

## AGENDA

### DEPARTMENT OF HEALTH BOARD OF PHARMACY FULL BOARD MEETING

February 6-7, 2013

Renaissance World Golf Village Resort  
500 South Legacy Trail  
St. Augustine, Florida 32092  
(904) 940-8000

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PLEASE TURN OFF ALL CELL PHONES, PAGERS AND BEEPERS DURING THE MEETING.  
THANK YOU.

#### Board Members

Albert Garcia, BPharm, MHL, Chair, Miami  
Jeffrey 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

#### Board Counsel:

David Flynn, Assistant Attorney General

#### Department of Health Staff

John J. Truitt, Assistant General Counsel

**Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the Board's website.**

#### **Wednesday, February 6, 2013 – 9:00 a.m.**

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

All Board Members were present except Ms. DeAnn Mullins.

Mr. Garcia requested that cell phones, pagers, and beepers be turned off. He informed everyone that the meeting is being recorded and an audio file will be posted on the Board's website after the meeting.

Mr. Garcia welcomed individuals in the audience, including in particular: Mr. Fritz Hayes, Bob Parrado, Rod Presnel, Ron Salem and Jim Powers.

Mr. Garcia extended awards to Dr. Griffin in recognition of her service as the Board's immediate past Chair and to Dr. Mesaros in recognition of his service on the Tripartite Committee.

Dr. Griffin extended awards to Mr. Garcia in recognition of his service as the Board's immediate past Vice Chair and for his service on the Board's Rules Committee.

## **TAB1**

## **REPORTS**

### **A. Chairs Report – Albert Garcia, BPharm, MHL, Chair**

#### **1. 2013 Committee Member Assignments**

Mr. Garcia appointed Board Members to serve on the following committees:

- Legislative Liaison: Ms. Glass
- Rules Committee: Dr. Mesaros
- Application Review: Dr. Griffin
- ULA Liaison: Ms. Mullins
- PDMP Liaison: Dr. Mesaros
- Wholesale Advisory Council: Mr. Garcia
- Negative Formulary Committee: TBD
- Tripartite Committee Chair: Dr. Griffin
- Administrative/Budget Liaison: Dr. Weizer
- Pharmacist Ordering Committee: TBD
- New Compounding Rules Committee: Dr. Weizer, Ms. Glass, Ms. Mullins

#### **2. 2013 Association Meeting Assignments**

Mr. Garcia appointed Board Members to attend the following Association Meetings:

#### **Florida Pharmacy Association**

- Law and Regulatory Compliance Conference, Tampa, April 20-21, 2013, Dr. Mesaros
- 123<sup>rd</sup> Annual Meeting and Convention, Orlando, July 10-14, 2013, Dr. Fallon
- 30<sup>th</sup> Annual Southeastern Gathering, Destin, August 4-7, 2013, Dr. Fallon
- Law & Regulatory Compliance Conference, Fort Lauderdale, September 7-8, 2013, Mr. Garcia

#### **Florida Society of Health-System Pharmacists**

- House of Delegates, Chair and the Executive Director are “Delegates”, Orlando, August 2, 2013, Dr. Weizer

#### **Nation Association of Boards of Pharmacy**

- MPJE Item Development Workshop, March 21-22, 2013, Ms. Glass
- NABP 109<sup>th</sup> Annual Meeting, May 18-21, 2013, Hyatt Regency St Louis at the Arch
- St Louis, MO, Mr. Garcia, Dr. Mesaros as Alternate
- The District 3 meeting, August 3-5, 2013, Hilton Nashville Downtown, Nashville, TN, Mr. Garcia
- Interactive Member Forum, Mr. Garcia
- NABP Interactive Executive Officers Forum, Mr. Whitten

## **MALTAGON**

- Annual Meeting, Crowne Plaza Resort, Asheville, NC, September 29 – October 1, 2013, Albert Garcia

### **B. Executive Director's Report – Mark Whitten**

1. Gavin Meshad Prescription
  - a. Prescription Drug Abuse Committee, (PDAC), Update

Mr. Meshad gave a report on the PDAC meeting including information on presentations given to the committee by Ms. Rebecca Poston with the Prescription Drug Monitoring Program, PDMP; Gayle Lane with the Drug Enforcement Agency, DEA and Lori Hall with the Jacksonville Police Department.

Mr. Meshad reported that the immediate focus of the committee is to understand the arena of prescription drug abuse and the authority the Board currently possesses within their regulations and rulemaking to make an impact in this area; and to look into legislation if necessary.

Mr. Meshad voiced the committee's support and shared their recommendations in helping to fund the continuation of the PDMP as well as their support in looking for ways to help increase utilization of the program.

Mr. Meshad reported on the DEA's concern on rogue pharmacies. He reported that many things have been passed down through recent legislation that should begin helping with this situation, and that the committee would be working on ways to utilize the application and review process to further help eliminate the loopholes for these pharmacies.

One process that was identified during the DEA report is the Board's rule that allows for transfer of stock, which is not considered a change of ownership, without application to the Board. The committee has recommended that the Board vote on amending this rule to require transfers of stock to be subject to an application for approval by the Board in an attempt to close this loophole.

Mr. Flynn interjected that Rule 64B16-28.2021, F.A.C. - Change of Ownership, already exist and that it may be tweaked to include 51% or more transfer of stock is considered a change of ownership and requires application to the Board.

This rule is being referred to the Rules Committee for further consideration.

Mr. Garcia commented that he would like to see specific recommendations come to the Board from the committee in a way that the Board could review and determine those that are most viable, then move those recommendations to the rules committee to work on ways to implement.

Mr. Garcia further commented on the Board's desire to help fund the PDMP through legislation that would allow the Board to charge a fee in conjunction with licensure or renewal fees. Discussion ensued on what it would take to get language together for this or future legislative sessions.

Mr. Bob Parrado approached the Board to suggest making utilization of the PDMP a part of the Standards of Practice under Rule 64B16-27.831, F.A.C., and asked Mr. Flynn if the Board would have authority to add this language.

Mr. Flynn responded that the Board does have this authority, and he would begin working on language to bring back to the committee.

Mr. Garcia asked PDMP Board of Trustee, Brian Kohn, Esq., if he would be willing to give an update on the budget for the PDMP. Mr. Kohn reported that a new Board of Trustees has been appointed by the Governor of the State of Florida and the first meeting of the new Board would be on February 18, 2013.

For the audience he clarified that the PDMP is an unfunded mandate by the legislature currently operated by two staff members and that the Board of Trustees is currently looking for funding support to help keep the program operating.

