

Meeting Minutes

DEPARTMENT OF HEALTH BOARD OF PHARMACY FULL BOARD MEETING

April 6-8, 2015

Tampa Marriott Westshore

1001 N Westshore Blvd

Tampa, Florida 33607

(813) 287-2555

Board Members

Michele Weizer, PharmD, Chair, Boca Raton
Debra B. Glass, BPharm, Vice-Chair, Tallahassee
Win Adams, CSA, Consumer Member, Fern Park
Goar Alvarez, PharmD, Cooper City
Leo "Lee" Fallon, BPharm, PhD, The Villages
Gavin Meshad, Consumer Member, Sarasota
Jeenu Philip, BPharm, Jacksonville
Mark Mikhael, PharmD, Orlando
Jeffrey J. Mesaros, PharmD, JD, Orlando

Board Staff

Allison Dudley, Executive Director
Emily Roach, Program Operations Administrator
Amber Greene, Regulatory Specialist III

Board Counsel

David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Department of Health Staff

Matthew Witters, Assistant General Counsel
Christopher Jurich, Assistant General Counsel

Monday, April 6, 2015 – 12 p.m.

Dr. Michele Weizer called the meeting to order at 12:02 p.m. All members were present except Gavin Meshad who was excused. Dr. Lee Fallon arrived at 12:20 p.m.; Dr. Jeffrey Mesaros arrived at 12:50 p.m.

TAB 1: APPLICATIONS REQUIRING BOARD REVIEW- Michele Weizer, PharmD, Chair

A. Non-Resident Sterile Compounding Permits

1. Downing Labs, LLC File : 172

Applicant was present. Applicant was not represented by counsel. Downing representatives present were Roger Mansfield, PDM and Ashley Downing, Owner.

David Flynn gave a briefing of current application and deficiencies.

David Flynn stated the Board needs to see current inspection within 6 months. Ms. Downing advised the Board does not have the most current inspection therefore is requesting a continuance.

Motion: by Dr. Mikhael seconded by Dr. Alvarez, to approve a continuance until current inspection is provided. Motion carried.

~~2. California Pharmacy & Compounding Center, File: 53 Moved to June meeting.~~

3. Pharmacy Creations, File :115

Applicant was present. Applicant was represented by Mark Boesen, an attorney not licensed in Florida. Joe Bitterman, CEO, was present.

Motion: by Mr. Philip, seconded by Ms. Glass to accept Mr. Boesen as qualified to represent the client.

David Flynn gave a briefing of current application and current deficiencies. Mr. Flynn then stated the Board is looking for current inspection and the pharmacy had prior discipline.

Mr. Boesen stated that Pharmacy Creations made a unique product for cataract surgery patients and that no other compounders engage in this type of cataract medicine.

Mr. Boesen made it known that none of the previous owners or managers is still affiliated with the pharmacy and a PCAB inspection had been done in the last six months and they are compliant and all deficiencies have been corrected. He also stated that Pharmacy Creations just received a probated license from Alabama. New Jersey requires inspections every six months, which are done by a private company not approved by the board.

Jeenu Philips asked for the exact date the pharmacy will be off probation in Indiana, but Mr. Bitterman was not sure of the exact date.

Dr. Weizer asked Mr. Bitterman to clarify the dates in which he purchased the rights to Pharmacy Creations. He advised the date was April 20, 2014.

Dr. Mikhael asked about discipline in New Jersey. Mr. Boesen stated the company signed a consent agreement to a voluntary restriction, stemming from FDA inspection from previous ownership.

Ms. Glass said the company had an acceptable inspection after the buyout, worked to correct the problems and now has a clean bill of health. Dr. Mikhael said he wants a safety net.

Motion: by Dr. Mikhael seconded by Dr. Fallon, to approve the application, but no product can be dispensed without sterility assurance -- sterility testing and endotoxin testing results to go out with each batch. Motion carried.

4. Coastal Meds, LLC, File: 122

Applicant was present. Applicant was not represented by counsel.

Representatives present were Joseph Johnson and Clay Clifton.

David Flynn gave briefing of application and current deficiencies.

Mr. Clifton went over structure of pharmacy and stated they are waiting on HOOD to be installed and are working hard to correct all deficiencies with the application. Dr. Weizer recommended withdrawing the application until a complete application can be submitted.

Clay Clifton withdrew the application and will re-apply once they have completed all questions pertaining to the application.

No motion due to the applicant withdrawing the current application.

5. Advanced Physician Solutions, File: 170

Applicant was not present. Applicant was not represented by counsel.

David Flynn gave briefing of application and current deficiencies.

Motion: by Dr. Fallon seconded by Dr. Mesaros, to reject the application due to delinquent status, non-current inspection and prior discipline. Applicant will have 14 days to withdraw application. Motion carried.

6. Cantrell Drug Company, File: 24

Applicant was present and not represented by counsel.

Representative present was James L. "Dell" McCarley, CEO.

David Flynn gave briefing of current application and current deficiencies. My. Flynn stated the Board needs a current policy and procedure manual, not a partial copy which is what was submitted with the application.

Mr. McCarley stated the current policy and procedure manual had confidential information.

Dr. Weizer stated the Board is not comfortable with what had been submitted and recommended he ask for a continuance until complete policy and procedure can be submitted.

Mr. McCarley requested a continuance.

Motion: by Dr. Mikhael, seconded by Dr. Fallon to grant a continuance until complete policy and procedure can be submitted. Motion carried.

7. South Coast Specialty Compounding, Inc. ,File :200

Applicant was present and represented by Mark Boesen.

Representative present was Joe Bitterman, CEO.

David Flynn gave briefing of current application and deficiencies.

Mr. Boesen stated PCAB inspection is off by a couple of weeks and apologizes for not getting the documentation to Board in a timely manner. Mr. Boesen did provide supplemental information to the Board before the meeting started. Mr. Bosen hoped to have the NABP report prior to the meeting but Joe Bitterman stated there were no deficiencies found.

