred to the Florida Recovery Center associated with Shands Hospital for treatment of alcohol related problems on or about September 6, 2005.

8. On or about September 5 and 6, 2005, Respondent was evaluated by the medical physician serving as Co Medical Director of Florida Recovery Program and Inpatient Addiction Director, a PRN and Department approved evaluator who diagnosed Respondent as follows:

Axis I Clinical Disorders including major mental disorders and developmental and learning disorders:
Alcohol Dependence;

Axis II Underlying pervasive or personality conditions:
Deferred;

Axis III Acute medical conditions and physical disorders:
Gastroesophageal Reflux Disease;

Axis IV Psychological and environmental factors contributing to the disorder:
Family and Professional Stressors; and

Axis V Global Assessment of Functioning:
50.

The Global Assessment of Functioning is a numeric scale (0 through 100) used by mental health clinicians and doctors to rate the social, occupational, and psychological functioning of adults; and a 50-55 means that Respondent has moderate symptoms of or moderate difficulty in functioning in social, occupational, or school situations.

9. On or about October 10, 2005, Respondent contacted PRN.

10. On or about October 21, 2005, Respondent executed his first PRN contract, which provided for treatment and monitoring for five years. This contract required Respondent to: participate in a random urine and blood drug screen program; abstain completely from use of any medications, alcohol, and other mood altering substances, including over the counter medications unless ordered by his primary physician; select and name his primary physician and monitoring professional; notify PRN of any changes in physical or mental health, address, or employment; attend a self help group four times a week; attend a PRN monitored professional support group; notify PRN in the event of use of mood altering substances without a prescription from an approved physician; provide appropriate release forms for drug screen results, treatment center records, therapist reports, and other written and verbal information; withdraw from practice for evaluation at the request of PRN; involve his family in his support and recovery; comply with the contract any non-compliance of which could

result in a report to the Department through PRN and withdrawal of PRN's advocacy; be courteous and cooperative in all contacts with PRN staff and representatives; return messages left by PRN within 24 hours; and complete an intensive outpatient program.

11. On or about January 20, 2006, Respondent was arrested in Alachua County, Florida for driving under the influence and for refusing to submit to a breathalyzer test.

12. On or about February 15, 2006, PRN was informed of Respondents relapse; and his contract was voided.

13. On or about May 2, 2006, Respondent was convicted of driving under the influence and refusing to submit to a breathalyzer test.

14. On or about June 9, 2006, Respondent executed his second PRN contract, which provided for treatment and monitoring for five years. This contract required Respondent to: participate in a random urine and blood drug screen program; abstain completely from use of any medications, alcohol, and other mood altering substances, including over the counter medications unless ordered by his primary physician; select and name his primary physician and monitoring professional; notify PRN of any changes in physical or mental health, address, or employment; attend

a self help group three times a week; attend a PRN monitored professional support group; notify PRN in the event of use of mood altering substances without a prescription from an approved physician; provide appropriate release forms for drug screen results, treatment center records, therapist reports, and other written and verbal information; withdraw from practice for evaluation at the request of PRN; involve his family in his support and recovery; comply with the contract any non-compliance of which could result in a report to the Department through PRN and withdrawal of PRN's advocacy; be courteous and cooperative in all contacts with PRN staff and representatives; return messages left by PRN within 24 hours; and complete intensive outpatient treatment.

15. On or about March 7, 2007, Respondent informed PRN that he had relapsed by drinking alcohol in January and in March 2007. He also informed PRN was inebriated in one of his pharmacy classes and was sent home.

16. On or about March 12, 2007, Respondent was evaluated by a PRN and Department approved medical physician who diagnosed Respondent as follows:

Axis I Clinical Disorders including major mental disorders and developmental and learning disorders:

Alcohol Dependence;

Axis II Underlying pervasive or personality conditions:
Deferred;

Axis III Acute medical conditions and physical disorders:
None;

Axis IV Psychological and environmental factors contributing to the disorder:
License suspension, Drinking in school, Violation of PRN

Axis V Global Assessment of Functioning:

55.

The Global Assessment of Functioning is a numeric scale (0 through 100) used by mental health clinicians and doctors to rate the social, occupational, and psychological functioning of adults; and a 50-55 means that Respondent has moderate symptoms of or moderate difficulty in functioning in social, occupational, or school situations.

17. On or about March 14, 2007, Respondent's second PRN contract was voided due to the relapses earlier in 2007.

18. On or about July 22, 2007, Respondent executed his third PRN contract, which provided for treatment and monitoring for five years. This contract required Respondent to: participate in a random urine and blood drug screen program; abstain completely from use of any medications, alcohol, and other mood altering substances, including over the counter medications unless ordered by his primary physician; select and name his

primary physician and monitoring professional; notify PRN of any changes in physical or mental health, address, or employment; attend a self help group three times a week; attend a PRN monitored professional support group; notify PRN in the event of use of mood altering substances without a prescription from an approved physician; provide appropriate release forms for drug screen results, treatment center records, therapist reports, and other written and verbal information; withdraw from practice for evaluation at the request of PRN; involve his family in his support and recovery; comply with the contract any non-compliance of which could result in a report to the Department through PRN and withdrawal of PRN's advocacy; be courteous and cooperative in all contacts with PRN staff and representatives; return messages left by PRN within 24 hours; and complete aftercare at Manatee Glens.

19. On or about October 26, 2007, Respondent was arrested in Alachua County, Florida for driving under the influence and for refusing to submit to a breathalyzer test.

20. On or about October 29, 2007, when Respondent informed PRN of his recent relapse and arrest, he was told that he would need a new evaluation.

21. PRN had no contact with Respondent after October 29, 2007; Respondent did not respond to PRN telephone calls; and Respondent did not attend his group meetings.

22. On or about November 19, 2007, Respondent's third PRN contract was voided for non-compliance and inability to remain sober.

23. On or about November 27, 2007, PRN reported to the Department that Respondent's PRN contract was voided for non-compliance with the terms of that contract.

24. Dr. Pomm stated that Respondent "is unable to practice, or remain an Intern, with reasonable skill and safety."

COUNT ONE

25. Petitioner realleges and incorporates paragraphs 1 through 24 as if fully set forth here.

26. Section 456.072(1)(hh), Florida Statutes (2007), provides that termination from a treatment program for impaired practitioners, which is overseen by an impaired practitioner consultant as described in Section 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

is grounds for disciplinary action by the Board.

27. On or about November 19, 2007, Respondent's contract with PRN was terminated.

28. Based on the foregoing, Respondent has violated Section 456.072(1)(hh), Florida Statutes, by termination of his contract with PRN voided.

COUNT TWO

29. Petitioner realleges and incorporates paragraphs 1 through 24 as if fully set forth here.

30. Section 465.016(1)(m), Florida Statutes (2007), provides that 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 is grounds for disciplinary action by the Board.

31. Respondent's history of alcohol abuse; his failure to appreciate and learn from the prior treatment, and monitoring; the significant likelihood of his continued alcohol use or abuse; and his noncompliance with the terms of his PRN contracts, demonstrate that he is unable to

practice pharmacy with reasonable skill and safety.

32. Based on the foregoing, Respondent has violated Section 464.016(1)(m), Florida Statutes, by being unable to practice pharmacy with reasonable skill and safety.

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 any other relief that the Board deems appropriate.

SIGNED this 28th **day of** February, **2008.**

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Raelene Reed
DATE 3.4.08

Billie Jo Owens
Assistant General Counsel

PCP: 2.26.08
PCP Members: Salem & Powers

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.

Arlen T. Harter, PSI, 2007-37871

Billie Jo Owens
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Florida Bar No. 0211958
850.245.4640
850.245.4682 FAX

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FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Rachel
DATE 11.1.07

VOLUNTARY AGREEMENT TO WITHDRAW FROM PRACTICE

The undersigned Licensee, Arlen Harter license number Intern No 15661, hereby agrees to withdraw from his/her practice of pharmacy intern in the State of Florida and states:

1. Licensee has agreed to voluntarily withdraw from his/her practice in the State of Florida.

2. The withdrawal from practice will remain in effect until the vendor through whom this form was submitted notifies the Department of Health in writing that the withdrawal may be rescinded, or until the Board of pharmacy enters an order authorizing the undersigned to rescind the withdrawal.

3. Respondent understands that this Agreement constitutes a legal obligation within the meaning of Section 456.072(1)(k), Florida Statutes. Respondent further understands that any violation of the terms of this Agreement by Respondent shall constitute sufficient probable cause for the issuance by Petitioner of an Emergency Suspension of Respondent's license to practice as a pharmacy intern in the State of Florida.

4. Licensee, being fully advised of the consequences of so doing and having the opportunity to consult with counsel of his/her choosing, hereby agrees that upon his/her execution of this Agreement, it shall immediately be made accessible to the public. In addition, Licensee's licensure status and, if applicable, profile with the Board of pharmacy will reflect the withdrawal/ restriction stated herein.

DATED this 30 of July 2007

Arlen Harter
Signature

STATE OF Florida

County of Manatee

Before me, personally appeared Arlen T Harder whose identity is known to me by FL Drivers License (type of identification) and who, under oath, acknowledges that his/her signature appears above. Sworn to and subscribed by Licensee before me this 30 day of July, 2007.

Notary Public

My Commission Expires: 6/15/2010

JOSHUA PISA
MY COMMISSION # DD 564412
EXPIRES: June 15, 2010
Bonded Thru Notary Public Underwriters

forms\voluntarywithdrawal.doh

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September 19, 2013

Clifton Webb
8801 NW 7th Street
Pembroke Pines, FL 33024

RE: Pharmacy Examination Application

Dear Mr. Webb:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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2201

F-44069

08/01/2013 295.00
ID: 44069 Type: F
BT: 3002424
VL: 913007267

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.doh.state.fl.us/mqa/pharmacy

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**	
Webb Jr.	Clifton		George	
Street address (ML – Mailing Address)	**City**		**State**	**Zip**
8801 N.W. 7th Street	Pembroke Pines		FL	33024
Work address (PL – Practice Location)	**City**		**State**	**Zip**
8801 N.W. 7th Street	Pembroke Pines		FL	33024
Home phone number	**Business phone number**	**E-mail address**		
(954) 254-6871	(954) 254-6871	Cliff727y@yahoo.com		
Date of birth	**Place of birth**			
December 1, 1984	Saint Thomas, U.S. Virgin Islands			

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

4. Name of University, College or School of Pharmacy attended

Florida Agricultural and Mechanical University

5. Date of graduation	6. Type of degree earned	7. Have you ever been licensed as an intern in Florida?
May 3, 2013	Doctorate of Pharmacy	Yes ✓ No _____ Intern License number: PSI 24273

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 _____ Date of transfer: _____ No ✓	Yes _____ Date of exam: _____ No ✓

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 ✓ No _____

11. Have you ever applied to take the Florida Pharmacist Examination? If yes, please indicate the date.

Yes _____ No ✓ Date _____

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
N/A				
N/A				
N/A				

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
N/A		
N/A		
N/A		

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 ✓

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 _____ 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 _____ No ✓
21. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No ✓
22. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No ✓
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 _____ 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 _____
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 _____
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 _____
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 ✓
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 ✓
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 ✓
28a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ 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 ✓ (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 _____ 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 July 29, 2013

NOTE: Please check to be sure that you have answered all of the questions above.

1851040

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
Webb, Jr.	Clifton	George

Maiden name/surname	Date of graduation
	May 4, 2013

Mailing address	City	State	Zip
8801 N.W. 7th Street	Pembroke Pines	FL	33024

Part II. – To be completed by College of Pharmacy Dean

Name of School/College of Pharmacy

Florida A&M University/College of Pharmacy and Pharmaceutical Sciences

Mailing address	City	State	Zip
1415 S. Martin Luther King, Jr., Boulevard	Tallahassee	FL	32307

Type of degree awarded	Date degree awarded	Dates of attendance
Doctor of Pharmacy	May 4, 2013	From: 08/25/08 To: 05/03/13

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.

Michael D. Thompson, PharmD
Print Name

Michael Thompson
Signature

(SCHOOL SEAL)

Dean, College of Pharmacy
Title

May 13, 2013
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

RECEIVED
MAY 14 2013
Florida Board of Pharmacy

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STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

PROVIDER INFORMATION

NAME Florida A&M University
College of Pharmacy and Pharmaceutical Sciences

Sponsored: Florida A&M University College of Pharmacy and Pharmaceutical Sciences
Knowledge-based CPE activity
CE Broker Tracking Number: 20-353265

UAN:0011-0000-12-020-L05-T	MEDICATION ERRORS	05/01/2013

PARTICIPANT INFORMATION

Name	Clifton Webb, Jr.
Address	8801 NW 7th Street
City, State, Zip	Pembroke Pines, FL 33024
License No. (s)	
NABP	DOB

Total Credit Issued 0.2 CEU'S
OR 2 Contact Hours

May 1, 2013
Date

Angela M. Thornton
Authorized Signature
Angela M. Thornton

September 18, 2013

Rodney Vuurens
1602 Preston Trail
Harlingen, TX 78552

RE: Application for Licensure by Endorsement

Dear Mr. Vuurens:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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2201-42822

01/29/2013 295.00
ID: 42822 Type: F
BT: 3013232
VL: 912040318

FLORIDA DEPARTMENT OF HEALTH

FLORIDA BOARD OF PI
P.O. Box 6320 • Tallahas
Phone: (850) 245-4292
www.doh.state.fl.us/mqa/

ITEM #2 – PHARMACIST ENDORSEMENT APPLICATION
FEE: $295.00

Please print or type legibly.

1. Biographical Data			
Last Name	**First Name**	**Middle Name**	
VUURENS	RODNEY	KIM	
Street Address (ML – Mailing Address)	**City**	**State**	**Zip**
1602 PRESTON TRL	HARLINGEN	TX	78552
Work Address (PL – Practice Location)	**City**	**State**	**Zip**
640 S. EXPRESSWAY 77 STE 1	RAYMONDVILLE	TX	78580
Home Phone Number	**Business Phone Number**	**E-Mail Address**	
956-425-0862	956-689-2424	RVuurens10@gmail.com	
Date of Birth	**Place of Birth**		
12-05-1954	HOLLAND, MI		

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:

FERRIS STATE COLLEGE

5. Date Of Graduation	**6. Type Of Degree Earned**	**7. Have you ever been licensed as an intern in Florida?**
MAY 1978	BS	Yes _____ No X Intern License Number: _____

VL

8. Please indicate the date you successfully completed the NAPLEX examination.

Date JUNE 30, 1978

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
6/06 → Pres	PETE'S PHARMACY	HARLINGEN, TX RAYMONDVILLE, TX	PHARMACIST	7000

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
TEXAS	41361	JAN 2003
MICHIGAN	53020 23502	Aug 1978

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 Suspended in MI as part of Final Action in MI. Not while pending, Not in other jurisdiction Unsure of How to Apply.
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 _____
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 _____
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 _____
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_____
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_____

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 _____
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 _____
26b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
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 _____

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.

Rodney K Varner — Applicant Signature

1-22-13 — Date

NOTE: Please check to be sure that you have answered all of the questions above.

1708746

42822

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
VUURENS	RODNEY	KIM

Maiden Name/Surname	Date of Graduation
	MAY 1978

Mailing Address	City	State	Zip
1602 PRESTON TRL	HARLINGEN	TX	78552

Part II. – To be completed by an official of the university

Name of School/College of Pharmacy			
Ferris State University			
Mailing Address	**City**	**State**	**Zip**
220 Ferris Drive	Big Rapids	MI	49307

Type of Degree Awarded	Date Degree Awarded	Dates of Attendance
Bachelor of Science in Pharmacy	November 21, 1977	From: 09/06/1973 To: 11/18/1977

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.

Stephen W. Durst
Print Name

Signature

(SCHOOL SEAL)

Dean
Title

February 5, 2013
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
FEB 11 REC'D
Pharmacy

Board of 1708695

FEB 07 REC'D

Pharmacy

42822

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**	
RODNEY KIM VUURENS	TX- 41361	956-425-0862	
Street Address	**City**	**State**	**Zip**
1602 PRESTON TRL	HARLINGEN	TX	78552

2. Have you submitted an application for the Florida Pharmacist Examination? If yes, please indicate date.

Yes X No _____ Date 1/22/13

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**	
PEDRO MANUEL YZAGUIRRE JR.		31431	
Pharmacy Name		**Permit Number**	
PETE'S PHARMACY III		26824	
Street Address	**City**	**State**	**Zip**
640 S. EXP. 77 SUITE 1	RAYMONDVILLE	TX	78580
Phone Number	**4. Dates of Experience**		
956-689-2424	From: 06/02/2006 To: PRESENT		
5. Average number of hours per week	**6. Total hours of experience**		
24 HRS	4,206		

(No more than 50 hours per week if you are a student and no more than 60 after graduation is allowed)

Rodney K Vuurens — Applicant's Signature

1/23/13 — Date

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

01/23/2013 — 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

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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 APPROVED COURSE

STATEMENT OF CONTINUING EDUCATION CREDIT

1/21/13

Provider Information

Continuing Education Network, Inc.
PO Box 1516
Martinez,CA 94553
1-800-798-3353

The Rx Consultant is a publication of Continuing Education Network, Inc. CE hours provided by CEN, Inc. (in The Rx Consultant) meet the ANCC criteria for formally approved continuing education hours.

Continuing Education Network, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education

Program Information

Title:	Patient Safety: Identifying Adverse Drug Reactions
Release Date:	12/01/11
ACPE Program:	428-0000-11-111-H05-P
CA BRN:	13118
Type of activity:	Knowledge-based

Participant Information

RODNEY VUURENS
1602 PRESTON TRL

HARLINGEN TX 78552

License ID:

Credit Information

Credits Earned:	.20 CEU
	2.0 Contact Hours
CE Category:	Pharmacology
Date Completed:	1/21/13
Date Issued:	1/21/13
Certificate Number:	1093889
Authorized by:	Terry M. Baker

Terry M. Baker

Home Page

Take Another Test

STATEMENT OF CONTINUING PHARMACEUTICAL EDUCATION PARTICIPATION

PROVIDER

The University of Texas at Austin
College of Pharmacy

This written statement confirms that the participant noted below has fulfilled all the requirements necessary for receiving the documented CEU(s) or contact hour(s) for the specified accredited program. Should there be a discrepancy in the report, it is the responsibility of the participant to make the correction and to notify The University of Texas at Austin College of Pharmacy of the same. It is also the participant's responsibility to check with the appropriate state board(s) of pharmacy in the event there is a concern about the acceptability of a program for CPE credit.

PROGRAM INFORMATION: 59th Pharmacy Practice Seminar (Knowledge)

ACPE UNIV. PROG. NO.	TITLE Date	CEU's	Contact Hours
0067-0000-11-030-L05-P	Medication Interest Model 09/17/2011	0.125	1.25
0067-0000-11-031-L01-P	Alzheimer's vs. Dementia 09/17/2011	0.15	1.50
0067-0000-11-032-L01-P	Advances in ADHD 09/17/2011	0.10	1.00
0067-0000-11-033-L01-P	Dermatology: 13 Going on 40 and Beyond 09/17/2011	0.10	1.00
0067-0000-11-034-L01-P	Counseling Cancer Patient in the Retail Setting 09/17/2011	0.15	1.50
0067-0000-11-035-L04-P	New Drug Update 09/17/2011	0.15	1.50
0067-0000-11-036-L04-P	*Healthcare Reform 09/18/2011	0.10	1.00
0067-0000-11-037-L04-P	eHealth: Communications in the Digital Age 09/17/2011	0.10	1.00
0067-0000-11-038-L03-P	*Texas Pharmacy Law Update 09/18/2011	0.10	1.00
0067-0000-11-039-L03-P	Texas Pharmacy Law Update Question/Answer 09/18/2011	0.05	0.50
0067-0000-11-040-L01-P	*Update on Substance Abuse 09/18/2011	0.10	1.00
0067-0000-11-041-L01-P	Clinical 101: Hypertension 09/18/2011	0.15	1.50
0067-000-11-042-L01-P	Diabetes: Empowering the Patient 09/18/2011	0.125	1.25

PARTICIPANT INFORMATION

Total credits issued: 1.50 CEU's
or 15.00 Contact Hours

Name: Rodney Vuurens

Address: 1602 Preston Trail
Harlingen, TX 78552

The University of Texas at Austin College of Pharmacy is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Authorized Signature

09/28/11
Dated

POWER-PAK C.E.®

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

0430-0000-11-028-H03-P

PROGRAM INFORMATION

TITLE:

Medication Disposal: Current Issues and Legal Considerations for Pharmacists

EXAM SUBMITTED ON:

11/12/2011

EXAM PROCESSED ON:

11/12/2011

PARTICIPANT INFORMATION

NAME:

Rodney Vuurens

ADDRESS:

1602 Preston Trail

CITY, STATE, ZIP:

Harlingen, Texas 78552

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: **5-B, 20-D**

STATEMENT ISSUED ON: **11/12/2011**

AUTHORIZED SIGNATURE

Susanne Batesko, RN. BSN

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:

2/11/2011

EXAM PROCESSED ON:

2/11/2011

PARTICIPANT INFORMATION

NAME:

Rodney K Vuurens

ADDRESS:

1602 Preston Trail

CITY, STATE, ZIP:

Harlingen, tx 78552

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED:

STATEMENT ISSUED ON: **2/11/2011**

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE

Susanne Bateska, RN, BSN

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ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

0430-0000-10-026-H01-P

PROGRAM INFORMATION

TITLE:

Head Lice: An Update on Diagnosis & Treatment

EXAM SUBMITTED ON:

2/11/2011

EXAM PROCESSED ON:

2/11/2011

PARTICIPANT INFORMATION

NAME:

Rodney K Vuurens

ADDRESS:

1602 Preston Trail

CITY, STATE, ZIP:

Harlingen, tx 78552

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED:

STATEMENT ISSUED ON: **2/11/2011**

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE 

Susanne Bateska, RN, BSN

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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:

Rodney Vuurens

ADDRESS:

1602 Preston Trail

CITY, STATE, ZIP:

Harlingen, Texas 78552

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: **9-D, 18-A**

STATEMENT ISSUED ON: **2/28/2012**

AUTHORIZED SIGNATURE

Susanne Bateskd, RN. BSN

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STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

0430-0000-10-009-H01-P

PROGRAM INFORMATION

TITLE:

Assessment and Management of Leg Cramps: A Homeopathic Approach

EXAM SUBMITTED ON:

10/7/2011

EXAM PROCESSED ON:

10/7/2011

PARTICIPANT INFORMATION

NAME:

Rodney Vuurens

ADDRESS:

1602 Preston Trail

CITY, STATE, ZIP:

Harlingen, Texas 78552

CREDIT INFORMATION

CREDITS EARNED:

2.00

QUESTIONS MISSED: **12-B, 19-C, 20-A**

STATEMENT ISSUED ON: **10/7/2011**

AUTHORIZED SIGNATURE

Susanne Bateska. RN. BSN

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STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

0430-0000-10-006-H01-P

PROGRAM INFORMATION

TITLE:

Common Cold, Influenza, and the Pharmacist: Rational Self-Care Recommendations

EXAM SUBMITTED ON:

2/21/2011

EXAM PROCESSED ON:

2/21/2011

PARTICIPANT INFORMATION

NAME:

Rodney K Vuurens

ADDRESS:

1602 Preston Trail

CITY, STATE, ZIP:

Harlingen, tx 78552

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED: **3-D**

STATEMENT ISSUED ON: **3/1/2011**

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE 

Susanne Bateske, RN, BSN

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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:

2/11/2011

EXAM PROCESSED ON:

2/11/2011

PARTICIPANT INFORMATION

NAME:

Rodney K Vuurens

ADDRESS:

1602 Preston Trail

CITY, STATE, ZIP:

Harlingen, tx 78552

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED:

STATEMENT ISSUED ON: **2/11/2011**

DUPLICATE STATEMENT

AUTHORIZED SIGNATURE

Susanne Bateske, RN, BSN

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STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

ACCREDITOR INFORMATION

NAME:

Postgraduate Healthcare Education, LLC

ACPE I.D.

0430-0000-10-023-H01-P

PROGRAM INFORMATION

TITLE:

Managing Joint Pain and Associated Conditions

EXAM SUBMITTED ON:

2/11/2011

EXAM PROCESSED ON:

2/11/2011

PARTICIPANT INFORMATION

NAME:

Rodney K Vuurens

ADDRESS:

1602 Preston Trail

CITY, STATE, ZIP:

Harlingen, tx 78552

CREDIT INFORMATION

CREDITS EARNED:

0.20 CEU or 2.00 Credit Hours

QUESTIONS MISSED:

STATEMENT ISSUED ON: **2/11/2011**

ORIGINAL STATEMENT

AUTHORIZED SIGNATURE

Susanne Batesko, RN, BSN

Back to Home

September 18, 2013

Mark Alan Kemp
135 E Prairie Ave
Decatur, IL 62523

RE: Application for Licensure by Endorsement

Dear Mr. Kemp:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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05/22/2013 295.00
ID: 43630 Type: F
BT: 3021515
VL: 912063089

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/mqa/pharmacy

ITEM #2 – PHARMACIST ENDORSEMENT APPLICATION
FEE: $295.00

Please print or type legibly. 2201436 30

1. Biographical Data			
Last Name	**First Name**	**Middle Name**	
KEMP	MARK	ALAN	
Street Address (ML – Mailing Address)	**City**	**State**	**Zip**
135 E. PRAIRIE AVE	DECATUR	IL	62523
Work Address (PL – Practice Location)	**City**	**State**	**Zip**
765 N. SUNNYSIDE RD.	DECATUR	IL.	62522
Home Phone Number	**Business Phone Number**	**E-Mail Address**	
773-294-6508	217-428-8575	M_KEMP@MSN.COM	
Date of Birth	**Place of Birth**		
8/13/70	BERWYN, ILLINOIS		

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:

University of Illinois Chicago School of Pharmacy

5. Date Of Graduation	**6. Type Of Degree Earned**	**7. Have you ever been licensed as an intern in Florida?**
5/2005	PharmD	Yes _____ No X Intern License Number: _____

V

8. Please indicate the date you successfully completed the NAPLEX examination.

Date 3/2006

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
2007-Present	Omnicare	Decatur, Fl.		

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
Illinois	051.291058	4/2006

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 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 X
23a. 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
23b. 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
23c. 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
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 X No _____
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.

_____ 4/6/13

Applicant Signature Date

NOTE: Please check to be sure that you have answered all of the questions above.

1810097

F:43630

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 #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
KEMP	MARK	ALAN

Maiden Name/Surname	Date of Graduation
	MAY 2005

Mailing Address	City	State	Zip
135 E PRAIRIE AVE	DECATUR	IL	62523

Part II. – To be completed by an official of the university

Name of School/College of Pharmacy

University of Illinois at Chicago

Mailing Address	City	State	Zip
833 S. WOOD ST. M/C 874	Chicago	IL	60612

Type of Degree Awarded	Date Degree Awarded	Dates of Attendance
Doctor of Pharmacy	05/08/2005	From: 08/20/2001 To: 05/06/2005

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.

Debra Agard
Print Name

Debra Agard
Signature

(SCHOOL SEAL)

Assistant Dean
Title

June 10, 2013
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

RECEIVED

JUN 14 2013

Florida Board of Pharmacy

1828123

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**	
MARK KEMP	051.291058	773-294-6508	
Street Address	**City**	**State**	**Zip**
135 E PRAIRIE AVE	DECATUR	IL	62523

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**	
MIKE LUTZ		057-035648	
Pharmacy Name		**Permit Number**	
ENLOE DRUGS LLC		N/A	
Street Address	**City**	**State**	**Zip**
796 SUNNYSIDE DR	DECATUR	IL	62522
Phone Number	**4. Dates of Experience**		
217-428-8575	From: 4/1/07 To: __/__/__ PRESENT		
5. Average number of hours per week	**6. Total hours of experience**		
40			

(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 6/12/13

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 6/12/13

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

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September 18, 2013

Darren James Palmer
1010 Seminole Drive, Apt 404
Ft. Lauderdale, FL 33304

RE: Application for Licensure by Endorsement

Dear Mr. Palmer:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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03/29/2013 295.00
ID: 42962 Type: F
BT: 3017529
VL: 912052084

Florida HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.doh.state.fl.us/mqa/pharmacy

ITEM #2 – PHARMACIST ENDORSEMENT APPLICATION
FEE: $295.00

Please print or type legibly. 2201-42962

1. Biographical Data			
Last Name	**First Name**		**Middle Name**
Palmer	Darren		James
Street Address (ML – Mailing Address)	**City**	**State**	**Zip**
P.O. Box 355 3733 Porter Rd. S	Seneca Falls	NY	13148
Work Address (PL – Practice Location)	**City**	**State**	**Zip**
Not Working			
Home Phone Number	**Business Phone Number**	**E-Mail Address**	
315-730-0534		dpalm76@rochester.rr.com	
Date of Birth	**Place of Birth**		
05/17/1976	Auburn, NY		

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:

Albany College of Pharmacy

5. Date Of Graduation	**6. Type Of Degree Earned**	**7. Have you ever been licensed as an intern in Florida?**
1999	R.Ph / Bach of Science	Yes _____ No X Intern License Number: _____

8. Please indicate the date you successfully completed the NAPLEX examination.

Date 06/99

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
'04 - '12	Palmer Pharmacy	Ithaca, Old Trumansburg NY		10,000+

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
New York	047063	08/99

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 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.)

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 _____ No X
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 X No _____
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 _____
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 _____
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 _____
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_____
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_____

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 _____
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 _____
26b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
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 _____

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 3/21/13

NOTE: Please check to be sure that you have answered all of the questions above.

1838631

42962

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 #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
Palmer	Darren	J

Maiden name/surname	Date of graduation
	June 6, 1999

Mailing address	City	State	Zip
4253 Seybolt Rd	Seneca Falls	NY	13148

Part II. – To be completed by College of Pharmacy Dean

Name of School/College of Pharmacy: Albany College of Pharmacy and Health Sciences

Mailing address	City	State	Zip
~~106 New Scotland Ave Albany, NY 12208~~			

Type of degree awarded	Date degree awarded	Dates of attendance
B.S. in Pharmacy	June 6, 1999	From: 09/ 94 To: 05/ 99

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.

Judith A. Schmonsky
Print Name

Judith A. Schmonsky
Signature

(SCHOOL SEAL)

Registrar
Title

6-28-13
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

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**	
Darren Palmer	047063	315-730-0534	
Street Address	**City**	**State**	**Zip**
3733 Parker Rd. S P.O. Box 355	Seneca Falls	NY	13148

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**	
Darren Palmer		047063	
Pharmacy Name		**Permit Number**	
Palmer Pharmacy		026807	
Street Address	**City**	**State**	**Zip**
2083 Rt 96	Trumansburg	NY	14886
Phone Number	**4. Dates of Experience**		
315-730-0534	From: 10/11/04 To: 7/13/12		
5. Average number of hours per week	**6. Total hours of experience**		
50+	10,000+		

(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: 3/21/13

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: 3/21/13

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

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1826734

Richard J Caron Foundation
PO Box 150
Wernersville, PA 19565-0150

Forms

Criteria : Darren Palmer; 04/15/2013

This document is effective from : 4/15/2013 to : 4/15/2020

April 15, 2013

Darren Palmer
PO Box 355
Seneca Falls, NY 13148

RE: Completion of Treatment

Dear Darren:

This is to certify that you were admitted to the Caron Primary Care Residential Services for the treatment of chemical dependency on July 16, 2012. You completed the program and discharged routinely on August 15, 2012. At the time of your discharge you were medically cleared from the facility.

If we can be of further assistance, please do not hesitate to contact the Medical Records Department at 1-800-678-2332.