2. Dr. Michele Weizer
  - a. Compounding Rules Committee Update

Dr. Weizer provided a report from the January 16, 2013 Compounding Rules Committee telephone conference call. During the report, Dr. Weizer provided a summary of the timely release of the Massachusetts Compounding Commission. She reported that the Commission would be evaluating the compounding accreditation process to include the necessity for accrediting in state as well as non-resident pharmacies; evaluating the policy and operational implications of establishing a single regulatory authority for all pharmacy practices which would include physician practices in addition to freestanding pharmacies and hospitals; and assessing the status of, and making recommendations for amending policies and procedures to include requiring all pharmacists and/or pharmacy technicians engaging in sterile compounding to complete annual continuing education. They will also be looking into having a special license for pharmacies engaging in sterile compounding.

The Commission addressed having specific requirements for training inspectors who would perform inspections on sterile compounding facilities including that they have at least five years of clinical experience, that they complete a certificate training program within their first year of employment and that they have specific expertise in the area of sterile compounding pharmacies.

The Commission discussed having category specific inspections for pharmacies depending on the type of compounding they are performing. For example, there would be a specific inspection for pharmacies based on USP 797 for sterile compounding and a specific inspection based on USP 795 for non-sterile compounding.

The Commission also discussed the statutory changes that would need to be addressed which would include adding new licenses.

Dr. Weizer reported that the Compounding Rules Committee discussed the differences between Low/Medium Risk versus High Risk Level Compounding; and the need to risk stratify between the two categories in regards to inspections. They discussed identifying those pharmacies that participate in mass producing or (high volume compounding) and acknowledged how this could increase inspection timeframes. They also discussed how drug shortages may be a factor in contributing to high volume compounding.

The Compounding Committee discussed and unanimously supported having unique/special licensing for sterile compounding of both in state and non-resident pharmacies; as well as making revisions to Rule 64B16-28.800, F.A.C. to create the special licensing.

Mr. Flynn stated that he had already opened Rules 64B16-28.800, F.A.C. and 64B16-28.802, F.A.C. for development and requested that the Board vote to allow a workshop for rule development.

**Motion:** by Dr. Weizer, seconded by Dr. Griffin to approve a workshop for rule development. Motion carried.

Mr. Garcia expressed a concern for the committee on how large the issues they are tasked to address may be getting, and recommended the creation of sub committees to review and expedite recommendations in an effort to keep things moving forward smoothly. Mr. Garcia also recommended the inclusion of USP 797 experts to help during the rule development process.

Dr. Weizer reported on the inability of our inspectors to cross state lines to inspect non-resident pharmacies; however, that Mr. Flynn has recommended the Board does have authority to modify the application process to require that non-resident pharmacies submit copies of their most recent two inspection reports upon applying for licensure in the State of Florida or provide other supporting information on what the inspection process is in their state. (i.e.: self-inspections or no inspections).

Dr. Weizer reported on two items previously mentioned by Mr. Whitten. One is a pilot project between NABP and the State of Iowa to have NABP inspectors conduct inspections on non-resident pharmacies. The second is legislation in the State of California that would allow them to cross state lines to conduct inspections on non-resident pharmacies.

Mr. Whitten reported on an update to the NABP pilot project, stating that NABP had sent out a questionnaire to all State Boards requesting information on their inspection process, which has been completed. NABP will be prioritizing their inspection process based on the results of this survey.

Dr. Weizer reported that the Committee discussed the possibility of requiring accreditation for non-resident pharmacies which could be a standardized, minimum level of competency since we cannot cross state lines to conduct our own inspections.

Mr. Flynn recommended that the Board vote on modifying the pharmacy permit application to require non-resident pharmacies to submit their last two inspection forms during the application process.

**Motion:** by Dr. Weizer, seconded by Dr. Griffin to modify the pharmacy permit application to require non-resident pharmacies to submit copies of their last two inspection forms as part of the application process. Motion carried.

Mr. Flynn asked if there would be an adverse impact or a regulatory impact of over \$200,000 in the aggregate within the first year of implementation on those businesses to mail the inspection forms to the department.

**Motion:** by Dr. Weizer, seconded by Dr. Griffin that there is no negative impact. Motion carried.

Dr. Weizer reported that the Committee discussed the idea of having a Florida licensed pharmacist physically located in non-resident pharmacies and decided this would not be beneficial because it would have no impact on ensuring that the pharmacy comply with Florida rules nor would it help to get these pharmacies inspected.

Dr. Weizer reported that the Committee had discussion on Rule 64B16-27.797, F.A.C. and how this rule was written when the original USP 797 guidelines were published and has not been modified since, even though USP has currently published their fourth revision in 2012.

The Committee has discussed making the Board rule more similar to current USP guidelines; however, there is some disagreement with the current guidelines, and that it would be beneficial to have experts in the field of USP 797 work with the committee to modify the Board rule while addressing those issues.

The Committee discussed the department inspection process, and felt it might be beneficial for each Board member to participate in a sterile compounding inspection to see the process first-hand.

Mr. Flynn stated that in the event an inspection resulted in a case before the Board; the Board member who participated in an inspection of that pharmacy would be recused in the discussion of that case.

Dr. Weizer reported that there was some discussion, and concern, about compounding in physician offices around the state and there seem to be some significant deficits in some of these facilities. The Committee feels that education of the Medical Board and the physicians performing compounding is needed.

Dr. Weizer reported that the Committee discussed that fee schedules should coincide with the amount of time it takes to conduct an inspection of a facility. This action would take legislation, and the suggestion made by Mr. Flynn is to obtain feedback from the inspectors on what inspections involve, then draft language to be presented to the legislature.

Dr. Weizer reported that the Committee discussed how during the inspection process, inspectors should take into consideration the volume of compounding and distinguish if compounding is for others verses for patient use.

Finally, Dr. Weizer reported on public comments from Mr. Montgomery with Orlando Health regarding centralized sterile compounding of IV products; Mr. Harlow with Martin Health regarding his suggestion that compounding pharmacies should provide sterility data for each compounded batch; and Mr. Makhil with CAPS regarding his suggestion that anyone using Beyond Use Dating outside of USP 797 guidelines should provide sterility data and stability information for each compounded batch.

Moving forward the Committee will be focusing on updating Rule 64B16-27.797, F.A.C.; the inspection process and non-resident pharmacies.

Mr. Makhil with CAPS approached the Board and commented that many boards of pharmacies are working together with the FDA to conduct inspections which has resulted in 11 closed pharmacies so far. He recommended this as a possible idea to the Florida Board.

Dr. Weizer reported that the FDA may soon begin to look at pharmacies in regards to patient specific verses compounding for use by a third party, and that some of these concerns might work out during this process; however, there is no way to know how long that might take.

Mr. Garcia recommended that it might be a good idea to invite some legislatures to future board meetings to try and generate some legislative interest in areas of concern.

b. Budget Liaison Update

There was no update on the budget.

3. Dr. Jeffrey Mesaros

a. Approval of HIV & Med Errors CE Course and Nov. 2012 Retroactive Approval for CE Participants

Mr. Robert Kraljevich was present on behalf of Broward General Medical Center.