Dr. Weizer stated this is patient specific pharmacy and they are following a higher standard.

Mr. Flynn said Florida statute requires inspection within six months, and by his count the inspection was current.

Motion: by Dr. Mikhael, seconded by Dr. Alvarez to approve the application. Motion carried.

8. Harry Everett Corporation, File: 25

Applicant was present and not represented by counsel.

Representative present was Eric Everett, co-owner.

David Flynn gave briefing of current application and deficiencies.

Dr. Weizer stated a corrective action plan had been submitted.

Mr. Everett stated the pharmacy was proactive and had been certified by PCAB eight years. The goal is that all compounding is done only by pharmacist; no technicians will do any compounding. He also made it known to the Board that Harry Everett Pharmacy currently participates in two FDA drug studies.

Motion: by Dr. Mikhael seconded by Dr. Alvarez, to approve the application. Motion carried.

9. Medquest Pharmacy, Inc. File: 189

Applicant was not present nor represented by counsel.

Dr. Weizer gave briefing of current application and deficiencies.

Dr. Weizer stated MedQuest submitted two self-inspections and there was quite a bit of discipline. She made it known that the Board is looking for inspections done by a third party that has been approved by the board.

There is no current inspection at this time.

Motion: by Dr. Fallon seconded by Dr. Mikhael, to reject the application based on prior discipline and not having current inspection done in the last six months. Motion carried.

10. PharMEDium Services, LLC. File: 10- Moved to Wednesday

11. PharMEDium Services, LLC. File: 11 Moved to Wednesday

12. PharMEDium Services, LLC. File: 12 Moved to Wednesday

13. PharMEDium Services, LLC. File: 13 Moved to Wednesday

14. M & O Enterprises, LLC File: 65

Applicant was not present nor represented by counsel.

David Flynn gave briefing of current application and deficiencies. Dr. Weizer then went over inspection comments.

Dr. Mikhael stated they are not compliant with 797 statutes; Dr. Weizer made it known they are not compliant in Alabama either.

Motion: by Dr. Fallon, seconded by Dr. Mesaros, to reject the application for not being 797 compliant; will allow 14 days to withdraw application. Motion carried.

15. Physician Preferred Medical, LLC. File: 117

Applicant was not present nor represented by counsel.

David Flynn gave briefing of current application and deficiencies.

Motion: by Dr. Mesaros seconded by Ms. Glass, to require an appearance at one of the next two board meetings or permit application will be denied. Motion carried.

Dr. Mikhael asked how pharmacies will know the Board had denied their permit and they are no longer allowed to ship to our state. Dr. Weizer informed the Board the pharmacy will receive a letter stating the decision the Board had made.

Mark Whitten with the Bureau of Enforcement stated there will be periodic checks verifying no shipping is being done.

Dr. Weizer opened the floor to public comments; none at this time.

Mr. Philip made a motion, Ms. Glass seconded to adjourn the meeting. Motion carried.

Meeting adjourned at 1:52 p.m.

Tuesday, April 7, 2015 – 9:00 a.m.

TAB 1: REPORTS - Michele Weizer, PharmD, Chair

All members were present except Gavin Meshad, who was excused.

Dr. Weizer called the meeting to order at 9:00 a.m.

A. Chair's Report – Michele Weizer, PharmD

1. Committee Assignments

Dr. Weizer went over past committee assignments and advised the Board of current committees needing assignments.

Rules Committee members will be Jeff Mesaros, chair, Jeenu Philip, Goar Alvarez and Lee Fallon.

Compounding Committee members will be Michele Weizer, chair, Debra Glass and Mark Mikhael.

The newest committee will be a Controlled Substance Standards Committee. Members will be Gavin Meshad, chair, Michele Weizer, Win Adams and Jeenu Philip.

Dr. Weizer and Allison Dudley are currently analyzing the Tripartite Committee due the size of this particular committee.

The budget liaison will be Michele Weizer.

2. NABP Consensus Documents

Allison Dudley reviewed NABP consensus documents and asked the Board to vote.

Dr. Fallon made a motion, seconded by Dr. Mesaros to support the NABP documents. Motion carried.

B. Executive Director's Report – Allison Dudley, Executive Director

1. Delegation of Authority and 2. Delegation of Authority Chart

Allison Dudley explained to the Board that the Delegation of Authority is what the Board members authorize the board staff to do on their behalf.

Dr. Alvarez made a motion, seconded by Dr. Mikhael to approve the delegations of authority.

3. Discussion on proposed dates for special conference calls

At this time Allison Dudley decided that face to face meetings are better suited than conference calls. Ms. Dudley stated conference calls are hard to set with everyone's schedules.

4. Sampling Devices-Brady Schwarz with Q.I Medical Inc. will be present

Brady Schwarz made an appearance and discussed sampling devices for surface sampling and fingertip testing.

Mr. Flynn said the rule states requirements about the medium, but not the shape of the agar container. He said he would discuss with Enforcement Bureau Chief Mark Whitten and that it should not be an issue to use the products QI Medical is using.

2. October Board meeting/location discussion

The board proposed locations for the October Board meeting. Proposed locations are Tampa and St. Augustine. The board staff will speak with meeting planner and see if we can get any of those locations with our current dates set for the October meeting.

3. Cloud iViewer update

Allison Dudley discussed with Board that in June the Department of Health will go live with Cloud iViewer. The Board of Pharmacy will be the first Board to move to the new platform. Ms. Dudley stated we hope to have a presentation at the next Board meeting. Jeenu Philip suggested we have a large screen at the next meeting so everyone can see how the new Cloud iViewer will work.

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

1. Rules Report – Lawrence Harris, Assistant Attorney General

David Flynn had nothing to report at this time; however he did ask that the compounding committee meet some time before the next meeting. Committee Chairwoman Dr. Weizer suggested meeting in May preferably in Tampa or Orlando.