Sincerely,

Kenneth Thompson, MD, FASAM

Dr. Kenneth W. Thompson, M.D., FASAM
Medical Director Caron Treatment Centers
Fellow American Society of Addiction Medicine
Diplomat American Board of Addiction Medicine
Diplomat American Board of Internal Medicine

Report ID: 1688653

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UNC ESHELMAN SCHOOL OF PHARMACY

STATEMENT OF CONTINUING PHARMACY EDUCATION CREDIT

PROVIDER: THE UNIVERSITY OF NORTH CAROLINA ESHELMAN SCHOOL OF PHARMACY

ACPE UNIVERSAL ACTIVITY NUMBER	ACTIVITY TITLE	ACTIVITY DATE	CONTACT HOURS	CEU
0046-9999-12-293-H01-P	**The Impact of Hyponatremia: Role of the Pharmacist in Improving Care: A Complimentary Knowledge-Based Home Study CPE Activity**	6/11/12 -6/11/14	0.1	1.00

Darren Palmer
PO Box 355

Seneca Falls, New York 13148

2/10/2013
Issue Date

Stephen C. DeDonick
AUTHORIZED SIGNATURE

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:
Darren Palmer

ADDRESS:
PO Box 355

CITY, STATE, ZIP:
Seneca Falls, New York 13148

CREDIT INFORMATION

CREDITS EARNED:
2.00

QUESTIONS MISSED: **10-A**

STATEMENT ISSUED ON: **2/10/2013**

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:
Darren Palmer

ADDRESS:
PO Box 355

CITY, STATE, ZIP:
Seneca Falls, New York 13148

CREDIT INFORMATION

CREDITS EARNED:
2.00

QUESTIONS MISSED: **6-D, 9-C, 12-C**

STATEMENT ISSUED ON: **2/11/2013**

AUTHORIZED SIGNATURE

Susanne Batesko, RN, BSN

American Pharmacists Association®
Improving medication use. Advancing patient care
APhA
2215 Constitution Ave NW
Washington, DC 20037-2985
(800) 237-2742
Fax: (202) 783-2351

STATEMENT OF CREDIT

Name: Darren Palmer

Date Completed: 1/25/2013

Course: Pharmacy-Based Immunization Delivery Self-Study

ACPE Universal
Activity Number: ACPE# 202-999-11-136-H01-P

Credits: 1.200

Activity Type: Application-Based

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Authorized Signature:

Shelby Englert
Senior Director of Education

American Pharmacists Association
Improving medication use. Advancing patient care
APhA
2215 Constitution Ave NW
Washington, DC 20037-2985
(800) 237-2742
Fax: (202) 783-2351

STATEMENT OF CREDIT

Name: Darren Palmer

Date Completed: 1/26/2013

Course: Pharmacy-Based Immunization Delivery Live Seminar

ACPE Universal
Activity Number: ACPE# 202-999-11-135-L01-P

Credits: 0.800

Activity Type: Application-Based

The American Pharmacists Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Authorized Signature:

Shelby Englert
Senior Director of Education

INSTITUTE FOR NATURAL RESOURCES (INR)

P.O. Box 5757 ♦ Concord, CA USA 94524-0757 ♦ TEL (925) 609-2820 ♦ FAX (925) 687-0860

STATEMENT OF CREDIT

PALMER, DARREN
PROF: RPH
CLASS CODE: U20130306SY

PROGRAM TITLE: **STRESS, ANXIETY AND DEPRESSION**

March 6, 2013
Date

Syracuse-Liverpool, NY
Location

Continuing credit information is listed below. This course is presented in a live interactive format.

REGISTERED NURSES (RNs) & LICENSED PRACTICAL NURSES (LPNs) (6 CONTACT HOURS):

Institute for Natural Resources (INR) is an approved provider of continuing nursing education by the Virginia Nurses Association, an accredited approver by the American Nurses' Credentialing Center's Commission on Accreditation. The code for this session of this course on this date is: U20130306SY.

Nurses licensed by the states of New York, Massachusetts, and Vermontean obtain (6) contact hours by successfully completing this course. Massachusetts-licensed nurses can use the six (6) contact hours earned at this continuing education activity for renewal of their state nursing licenses. INR has been accredited as a continuing education provider by the California Board of Registered Nursing (CEP #06136), the Florida Board of Nursing (#50-3026-1), the Iowa Board of Nursing (#288), and the Kansas Board of Nursing (#LT0140-0927).

PHARMACISTS (6 CONTACT HOURS): INR is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. The Illinois Board of Pharmacy and the boards of pharmacy of all 50 states will accept, for credit toward license renewal, courses presented by an ACPE-accredited organization. The ACPE universal activity number (UAN) for this course is 0751-0000-12-035-L01-P. This is a knowledge based CPE activity.

REGISTERED DIETITIANS & DTRs (6 CONTACT HOURS): INR, under Provider Number IN001, is a Continuing Professional Education (CPE) Accredited Provider with the Commission on Dietetic Registration (CDR). Registered dietitians (RDs) and dietetic technicians, registered (DTRs) will receive 6 hours worth of continuing professional education units CPEUs) for completion of this program/materials. Continuing Professional Education Provider Accreditation does not constitute endorsement by CDR of a provider, program, or materials. CDR is the credentialing agency for the Academy of Nutrition and Dietetics (AND).

PSYCHOLOGISTS (6 CONTACT HOURS):: INR is approved by the American Psychological Association to sponsor continuing education for psychologists. INR maintains responsibility for this program and its content.

SOCIAL WORKERS (6 CONTACT HOURS): Under Sponsor #159-000260, the State of Illinois Department of Professional Regulation has approved INR as a sponsor of continuing education for Illinois-licensed social workers. This program is approved by the National Association of Social Workers (Provider #886502971-1419) for 6 social work continuing education contact hours.

OCCUPATIONAL & PHYSICAL THERAPISTS (6 CONTACT HOURS): INR is an AOTA Approved Provider of continuing education. Provider #5347. INR has assigned 0.6 AOTA CEUs for this course. The assignment of AOTA CEUs does not imply endorsement of specific course content, products, or clinical procedures by AOTA.

Application for approval of this course has been made to the American Physical Therapy Association – New York Chapter for 6 hours of continuing education credit.

CASE MANAGERS (6 CONTACT HOURS): This program has been pre-approved by the Commission for Case Manager Certification to provide continuing education credit to Certified Case Managers (CCMs). This course is approved for six (6) continuing education contact hours. Activity code: S0001260 Approval #20131768.

NURSING HOME ADMINISTRATORS (6 CONTACT HOURS): This educational offering has been reviewed by the National Continuing Education Review Service (NCERS) of the National Association of Long Term Care Administrator Boards (NAB) and approved for 6.00 clock hours and 6.00 participant hours—Approval #05122012-6.00-10227-in. INR (Sponsor #139-000175) has been approved by the State of Illinois Department of Professional Regulation as a sponsor of continuing education for nursing home administrators.

COUNSELORS (6 CONTACT HOURS): INR is an NBCC-Approved Continuing Education Provider (ACEP) and may offer NBCC-approved clock hours for events that meet NBCC requirements. The ACEP solely is responsible for all aspects of the program.

MASSAGE THERAPISTS (6 CONTACT HOURS): Institute for Natural Resources is approved by the National Certification Board of Therapeutic Massage and Bodywork (NCBTMB) as a continuing education Approved Provider. INR has approval #299936-00.

OTHER HEALTH PROFESSIONALS (6 CONTACT HOURS): Participants successfully completing this course will receive course completion certificates. For rules governing continuing education credits, participants should contact their respective regulatory boards.

Richard S. Colman

RICHARD S. COLMAN, Ph.D., Program Administrator, March 6, 2013

W1500

PRIME®

Accredited provider of medical and professional education

Statement of Credit

Preventing Medication Errors to Improve Patient Outcomes

Congratulations

Darren Palmer

Date Completed: **March 22, 2013**

Universal Activity Number: **0255-0000-11-032-H05-P**

Activity Type: Knowledge

This activity has been approved for **2.0 contact hour(s)** of continuing education for pharmacists by PRIME Education, Inc. (PRIME®), an ACPE Accredited Provider.

PRIME® is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Pharmacist License Number: NY 047063

Lynn Goldenberg, R.N., B.S.N.

Lynn Goldenberg, RN, BSN

Signed and issued on: **March 22, 2013**

September 18, 2013

Richard P. Becker
2800 E. Sunrise Blvd., Unit 17E
Fort Lauderdale, FL 33304

RE: Application for Licensure by Endorsement

Dear Mr. Becker:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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12/11/2012 295.00
ID: 42747 Type: F
BT: 3010262
VL: 912031341

FLORIDA DEPARTMENT OF HEALTH

FLORIDA BOARD
P.O. Box 6320 • Ta
Phone: (850) 245-4
www.doh.state.fl.us

ITEM #2 – PHARMACIST ENDORSEMENT APPLICATION
FEE: $295.00

2201-42747 **Please print or type legibly.**

1. Biographical Data				
Last Name	**First Name**	**Middle Name**		
BECKER JR	RICHARD	PAUL		
Street Address (ML – Mailing Address)	**City**	**State**	**Zip**	
372 NORTH ROAD	CHESTER	NJ	07930	
Work Address (PL – Practice Location)	**City**	**State**	**Zip**	
6201 SOUTH FREEWAY	FORT WORTH	TX	76134	
Home Phone Number	**Business Phone Number**	**E-Mail Address**		
908-879-0031	817-551-3021	RXSTONEWALL@AOL.COM		
Date of Birth	**Place of Birth**			
02/04/1965	BELLEVILLE, NJ			

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 ✓

NAME	DATE

4. Name of university, college or school of pharmacy attended:

PHILADELPHIA COLLEGE OF PHARMACY & SCIENCES

5. Date Of Graduation	6. Type Of Degree Earned	7. Have you ever been licensed as an intern in Florida?
MAY, 1988	BS in PHARMACY	Yes _____ No ✓ Intern License Number: _____

W

8. Please indicate the date you successfully completed the NAPLEX examination.

Date _____

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 _____ 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.

✓ 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

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
NEW JERSEY	RI20131	March 1, 1989

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 ✓

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 ✓

(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 _____ No ✓_____
20. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No ✓_____
21. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No ✓_____
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 ✓_____
23. 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 ✓_____
23a. 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 _____
23b. 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 _____
23c. 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_____
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 ✓_____
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_____

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 ✓
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 ✓
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 ✓
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 _____
26b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
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 ✓
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 _____

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

October 30, 2012
Date

NOTE: Please check to be sure that you have answered all of the questions above.

1661831

Board of

DEC 27 REC'D

Pharmacy

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

42747

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
BECKER JR	RICHARD	PAUL

Maiden Name/Surname	Date of Graduation
	MAY, 1988

Mailing Address	City	State	Zip
372 NORTH ROAD	CHESTER	NJ	07930

Part II. – To be completed by an official of the university

Name of School/College of Pharmacy

University of the Sciences in Philadelphia

Mailing Address	City	State	Zip
600 South 43rd Street Philadelphia, PA 19104			

Type of Degree Awarded	Date Degree Awarded	Dates of Attendance
BS IN PHARMACY	5/21/88	From: __/__/83 To: __/__/88

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.

Therese M. Anderson	Therese M. Anderson	(SCHOOL SEAL)
Print Name	Signature	
Registrar	DEC 14 2012	
Title	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

Richard Becker R. Ph., MBA

2800 East Sunrise Blvd., Unit 17E
Fort Lauderdale, FL 33304
(954) 566-7222 – Home
(973) 229-2729 – Cell
richardpbeckerjr@gmail.com

OVERVIEW: Innovative **Pharmaceutical Marketing Professional** with 19 years of distinguished success leading large, medium and entrepreneurial companies to record growth in fiercely competitive markets. High-performance track record in building commercial infrastructures, new product launches, life-cycle management, strategic planning, business development, branding and key opinion leader development for Global and US businesses. Successful team leader with very strong interpersonal skills and proven ability to formulate bold visions and guide them to strategic implementation. MBA Marketing. BS Pharmacy with honors.

PROFESSIONAL EXPERIENCE:

August, 2012 - Current

ALCON LABORATORIES, Fort Worth, TX
Global Brand Leader - JETREA®

- Lead the Pharmaceutical Retina Division in launching a first in class product in Europe.
- Implementing market development strategy for Latin America, which includes building the commercial operations and distributor interfacing.
- Providing strategic leadership to successfully drive sales growth for approved indications as well as contribute to the life-cycle development strategy.
- Collaborate closely with regional and country teams to enable tactical implementation of brand promotional & medical education strategies worldwide.
- Developed and executed the Global Launch Plan, ongoing strategic business plan, tactical program development & implementation, and ROI assessment.
- Lead the cross functional and international brand teams for customer initiatives (e.g., core promotional tools, International meetings, public relations, publications, internal communications, etc.) to maximize product sales potential.
- Monitor and control brand budgets, forecasts and expenses and assess the marketing mix of assigned products to evaluate cost effectiveness and results.

September, 2011 - August, 2012

TOPOTARGET A.S., Copenhagen, Denmark
Consultant / Acting Commercial Leader reporting to CEO

- Developed Strategic Commercialization plans for belinostat in hematology & oncology.
- Participated in developing overall corporate strategy including operations and distributor strategies for Latin America and Asia Pacific.
- Developed U.S. strategic business plan for Totect® which improved sales by 120%
- Led U.S. divesture activities of Topotarget USA and Totect®

August, 2011 - February, 2012

TG THERAPEUTICS, Inc., New York, NY
President, Emerging Markets

- Led the commercial and clinical development strategies for ublituximab in oncology, immunology and renal disease
- Developed operating business model through commercial assessment of product forecasts, life-cycle opportunities and optimizing target product profile
- Participated in execution of fundraising process for private and public markets
- Participated in developing overall corporate strategy and oversaw execution of the strategy, as formulated by the CEO
- Optimized product positioning and customer value through advisory boards, market research and competitive intelligence analysis

December, 2005 - August, 2011

MERCK & CO., Whitehouse Station, NJ

Regional Oncology Franchise Leader, Asia Pacific + Japan (1/10- 09/11)

- Managed portfolio, regional P&L and commercial operations; Grew sales by 32% vs 2010 and 24% vs 2009, while combating new generic entries
- Led Commercial Business Development across the Emerging Markets, resulting in partnerships for India, China and Japan.
- Created strategic business models in China, Korea and Japan which will grow the oncology business by 20+% annually over a three-year forecast horizon.
- Launched 3 new products across Asia Pacific
- Implemented a regional sales training program
- Developed & implemented two patient registry programs
- Designed & implemented a Multi-Channel Marketing program for Japan & China
- Executed patient access & reimbursement strategies to drive customer value.
- Built and managed a staff of three.

Global Brand Leader, Marketing (Oncology) (06/06 – 12/09)

- Launched Zolinza® in U.S. and Latin American markets for Cutaneous T-cell Lymphoma, resulting in a first-year market penetration of 25%.
- Led all commercialization and P&L activities for Zolinza®
- In conjunction with Latin America regional leadership, developed commercial and operational plans with internal and external partners.
- Created global life-cycle plan for Zolinza® for both solid and liquid tumors, which will generate over $1 Billion in probabilized peak sales.
- Developed strategic plan which will improve development time lines by 6 months, resulting in a potential cumulative sales gain of $60 Million.
- Designed cross-divisional processes and infrastructure to drive compound assessments, go/no-go decisions and target profile development for Zolinza®
- Co-Chaired the Thoracic and Hematology Strategy teams.
- As Executive Sponsor - Developed Standard Operating Procedures for product sourcing & patient access programs, resulting in cost savings of $22 and $14 M
- Built and managed a staff of six.

Director – Early Commercial Development (Oncology) (12/05 – 6/06)

- Led commercial assessment and successful in-licensing efforts for ridaforolimus
- Developed and executed commercialization strategies for pipeline including Target Product Profile's, forecast's and life-cycle plans
- Supported Business Development team in identifying and evaluating potential deals.
- Assumed Global Brand Leader responsibilities for Aurora Kinase portfolio

May, 2004 - December, 2005

OSI PHARMACEUTICALS, Melville, NY

Brand Director, Marketing (Oncology) – Tarceva®

- Responsible for consolidated (U.S. + International) P&L.
- Successfully launched Tarceva® in United States for two indications. The launch in 2nd / 3rd-line NSCLC was the third highest revenue generating in oncology history with a first-year market share of 25 and 40% respectively.
- Developed and executed strategic business plans with external partners.
- Developed / implemented brand and life-cycle strategies.
- Awarded launch of year, brand of year, number one product management team and small molecule of the year by *Product Management Today* (Oct., 2005)
- Championed Global Brand team and leader of several tripartite cross-functional teams to maximize commercial value.

March, 2002 - May, 2004

NOVARTIS PHARMACEUTICALS, Florham Park, NJ
Global Brand Director, Early Commercial Development (Oncology)

- Developed initial global commercialization strategies for two phase III and three phase II compounds, including Afinitor® and Tasigna®.
- Initiated global marketing commercialization activities including marketing plan development, communication planning, life-cycle management, medical education coordination, opinion leader and advisory board development.
- Championed cross-functional teams to craft optimal target product profiles, clinical development plans and pre-launch marketing strategies.
- Led commercial assessment and successful in-licensing efforts for gimatecan.
- Awarded four patents on epothilone B combinations
- Completed Novartis Marketing Excellence training for high potential leaders.

November, 2000 - March, 2002

BAYER CORPORATION, West Haven, CT
Deputy Director, U.S. New Business Development (Oncology)

- Led U.S. business development and licensing efforts, which expanded portfolio by 40% through product and business acquisitions.
- Developed long-term product and portfolio strategic plans for US market.
- Managed and developed U.S. pipeline commercialization strategies, including Nexavar® for Renal Cell Cancer.
- Profit and Loss responsibilities for DTIC-Dome®.

June, 1996 - November, 2000

BASF CORPORATION, Mount Olive, NJ
Marketing Leader – America's Region - Pharmaceutical Specialties (1998-2000)

- Developed and executed America's business plan and product launches.
- Global P&L responsibilities for antiseptic and oncology portfolios.
- Developed and implemented strategic marketing plans, which maximized immediate and long-term portfolio growth. Cumulative sales growth of 105% over two years.
- Formulated a new marketing campaign for a stagnate product that achieved 65% market share and a 900% revenue increase in eighteen months.
- Built and managed a staff of four with dotted-line responsibilities for Canada, Mexico and Central America.

Sales Development Specialist (1996–98)

- Strategic key sales account and market development for North America.
- Obtained product approvals at key accounts, while facilitating development of new and existing products.
- Provided market research, which determined value-added products / services for the pharmaceutical market.
- Technically interfaced with customers' R&D departments to provide assistance and new product training.

Prior Relevant Experience:

PRIMARY HEALTH SERVICES	**- Director - Marketing & Pharmacy**	(1995-96)
CURAFLEX INFUSION SERVICES	**- Director of Oncology Services**	(1993-95)
FARRINGTON LAKE PHARMACY	**- Pharmacy Manager**	(1991-93)
RITE AID PHARMACY	**- Regional Manager**	(1988-91)
MERCK & Co.	**- Process Pharmacist - Mevacor® launch team**	(1987-88)
ELI LILLY & SMITHKLINE	**- Sales / Marketing intern programs**	(1988)

Education:

Drexel University — **Philadelphia, PA**
Masters in Business Administration – Marketing

Philadelphia College of Pharmacy & Science — **Philadelphia, PA**
Bachelor of Science (with honors) - Pharmacy

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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F 43747 Richard Becker 1862639

CERTIFICATE OF COMPLETION

First RICHARD MI P Last BECKER JR
Address 372 NORTH ROAD City/State CHESTER, NJ Zip 07930
License # RI 20131 Seminar Date 11/17/2011 Location of Seminar Plantation, FL

This is to certify that the individual listed above has attended and has met the required standards of completion for continuing education for the seminar entitled:

Food For Thought: How Nutrients Affect Mental Health and the Brain

Presented by Nick R.S. Hall, Ph.D.

NURSES: Institute for Brain Potential (IBP) is an approved by the Florida Board of Nursing. This program is 6 contact hours for Florida RNs and LPNs.

IBP is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

PSYCHOLOGISTS: This course is approved by the Florida Board of Psychology to provide 6 hours of continuing education. IBP is approved by the American Psychological Association to sponsor continuing education for psychologists. IBP maintains responsibility for this 6-hour program.

SOCIAL WORKERS, MARRIAGE AND FAMILY THERAPISTS, & COUNSELORS: IBP has been approved to provide 6 hours of continuing education credit by the Florida Board of Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling.

PHARMACIST STATEMENT OF CREDIT: IBP is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This application-based activity is designated for 6 hours (.6 CEU). Initial release date: 7/11/11. UAN: 492-0000-11-024-L04-P.

DENTAL PROFESSIONALS: IBP is an approved provider of the Florida Board of Dentistry. IBP is designated as an Approved PACE Program Provider by the Academy of General Dentistry (AGD). The formal continuing dental education programs of this provider are accepted by the AGD for Fellowship/Mastership and membership maintenance credit. Approval does not imply acceptance by a state or provincial board of dentistry or AGD endorsement. Subject Code 557, Verification Code NMHFL2F11, for 6 hours of credit. The current term of approval extends from 12/01/10 – 11/30/14.

OCCUPATIONAL THERAPISTS: This course is approved by the Florida Board of Occupational Therapy Practice for 6 hours of continuing education. IBP is an approved provider of the American Occupational Therapy Association (AOTA), provider #6050. The assignment of AOTA CEUs does not imply endorsement of specific course content, products, or clinical procedures by AOTA.

MASSAGE THERAPISTS: This course is approved by the Florida Board of Massage Therapy for 6 CE hours.

ACUPUNCTURISTS: This course is pending approval by the Florida Board of Acupuncture for 6 CE hours. Replacement certificates will be provided once approved. For accreditation updates, contact customer service at (650) 960-3536 or visit www.cebroker.com, provider #50-9415.

NURSING HOME ADMINISTRATORS: IBP is an approved provider by the Florida Board of Nursing Home Administration. The program provides 6 hours of credit.

CASE MANAGERS: The course listed above was completed on November 17, 2011 and is approved for 6.0 CEUs. Approval number: 790002250. To claim these CEUs, log into your CE Center account at www.ccmcertification.org.

SPEECH-LANGUAGE PATHOLOGISTS AND AUDIOLOGISTS: This program has been approved for .6 CEUs or 6 hours of continuing professional development by the Florida Board of Speech-Language Pathology and Audiology.

DIETITIANS & NUTRITIONISTS: IBP is a Continuing Professional Education (CPE) Accredited Provider with the Commission on Dietetic Registration (CDR). Registered dietitians and dietetic technicians, registered will receive 6 continuing professional education units (CPEUs) for completion of this program.

OPTOMETRISTS: This program is pending approval with the Florida Board of Optometry for 6 hours of continuing education credit. Replacement certificates will be provided once approved. For accreditation updates, contact customer service at (650) 960-3536 or visit www.cebroker.com, provider #50-9415.

PHYSICAL THERAPISTS: This program is approved by the Florida Physical Therapy Association (FPTA) for 7 hours of continuing education credit. FPTA Accreditation Number: CE111017536.

Retain this certificate for your professional records. Do not send a copy of this certificate to your Board unless specifically requested.

INSTITUTE FOR BRAIN POTENTIAL, 1049 C El Monte Ave. #320, Mountain View, CA 94040

William P. Gordon, Ph.D., President
Issued: 11/17/2011

RUTGERS
Ernest Mario School of Pharmacy

Statement of Continuing Pharmaceutical Education Credit

Provider Information

Name **Rutgers University Ernest Mario School of Pharmacy**

Program Information			Credit	
ACPE Universal Program Number	Title	Date	CEUs	Contact Hours
0038-0000-11-016-L04-P	Oncology and Supportive Care - Knowledge-Based CPE Activity	4/20/2011	0.60	6.00

Participant Information

License No.(s)

Name Richard Becker

Address 372 North Road

City, State, Zip Chester, NJ 07930

Total Credits Issued 0.6 CEU'S

or 6.00 Contact Hrs

4/21/2011
Date

Joseph Barone
Signature

INSTITUTE FOR NATURAL RESOURCES (INR)

P.O. Box 5757 ♦ Concord, CA USA 94524-0757 ♦ TEL (925) 609-2820 ♦ FAX (925) 687-0860

STATEMENT OF CREDIT

Prof. RPH U20111020CL
Lic. # RI20131

BECKER, RICHARD
372 NORTH ROAD
CHESTER, NJ 07930

PROGRAM TITLE: **CONQUERING PAIN**

October 20, 2011
Date

Clinton, NJ
Location

Continuing education credit information is listed below:

REGISTERED NURSES (RN's) & LICENSED PRACTICAL NURSES (LPN's) (6 CONTACT HOURS):

Institute for Natural Resources is an approved provider of continuing nursing education by the Virginia Nurses Association, an accredited approver by the American Nurses' Credentialing Center's Commission on Accreditation. The code for this session of this course on this date is: U20111020CL.

New Jersey, Pennsylvania, and Delaware nurses can use the six (6) contact hours earned at this continuing education activity for renewal of their state nursing licenses. Nurses licensed by the states of New Jersey, New York, Pennsylvania, and Delaware can obtain (6) contact hours by successfully completing this course. This course's contact hours may satisfy requirements established by professional associations and employers. Please check with the appropriate entity. INR has been accredited as a continuing education provider by the California Board of Registered Nursing (CEP #06136), the Florida Board of Nursing (#50-3026-1), the Iowa Board of Nursing (#288), and the Kansas Board of Nursing (#LT0140-0927).

PHARMACISTS (6 CONTACT HOURS): INR is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. The New Jersey, New York, Pennsylvania, and Delaware Boards of Pharmacy and the boards of pharmacy of all 50 states will accept, for credit toward license renewal, courses presented by an ACPE-accredited organization. The ACPE universal program number (UPN) for this course is 751-000-11-007-L01-P. This is a knowledge-based CPE activity.

DIETITIANS (6 CONTACT HOURS): INR, under Provider Number IN001, is a Continuing Professional Education (CPE) Accredited Provider with the Commission on Dietetic Registration (CDR). Registered dietitians (RDs) and dietetic technicians, registered (DTRs) will receive 6 hours worth of continuing professional education units (CPEUs) for completion of this program/materials. Continuing Professional Education Provider Accreditation does not constitute endorsement by CDR of a provider, program, or materials. CDR is the credentialing agency for the American Dietetic Association (ADA).

PSYCHOLOGISTS (6 CONTACT HOURS): INR is approved by the American Psychological Association to offer continuing education for psychologists. INR maintains responsibility for this program and its content.

SOCIAL WORKERS (6 CONTACT HOURS): This program is approved by the NASW (Provider #886502971-8403) for 6 pain/symptom management continuing education contact hours. This program has been approved by NASW-New York State for 6. contact hours under approval number S-464-O.

OCCUPATIONAL THERAPISTS (6 CONTACT HOURS): New Jersey, New York, and Pennsylvania-licensed occupational successfully completing this course will receive course completion certificates. This course has been approved by the Delaware Professional Regulation – Board of Occupational Therapy for 6 hours of continuing education credit. INR is an AOTA Approved Provider (#5347). The assignment of AOTA CEUs does not imply endorsement of specific course content, products, or clinical procedures by AOTA. This intermediate level course has been assigned 0.6 AOTA CEUs.

PHYSICAL THERAPISTS (6 CONTACT HOURS): The Delaware Professional Regulation – Examining Board of Physical Therapists will accept courses approved by other physical therapy boards and associations. This course has been approved by the New Jersey State Board of Physical Therapy Examiners, Approval #1005-2010 and by the American Physical Therapy Association – New York Chapter for 6 hours of continuing education credit. Approval #11/4/2007. The Pennsylvania State Board of Physical Therapy has approved this course for 6 hours of continuing education credit, Approval #PTCE002231.

CASE MANAGERS (6 CONTACT HOURS): The course title Conquering Pain was completed on October 20, 2011 and is approved for 6.0 CEUs. Approval number A427. To claim these CEUs, log into your CE Center account at www.ccmcertification.org.

NURSING HOME ADMINISTRATORS (6 CONTACT HOURS): This educational offering has been reviewed by the National Continuing Education Review Service (NCERS) of the National Association of Long Term Care Administrator Boards (NAB) and approved for 6.00 clock hours and 6.00 participant hours—Approval # 1632011-6.00-7120-in. The Pennsylvania State Board of Examiners of Nursing Home Administrator has approved this course for 6 hours of continuing education credit, Approval #NHCE100915.

COUNSELORS (6 CONTACT HOURS): INR (Provider #5736) is recognized by the National Board for Certified Counselors to offer continuing education for National Certified Counselors. INR adheres to NBCC Continuing Education Guidelines.

MASSAGE THERAPISTS (6 CONTACT HOURS): Institute for Natural Resources is approved by the National Certification Board of Therapeutic Massage and Bodywork (NCBTMB) as a continuing education Approved Provider. INR has approval #299936-00.

OTHER HEALTH PROFESSIONALS (6 CONTACT HOURS): Participants successfully completing this course will receive course completion certificates. For rules governing continuing education credits, participants should contact their respective regulatory boards.

Richard S. Colman

RICHARD S. COLMAN, Ph.D., Program Administrator, October 20, 2011

U3150

INSTITUTE FOR NATURAL RESOURCES (INR)

P.O. Box 5757 ♦ Concord, CA USA 94524-0757 ♦ TEL (925) 609-2820 ♦ FAX (925) 687-0860

STATEMENT OF CREDIT

Prof. RPH U20111215ED
Lic. # RI20131 - - - - - - - - -

BECKER, RICHARD
372 NORTH ROAD
CHESTER, NJ 07930

PROGRAM TITLE: **THE TRANQUIL BRAIN: MOOD SWINGS, HORMONES & STRESS**

December 15, 2011 — Date
Edison, NJ — Location

Continuing education credit information is listed below:

REGISTERED NURSES (RN's), & LICENSED PRACTICAL NURSES (LPN's) (6 CONTACT HOURS):

Institute for Natural Resources is an approved provider of continuing nursing education by the Virginia Nurses Association, an accredited approver by the American Nurses' Credentialing Center's Commission on Accreditation. The code for this session of this course on this date is: U20111215ED.

New Jersey, Pennsylvania, and Delaware nurses can use the six (6) contact hours earned at this continuing education activity for renewal of their state nursing licenses. Nurses licensed by the states of New Jersey, New York, Pennsylvania, and Delaware can obtain (6) contact hours by successfully completing this course. This course's contact hours may satisfy requirements established by professional associations and employers. Please check with the appropriate entity. INR has been accredited as a continuing education provider by the California Board of Registered Nursing (CEP #06136), the Florida Board of Nursing (#50-3026-1), the Iowa Board of Nursing (#288), and the Kansas Board of Nursing (#LT0140-0927).

PHARMACISTS (6 CONTACT HOURS): INR is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. The New Jersey, New York, Pennsylvania, and Delaware Boards of Pharmacy and the boards of pharmacy of all 50 states will accept, for credit toward license renewal, courses presented by an ACPE-accredited organization. The ACPE universal program number (UPN) for this course is 751-000-11-008-L01-P. This is a knowledge-based CPE activity.

DIETITIANS (6 CONTACT HOURS): INR, under Provider Number IN001, is a Continuing Professional Education (CPE) Accredited Provider with the Commission on Dietetic Registration (CDR). Registered dietitians (RDs) and dietetic technicians, registered (DTRs) will receive 6 hours worth of continuing professional education units (CPEUs) for completion of this program/materials. Continuing Professional Education Provider Accreditation does not constitute endorsement by CDR of a provider, program, or materials. CDR is the credentialing agency for the American Dietetic Association (ADA).

PSYCHOLOGISTS (6 CONTACT HOURS): INR is approved by the American Psychological Association to offer continuing education for psychologists. INR maintains responsibility for this program and its content.

SOCIAL WORKERS (6 CONTACT HOURS): This program is approved by the NASW (Provider #886502971-8402) for 6 clinical social work continuing education contact hours.

OCCUPATIONAL THERAPISTS (6 CONTACT HOURS: INR is an AOTA Approved Provider (#5347). The assignment of AOTA CEUs does not imply endorsement of specific course content, products, or clinical procedures by AOTA. This intermediate level course has been assigned 0.6 AOTA CEUs.

PHYSICAL THERAPISTS (6 CONTACT HOURS: This course has been approved by the New Jersey State Board of Physical Therapy Examiners (Approval# 1140-2010) for 6 hours of continuing education credit. This course, The Tranquil Brain: Mood Swings, Hormones & Stress and Course #11/4/2008 has been approved for 6 hours by the American Physical Therapy Association – New York Chapter, the Pennsylvania State Board of Physical Therapy, Approval #PTCE002232, and the Delaware Professional Regulation – Examining Board of Physical Therapists for 6 hours of continuing education credit.

CASE MANAGERS (6 CONTACT HOURS): The course title The Tranquil Brain was completed on December 15, 2011 and is approved for 6.0 CEUs. Approval number A426. To claim these CEUs, log into your CE Center account at www.ccmcertification.org.

NURSING HOME ADMINISTRATORS (6 CONTACT HOURS): This educational offering has been reviewed by the National Continuing Education Review Service (NCERS) of the National Association of Long Term Care Administrator Boards (NAB) and approved for 6.00 clock hours and 6.00 participant hours—Approval # 1532011-6.00-7119-in.

COUNSELORS (6 CONTACT HOURS): INR (Provider #5736) is recognized by the National Board for Certified Counselors to offer continuing education for National Certified Counselors. INR adheres to NBCC Continuing Education Guidelines.

MASSAGE THERAPISTS (6 CONTACT HOURS): Institute for Natural Resources is approved by the National Certification Board of Therapeutic Massage and Bodywork (NCBTMB) as a continuing education Approved Provider. INR has approval #299936-00.

OTHER HEALTH PROFESSIONALS (6 CONTACT HOURS): Participants successfully completing this course will receive course completion certificates. For rules governing continuing education credits, participants should contact their respective regulatory boards.

Richard S. Colman

RICHARD S. COLMAN, Ph.D., Program Administrator, December 15, 2011

U3570

1838724

INSTITUTE FOR NATURAL RESOURCES (INR)

P.O. Box 5757 ♦ Concord, CA USA 94524-0757 ♦ TEL (925) 609-2820 ♦ FAX (925) 687-0860

STATEMENT OF CREDIT

42747

BECKER, RICHARD
PROF.: RPH
CLASS CODE: U20130620WE

PROGRAM TITLE: UNDERSTANDING DEMENTIA

June 20, 2013
Date

6

West Palm Beach, FL
Location

Continuing credit information is listed below. This course is presented in a live interactive format.