Mr. Kraljevich stated that they offered a continuing education program consisting of both HIV Aids and Medical Errors courses in November of 2012, and mistakenly thought their courses were automatically approved because they were an Accreditation Council for Pharmacy Education, (ACPE), approved provider.

Mr. Kraljevich requested retroactive approval of the two courses, as well as retroactive approval for the participants who took the courses.

Dr. Mesaros requested that Dr. Weizer report to the Board as the continuing education materials had been forwarded to her directly from Broward General Medical Center.

Dr. Weizer reported that the Medical Errors program fully meets all requirements for approval; however, the HIV Aids program is missing many of the requirements needed for approval. Dr. Weizer recommended that the Board offer a six month period for participants to take a Board approved HIV Aids course.

Dr. Weizer further explained the normal process for course approval, and stated that this would have ensured the program met all requirements for approval prior to the course being offered.

**Mr. Garcia expressed that the Board does not approve of courses being brought forward for retroactive approval when there has been a rule and process in place for some time that outlines the necessary steps to obtain prior approval.**

**Motion:** by Dr. Weizer, seconded by Dr. Fallon to approve the Medical Errors course and the retroactive approval for the participants who took it; also, to allow the participants six months to obtain a Board approved HIV Aids course. Motion carried.

The Board recommended that Mr. Kraljevich contact all of the participants who took the HIV Aids course in November and let them know that the course they took was not approved by the Board and inform them that they have six months to take a Board approved HIV Aids course. Dr. Weizer suggested that it would be good if Broward General Medical Center offered the participants a Board approved course. Mr. Kraljevich is to provide the Pharmacy Board office with a list of names for the participants who took the un-approved course in November.

After a short break, Mr. Richard Montgomery from Florida Hospital in Orlando approached the Board with comments. He stated that in February 2011 Orlando Health asked for a declaratory statement from the Board regarding central Fill; however, the Board did not rule on the request at that time and referred the matter to the Rules Committee for consideration.

#### 4. Update on “Abandoned Pharmacy”

Mr. Whitten stated there is newly introduced legislation that has come about due to the Prosecuting Services Unit having recently recognized the need to define the term “abandonment” and to have disciplinary guidelines created. Mr. Whitten turned the floor over to Mr. Truitt with the Prosecuting Services Unit to explain the legislation.

Mr. Truitt reported that the Prosecuting Services Unit were noticing gaps in the statutes in regards to abandoned pharmacies, so they drafted language to help give the Board rule making authority to define what is considered an abandoned pharmacy and to create disciplinary guidelines to help with regulation and enforcement.

**Motion:** by Dr. Weizer, seconded by Dr. Griffin to accept the proposed language. Motion carried.

#### 5. Compounding Survey Results

Mr. Whitten gave the latest update on the Compounding Survey Results reporting that the compliance rate is currently at 92%. Mr. Whitten reported that Pharmacy board staff is currently making personal outreach efforts to obtain 100% compliance; and although the ultimate goal is compliance with the survey and not disciplinary action, at some point we will have no alternative but to report those pharmacies that remain non-compliant to enforcement.

Mr. Whitten suggested that the information in this survey could be a good tool for use by the Compounding Rules Committee, and reported that the Enforcement Unit has begun prioritizing their inspections based on the survey results.

#### 6. State-by-State Comparison of Board Actions resulting from NECC

#### 7. Survey of Pharmacy Law

Mr. Whitten reported on sections 6 and 7 above, together. Mr. Whitten reported that the Board Office has conducted research on the web as well as contacting other state board offices via telephone in an effort to gather information about what actions they are taking as a result of the NECC incident. He was able to identify six states that were working on rule making, but a majority of the states are waiting on legislation. The actions taken by the Florida Board of Pharmacy continue to be reported on the NABP website, and Mr. Whitten will continue working with NABP and other state boards in regards to this issue.

#### 8. NABP

Mr. Whitten reported on NABP during Dr. Weizer’s Compounding Committee report.

9. Board of Pharmacy Delegation of Authority

**Motion:** by Dr. Weizer, seconded by Ms. Glass to approve the proposed Annual Board of Pharmacy Delegation of Authority. Motion carried.

10. April Board Meeting Location Change

**Motion:** by Dr. Fallon, seconded by Ms. Glass to change the location of the April 2013 Board meeting from Tampa to St. Petersburg due to accommodation issues. Motion carried.

11. Request for Modification of Business Hours  
a. LMC Pharmacy

Petitioner was not present nor represented.

The Board had discussion around the necessity for a business to define what their business hours would be if reduced, and explain the circumstances.

**Motion:** by Dr. Weizer, seconded by Ms. Glass to require that the petitioner appear at one of the next two meetings of the Board. Motion carried.

12. Legislative Update

Mr. Whitten gave an update on SB 294, which adds certain substances to the Schedule I list; SB 23/HB 50 regarding public meetings; and HB 365 regarding the substitution of bio-similar products. Dr. Weizer requested that Mr. Whitten forward the language for HB 365 to the Board Members.

Mr. Whitten confirmed that board office staff will continue to provide regular legislative updates to board members throughout the 2013 Legislative Session.

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

1. Rules Report

Mr. Flynn reported that the Pharmacy Permit application will be adopted on February 1, 2013 and shall become effective on February 21, 2013; the Records Rule 64B16-29.004, F.A.C., is adopted and shall become effective February 7, 2013; and the Disciplinary Guidelines were adopted and become effective on January 14, 2013.

2. Rule 64B16-28.100, F.A.C. – Determination of Rule Language

Mr. Flynn reported this was adopted and became effective and since the Board voted to update the forms at the December 2012 meeting, he will now move forward with making the updates.

3. Rule 64B16-26.206, F.A.C.  
a. Form 1196

Mr. Flynn reported that this rule was previously withdrawn due to time expirations. JAPC concerns have now been addressed and the form re-dated February 2013. Mr. Flynn requested that the Board vote to incorporate this form.

**Motion:** by Dr. Weizer, seconded by Dr. Griffin to incorporate the form. Motion Carried.

Mr. Flynn asked if there would be an adverse impact or a regulatory impact of over \$200,000 in the aggregate within the first year of implementation on small businesses.

**Motion:** by Dr. Weizer, seconded by Dr. Fallon that there is no adverse impact on small businesses. Motion carried.

4. Storage Rule 64B16-29.005, F.A.C.

Mr. Flynn informed the Board he needed their vote to add drug language for euthanasia used by veterinarians to Storage Rule 64B16-29.005, F.A.C.