2. Declaratory Statements – David Flynn, Assistant Attorney General

a. Lato Drug Company. Inc. d/b/a Post Haste Pharmacy

Brian Kahan represented Lato Drug Company. Prior to the meeting Mr. Kahan provided a packet to the Board with relevant statutes. Mr. Kahan referred to Section 474.202, F.S., which stated “animal” means any mammal other than a human being.

Mr. Kahan wanted the Board to assist in understanding the statute wording of animal – is an animal a patient. He said the federal kickback statute is the origin of all kickback statutes, and it says “human patient.” The statute aims to stop insurance fraud.

Mr. Flynn asked if a patient under Section 465 F.S. for the pharmacist is an animal, advised the Board to decide what is considered a patient under Chapter 465.

Dr. Mesaros asked if the Board had the opportunity to reconcile the definitions of Section 474, F.S., into our current definitions and would it help if we had flexibility by defining the rule.

Mr. Flynn advised the board to vote on the definition of animal.

Motion: by Dr. Mikhael, seconded by Dr. Alvarez in statute 465.185 patient with pharmacy does refer to human and animal. Motion carried.

Mr. Flynn advised Mr. Kahan he can appeal or have this go to rule making. Mr. Flynn thinks this should go to rule making.

Motion: by Dr. Mikhael, seconded by Dr. Fallon to deny Declaratory Statement based on board's interpretation of the definition of patient. Motion carried.

After the 10:30 morning break Mr. Kahan withdrew the Declaratory Statement.

Motion: by Dr. Mesaros, seconded by Ms. Glass to accept the withdrawal of the Declaratory Statement. Motion carried.

~~b. Palm Springs General Hospital (Withdrawn)~~

c. Hendrix, Schwartzman, Pitts and Centra Care

Represented by: Counsel Cynthia Mikos.

Dr. Mikhael recused himself due to the company he works for having a joint venture with Centra Care.

This Declaratory Statement is asking for definition of Section 465.0276(c), F.S., which is the definition of Dispensing Practitioners. The statement is asking if Centra Care's method of handling patients and prescriptions satisfies the requirement in which the dispensing practitioner must give a written prescription to the patient and advise them they can have it filled at any pharmacy.

The respondent is concerned with the Dispensing Practice Act and being disciplined. Respondent is looking for a uniform understanding of what it means to give a written prescription to patient.

The respondent is looking for the meaning of "give" when referring to a prescription as stated in Section 465.0276(2)(c).

Ms. Mikos disagreed that a written prescription means a piece of paper; stated dispensing practitioners will have to keep a record of the patient's choice of the method of prescription.

Mr. Harris stated if health care practitioners decide to become dispensing practitioners they have to abide by higher standards. If they choose to sell drugs from their practice there is a higher standard; statute is very clear if they don't want to not give a written copy of prescription then don't dispense from practice.

Dr. Weizer stated a prescription can come in many different formats and it's ultimately up to the patient on which method they prefer.

Motion: by Dr. Alvarez, seconded Ms. Glass that language in Section 465.0276(2)(c) is clear; dispensing practice must provide paper copy of prescription and advise patient they can have it filled at any pharmacy or dispensing practitioner. Motion carried.

Break 10:30

d. Publix Super Market's, Inc. (store#3201)

Represented by: Counsel Martin Dix

Publix Super Market's, Inc. is seeking the Board's opinion as to the applicability of Rule 64B16-28.608(5)(e), F.A.C., as it applies to Publix Super Market. Specifically, Petitioner seeks a declaration that Publix Central Fill Pharmacy's Triple Scan System verification process satisfies the alternative method of verification authorized by said rule.

Mr. Dix showed the Board examples of products that can't go into the automated system. Mr. Dix then explained how the triple scan process works. He stated the Pharmacist technician would print the label, go get the product, place the label on product making sure not to cover the bar code, scan the product and prescription label once more, if they match the process can go to the next step which is transmitting to originating pharmacy.

Mr. Flynn stated subsection 5(e) is not applicable to triple scan process.

Dr. Mesaros asked Mr. Dix where the Pharmacist involvement is during verification of product and scanning. Mr. Dix stated the Pharmacist would intervene if the product and the label did not match.

Mr. Dix withdrew Petition for Declaratory Statement.

3. Petition for Variance or Waiver

a. Care America Pharmacy Service

Pharmacist present- Robert Haghgou

Care America submitted Variance request for Rule 64B16-28.820 Sterile Products and Special Parenteral/Enteral Compounding.

Care America Pharmacy Services is requesting to be allowed to compound non-sterile medicines. Mr. Haghgou stated The Board of Pharmacy had no type of permit that allows both sterile and non-sterile compounding without multiple permits.

Mr. Haghgou stated in his petition for variance that they are not co-mingling non-sterile and sterile procedures; they will prepare non-sterile compounds in a separate clean area away from the sterile cleanroom; constructed a separate clean room with a certification of ISO 8 or better and have the

compounding environment exhausted to the outside air, not back into the common air of the pharmacy. (When non-sterile powder medicines are compounded, they can become air-borne and ingested by the pharmacy staff and/or general public. This environment for non-sterile compounding will eliminate the air-borne particles from the medicines to reach the pharmacy staff or the general public outside of this room.); obey all prescription requirements and only dispense "patient specific" medicines for individual patients; not bulk compound or deliver non ordered medicines to anyone including physicians; Apply all dispensing laws and rules for sterile-compounded medicines, pursuant to USP 795 regulations.

Motion: by Dr. Mikhael, seconded by Mr. Adams to grant variance or waiver based as described maintaining that he agrees to comply with items listed in variance. Motion carried.

b. Publix Super Market's, Inc. (store#3201)

Represented by: Counsel Martin Dix

Publix Super Market's Inc. had filed a petition for variance or waiver of Rule 64B16-28.608, F.A.C, requesting that in the event Publix Central Fill Pharmacy's Triple Scan System verification process is not declared to be an electronic verification process, the Board then permanently waive the rule's requirements as applied to unit of use drugs which do not fit into the automated dispensing system.