REGISTERED NURSES (RN's) & LICENSED PRATICAL NURSES (LPN's) (6 CONTACT HOURS).

Institute for Natural Resources (INR) is an approved provider of continuing nursing education by the Virginia Nurses Association, an accredited approver by the American Nurses' Credentialing Center's Commission on Accreditation. The code for this session of this course on the date is 1/20130620WE.

Nurses licensed by the State of Florida can obtain six (6) contact hours by successfully completing this course. Under CE Broker #50-3026-1, INR is an approved provider by the Florida Board of Nursing to provide continuing nursing education courses. INR has been accredited as a continuing education provider by the California Board of Registered Nursing (CEP #06136), the Iowa Board of Nursing (#285), and the Kansas Board of Nursing (#LT0148-0927).

PHARMACISTS (6 CONTACT HOURS): INR is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. The Florida Board of Pharmacy and the boards of pharmacy of all 50 states will accept, for credit toward license renewal, courses presented by an ACPE-accredited organization. The ACPE universal activity number (UAN) for this course is 0751-0000-13-025-L01-P. This is a knowledge-based CPE activity.

REGISTERED DIETITIANS & DTR's (6 CONTACT HOURS): INR, under Provider Number IN001, is a Continuing Professional Education (CPE) Accredited Provider with the Commission on Dietetic Registration (CDR). Registered dietitians (RDs) and dietetic technicians, registered (DTRs) will receive 6 hours worth of continuing professional education units (CPEUs) for completion of this program/materials. Continuing Professional Education Provider Accreditation does not constitute endorsement by CDR of a provider, programs, or materials. CDR is the credentialing agency for the Academy of Nutrition and Dietetics (AND).

PSYCHOLOGISTS (6 CONTACT HOURS): INR is approved by the American Psychological Association to sponsor continuing education for psychologists. INR maintains responsibility for this program and its content. Under CE Broker #50-3026-4, INR is an approved provider by the Department of Health, Medical Therapies/Psychology to provide continuing education courses for Florida-licensed psychologists.

SOCIAL WORKERS, MARRIAGE & FAMILY THERAPISTS, & MENTAL HEALTH COUNSELORS (6 CONTACT HOURS): Under CE Broker #50-3026-3, INR is an approved provider by the Florida Board of Clinical Social Work, Marriage and Family Therapy and Mental Health Counseling to provide continuing education courses for Florida-licensed social workers, marriage and family therapists, and mental health counselors. This program is approved by the National Association of Social Workers (Provider #886502971-6/1955 for 6 social work continuing education contact hours.

OCCUPATIONAL THERAPISTS (6 CONTACT HOURS): Under CE Broker #50-3026-5, INR is an approved provider by the Florida Board of Occupational Therapy Practice to provide continuing education courses for licensed occupational therapists.

PHYSICAL THERAPISTS (6 CONTACT HOURS): The Florida Physical Therapy Association has approved this course for 6 contact hours (Approval #CP130620311). Accreditation of this course does not necessarily imply the FPTA supports the views of the presenter or the sponsors.

CASE MANAGERS (6 CONTACT HOURS): This program has been pre-approved by The Commission for Case Manager Certification to provide continuing education credit to CCM board certified case managers. The course is approved for 6 CE contact hours. Activity code: 50003287 Approval number: # 20135200. To claim these CEs, log into your CE Center account at www.cemcertification.org.

NURSING HOME ADMINISTRATORS (6 CONTACT HOURS): This educational offering has been reviewed by the National Continuing Education Review Service (NCERS) of the National Association of Long Term Care Administrator Boards (NAB) and approved for 6.00 clock hours and 6.00 participant hours – Approval #1363013-6.00-13091-in

COUNSELORS (6 CONTACT HOURS): INR is an NBCC-Approved Continuing Education Provider (ACEP) and may offer NBCC-approved clock hours for events that meet NBCC requirements. The ACEP solely is responsible for all aspects of the program.

MASSAGE THERAPISTS (6 CONTACT HOURS): Institute for Natural Resources is approved by the National Certification Board of Therapeutic Massage and Bodywork (NCBTMB) as a continuing education Approved Provider. INR has approval #290046-00. Under CE Broker #50-3026, INR is an approved provider by the Florida Board of Massage Therapy to provide continuing education courses.

OTHER HEALTH PROFESSIONALS (6 CONTACT HOURS): Participants successfully completing this course will receive course completion certificates. For rules governing continuing education credits, participants should contact their respective regulatory boards.

Richard S. Colman

RICHARD S. COLMAN, Ph.D., Program Administrator. June 20, 2013

W2140

September 18, 2013

Janet Dwigans
6974 W CO Road 255
Greencastle, IN 46135

RE: Application for Licensure by Endorsement

Dear Ms. Dwigans:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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06/12/2013 295.00
ID: 43834 Type: F
BT: 3022956
VL: 912066980

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.doh.state.fl.us/mqa/pharmacy

ITEM #2 – PHARMACIST ENDORSEMENT APPLICATION
FEE: $295.00

Please print or type legibly. 2201-43834

1. Biographical Data			
Last Name	**First Name**	**Middle Name**	
Dwigans	Janet	Marie	
Street Address (ML – Mailing Address)	**City**	**State**	**Zip**
6974 W Co Rd 25S	Greencastle	IN	46135
Work Address (PL – Practice Location)	**City**	**State**	**Zip**
905 E. Washington St.	Greencastle	IN	46135
Home Phone Number	**Business Phone Number**	**E-Mail Address**	
765-653-8933	804-353-2972	jdwigans@wildblue.net	
Date of Birth	**Place of Birth**		
12/30/62	Greencastle, IN		

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 X No ____

NAME	DATE
Sutherlin (Maiden Name)	12/30/62
Small (1st Marriage)	8/1/87 - 6/1/92

4. Name of university, college or school of pharmacy attended:

Purdue University

5. Date Of Graduation	6. Type Of Degree Earned	7. Have you ever been licensed as an intern in Florida?
5/17/87	B.S. Pharmacy	Yes ____ No X Intern License Number: ____

8. Please indicate the date you successfully completed the NAPLEX examination.

Date 7/27/87

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 _____ No X

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
4/11-Present	Parallon Supply Chain Solutions	Richmond, VA CI work from home	Licensed Pharmacist	~4,000

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
Indiana	20016126A	7/27/87
Kentucky	016332	1/8/13

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 _____ N/A
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 _____ N/A
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 _____ N/A
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 _____ N/A
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 _____ N/A

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 _____ N/A
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 _____ N/A
26b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
27. 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
28. 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 _____ N/A

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.

Janet M. Dwyer _____ 5/29/13 _____

Applicant Signature Date

NOTE: Please check to be sure that you have answered all of the questions above.

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
Diwigans	Janet	Marie

Maiden Name/Surname	Date of Graduation
Sutherlin	5/17/87

Mailing Address	City	State	Zip
6974 W Co Rd 25 S	Greencastle	IN	46135

Part II. – To be completed by an official of the university

Name of School/College of Pharmacy

Mailing Address	City	State	Zip

Type of Degree Awarded	Date Degree Awarded	Dates of Attendance
		From: __/__/__ To: __/__/__

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.

Robert A. Kubat
Print Name

Robert A. Kubat
Signature

(SCHOOL SEAL)

University Registrar
Title

June 3, 2013
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

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Florida 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
Janet Dwigans	IN – 26016126	765-653-8933
Street Address	**City**	**State** / **Zip**
6974 W Co Rd 25 S	Greencastle	IN / 46135

2. Have you submitted an application for the Florida Pharmacist Examination? If yes, please indicate date.

Yes X No _____ Date 6/2/2013

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
GARY WAYNE BRADLEY		VIRGINIA 0202-011713
Pharmacy Name		**Permit Number**
PARAGON CENTRAL ORDER ENTRY PHARMACY		VIRGINIA 0201 004050
Street Address	**City**	**State** / **Zip**
7702 EAST PARHAM RD, SUITE 314	RICHMOND	VA / 23294
Phone Number	**4. Dates of Experience**	
804-545-4864	From: 4/14/11	To: 1/1/PRESENT

5. Average number of hours per week	6. Total hours of experience
70 HOURS/14 DAYS	> 3000 HOURS

(No more than 50 hours per week if you are a student and no more than 60 after graduation is allowed)

Janet M. Dwigans
Applicant's Signature

5/30/13
Date

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

6/10/13
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

RECEIVED
JUN 13 2013
Florida Board of Pharmacy

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18388331

STATE OF INDIANA

Michael R. Pence

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2980
Fax: (317) 233-4236

Official Proof of Licensure
Digitally Certified Record

Personal Information

Name:	Janet Marie Dwigans
Address:	6974 W Co Rd 25 S Greencastle, IN 46135
Date of Birth:	12/30/1962

License Information

Number Issued:	26016126A
License Type:	Pharmacist
Status:	Active
Issue date:	07/27/1987
Expiration Date:	06/30/2014
Obtained By:	Examination
Disciplinary Action:	None

This licensee has met ALL requirements for licensure in the State of Indiana - including successfully passing all required exams.

For additional information including questions regarding Disciplinary Action, contact the appropriate Board or Commission at www.in.gov/pla/boards.htm

Digitally Certified on: Mon Jul 08 02:29:15 PM EDT 2013

UNITED STATES POSTAL SERVICE
Electronic Postmark

STATE OF INDIANA

Michael R. Pence

Indiana Professional Licensing Agency
402 W. Washington St. Room W072
Indianapolis, IN 46204
Phone: (317) 232-2980
Fax: (317) 233-4236

Digitally Certified Proof of Licensure

RE: Janet Marie Dwigans

I, Nicholas W. Rhoad, Executive Director of the Indiana Professional Licensing Agency and custodian of the records therein, hereby certify that the attached is the digitally certified proof of licensure, as requested, and as it appears in the files of the Indiana Professional Licensing Agency on the date/time certified.

This digital certification follows the requirements of Indiana's Electronic Digital Signature Act (Indiana Code 5-24-1-1 et seq.) and rules developed by the Indiana State Board of Accounts, 20 IAC 3-1 et seq. to establish a valid digital electronic signature

If you have the need to verify the authenticity of the digital certification as of the date and time stamp below, go to https://secure.in.gov/apps/pla/verify.htm and use our free web service to "Verify an Electronic Certified Record". Simply browse to the location you saved the secure pdf document sent to you and upload to validate.

Nicholas W. Rhoad

Nicholas W. Rhoad, Executive Director
Mon Jul 08 02:29:15 PM EDT 2013

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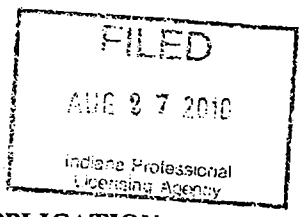
BEFORE THE INDIANA BOARD OF PHARMACY CAUSE NUMBER: 2010 IBP 0038

IN THE MATTER OF THE INDIANA PHARMACIST LICENSE RENEWAL APPLICATION OF:

JANET DWIGANS, R.PH., LICENSE NUMBER: 26016126A.



DECISION ON RENEWAL APPLICATION

Janet Dwigans ("Applicant") made a personal appearance before the Indiana Board of Pharmacy ("Board") on June 14, 2010, in Room B of the Conference Center of the Indiana Government Center South, 402 West Washington Street, Indianapolis, Indiana, concerning her application to renew her license as a pharmacist.

The Board, after considering the file and statements of the Applicant, votes 4 to 0 to renew her pharmacist license on probation.

BACKGROUND

1. The Applicant, whose mailing address is 6974 West County Line Road 25 South, Greencastle, Indiana 46135, applied to renew her pharmacist license in 2010.

2. The Applicant revealed that in 2009 she started abusing her husband's prescription medications and ultimately overdosed on a combination of them in December of that year.

3. She signed a five year recovery agreement with the Pharmacists Recovery Network (PRN) on January 12, 2010.

4. Applicant has demonstrated to the Board that she is able to practice with reasonable skill and safety to the public provided she complies with the probationary terms set out below. She agrees to those terms.

TERMS AND CONDITIONS

Based upon the foregoing Information, the Board imposes the following Terms and Conditions on the Applicant's license:

1. The Applicant's license as a pharmacist will be renewed on **INDEFINITE PROBATION**. She may apply to have the probation withdrawn from her license after the successful completion of her recovery agreement with the PRN.

2. The Applicant's practice as a pharmacist shall be governed by the following **TERMS AND CONDITIONS**:

a) CONTACT INFORMATION: Applicant must keep the Board apprised of the following information in writing and update it as necessary:

1. Current home address, mailing address, e-mail address, and residential telephone number.
2. Current place of employment, employment telephone number, employment e-mail address, and name of supervisor.
3. Occupation and work schedule, including number of hours worked per week.

b) Applicant shall cause her pharmacy employer to submit reports to the Board indicating the Applicant's professional competence, sense of responsibility, work habits, mental attitude and ability to work with others. The reports shall be submitted monthly for the first year she is on probation and quarterly thereafter.

c) Applicant shall provide a copy of all Board orders imposing discipline or limiting practice to any pharmacy employer who shall sign and return a copy of such orders to the Board within ten (10) days of employment or receipt of this order.

d) Applicant shall submit self reflection reports detailing her current status, her progress in recovery, issues or problems she is experiencing, and the value she has gained by attending counseling or group recovery sessions. The reports shall be submitted monthly for the first year she is on probation and quarterly thereafter.

e) Applicant shall immediately notify the Board of any relapse.

f) Applicant shall immediately notify the Board in writing of any discipline incurred in other states during the duration of the probation; including criminal or licensing charges pending.

g) Applicant shall submit a copy of any prescriptions she receives for personal consumption to the Board.

h) Applicant may not be a qualifying pharmacist while she is on probation.

i) Applicant will make probationary appearances monthly for the first year she is on probation and quarterly thereafter. **Applicant's first probationary appearance will be at the October, 2010 meeting of the Board (please note that the October meeting is the first Monday of October and NOT the second Monday as it is with every other month).**

j) Applicant shall maintain her recovery agreement with the PRN and comply with its terms.

k) Applicant may work two 12 hour shifts in one week, otherwise, she shall not work more than 10 hours in a single day, or 74 hours in two weeks.

l) Applicant shall perform 12 hours of community service a quarter and submit documentation of the completion of the community service when she makes her personal appearances.

m) Applicant shall not violate any laws regulating the practice pharmacy.

3. The failure of Applicant to comply with the terms of this decision may subject her to a show cause hearing and the imposition of further sanctions.

ORDERED, this 27 day of August, 2010.

INDIANA BOARD OF PHARMACY

By: _____

Frances L. Kelly
Executive Director
Indiana Professional Licensing Agency

NOTICE OF RIGHT TO PETITION FOR REVIEW OF THIS DECISION

You may petition for review of this decision under Ind. Code § 4-21.5-3-7. The petition must be filed with the Indiana Board of Pharmacy in writing, identifying the reasons for review and demonstrating that you have been aggrieved or adversely affected by the Board's decision. The petition for review must be filed no later than eighteen days from the issuance of this decision unless such date is a Saturday, a Sunday, a legal holiday under state statute or a day the Indiana Professional Licensing Agency's offices are closed during regular business hours in which case the deadline would be the first day which is not a Saturday, a Sunday, a legal holiday under state statute or a day the Indiana Professional Licensing Agency's offices are closed during regular business hours.

If your petition for review is timely filed and review granted, you will receive notification of an administrative hearing. You or your representative must be present at that hearing. You have the right to be represented by an attorney at your own expense. A deputy attorney general may be present to represent the state of Indiana. As petitioner, you will have the burden of proving that the Board's decision is incorrect.

Copies To:

Janet Dwigans
6974 West County Line Road 25 South
Greencastle, Indiana 46135
SENT CERTIFIED MAIL NUMBER: 91 7190 0005 2720 0003 0020
RETURN RECEIPT REQUESTED.

BEFORE THE INDIANA
BOARD OF PHARMACY
CAUSE NUMBER: 2010 IBP 0038

IN THE MATTER OF THE INDIANA)
PHARMACIST LICENSE OF:)
)
JANET DWIGANS, R.PH.,)
LICENSE NUMBER: 26016126A.)

FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

The Indiana Board of Pharmacy ("Board") held an administrative hearing on February 14, 2011, in Room W064 of the Indiana Government Center South, 402 West Washington Street, Indianapolis, Indiana, concerning the request by Janet Dwigans, R.Ph. ("Respondent") to modify the terms of probation on her license.

The State of Indiana was represented by Deputy Attorney General, Darren Covington. Respondent appeared in person and waived her right to be represented by counsel.

The Board, after considering the evidence presented and taking official notice of its file in this matter, voted 6 to 0 to issue the following Findings of Fact, Conclusions of Law, and Order:

FINDINGS OF FACT

1. Respondent, whose mailing address is 6974 West County Line Road 25 South, Greencastle, Indiana 46135, is a duly licensed pharmacist in the State of Indiana holding license number 26016126A.

2. The Indiana Professional Licensing Agency sent, and Respondent received, timely and proper notice of the date, time, and location of this hearing pursuant to Ind. Code § 4-21.5-3-20.

3. The Board is empowered to hold this administrative hearing pursuant to the authority of Ind. Code § 25-1-9-9 and Ind. Code § 4-21.5-3.

4. The Board renewed Respondent's license on probation in June 2010 because she had abused her husband's prescription medications and eventually overdosed on those medications. She subsequently signed a recovery agreement with the Pharmacists Recovery Network ("PRN") in January 2010 and appeared to be in recovery.

5. In a request submitted in January 2011, Respondent asked that the probation on her license be modified. She wanted relief from the prohibition of not working more than 10 hours in a single day or more than 74 hours in a two week period.

6. Respondent requested that the conditions on her probation be modified because it would allow her more work flexibility. The medical director of PRN supports her request that she be allowed to work up to 45 hours a week and that she be allowed to work 12 hour shifts provided the 12 hour shifts are not consecutive.

7. Respondent has complied with all the Terms and Conditions of probation on her license and the Board concludes she can safely work if her probation is modified in a manner that reflects the recommendations of PRN

8. The deficiency that led to the discipline on Respondent's license involved abuse of medications. Respondent's compliance with her probation and commitment to recovery constitutes changed circumstances warranting a modification of the Terms and Conditions of probation on her license.

CONCLUSIONS OF LAW

1. "The board may withdraw or modify the probation ... if it finds, after a hearing, that the deficiency that required disciplinary action has been remedied, or that changed circumstances warrant a modification of the order." Ind. Code § 25-1-9-9(b).

2. Respondent's compliance with her probation and commitment to recovery constitute changed circumstances warranting a modification of the Terms and Conditions of probation on her license.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, the Board **MODIFIES** the probationary order on Respondent's license, which was issued on August 27, 2010, as follows:

1. Paragraph 2, k. of the Terms and Conditions on Respondent's license is modified to read as follows:

   k. ***Respondent may not work more than 45 hours a week. She may work 12 hour shifts during a week provided the 12 hour shifts are not consecutive.***

2. Paragraph 2, i. of the Terms and Conditions on Respondent's license is modified to provide that, starting this month, she must make an additional nine (9) personal appearances on a monthly basis.

3. All other terms and conditions on Respondents' license will remain in full force and effect.

ORDERED, this 08 of March, 2011.

INDIANA BOARD OF PHARMACY

By: _____
Frances L. Kelly
Executive Director
Indiana Professional Licensing Agency

Copies To:

Janet Dwigans, R.Ph.
6974 West County Line Road 25 South
Greencastle, Indiana 46135
SENT CERTIFIED MAIL NUMBER: 91 7190 0005 2720 0006 7033
RETURN RECEIPT REQUESTED.

Darren Covington
Deputy Attorney General
Office of the Indiana Attorney General
IGCS 5th Floor
302 W. Washington St.
Indianapolis, IN 46204

BEFORE THE INDIANA BOARD OF PHARMACY
CAUSE NUMBER: 2010 IBP 0038

IN THE MATTER OF THE INDIANA PHARMACIST LICENSE OF:

JANET DWIGANS, R.PH.
LICENSE NUMBER: 26016126A

FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER

Janet Dwigans appeared at a hearing before the Indiana Board of Pharmacy ("Board") on August 13, 2012, in Room W064 of the Indiana Government Center South, 402 West Washington Street, Indianapolis, Indiana concerning her request to have the probationary terms withdrawn from her license as a pharmacist.

The state of Indiana appeared by Joshua Timmons, Graduate Legal Intern and Darren Covington, Deputy Attorney General. Dwigans appeared in person and waived her right to be represented by counsel.

The Board, after considering the file and the testimony of Dwigans, by a vote of 7 to 0, issued the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

1. Janet Dwigans, whose mailing address is 6974 W County Road 25 S, Greencastle, Indiana 46135, is a duly licensed pharmacist in the State of Indiana holding license number 26016126A.

2. The Indiana Professional Licensing Agency sent, and Dwigans received, timely and proper notice of the date, time and location of this hearing pursuant to Ind. Code § 4-21.5-3-20.

3. The Board is empowered to hold this administrative hearing pursuant to the authority of Ind. Code § 25-1-9-9 and Ind. Code § 4-21.5-3.

4. This Board renewed Dwigans' license on probation in August 2010 because in 2009 she had started abusing her husband's prescription medications and ultimately overdosed on a combination of them in December of that year. She signed a three year recovery agreement with the Pharmacists Recovery Network (PRN) on January 12, 2010.

5. In July 2012, Dwigans asked that the probation on her license be withdrawn.

6. At the hearing on withdrawal of probation, Dwigans testified that she has complied fully with the terms of her probation, which included abiding by her recovery agreement with the PRN. Richard Hinchman, M.D., medical director of the PRN, recommends an early release from her agreement which is currently due to end in six months. Letter from Richard Hinchman, M.D. dated July 18, 2012.

7. Dwigans testified that she will continue going to 12 Step meetings in the future and PRN considers her to be a model of recovery.

8. The deficiencies that led to the probation of Dwigans' license involved substance abuse. Dwigans' compliance with her probation constitutes evidence that this problem has been remedied.

CONCLUSIONS OF LAW

1. "The board may withdraw or modify the probation ... if it finds, after a hearing, that the deficiency that required disciplinary action has been remedied, or that changed circumstances warrant a modification of the order." Ind. Code § 25-1-9-9(b).

2. Dwigans' compliance with her probation constitutes evidence that the deficiency that required disciplinary action has been remedied.

ORDER

Based upon the foregoing Findings of Fact and Conclusions of Law, the Board **WITHDRAWS** the probation on Dwigans' license.

ORDERED this 28 of August, 2012.

INDIANA BOARD OF PHARMACY

By: _____
Frances L. Kelly
Executive Director.
Indiana Professional Licensing Agency

CERTIFICATE OF SERVICE

I certify that a copy of the "Findings of Fact, Conclusions of Law and Order" has been duly served upon:

Janet Dwigans
6974 W County Road 25 S
Greencastle, IN 46135
Service by U.S. Mail

Darren Covington, Deputy Attorney General
Office of the Indiana Attorney General
Indiana Government Center South
302 West Washington Street, Fifth Floor
Indianapolis, IN 46204
Service by e-mail

8/28/18
Date

Greg Pachmayr

Indiana Board of Pharmacy
Indiana Government Center South
402 West Washington St., Room W072
Indianapolis, IN 46204
Phone: 317-234-2067
Fax: 317-233-4236
Email: pla4@pla.in.gov

Explanation of Service Methods
Personal Service: by delivering a true copy of the aforesaid document(s) personally.
Service by U.S. Mail: by serving a true copy of the aforesaid document(s) by First Class U.S. Mail, postage prepaid.
Service by Email: by sending a true copy of the aforesaid document(s) to the individual's electronic mail address.

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18383323

License Verification Details

Kentucky Board of Pharmacy
State Office Building Annex, Ste 300
125 Holmes Street
Frankfort, KY 40601

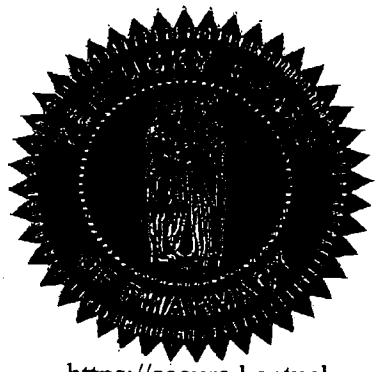
Detail for License Number 016332

JANET MARIE DWIGANS
GREENCASTLE, IN 46135-

License Information

Expiration Date: 2/28/2014
Effective Date: 1/8/2013
Status of License: Active
Preceptor:
Board Action: No
Case Number(s):

The Kentucky Board of Pharmacy website is considered primary source verification and is actually the preferred method of licensure verification. Both JCAHO and the Cabinet for Health and Family Services, Office of the Inspector General, consider verification through the website as evidence of licensure.



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1000006080

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PHARMACIST'S LETTER

Published by Therapeutic Research Center, Jeff M. Jellin, Pharm.D., Editor
3120 W. March Lane, Stockton, CA 95219
www.pharmacistsletter.com, Email: CE@PLetter.com
Ph (209) 472-2240, Fax (209) 472-2249

Statement of Credit

Pharmacist's Letter/Therapeutic Research Center confirms that

Janet Dwigans

on July 8, 2013 successfully completed the
Pharmacist's Letter knowledge-based Continuing Education Course
Volume 11, No. 314

***Medication Safety: Strategies for Preventing Medication Errors* on 7/8/2013.**
CE Broker #20-327873

ACPE Universal Program #0422-0000-11-314-H05-P and is awarded:
2.00 contact hours of credit or (0.2 CEU's).

CE Broker# 20-327873, FL Board approved on 10/11/2011

Tony R. Martin, Pharm.D., MBA July 14, 2013

This course is sponsored by
Pharmacist's Letter, Stockton CA 95219
TEL: 209/472-2240 FAX: 209/472-2249
CE Broker Provider # 50-2973

Statement of Credit for:
Janet Dwigans
Parallon Supply Chain Services

, VA

Statement of Credit

Print

Janet Dwigans

, VA

PHARMACIST'S LETTER

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With this Statement of Credit *Pharmacist's Letter* Therapeutic Research Center confirms that Janet Dwigans has successfully completed the courses below:

State: Indiana

Renewal Period: 1/1/2012 - 12/31/2013 1f485627-20d4-4e1c-87f4-6972520562c0

Course Title & CE Provider	Date Completed	Contact Hours	Requirements Met
Emerging Developments in Drug Therapy and Implementation into Patient Care December 2011 ACPE#: 0422-0000-11-012-H01-P Knowledge-based CE 486c26ec-b181-4e30-ba25-7d9430fdff50 (printed previously)	05/01/12	1.00	General CE
Emerging Developments in Drug Therapy and Implementation into Patient Care January 2012 ACPE#: 0422-0000-12-001-H01-P Knowledge-based CE 486c26ec-b181-4e30-ba25-7d9430fdff50 (printed previously)	05/01/12	1.00	General CE
Emerging Developments in Drug Therapy and Implementation into Patient Care February 2012 ACPE#: 0422-0000-12-002-H01-P Knowledge-based CE 486c26ec-b181-4e30-ba25-7d9430fdff50 (printed previously)	06/13/12	1.00	General CE
Emerging Developments in Drug Therapy and Implementation into Patient Care May 2012 ACPE#: 0422-0000-12-005-H01-P Knowledge-based CE 486c26ec-b181-4e30-ba25-7d9430fdff50 (printed previously)	09/02/12	1.00	General CE
Emerging Developments in Drug Therapy and Implementation into Patient Care June 2012 ACPE#: 0422-0000-12-006-H01-P Knowledge-based CE 486c26ec-b181-4e30-ba25-7d9430fdff50 (printed previously)	09/02/12	1.00	General CE
Emerging Developments in Drug Therapy and Implementation into Patient Care July 2012 ACPE#: 0422-0000-12-007-H01-P Knowledge-based CE 486c26ec-b181-4e30-ba25-7d9430fdff50 (printed previously)	09/02/12	1.00	General CE
Emerging Developments in Drug Therapy and Implementation into Patient Care August 2012 ACPE#: 0422-0000-12-008-H01-P Knowledge-based CE 486c26ec-b181-4e30-ba25-7d9430fdff50 (printed previously)	09/02/12	1.00	General CE
Emerging Developments in Drug Therapy and Implementation into Patient Care September 2012 ACPE#: 0422-0000-12-009-H01-P Knowledge-based CE 486c26ec-b181-4e30-ba25-7d9430fdff50 (printed previously)	09/02/12	1.00	General CE
Medication Errors in Specific Situations and Populations ACPE#: 0422-0000-11-313-H05-P Knowledge-based CE cdd7c0bc-670a-4e1d-86f6-abaef7cdbb50 (printed previously)	01/22/13	1.00	General CE

Dosing Considerations for Adult Patients Part 1: Patient Specific Factors ACPE#: 0422-0000-10-209-H01-P Knowledge-based CE 486c26ec-b181-4e30-ba25-7d9430fdff50 (printed previously)	02/03/13	1.00	General CE
Pediatric Pharmacy Practice: An Introduction for Pharmacists ACPE#: 0422-0000-11-205-H04-P Knowledge-based CE 486c26ec-b181-4e30-ba25-7d9430fdff50 (printed previously)	02/15/13	1.00	General CE
Medication Safety: Strategies for Preventing Medication Errors ACPE#: 0422-0000-11-314-H05-P Knowledge-based CE 20cb38d8-4fa5-4614-981b-21caa3cf4082 (printed previously)	07/08/13	2.00	General CE
End of Life Care and Pain Management ACPE#: 0422-0000-12-214-H01-P Knowledge-based CE 1f485627-20d4-4e1c-87f4-6972520562c0	07/14/13	2.00	General CE

and is awarded 15.00 total Contact Hours

Tony R. Martin, Pharm.D., MBA July 14, 2013

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TEL: (209) 472-2240 FAX: (209) 472-2249

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15 + 16 = 31 from 5/2011 - 7/2013

Janet Dwigans

, VA

PHARMACIST'S LETTER

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Indiana

Renewal Period: **1/1/2010 - 12/31/2011**

Course Title & CE Provider	Date Completed	Hours	Requirements Met
CE-in-the-Letter Feb 2009 Pharmacist's Letter ACPE#: 0422-0000-09-002-H01-P	01/20/10	1.00	General CE
CE-in-the-Letter Mar 2009 Pharmacist's Letter ACPE#: 0422-0000-09-003-H01-P	01/20/10	1.00	General CE
CE-in-the-Letter Apr 2009 Pharmacist's Letter ACPE#: 0422-0000-09-004-H01-P	01/20/10	1.00	General CE
CE-in-the-Letter Jun 2009 Pharmacist's Letter ACPE#: 0422-0000-09-006-H01-P	01/20/10	1.00	General CE
CE-in-the-Letter Jul 2009 Pharmacist's Letter ACPE#: 0422-0000-09-007-H01-P	01/20/10	1.00	General CE
CE-in-the-Letter May 2009 Pharmacist's Letter ACPE#: 0422-0000-09-005-H01-P	01/20/10	1.00	General CE
CE-in-the-Letter Aug 2009 Pharmacist's Letter ACPE#: 0422-0000-09-008-H01-P	02/04/10	1.00	General CE
CE-in-the-Letter Sep 2009 Pharmacist's Letter ACPE#: 0422-0000-09-009-H01-P	02/04/10	1.00	General CE
CE-in-the-Letter Oct 2009 Pharmacist's Letter ACPE#: 0422-0000-09-010-H01-P	02/04/10	1.00	General CE
CE-in-the-Letter Nov 2009 Pharmacist's Letter ACPE#: 0422-0000-09-011-H01-P	02/04/10	1.00	General CE
Safe Use of Opiates - Pharmacists HCA Inc. ACPE#: ACPE UPN: 0456-0000-10-001-H05-P Edit / Delete	04/01/10	1.00	General CE
CE-in-the-Letter Dec 2009 Pharmacist's Letter ACPE#: 0422-0000-09-012-H01-P	08/29/10	1.00	General CE
CE-in-the-Letter Jan 2010 Pharmacist's Letter ACPE#: 0422-0000-10-001-H01-P	08/29/10	1.00	General CE
CE-in-the-Letter Feb 2010 Pharmacist's Letter ACPE#: 0422-0000-10-002-H01-P	08/29/10	1.00	General CE
CE-in-the-Letter Mar 2010 Pharmacist's Letter	08/29/10	1.00	General CE

ACPE#: 0422-0000-10-003-H01-P			
CE-in-the-Letter May 2010 Pharmacist's Letter ACPE#: 0422-0000-10-005-H01-P	08/29/10	1.00	General CE
CE-in-the-Letter Apr 2010 Pharmacist's Letter ACPE#: 0422-0000-10-004-H01-P	08/29/10	1.00	General CE
CE-in-the-Letter Jun 2010 Pharmacist's Letter ACPE#: 0422-0000-10-006-H01-P	08/29/10	1.00	General CE
CE-in-the-Letter Jul 2010 Pharmacist's Letter ACPE#: 0422-0000-10-007-H01-P	08/29/10	1.00	General CE
Medication Management Standards for the Frontline Pharmacist HCA Inc. ACPE#: ACPE UPN: 0456-000-11-006-H04-P Edit / Delete	05/13/11	1.00	General CE
Pharmacy & Core Measures: Core Measure 3.3 Specefication Up HCA inc. ACPE#: ACPE UPN: 0456-0000-11-005-h04-P Edit / Delete	06/15/11	1.00	General CE
CE-in-the-Letter Aug 2010 Pharmacist's Letter ACPE#: 0422-0000-10-008-H01-P	06/16/11	1.00	General CE
CE-in-the-Letter Sep 2010 Pharmacist's Letter ACPE#: 0422-0000-10-009-H01-P	06/16/11	1.00	General CE
CE-in-the-Letter Oct 2010 Pharmacist's Letter ACPE#: 0422-0000-10-010-H01-P	06/16/11	1.00	General CE
2011 Pharmacist Competency Microbiology Testing & Antibiogra HCA Inc. ACPE#: ACPE UPN: 0456-0000-10-H01-P Edit / Delete	08/12/11	1.00	General CE
CE-in-the-Letter Jul 2011 Pharmacist's Letter ACPE#: 0422-0000-11-007-H01-P	12/23/11	1.00	General CE
CE-in-the-Letter Aug 2011 Pharmacist's Letter ACPE#: 0422-0000-11-008-H01-P	12/23/11	1.00	General CE
CE-in-the-Letter Oct 2011 Pharmacist's Letter ACPE#: 0422-0000-11-010-H01-P	12/23/11	1.00	General CE
CE-in-the-Letter Sep 2011 Pharmacist's Letter ACPE#: 0422-0000-11-009-H01-P	12/23/11	1.00	General CE
CE-in-the-Letter Nov 2011 Pharmacist's Letter ACPE#: 0422-0000-11-011-H01-P	12/23/11	1.00	General CE
CE-in-the-Letter Nov 2010 Pharmacist's Letter ACPE#: 0422-0000-10-011-H01-P	12/23/11	1.00	General CE
CE-in-the-Letter Dec 2010 Pharmacist's Letter	12/23/11	1.00	General CE

ACPE#: 0422-0000-10-012-H01-P			
CE-in-the-Letter Jan 2011 Pharmacist's Letter ACPE#: 0422-0000-11-001-H01-P	12/23/11	1.00	General CE
CE-in-the-Letter Feb 2011 Pharmacist's Letter ACPE#: 0422-0000-11-002-H01-P	12/23/11	1.00	General CE
CE-in-the-Letter Mar 2011 Pharmacist's Letter ACPE#: 0422-0000-11-003-H01-P	12/23/11	1.00	General CE

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September 19, 2013

Rosemary Tecza
151 Koontz Road
Wadsworth, OH 44281

RE: Pharmacy Endorsement Application

Dear Ms. Tecza:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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08/14/2013 295.00
Type: F

Florida HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.doh.state.fl.us/mqa/pharmacy

ITEM #2 – PHARMACIST ENDORSEMENT APPLICATION
FEE: $295.00

Please print or type legibly.