**Motion:** by Ms. Glass, seconded by Dr. Weizer to approve. Motion carried.

5. Rule 64B16-27.700, F.A.C.

a. JAPC Correspondence

Mr. Flynn summarized the JAPC challenge to the Boards authority to have office use compounding in their rule. After many comments and much discussion from the Board and public members:

**Motion:** by Dr. Mesaros, seconded by Mr. Garcia to respond to JAPC and move forward with the rule. Motion carried.

6. Rule 64B16-28.108, F.A.C.

Mr. Flynn gave the Board a report on his research into beyond use and expiration dating; then presented clarification language/definitions for the Boards approval.

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

7. Chapter 456.0635, F.S. – Informational Update

Mr. Flynn added this as an informational item for the Board, and went over some of the legislative amendments that were made to this statute in the anticipation that a relevant case may be presented at a later time. Mr. Flynn updated the Board on some of the legal interpretations that have occurred as a result of the amendments to this statute.

8. Chapter 465.017(1), F.S.

Mr. Garcia read Mr. Flynn's modifications to the above statute into the record to include the following added language: or any other place located out-side the boundaries of Florida that are licensed by the department.

**Motion:** by Dr. Weizer, seconded by Dr. Griffin to approve. Motion Carried.

## **D. Prosecuting Services Report – John Truitt, Assistant General Counsel**

### **1. Prosecuting Services Report**

Mr. Truitt updated the Board on the case load for the Prosecuting Services Unit. He reported that as of January 31, 2013, the Case load is down to 273 from 284 cases, and 22 from 24 cases that are 2010 and older. The 13 attorneys in the Prosecuting Services Unit have gone through 626 Pharmacy cases since February 2012, and the anticipated caseload for pharmacy is currently from 225 to 250.

Mr. Truitt requested that the Board allow the Prosecuting Services Unit to continue prosecuting cases that are over 1 year old.

Mr. Garcia congratulated Mr. Truitt on his recent promotion to Section Manager in the Prosecuting Services Unit.

**Motion:** by Dr. Weizer, seconded by Ms. Glass to continue prosecuting these cases. Motion carried.

## **E. Chief Investigative Services Report – Jean Clyne**

Ms. Clyne reported that the Investigative Services Unit is currently ahead of schedule on their general inspections for the fiscal year having inspected over 60% of dispensing practitioners and 70% of the pharmacies.

Ms. Clyne reported that prior to the Compounding Survey inspectors were performing sterile compounding inspections based on their best guess on who was compounding sterile products.

On January 23, 2013, due to the survey results, they were able to generate a spreadsheet identifying those pharmacies who indicated they were performing sterile compounding.

Out of 188 pharmacies who indicated they perform sterile compounding only, Investigative Services has completed 43 inspections.

Out of 458 pharmacies who indicated they perform both sterile and non-sterile compounding, they have completed 102 inspections.

Ms. Clyne stated that due to the Board rule, inspectors have now been instructed to complete all the “sterile only” facilities first. There are 145 of these facilities remaining, and they are being treated as a high priority.

Ms. Clyne gave the Board a report on the current process used for inspecting sterile compounding facilities and the training that is being prepared and provided to the inspectors.

Ms. Clyne reported on the status of employing additional pharmacists to help perform sterile compounding inspections.

Mr. Kahn approached the Board with a request for pharmacies that were inspected in the past and found compliant, but are now non-compliant with the sterile compounding guidelines, have a period of time to become compliant prior to any disciplinary action.

The Board recommended that responsible parties become familiar and compliant with the rules and regulations.

Mr. Flynn provided a brief explanation of the probable cause process and offered that this process provides an opportunity for corrective action prior to disciplinary action in most cases.

**TAB2**            **Business – Albert Garcia, BPharm, MHL, Chair**

**A. Ratification of Issued Licenses/Certificates & Staffing Ratios**

1. Pharmacist (Licensure)(Client 2201) – 115
2. Pharmacist (Exam Eligibility)(Client 2201) – 83
3. Pharmacist Interns (Client 2202) – 74
4. Registered Pharmacy Technicians (Client 2208) - 1,016
5. Consultant Pharmacist (Client 2203) – 20
6. Nuclear Pharmacist (2204) – 1
7. Pharmacist/Facilities (2205) – 131
8. Registered Pharmacy Technician Ratios (2:1 or 3:1) – 44
9. Pharmacy Technician Training Program (Client 2209) – 23
10. CE Providers – 17
11. CE Courses – 33
12. CE Individual Request (Approved) – 8
13. CE Individual Request (Denied) – 0

**Motion:** By Dr. Fallon, seconded by Ms. Glass to ratify issued licenses, certificates and staffing ratios. Motion carried.

**B. Review and Approval of Minutes**

**1. December 11 – 12, 2012 Meeting Minutes**

**Motion:** by Dr. Griffin, seconded by Dr. Weizer to approve minutes. Motion carried.

Public Comments:

Michael Jackson with the Florida Pharmacy Association approached the Board to share that the FPA considers the compounding issues very important and at their annual meeting this year, they will be dedicating 6 hours of continuing education focusing on sterile and non-sterile compounding with a presentation from Ms. Jean Clyne.

A representative from Central Admixture Pharmacy Services, Inc. approached the Board to comment that they provided a handout on their corporate position about compounding pharmacies.

Robert Jernigan with the Drugs Devices and Cosmetics Program approached the Board with the authority of the Secretary of the Department of Business and Professional Regulation to offer their support on compounding issues that could possibly cross over into the area of distribution.

Fritz Hayes, Former Member of the Board, approached the Board to commend the Board and the Board staff on the apparent smoothness of the recent Registered Pharmacy Technician renewal process.

**Motion:** by Dr. Weizer, seconded by Dr. Fallon to adjourn the meeting at 2:30 p.m. Motion carried.

**Thursday, February 7, 2013 – 8:00 a.m.**

**8:00 a.m. Call to Order by Albert Garcia, BPharm, MHL, Chair**

All Board Members were present except Ms. DeAnn Mullins.

Mr. Garcia requested that cell phones, pagers, and beepers be turned off. He informed everyone that the meeting is being recorded and an audio file will be posted on the Board's website after the meeting.

**TAB 2 BUSINESS (continued) – Albert Garcia, BPharm, MHL, Chair**

**C. Presentations**

1. Karla Kiriako – Transitions of Care Upon Hospital Discharge for Patients who are Receiving Multi-Dose Meds

Ms. Kiriako approached the Board to request that the Board consider approving a program that would allow medications that have been administered to a patient in a medical facility be dispensed to the patient upon discharge from the medical facility.

Ronald Fase also approached the Board with comments in support of Ms. Kiriako's request.

Mr. Garcia commented that there is already a process in place, it just requires additional permitting. He also commented on other available options that enable patients to get their medications upon discharge from a medical facility.