Dr. Mesaros asked Mr. Flynn if the Board can issue a temporary variance or waiver until another presentation with data had been made to see if the process worked. Mr. Flynn stated the board can limit duration of a temporary variance.

Dr. Mikhael is very cautious since it no longer applies to automated filling system; the environment becomes where there is no more final check.

Dr. Mesaros suggested a pilot program; Mr. Philip agreed a pilot program would work.

Dr. Mikhael suggested opening Rule 64B16-28.608 for rule making by adding automated filling provisions for items that do not fit into machine. Mr. Flynn agreed the board needs to know more about this system and know how the product essentially gets from point A to B.

Dr. Mesaros stated Board may not have to edit entire rule, start with editing the title of rule to automated systems and processes and have definitions of the process, put safeguards into the language.

Motion: by Dr. Mesaros, seconded by Ms. Glass to open Rule 64B16-28.608, F.A.C, for development. Motion carried.

Mr. Adams requested a video for the next board meeting to see how the process actually works. Mr. Dix stated that can be arranged.

D. Prosecution Services Report – Matt Witters, Assistant General Counsel

Mr. Witters stated the inventory was 345 cases last time and is now down to 326 cases.

Mr. Witters stated we currently have 302 cases that are 1 year or older and asked the Board to consider allowing to continue to prosecute those cases.

Motion: by Debra Glass, seconded by Dr. Fallon to allow PSU to continue prosecuting cases one year and older. Motion carried.

E. Investigative Services Report – Mark Whitten, Chief of Enforcement

Mr. Whitten stated out of 6,787 pharmacies, 5,025 have been inspected (76 %).

Mr. Whitten stated out of 8,482 Dispensing Practitioners, 5,252 have been inspected (62%).

Mr. Whitten stated that Enforcement is currently at 80% compliance.

TAB 2: BUSINESS – Michele Weizer, PharmD, Chair

A. Ratification of Issued Licenses/Certificates & Staffing Ratios

1. Pharmacist (Licensure)(Client 2201) – 120
2. Pharmacist (Exam Eligibility)(Client 2201) – 103
3. Pharmacist Interns (Client 2202) – 84
4. Registered Pharmacy Technicians (Client 2208) – 1,275
5. Consultant Pharmacist (Client 2203) – 30
6. Nuclear Pharmacist (Client 2204) – 3
7. Pharmacy/Facilities (Client 2205) – 148
8. Nonresident Sterile Compounding (Client 2210) – 39
9. CE Providers – 10
10. CE Courses – 20
11. CE Individual Request (Approved) – 0
12. CE Individual Request (Denied) – 0

Motion: by Dr. Fallon seconded by Debra Glass to ratify items listed above. Motion carried.

B. Review and Approval of Minutes

1. February 10-11, 2015 Meeting Minutes

Jeenu Philip stated there was an error with the February minutes on page 6 of the draft minute's 2(b) verbiage should read "**or** within 90 days of hire date."

Allison Dudley stated board staff will make the correction.

Motion: by Dr. Fallon, seconded by Jeenu Philip to approve minutes. Motion carried.

B. Appearance- PRN, Penelope Ziegler, M.D.

Dr. Ziegler clarified to the Board and audience what role PRN had and how they assist the Board. Professional Resource Network has a contract with the Department of Health to provide services to about 30 different boards excluding Board of Nursing. Dr. Ziegler explained that PRN evaluates the needs of Pharmacists and interns to put a plan into place to seek treatment to become safe to practice well as monitoring treatment plans.

Dr. Ziegler stated there had only been one incident in which PRN had refused a person, and that happened to be a pharmacist. She apologized to the Board for that particular situation. Dr. Ziegler made it known to the Board that if for some reason they cannot provide direct **monitoring** they will find an alternative option, but they will still be responsible for reporting back to the Board. She advised it is not the Board's responsibility to find alternate monitoring. Dr. Ziegler stated to the students in the audience as well as the Board members that practitioners can self-report to PRN and treatment would be unknown to the Board as long as the contract was followed. Seventy percent of people in treatment are unknown to the boards, she said, and pharmacy has a higher percentage.

Lunch Break 12:15

Reconvened at 1:37 p.m.

D. Legislation- Allison Dudley, Executive Director

1. Clinical Laboratories

Allison Dudley described HB 675/SB738. The bill clarifies that clinical labs cannot charge different prices for different health care professions. Ms. Dudley advised the Board they had the right to vote to support the bills, oppose bills or remain neutral.

Motion made by Dr. Alvarez, seconded by Dr. Fallon to support clinical labs. Motion carried.

2. Health Care

Allison Dudley described CS/SB 784 and HB 863.

Ms. Dudley advised the Board they had the right to vote to support the bills, oppose bills or remain neutral.

Senate: Right Medicine, Right Time Act

House: Florida Patient Protection Act

Michael Jackson, President of Florida Pharmacy Association stated FPA and Florida Society of Health System Pharmacist are fully supportive of the bills.

The board did not take action.

3. March Legislative update

Ms. Dudley discussed the legislative update that was held on March 13, 2015 via teleconference with the Board members and public. She advised the Board they have the right to support, oppose or remain neutral on the following 4 bills:

1. Pharmacy

SB 792, sponsored by Sen. Aaron Bean, R-Green Cove Springs
HB 279, sponsored by Rep. Cary Pigman, R-Avon Park

Both bills expand Chapter 465.189, F.S. to allow: a registered intern under supervision of a pharmacist to administer vaccines to an adult with 20 hours of Board-approved coursework, administration of all immunizations or vaccines recommended by the U.S. Centers for Disease Control for international travel, and administration of vaccines during a State of Emergency.

2. Emergency treatment of opioid overdose

SB 758, sponsored by Sen. Greg Evers, R-Baker
HB 751, sponsored by Rep. Julio Gonzalez, R-Venice, Rep. Ronald Renuart, R-Ponte Vedra Beach

Senate version: Florida Opioid Overdose Prevention Act

House version: Emergency Treatment and Recovery Act

Both bills create a new law with the purpose of providing a prescription of an emergency opioid antagonist to patients and caregivers for use during a suspected opioid overdose when no physician/authorized health care practitioner is immediately available.