1. Biographical Data

Last Name	First Name	Middle Name
Tecza	Rosemary	Margaret

Street Address (ML – Mailing Address)	City	State	Zip
151 Koontz Road	Wadsworth	OH	44281

Work Address (PL – Practice Location)	City	State	Zip
8614 Hartman Road	Wadsworth	OH	44281

Home Phone Number	Business Phone Number	E-Mail Address
330-419-9788		rosetecza@yahoo.com

Date of Birth	Place of Birth
01/09/1988	Akron, OH

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 _____

NAME	DATE
Rosemary Margaret Ozbolt	10/7/2010

4. Name of university, college or school of pharmacy attended:
University of Toledo, College of Pharmacy

5. Date Of Graduation	6. Type Of Degree Earned	7. Have you ever been licensed as an intern in Florida?
05/06/2012	Pharm D.	Yes _____ No ✓ Intern License Number: _____

RECEIVED
AUG 15 2013
Florida Board of Pharmacy

8. Please indicate the date you successfully completed the NAPLEX examination.

Date 09/14/2012

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 ✓ 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.

_____ 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

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
Ohio	OH-0313213 2	09/14/2012

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 ✓

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 ✓

(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 _____ No ✓
20. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No ✓
21. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No ✓
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 ✓
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 ✓ N/A
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 ✓ N/A
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 ✓ N/A
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 ✓ N/A
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 ✓
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 ✓ N/A

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 ✓

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 ✓ N/A

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 ✓

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 _____ N/A

26b. Did the termination occur at least 20 years prior to the date of this application?

Yes _____ No ✓ N/A

27. 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 ✓

28. 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 _____ N/A

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 6/30/13

NOTE: Please check to be sure that you have answered all of the questions above.

F 44281

1862720

Florida 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
Tecza	Rosemary	Margaret

Maiden Name/Surname	Date of Graduation
Ozbolt	05/06/2012

Mailing Address	City	State	Zip
151 Koontz Road	Wadsworth	OH	44281

Part II. – To be completed by an official of the university

Name of School/College of Pharmacy

University of Toledo College of Pharmacy and Pharmaceutical Sciences

Mailing Address	City	State	Zip
3000 Arlington Ave.	Toledo	OH	43614

Type of Degree Awarded	Date Degree Awarded	Dates of Attendance
Doctor of Pharmacy	5-4-12	From: 8/21/06 To: 5/3/13

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.

Christine N. Hinko, PhD
Print Name

Christine N. Hinko
Signature

(SCHOOL SEAL)

Executive Associate Dean
Dean for Student Affairs
Title

8-8-13
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

RECEIVED
AUG 19 2013
Florida Board of Pharmacy

DH-MQA 100, 02/09
Rule 64B16-26.205, F.A.C.

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OHIO License CENTER

Name and Address	
Name	ROSEMARY MARGARET TECZA RPH
Public Address	OH

License and Registration Information

License	First Issue Date	Current Issue Date	Expiration Date	Status
INT.06007895-GRAD	09/18/2008	09/16/2011	09/15/2012	INACTIVE
License Type: Intern - Graduate - Renewable Once **How issued:**				
RPH.03132132-1	09/14/2012	09/16/2013	09/15/2014	ACTIVE IN RENEWAL - PAID
License Type: Pharmacist **How issued:** E - Examination				

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 8/30/2013.

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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PHARMACIST'S LETTER
Published by Therapeutic Research Center, Jeff M. Jellin, Pharm.D., Editor
3120 W. March Lane, Stockton, CA 95219
www.pharmacistsletter.com, Email: CE@PLetter.com
Ph (209) 472-2240, Fax (209) 472-2249

Statement of Credit

Pharmacist's Letter/Therapeutic Research Center confirms that

Rosemary Tecza

on March 30, 2013 successfully completed the
Pharmacist's Letter knowledge-based Continuing Education Course
Volume 11, No. 314

***Medication Safety: Strategies for Preventing Medication Errors* on 3/30/2013.**
CE Broker #20-327873

ACPE Universal Program #0422-0000-11-314-H05-P and is awarded:
2.00 contact hours of credit or (0.2 CEU's).

CE Broker# 20-327873, FL Board approved on 10/11/2011

Tony R. Martin, Pharm.D., MBA July 28, 2013

This course is sponsored by
Pharmacist's Letter, Stockton CA 95219
TEL: 209/472-2240 FAX: 209/472-2249
CE Broker Provider # 50-2973

Statement of Credit for:
Rosemary Tecza
8614 Hartman Road
Wadsworth, OH 44281

September 18, 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, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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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.

Victor Drew
(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)

(SCHOOL SEAL)

Christine N. Hinko, PhD
(PRINT NAME OF DEAN)

Christine N. Hinko
(SIGNATURE OF DEAN)

7-22-13
(DATE)

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OHIO License CENTER

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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September 18, 2013

Joshua Klasinski
4475 Streamside Court
Sarasota, FL 34233

RE: Registered Pharmacy Technician Application

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, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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FLORIDA DEPARTMENT OF HEALTH

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

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

6-13-13
Date

DH-MQA PH1183, 09/09
Rule 64B16-26.350, F.A.C.

Certificate of Completion

Florida Pharmacy Association

PassAssured

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 A. Jackson
FPhA Signature — May 25, 2013 Date Completed

PassAssured, LLC
1504 West Park Avenue
Orange, TX 77630

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.

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

STATE OF FLORIDA
BOARD OF MEDICINE

DEPARTMENT OF HEALTH,

Petitioner,

vs.

DOH CASE NO.: 2012-04092
LICENSE NO.: PA9105912

JOSHUA KLASINSKI, P.A.,

Respondent.
_____/

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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 040584
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 December, 2012.

JOHN H. ARMSTRONG, MD,
State Surgeon General and Secretary of Health
Florida Department of Health

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE OCT 04 2012

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

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.

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September 18, 2013

Whitney Elizabeth Mack
12301 Kernan Forest Blvd., #1105
Jacksonville, FL 32225

RE: Registered Pharmacy Technician Application

Dear Ms. Mack:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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03/04/2013 105.00
ID: 49600 Type: F
BT: 3015510
VL: 912046769

FLORIDA DEPARTMENT OF HEALTH

FLORIDA BOAR
P.O. Box 6320 •
Phone: (850) 48
http://www.doh.s

ITEM #2 - Pharmacy Technician Registration Application

FEE: $105.00

Please print or type legibly 2208-49600

1. Biographical data			
Last name	**First name**	**Middle name**	
Mack	Whitney	Elizabeth	
Street address (ML – Mailing Location)	**City**	**State**	**Zip**
12301 Kernan Forest Blvd. #1105	Jacksonville	FL	32225
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**
670 Marsh Landing Pkwy	Jacksonville Beach	FL	32250
Home phone number	**Business phone number**	**Date of birth**	
(904) 600-6781	(904) 273-7606	6/30/93	
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?**		
laugh-livelove@hotmail.com	Yes _____ No X		

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	N/A	Date	N/A

4. Have you completed a board approved training course according to Rule 64B16-26.351 (3), FA.C.?	
Yes X 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 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.)**	
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 X	
7. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?	
Yes _____ No X	
8. Are you presently under investigation 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 _____ N/A
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 _____ N/A
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 _____ N/A
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_____ N/A
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 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_____ N/A
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 _____ N/A
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 X No _____
16b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____ N/A
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 X
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 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 5-16b, 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.

Whitney Mack
Applicant Signature

1/1/13
Date

DH-MQA PH1183, 09/09
Rule 64B16-26.350, F.A.C.

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PUBLIX

PHARMACY

Feeling well. Living better.

presents

Certificate of Completion

to

Whitney Mack

for satisfactory completion of the

Publix Pharmacy Technician Basics

Date completed : 10/03/2012

Fred Ottolino

Fred Ottolino, VP of Pharmacy Operations

RTTP15

September 18, 2013

Wiley Chemists Pharmacy, Inc.
DBA Wiley Chemists Pharmacy, Inc.
Attn: Bruce Bowman
1676 Hospital Drive
Santa Fe, NM 87505

RE: Non-Resident Pharmacy Application

Dear Mr. Bowman:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000. The meeting begins 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. 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.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

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

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

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FLORIDA DEPARTMENT OF HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.doh.state.fl.us/mqa/pharmacy

04/05/2013 255.00
ID: 19943 Type: F
BT: 3018000
VL: 912053358

NON-RESIDENT PHARMACY REGISTRATION

Application Type – Please choose one of the following:

✓ New Establishment ($255.00 Fee) – Non Resident Reg.
___ 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: _____ 2205-19943

List Federal Employer Identification Number: 451 483 615.

1. Corporate Name	Telephone Number
Wiley Chemists Pharmacy Inc.	505-983-7169
2. Doing Business As (d/b/a)	**E-Mail Address**
Wiley Chemists Pharmacy Inc.	Wileychemist@gmail.com.

3. Mailing Address
1676 Hospital Drive

City	State	Zip
Santa Fe	New Mexico	87505

4. Physical Address
1676 Hospital Drive

City	State	Zip
Santa Fe	NM	87505

5. List Prescription Department Manager (PDM)

Name	License No.	Start Date	Signature
Bruce Bowman	RP 0000 4140	☐	☐

6. Contact Person	Telephone Number
Elva Gurule or Bruce Bowman	505-983-7169
7. DEA Registration Number	**8. Do you have 24 hour access to patient records?**
☐ FW 2673778	___ 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	
McKesson	415-983-8300	505036	
Street Address	**City**	**State**	**Zip**
One Post Street	San Francisco	CA	94104

10. Operating Hours	10a. Provide the Toll-Free Telephone number available six days a week for 40 hours below:
9-6 M-F	(888) 945-3988.

Prescription Department Hours
Monday-Friday: Open 9 Close: 6
Saturday: Open: N/A Close: N/A
Sunday: Open: N/A Close: N/A

WC

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
☐ Teresa Susan Wiley-owner	11-1-52	1676 Hospital Dr. Santa Fe NM 87505	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 contendre 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? N/A.

Yes _____ No ~~✓~~ DUR SJ

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 X

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 X (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 X 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 X No _____

State	Permit Type	Permit Number
California	non-Resident	NRP - 1238

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

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 OWNER DATE 3/28/13
Owner/Officer

State of New Mexico)
County of Santa Fe) ss.
The foregoing instrument was acknowledged before me this 28th day of March 2013
by David Wright
My Commission Expires: 2/1/2014
_____
Notary Public

OFFICIAL SEAL
David Wright
NOTARY PUBLIC - STATE OF NEW MEXICO
My Commission Expires 2/1/2014

New Mexico

NEW MEXICO BOARD OF PHARMACY
5200 OAKLAND N.E., SUITE A
ALBUQUERQUE, NM 87113
(505) 222-9830 (800) 565-9102
Fax (505) 222-9845
www.state.nm.us/pharmacy

PHARMACY
PRELIMINARY INSPECTION

NEW/CHANGE OF OWNERSHIP ___ **REMODEL** ___ **RELOCATION**

AME: Wiley Chemists, Inc.
DDRESS: 1676 Hospital Drive
TY: Santa Fe. ZIP: 87506
ELEPHONE: 1-800-929-9463
AX: DATE: 6/1/2011
MAIL: help@wileychemists.com.

HARMACY DIMENSIONS: Adequate - Approved w/ Application
USABLE FLOOR SPACE (sq. ft.):
OUNTER DIMENSIONS: Adequate - Approved w/ Application.
COUNTER SPACE (sq. ft.):

NTERNET ACCESS: ✓ YES; ___ NO.

URRENT NM PHARMACY LAWS / REGULATIONS: ___ CD-ROM; ___ BOOK; ✓ INTERNET

URRENT REFERENCE: w/ computer. ___ CD-ROM; ___ BOOK; ✓ INTERNET

EFRIGERATOR: on order. THERMOMETER: discussed
ATER: yes. ✓ HOT; ✓ COLD
ECESSARY EQUIPMENT:
DEQUATE SECURITY/LOCKS TO RESTRICTED AREA: yes. alarm. deadbolts.

OLICY MANUAL:
STORING AND SAFEKEEPING OF DRUGS:
RECORD KEEPING SYSTEM FOR DRUGS :
___ PURCHASE
___ SALE
___ POSSESSION
___ RETURN
___ PATIENT PROFILE
} Approved w/ Application
ERROR PREVENTION PROCEDURES:
ADVERSE DRUG EVENT REPORTING:

OMMENTS: No sterile compounding - Maybe in future.
OK for License.

NSPECTOR: Katie Klein

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New Mexico Regulation and Licensing Department
BOARDS AND COMMISSIONS DIVISION
Board of Pharmacy
5200 Oakland Avenue, NE • Suite A • Albuquerque, New Mexico 87113
(505) 222-9830 • Fax (505) 222-9845 • (800) 565-9102
http://www.rld.state.nm.us/boards/pharmacy.aspx

Certification of New Mexico Board of Pharmacy Retail Pharmacy license for the licensee listed below:

Name of Licensee (as it appears in our records): **Wiley Chemists, Inc.**

License Number: PH00003297

Current Status: Active

Original Date of Licensure: 06/06/2011

Expiration Date: 12/31/2014

If licensee has an * asterisk next to their name there are board actions against them please go to this link to view actions. http://www.rld.state.nm.us/boards/Pharmacy_Disciplinary_Actions.aspx

Signature:

Title: Licensing Assistant

Date: March 28, 2013

DEPARTMENT OF CONSUMER AFFAIRS
BOARD OF PHARMACY

BOARD OF PHARMACY

Licensee Name:	WILEY CHEMISTS INC
License Type:	NON RESIDENT PHARMACY
License Number:	1238
License Status:	CLEAR Definition
Expiration Date:	July 01, 2013
Issue Date:	July 10, 2012
Address:	1676 HOSPITAL DR
City:	SANTA FE
State:	NM
Zip:	87505
County:	OUT OF STATE
Actions:	No

Related Licenses/Registrations/Permits

No records returned

Public Disclosure

No information available from this agency

This information is updated Monday through Friday - Last updated: JAN-31-2013

Back

This State Controlled Substance Registration is issued pursuant to NMSA 30-31-12 & 13 and NMAC 16.19.20.8 & 9 for the following person/facility at the shown location and for the period show hereon.

License Number: **CS00216610**

Original Issue Date: **06/06/2011**
Expiration Date: **05/31/2013**

Schedule of Drugs: **2 2N 3 3N 4 5**

Wiley Chemists, Inc.

1676 Hospital Drive
Santa Fe, NM 87505

Richard Mazzoni, **CHAIRMAN**

NON-TRANSFERABLE

REMINDERS: (Please read important information)

* You need to keep the Board apprised of the current mailing address, by submitting a written or faxed request for a change of address. Please include facility name and license number.

* Please pay attention to the expiration date of your license. If you do not receive a renewal notice, at least four (4) weeks prior to 12/31/2014, contact the Board Office and request that a renewal form be mailed to you.

* You may also download a generic application on line through our website http://www.rld.state.nm.us/boards/ once there click on Individuals Boards and Commissions then click on Pharmacy then click on forms and applications.

* A change of name requires that you submit a written request along with a $10.00 fee, and copy of the legal document supporting the name change, also the request must specify if there was a change of ownership.

Wiley Chemists, Inc.

PH00003297 **Retail**

12/31/2014

Original Issue Date: 06/06/2011

License is hereby granted to operate a Pharmacy Retail in accordance with provisions under chapter 61-11-14, 26, 30 NMSA 1978 Comp., Laws of New Mexico at the address and for the period shown hereon.

License Number: **PH00003297**

Original Issue Date: **06/06/2011**
Expiration Date: **12/31/2014**

Wiley Chemists, Inc.

1676 Hospital Drive
Santa Fe, NM 87505

Richard Mazzoni, **CHAIRMAN**

NON-TRANSFERABLE

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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.

OFFICE OF THE
PUBLIC REGULATION COMMISSION

CERTIFICATE OF INCORPORATION

OF

WILEY CHEMISTS INC.

4424677

The Public Regulation Commission certifies that the Articles of Incorporation, duly signed and verified pursuant to the provisions of the
BUSINESS CORPORATION ACT
(53-11-1 to 53-18-12 NMSA 1978)
have been received by it & are found to conform to law.

Accordingly, by virtue of the authority vested in it by law, the Public Regulation Commission issues this Certificate of Incorporation & attaches hereto, a duplicate of the Articles of Incorporation.

Dated: MARCH 24, 2011

In testimony whereof, the Public Regulation Commission of the state of New Mexico has caused this certificate to be signed by its chairman and the seal of said Commission to be affixed in the City of Santa Fe.

Patrick H. Lyons
Chairman

Ornette Drake
Bureau Chief

SUBMIT ORIGINAL AND A COPY
TYPE OR PRINT LEGIBLY

Profit Corporation
ARTICLES OF INCORPORATION

The undersigned, acting as incorporator(s) to form a corporation under the New Mexico Business Corporation Act, adopt the following Articles of Incorporation:

ARTICLE ONE: The name of the corporation is: **Wiley Chemists Inc.**

ARTICLE TWO: The period of duration (if other than perpetual) is: _____

ARTICLE THREE: The purpose for which the corporation is organized is: **to engage in the business of Retail, Pharmacy**

ARTICLE FOUR: The aggregate number of shares which the corporation shall have authority to issue is: (*attach schedule if needed*) **100,000**

ARTICLE FIVE:
(1) The New Mexico street address of the corporation's initial registered office is:
4801 Lang Avenue, Suite 110, Albuquerque, NM 87109
(P.O. Box is not acceptable. Provide a description of the geographical location if a street address does not exist.)

(2) The name of the initial registered agent at the address of the initial registered office is:
United States Corporation Agents, Inc.

ARTICLE SIX: The names and addresses of the initial board of directors are: *(attach schedule if needed)*

NAME	ADDRESS
Teresa Sue Wiley	518 Old Santa Fe Trail, #597, Santa Fe, New Mexico 87505

ARTICLE SEVEN: The name and address of each incorporator is: *(attach schedule if needed)*

NAME	ADDRESS
LegalZoom.com, Inc.	101 N. Brand Blvd., 11th Floor, Glendale, CA 91203

Dated: 3/23/2011

LegalZoom.com, Inc., Incorporator

Eileen Gallo, Authorized Signatory

Signature of Incorporator(s)
(each person named in Article Seven must sign)

Form DPR
(revised 7/03)

STATEMENT OF ACCEPTANCE OF APPOINTMENT
BY DESIGNATED INITIAL REGISTERED AGENT

I, **Jacob Varghese**

hereby acknowledge that the undersigned individual or corporation accepts appointment

as Initial Registered Agent of **Wiley Chemists Inc.**,

the corporation which is named in the annexed Articles of Incorporation.

(Sign on this line if the registered agent named in the Articles of Incorporation is an individual. If this line is signed, the two lines below do not apply and must be left blank.)

CORPORATION ACTING AS A REGISTERED AGENT ONLY

(If the following lines are used, the signature line above does not apply and must be left blank)

United States Corporation Agents, Inc.

(If the registered agent named in the Articles of Incorporation is a corporation, type or print the name of that corporation here.)

By

(An authorized officer of the corporation being appointed as registered agent must sign here)

Form D-STMNT
(revised 07/03)

BYLAWS

OF

Wiley Chemists Inc.

ARTICLE I

Shareholders

Section 1.1. Annual Meetings. An annual meeting of shareholders shall be held for the election of directors on a date and at a time and place either within or without the State of New Mexico fixed by resolution of the Board of Directors. Any other proper business may be transacted at the annual meeting, except as limited by any notice or other requirements under the New Mexico Business Corporation Act.

Section 1.2. Special Meetings. Special meetings of the shareholders may be called at any time by the Board of Directors or the holders of shares entitled to cast not less than 10% of the votes at the meeting, such meeting to be held on a date and at a time and place either within or without the State of New Mexico as may be stated in the notice of the meeting.

Section 1.3. Notice of Meetings. Whenever shareholders are required or permitted to take any action at a meeting a written notice of the meeting shall be given not less than ten (10) nor more than fifty (50) days before the date of the meeting to each shareholder entitled to vote thereat. Such notice shall state the place, date and hour of the meeting, and (i) in the case of a special meeting, the general nature of the business to be transacted, and no other business may be transacted, or (ii) in the case of the annual meeting, those matters which the Board, at the time of the mailing of the notice, intends to present for action by the shareholders. The notice of any meeting at which directors are to be elected shall include a list of the names of the nominees intended at the time of the mailing of the notice to be presented by the Board for election.

Notice of a shareholders' meeting or any report shall be given either personally or by first-class mail or other means of written communication, addressed to the shareholder at the address of such shareholder appearing on the books of the corporation or given by the shareholder to the corporation for the purpose of notice. The notice shall be deemed to have been given at the time when delivered personally or deposited in the mail or sent by other means of written communication.

Section 1.4. Adjournments. When a shareholders' meeting is adjourned to another time or place, except as otherwise provided in this Section 1.4, notice need not be given of any such adjourned meeting if the time and place thereof are announced at the meeting at which the adjournment is taken. At the adjourned meeting the corporation

may transact any business which might have been transacted at the original meeting. If the adjournment is for more than 45 days or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each shareholder of record entitled to vote at the meeting.

Section 1.5. Validating Meeting of Shareholders; Waiver of Notice. The transactions of any meeting of shareholders, however called and noticed, and wherever held, are as valid as though had at a meeting duly held after regular call and notice, if a quorum is present either in person or by proxy, and if, either before or after the meeting, each of the persons entitled to vote, not present in person or by proxy, signs a written waiver of notice or a consent to the holding of the meeting or an approval of the minutes thereof. All such waivers, consents and approvals shall be filed with the corporate records or made a part of the minutes of the meeting. Attendance of a person at a meeting shall constitute a waiver of notice of and presence at such meeting, except when the person objects, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened and except that attendance at a meeting is not a waiver of any right to object to the consideration of matters required by law to be included in the notice but not so included, if such objection is expressly made at the meeting. Neither the business to be transacted at nor the purpose of any regular or special meeting of shareholders need be specified in any written waiver of notice, consent to the holding of the meeting or approval of the minutes thereof, except as required by the New Mexico Business Corporation Act.

Section 1.6. Quorum. A majority of the shares entitled to vote, represented in person or by proxy, shall constitute a quorum at a meeting of the shareholders. The shareholders present at a duly called or held meeting at which a quorum is present may continue to transact business until adjournment notwithstanding the withdrawal of enough shareholders to leave less than a quorum, if any action taken (other than adjournment) is approved by at least a majority of the shares required to constitute a quorum. In the absence of a quorum, any meeting of shareholders may be adjourned from time to time by the vote of a majority of the shares represented either in person or by proxy, but no other business may be transacted, except as provided in this Section 1.6.

Section 1.7. Organization. Meetings of shareholders shall be presided over by the Chairman of the Board of Directors, if any, or in the absence of the Chairman of the Board by the Vice Chairman of the Board, if any, or in the absence of the Vice Chairman of the Board by the President, or in the absence of the foregoing persons by a chairman designated by the Board of Directors, or in the absence of such designation by a chairman chosen at the meeting. The Secretary, or in the absence of the Secretary, an Assistant Secretary, shall act as secretary of the meeting, or in their absence the chairman of the meeting may appoint any person to act as secretary of the meeting.

Section 1.8. Voting. Unless otherwise provided in the articles of incorporation, each outstanding share, regardless of class, shall be entitled to one vote on each matter submitted to a vote of shareholders.

Any holder of shares entitled to vote on any matter may vote part of the shares in favor of the proposal and refrain from voting the remaining shares or vote them against the proposal, other than elections to office, but, if the shareholder fails to specify the number of shares such shareholder is voting affirmatively, it will be conclusively presumed that the shareholder's approving vote is with respect to all shares such shareholder is entitled to vote.

If a quorum is present, directors shall be elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors. In all other matters, unless otherwise provided by New Mexico law or by the articles of incorporation or these bylaws, the affirmative vote of the holders of a majority of the shares entitled to vote on the subject matter at a meeting in which a quorum is present shall be the act of the stockholders. Where a separate vote by class or classes is required, the affirmative vote of the holders of a majority of the shares of such class or classes at a meeting in which a quorum is present shall be the act of such class or classes, except as otherwise provided by New Mexico law or by the articles of incorporation or these bylaws.

Section 1.9. Shareholder's Proxies. At all meetings of shareholders, a shareholder may vote by proxy executed in writing by the shareholder or by his duly authorized attorney-in-fact. Such proxy shall be filed with the Secretary of the corporation before or at the time of the meeting. No proxy shall be valid after the expiration of eleven months from the date thereof unless otherwise provided in the proxy. Every proxy continues in full force and effect until revoked by the person executing it prior to the vote pursuant thereto, except as otherwise provided in this Section 1.9. Such revocation may be effected by a writing delivered to the corporation stating that the proxy is revoked or by a subsequent proxy executed by the person executing the prior proxy and presented to the meeting, or as to any meeting by attendance at such meeting and voting in person by the person executing the proxy.

Section 1.10. Inspectors. In advance of any meeting of shareholders the Board of Directors may appoint inspectors of election to act at the meeting and any adjournment thereof.

Section 1.11. Fixing Date for Determination of Shareholders of Record. In order that the corporation may determine the shareholders entitled to notice of any meeting or to vote or to express consent to corporate action in writing without a meeting or entitled to receive payment of any dividend or other distribution or allotment of any rights or entitled to exercise any rights in respect of any other lawful action, the Board of Directors may fix, in advance, a record date, which shall not be more than sixty nor less than ten days prior to the date of such meeting nor more than sixty days prior to any other action.

If no record date is fixed: (1) the record date for determining shareholders entitled to notice of or to vote at a meeting of shareholders shall be at the close of business on the business day next preceding the day on which notice is given or, if notice

is waived, at the close of business on the business day next preceding the day on which the meeting is held; (2) the record date for determining shareholders entitled to give consent to corporate action in writing without a meeting, when no prior action by the Board has been taken, shall be the day on which the first written consent is given; and (3) the record date for determining shareholders for any other purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto or the sixtieth day prior to the date of such other action, whichever is later. When a determination of shareholders entitled to vote at any meeting of shareholders has been made as provided in this section, such determination shall apply to any adjournment thereof.

Section 1.12. Consent of Shareholders in Lieu of Meeting. Except as otherwise provided in the articles of incorporation or under the New Mexico Business Corporation Act, any action which may be taken at any annual or special meeting of the shareholders may be taken without a meeting and without prior notice, if a consent in writing, setting forth the action so taken, shall be signed by the holders of all outstanding shares entitled to vote thereon.

ARTICLE II

Board of Directors

Section 2.1. Powers; Number; Qualifications: The business and affairs of the corporation shall be managed by, and all corporate powers shall be exercised by or under, the direction of the Board of Directors, except as otherwise provided in these by-laws or in the articles of incorporation. The number of directors comprising the first Board of Directors shall be fixed in the initial Articles of Incorporation. Thereafter, the Board of Directors shall consist of one or more members, the exact number to be fixed from time to time by the Board.

Section 2.2. Election; Term of Office; Resignation; Vacancies. At each annual meeting of shareholders, directors shall be elected to hold office until the next annual meeting. Each director, including a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until a successor has been elected and qualified. Any director may resign effective upon giving written notice to the Chairman of the Board, the Secretary or the Board of Directors of the corporation, unless the notice specifies a later time for the effectiveness of such resignation. If the resignation is effective at a future time, a successor may be elected to take office when the resignation becomes effective.

Subject to the provisions of the New Mexico Business Corporation Act, any director may be removed with or without cause at any time by the shareholders of the corporation at a special meeting called for such purpose. In addition, any director may be removed for cause by action of the Board.

Unless otherwise provided in the articles of incorporation or these by-laws and except for a vacancy caused by the removal of a director, vacancies on the Board may be filled by appointment by the Board. The shareholders may elect a director at any time to fill a vacancy not filled by the Board of Directors.

Section 2.3. Regular Meetings. Regular meetings of the Board of Directors may be held without notice at such places within or without the State of New Mexico and at such times as the Board may from time to time determine.

Section 2.4. Special Meetings; Notice of Meetings; Waiver of Notice. Special meetings of the Board of Directors may be held at any time or place within or without the State of New Mexico whenever called by the Chairman of the Board, by the Vice Chairman of the Board, if any, or by any two directors. Subject to any greater notice requirements set forth in the New Mexico Business Corporation Act, special meetings shall be held on five days' notice by mail or 48 hours' notice delivered personally or by telephone, fax, e-mail or any other means of communication authorized by the New Mexico Business Corporation Act. Notice delivered personally or by telephone may be transmitted to a person at the director's office who can reasonably be expected to deliver such notice promptly to the director.

Notice of a meeting need not be given to any director who signs a waiver of notice or a consent to holding the meeting or an approval of the minutes thereof, whether before or after the meeting, or who attends the meeting without protesting, prior thereto or at its commencement, the lack of notice to such director. All such waivers, consents and approvals shall be filed with the corporate records or made a part of the minutes of the meeting. A notice, or waiver of notice, need not specify the purpose of any regular or special meeting of the Board.

Section 2.5. Participation in Meetings by Conference Telephone Permitted. Members of the Board, or any committee designated by the Board, may participate in a meeting of the Board or of such committee, as the case may be, through the use of conference telephone or similar communications equipment permitted by the New Mexico Business Corporation Act, so long as all members participating in such meeting can hear one another, and participation in a meeting pursuant to this Section 2.5 shall constitute presence in person at such meeting.

Section 2.6. Quorum; Adjournment; Vote Required for Action. At all meetings of the Board of Directors one-half of the authorized number of directors shall constitute a quorum for the transaction of business. Subject to the provisions of the New Mexico Business Corporation Act, every act or decision done or made by a majority of the directors present at a meeting at which a quorum is present shall be the act of the Board unless the articles of incorporation or these by-laws shall require a vote of a greater number.

A majority of the directors present, whether or not a quorum is present, may adjourn any meeting to another time and place. If the meeting is adjourned for more

than 24 hours, notice of any adjournment to another time or place shall be given prior to the time of the adjourned meeting to the directors who were not present at the time of the adjournment.

Section 2.7. Organization. Meetings of the Board of Directors shall be presided over by the Chairman of the Board, or in the absence of the Chairman of the Board by the Vice Chairman of the Board, if any, or in their absence by a chairman chosen at the meeting. The Secretary, or in the absence of the Secretary an Assistant Secretary, shall act as secretary of the meeting, but in the absence of the Secretary and any Assistant Secretary the chairman of the meeting may appoint any person to act as secretary of the meeting.