**TAB 3 DISCIPLINARY CASES – John Truitt, Esq. & Albert Garcia, BPharm, MHL, Chair**

**A. Settlement Agreements – Appearance Required**

- A-1 Debra Lee Campbell, PS 37100, Parrish, FL- (Second Request)  
Case No. 2011-13921 – PCP Weizer/Mesaros

Respondent Violated:

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

Settlement Agreement:

Respondent shall be present. Respondent shall pay a fine in the amount of \$250.00 and costs in the amount of \$1,775.66. Respondent shall complete an 8 hour prevention of medical errors CE course within one year.

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

**Motion:** by Mr. Garcia, seconded by Dr. Griffin to reject the settlement agreement. Motion carried.

**Motion:** by Dr. Fallon, seconded by Dr. Griffin to accept the terms of the settlement agreement with the amendment that the fine be increased to \$500. Motion carried.

A-2 Randolph E. McEwen, PS 25912, Tampa, FL  
Case No. 2010-12676 – PCP Mullins/Risch

Respondent Violated:

Ct I: Section 465.016(1)(i), F.S., compounding, dispensing, or distributing a legend drug other than in the course of the professional practice of pharmacy.

Ct II: Section 465.016(1)(n), F.S., by violating Rule 64B16-27.810, F.A.C., by failing to review the patient record and each new refill prescription presented for dispensing in order to promote therapeutic appropriateness by identifying several listed factors.

Settlement Agreement:

Respondent shall be present. Respondent shall pay a fine of \$1,000 and costs in the amount of \$2,761.79. Respondent shall complete 12 hour laws and rules and 2 hour controlled substance dispensing responsibilities CE courses within one year.

Respondent was present and sworn in by the court reporter. Respondent was represented by Edwin Bayo, Esq.

**Motion:** by Ms. Glass, seconded by Dr. Weizer to reject the settlement agreement. Motion carried.

**Motion:** by Mr. Meshad, seconded by Dr. Weizer to counter offer for voluntary relinquishment of license. Motion carried.

A-3 Fletcher Discount Pharmacy, PH 22386, Tampa, FL  
Case No. 2010-13599 – PCP Mullins/Risch

Respondent Violated:

Ct I: Section 465.023(1)(c), F.S., by violating Section 465.016(1)(i), F.S., compounding, dispensing, or distributing a legend drug other than in the course of the professional practice of pharmacy.

Ct II: Section 465.023(1)(c), F.S., by violating Rule 64B16-27.810, F.A.C., by failing to review the patient record and each new refill prescription presented for dispensing in order to promote therapeutic appropriateness by identifying several listed factors.

Settlement Agreement:

Respondent shall be present. Respondent shall pay a fine of \$1,000 and costs in the amount of \$2,197.12.

Respondent was present and sworn in by the court reporter. Respondent was represented by Edwin Bayo, Esq.

**Motion:** by Ms. Glass, seconded by Dr. Weizer to reject the settlement agreement. Motion carried.

**Motion:** by Mr. Meshad, seconded by Dr. Weizer to counter offer for voluntary relinquishment of license. Motion carried.

A-4 Richard Alonso, PS 39780, Safety Harbor, FL  
Case No. 2012-06981 – PCP Meshad/Glass

Respondent Violated:

Ct I: Section 456.072(1)(hh), F.S., being terminated from a treatment program for impaired practitioners.

Ct II: Section 456.072(1)(k), F.S., failing to perform any statutory or legal obligation placed upon a licensee.

Settlement Agreement:

Respondent shall be present. Respondent shall pay a fine of \$1,000 and costs in the amount of \$5,000. Respondent shall complete a PRN evaluation and follow recommendations.

Respondent shall complete 5 years of probation. Respondent may not work as a PDM.

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

**Motion:** by Dr. Weizer, seconded by Dr. Fallon to reject the settlement agreement. Motion carried.

**Motion:** by Dr. Weizer, seconded by Dr. Fallon to accept the settlement agreement with the amendment that respondent work in a setting that does not allow access to any medications. Motion carried.

A-5 Kenneth S. Ginsburg, PS 25202, Lake Worth, FL  
Case No. 2011-14869 – PCP Meshad/Glass

Respondent Violated:

Section 465.016(1)(e), F.S., by violating Section 893.04(1)(b), F.S., by filling a written prescription for a controlled substance when the prescription was not dated and/or signed by the prescribing practitioner.

Settlement Agreement:

Respondent shall be present. Respondent shall pay a fine of \$5,000 and costs in the amount of \$1,735.58. Respondent shall complete 6 months of probation and a 12 hour laws and rules CE course.

Respondent was present and sworn in by court reporter. Respondent was represented by Randal Gilbert, Esq.

**Motion:** by Dr. Fallon, seconded by Dr. Mesaros to accept settlement agreement. Motion carried with Mr. Garcia in opposition.

A-6 Premier Compounding Pharmacy, Inc., PH 23481, Palm Beach Gardens, FL  
Case No. 2012-02690 – PCP Weizer/Mesaros

Respondent Violated:

Section 465.023(1)(c), F.S., by violating Section 499.005(22), F.S., which states 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 repackage permit.

Settlement Agreement:

Respondent shall be present. Respondent shall pay a fine of \$3,000 and costs in the amount of \$3,976.92.

Respondent was present and sworn in by court reporter. Respondent was represented by Edwin Bayo, Esq.

**Motion:** by Dr. Griffin, seconded by Ms. Glass to reject settlement agreement.

**Motion:** by Dr. Griffin, seconded by Dr. Fallon to accept the settlement agreement with the amendment that respondent complete 2 years of probation. Respondent and PDM must complete 12 hours of CE's in laws and rules and biannual inspections to be completed over 2 year period at the expense of the respondent. A letter of concern. Motion carried.

Dr. Weizer made comments for the audience and for the record in regards to Rule 64B16-27.797, F.A.C. and sterile compounding. Dr. Weizer stated that this rule has been in the Pharmacy books since 2008 and was modified in 2010. She expressed concerns in conjunction with the different types of accreditation and not knowing what inspection standards is used. She also stated for the benefit of the students that inspectors are looking for additional sterility testing any time a beyond use date is used that is different than what is specified in rule.

Mr. Garcia made additional statements in support of Dr. Weizer's comments in regard to accreditation.

A-7 Rejuvi Pharmaceuticals, Inc., PH 23297, Boca Raton, FL  
Case No. 2012-14670 – PCP Mullins/Mesaros  
Case No. 2010-08677 – PCP Garcia/Glass

Respondent Violated:

Ct I: Section 465.023(1)(c), by violating Rule 64B16-28.102(4), F.A.C., failing to ensure the prescription department was operating under clean, sanitary, un-crowded, and healthy conditions.

Ct II: Section 465.023(1)(c), F.S., by violating Rule 64B16-27.101, F.A.C., by possessing drugs that were improperly labeled as described by the Florida Drug and Cosmetic Law.