3. Practice of Pharmacy

SB 1180, sponsored by Sen. Jack Latvala, R-Clearwater
HB 1049, sponsored by Rep. Kathleen Peters, R-South Pasadena

Both bills create a statutory definition of “office use compounding” and create a distinction for office use compounding of veterinary medications.

4. Ordering of Medication

SB 532, sponsored by Sen. Denise Grimsley, R-Sebring
HB 281, sponsored by Rep. Cary Pigman, R-Avon Park

Both bills authorize a licensed physician assistant or ARNP to order medication under direction of a supervising physician for a specific patient under certain circumstances; revise the definition of “prescription” and make a distinction between an order and a prescription.

Motion made by Dr. Mikhael, seconded by, Jeenu Philip to support all four bills listed above. Motion carried.

E. Michael Jackson- On the Face Letter

Michael Jackson, President of FPA and Jon Lockwood, General Counsel for FPA were present.

Mr. Jackson stated FPA is looking for discussion for changes in 893.04(1)(c), *F.S.*, and what exactly “on the face” means when it come to the prescription. Mr. Jackson held up an example of written prescription for the Board members. Dr. Weizer stated the Board has interpreted that to mean anything on the front or back of a written prescription, and/or information in the electronic prescription or record. Mr. Jackson thanked the Board for clarification and said he can report back to his members that their records are complete.

TAB 3: RULES – Jeff Mesaros, PharmD

A. Monthly Rules Report – Lawrence Harris, Assistant Attorney General

B. Rules for Consideration and Action – David Flynn, Assistant Attorney General

1. Rule 64B16-28.450/64B16-28.140

Discussion on open rules Rule 64B16-28.450/64B16-28.140

Mr. Harris received comments on Rule 64B16-28.450/64B16-28.140 from Joint Administrative Procedures Committee Chief Attorney, Marjorie Holladay and addressed those comments with the Board.

Rule 64B16-28.450 tried to move to four-year records retention schedule.

Mr. Harris said language currently stated to maintain the original prescription for a period of four years from the date the prescription was last refilled. Pursuant to Section 893.04(1)(d), F.S., original prescriptions for controlled substances must be maintained for two years; thereafter an image of the original prescription must be maintained for additional two years.

Mr. Harris stated he can do a Notice of Change to clean up language.

Dr. Mesaros stated Board should have Mr. Harris clean up language on Rule 64B16-28.450(4)(a)(4) to reconcile with Chapters 893 and 465.

Mr. Flynn suggested writing as response letter back to JAPC stating to maintain all records for four years.

The Board discussed the definition of "timely manner" as stated in rule 64B16-28.450(5).

Rule 64B16-28.450(5) currently reads: Delivery of medications. All deliveries of medications from central fill pharmacy to originating pharmacy or to ultimate consumer's agent must be made within seven days of receipt by the central fill pharmacy in a timely manner.

Motion: by Dr. Fallon, seconded by Dr. Mikhael to change within seven days to within five days and remove timely manner from rule 28.450(5) and to allow Mr. Harris to write response letter.

Mr. Flynn didn't think a specific time frame needs to be in the rule. Mr. Harris believed timely manner is the correct language.

Amended Motion: by Dr. Fallon, seconded by Dr. Mikhael to strike five days from previous motion.

Discussion on 28.450(4)(a)(4).

Rule 64B16-28.450(4)(a)(4) currently reads: Excepting prescriptions for controlled substances, maintain the original prescription for a period of four years from the date the prescription was last refilled. Pursuant to Section 893.04(1)(d), F.S., original prescriptions for controlled substances must only be maintained for two years; thereafter an image of the original prescription must be maintained for an additional two years.

Motion: by Dr. Fallon, seconded by Dr. Mikhael to change language on Rule 64B16-28.450(4)(a)(4); change refilled to filled ; allowing retention for four years for original prescription and leave subsection (5) as is, timely being the specific context. Motion carried.

Motion: by Dr. Mikhael, seconded by Ms. Glass changes not to effect small business; cost to not exceed \$200,000 in one year or \$1 million in five years. Motion carried.

2. Rule 64B16-26.1031

The Board had discussion on Rule 64B-16-26.1031 Vaccine Certification Program.

Mr. Harris received comments from JAPC regarding subsection (2)(c) of this rule. Subsection (2)(c) currently reads:

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.

Mr. Harris stated Form DH 1997 is not the Department's form. Mr. Harris advised the Board of two options. The first option would be to open the rule to fix language. The second option would be to respond to JAPC that legislation is moving and to update the rule to fix subsection (2)(c) once that passes. He can respond or open rule for development if it does not pass the Legislature this session.

Motion: by Dr. Alvarez, seconded by Ms. Glass to respond to Ms. Holladay to give her an update legislatively regarding vaccines and respond to her request in a timely manner.

Dr. Mikhael asked Mr. Harris if the Board is opening the rule. Mr. Harris stated the rule is being opened.

Motion: by Dr. Mikhael, seconded by Ms. Glass to open rule for development. Motion carried.

3. Rule 64B16-27.410/64B16-27.420

Mr. Harris received comments from Ms. Holladay, Attorney for JAPC regarding Rule 64B16-27.410 (1) and (2)(b).

Ms. Holladay's comment for 27.410(1) was the first sentence of subsection 1 did not appear to meet the definition of a "rule" and the second sentence had a grammatical error in which "supervise more than one" should be used instead of "greater than one."

Mr. Harris stated that the Board can vote to strike the first sentence of this rule or allow him to respond that it's a policy statement.

Mr. Harris stated there was an error with the Notice of Change and the second sentence on Rule 27.410(1) should read: A pharmacist shall not supervise **more than 1** registered pharmacy technician nor shall a pharmacy allow a supervision ratio of more than one registered pharmacy technician to on pharmacist, unless specifically authorized to do so pursuant to provisions of this rule.