Section 2.8. Action by Directors Without a Meeting. Any action required or permitted to be taken by the Board of Directors, or any committee thereof, may be taken without a meeting if all members of the Board or of such committee, as the case may be, shall individually or collectively consent in writing to such action. Such written consent or consents shall be filed with the minutes of the proceedings of the Board. Such action by written consent shall have the same force and effect as a unanimous vote of such directors.

Section 2.9. Compensation of Directors. The Board of Directors shall have the authority to fix the compensation of directors for services in any capacity.

ARTICLE III

Executive and Other Committees

Section 3.1. Executive and Other Committees of Directors. The Board of Directors, by resolution adopted by a majority of the authorized number of directors, may designate an executive committee and other committees, each consisting of two or more directors, to serve at the pleasure of the Board, and each of which, to the extent provided in the resolution but subject to the New Mexico Business Corporation Act, shall have all the authority of the Board.

The Board of Directors may designate one or more directors as alternate members of any such committee, who may replace any absent member or members at any meeting of such committee.

Unless the Board of Directors otherwise provides, each committee designated by the Board may adopt, amend and repeal rules for the conduct of its business. In the absence of a provision by the Board of Directors or a provision in the rules of such committee to the contrary, each committee shall conduct its business in the same manner as the Board of Directors conducts its business pursuant to Article II of these by-laws.

ARTICLE IV

Officers

Section 4.1. Officers; Election. As soon as practicable after the annual meeting of shareholders in each year, the Board of Directors shall elect a President, a Treasurer and a Secretary. The Board may also elect one or more Vice Presidents, one or more Assistant Secretaries, and such other officers as the Board may deem desirable or appropriate and may give any of them such further designations or alternate titles as it considers desirable. Any number of offices may be held by the same person.

Section 4.2. Term of Office; Resignation; Removal; Vacancies. Except as otherwise provided in the resolution of the Board of Directors electing any officer, each officer shall hold office until his or her successor is elected and qualified or until his or her earlier resignation or removal. Any officer may resign at any time upon written notice to the Board or to the Chairman of the Board or the Secretary of the corporation. Such resignation shall take effect at the time specified therein, and unless otherwise specified therein no acceptance of such resignation shall be necessary to make it effective. The Board may remove any officer with or without cause at any time. Any such removal shall be without prejudice to the contractual rights of such officer, if any, with the corporation, but the election of an officer shall not of itself create contractual rights. Any vacancy occurring in any office of the corporation by death, resignation, removal or otherwise may be filled for the unexpired portion of the term by the Board at any regular or special meeting.

Section 4.3. Powers and Duties. The officers of the corporation shall have such powers and duties in the management of the corporation as shall be stated in these by-laws or in a resolution of the Board of Directors which is not inconsistent with these by-laws and, to the extent not so stated, as generally pertain to their respective offices, subject to the control of the Board. The Secretary shall have the duty to record the proceedings of the meetings of the shareholders, the Board of Directors and any committees in a book to be kept for that purpose.

Section 4.4. Salaries. The salaries, compensation and other benefits, if any, of the officers shall be fixed from time to time by the Board of Directors, and no officer shall be prevented from receiving such salary by reason of the fact that he is also a Director of the corporation.

ARTICLE V

Forms of Certificates; Loss and Transfer of Shares

Section 5.1. Forms of Certificates. Every holder of shares in the corporation shall be entitled to have a certificate signed in the name of the corporation by (1) the President, any Vice President, Chairman of the Board or Vice Chairman, and (2) by the Chief Financial Officer, Treasurer, Assistant Treasurer, Secretary or Assistant Secretary, of the corporation, certifying the number of shares and the class or series of shares owned by such shareholder. If such certificate is manually signed by one officer or manually countersigned by a transfer agent or by a registrar, any other signature on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if such person were such officer, transfer agent or registrar at the date of issue.

Section 5.2. Lost, Stolen or Destroyed Stock Certificates; Issuance of New Certificates. The corporation may issue a new share certificate or a new certificate for any other security in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the corporation a bond sufficient to indemnify it against any claim that may be made against it (including any expense or liability) on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate.

ARTICLE VI

Records and Reports

Section 6.1. Shareholder Records. The corporation shall keep at its principal executive office or at the office of its transfer agent or registrar a record of the names and addresses of all shareholders and the number and class of shares held by each shareholder.

Section 6.2. Corporate Documents and By-laws. The corporation shall keep at its principal executive office the original or a copy of the articles of incorporation and by-laws as amended to date, which shall be open to inspection by the shareholders at all reasonable times during office hours. The corporation shall, upon the written request of any shareholder, furnish to that shareholder a copy of the articles of incorporation or by-laws as amended to date.

Section 6.3. Minutes and Accounting Records. The minutes of proceedings of the shareholders, the Board of Directors, and committees of the Board,

and the accounting books and records shall be kept at the principal executive office of the corporation, or at such other place or places as designated by the Board of Directors. The minutes shall be kept in written form, and the accounting books and records shall be kept either in written form or in a form capable of being converted into written form.

Section 6.4. Inspection by Directors. Subject to applicable New Mexico law, every director shall have the right at any reasonable time to inspect all books, records, and documents of every kind and the physical properties of the corporation and each of its subsidiary corporations for purposes relating to his or her status as director. This inspection by a director may be made in person or by an agent or attorney and the right of inspection includes the right to copy and make extracts of documents.

Section 6.5. Annual Report to Shareholders. Subject to the New Mexico Business Corporation Act, for as long as the corporation has fewer than the number of shareholders specified in the applicable statute, if any, any requirement of an annual report to shareholders is expressly waived. However, nothing in this provision shall be interpreted as prohibiting the Board of Directors from issuing annual or other periodic reports to the shareholders, as the Board considers appropriate.

Section 6.6. Financial Statements. The corporation shall keep a copy of each annual financial statement, quarterly or other periodic income statement, and accompanying balance sheets prepared by the corporation on file in the corporation's principal office for 12 months; these documents shall be exhibited at all reasonable times, or copies provided, to any shareholder on demand.

Section 6.7. Form of Records. Any records maintained by the corporation in the regular course of its business, with the exception of minutes of the proceedings of the shareholders, and of the Board of Directors and its committees, but including the corporation's stock ledger and books of account, may be kept on, or be in the form of magnetic tape, photographs, microphotographs or any other information storage device, provided that the records so kept can be converted into clearly legible form within a reasonable time. The corporation shall so convert any records so kept upon the request of any person entitled to inspect the same.

ARTICLE VII

Miscellaneous

Section 7.1. Principal Executive or Business Offices. The Board of Directors shall fix the location of the principal executive office of the corporation at any place either within or without the State of New Mexico.

Section 7.2. Fiscal Year. The fiscal year of the corporation shall be determined by the Board of Directors.

Section 7.3. Seal. The corporation may have a corporate seal which shall have the name of the corporation inscribed thereon and shall be in such form as may be approved from time to time by the Board of Directors. The corporate seal may be used by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

Section 7.4. Indemnification. The corporation shall have the power to indemnify, to the maximum extent and in the manner permitted by the New Mexico Business Corporation Act (the "Code"), each of its directors, officers, employees and agents against expenses, judgments, fines, settlements, and other amounts actually and reasonably incurred in connection with any proceeding arising by reason of the fact that such person is or was an agent of the corporation.

The corporation shall have the power, to the extent and in the manner permitted by the Code, to indemnify each of its employees and agents (other than directors and officers) against expenses, judgments, fines, settlements, and other amounts actually and reasonably incurred in connection with any proceeding, arising by reason of the fact that such person is or was an agent of the corporation.

Section 7.5. Contracts. The Board of Directors may authorize any officer or officers, agent or agents, to enter into any contract or execute and deliver any instrument in the name of and on behalf of the corporation, and such authority may be general or confined to specific instances.

Section 7.6. Dividends. The Board of Directors may from time to time declare, and the corporation may pay dividends on its outstanding shares in the manner and upon the terms and conditions provided by New Mexico law and its articles of incorporation.

Section 7.7. Amendment of By-Laws. To the extent permitted by law, these by-laws may be amended or repealed, and new by-laws adopted, by the Board of Directors. The shareholders entitled to vote, however, retain the right to adopt additional by-laws and may amend or repeal any by-law whether or not adopted by them.

CONFIDENTIAL AND EXEMPT MATERIALS

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September 19, 2013

Entirely Pets Pharmacy, LLC
Rita Ghumman
34571 Seventh Street
Union City, CA 94587

RE: Request to Appeal Notice of Intent to Deny

Dear Ms. Ghumman:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, October 9, 2013 at 9:00a.m. The meeting is being held at the Wyndham Bay Point Resort, 4114 Jan Cooley Drive, Panama City Beach, FL 32408, (850) 236-6000.

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.floridaspharmacy.gov/meeting-information/upcoming-meetings/

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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THE FLORIDA
BOARD OF PHARMACY

ENTIRELYPETS PHARMACY, LLC,
Petitioner,

v.

Board of Pharmacy Case No.

FLORIDA BOARD OF PHARMACY,

Respondent

_____ /

Petitioner's Request for Hearing to Appeal Denial of Non-Resident Pharmacy License, Brought Per Section 120.57(2) Florida Statutes

Comes now the Petitioner EntirelyPets Pharmacy, LLC ("EntirelyPets"), which petitions the Flordia Board of Pharmacy ("Board"), through its Executive Director, for a hearing to consider EntirelyPets' appeal from the denial of its application for a non-resident pharmacy permit, as follows:

1. Petitioner received notice of the Board's action, denying EntirelyPets' application for a non-resident pharmacy permit ("Application"), through the Board's letter, mailed June 26, 2013, a copy of which is attached hereto as Exhibit 1.

2. Petitioner is represented in this Petition by attorney Noah E. Jussim, whose address is Noah Jussim, McGuireWoods LLP, 1800 Century Park East, 8th Floor, Los Angeles, CA 90067, having telephone number (310) 315-8225, fax number (310) 956-3125, and email address njussim@mcguirewoods.com. EntirelyPets' address is 34501 Seventh Street, Union City, CA 94587.

3. Petitioner's substantial interest will be affected by the Board's determination because: (1) it would be unable to dispense medication to veterinary patients in Florida, when the owners of the patient animals may wish that EntirelyPets could serve their prescription needs; and (2) the Board's adverse determination will likely affect EntirelyPets' applications for licensure in other states.

4. While there is no dispute of the material fact that EntirelyPets' license has been disciplined by the California State Board of Pharmacy ("California Board"), which is EntirelyPets' domicile state licensing agency, the California Board had determined in the first instance to issue a resident pharmacy license to EntirelyPets subject to discipline, to resolve citations pending against EntirelyPets concerning alleged pre-license activity. Given that the California Board did not deny a license altogether to EntirelyPets, but, determined it to be in the public interest to issue a license to EntirelyPets, subject to discipline, the Board should exercise its discretion to take some lesser action against EntirelyPets, rather than denying EntirelyPets' application. Florida Statute 456.072(2) specifically empowers the Board to take such a lesser step under these circumstances.

We thank the Board very much for its time and consideration.

Respectfully submitted,

Noah E. Jussim
Attorney for Petitioner EntirelyPets Pharmacy, LLC
California State Bar Number 194103
McGuireWoods LLP
1800 Century Park East
8th Floor
Los Angeles, CA 90067
(310) 315.8297
(310) 315.8210 (facsimile)

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE JUN 26 2013

STATE OF FLORIDA
BOARD OF PHARMACY

IN RE: APPLICATION FOR NON-RESIDENT PHARMACY PERMIT
ENTIRELYPETS PHARMACY, LLC.

NOTICE OF INTENT TO DENY

This matter came before the Board of Pharmacy (hereinafter the "Board") at a duly noticed public meeting held on June 5, 2013, in Miami, Florida, pursuant to the Applicant's request for license. The applicant was not present.

The Applicant is a licensed pharmacy in the State of California. Applicant's license has been disciplined by the California State Board of Pharmacy by way of stipulation on September 21, 2012, with an effective date of October 22, 2012.

Pursuant to Section 456.072(2); 456.072(1)(f); 465.023(1); and 465.23(1)(e), Florida Statutes, the board may deny the application based on the out-of-state disciplined imposed against the license.

Therefore, based on the prior discipline, the application for a non-resident permit is hereby **DENIED**.

DONE AND ORDERED this 25 day of June, 2013.

BOARD OF PHARMACY

Mark Whitten, Executive Director *for*
Albert Garcia, BPharm, Chair

EXHIBIT 1

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 **Entirely Pets Pharmacy, LLC**, 34571 Seventh Street, Union City, California 94587; by electronic mail to **David D. Flynn**, Assistant Attorney General, Office of the Attorney General, david.flynn@myfloridalegal.com ; this 20th day of June, 2013.

7012 1010 0000 2223 9707 [redacted]

Angel Sanders

Deputy Agency Clerk

FLORIDA DEPARTMENT OF HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320
Tallahassee, FL 32314-6320
Telephone (850) 488-0595
http://www.doh.state.fl.us/mqa/pharmacy

03/14/2013 . 255.00
ID: 19899 Type: F
BT: 3016403
VL: 912049135

NON-RESIDENT PHARMACY REGISTRATION

Application Type – Please choose one of the following:

2205-19899

✓ 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: 45-3560777

1. Corporate Name EntirelyPets Pharmacy LLC.	**Telephone Number** 800-738-7209
2. Doing Business As (d/b/a) N/A	**E-Mail Address** pharmacist@entirelypetspharmacy.com
3. Mailing Address 34571 Seventh St.	
City Union City	**State** CA **Zip** 94587
4. Physical Address As above (Mailing address)	
City	**State** **Zip**

5. List Prescription Department Manager (PDM)

Name	License No.	Start Date	Signature
Rashmi Shingari	50133	3/5/2013	Rashmi Shingari

6. Contact Person Ritu Ghumman	**Telephone Number** (650) 796 4411
7. DEA Registration Number N/A	**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
Animal Health International, Inc	970 353 2600	1000861
Street Address 822 7th St.	**City** Greeley	**State** CO **Zip** 80631

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 am Close: 5 pm Saturday: Open: CLOSE Close: _____ Sunday: Open: CLOSE Close: _____	(800) 738 - 7209

WC

11. Ownership Information

a. Type of Ownership: ____Individual ____Corporation ____Partnership
✓ 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 ✓ 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
Ritu Ghumman	09/27/1972	34571, 7th St, Union City, CA.	90.1%
Mandeep Ghumman	06/17/1970	34501, 7th St, Union City, CA	9.9%

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 contendre 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 ____ 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. 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 N/A 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 N/A 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
CALIFORNIA	Closed Door Pet Pharmacy (Internet)	50832

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

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)

See Attached letter of Licensure verification and "A"

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

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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 Rita K Chrisman TITLE Owner DATE 3/11/13
Owner/Officer

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
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Statement of Issues Against: **ENTIRELYPETS PHARMACY** **Applicant for Community Pharmacy License** Respondent.	Case No. 4294

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on October 22, 2012.

It is so ORDERED on September 21, 2012.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By _____
STANLEY C. WEISSER
Board President

KAMALA D. HARRIS
Attorney General of California
FRANK H. PACOE
Supervising Deputy Attorney General
JOSHUA A. ROOM
Deputy Attorney General
State Bar No. 214663
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 703-1299
Facsimile: (415) 703-5480
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Statement of Issues Against: **ENTIRELYPETS PHARMACY** **Applicant for Community Pharmacy License** Respondent.	Case No. 4294 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER**

In the interest of a prompt and speedy settlement of this matter, consistent with the public interest and the responsibility of the Board of Pharmacy, Department of Consumer Affairs, the parties hereby agree to the following Stipulated Settlement and Disciplinary Order that is to be submitted to the Board for approval and adoption in final disposition of the Statement of Issues.

PARTIES

1. Virginia Herold (Complainant), Executive Officer of the Board of Pharmacy, brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, by Joshua A. Room, Deputy Attorney General.

2. EntirelyPets Pharmacy (Respondent) is represented in this proceeding by attorney Noah E. Jussim, whose address is: McGuireWoods LLP, 1800 Century Park East, 8th Floor, Los Angeles, CA 90067 (telephone (310) 315-8225).

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APPLICATION AND CITATIONS

3. On or about October 21, 2011, the Board of Pharmacy received a Community Pharmacy Permit Application from EntirelyPets Pharmacy, listing its parent entity as EntirelyPets Pharmacy, LLC, owned 90.1% by Ritu Ghumman and 9.9% by HealthyPets, Inc. (Respondent). HealthyPets, Inc. is in turn owned 50% by Ritu Ghumman and 50% by Mandeep Ghumman.[1] On or about October 14, 2011, Ritu Ghumman and Mandeep Ghumman, as owner(s) and officer(s), signed a certification under penalty of perjury as to the truthfulness of all statements, answers, and representations in the Application. The Board denied the application on January 18, 2012.

4. Respondent and its affiliated entities have also received and/or been the subject(s) of four (4) citations and fines issued by the Board. All have appeals pending. These include:

a. Citation No. CI 2009 41054, dated November 18, 2010, with $5,000.00 fine, alleging violations of Business and Professions Code section(s) 4110 and/or 4112 (conducting a pharmacy/nonresident pharmacy without a license), 4076 and/or 4077 (dispensing in inadequately labeled container(s)), and California Code of Regulations, title 16, section 1716 (deviating from a written prescription). Respondent has appealed this Citation.

b. Citation No. CI 2009 42223, dated November 22, 2010, with a $55,000.00 fine, alleging violations of Business and Professions Code section(s) 4110 and/or 4112 (conducting a pharmacy/nonresident pharmacy without a license), 4067 and/or California Code of Regulations, title 16, section 1761 (dispensing/furnishing Internet prescriptions issued without a good faith prior examination, with significant error, omission, irregularity, uncertainty, ambiguity or alteration, and/or not for a legitimate medical purpose). Respondent has appealed this Citation.

c. Citation No. CI 2011 49563, dated December 7, 2011, with a $5,000.00 fine, alleging violations of Business and Professions Code section(s) 4160 and/or 4161 (conducting a wholesaler/nonresident wholesaler without a license). Respondent has appealed this Citation.

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[1] Both Ritu Ghumman and Mandeep Ghumman are Doctors of Veterinary Medicine, and both are licensed by the California Veterinary Medical Board. License No. 14261, issued to Dr. Ritu Ghumman, is in inactive status, and she may not practice veterinary medicine at this time. License No. 12996, issued to Dr. Mandeep Ghumman, is active and unrestricted at this time.

d. Citation No. CI 2011 49569, dated December 7, 2011, with a $5,000.00 fine, alleging violations of Business and Professions Code section(s) 4160 and/or 4161 (conducting a wholesaler/nonresident wholesaler without a license). Respondent has appealed this Citation.

This Stipulated Settlement and Disciplinary Order is also intended to serve as a settlement of all pending appeals and other matters pertaining to the above-listed citations and fines.

JURISDICTION

4. Statement of Issues No. 4294 was filed before the Board of Pharmacy (Board), and is currently pending against Respondent. The Statement of Issues and all other statutorily required documents were properly served on Respondent on May 31, 2012. A copy of Statement of Issues No. 4294 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Statement of Issues No. 4294, and in each of the above-listed citations. Respondent has also carefully read, fully discussed with counsel, and understands the effects of, this Stipulated Settlement and Disciplinary Order.

6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Statement of Issues or in any pending citations; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

8. Respondent further withdraws any notices of appeal or other requests for hearing on the above-listed citations, and agrees that those citations will now be final as issued.

CULPABILITY

9. Respondent, by its authorized representative, admits the truth of each and every charge and allegation in Statement of Issues No. 4294. Respondent further agrees that its Community Pharmacy Permit Application is subject to denial, and agrees to be bound by the Board of Pharmacy (Board)'s probationary terms as set forth in the Disciplinary Order below.

RESERVATION

10. Admissions made by Respondent herein are only for the purposes of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement with regard to the Statement of Issues and the above-listed citations. As to those matters, this written agreement supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

13. The parties understand and agree that facsimile copies of this stipulation, including facsimile signatures thereto, shall have the same force and effect as the originals.

14. In consideration of the foregoing, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that, upon satisfaction of statutory and regulatory requirements for issuance thereof, including but not limited to submission of documentation demonstrating the compliance of its ownership structure(s) with Business and Professions Code section 4111 as specified below, a Pharmacy License shall be issued by the Board of Pharmacy to EntirelyPets Pharmacy (Respondent), and immediately revoked. Revocation is stayed and the license is placed on probation for five (5) years on the terms and conditions detailed below.

1. **Compliance with Business and Professions Code section 4111**

Prior to issuance of the license, and as a condition precedent to issuance of the license and commencement of the period of probation, Respondent shall gather or prepare, and submit to the Board, documentation demonstrating that its ownership does not violate Business and Professions Code section 4111, i.e., that no person or persons authorized to prescribe or write a prescription in California: is a sole or controlling owner of Respondent; shares a community or other financial interest in a sole or controlling ownership of Respondent; controls or owns a 10 percent or greater share of a corporation or other entity that is a sole or controlling owner of Respondent; or shares a community or other financial interest in a greater than 10 percent share of a corporation or other entity that is a sole or controlling owner of Respondent. Respondent shall submit such materials and documentation as are requested by the Board or its designee, and the Board or its designee shall have sole discretion to determine whether satisfactory documentation has been submitted. The documentation shall include, at least, affidavits signed under penalty of perjury by all owners and officers of Respondent or Respondent's owners or parent entities, stating that he or she: (a) is not now authorized to prescribe in California, and/or (b) does not have an ownership share, either directly or through community or other shared interest, sufficient to trigger section 4111.

All such affidavits shall be supported by documentation demonstrating the accuracy of the statements made therein. The Board or its designee may require additional documentation.

At no point during its licensure by the Board, including after the expiration of the period of probation, may Respondent's ownership violate this ownership limitation.[2] Pursuant to Business and Professions Code section 4111, subdivision (c), the Board or its designee may require any information that it deems reasonably necessary for the enforcement of this section, including but not limited to supplemental affidavits and documentation required at each renewal.

2. **Civil Penalty**

Respondent shall pay to the Board a civil penalty of $50,000.00. Payments shall be made as follows: Prior to issuance of the license, and as a condition precedent to issuance of the license and commencement of the period of probation, Respondent shall make a payment of $5,000.00. Thereafter, once probation commences, Respondent shall make sixteen (16) quarterly payments of $2,812.50 each. Payment shall be made in full within four (4) years of the start of probation.

Respondent understands and agrees that this civil penalty is an administrative fine pursuant to 11 U.S.C. § 523(a)(7), and is non-dischargeable in bankruptcy. Respondent further understands and agrees that the filing of bankruptcy by Respondent shall not relieve Respondent of the obligation to pay the balance of the civil penalty to the Board.

Payment of this civil penalty shall satisfy all of the assessed, outstanding, pending, and appealed fines included in the above-listed citations. Upon full payment of the civil penalty, all of the above-listed citations shall be deemed satisfactorily resolved, and shall be so represented in any future public disclosure of those citations by the Board.

Failure to timely pay this civil penalty shall be considered a violation of probation. Further, absent prior written approval by the Board or its designee, Respondent may not successfully complete probation until this amount is paid in full.

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[2] This shall include that any owner avoiding the prohibition(s) in section 4111 by making his or her license to prescribe in California inactive or otherwise not an authorization to prescribe, shall at no time during his or her ownership of Respondent reactivate that license or have his/her authorization to prescribe reinstated. Should any person meeting the ownership threshold(s) in section 4111 hereafter become authorized to prescribe in California, he or she must immediately divest and/or transfer his or her ownership share to come into compliance with section 4111.

3. **Obey All Laws**

Respondent shall obey all state and federal laws and regulations. Respondent shall report to the Board, in writing, within seventy-two (72) hours of such occurrence, any of the following with regard to Respondent or any of its owners, officers, managers, or employees:

- an arrest or issuance of a criminal complaint for violation of any provision of the Pharmacy Law, state and federal food and drug laws, or state and federal controlled substances laws
- a plea of guilty or nolo contendre in any state or federal criminal proceeding to any criminal complaint, information or indictment
- a conviction of any crime
- discipline, citation, or other administrative action filed by any state or federal agency which involves Respondent's wholesaler license or which is related to the practice of pharmacy or the manufacturing, obtaining, handling or distributing, billing, or charging for any drug, device or controlled substance.

Failure to timely report any such occurrence shall be considered a violation of probation.

4. **Engagement of Consultant**

During probation, Respondent shall, at its expense, retain an independent consultant who shall be responsible for reviewing pharmacy operations on a monthly basis for compliance by Respondent with state and federal laws and regulations governing the practice of pharmacy and for compliance by the pharmacist in charge for Respondent with the obligations of a pharmacist in charge. The consultant shall be a pharmacist licensed by and not on probation with the Board and whose name shall be submitted to the Board or its designee, for prior approval, within thirty (30) days of the effective date of this decision. Failure to timely retain, seek approval of, or ensure timely reporting by the consultant shall be considered a violation of probation

5. **Interview with the Board**

Upon receipt of reasonable prior notice, an owner or officer of Respondent shall appear in person for interviews with the Board or its designee, at intervals and locations as determined by the Board or its designee. Failure to appear for any scheduled interview without prior notification to Board staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee during the period of probation, shall be considered a violation of probation.

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6. **Report to the Board**

Respondent, through an owner or officer, shall report to the Board quarterly, on a schedule as directed by the Board or its designee. The report shall be made either in person or in writing, as directed. Among other requirements, the reporting owner or officer shall state in each report under penalty of perjury whether there has been compliance with all the terms and conditions of probation. Failure to submit timely reports in a form as directed shall be considered a violation of probation. Any period(s) of delinquency in submission of reports as directed may be added to the period of probation. Moreover, if a final probation report is not made as directed, probation shall be automatically extended until such time as the final report is made and accepted by the Board.

7. **Cooperate with Board Staff**

Respondent owner shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

8. **Probation Monitoring Costs**

Respondent owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

9. **Status of License**

Respondent shall, at all times while on probation, maintain current licensure with the Board. If Respondent submits an application to the Board, and the application is approved, for a change of location, change of permit or change of ownership, the Board shall retain continuing jurisdiction over the license, and Respondent shall remain on probation as determined by the Board. Failure to maintain current licensure shall be considered a violation of probation.

If Respondent's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication Respondent's license shall be subject to all terms and conditions of this probation not previously satisfied.

10. **Notice to Employees**

Respondent shall, upon or before the effective date of this decision, ensure that all employees involved in permit operations are made aware of all the terms and conditions of probation, either by posting a notice of the terms and conditions, circulating such notice, or both. If the notice required by this provision is posted, it shall be posted in a prominent place and shall remain posted throughout the probation period. Respondent shall ensure that any employees hired or used after the effective date of this decision are made aware of the terms and conditions of probation by posting a notice, circulating a notice, or both. Additionally, Respondent shall submit written notification to the Board, within fifteen (15) days of the effective date of this decision, that this term has been satisfied. Failure to submit such notification to the Board shall be considered a violation of probation.

"Employees" as used in this provision includes all full-time, part-time, volunteer, temporary, and relief employees and independent contractors employed or hired at any time during probation.

11. **Posted Notice of Probation**

Respondent shall prominently post a probation notice provided by the Board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason(s) for the probation.

Failure to post such notice shall be considered a violation of probation.

12. **Owners and Officers: Knowledge of the Law**

Respondent shall provide, within thirty (30) days after the effective date of this decision, signed and dated statements from its owners, including any owner or holder of ten percent (10%) or more of the interest in Respondent or Respondent's stock, and any officer, stating under penalty of perjury that said individuals have read and are familiar with state and federal laws and regulations governing the practice of pharmacy. The failure to timely provide said statements under penalty of perjury shall be considered a violation of probation.

13. **License Surrender While on Probation/Suspension**

Following the effective date of this decision, should Respondent discontinue business, Respondent may tender the premises license to the Board for surrender. The Board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation. This surrender constitutes a record of discipline and shall become a part of the Respondent's license history with the Board.

Upon acceptance of the surrender, Respondent shall relinquish the premises wall and renewal license to the Board within ten (10) days of notification by the Board that the surrender is accepted. Respondent shall further submit a completed Discontinuance of Business form according to Board guidelines and shall notify the Board of the records and inventory transfer.

Neither Respondent nor its officers or owners may apply for any new Board license for three (3) years from the effective date of the surrender. Any applicant shall meet all requirements applicable to the license sought as of the date the application is submitted to the Board.

Respondent further stipulates that any applicant shall reimburse the Board for its costs of investigation and prosecution prior to the acceptance of the surrender.

14. **Violation of Probation**

If Respondent has not complied with any term or condition of probation, the Board shall have continuing jurisdiction over Respondent's license, and probation shall be automatically extended, until all terms and conditions have been satisfied or the Board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If Respondent violates probation in any respect, the Board, after giving Respondent notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If a petition to revoke probation or an accusation is filed against Respondent during probation, the Board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

15. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Noah E. Jussim. I understand the stipulation and the effect it will have on my Community Pharmacy Permit Application, and on the above-listed citations that are also the subject of and resolved by this agreement. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 6/20/12

Rita Ghumman, for
ENTIRELYPETS PHARMACY
Respondent

I have read and fully discussed with the executive officer(s) for Respondent EntirelyPets Pharmacy the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: 6/21/12

NOAH E. JUSSIM
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated:

KAMALA D. HARRIS
Attorney General of California
FRANK H. PACOE
Supervising Deputy Attorney General

JOSHUA A. ROOM
Deputy Attorney General
Attorneys for Complainant

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15. **Completion of Probation**

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Noah E. Jussim. I understand the stipulation and the effect it will have on my Community Pharmacy Permit Application, and on the above-listed citations that are also the subject of and resolved by this agreement. I enter into this Stipulated Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

Ritu Ghumman, for
ENTIRELYPETS PHARMACY
Respondent

I have read and fully discussed with the executive officer(s) for Respondent EntirelyPets Pharmacy the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and content.

DATED: _____

NOAH E. JUSSIM
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 6/21/2012

KAMALA D. HARRIS
Attorney General of California
FRANK H. PACOE
Supervising Deputy Attorney General

JOSHUA A. ROOM
Deputy Attorney General
Attorneys for Complainant

SF2012204087; 40548617.doc

Exhibit A

Statement of Issues No. 4294

KAMALA D. HARRIS
Attorney General of California
FRANK H. PACOE
Supervising Deputy Attorney General
JOSHUA A. ROOM
Deputy Attorney General
State Bar No. 214663
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004
Telephone: (415) 703-1299
Facsimile: (415) 703-5480
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Statement of Issues Against:	Case No. 4294
ENTIRELYPETS PHARMACY	
Applicant for Community Pharmacy License	**STATEMENT OF ISSUES**
Respondent.	

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Statement of Issues solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about October 21, 2011, the Board of Pharmacy received a Community Pharmacy Permit Application from EntirelyPets Pharmacy, listing its parent entity as EntirelyPets Pharmacy, LLC, owned 90.1% by Ritu Ghumman and 9.9% by HealthyPets, Inc. (Respondent). HealthyPets, Inc. is in turn owned 50% by Ritu Ghumman and 50% by Mandeep Ghumman.[1] On or about October 14, 2011, Ritu Ghumman and Mandeep Ghumman, as owner(s) and officer(s), signed a certification under penalty of perjury as to the truthfulness of all statements, answers, and representations in the Application. The Board denied the application on January 18, 2012.

[1] Both Ritu Ghumman and Mandeep Ghumman are Doctors of Veterinary Medicine, and both are licensed by the California Veterinary Medical Board. License No. 14261, issued to Dr. Ritu Ghumman, is in inactive status, and she may not practice veterinary medicine at this time. License No. 12996, issued to Dr. Mandeep Ghumman, is active and unrestricted at this time.

JURISDICTION AND STATUTORY/REGULATORY PROVISIONS

3. This Statement of Issues is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 480 of the Code states, in pertinent part:

"(a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:

"(1) Been convicted of a crime. . . . Any action which a board is permitted to take following the establishment of a conviction may be taken . . . irrespective of a subsequent order under the provisions of Section 1203.4 of the Penal Code.

"(2) Done any act involving dishonesty, fraud or deceit with the intent to substantially benefit himself or another, or substantially injure another; or

"(3) Done any act which if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

"The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions or duties of the business or profession for which application is made."

5. Section 4300, subdivision (c), of the Code states:

"(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. . . ."

6. Section 4301 of the Code provides, in pertinent part, that "unprofessional conduct" is defined to include, but not be limited to, any of the following:

(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

(o) Violating or attempting to violate, directly or indirectly, or assisting or abetting the violation of, or conspiring to violate, any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

7. Section 4037 of the Code defines "pharmacy" to mean and include any area, place, or premises licensed by the Board wherein the profession of pharmacy is practiced, prescriptions are compounded, controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail.

8. Section 4043 of the Code defines "wholesaler" to mean and include any person/entity that acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in Section 4022 (dangerous drugs and dangerous devices).

9. Section 4067 of the Code provides, in pertinent part, that no person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022 of the Code, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations. A "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242 of the Code and the requirements for a veterinarian in Section 2032.1 of Title 16 of the California Code of Regulations.

10. Section 4110 of the Code provides, in pertinent part, that no person shall conduct a pharmacy in California without first obtaining a license issued by the Board.