Ct III: Section 465.023(1)(c), F.S., by violating 64B16-28.110, F.A.C., by failing to remove from the prescription department all pharmaceuticals which bear upon the container an expiration date which has been reached.

Ct IV: Section 465.023(1)(c), F.S., by violating Rule 64B16-28.140(3)(a), (b), F.A.C., by failing to identify the responsible dispensing pharmacist in the prescription records.

Ct V: Section 465.023(1)(c), F.S., by violating Rule 64B16-28.140(4), F.A.C., by failing to properly maintain compounding logs.

In 2012-14670

Ct I: Section 465.023(1), F.S., by violating Rule 64B16-28.109(1), F.A.C., by having the prescription department open without a pharmacist present and on duty.

Ct II: Section 465.023(1), F.S., by violating Rule 64B16-27.420(4)(a), F.A.C., by having personnel not wearing an ID badge identifying them as a registered pharmacy technician.

Ct III: Section 465.023(1), F.S., by violating Rule 64B16-27.410(1), F.A.C., by allowing an RPT in the prescription department without the direct supervision of a pharmacist.

Ct IV: Section 465.023(1), F.S., by violating Rule 64B16-27.800, F.A.C., by not maintaining a patient record system.

Ct V: Section 465.023(1), F.S., by violating Rule 64B16-28.102(4), F.A.C., by failing to have adequate sanitation to ensure the prescription department operated under clean, sanitary, uncrowded, and healthy conditions.

Ct VI: Section 465.023(1), F.S., by violating Rule 64B16-28.108, F.A.C., by failing to properly label each container of medicinal drugs.

Ct VII: Section 465.023(1), F.S., by violating Section 465.0255, F.S., by failing to display the expiration date in a readable fashion on the container and packaging of each drug.

Ct VIII: Section 465.023(1), F.S., by violating Rule 64B16-28.140(3)(b), F.A.C., by failing to maintain a record of each prescription drug order that was filled or refilled in a data processing system.

Ct IX: Section 465.023(1), F.S., by violating Rule 64B16-28.140(3)(d), (e), F.A.C., by failing to have each pharmacist sign a print out of the daily log or an attestation in a log book.

Ct X: Section 465.023(1), F.S., by violating Rule 64B16-28.140(4), F.A.C., by failing to maintain a written record, for each batch and sub batch of product it compounded.

Ct XI: Section 465.023(1), F.S., by violating Section 465.015(2)(c), F.S., by dispensing drugs without first being furnished with a prescription and/or not recording the orders in a data processing system.

Ct XII: Section 465.023(1), F.S., by violating Section 465.016(1)(r), F.S., by dispensing medicinal drugs pursuant to prescription which did not contain all of the required information.

Ct XIII: Section 465.023(1), F.S., by violating Rule 64B16-27.797(5)(a), F.A.C., by failing to have an anteroom or ante area.

Ct XIV: Section 465.023(1), F.S., by violating Rule 64B16-27.797(5)(b)2, F.A.C., by failing to have appropriate disposal containers for used needles and syringes.

Ct XV: Section 465.023(1), F.S., by violating 64B16-27.797(7)(a), F.A.C., by failing to have a documented ongoing quality assurance program.

Ct XVI: Section 465.023(1), F.S., by violating Rule 64B16-27.797(7)(b), F.A.C., by having a person inadequately skilled, educated, instructed, and trained to correctly perform and document the preparation of media fills.

Ct XVII: Section 465.023(1), F.S., by violating Rule 64B16-27.797(1)(n)6, F.A.C., by having a person being unable to demonstrate competency by completing a media-filled test.

Ct XVIII: Section 465.023(1), F.S., by violating Rule 64B16-27.100(1), F.A.C., by not having licenses displayed.

#### Settlement Agreement:

Respondent shall be present. Respondent shall pay a fine of \$18,250 and costs in the amount of \$8,633.12. Suspension shall remain in effect until notification of new PDM. A restriction of no sterile compounding. Respondent shall complete 4 years of probation with quarterly inspections to be completed over a 2 year period at the expense of the respondent.

Respondent was present and sworn in by court reporter. Respondent was represented by Marty Dix, Esq.

**Motion:** by Dr. Weizer, seconded by Ms. Risch to accept settlement agreement with the amendment that respondent is permanently restricted from working with controlled substances. Motion carried.

Due to some comments having been made throughout this meeting; Mr. Garcia clarified for the record that our inspectors have always been inspecting for sterile compounding and this is not a new occurrence. He stated that NECC is not the beginning of the Board taking steps for patient safety; regulations and policies have always been in place for the protection of the public.

## **B. Determination of Waivers**

DOW-1            Garcia Pharmacy & Discount Corp., PH 25079, Miami, FL  
Case No. 2012-03329 – PCP Garcia/Risch

Respondent violated:

Ct I: Section 465.023(1)(c), Florida Statutes (2011), by violating Section 465.022(10), F.S., failing to notify the department within 10 days after any change in PDM and/or Section 465.022(11), F.S., failing to notify the department of the identity of the PDM within 10 days after employment.

Ct II: Section 465.023(1)(c), F.S., by violating Rule 64B16-28.1081, F.A.C., by failing to be open the required 40 hours per week.

Respondent was not presented nor represented by counsel.

**Motion:** by Dr. Griffin, seconded by Ms. Glass, 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 waived the right to 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. 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.

**Motion:** by Dr. Weizer, seconded by Dr. Griffin, to accept the recommendations of the Department for revocation of license. Motion carried.

DOW-2            Complete Pharmacy & Discount, Corp., PH 25466, Miami, FL  
Case No. 2012-05211 – PCP Garcia/Risch

Respondent Violated:

Section 465.023(1)(c), F.S., by violating Rule 64B16-28.202(3), F.A.C., by failing to follow proper closing procedures for a pharmacy.

Respondent was not present nor represented by counsel.

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

**Motion:** by Dr. Griffin, seconded by Dr. Weizer, to find that respondent was properly served and has waived the right to 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.

**Motion:** by Dr. Griffin, seconded by Dr. Weizer, to accept the recommendations of the Department for revocation of license. Motion carried.

DOW-3            Garcia Pharmacy & Discount Corp., PH 25078, Miami, FL  
Case No. 2012-03364 – PCP Garcia/Risch

Respondent violated:

Section 465.023(1)(c), F.S., by violating Rule 64B16-28.830(5), F.A.C., which requires a special-closed system pharmacy permittee shall be under the supervision of a PDM.

**Motion:** by Ms. Glass, seconded by Dr. Fallon, 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 waived the right to a formal hearing. Motion carried.

**Motion:** by Ms. Glass seconded by Dr. Fallon, 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.

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

DOW-4            Ben Todd Fruge, RPT 16311, Jacksonville, FL  
Case No. 2012-04933 – PCP Meshad/Glass

Respondent violated:

Ct I: Section 456.072(1)(x), F.S., failing to report to the board, or 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.