Ms. Holladay's comment for 27.410(2)(b) asked for an explanation on why this rule paragraph changes the compliance date to April 1, 2015, or within 90 days from the date the registered pharmacy

technician is hired, it would appear the new date of April 1 would shorten the previous deadline for compliance, which is April 7.

Mr. Harris stated he will change the dates in subsection (2)(b) from April 1 to April 7.

Mr. Harris read comments from Ms. Holladay regarding Rule 420(1)(i). Ms. Holladay believed technicians should not be allowed to assist in sterile compounding.

Mr. Flynn recommended striking 420(1)(i) .

Motion: by Dr. Mikhael, seconded by Dr. Alvarez to allow Mr. Harris to make proposed changes to 410.(1)(2)(b) by keeping the first sentence of 410(1) due to it being statement of policy; authorize Mr. Harris to correct the grammar in sentence two, changing “greater than” to “more than”; 410(2)(b) changing compliance date from April 1 to April 7; striking paragraph 27-420(1)(i) strike entire paragraph. Motion carried.

Motion: by Dr. Mesaros, seconded by Dr. Fallon that proposed changes in rules do not effect small business; cost not to exceed \$200,000 in 1 year or \$1 million in 5 years. Motion carried

Audience member stated the changes should be made to 27-420(2)(i) not (1)(i).

Mr. Harris will make the correction with the subsection on Rule 64B16-27.420.

Public Comments:

None at this time.

Motion by Dr. Fallon, seconded by Ms. Glass to adjourn the meeting at 3:07 p.m. Motion carried.

Wednesday, April 8, 2015 - 9:00a.m.

Meeting called to order by Dr. Weizer at 9:02 a.m.

All members were present except Gavin Meshad, who was excused.

TAB 4: RULES REPORTS & ACTIONS (FROM 4/7) - Michele Weizer, PharmD, Chair; Jeff Mesaros, PharmD, and David Flynn, Assistant Attorney General

TAB 5: DISCIPLINARY CASES - Matthew Witters, Esq. & Jeff Mesaros, PharmD, Chair

SETTLEMENT AGREEMENTS - APPEARANCE REQUIRED

SA-1 Madhavi Chowdary Balineni, R.Ph, Case No. 2014-03209

Respondent was not present. Respondent was not represented by counsel. Board skipped SA-1 and returned to it at 11:35 a.m. Respondent was still not present, nor was counsel.

Dr. Alvarez and Dr. Weizer were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Florida Statute 465.016(1)(g), FS (2013), by using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any matter from the ingredient or article prescribed.

The terms of the Settlement Agreement were: An appearance in front the Board; a fine of \$500.00 to be paid within 30 days of filing of Final Order; costs not to exceed \$2,010.64 to be paid within 90 days of filing of Final Order; complete an 8-hour prevention of medical errors continuing education course with in 1 year of the filing of Final Order.

Motion to waive appearance was made by Jeenu Philip, failed due to no second.

The Board required the respondent to appear at the June meeting.

SA-2 Temitope Ayodluwa Epoyum, R.Ph. Case No. 2014-10959

Respondent was present. Respondent was represented by Attorney Ed Bayo.

Dr. Alvarez and Dr. Fallon were recused due to participation on the probable cause panel.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Florida Statute 456.072(1)(k), FS (2014), by and through violation of Section 465.022(11)(a), FS (2014), by failing to ensure the permittee's compliance with one or more of the following rules of the Board of Pharmacy: Rule 64B16-28.109(1), Rule 64b16-28.109(5), Rule 64b16-27.300(3)(a), and/or Rule 64b16-28.140(3)(d), Florida Administrative Code.

The terms of the Settlement Agreement were: An appearance in front the Board; a fine of \$1,000.00 paid within 30 days of filing of Final Order; costs not to exceed \$1,493.19 to be paid within one year of filing of Final Order; complete a 12-hour Laws and Rules continuing education course with in 1 year of the filing of Final Order.

Mr. Jurich said current costs were \$745.98.

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

SA-3 Tadj Multiservices, LLC d/b/a Rehboth Pharmacy Case No. 2014-10961

Respondent was present. Respondent was represented by Attorney Ed Bayo.

Dr. Alvarez and Dr. Fallon were recused due to participation on the probable cause panel.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: Count One, violation of Section 456.072(1)(k), FS (2014), by through a violation of Section 465.023(1)(c), FS (2014) and by and through violation of Section 465.025(7), FS. (2014). Count two: violation of Section 456.072(1)(k), FS. (2014), by and through a violation of one or more of the following rules of the Board of Pharmacy: Rule 64B16-28.109(1), Rule 64B16-28.109(5), Rule 64B16-27.300(3)(a), and/or Rule 64B16-28.140(3)(d) Florida Administrative Code. Count three: violation of Section 456.0729(1)(k), FS. (2014), by and through a violation of Section 465.023(1)(c), FS (2014), by and through a violation of Section 499.005(14), FS.

The terms of the Orally Amended Settlement Agreement were: An appearance in front the Board; a fine of \$2,000.00 paid within 90 days of filing of Final Order; costs not to exceed \$1,656.30 to be paid within 90 days of filing of Final Order; Semi-Annual inspection at the Respondent's expense.

Mr. Jurich said current costs were \$992.81.

Mr. Jurich provided the Board with a copy of the inspection for new location.

Motion by: Mr. Philip, seconded by Dr. Mikhael to accept the orally amended Settlement Agreement. Motion carried.

SA-4 Hybrid Pharma, LLC Case No. 2013-09618

Respondent was present. Respondent was represented by Attorney Mitchel McRae.

Dr. Weizer and Debra Glass were recused due to participation on the probable cause panel. Dr. Mikhael chaired the meeting.