11. Section 4112 of the Code provides, in pertinent part, that no person/entity located outside the state may ship, mail, or deliver controlled substances, dangerous drugs, or dangerous devices into California without first obtaining a nonresident pharmacy license from the Board.

12. Section 4160 of the Code provides, in pertinent part, that no person/entity may act as a wholesaler of a dangerous drug or device without first obtaining a license from the Board.

13. Section 4161 of the Code provides, in pertinent part, that no person/entity located outside the state may ship, sell, mail, or deliver dangerous drugs or dangerous devices into this state, or sell, broker, or distribute dangerous drugs or dangerous devices within this state, without first obtaining a nonresident wholesaler license issued by the Board.

14. Section 4076 of the Code requires, in pertinent part, that a pharmacist shall not dispense a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with the information specified by that section.

15. Section 4077 of the Code provides, in pertinent part, that except under circumstances not relevant here, no person shall dispense any dangerous drug except in a container correctly labeled with the information required by section 4076.

16. California Code of Regulations, title 16, section 1716, states in pertinent part:

"Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073. . . ."

17. California Code of Regulations, title 16, section 1761, provides in pertinent part, that no pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, shall contact the prescriber to obtain the information needed to validate the prescription, and even after conferring with the prescriber, shall not compound or dispense a controlled substance prescription where the pharmacist knows or has objective reason to know the prescription was not issued for a legitimate medical purpose.

18. Section 4111, subdivision (a), of the Code provides that the Board shall not issue or renew a license to conduct a pharmacy to a person or persons authorized to prescribe or write a prescription within the State of California, to any person or persons sharing a community or other financial interest with such prescriber, or to any corporation that is controlled by, or in which 10 percent or more of the stock is owned by, such a prescriber or any person with a community or other financial interest in common with such a prescriber.

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CITATION AND FINE AUTHORITY

19. Section 125.9 of the Code provides, in pertinent part, that the Board may establish, by regulation, a system for issuance to a licensee of a citation to contain an order of abatement or an order to pay an administrative fine assessed by the Board, or both, and the system shall include a provision whereby failure of a licensee to pay a fine within 30 days of the date of assessment by a citation not being appealed, may result in disciplinary action being taken.

20. Section 148 of the Code provides, in pertinent part, that the Board may establish, by regulation, a similar system for issuance of a citation to an unlicensed person/entity acting in the capacity of a licensee or registrant under the jurisdiction of the Board.

21. Section 4314 of the Code similarly provides, in pertinent part, that the Board may issue citations containing fines and orders of abatement for any violation of the Pharmacy Law.

22. California Code of Regulations, title 16, section 1775 et seq. provide, in pertinent part, that the Executive Officer for the Board may issue citations containing either or both a fine and an order of abatement for any violation of the Pharmacy Law.

FACTUAL BACKGROUND

23. During the events and time periods described in the following, Respondent and/or its affiliated entities were acting under, by and/or through entity names including HealthyPets, Inc., EntirelyPets.com, and/or Pet Pharmacy Plus. "Respondent" shall refer to all of these entities.

24. On or about May 15, 2009, Respondent dispensed/mailed RX 6205953, a prescription container containing **Metacam 1.5 mg/ml** (a trade name for the generic drug **meloxicam**), a dangerous drug, to a California customer (for a feline patient). Respondent used addresses both within and outside California. Respondent was not licensed by the Board as a pharmacy. The container label did not include the prescriber name or the name and address of the dispensing pharmacy. The prescription called for **Metacam .5 mg/ml** instead of the dispensed **Metacam 1.5 mg/ml**, and the directions for use were written as "eight pound dose by mouth once daily" but were printed on the container label as being "use as directed by your veterinarian."[2]

[2] These allegations are also the subject of Citation No. CI 2009 41054, issued November 18, 2010. Respondent has appealed that Citation, and that appeal is now pending.

25. On or about July 29 and July 30, 2009, Respondent dispensed/mailed RX 6205953, a prescription container containing **Soloxine .1 mg**, and RX 6227612, a prescription container containing **Soloxine .8 mg** (generic: **levothyroxine**), a dangerous drug, to a California customer (canine patient). Respondent used addresses both within and outside California. Respondent was not licensed by the Board as a pharmacy. The prescriptions were dispensed and/or transacted via the Internet and/or without a prescription issued pursuant to a good faith prior examination and/or the prescriptions contained a significant error, omission, irregularity, uncertainty, ambiguity or alteration and/or there was reason to know they were not issued for a legitimate medical purpose.[3]

26. Between on or about September 25, 2009 and on or about October 27, 2009, using an address outside of California, Respondent sold, traded, or otherwise transferred dangerous drugs to a pharmacy licensed by the Board located in California.[4]

27. Between on or about February 24, 2010 and on or about March 4, 2010, using an address in California, Respondent sold, traded, or otherwise transferred dangerous drugs to a pharmacy licensed by the Board located in California.[5]

FIRST CAUSE FOR DENIAL OF APPLICATION

(Unlicensed Practice of Pharmacy)

28. Respondent's application is subject to denial under the following section(s) of the Code: 4110 and/or 4112; 480(a)(3) by reference to 4301(j), (o), 4110 and/or 4112; or 4300(c) by reference to 4301(j), (o), 4110 and/or 4112; in that Respondent, as described in paragraph(s) 24 and/or 25 above, acted as a pharmacy without a pharmacy or nonresident pharmacy license, and thereby violated the Pharmacy Law; did acts constituting cause for discipline against a license; engaged in unprofessional conduct; violated statutes regulating controlled substances / dangerous drugs; and/or violated/attempted to violate, directly or indirectly, or assisted or abetted violation of, or conspired to violate, federal or state laws and regulations governing pharmacy.

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[3] These allegations are also the subject of Citation No. CI 2009 42223, issued November 22, 2010. Respondent has appealed that Citation, and that appeal is now pending.

[4] These allegations are also the subject of Citation No. CI 2011 49569, issued December 7, 2011. Respondent has appealed that Citation, and that appeal is now pending.

[5] These allegations are also the subject of Citation No. CI 2011 49563, issued December 7, 2011. Respondent has appealed that Citation, and that appeal is now pending.

SECOND CAUSE FOR DENIAL OF APPLICATION

(Inadequate Labeling and/or Deviation from Prescription)

29. Respondent's application is subject to denial under the following section(s) of the Code and applicable regulations: 4076, 4077, and/or California Code of Regulations, title 16, section 1716; 480(a)(3) by reference to 4301(j), (o), 4076, 4077, and/or California Code of Regulations, title 16, section 1716; or 4300(c) by reference to 4301(j), (o), 4076, 4077, and/or California Code of Regulations, title 16, section 1716; in that Respondent, as described in paragraph 24 above, failed to include prescriber name, pharmacy name and address, and correct directions for use on the prescription container label, and/or deviated from the prescription, and thereby violated the Pharmacy Law; did acts constituting cause for discipline against a license; engaged in unprofessional conduct; violated statutes regulating controlled substances / dangerous drugs; and/or violated/attempted to violate, directly or indirectly, or assisted or abetted violation of, or conspired to violate, federal or state laws and regulations governing pharmacy.

THIRD CAUSE FOR DENIAL OF APPLICATION

(Improper Dispensing Pursuant to Internet Prescriptions)

30. Respondent's application is subject to denial under the following section(s) of the Code and applicable regulations: 4067 and/or California Code of Regulations, title 16, section 1761; 480(a)(3) by reference to 4301(j), (o), 4067 and/or California Code of Regulations, title 16, section 1761; or 4300(c) by reference to 4301(j), (o), 4067 and/or California Code of Regulations, title 16, section 1761; in that Respondent, as described in paragraph 25 above, dispensed and/or transacted one or more prescriptions via the Internet and/or without a prescription issued pursuant to a good faith prior examination and/or the prescriptions contained a significant error, omission, irregularity, uncertainty, ambiguity or alteration and/or there was reason to know they were not issued for a legitimate medical purpose, and thereby violated the Pharmacy Law; did acts constituting cause for discipline against a license; engaged in unprofessional conduct; violated statutes regulating controlled substances / dangerous drugs; and/or violated/attempted to violate, directly or indirectly, or assisted or abetted violation of, or conspired to violate, federal or state laws and regulations governing pharmacy.

FOURTH CAUSE FOR DENIAL OF APPLICATION

(Unlicensed Wholesaling)

31. Respondent's application is subject to denial under the following section(s) of the Code: 4160 and/or 4161; 480(a)(3) by reference to 4301(j), (o), 4160 and/or 4161; 4300(c) by reference to 4301(j), (o), 4161 and/or 4161; in that Respondent, as described in paragraph(s) 26 and/or 27 above, acted as a wholesaler without a wholesaler or nonresident wholesaler license, and thereby violated the Pharmacy Law; did acts constituting cause for discipline against a license; engaged in unprofessional conduct; violated statutes regulating controlled substances / dangerous drugs; and/or violated/attempted to violate, directly or indirectly, or assisted or abetted violation of, or conspired to violate, federal or state laws and regulations governing pharmacy.

FIFTH CAUSE FOR DENIAL OF APPLICATION

(Dishonesty, Fraud, Deceit, or Corruption)

32. Respondent's application is subject to denial under the following section(s) of the Code: 480(a)(2); 4301(f); 480(a)(3) by reference to 4301(f), (j), and/or (o); or 4300(c) by reference to 4301(f), (j), and/or (o); in that Respondent, by the conduct described in paragraphs 23 to 31, did acts involving dishonesty, fraud or deceit with intent to substantially benefit itself or another, or substantially injure another; did acts involving moral turpitude, dishonesty, fraud, deceit, or corruption; did acts constituting causes for discipline against a license; engaged in unprofessional conduct; violated statutes regulating controlled substances and dangerous drugs; and/or violated/attempted to violate, directly or indirectly, assisted/abetted violation of, or conspired to violate, federal or state laws and regulations governing pharmacy.

SIXTH CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct)

33. Respondent's application is subject to denial under the following section(s) of the Code: 4300(c); 480(a)(3) by reference to 4301; and/or 4300(c) by reference to 4301, in that Respondent, by the conduct described in paragraphs 23 to 32, engaged in unprofessional conduct.

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OTHER CONSIDERATIONS

34. As additional consideration(s) in determining whether Respondent's application is subject to denial, Complainant further alleges the following:

a. Section 4111 of the Code prohibits issuance or renewal of a license to conduct a pharmacy to a person or persons authorized to prescribe or write a prescription in California, to any person or persons sharing a community or other financial interest with such prescriber, or to any corporation controlled by, or in which 10% or more of the stock is owned by, a prescriber or any person with a community or other financial interest in common with such a prescriber;

b. Dr. Ritu Ghumman, D.V.M., License No. 14261, is a veterinarian licensed by the California Veterinary Medical Board. Her license is in inactive status, and therefore she may not practice veterinary medicine in California at this time.

c. Dr. Mandeep Ghumman, D.V.M., License No. 12996, is a veterinarian licensed by the California Veterinary Medical Board. His license is active and unrestricted at this time.

d. Mandeep Ghumman and Ritu Ghumman are husband and wife.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Denying the Community Pharmacy Permit Application received from EntirelyPets Pharmacy, listing its parent entity as EntirelyPets Pharmacy, LLC, owned 90.1% by Ritu Ghumman and 9.9% by HealthyPets, Inc., where HealthyPets, Inc. is in turn owned 50% by Dr. Ritu Ghumman, D.V.M. and 50% by Dr. Mandeep Ghumman, D.V.M. (Respondent);

2. Taking such other and further action as is deemed necessary and proper.

DATED: 5/31/12

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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CITATION AND FINE
CI 2009 41054

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2009 41054	EntirelyPets.com, Unlicensed

JURISDICTION: Bus. & Prof. Code § 4005; CCR, title 16, § 1775;

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4110 subd. (a)/Bus. & Prof. Code § 4112 subd. (a) & (b)	No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board/Nonresident pharmacy: Registration required/All nonresident pharmacies shall register with the board...	$3,000.00
CCR, Title 16, § 1716/Bus. & Prof. Code § 4077 subd. (a)/Bus. & Prof. Code § 4076 subd. (a)(1)(2)(6)	Variation from prescription/Dispensing dangerous drugs in an incorrectly labeled container/Prescription Container - Requirements for Labeling; Container must meet requirements of law with proper labeling, Drug name or active ingredients; Directions for use; Name and address of pharmacy, and prescription number	$2,000.00

CONDUCT:

Unlicensed Activity: Business and Professions Code section 4110 subd. (a) said no person shall conduct a pharmacy in the state of California unless he or she has obtained a license from the Board and Business and Professions Code section 4112 subd. (a) said any pharmacy located outside of this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy and 4112 subd. (b) said all nonresident pharmacies shall register with the Board. EntirelyPets.com was not in compliance with the laws. Specifically, on 5/15/2009 EntirelyPets.com located at an unknown address, using Postal Mail Box #384 at 710 South 13th Street, Suite 900, in Norfolk, NE 68701 and product returns address 43450 Mintwood Street in Fremont, CA 94538, and which was part of HealthyPets Inc. located at 34501 Seventh Street in Union City, CA 94587, mailed RX 6205953, a prescription for Metacam 1.5mg/ml, to a California customer using the pharmacy name Pet Pharmacy Plus, when neither EntirelyPets.com nor Pet Pharmacy Plus were licensed as a California pharmacy or a California nonresident pharmacy. This was a violation of pharmacy law.

Medication Error: California Code of Regulations section 1716 prohibited the variation from a prescription without prescriber authorization and Business and Professions Code section 4077 subd. (a) required a prescription to be dispensed in a container labeled with the information required in Business and Professions Code section 4076 subd. (a)(1) the name of the prescriber, (2) the directions for use, and (6) the name and address of the pharmacy. EntirelyPets.com was not in compliance with the laws. Specifically, on 5/15/2009 EntirelyPets.com located at an unknown address, using Postal Mail Box #384 at 710 South 13th Street, Suite 900, in Norfolk, NE 68701 and product returns address 43450 Mintwood Street in Fremont, CA 94538, and which was part of HealthyPets Inc. located at 34501 Seventh Street in Union City, CA 94587, dispensed RX 6205953 for Armstrong feline as Metacam 1.5mg/ml instead of the prescribed Metacam .5mg/ml using pharmacy name Pet Pharmacy Plus. Furthermore, the directions for use on the label said to "use as directed by your veterinarian" instead of the prescribed "eight pound dose by mouth once daily." Also, the prescriber name was missing, and the correct name and address of the pharmacy was missing. This was a violation of pharmacy law.

CITATION ISSUED ON: November 18, 2010	TOTAL AMOUNT OF FINE(S): $5,000.00
PAYMENT OF FINE(S) DUE BY: December 18, 2010	

CITATION AND FINE
CI 2009 42223

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2009 42223	Entirely Pets.com DBA Pet Pharmacy Plus, Unlicensed

JURISDICTION: Bus. & Prof. Code § 4005; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4110 subd. (a)/Bus. & Prof. Code § 4112 subd. (a) & (b)	No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board/Nonresident pharmacy: Registration required/All nonresident pharmacies shall register with the board...	$5,000.00
Bus. & Prof. Code § 4067 subd. (a)	No person shall dispense or furnish, or cause to be furnished dangerous drugs...on the internet...without a prescription issued pursuant to a good faith examination	$50,000.00

CONDUCT:

Unlicensed Activity: Business and Professions Code section 4110(a) said no person shall conduct a pharmacy in the state of California unless he or she has obtained a license from the Board and Business and Professions Code section 4112(a) said any pharmacy located outside of this state that ships, mails, or delivers, in any manner, controlled substances, dangerous drugs, or dangerous devices into this state shall be considered a nonresident pharmacy and 4112(b) said all nonresident pharmacies shall register with the Board. EntirelyPets.com was not in compliance with the laws. Specifically, on 7/29/2009 and 7/30/2009 EntirelyPets.com located at 34501 Seventh Street in Union City, CA 94587, using Postal Mail Box #384 at 710 South 13th Street, Suite 900, in Norfolk, NE 68701 and a product return address 43450 Mintwood Street in Fremont, CA 94538 shipped RX 6227029, Soloxine .1mg, and RX 6227612, Soloxine .8mg, to a California customer, SA, using the pharmacy name Pet Pharmacy Plus, when neither EntirelyPets.com nor Pet Pharmacy Plus were licensed as a California pharmacy or a California nonresident pharmacy. This was a violation of pharmacy law.

CITATION AND FINE
CI 2011 49563

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No.
CI 2011 49563	Healthy Pets Inc., Unlicensed

JURISDICTION: Bus. & Prof. Code § 4005; CCR, title 16, § 1775; Bus. & Prof. Code § 4314, subd. (1), 148		
VIOLATION CODE SECTION	**OFFENSE**	**AMOUNT OF FINE**
Bus. & Prof. Code § 4043 subd (a)/Bus. & Prof. Code § 4160 subd. (a)	**Wholesaler means and includes every person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, or agent who sells, negotiates for distribution or takes possession of**	**$5,000.00**

CONDUCT:

Unlicensed Wholesaler. Business and Professions Code section 4043(a) defines a wholesaler to include a person who acts as a wholesale merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for resale, or negotiates for distribution, or takes possession of, any drug or device included in section 4022 and Business and Professions Code section 4160(a) states a person may not act as a wholesaler of any dangerous drug unless licensed by the Board. Healthy Pets Inc. was non-compliant. Specifically, from on or about 2/24/10 to on or about 3/4/10, Healthy Pets Inc., an unlicensed wholesaler located at 43500 Mintwood St., Fremont, CA 94538, sold dangerous drugs to Pet Meds N More, Inc., located in Los Angeles, CA without first obtaining a license from the Board. This was a violation of pharmacy law.

Wholesaler	Date	Amount	Sold To	Ship To Name	Ship To Address
Healthy Pets Inc.	2/24/10	$8,534.63	Pet Meds N More, Inc.	Pet Meds N More, Inc.	11901 Santa Monica Blvd. #429, Los Angeles
Healthy Pets Inc.	3/4/10	$19,678.82	Pet Meds N More, Inc.	Pet Meds N More, Inc.	11901 Santa Monica Blvd. #429, Los Angeles

CITATION ISSUED ON: December 7, 2011 — TOTAL AMOUNT OF FINE(S): $5,000.00

PAYMENT OF FINE(S) DUE BY: January 6, 2012

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No.
CI 2011 49569	Entirelypets.com, Unlicensed

JURISDICTION: Bus. & Prof. Code § 4005; CCR, title 16, § 1775; Bus. & Prof. Code § 4314, subd. (1), 148		
VIOLATION CODE SECTION	**OFFENSE**	**AMOUNT OF FINE**
Bus. & Prof. Code § 4161 subd. (a) & (b)	**Nonresident Wholesaler Requirements/License required**	**$5,000.00**

CONDUCT:

Unlicensed Nonresident Wholesaler. Business and Professions Code section 4161(a) states a person located outside of this state that (1) ships, sells, mails, or delivers dangerous drugs into this state or (2) sells, brokers, or distributes dangerous drugs within this state shall be considered a nonresident wholesaler and Business and Professions Code 4161 (b) states a nonresident wholesaler shall be licensed by the Board prior to shipping, selling, mailing, or delivering dangerous drugs to a site located in this state or selling, brokering, or distributing dangerous drugs within this state. Entirelypets.com was non-compliant. Specifically, from on or about 9/25/09 to on or about 10/27/09, entirelypets.com, an unlicensed wholesaler located at 710 S. 13th St. #900, PMB 384, Norfolk, NE 68701, sold dangerous drugs to Pet Meds N More, Inc., located in Los Angeles, CA without first obtaining a license from the Board. This was a violation of pharmacy law.

Wholesaler	Date	Amount	Sold To	Ship To Name	Ship To Address
Entirelypets.com	9/25/09	$2,120.40	Pet Meds N More, Inc.	Pet Meds N More, Inc.	11901 Santa Monica Blvd. #429, Los Angeles
Entirelypets.com	10/19/09	$3,927.08	Pet Meds N More, Inc.	Pet Meds N More, Inc.	11901 Santa Monica Blvd. #429, Los Angeles
Entirelypets.com	10/27/09	$2,705.30	Pet Meds N More, Inc.	Pet Meds N More, Inc.	11901 Santa Monica Blvd. #429, Los Angeles

CITATION ISSUED ON: December 7, 2011 | TOTAL AMOUNT OF FINE(S): $5,000.00

PAYMENT OF FINE(S) DUE BY: January 6, 2012

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219 Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

Inspection Report I.R.

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 12/18/2012 Inspector: Ijeoma Eleazu

Firm: ENTIRELY PETS PHARMACY Phone: (800) 738-7209

Address: 34571 7TH STREET City: UNION CITY Zip: 94587

Ownership: CORPORATION

Permit #: PHY50832 Permit Exp: DEA#: DEA Exp:

Date of Self Assessment Form: Other Permit #: N/A Date of DEA Inventory:

Hours M-F: 9AM-5PM Hours Saturday CLOSED Hours Sunday: CLOSED

PIC RASHMI SHINGARI RPH50133 Administrator

RPH Consultant

Staff RPH Name:	License #:	Staff Name:	License #:
		BOBBY S RAI	TCH123637
		RITU GHUMANN, DVM	OWNER

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219 Sacramento, CA 95834
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR

INSPECTION REPORT

Inspector Remarks:
New pharmacy inspection. This is a closed-door, mail-order pharmacy that will be servicing animals only. Currently do not plan to do any compoudning at this point in time.

Compounding - Mark an X in the parentheses of each that applies:
(x) No; ( )Yes; ( ) In CA; ( ) Out of State

( ) Per Rx ( ) For PHY Future dispensing; ( ) Doctor administration i.e. for MD offcie use ( ) Doctor dispensing

( ) Sterile to Sterile Inj. ( ) Nonsterile to sterile Inj.

Nonsterile products:
( ) Tabs/Caps/Supp/liquids; ( ) Cream/Ointments/Lotions; ( ) Other:

Sterile products:
( ) Eye drops/Ear drops; ( ) Inhalation products ( ) Other:

Pharmacy dispensing (rxs/month):
(x) <25; ( ) 25 to 50; ( ) 50 to 100; ( ) > 100

For Doctor Office Use (units/month):
( ) <25; ( ) 25 to 50; ( ) 50 to 100; ( ) > 100

is reviewed:
The following were reviewed: NTC (provided new NTC to Owner Ghumann), H/C water, pharmacy security, purchase inventory from MWI Veterinary Supply Inc. and Animal Health International, both companies will also serve as the reverse distributors.

QA for med errors:
*QA for med errors not yet in place; reviewed requirements with Owner Ghumann

Patient Centered Labeling/Interpretive Services:
*Reviewed labeling and interpretive services requirements with Owner Ghumann

CURES: no controlled substance dispensing will be done per Owner Ghumann

The following were discussed: (delete if not applicable)
*PIC should complete the Pharmacy Self-Assessment within 30 days
*Reviewed with Owner Ghumann, alll P&Ps that PIC Shingari will need to draft and keep a record of in the pharamcy.

Licensee Remarks:

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219 Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR

INSPECTION REPORT

I have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) _____

Inspector (sign) _____

Inspector (print) IJEOMA ELEAZU

Owner(sign) Ritu K Ghumman

Owner(print) Ritu K Ghumman

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

Fax to Inspector Eleazu at 510-881-0647 Email to Ijeoma.Eleazu@dca.ca.gov

State of California
Secretary of State

LIMITED LIABILITY COMPANY CERTIFICATE OF AMENDMENT

A $30.00 filing fee must accompany this form.

IMPORTANT – Read instructions before completing this form.

ENDORSED - FILED
in the office of the Secretary of State
of the State of California

SEP 2 1 2011

This Space For Filing Use Only

1. SECRETARY OF STATE FILE NUMBER: **201124110110**
2. NAME OF LIMITED LIABILITY COMPANY: Healthy Pets Pharmacy, LLC

3. COMPLETE ONLY THE SECTIONS WHERE INFORMATION IS BEING CHANGED. ADDITIONAL PAGES MAY BE ATTACHED IF NECESSARY.

A. LIMITED LIABILITY COMPANY NAME (END THE NAME WITH THE WORDS "LIMITED LIABILITY COMPANY," "LTD. LIABILITY CO." OR THE ABBREVIATIONS "LLC" OR "L.L.C.")

Entirely Pets Pharmacy, LLC

B. THE LIMITED LIABILITY COMPANY WILL BE MANAGED BY (CHECK ONE):

- ☐ ONE MANAGER
- ☐ MORE THAN ONE MANAGER
- ☐ ALL LIMITED LIABILITY COMPANY MEMBER(S)

C. AMENDMENT TO TEXT OF THE ARTICLES OF ORGANIZATION:

D. OTHER MATTERS TO BE INCLUDED IN THIS CERTIFICATE MAY BE SET FORTH ON SEPARATE ATTACHED PAGES AND ARE MADE A PART OF THIS CERTIFICATE. OTHER MATTERS MAY INCLUDE A CHANGE IN THE LATEST DATE ON WHICH THE LIMITED LIABILITY COMPANY IS TO DISSOLVE OR ANY CHANGE IN THE EVENTS THAT WILL CAUSE THE DISSOLUTION.

4. FUTURE EFFECTIVE DATE, IF ANY: MONTH DAY YEAR

5. NUMBER OF PAGES ATTACHED, IF ANY:

6. IT IS HEREBY DECLARED THAT I AM THE PERSON WHO EXECUTED THIS INSTRUMENT, WHICH EXECUTION IS MY ACT AND DEED.

Ritu G. Ghumman — 9/20/11

SIGNATURE OF AUTHORIZED PERSON — DATE

Ritu Ghumman, Manager

TYPE OR PRINT NAME AND TITLE OF AUTHORIZED PERSON

7. RETURN TO:

NAME Roger Royse
FIRM Royse Law Firm, PC
ADDRESS 1717 Embarcadero Road
CITY/STATE Palo Alto, CA
ZIP CODE 94303

SEC/STATE FORM LLC-2 (Rev. 03/2005) – FILING FEE $30.00 — APPROVED BY SECRETARY OF STATE

I hereby certify that the foregoing transcript of 1 page(s) is a full, true and correct copy of the original record in the custody of the California Secretary of State's office.

OCT 10 2011

Date: _____

Debra Bowen

DEBRA BOWEN, Secretary of State

LLC-1

File # 201124110110

State of California
Secretary of State

Limited Liability Company
Articles of Organization

ENDORSED - FILED
In the office of the Secretary of State
of the State of California
AUG 29 2011

A $70.00 filing fee must accompany this form.

Important – Read instructions before completing this form.

This Space For Filing Use Only

Entity Name (End the name with the words "Limited Liability Company," or the abbreviations "LLC" or "L.L.C." The words "Limited" and "Company" may be abbreviated to "Ltd." and "Co.," respectively.)

1. NAME OF LIMITED LIABILITY COMPANY
   Healthy Pets Pharmacy, LLC

Purpose (The following statement is required by statute and should not be altered.)

2. THE PURPOSE OF THE LIMITED LIABILITY COMPANY IS TO ENGAGE IN ANY LAWFUL ACT OR ACTIVITY FOR WHICH A LIMITED LIABILITY COMPANY MAY BE ORGANIZED UNDER THE BEVERLY-KILLEA LIMITED LIABILITY COMPANY ACT.

Initial Agent for Service of Process (If the agent is an individual, the agent must reside in California and both Items 3 and 4 must be completed. If the agent is a corporation, the agent must have on file with the California Secretary of State a certificate pursuant to California Corporations Code section 1505 and Item 3 must be completed (leave Item 4 blank).

3. NAME OF INITIAL AGENT FOR SERVICE OF PROCESS
   Roger Royse

4. IF AN INDIVIDUAL, ADDRESS OF INITIAL AGENT FOR SERVICE OF PROCESS IN CALIFORNIA

ADDRESS	CITY	STATE	ZIP CODE
1717 Embarcadero Road	Palo Alto	CA	94303

Management (Check only one)

5. THE LIMITED LIABILITY COMPANY WILL BE MANAGED BY:

- [x] ONE MANAGER
- [ ] MORE THAN ONE MANAGER
- [ ] ALL LIMITED LIABILITY COMPANY MEMBER(S)

Additional Information

6. ADDITIONAL INFORMATION SET FORTH ON THE ATTACHED PAGES, IF ANY, IS INCORPORATED HEREIN BY THIS REFERENCE AND MADE A PART OF THIS CERTIFICATE.

Execution

7. I DECLARE I AM THE PERSON WHO EXECUTED THIS INSTRUMENT, WHICH EXECUTION IS MY ACT AND DEED.

August 29, 2011
DATE

SIGNATURE OF ORGANIZER

Roger Royse
TYPE OR PRINT NAME OF ORGANIZER

I hereby certify that the foregoing transcript of 1 page(s) is a full, true and correct copy of the original record in the custody of the California Secretary of State's office.

AUG 29 2011

Date:

Debra Bowen

DEBRA BOWEN Secretary of State

OPERATING AGREEMENT
OF
ENTIRELYPETS PHARMACY, LLC

THIS OPERATING AGREEMENT (this "Agreement") is made and entered into as of October 7th, 2011, between and among the Manager(s), and the Persons who sign a counterpart to this Agreement (collectively, the "Members") for the purpose of providing for the organization and operation of EntirelyPets Pharmacy, LLC, a California limited liability company (the "Company")

NOW, THEREFORE, in consideration of the mutual promises and obligations set forth herein, and with the intent of being legally bound, the parties hereto hereby agree as follows:

ARTICLE I
DEFINED TERMS

The following capitalized terms shall have the respective meanings specified in this Article I. Capitalized terms not defined in this Agreement shall have the meaning specified in the Act.

"Act" means the Beverly-Killea Limited Liability Company Act, as amended from time to time, or any corresponding provision or provisions of any succeeding or successor law of the state of California.

"Adjusted Capital Account Deficit" means, with respect to any Interest Holder, the deficit balance, if any, in such Interest Holder's Capital Account as of the end of the relevant Fiscal Year, after giving effect to the following adjustments:

(i) Credit to such Capital Account any amounts which such Interest Holder is obligated to restore pursuant to any provision of this Agreement or is deemed obligated to restore pursuant to the penultimate sentences of Regulations Sections 1.704-2(g)(1) and 1.704-2(i)(5); and

(ii) Debit to such Capital Account the items described in Regulations Sections 1.704-1(b)(2)(ii)(d)(4), 1.704-1(b)(2)(ii)(d)(5), and 1.704-1(b)(2)(ii)(d)(6).

The foregoing definition of "Adjusted Capital Account Deficit" is intended to comply with the provisions of Regulations Section 1.704-1(b)(2)(ii)(d) and shall be interpreted consistently therewith.

"Affiliate" shall mean, for any Person, (a) any Person directly or indirectly controlling, controlled by or under common control with the Person, (b) any other Person owning or controlling 25% or more of the outstanding voting securities of the Person, (c) any officer, director, or member of the Person, or (d) if the person is an officer, director, or manager, any company for which the Person acts in any similar capacity.

"Agreement" means this Operating Agreement, as amended from time to time.

"Assignee" means a Person who has acquired an Economic Interest in the Company but is not a Member.

"Capital Account" means the account to be maintained by the Company for each Interest Holder in accordance with the following provisions:

(i) an Interest Holder's Capital Account shall be credited with the amount of money and the fair market value (as determined by the Manager(s) and the contributing Interest Holder) of any property contributed to the Company (net of liabilities secured by such property that the Company either assumes or to which such property is subject), the amount of any Company unsecured liabilities assumed by the Interest Holder, and the Interest Holder's distributive share of Profit and (to the extent required by the Regulations) any item in the nature of income or gain specially allocated to the Interest Holder pursuant to the provisions of Section 4.3; and

(ii) an Interest Holder's Capital Account shall be debited with the amount of money and the fair market value (as determined by the Manager(s) in his, her or their sole discretion) of any Company property distributed to the Interest Holder (net of liabilities secured by such distributed property that the Interest Holder either assumes or to which such property is subject), the amount of any unsecured liabilities of the Interest Holder assumed by the Company, and the Interest Holder's distributive share of Loss and (to the extent required by the Regulations) any item in the nature of expenses or losses specially allocated to the Interest Holder pursuant to the provisions of Section 4.3.

If any Interest is transferred pursuant to the terms of this Agreement, the transferee shall succeed to the Capital Account of the transferor to the extent the Capital Account is attributable to the transferred Interest. It is intended that the Capital Accounts of all Interest Holders shall be maintained in compliance with the provisions of Regulation Section 1.704-1(b), and all provisions of this Agreement relating to the maintenance of Capital Accounts shall be interpreted and applied in a manner consistent with that Regulation.

"Capital Proceeds" means the gross receipts received by the Company from any transaction not in the ordinary course of business which results in the Company's receipt of cash or other consideration other than Contributions, including, without limitation, proceeds of sales, exchanges, or other dispositions of property not in the ordinary course of business, financings, refinancings, condemnations, recoveries of damage awards, and insurance proceeds.

"Cash Available for Distribution" means all cash of the Company available after paying all ordinary and necessary expenses and expenditures of the Company, and after establishing reserves to meet current or reasonably expected obligations of the Company, other than Capital Proceeds.

"Certificate of Cancellation" means such certificate as is required to be filed with the Secretary of State in order to dissolve the Company.

"Code" means the Internal Revenue Code of 1986, as amended, or any corresponding provision of any succeeding revenue law.