Ct II: Section 456.072(1)(c), F.S., being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

Respondent was not present nor represented by counsel.

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

**Motion:** by Dr. Fallon, seconded by Dr. Griffin, to find that respondent was properly served and has waived the right to a formal hearing. Motion carried.

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

**Motion:** by Dr. Griffin, 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.

**Motion:** by Dr. Fallon, seconded by Dr. Griffin, to accept the recommendations of the Department for revocation of license. Motion carried.

DOW-5            Mehrdad Hariri, PS 21339, Maitland, FL  
                         Case No. 2011-18154 – PCP Meshad/Glass

Respondent violated:  
Section 465.016(1)(r), F.S., by violating Section 465.022(11)(b), F.S., by failing to ensure the security of the prescription department.

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

The prosecuting attorney requested to withdraw the motion for waiver and proceed with an informal hearing.

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

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

**Motion:** by Dr. Griffin 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. 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.

**Motion:** by Mr. Garcia, seconded by Dr. Mesaros, for costs in the amount of 877.95, a fine in the amount of \$5,000, five years of probation with semi-annual inspections at the cost of the respondent, may not practice as PDM and completion of a 12 hour continuing education course in Laws and Rules. Motion carried.

DOW-6 Jeffrey Lee Williams, PS 15810, Orlando, FL  
Case No. 2011-19646 – PCP Glass/Risch

Respondent violated:

Ct I: Section 465.016(1)(m), F.S., by being unable to practice pharmacy with reasonable skill and safety due to use of drugs, narcotics or chemicals and or as a result of a mental condition.  
Ct II: Section 456.072(1)(hh), F.S., by being terminated from a treatment program for impaired practitioners.

Respondent was not present nor represented by counsel.

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

**Motion:** by Dr. Griffin, seconded by Dr. Weizer, to find that respondent was properly served and has waived the right to a formal hearing. Motion carried.

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

**Motion:** by Dr. Griffin, 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.

**Motion:** by Mr. Meshad, seconded by Dr. Weizer, to accept the recommendations of the Department for revocation of license. Motion carried.

### **C. Voluntary Relinquishments**

VR-1 Jarrod John Kirkpatrick, RPT 11115, Gainesville, FL  
Case No. 2012-02985 – PCP Glass/Risch

**Motion:** by Dr. Griffin, seconded by Dr. Weizer to accept the voluntary relinquishment. Motion carried.

**VR's voted on at one time:** VR2, VR3, VR4, VR5

**Motion:** by Ms. Glass, seconded by Dr. Fallon to accept the above listed voluntary relinquishments. Motion carried.

VR-2 Yun Pharma, Inc., PH 25843, Miami, FL  
Case No. 2012-13121 – PCP N/A

Respondent was not present, nor represented by counsel.

**See:** motion's made above VR2.

VR-3 Debra Ann Hahn, RPT 23664, Gainesville, FL  
Case No. 2012-13494 – PCP Waived

Respondent was not present, nor represented by counsel.

**See:** motion's made above VR2.

VR-4 Justin Wayne Buffington, RPT 43983, Tampa, FL  
Case No. 2012-16940 – PCP Waived

Respondent was not present, nor represented by counsel.

**See:** motion's made above VR2.

VR-5 Haroun T. El-Nil, PS 32583, Royal Palm Beach, FL  
Case No. 2008-25455 – PCP Waived

Respondent was not present, nor represented by counsel.

**See:** motion's made above VR2.

VR-6 Michael C. Lomangino, PS 28489, Edgewater, FL  
Case No. 2012-02056 – PCP Weizer/Meshad

**Motion:** by Dr. Fallon, seconded by Ms. Glass to accept the voluntary relinquishment. Motion carried.

VR-7 Med Express, LLC, PH 25533, Lakeland, FL  
Case No. 2012-14602 – PCP Mullins/ Mesaros

**Motion:** by Dr. Griffin, seconded Dr. Weizer to accept the voluntary relinquishment. Motion carried.

**VR's voted on at one time:** VR8, VR9, VR10

**Motion:** by Dr. Weizer, seconded by Dr. Fallon to accept the above listed voluntary relinquishments. Motion carried.

VR-8 People's Choice Pharmacy, LLC, PH 24693, Tamarac, FL  
Case No. 2012-15877 – PCP Waived

Respondent was not present, nor represented by counsel.

**See:** motion's made above VR8.

VR-9 Shannon Roddenberry, RPT 17888 – PCP Waived  
Case No. 2012-01444 – PCP Waived

Respondent was not present, nor represented by counsel.

**See:** motion's made above VR8.

VR-10 AJ Cargo Express, Inc., PH 24290, Miami, FL  
Case No. 2012-12176 & 2012-11578 – PCP Waived

Respondent was not present, nor represented by counsel.

**See:** motion's made above VR8.

VR-11 Carrie Ann Ivey, RPT 13274, Hillard, FL  
Case No. 2012-14416 – PCP Mullins/Mesaros

**Motion:** by Dr. Weizer, seconded by Ms. Glass to accept the voluntary relinquishment. Motion carried.

VR-12 Karla Dianne Calhoun, RPT 42465, Abbeville, AL  
Case No. 2012-14343 – PCP Weizer/Risch

**Motion:** by Dr. Griffin, seconded by Ms. Glass to accept the voluntary relinquishment. Motion carried.

#### **D. Informals**

I-1 David E. Muforo, PS 24082, Brandon, FL  
Case No. 2010-14846 – PCP Weizer/Risch

Respondent violated:

Section 465.016(1)(r), F.S., by violating Rule 64B16-27.1001(3), F.A.C., by failing to make the final check of the completed prescription before the prescription was dispensed to the patient.

Respondent was present and sworn in by the court reporter. Respondent was represented by Dale Cisco, 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 Dr. Griffin, 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.

**Motion:** by Dr. Griffin, seconded by Ms. Glass, to accept the recommendations of the Department of costs in the amount of \$548.13, a fine in the amount of \$500.00 and completion of an 8 hour continuing education course in the prevention of medical errors. Motion carried.

I-2 Apothecure, Inc., PH 21213, Dallas, TX  
Case No. 2012-12302 – PCP Meshad/Glass

Apothecure, Inc. withdrew the motion for informal hearing, and submitted a request for Voluntary Relinquishment.

**Motion:** by Dr. Weizer, seconded by Dr. Griffin to accept the voluntary relinquishment. Motion carried.

I-3 Ronald Jacobs, PS 18373, Lake Worth, FL  
Case No. 2011-17701 – PCP Fallon/Weizer

Respondent violated:

Section 465.016(1)(e), Florida Statutes (2009-2011), through a violation of Section 893.07(3), Florida Statutes (2009-2011), which provides that every person who engages in the compounding, or dispensing, of controlled substances shall keep records of all controlled substances sold, administered, dispensed, or otherwise disposed of and Section 465.016(1)(e), Florida Statutes (2010-2011), by violating Section 893.07(5), Florida Statutes (2009-2011), provides that 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 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.