Representatives present were Jeff Goldridge, Nicholas Pick and owner Ponswamy Rajalingam.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: Count One, violation of Section 456.072(1)(k), FS (2012-2013), by and through a violation of Section 465.023(1)(c), FS (2012-2013), by and through a violation of one or more of the following rules of the Board of Pharmacy: Rules 64b16-27.797(1)(i)(4), 64B16-27.797(7)(a)(3), 64B16-27.797 (1)(i)7, Florida Administrative Code. Count two: violation of Section 456.072(1)(k), FS (2012-2013), by and through a violation of Section 465.023(1)(c), FS (2012-2013), by and through a violation of Rule 64B16-28.140(4), Florida Administrative Code.

The terms of the Settlement Agreement were: An appearance in front the Board; a fine of \$3,000.00 paid within 30 days of filing of Final Order; costs \$3,500.00 to be paid within 90 days of filing of Final Order; semi-annual inspections to ensure compliance with the Florida Statutes and rules of the Board of Pharmacy at the Respondent's cost for one year from the filing of Final Order; complete a 20-hour

Sterile Compounding continuing education course with in one year of the filing of Final Order; correct and address all alleged deficiencies and violations listed in the Administrative Complaint.

Mr. Jurich said current costs exceed the \$3,500.

Mr. Jurich stated the pharmacy had signed a voluntary attestation form in April 2014 not to sterile compound.

Motion by: Mr. Philip seconded by Dr. Mikhael to accept the Settlement Agreement. Motion carried.

SA-5 Niraj Banjara, R.Ph Case No. 2014-10465

Respondent was present. Respondent was represented by Attorney Saqib Ishaq.

Dr. Alvarez and Dr. Mikhael were recused due to participation on the probable cause panel.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072(1)(j) FS (2013-2014), aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice profession contrary to this chapter, the chapter regulating the profession or the rules of the department of the board.

The terms of the orally amended Settlement Agreement are: An appearance in front the Board; a fine of \$2,500.00 paid within 30 days of filing of Final Order; costs \$ 1,508.55 to be paid within one year of filing of Final Order; complete a 12-hour Laws and Rules continuing education course with in one year of filing of Final Order, **and work for no more than two pharmacies other than Winn Dixie #728.**

Mr. Jurich said current costs were \$803.48.

Motion: by Mr. Philip, seconded by Dr. Fallon to accept the orally amended Settlement Agreement. Motion carried.

SA-6 Farmacia Adelfa & Paty, Inc. Case No. 2014-06324

Respondent was present. Respondent was represented by Attorney Ivan Guerrero.

Dr. Weizer and Mr. Philip were recused due to participation on the probable cause panel. Ms. Glass chaired the meeting.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: Count one: violation of Section 465.023(1)(c), FS (2011-2014), by violating Rule 64B16-28.109 Florida Administrative Code; Count two: by violating Section 465.023(1)(c), by violating Rule 64B16-28.100(1)(b), Florida Administrative Code.

The terms of the Settlement Agreement were: An appearance in front the Board; a fine of \$5,000.00 paid within one year of filing of Final Order; costs not to exceed \$2,821.31 to be paid within one year of filing of Final Order; with suspension until respondent passes a department inspection with vice chair having authority to review inspection and direct that the suspension be lifted; probation for one year following the lifting of the Board's suspension with specific terms and conditions; correct all alleged deficiencies or violations.

Motion by: Dr. Mikhael, seconded by Dr. Alvarez to reject orally amended the Settlement Agreement. Motion carried.

Counter Offer- Revocation; Respondent will have 7 business days to accept counter offer.

Motion by: Dr. Mikhael, seconded by Dr. Fallon to accept the counter Settlement Agreement of license revocation. Motion carried.

SA-7 Jessica Ellen Dileo, R.Ph Case No. 2014-09491

Respondent was present. Respondent was represented by Attorney Martin Dix. SA-11 was moved up after SA-7 as a related case.

Mr. Meshad and Dr. Mikhael were recused due to participation on the probable cause panel.

Appearance by Nancy Fitzpatrick, mother of the deceased, who asked that the settlement agreement be delayed while she was getting the pills tested. She said she had requested them from evidence at Citrus County Sheriff's Office.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072(1)(k), FS (2012), by and through the violation of Section 465.016(1)(e) , FS (2012), by and through the Title 21 U.S.C. Section 331(d) which prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of Section 355 of this title.

The terms of the Settlement Agreement were: An appearance in front the Board; a fine of \$2,000.00 paid within 30 days of filing of Final Order; costs not to exceed \$2,047.22 to be paid within one year of filing of Final Order; complete a 12-hour Laws and Rules continuing education course with in one year of filing of Final Order.

Mr. Jurich said current costs were \$1,184.15.

Motion by: Mr. Philip, seconded by Dr. Alvarez to reject the Settlement Agreement. Motion carried.

Counter Settlement Agreement Terms:

The terms of the Settlement Agreement are: An appearance in front the Board; a fine of \$2,000.00 paid within 30 days of filing of Final Order; costs \$ 2,047.22 to be paid within one year of filing of Final Order;

complete a 12-hour Laws and Rules continuing education course with in one year of filing of Final Order; 2-year probation and only allowed to work at one location; not allowed to supervise any interns nor add any training tech programs.

Motion by: Mr. Philip, seconded by Dr. Alvarez to reject the Settlement Agreement and counter-offer. Motion carried.

Dileo accepted the counter-offer.

SA-11 was moved up as a companion case.

BREAK from 10:55-11:17 a.m.

SA-8 Martin Reisky, R.Ph Case No. 2014-03990

Respondent was present. Respondent was represented by Attorney Ed Bayo.

Dr. Weizer and Mr. Philip were recused due to participation on the probable cause panel. Ms. Glass chaired the meeting.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072(1)(k), FS (2011-2013), by and through violation of Section 465.016(1)(e), FS (2011-2013), by and through a violation of Section 499.005(22), FS (2011-2013), failing 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.

The terms of the Settlement Agreement were: An appearance in front the Board; a fine of \$1,000.00 paid within 30 days of filing of Final Order; costs not to exceed \$ 1,500.00 to be paid within 90 days of filing of Final Order; complete a 12-hour Laws and Rules continuing education course with in one year of filing of Final Order.