"Company" means EntirelyPets Pharmacy, LLC, a California limited liability company.

"Company Address" means 34501 Seventh Street, Union City, CA 94587, or such other address as may be designated by the Manager(s) from time to time.

"Contribution" means the total amount of cash and the fair market value of any other assets contributed or deemed contributed to the Company by an Interest Holder in accordance with the Code, net of liabilities assumed or to which the assets are subject.

"Distribution" means a payment to an Interest Holder in its capacity as an Interest Holder.

"Economic Interest" means a Person's right to share in the income, gains, losses, deductions, credit, or similar items of, or to receive Distributions from, the Company, but does not include any other rights of a Member including, without limitation, the right to vote or to participate in management, or any right to information concerning the business and affairs of the Company.

"Fiscal Year" means the Company's taxable year, which shall be selected by the Manager(s), subject to the requirements and limitations of the Code.

"Interest" means a Member's rights in the Company, collectively, including the Member's Economic Interest, any right to vote or participate in management, and any right to information concerning the business and affairs of the Company.

"Interest Holder" means any Person who holds an Economic Interest, whether as a Member or as an Assignee of a Member. An Assignee of a Member shall have only the Economic Interest with respect to the Units acquired from the Member, and shall acquire such Units subject to all the terms, conditions and restrictions of this Agreement that are applicable to the transferring Member, including the restrictions set forth in Section 7.4 and the contribution obligations under Section 4.1.3 to the extent that they relate to the Economic Interest transferred.

"Involuntary Withdrawal" shall mean, with respect to any Interest Holder, the occurrence of any of the following events:

(i) the Interest Holder makes an assignment for the benefit of creditors;

(ii) the Interest Holder files a voluntary petition of bankruptcy;

(iii) the Interest Holder is adjudged bankrupt or insolvent or there is entered against the Interest Holder an order for relief in any bankruptcy or insolvency proceeding;

(iv) the Interest Holder files a petition or answer seeking for the Interest Holder any reorganization, arrangement, composition, readjustment, liquidation, dissolution, or similar relief under any statute, law, or regulation;

(v) the Interest Holder seeks, consents to, or acquiesces in the appointment of a trustee, receiver, or liquidator of the Interest Holder or of all or any substantial part of the Interest Holder's properties;

(vi) if the Interest Holder is an individual, the Interest Holder's death or adjudication by a court of competent jurisdiction as incompetent to manage the Interest Holder's person or property;

(vii) if the Interest Holder is acting as an Interest Holder by virtue of being a trustee of a trust, the termination of the trust;

(viii) if the Interest Holder is a partnership or another limited liability company, the dissolution and commencement of winding up of the partnership or limited liability company;

(ix) if the Interest Holder is a corporation, the dissolution of the corporation or the revocation of its charter; or

(x) if the Interest Holder is an estate, the distribution by the fiduciary of the estate's entire interest in the Company.

"Majority Vote" or "Majority of the Members" means the vote or consent of the Members holding a majority of the issued and outstanding Units held by all Members.

"Manager(s)" means the Person(s) designated as such in this Agreement.

"Member" means each Person signing this Agreement and any Person who subsequently is admitted as a member of the Company in accordance with the terms of this Agreement.

"Member Nonrecourse Debt" has the meaning set forth in Regulation Section 1.704-2(b)(4) with respect to "partner nonrecourse debt," substituting the word "member" for "partner" and "company" for "partnership" wherever they appear.

"Member Nonrecourse Debt Minimum Gain" means an amount, with respect to each Member Nonrecourse Debt, equal to the Company Minimum Gain that would result if such Member Nonrecourse Debt were treated as a Nonrecourse Liability, determined in accordance with Regulation Section 1.704-2(i)(3).

"Member Nonrecourse Deductions" has the meaning set forth in Regulation Sections 1.704-2(i)(1) and 1.704-2(i)(2) with respect to "partner nonrecourse deductions," substituting the word "member" for "partner" and "company" for "partnership" wherever they appear.

"Minimum Gain" has the meaning set forth in Regulation Section 1.704-2(d). Minimum Gain shall be computed separately for each Interest Holder in a manner consistent with the Regulations under Code Section 704(b).

"Negative Capital Account" means a Capital Account with a balance of less than zero.

"Nonrecourse Deductions" has the meaning set forth in Regulation Section 1.704-2(b)(1). The amount of Nonrecourse Deductions for a taxable year of the Company equals the net increase, if any, in the amount of Minimum Gain during that taxable year, determined according to the provisions of Regulation Section 1.704-2(c).

"Nonrecourse Liability" has the meaning set forth in Regulation Section 1.704-2(b)(3).

"Organizing Documents" means the Articles of Organization filed with the Secretary of State.

"Percentage" means, as to each Interest Holder, the ratio that the number of Units held by the Interest Holder bears to the number of all the issued and outstanding Units held by all Interest Holders.

"Permitted Transfer" shall mean a voluntary lifetime Transfer of an Interest by any individual Interest Holder to the following "Permitted Transferee:" (i) such Interest Holder's spouse, children or grandchildren, or any combination thereof (the "Family"), (ii) a trust for the benefit of such Interest Holder or his or her Family, or (iii) a limited partnership or limited liability company in which all the beneficial interests are owned by the Interest Holder and his or her Family, provided such Interest Holder is the trustee, general partner or manager of such transferee. No Transfer shall be deemed to be a Permitted Transfer unless and until all Conditions of Transfer specified in Section 6.1 have been satisfied.

"Person" means and includes an individual, corporation, partnership, association, limited liability company, trust, estate, or other entity.

"Positive Capital Account" means a Capital Account with a balance greater than zero.

"Preferred County" means the county of the Company Address.

"Profit" and "Loss" means, for each taxable year of the Company (or other period for which Profit or Loss must be computed), the net income and net loss, respectively, of the Company (determined by including all items that adjust Capital Accounts pursuant to Regulation Section 1.704-1(b)(2)(iv)) determined strictly in accordance with federal income tax principles (including rules governing depreciation and amortization), except that in computing net income or net loss, the 'book' value of an asset (determined in accordance with the principles of Regulation Section 1.704-1(b)(2)(iv)) will be substituted for its adjusted tax basis if the two differ, and these items shall be excluded from the computation of: (i) any gain, income, deductions or losses specially allocated under the minimum gain chargeback, the partner

minimum gain chargeback, or the qualified income offset, (ii) any nonrecourse deductions, (iii) any partner nonrecourse deductions, and (iv) any specially allocated items under Section 4.3.

"Regulation" means the income tax regulations, including any temporary regulations, from time to time promulgated under the Code.

"Schedule of Members" means Exhibit A of this Agreement, which shall be maintained by the Manager(s) and updated from time to time to reflect the admission of new Members. The Schedule of Members shall state each Member's name and address, Contribution, date of admission, number of Units, and any vesting terms.

"Secretary of State" means the Secretary of State of the State of Organization.

"State of Organization" means California.

"Tax Matters Partner" means Ritu Ghumman.

"Total Number of Authorized Units" means 1,000,000 Units of the Company.

"Transfer" means, when used as a noun, any sale, hypothecation, pledge, assignment, attachment, or other transfer, and, when used as a verb, to sell, hypothecate, pledge, assign, or otherwise transfer.

"Units" mean the Interests to be issued or granted by the Company in accordance with this Agreement. Units shall have the rights and be subject to the restrictions set forth in this Agreement. The Total Number of Authorized Units shall be authorized for issuance by the Manager(s).

"Voluntary Withdrawal" means an Interest Holder's dissociation with the Company by means other than by a Transfer in compliance with this Agreement or an Involuntary Withdrawal.

ARTICLE II
FORMATION AND NAME; OFFICE; PURPOSE; TERM

2.1. Organization. The parties have organized a limited liability company pursuant to the Act and the provisions of this Agreement and have caused the Organizing Documents to be prepared, executed, and filed with the Secretary of State. The Members hereby authorize and ratify the filing of the Organizing Documents.

2.2. Name of the Company. The name of the Company is EntirelyPets Pharmacy, LLC. The Company may do business under that name and under any other name or names upon which the Manager(s) select in his, her or their discretion. If the Company does business under a name other than that set forth in the Organizing Documents, then the Company shall file a fictitious name statement or any other documents as required by applicable law.

2.3. Purpose. The Company is formed for the object and purpose of, and the nature of the business to be conducted and promoted by the Company is, to engage in any lawful act or activity for which limited liability companies may be formed under the Act.

2.4. Term. The term of the Company shall begin upon the acceptance of the Organizing Documents by the office of the Secretary of State and shall continue in existence until its existence is terminated pursuant to Article VII of this Agreement.

2.5. Principal Place of Business. The Company's Principal Place of Business shall be located at the Company Address, or at such other location as the Manager(s) may determine from time to time. The Company may also have such offices, anywhere within or without the State of Organization, as the Manager(s) may determine from time to time.

ARTICLE III
MEMBERS; CAPITAL; CAPITAL ACCOUNTS

3.1. Contributions. Promptly upon the execution of this Agreement, the Members, excluding any Members who have been or are granted Units as profits interests, shall contribute, or have contributed, as Contributions, cash and/or property set forth on Exhibit A, and as set forth in any Contribution and Assignment Agreement entered into by and between the Company and such Member, if any, which Contribution and Assignment Agreement shall be attached to this Agreement.

3.2. No Additional Contributions. An Interest Holder may not contribute additional capital to the Company unless the Interest Holder purchases additional Units, with the consent of the Manager(s). No Interest Holder shall have personal liability for any obligation of the Company except as expressly provided by law. In lieu of accepting additional contributions from the Interest Holders, the Manager(s), in his, her or their sole and absolute discretion, may cause the Company to borrow funds to satisfy its cash requirements. Any such borrowing may be made from any third party, or from any Interest Holder, subject to Section 3.6 below.

3.3. No Interest on Contributions. Interest Holders shall not be paid interest on their Contributions or Capital Account balance.

3.4. Return of Contributions. Except as otherwise provided in this Agreement, no Interest Holder shall have the right to receive the return of any Contribution or withdraw from the Company.

3.5. Capital Accounts. A separate Capital Account shall be maintained for each Interest Holder.

3.6. Loans and Other Business Transactions. Any Interest Holder may, at any time, make or cause a loan to be made to the Company in any amount and on those terms which have been approved or ratified by a Majority Vote. Interest Holders may, with the consent of a Majority of the Members, transact other business with the Company and, in doing so, they shall have the same rights and be subject to the same obligations arising out of any such business

transaction as would be enjoyed by and imposed upon any Person, not an Interest Holder, engaged in a similar business transaction with the Company.

3.7. Matters Pertaining to Profits Interests. The Manager(s) are hereby authorized and directed to elect the "safe harbor" valuation method embodied in Proposed Regulation Section 1.83-3(l) (the "Safe Harbor"). The Company and each Member (including any Persons to whom an Interest is transferred in connection with the provision of services, and any Person to whom an Interest is transferred by another Member) agree to comply with all requirements of the Safe Harbor while such election remains in effect, including making tax filings (if any) consistent with the applicable requirements of such Safe Harbor and any relevant Regulations. By executing this Agreement, each Member expressly authorizes and directs the Manager(s) to take any and all action which is reasonably necessary under applicable federal income tax law (as such law may be revised from time to time) to cause the "liquidation value" methodology to apply to the valuation for federal income tax purposes of interests in the Company transferred in connection with the performance of services, and acknowledges and agrees that the provisions of this Section 3.7 are legally binding on such party, and that such provisions will survive such party ceasing to be a Member of the Company and/or the termination of the Company.

ARTICLE IV
PROFIT, LOSS, AND DISTRIBUTIONS

4.1 Distributions.

4.1.1. Distributions of Cash Available for Distribution. The Company shall distribute Cash Available for Distribution, at such times and in such amounts as shall be determined by the Manager(s), to the Interest Holders, pro rata in accordance with their Percentages.

4.1.2. Distributions of Capital Proceeds. The Company shall distribute Capital Proceeds, at such times and in such amounts as shall be determined by the Manager(s), in the following order and priority:

(a) First, to the payment of all expenses of the Company incident to the Capital Transaction giving rise to such Capital Proceeds;

(b) Then, to the payment of debts and liabilities of the Company then due and outstanding (including all debts due to any Interest Holder);

(c) Then, to the establishment of any reserves which the Manager(s) deem(s) necessary for liabilities or obligations of the Company; and

(d) Then, to the Interest Holders in accordance with Section 4.1.1, as if the amounts so distributed were a distribution of Cash Available for Distribution.

4.1.3. Tax Payment Distributions. Notwithstanding the provisions of Sections 4.1.1 and 4.1.2, unless the Manager(s) shall otherwise determine, the Company shall distribute

annually to each Interest Holder, no later than ninety (90) days after the close of each calendar year, an amount of Cash Available for Distribution, if any, equal to the estimated tax liability, as determined by the Manager(s) in his, her or their sole discretion, resulting from the income of the Company allocable to that Interest Holder and treated as realized by that Interest Holder for U.S. tax purposes for that year. All sums distributed to an Interest Holder pursuant to this Section 4.1.3 shall be credited against Distributions otherwise payable to such Interest Holder pursuant to Sections 4.1.1 and 4.1.2. If, following the dissolution, winding up and termination of the Company and the distribution of all or substantially all of the Company's assets pursuant to Section 4.4.2, (i) the aggregate amount received by any Interest Holder pursuant to this Section 4.1.3 exceeds (ii) the aggregate amount to which such Interest Holder is entitled for all Fiscal Years pursuant to Section 4.1.1 and 4.1.2, then such Interest Holder shall contribute to the Company an amount equal to the excess of the amount set forth in clause (i) above over the amount set forth in clause (ii) above.

4.2. Allocation of Profit and Loss. The rules set forth below in this Section 4.2 shall apply for the purpose of determining each Interest Holder's allocable share of the items of income, gain, loss and expense of the Company comprising Profit or Loss of the Company for each Fiscal Year, determining special allocations of other items of income, gain, loss and expense, and adjusting the balance of each Interest Holder's Capital Account to reflect the aforementioned general and special allocations.

4.2.1. In General. As of the end of each Fiscal Year of the Company and after giving effect to the special allocations set forth in the other provisions of this Article IV, the income and gain of the Company for such Fiscal Year shall be allocated to the Capital Accounts of the Interest Holders in the amounts and proportions necessary to ensure that, to the extent feasible, the balance of each Interest Holder's Capital Account at the end of any taxable year would be equal to the amount of cash that the Interest Holder would receive pursuant to this Agreement (or would be negative in the amount of cash that such Interest Holder would be required to contribute to the Company pursuant to this Agreement) if the Company sold all of its property for an amount of cash equal to the book value (as determined pursuant to Regulations Section 1.704-1(b)(2)(iv)) of such property, and all of the cash of the Company remaining after payment of all liabilities of the Company were distributed immediately following the end of such taxable year pursuant to this Agreement.

4.2.2. Adjustments. The Manager(s) may adjust such allocations for U.S. federal, state and local income tax purposes as may be necessary or desirable to maintain substantial economic effect, or to ensure that such allocations are in accordance with the interests of the Interest Holders in the Company, in each case within the meaning of the Code and Regulations.

4.2.3. Loss Limitation; Loss Allocation. Loss and expense of the Company shall be allocated to the Interest Holders pro rata in accordance with Positive Capital Account balances, until such balances are reduced to zero and thereafter in accordance with Percentages. Notwithstanding anything to the contrary in this Section 4.2, the amount of items of Company expense and loss allocated pursuant to this Section 4.2 to any Interest Holder shall not exceed the maximum amount of such items that can be so allocated without causing such Interest Holder to

have an Adjusted Capital Account Deficit at the end of any Fiscal Year. All such items in excess of the limitation set forth in this Section 4.2.3 shall be allocated first to Interest Holders who would not have an Adjusted Capital Account Deficit, pro rata in proportion to their Capital Account balances as adjusted in accordance with subdivisions (i) and (ii) of the definition of Adjusted Capital Account Deficit, until no Interest Holder would be entitled to any further allocation, and thereafter to all Interest Holders in accordance with their Percentages.

4.2.4. Transfers of Economic Interests. A Person who succeeds to an Interest Holder's Economic Interest shall be allocated the Profit or Loss with respect to the interest transferred. For any Fiscal Year during which any part of an Interest is Transferred between Interest Holders or to another Person, the portion of the Profit, Loss and other items of income, gain, loss, deduction and credit that are allocable with respect to such part of an Economic Interest shall be apportioned between the transferor and the transferee under any method allowed pursuant to Section 706 of the Code and the applicable Regulations as determined by the Manager(s).

4.2.5. Adjustments to Capital Accounts. In the event of: (i) the acquisition of an additional Interest by any Interest Holder in exchange for more than a de minimis contribution; (ii) the Distribution by the Company to an Interest Holder of more than a de minimis amount of property as consideration for an Interest; (iii) the liquidation of the Company within the meaning of Regulations Section 1.704-1(b)(2)(ii)(g); or (iv) the issuance of an Interest for services under Regulations Section 1.704-1(b)(2)(iv)(f)(5)(iii); the Capital Accounts of the Interest Holders shall first be adjusted to reflect the manner in which the unrealized income, gain, loss and deduction inherent in all of the Company's property (that has not been reflected in the Capital Account previously) would be allocated among the Interest Holders pursuant to Section 4.2 if there were a taxable disposition of such property at fair market value; provided, that the Manager(s) reasonably determine(s) that such adjustments are necessary or appropriate to reflect the relative economic interests of the Interest Holders.

4.3. Regulatory Allocations.

4.3.1. Impermissible Deficits and Qualified Income Offset. No Interest Holder shall be allocated Losses or deductions if the allocation causes the Interest Holder to have a Negative Capital Account, as adjusted as provided in Sections 1.704-1(b)(2)(ii), 1.704-2(g), and 1.704-2(i)(5) of the Regulations; instead, such items shall be allocated to the other Interest Holders in proportion to their Percentages. If an Interest Holder for any reason (whether or not expected) receives (1) an allocation of Loss or deduction (or item thereof) or (2) any Distribution (or reasonably expected Distribution), which causes the Interest Holder to have an Adjusted Capital Account Deficit at the end of any taxable year, then all items of income and gain of the Company (consisting of a pro rata portion of each item of Company income, including gross income and gain) for that taxable year shall be allocated to that Interest Holder, before any other allocation is made of Company items for that taxable year, in the amount and in proportions required to eliminate the excess as quickly as possible. This Section 4.3.1 is intended to comply with, and shall be interpreted consistently with, the "alternate test for economic effect" and "qualified income offset" provisions of the Regulations promulgated under Code Section 704(b).

4.3.2. Income Tax Provisions. The Interest Holders are aware of the income tax consequences of this Article IV and agree to be bound by these provisions in reporting their shares of Profit, Losses, and other items for federal and state income tax purposes. The Interest Holders acknowledge that if an Interest Holder makes a loan to the Company, or bears the risk of loss with respect to a Company debt, this Agreement must be amended to comply with applicable Regulations relating to the special allocation of Member Nonrecourse Deductions.

4.3.3. Guaranteed Payments. Any compensation which the Company pays to an Interest Holder for services rendered to the Company may be treated as a guaranteed payment under Code Section 707(c). To the extent any compensation paid to any Interest Holder by the Company, is determined by the Internal Revenue Service not to be a guaranteed payment under Code Section 707(c) or is not paid to the Interest Holder other than in the Person's capacity as an Interest Holder within the meaning of Code Section 707(a), the Interest Holder shall be specially allocated gross income of the Company in an amount equal to the amount of that compensation, and the Interest Holder's Capital Account shall be adjusted to reflect the payment of that compensation.

4.3.4. Contributed Property and Book-Ups. In accordance with Code Section 704(c) and the Regulations thereunder, including Regulation Section 1.704-l(b)(2)(iv)(d)(3), income, gain, loss, and deduction with respect to any property contributed (or deemed contributed) to the Company shall, solely for tax purposes, be allocated among the Interest Holders so as to take account of any variation between the adjusted basis of the property to the Company for federal income tax purposes and its fair market value at the date of contribution (or deemed contribution). If the adjusted book value of any Company asset is adjusted under Regulation Section 1.704-1(b)(2)(iv)(f), subsequent allocations of income, gain, loss, and deduction with respect to the asset shall take into account any variation between the adjusted basis of the asset for federal income tax purposes and its adjusted book value in the manner required under Code Section 704(c) and the Regulations thereunder. The parties hereto agree to use any method described in Regulation Section 1.704-3 for making Code Section 704(c) allocations as the Manager(s) may determine in his, her or their discretion.

4.3.5. Code Section 754 Adjustment. To the extent an adjustment to the tax basis of any Company Asset pursuant to Code Section 734(b) or Code Section 743(b) is required, pursuant to Regulation Section 1.704-1(b)(2)(iv)(m), to be taken into account in determining Capital Accounts, the amount of the adjustment to the Capital Accounts shall be treated as an item of gain (if the adjustment increases the basis of the asset) or loss (if the adjustment decreases basis), and the gain or loss shall be specially allocated to the Interest Holders in a manner consistent with the manner in which their Capital Accounts are required to be adjusted pursuant to that Section of the Regulations.

4.3.6. Minimum Gain Chargebacks. In order to comply with the "minimum gain chargeback" requirements of Regulation Sections 1.704-2(f)(1) and 1.704-2(i)(4), and notwithstanding any other provision of this Agreement to the contrary, in the event there is a net decrease in an Interest Holder's share of Minimum Gain and/or Member Nonrecourse Debt Minimum Gain during the Company's taxable year, such Interest Holder shall be allocated items of income and gain for that year (and if necessary, other years) as required by and in accordance

with Regulation Sections 1.704-2(f)(1) and 1.704-2(i)(4) before any other allocation is made. It is the intent of the parties hereto that any allocation pursuant to this Section 4.3.6 shall constitute a "minimum gain chargeback" under Regulation Section 1.704-2(f) and 1.704-2(i)(4).

4.3.7. Nonrecourse Liabilities. Solely for purposes of determining an Interest Holder's proportionate share of "excess nonrecourse liabilities" of the Company within the meaning of Regulation Section 1.752-3(a)(3), the Interest Holders' interest in Company profits shall be based on their respective Percentages.

4.3.8. Interpretation. The Profit and Loss allocation provisions of this Agreement shall be fairly interpreted to effect the intent of this Agreement and in the event of an ambiguity or dispute in the application of any provision hereof, the Interest Holders agree that the matter shall be submitted to the Company's accountant, whose determination on such matter shall be final. In the event that the Company's accountant is unable or unwilling to resolve the matter, the dispute shall be resolved under Section 9.11 below.

4.4. Liquidation and Dissolution.

4.4.1. After taking into account all Capital Account adjustments (including those set forth in Section 4.2.5) of the Company for the taxable year during which the liquidation occurs, upon liquidation of the Company, the assets of the Company shall be distributed to the Interest Holders as follows:

(a) First, to the payment of all expenses of the Company incident to the liquidation;

(b) Then, to the payment of debts and liabilities of the Company then due and outstanding (including all debts due to any Interest Holder);

(c) Then, to the establishment of any reserves which the Manager(s) deem necessary for liabilities or obligations of the Company;

(d) Then, to the Interest Holders in accordance with Positive Capital Account Balances until such balances are reduced to zero; and

(e) Then, to the Interest Holders in accordance with Section 4.1.1, as if the amounts so distributed were a distribution of Cash Available for Distribution.

4.4.2. Subject to Section 4.1.3, no Interest Holder shall be obligated to restore a Negative Capital Account.

4.4.3. The tax allocation provisions of this Agreement are intended to produce final Capital Account balances of the Interest Holders that will permit liquidating Distributions that are made under Section 4.4.1 to be equal to the Distributions that would occur if such Distributions were made to the Interest Holders in proportion to positive Capital Account balances, after giving effect to all Contributions, Distributions, and allocations for all periods, in

accordance with Regulation Section 1.704-1(b)(2)(ii)(b)(2). To the extent that the tax allocation provisions of this Agreement would not produce such final Capital Account balances, (1) such provisions shall be amended by the Manager(s) if and to the extent necessary to produce such result and (2) taxable income or taxable loss of the Company for prior open years (or items of gross income and deduction of the Company) shall be reallocated among the Interest Holders to the extent it is not possible to achieve such result with allocations of income (including gross income) and loss (or items of deduction for the current year and future years. This Section 4.4.3 shall control notwithstanding any reallocation or adjustment of taxable income, taxable loss, or items thereof by the Internal Revenue Service or any other taxing authority.

4.5. General.

4.5.1. If any assets of the Company are distributed in kind to the Interest Holders, those assets shall be valued on the basis of their fair market value, as determined in good faith by the Manager(s) in his, her or their sole discretion. The Profit or Loss for each unsold asset shall be determined as if the asset had been sold at its fair market value, and the Profit or Loss shall be allocated as provided in Section 4.2 and shall be properly credited or charged to the Capital Accounts of the Interest Holders prior to the Distribution of the assets in liquidation pursuant to Section 4.4.

4.5.2. All Profit and Loss shall be allocated and all Distributions shall be made to the Persons shown on the records of the Company to have been Interest Holders as of the last day of the taxable year for which the allocation or Distribution is to be made, subject to Section 4.2.4 above.

4.5.3. For purposes of determining the Profits, Losses, or any other items allocable to any period, Profits, Losses, and any such other items shall be determined on a daily, monthly, or other basis, as determined by the Manager(s) using any permissible method under Code Section 706 and the Regulations thereunder.

4.5.4. The Manager(s) are hereby authorized, upon the advice of the Company's tax counsel, to amend this Article IV to comply with the Code and the Regulations promulgated under Code Section 704(b); provided, however, that no amendment shall materially affect Distributions to an Interest Holder without the Interest Holder's prior written consent.

ARTICLE V
MANAGEMENT: RIGHTS, POWERS, AND DUTIES

5.1.1. Manager(s). The Company shall be managed by one or more Managers, each of whom may, but need not be a Member. Ritu Ghumman shall serve as the initial Manager(s) until his, her or their death, incapacity, disability, resignation or removal in accordance with the terms of this Agreement.

5.1.2. General Powers. A Manager does not have the authority to act without the approval of all Manager(s). The Manager(s) may exercise his, her or their discretion, power, or authority to act under this Agreement, subject in all cases to the other provisions of this

Agreement and the requirements of applicable law, to manage, control, administer, and operate the business and affairs of the Company for the purposes herein stated, and to make all decisions affecting such business and affairs, including without limitation, for Company purposes, the power to:

(a) Enter into agreements and contracts in connection with the Company's business;

(b) Execute any and all other instruments and documents which may be necessary or in the opinion of the Manager(s) desirable to carry out the intent and purpose of this Agreement;

(c) Make any and all expenditures which the Manager(s), in his, her or their discretion, deem(s) necessary or appropriate in connection with the management of the affairs of the Company and the carrying out of the obligations and responsibilities under this Agreement, including, without limitation, all legal, accounting, and other related expenses incurred in connection with the organization, financing, and operation of the Company;

(d) Enter into any kind of activity necessary to, in connection with, or incidental to, the accomplishment of the purposes of the Company;

(e) Engage in business in any jurisdiction which does not provide for the registration of limited liability companies;

(f) Elect to continue the Company following the withdrawal of an Interest Holder;

(g) [Reserved].

(h) Admit a Member to the Company;

(i) Borrow money and incur debts on behalf of the Company;

(j) Approve a Transfer pursuant to Section VI herein;

(k) Accept or assign an Offer pursuant to Section 6.1.3;

(l) Accept a Withdrawal Offer pursuant to Section 6.3; or

(m) Amend the Total Number of Authorized Units.

5.1.3. Actions Requiring Majority Vote. Notwithstanding Section 5.1.2. above, without the approval of a Majority Vote, the Manager(s) shall not:

(a) Declare bankruptcy, dissolve, voluntarily liquidate or wind up the Company's operations;

(b) Sell all or substantially all of the Company's assets or property;

(c) Merge with or into another Person;

(d) Unless otherwise provided herein, amend this Agreement pursuant to Section 9.12.

5.1.4. Limitation on Authority of Interest Holders.

(a) No Interest Holder is an agent of the Company solely by virtue of being an Interest Holder, and no Interest Holder has authority to act for the Company solely by virtue of being an Interest Holder.

(b) This Section 5.1 supersedes any authority granted to the Interest Holders pursuant to the Act. Any Interest Holder who takes any action or binds the Company in violation of this Section 5.1 shall be solely responsible for any loss and expense incurred by the Company as a result of the unauthorized action and shall indemnify and hold the Company harmless with respect to the loss or expense.

5.1.5. Removal of Manager(s). A Manager may be removed for Cause by a disinterested Majority Vote. "Cause" shall mean the commission of a felony involving dishonesty, or gross negligence or willful misconduct having a material adverse effect on the Company. Should a Manager be removed who is also an Interest Holder, such removal shall not affect the person's rights as an Interest Holder.

5.1.6. Resignation of Manager(s). A Manager may resign from his position as a Manager at any time by written notice to the Members. Such resignation shall become effective when such notice is received, unless a later effective date is specified in such notice.

5.1.7. Replacement of Manager(s). If a Manager either is removed, resigns, dies or becomes incapacitated or disabled, in accordance with the terms of this Article V, the Members may appoint a replacement Manager by a Majority Vote.

5.2. Meetings of and Voting by Members.

5.2.1. Meetings of the Members are not required, however, a meeting of the Members may be called at any time by the Manager(s) or by those Members holding at least a majority of the Percentages then held by Members. Meetings of Members shall be held at the Company's principal place of business or at any other place designated by the Person calling the meeting. Not less than ten (10) nor more than ninety (90) days before each meeting, the Person calling the meeting shall give written notice of the meeting to each Member entitled to vote at the meeting. The notice shall state the time, place, and purpose of the meeting. Notwithstanding the foregoing provisions, each Member who is entitled to notice waives notice if before or after the meeting, the Member signs a waiver of the notice which is filed with the records of Members' meetings, or if such Member is present at the meeting in person or by proxy. Unless this

Agreement provides otherwise, at a meeting of Members, the presence in person or by proxy of Members holding not less than a majority of the Percentages then held by Members constitutes a quorum. A Member may vote either in person or by written proxy signed by the Member or by his or her duly authorized attorney in fact.

5.2.2. Except as otherwise provided in this Agreement, whenever this Agreement requires the approval of the Members, the affirmative vote of Members holding a majority or more of the Percentages then held by Members shall be required to approve the matter.

5.2.3. In lieu of holding a meeting, the Members may vote or otherwise take action by a written instrument indicating the consent of Members holding the Percentage required to approve such action, as determined under this Agreement.

5.3. Personal Services.

5.3.1. No Member shall be required to perform services for the Company solely by virtue of being a Member. Unless approved by the Manager, no Interest Holder shall perform services for the Company or be entitled to compensation for services performed for the Company.

5.3.2. The Manager(s) shall be entitled to reimbursement for expenses reasonably incurred in connection with the activities of the Company.

5.4. Duties of Parties.

5.4.1. The Manager(s) shall devote such time to the business and affairs of the Company as is necessary to carry out his, her or their duties set forth in this Agreement. At the discretion of the Manager(s) and until such time as may be required, the Interest Holders shall not be required to devote such time to the business and affairs of the Company.

5.4.2. Each Interest Holder understands and acknowledges that the conduct of the Company's business may involve business dealings and undertakings with other Interest Holders. In any of those cases, those dealings and undertakings shall be at arm's length and on commercially reasonable terms as determined by the Manager(s).

5.5. Officers.

5.5.1. The Manager(s) may appoint officers (each an "Officer") from time to time. The same person may hold any two or more of such offices.

5.5.2. The term of office and salary of each Officer and the manner and time of the payment of such salaries shall be fixed and determined by the Manager(s) and may be altered by the Manager(s) from time to time at the pleasure of the Manager(s), subject to the rights, if any, of such Officers under any written contract of employment signed on behalf of the Company by an authorized person other than the employee under the Agreement.

5.5.3. Subject to any agreement between the Company and an Officer to the contrary, any Officer may be removed at the pleasure of the Manager(s) or at the pleasure of any other Officer who may be granted such power by the Manager. Any Officer may resign at any time upon written notice to the Company without prejudice to the rights, if any, of the Company under any contract to which the Officer is a party.

5.5.4. The Officers shall have only such authority as is expressly granted in writing by the Manager(s).

5.6. Liability and Indemnification.

5.6.1 Notwithstanding any other provision of this Agreement, whether express or implied, neither the Manager(s), any Affiliate of the Manager(s) nor any officer, director, manager, shareholder, member, partner, employee, agent or representative of an Affiliate (each a "Related Person"), shall be liable to the Company or any Interest Holder or any agent or Affiliate of any Interest Holder for any act or omission taken or omitted in good faith by the Manager(s) or such Related Person, unless and then only to the extent that such act or omission constituted fraud, gross negligence or willful and material breach of this Agreement. To the extent permitted by applicable law, the Company and the Interest Holders waive any and all rights any of them may have to recover punitive damages from the Company, the Manager(s), and all Related Persons. To the extent that, at law or in equity, the Manager(s) or any Related Person has duties (including fiduciary duties) and liabilities relating thereto to the Company or to an Interest Holder, the Manager(s) acting under this Agreement and any Related Person acting in connection with the Company's business or affairs shall not be liable to the Company or to any such Interest Holder for his, her or their good faith reliance on the provisions of this Agreement. The provisions of this Agreement, to the extent that they restrict the duties and liabilities of the Manager(s) otherwise existing at law or in equity, are agreed by the Interest Holders to replace such other duties and liabilities of the Manager(s).