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

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

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

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

**Motion:** by Dr. Griffin, 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.

**Motion:** by Mr. Garcia, seconded by Dr. Griffin, for costs in the amount of \$825.38, a fine in the amount of \$1,000, a 12 hour continuing education course in Laws and Rules, probation for 1 year, may not serve as the PDM, and semi-annual inspections at the cost of the respondent. Motion carried.

I-4 Meds Rx Pharmacy, LLC, PH 24081, Deerfield Beach, FL  
Case No. 2011-17700 – PCP Fallon/ Weizer

Respondent violated:

Section 465.023(1)(c), Florida Statutes (2009-2011), through a violation of Section 893.07(3), Florida Statutes (2009-2011), which provides that every person who engages in the compounding, or dispensing, of controlled substances shall keep records of all controlled substances sold, administered, dispensed, or otherwise disposed of and Section 465.016(1)(e), Florida Statutes (2010-2011), by violating Section 893.07(5), Florida Statutes (2009-2011), provides that 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 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.

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

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

**Motion:** by Dr. Griffin, seconded by Ms. Glass, 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 Dr. Griffin, 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.

**Motion:** by Mr. Garcia, seconded by Dr. Griffin, for costs in the amount of \$1,878, a fine in the amount of \$1,000 and 2 semi-annual inspections during the year following the Order, at the costs of the respondent, with audits of five randomly selected controlled substances. Motion carried.

I-5 Jessica Cobo Barroso, PS 41346, Key West, FL  
Case No. 2012-09645 – PCP Meshad/Glass

Respondent violated:

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

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

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

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

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

**Motion:** by Dr. Griffin, 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.

**Motion:** by Dr. Fallon, seconded by Dr. Griffin, to accept the recommendations of the Department for costs in the amount of \$798.74, a fine in the amount of \$500 and completion of an 8 hour course in the prevention of medical errors. Motion carried.

I-6 James Rodney Raines, PS 15205, Coral Springs, FL  
Case No. 2011-17290 – PCP Garcia/Mesaros

The prosecuting attorney requested that this case be continued to the April 2013 meeting of the Board.

**TAB 4**            **APPLICATIONS REQUIRING BOARD REVIEW – Cynthia Griffin, Pharm D**

- A. Registered Pharmacy Technician Applicant
  - 1. Marlene Desimone, File No. 473, West Chapel, FL

Applicant was not present, nor represented by counsel.

**Motion:** by Dr. Griffin, seconded by Dr. Weizer to approve license upon the condition that respondent receive a PRN evaluation within 60 days and, if determined a contract is necessary, enter into and comply with any and all terms of the PRN contract. If not, the license shall be issued un-encumbered. Motion carried.

- B. Pharmacist Endorsement Applicant
  - 1. Matthew Kolb, File No. 42476, Chicago, IL

Applicant was not present, nor represented by counsel.

**Motion:** by Dr. Griffin, seconded by Dr. Weizer to approve license by endorsement. Motion carried.

- C. Pharmacist Examination Applicant
  - 1. Catherine Crowe, File No. 23418, Jacksonville, FL

Applicant was present and sworn in by court reporter. Respondent was represented by Edwin Bayo, Esq.

**Motion:** by Dr. Griffin, seconded by Dr. Weizer to approve the application on the following conditions: The applicant shall enter into a contract with PRN and comply with any recommendations, the applicant shall be on probation for a term of not less than 4 years and no greater than the PRN contract. During probation applicant shall not act as a PDM. After two years, applicant may petition the board requesting the right to act as a PDM. The board shall grant the request if PRN is in support of the request. Additional terms of probation include the following: a) The applicant may not work in more than two pharmacies per quarter; b) applicant must submit quarterly reports detailing applicant's compliance with this Order and notification of her current employment; c) applicant shall have her supervisor submit quarterly reports detailing her working status, applicant shall not engage in the active practice of pharmacy until PRN finds that she is safe to practice with reasonable skill and safety. The Board delegates the authority to assess compliance with this Notice and authorizes returning to active practice when its Chair finds the applicant has met the above listed conditions. Motion carried.

2. Lauren Dickenson, File No. 42063, West Palm Beach, FL

Applicant was present and sworn in by court reporter. Respondent was represented by Edwin Bayo, Esq.

**Motion:** by Dr. Griffin, seconded by Dr. Weizer, to approve with the following conditions: The applicant shall continue to comply with her current PRN contract, and shall comply with all the outstanding conditions of previous final order DOH-13-0024-S-MQA. Motion carried.

**TAB 5**            **LICENSURE ISSUES**

A. Request for Termination of Probation

1. William Wood, PS 31383, Jacksonville, FL

Respondent was present and sworn in by court reporter. Respondent was represented by Edwin Bayo, Esq.

**Motion:** by Dr. Fallon, seconded by Dr. Weizer to grant the request for termination of probation. Motion carried.

2. Michelle Salkey, PS 23286, Port Orange, FL

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

**Motion:** by Dr. Griffin, seconded by Dr. Fallon to grant the request for termination of probation. Motion carried.

3. Kenneth Marsh, PS 25269, Seminole, FL

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

**Motion:** by Dr. Weizer, seconded by Ms. Glass to grant the request for termination of probation. Motion carried.

B. Request for Reconsideration

1. Veronica Taran & Pharmacy Doctors Enterprises, Inc., PS 39928 & Pharmacy Doctors Enterprises, Inc., PH 23558, Hallandale, FL

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

The Board chose not to reconsider this case.

Respondent made a request for extension on time to pay costs and fines.

**Motion:** by Dr. Griffin, seconded by Ms. Glass to grant the request for extension of time to pay costs and fines to six months. Motion carried.

C. Request for Modification of Probation & release from PRN Monitoring Contract  
1. Brian Bulfer, PS 21587, Miami Shores, FL

Respondent was present and sworn in by court reporter. Respondent was represented by Edwin Bayo, Esq.

Motion: by Dr. Fallon, seconded by Ms. Glass to grant the request for Modification of Probation to the following: Respondent's PRN contract is hereby terminated, and probation is modified as follows: The professional practice of pharmacy, for purposes of this settlement agreement only, shall mean working in the field of pharmacy for not less than 35 hours per week. This amendment anticipates that applicant may be self-employed. In this event, applicant shall still comply with all quarterly reports and supervisor quarterly reports himself. Motion carried.

Mr. Garcia called for comments from the public and hearing none, called for a motion to adjourn the meeting.

**Motion:** by Dr. Griffin, seconded by Ms. Glass to adjourn the meeting at 3:24 p.m.