5.6.2. To the fullest extent permitted by law, the Company shall indemnify the Manager(s) and Related Persons (each, an "Indemnitee") against any loss, liability, damage, settlement, cost, or other expense, including reasonable attorneys' fees in connection therewith (each a "Loss"), to which any such Indemnitee may directly or indirectly become subject by reason of any acts or omissions or any alleged acts or omissions arising out of such Indemnitee's or any other Indemnitee's activities in connection with the Company; provided, that an Indemnitee shall be entitled to indemnification hereunder only to the extent that such Indemnitee (i) acted in good faith in what such Person believed to be the best interests of the Company and (ii) was neither grossly negligent nor engaged in willful misconduct. To the fullest extent permitted by law, the Company may, in the sole discretion of the Manager(s), pay the expenses incurred by any Indemnitee in connection with any proceeding in advance of the final disposition of such proceeding upon receipt of an undertaking by such Indemnitee to repay the full amount advanced if there is a final determination that such Person did not satisfy the standards set forth in clauses (i) and (ii) above or that such Person is not entitled to indemnification as provided herein for other reasons. The termination of any action, suit or proceeding by settlement shall not, of itself, create a presumption that a Person did not act in good faith. The Manager(s) may cause the Company to obtain insurance to cover the Company's obligations hereunder.

5.7. Power of Attorney.

5.7.1. Grant of Power. Each Interest Holder constitutes and appoints each of the Manager(s) as the Interest Holder's true and lawful attorney-in-fact ("Attorney-in-Fact"), and in the Interest Holder's name, place and stead, to make, execute, sign, acknowledge, and file:

(a) The Organizing Documents;

(b) All documents (including amendments to the Organizing Documents) which the Attorney-in-Fact deems appropriate to reflect any amendment, change, or modification of this Agreement;

(c) Any and all other certificates or other instruments required to be filed by the Company under the laws of the State of Organization or of any other state or jurisdiction, including, without limitation, any certificate or other instruments necessary in order for the Company to continue to qualify as a limited liability company under the laws of the State of Organization;

(d) One or more fictitious or trade name certificates; and

(e) All documents which may be required to dissolve and terminate the Company and to cancel its Organizing Documents.

5.7.2. Irrevocability. The foregoing power of attorney is irrevocable and is coupled with an interest, and, to the extent permitted by applicable law, shall survive the death or disability of an Interest Holder and be binding on such Interest Holder's heirs. It also shall survive the Transfer of an Interest, and if the transferee is approved for admission as a Member, this power of attorney shall survive the delivery of the assignment and enable the Attorney-in-Fact to execute, acknowledge and file any documents needed to effectuate the substitution. Each Interest Holder shall be bound by any representations made by the Attorney-in-Fact acting in good faith pursuant to this power of attorney, and each Interest Holder hereby waives any and all defenses which may be available to contest, negate or disaffirm the action of the Attorney-in-Fact taken in good faith under this power of attorney.

ARTICLE VI
TRANSFER OF INTERESTS, WITHDRAWALS, BUY SELL

6.1. Transfers. Except as provided in this Section 6, no Interest Holder may Transfer any portion of, or any interest or rights in, an Interest or Unit.

6.1.1. An Interest Holder may Transfer all or any portion of or any interest or rights in his or her Economic Interest if each of the following conditions ("Conditions of Transfer") is satisfied or waived by the Manager(s) (in his, her or their sole discretion):

(a) Such Transfer will not require registration of Interests under any federal or state securities laws;

(b) The transferee delivers to the Company a written instrument agreeing to be bound by the terms of this Agreement.

(c) Such Transfer will not result in the termination of the Company pursuant to Code Section 708;

(d) Such Transfer will not result in the Company being subject to the Investment Company Act of 1940, as amended;

(e) The transferor or the transferee delivers the following information to the Company: (i) the transferee's taxpayer identification number and (ii) the transferee's initial tax basis in the transferred Economic Interest;

(f) Such Transfer will not result in the Company being taxed as a corporation for federal or state income tax purposes; and

(g) Except in the event of a Permitted Transfer, the transferor complies with the provisions set forth in Section 6.1.3.

6.1.2. Rights of Transferee, Substitute Member. If the Conditions of Transfer are satisfied, then an Interest Holder may Transfer all or any portion of that Interest Holder's Economic Interest. The Transfer of an Economic Interest pursuant to this Section 6.1 shall not result, however, in the Transfer of any of the transferor's other Interest, if any, and the transferee of the Economic Interest shall have no right to: (i) become a Member without the consent of the Manager(s) as required by this Agreement; or (ii) exercise any rights of a Member other than those specifically pertaining to the ownership of an Economic Interest. In the event that a transferee is admitted as a Member of the Company, the Schedule of Members shall be amended to reflect such admission.

6.1.3. Right of First Refusal.

(a) Except in the case of a Permitted Transfer, if an Interest Holder (a "Transferor") receives a bona fide written offer which the Interest Holder desires to accept (the "Transferee Offer") from any other Person, including another Interest Holder (a "Transferee") to purchase all or any portion of or any interest or rights in the Transferor's Economic Interest (the "Transferor Interest") then, prior to any Transfer of the Transferor's Interest, the Transferor shall give the Company written notice (the "Transfer Notice") containing the Transferee's identify; a true and complete copy of the Transferee Offer; and the Transferor's offer (the "Offer") to sell the Transferor Interest and any related Interest held by the Transferor to the Company pursuant to this Section 6.1.3 for consideration equal to that contained in the Transferee Offer or, if the consideration specified in the Transferee Offer is not specified as cash, then for reasonably equivalent consideration in U.S. Dollars (the "Transfer Purchase Price").

(b) The Offer shall be and remain irrevocable for a period (the "Offer Period") ending at 11:59 P.M. local time at the Company's principal office, on the thirtieth (30th) day following the date the Transfer Notice is given to the Company. At any time during the Offer Period, the Company (or its assignee) may accept the Offer by notifying the Transferor in writing that the Company (or its assignee) desires to purchase all or part of the Transferor Interest. The Transferor shall not be entitled to vote, either as a Member or Manager, in the Company's acceptance or rejection of the Offer.

(c) If the Company and/or its assignee (collectively, the "Purchasers") have accepted the Offer prior to the end of the Offer Period, any Purchaser may give written notice to that effect to the Transferor specifying a closing date (the "Transfer Closing Date") for the purchase which shall be no earlier than ten (10) nor later than sixty (60) days after the expiration of the Offer Period. On the Transfer Closing Date the Purchasers shall pay the Transfer Purchase Price unless the Purchasers elect prior to or on the Transfer Closing Date to pay the Transfer Purchase Price in installments pursuant to the provisions of Section 6.4 of this Agreement.

(d) If the Company does not accept the Offer (within the time and in the manner specified in this Section), then the Transferor shall be free for a period (the "Permitted Transfer Period") of thirty (30) days after the expiration of the Offer Period to Transfer the Transferor Interest to the Transferee, for the same or greater price and on the same terms and conditions as set forth in the Transfer Notice. The Transfer shall be subject, however, to the Conditions of Transfer and the provisions of Section 6.1.2. If the Transferor does not Transfer the Transferor's Interest within the Permitted Transfer Period, the Transferor's right to Transfer the Transferor Interest pursuant to this Section shall cease and terminate.

(e) Any Transfer by the Transferor after the last day of the Permitted Transfer Period or without strict compliance with the terms, provisions, and conditions of this Section and the other terms, provisions, and conditions of this Agreement, shall be null and void and of no force or effect.

6.1.4. Reasonableness. Each Interest Holder hereby acknowledges the reasonableness of the prohibition contained in this Section 6.1 in view of the purposes of the Company and the relationship of the Interest Holders. The Transfer of any Interests in violation of the prohibition contained in this Section 6.1 shall be deemed invalid, null and void, and of no force or effect. Any Person to whom Interests are attempted to be transferred in violation of this Section 6.1 shall not be entitled to vote on matters coming before the Members, participate in the management of the Company, act as an agent of the Company or have any other rights in or with respect to the Interests.

6.2. Voluntary Withdrawal. No Interest Holder shall have the right or power to effect a Voluntary Withdrawal from the Company. Any Interest Holder who effectuates a Voluntary Withdrawal in violation of this Agreement shall not be permitted to receive the fair value of its Interest as of the date of the Voluntary Withdrawal as otherwise provided by the Act.

6.3. Optional Buy-out in Event of Withdrawal.

6.3.1. After an Involuntary Withdrawal, the withdrawn Interest Holder or the successor in interest to such Interest Holder (the "Withdrawn Member") shall be deemed to offer for sale to the Company (the "Withdrawal Offer") all of the Interests of the Withdrawn Member (the "Withdrawal Interest").

6.3.2. The Withdrawal Offer shall be and remain irrevocable for a period (the "Withdrawal Offer Period") ending at 11:59 P.M. local time at the Company's principal office on the ninetieth (90th) day following the date that the Manager(s) are notified of the withdrawal. At any time during the Withdrawal Offer Period, the Company may accept the Withdrawal Offer by notifying the Withdrawn Member of its acceptance (the "Withdrawal Notice"). Neither the Withdrawn Member nor any of its predecessors shall be entitled to vote, either as a Member or Manager, in the Company's acceptance or rejection of the Withdrawal Offer.

6.3.3. If the Company accepts the Withdrawal Offer, the Withdrawal Notice shall fix a closing date (the "Withdrawal Closing Date") for the purchase which shall be not earlier than ten (10) or later than ninety (90) days after the expiration of the Withdrawal Period.

6.3.4. If the Company accepts the Withdrawal Offer, the Company (or its assignee) shall purchase the Withdrawal Interest for the price equal to the fair market value of the Withdrawal Interest (the "Withdrawal Purchase Price") as determined by the disinterested Manager(s) in good faith. The Withdrawal Purchase Price shall be paid, at the Company's option, in cash on the Withdrawal Closing Date or in installments pursuant to the provisions of Section 6.4 of this Agreement.

6.3.5. If the Company fails to accept the Withdrawal Offer, then the Withdrawn Member (or its predecessor), upon the expiration of the Withdrawal Offer Period, thereafter shall be an Interest Holder but shall not continue to be a Member.

6.3.6. The Withdrawn Member shall not be entitled to receive the fair market value of its Interest as of the date of the Involuntary Withdrawal from the Company as otherwise provided by the Act.

6.4. Installment Buy-outs. If the Company or its assignee (the "Buyer"), is entitled under this Agreement to pay the purchase price on an installment basis, the Buyer may pay 25% of the purchase price on closing of the transaction and the remainder by executing and delivering its promissory note for the balance, to the Company, Interest Holder or Transferor, which note shall carry interest at the rate of 2% and provide for the payment of the remainder of the purchase price in three equal annual installments beginning one year after the closing of the transaction.

6.5. Rights of Interest Holder Who Has Transferred Economic Interest. In the event that an Interest Holder transfers his or her entire Economic Interest in the Company to a Person other than a Permitted Transferee, or has withdrawn from the Company, that Interest Holder shall not be entitled to vote or to participate in management, or any right to information concerning the business and affairs of the Company.

ARTICLE VII
DISSOLUTION, LIQUIDATION, AND TERMINATION OF THE COMPANY

7.1. Events of Dissolution. The Company shall be dissolved upon the happening of any of the following events:

7.1.1. When the period fixed for its duration in Section 2.4 has expired;

7.1.2. Upon a Majority Vote to dissolve;

7.1.3. Upon the sale of all or substantially all of the assets of the company; or

7.1.4. The entry of a decree of judicial dissolution.

7.2. Procedure for Winding-Up and Dissolution. If the Company is dissolved, the Manager(s) or, if there is no remaining Manager, any Person elected by a Majority Vote, shall wind up its affairs. On winding up of the Company, the assets of the Company shall be distributed, first to creditors of the Company, including Interest Holders who are creditors, in satisfaction of the liabilities of the Company, and then to the Interest Holders in accordance with Section 4.4 of this Agreement.

7.3. Filing of Certificate of Cancellation. Upon completion of winding up the affairs of the Company, the Manager(s) shall promptly file the Certificate of Cancellation with the Secretary of State. If there is no remaining Manager, such Certificate of Cancellation shall be filed by the Members. If there are no remaining Members, the Certificate of Cancellation shall be filed by the last Person to be a Member (or the legal or personal representatives of the last Person to be a Member).

7.4. Conversion to Corporation. Upon the approval of a majority of the Manager(s) and a Majority of the Members, the Company shall be converted (by merger, consolidation, share exchange, state law conversion, transfer of assets of the Company to a newly formed corporation in exchange for stock followed by the liquidation of the Company, or transfer of Interests to a newly formed corporation in exchange for stock) into a newly formed corporation so as to convert the Company to a corporation. Such corporation shall have articles of incorporation and bylaws which the Manager(s) determine(s) are customary for corporations comparable to the Company at the time. The outstanding equity capitalization of the corporation upon consummation of such conversion shall, to the fullest extent possible, be identical to that of the Company immediately prior to such conversion, and the Units shall, automatically and with no further action by the Interest Holders, convert to shares of stock or other equity or substituted non-equity interests of reasonably equivalent value as determined by the Manager(s) in his, her or their sole discretion. Upon such conversion, the provisions of this Agreement shall be embodied in a stockholders agreement, which all of the Interest Holders agree to execute on the demand of the Manager. The Interest Holders shall take any actions and execute any documents reasonably requested by the Manager(s) in connection with any such conversion.

7.5. Drag-Along Rights.

7.5.1. Notwithstanding any other provision of this Agreement, unless the Manager(s) elect to apply the provisions of Section 7.4, in the event that a Majority of the Members agree to:

(a) Sell or exchange all or substantially all of the Units held by Interest Holders (including, but not limited to, an incorporation, merger, conversion, consolidation or amalgamation of the Company with another limited liability company, corporation or other entity) in a single transaction or series of related transactions, or

(b) To initiate on behalf of the Company a transfer or sale of all or substantially all of the assets of the Company, such transaction shall be a "Qualifying Transfer" for purposes of this Section 7.5 and shall be treated as a liquidation under Section 4.2.5. The Members that have initially agreed to participate in the Qualifying Transfer shall be referred to herein as the "Proposing Members".

7.5.2. A Proposing Member shall, within 30 days of their agreement to participate in the Qualifying Transfer described in subsection 7.5.1(b), by written notice (the "Transfer Notice") to all the Interest Holders, require all the Interest Holders who are Members to vote their Units in favor of the Qualifying Transfer in accordance with Section 5.2.2.

7.5.3. In the event of a Qualifying Transfer described in subsection 7.5.1(a) above, the Transfer Notice shall require all Interest Holders to sell or exchange in the Qualifying Transfer the Units then held by such Interest Holders.

7.5.4. The proceeds of the Qualifying Transfer shall be distributed to the Interest Holders in the order and priority set forth in Section 4.1.2, after the adjustments described in Sections 4.2.5(ii) and (iii).

7.5.5. To the extent required to effectuate this Section 7.5, each Member hereby grants to the Proposing Members an irrevocable proxy, coupled with an interest, to vote all of the Units held by such Member (whether at a meeting or by written consent) in favor of any Qualifying Transfer.

ARTICLE VIII
BOOKS, RECORDS, ACCOUNTING, AND TAX ELECTIONS

8.1. Bank Accounts. All funds of the Company shall be deposited in a bank account or accounts opened in the Company's name. The Manager(s) shall determine the financial institution or institutions at which the accounts will be opened and maintained, the types of accounts, and the Persons who will have authority with respect to the accounts and the funds therein.

8.2. Maintenance of Books and Records.

8.2.1. The Manager(s) shall keep or cause to be kept complete and accurate books and records of the Company and supporting documentation of the transactions with respect to the conduct of the Company's business. The records shall include, but not be limited to, complete and accurate information regarding the state of the business and financial condition of the Company, a copy of the Organizing Documents and this Agreement and all amendments to the Organizing Documents and this Agreement; a current list of the names and last known business, residence, or mailing addresses of all Interest Holders; and the Company's federal, state, or local tax returns.

8.2.2. The books and records shall be maintained in accordance with generally accepted accounting practices and shall be available at the Company's principal office for examination by any Member or the Member's duly authorized representative at any and all reasonable times during normal business hours for any purpose reasonably related to such Member's interest as a Member.

8.2.3. Each Member shall reimburse the Company for all costs and expenses incurred by the Company in connection with the Member's inspection and copying of the Company's books and records.

8.3. Annual Accounting Period. The annual accounting period of the Company shall be its taxable year. The Company's taxable year shall be selected by the Manager(s), subject to the requirements and limitations of the Code.

8.4. Reports. Within seventy-five (75) days after the end of each taxable year of the Company, the Manager(s) shall cause to be sent to each Person who was a Member at any time during the accounting year then ended: (i) an annual compilation report, prepared by the Company's independent accountants in accordance with standards issued by the American Institute of Certified Public Accountants, and (ii) a report summarizing the fees and other remuneration paid by the Company to any Member, the Manager(s) or any Affiliate in respect of the taxable year. In addition, within seventy-five (75) days after the end of each taxable year of the Company, the Manager(s) shall cause to be sent to each Person who was an Interest Holder at any time during the taxable year then ended, that tax information concerning the Company which is necessary for preparing the Interest Holder's income tax returns for that year. At the request of any Member, and at the Member's expense, the Manager(s) shall cause an audit of the Company's books and records to be prepared by independent accountants for the period requested by the Member.

8.5. Tax Matters Partner. The Tax Matters Partner shall have all powers and responsibilities provided in Code Section 6231, *et seq*. The Tax Matters Partner shall keep all Members informed of all notices from government taxing authorities which may come to the attention of the Tax Matters Partner. The Company shall pay and be responsible for all reasonable third-party costs and expenses incurred by the Tax Matters Partner in performing those duties. Any Interest Holder shall be responsible for any costs incurred by such Interest Holder with respect to any tax audit or tax-related administrative or judicial proceeding against any Interest Holder, even though it relates to the Company. The Tax Matters Partner may not

compromise any dispute with the Internal Revenue Service without the approval of majority of the Member Units.

8.6. Tax Elections. The Manager(s) shall have the authority to make all Company elections permitted under the Code, including, without limitation, elections of methods of depreciation and elections under Code Section 754. The decision to make or not make an election shall be made in the sole and absolute discretion of the Manager(s).

8.7. Title to Company Assets.

8.7.1. Except as provided in Section 8.7.2, all Company assets shall be held by the Company in its name.

8.7.2. The Manager(s) may direct that legal title to all or any portion of the Company's Assets be acquired or held in a name other than the Company's name. Without limiting the foregoing, the Manager(s) may cause title to be acquired and held in the names of the Manager(s) or in the names of trustees, nominees, or straw parties for the Company. It is expressly understood and agreed that the manner of holding title to the Company's assets (or any part thereof) is solely for the convenience of the Company, and all of the assets shall be treated as Company assets.

ARTICLE IX
GENERAL PROVISIONS

9.1. Assurances. Each Interest Holder shall execute all certificates and other documents and shall do all such filing, recording, publishing, and other acts as the Manager(s) deem(s) appropriate to comply with the requirements of law for the formation and operation of the Company and to comply with any laws, rules, and regulations relating to the acquisition, operation, or holding of the property of the Company.

9.2. Notifications. Any notice, demand, consent, election, offer, approval, request, or other communication (collectively a "notice") required or permitted under this Agreement must be in writing and either delivered personally or sent by certified or registered mail, postage prepaid, return receipt requested. Any notice to be given hereunder by the Company shall be given by the Manager(s). A notice must be addressed to an Interest Holder at the Interest Holder's last known address on the records of the Company. A notice to the Company must be addressed to the Company's principal office. A notice delivered personally will be deemed given only when acknowledged in writing by the person to whom it is delivered. A notice that is sent by mail will be deemed given three (3) business days after it is mailed. Any party may designate, by notice to all of the others, substitute addresses or addressees for notices; and, thereafter, notices are to be directed to those substitute addresses or addressees.

9.3 Complete Agreement. This Agreement constitutes the complete and exclusive statement of the agreement among the Members with respect to the subject matter. It supersedes all prior written and oral statements, including any prior representation, statement, condition, or warranty.

9.4. Applicable Law. All questions concerning the construction, validity, and interpretation of this Agreement and the performance of the obligations imposed by this Agreement shall be governed by the internal law, not the law of conflicts, of the State of Organization. The parties of this Agreement consent to the exclusive jurisdiction of the courts of, and the exclusivity of arbitration in, the State in which the Company Address is located.

9.5. Section Titles. The headings herein are inserted as a matter of convenience only and do not define, limit, or describe the scope of this Agreement or the intent of the provisions hereof.

9.6. Binding Provisions. This Agreement is binding upon, and to the limited extent specifically provided herein, inures to the benefit of, the parties hereto and their respective heirs, executors, administrators, personal and legal representatives, successors, and assigns.

9.7. Terms. Common nouns and pronouns shall be deemed to refer to the masculine, feminine, neuter, singular and plural, as the identity of the Person may in the context require.

9.8. Independent Counsel. This Agreement has been prepared by counsel to the Company. Each Member has been given the opportunity to consult with independent counsel of its own choosing with respect to entering into this Agreement.

9.9. Separability of Provisions. Each provision of this Agreement shall be considered separable; and if, for any reason, any provision or provisions herein are determined to be invalid and contrary to any existing or future law, such invalidity shall not impair the operation of or affect those portions of this Agreement which are valid.

9.10. Counterparts. This Agreement may be executed simultaneously in two or more counterparts or fax copies, each of which shall be deemed an original and all of which, when taken together, constitute one and the same document. The signature of any party to any counterpart or fax copy shall be deemed a signature to, and may be appended to, any other counterpart.

9.11. Mediation and Arbitration.

9.11.1. Mediation. Before commencing any action or arbitration, the Interest Holders agree to mediate in a good faith attempt to mediate any dispute arising out of or related to this Agreement or any matter related to the operation of the Company. The Interest Holder seeking "Mediation" shall propose three mediators who have at least two years of mediating disputes arising out of or related to contractual disputes and who have no prior relationship, either personal or commercial in nature, with the Interest Holder. Within 10 days of such proposal, the other Interest Holder shall choose a "Mediator" from the three proposed mediators. After selection of a Mediator, the Interest Holder seeking mediation shall send the other party a "Notice of Mediation" which state the name and address of the Mediator and a date and time for mediation; provided that the date and time for mediation shall be no sooner than thirty (30) days after the Notice of Mediation and no later than ninety (90) days after the Notice of Mediation.

The Notice of Mediation must include a description of the issues that the Interest Holder seeks to mediate. An Interest Holder may change the date of the mediation by notifying the other Interest Holder five days after receiving the Notice of Mediation. The Interest Holder seeking the change in mediation can choose another date for the mediation by obtaining the agreement of the other Interest Holder to a new date for the mediation. If the Interest Holders cannot agree to a new mediation date within 10 days after the request for a change in the date of mediation is made, any Interest Holder may submit available dates for a new date for mediation to the Mediator. All other Interest Holders will be required to submit available dates for a new date for mediation to the Mediator, and the Mediator is empowered to choose a new date for mediation. The Interest Holders will be required to attend mediation on the date that the Mediator selects. Any Interest Holder may petition or move to compel mediation in any court of competent jurisdiction. The Interest Holders agree that the prevailing party will be entitled to attorneys' fees and costs. The Interest Holders agree that they will each bear a pro rata share of the costs of mediation, including the costs of the mediator or any other fees associated with the mediation.

9.11.2. Arbitration. Any disputes arising hereunder which have not been resolved following mediation as provided in Section 9.11.1 above, shall be settled by "Arbitration" in the Preferred County, in accordance with the rules of the American Arbitration Association for Commercial Arbitration. The Interest Holders agree that the Preferred County is a convenient forum for all parties. Such arbitration will be final and binding on Interest Holders and the Company, no appeals may be taken therefrom and judgment upon any award rendered may be entered in any court having jurisdiction therefor.

9.12. Amendments; Waivers.

9.12.1. Subject to any contrary provisions herein, this Agreement may be amended only upon a Majority Vote and with the consent of the Manager(s). Any provision of this Agreement may be waived from time to time with respect to rights of any Interest Holder by a written instrument executed by such Interest Holder, and any provision of this Agreement may be waived from time to time (other than a provision which by its own terms imposes a different vote requirement for its waiver) upon the consent of the Manager(s) and the affirmative vote of the same number of Members as would be required to amend such provision. Any Amendment shall be deemed to have prospective effect from the date that the Majority of the Members have executed the amendment unless otherwise stated to have an earlier effective date.

9.12.2. Except with regard to amendments otherwise required or authorized under this Agreement, there shall be no amendment to this Agreement which would adversely affect an Interest Holder's right to Distributions unless the amendment: (i) is consented to by such Interest Holder or (ii) by its terms applies to each Interest Holder in a nondiscriminatory manner. There shall be no amendment that: (i) increases an Interest Holder's obligation to make capital contributions to the Company or (ii) imposes personal liability upon an Interest Holder for any debts or obligations of the Company unless, in each case, the amendment is consented to by such Interest Holder. No amendment to this Agreement pursuant to Sections 4.2.2, 4.3.2, 4.4.3 or 4.5.4 shall be deemed to materially and adversely impact upon the economic rights of any Interest Holders.

9.13 Confidentiality. Each party hereto agrees that the provisions of this Agreement, all understandings, agreements and other arrangements between and among the parties, and all other non-public information received from or otherwise relating to, the Company shall be confidential, and shall not be disclosed or otherwise released to any other Person (other than another party hereto), without the written consent of the Manager(s); provided, however, that each party may disclose such information to its professional advisors, including its attorneys and accountants. The obligations of the parties hereunder shall not apply to the extent that the disclosure of information otherwise determined to be confidential is required by applicable law; provided, that prior to disclosing such confidential information, a party shall notify the Company thereof, which notice shall include the basis upon which such party believes the information is required to be disclosed.

9.14. Acknowledgment of Certain Facts. Each Interest Holder acknowledges their awareness and understanding of the following:

9.14.1. The purchase of Units is a speculative investment which involves a high degree of risk of loss of the entire investment.

9.14.2. Such Interest Holder has both the knowledge and experience in financial matters sufficient to evaluate the purchase of Units and is able to bear the economic risk of the purchase.

9.14.3. No federal or state agency has made any finding or determination as to the fairness for public investment, nor any recommendation or endorsement of, Units.

9.14.4. There are restrictions on the transferability of Units; there will be no market for Units; accordingly, it may not be possible to liquidate readily, or at all, an investment in the Company.

9.14.5. Units have not been registered under the Securities Act of 1933, as amended, or any state securities law.

9.14.6. Units have been acquired pursuant to an investment representation by each Interest Holder and may not be sold, pledged, hypothecated, donated, or otherwise transferred, whether or not for consideration, except in compliance with the terms of this Agreement.

9.14.7. Any document or certificate representing Units which is issued by the Company, if any, shall be imprinted with conspicuous legends in substantially the following form:

> "THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR UNDER THE SECURITIES LAWS OF CERTAIN STATES. THESE SECURITIES ARE SUBJECT TO RESTRICTIONS ON

TRANSFERABILITY AND RESALE AND MAY NOT BE TRANSFERRED OR RESOLD EXCEPT AS PERMITTED UNDER THE ACT AND THE APPLICABLE STATE SECURITIES LAWS PURSUANT TO REGISTRATION OR EXEMPTION THEREFROM. UNITHOLDERS SHOULD BE AWARE THAT THEY MAY BE REQUIRED TO BEAR THE FINANCIAL RISKS OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME. THE ISSUER OF THESE SECURITIES MAY REQUIRE ANY OPINION OF COUNSEL IN FORM AND SUBSTANCE SATISFACTORY TO THE ISSUER TO THE EFFECT THAT ANY PROPOSED TRANSFER OR RESALE IS IN COMPLIANCE WITH THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS.

THE SECURITIES REPRESENTED HEREBY MAY BE SUBJECT TO A RIGHT OF FIRST REFUSAL UPON AN ATTEMPTED TRANSFER OF SUCH SECURITIES AND CERTAIN REPURCHASE RIGHTS IN FAVOR OF THE COMPANY, AND SUCH SECURITIES MAY NOT BE SOLD OR OTHERWISE TRANSFERRED IF SUCH SECURITIES ARE SUBJECT TO SUCH COMPANY RIGHTS."

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date set forth above.

MEMBERS:

Ritu Ghumman

HEALTHYPETS, INC.

By: _____
Dr. M. Ghumman, President

MANAGER(S):

Ritu Ghumman

SIGNATURE PAGE TO
LIMITED LIABILITY AGREEMENT OF ENTIRELYPETS PHARMACY, LLC

EXHIBIT A
SCHEDULE OF MEMBERS

Member Name and Address	Contribution	Date of Admission	Percentage/Number of Units	Vesting Terms
Ritu Ghumman 2053 Sandalwood Ct. Palo Alto, CA 94303	$10,000	Oct. 7, 2011	90.1% (901,000 units)	N/A
HealthyPets, Inc. c/o Dr. Mandeep Ghumman 34501 Seventh St. Union City, CA 94587	$1000	Oct. 7, 2011	9.9% (99,000 units)	N/A

The 2012 Florida Statutes

Chapter 465 Pharmacy

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

property-related public nuisances and criminal gang activity.

893.145“Drug paraphernalia” defined.

893.146Determination of paraphernalia.

893.147Use, possession, manufacture, delivery, transportation, or advertisement of drug paraphernalia.

893.149Unlawful possession of listed chemical.

893.1495Retail sale of ephedrine and related compounds.

893.15Rehabilitation.

893.165County alcohol and other drug abuse treatment or education trust funds.

893.20Continuing criminal enterprise.

893.21Drug-related overdoses; medical assistance; immunity from prosecution.

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.

(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

499.067 Denial, suspension, or revocation of permit, certification, or registration.

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

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.

CHAPTER 120

ADMINISTRATIVE PROCEDURE ACT

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.

120.541 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.

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.

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, 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 HCl.

(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

64B16-28.820 Sterile Products and Special Parenteral/Enteral Compounding
64B16-28.830 Special – Closed System Pharmacy
64B16-28.840 Special – Non Resident (Mail Service)
64B16-28.850 Special Pharmacy – ESRD
64B16-28.860 Special Pharmacy – Parenteral/Enteral Extended Scope Permit
64B16-28.870 Special-ALF
64B16-28.900 Definitions – Nuclear Pharmacy
64B16-28.901 Nuclear Pharmacy – General Requirements
64B16-28.902 Nuclear Pharmacy – Minimum Requirements
64B16-28.903 Training Qualifications (Repealed)
64B16-28.904 Nuclear Pharmacist – Continuing Education (Repealed)

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.

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.

(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

U.S. PHARMACOPEIA
The Standard of Quality℠

⟨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.

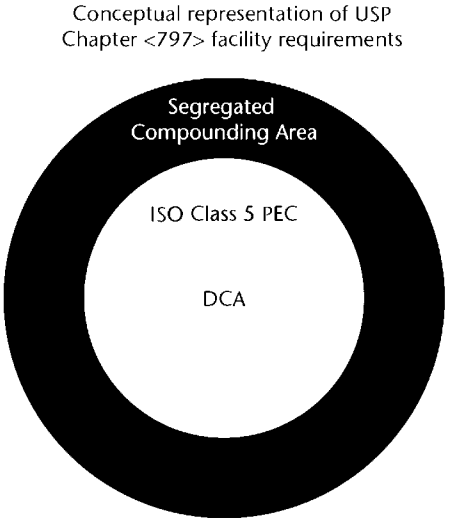

Figure 1. Conceptual representation of the placement of an ISO Class 5 PEC in a segregated compounding area used for low-risk level CSPs with 12-hour or less BUD.

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.

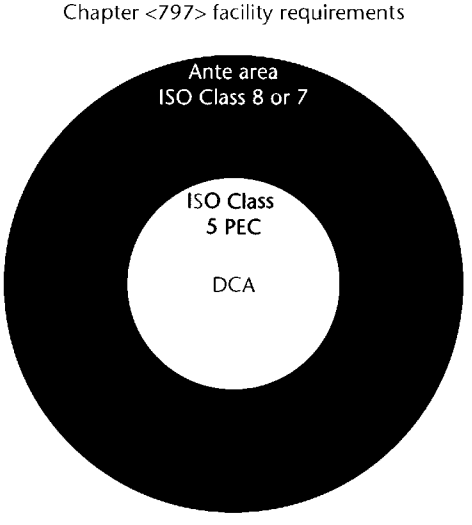

Figure 2. Conceptual representation of the arrangement of a facility for preparation of CSPs categorized as low-, medium-, and high-risk level.

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 re-instructed 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.

APPENDICES

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).

APPENDICES

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.

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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)*

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

[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)

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,

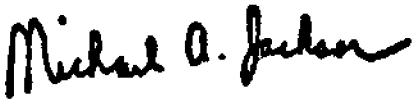
and to find an appropriate, balanced approach to assure public safety and continued access to compounded medications.

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

[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

[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.