Mr. Jurich said current costs were \$1,243.69.

Motion by: Dr. Alvarez seconded by Mr. Adams to accept the Settlement Agreement. Motion carried.

SA-12 was moved up as a companion case.

~~SA-9 Alan E. Wingerter, R.Ph Case No. 2014-11272 (Continued to June Meeting)~~

SA-10 Michael Joseph Duran, RPT Case No. 2013-12134

Respondent was not present. Respondent was not represented by counsel.

Dr. Alvarez and Ms. Glass were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072(1)(aa), FS (2013).

The terms of the Settlement Agreement are: An appearance in front the Board; costs not to exceed \$2,000.00 to be paid within 90 days; undergo evaluation and treatment facilitated by PRN within 60 days of filing of Final Order; probation for one year with specific terms and conditions.

Motion by: Dr. Mesaros seconded by Mr. Adams waive appearance. Motion carried.

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

SA-11 Custom Meds, Inc. f/k/a McCully-Snyder Pharmacy, Inc. Case No.2013-18732

Respondent was present. Respondent was represented by Attorney Martin Dix.

Appearance by Nancy Fitzpatrick, mother of the deceased.

Dr. Mikhael and Mr. Meshad were recused due to participation on the probable cause panel.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072(1)(k), FS (2012), by and through a violation of Section 465.023(1)(c), FS (2012) by and through a violation of Title U.S.C. Section 331(d) which prohibits the introduction or delivery for introduction into interstate commerce of any article in violation of Section 355 of this title.

The terms of the Settlement Agreement were: An appearance in front the Board; a fine of \$2,000.00 paid within 30 days of filing of Final Order; costs not to exceed \$3,817.94 to be paid within 90 days of filing of Final Order.

Mr. Jurich said current costs were \$3,123.39.

Motion: by Dr. Fallon, seconded by Dr. Mesaros to reject the Settlement Agreement. Motion Carried.

Counter Settlement Agreement:

The terms of the Settlement Agreement were: An appearance in front the Board; a fine of \$2,000.00 paid within 30 days of filing of Final Order; costs \$3,817.94 to be paid within 90 days of filing of Final Order; 2-year probation with two inspections per year at the cost of the pharmacy.

Motion: by Dr. Fallon, seconded by Dr. Mesaros to accept the counter Settlement Agreement. Motion Carried.

Break: 10:55

SA-12 Manasota Pharmacy Services, d/b/a Bradenton Hometown Pharmacy
Case No. 2014-03992

Respondent was present. Respondent was represented by Attorney Ed Bayo.

Present: Martin Reisky, R.Ph

Dr. Weizer and Mr. Philip were recused due to participation on the probable cause panel. Ms. Glass chaired the meeting.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072(1)(k), FS (2011-2013), by and through a violation of Section 499.023(1)(c) , FS (2011-2013), by and through a violation of Section 499.005(22), FS (2011-2013), failing 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.

The terms of the Orally amended Settlement Agreement were: An appearance in front the Board; costs not to exceed \$2,000.00 to be paid within 90 days of filing of Final Order; correct and address all alleged deficiencies or violations; inspection must be done within six months and respondent will be responsible for cost.

Mr. Jurich said the current costs were \$1,687.86.

Motion by: Dr. Mikhael, seconded by Dr. Alvarez to accept the orally amended Settlement Agreement. Motion carried.

DETERMINATION OF WAIVERS

DOW-1 Martha Otano, RPT Case No. 2013-10748

Respondent was not present. Respondent was not represented by counsel

Dr. Weizer and Ms. Glass were recused due to participation on the probable cause panel. Dr. Mikhael chaired the meeting.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072(1)(x), FS (2013), by failing to report to the board,

or the department if there is no board, in writing within 30 days after the licensee had been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction.

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

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

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

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

PSU withdrew motion to assess cost.

DOW-2 Beverly Joan Raymer, RPT Case No. 2014-00967

Respondent was not present. Respondent was not represented by counsel.

Dr. Weizer and Ms. Glass were recused due to participation on the probable cause panel. Dr. Mikhael chaired the meeting.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: Count one: violation of Section 456.072(1)(x), FS (2013), 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: violating Section 456.072(1)(c), FS (2010), 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: Dr. Fallon, seconded by Dr. Alvarez to find that respondent was properly served and has requested a formal hearing. Motion carried.

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

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

Motion: by Dr. Fallon, seconded by Dr. Alvarez 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. Fallon, seconded by Dr. Alvarez, to accept the recommendation of the Department. Motion carried.

PSU withdrew motion to assess cost.

DOW-3 Flagler's Drug Store Case No. 2014-02300

Respondent was not present. Respondent was not represented by counsel.

Dr. Weizer and Ms. Glass were recused due to participation on the probable cause panel. Dr. Mikhael chaired the meeting.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072(1)(k), FS (2013) by violating Section 465.023(1)(c), FS (2013), by violating rule of the Board of Pharmacy, through violation of Rule 64B16-28.202(3), Florida Administrative Code.

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

Motion by: Dr. Fallon seconded by Mr. Philip to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried

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

Motion: by Dr. Fallon seconded by Mr. Philip 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. Fallon seconded by Mr. Philip to accept the recommendation of the Department. Motion carried.

PSU withdrew motion to assess cost.

Respondent was not present. Respondent was not represented by counsel.

Dr. Weizer and Mr. Philip were recused due to participation on the probable cause panel. Ms. Glass chaired the meeting.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: Count one: violation of Section 456.072(1)(x), FS (2014), 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: violating Section 456.072(1)(c), FS (2013), 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 three: violation of Section 456.072(1)(ii), FS (2013), being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication.

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

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

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

Motion: by Dr. Mikhael seconded by Dr. Mesaros, 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. Mikhael seconded by Dr. Mesaros to accept the recommendation of the Department. Motion carried.

PSU withdrew motion to assess cost.

Respondent was not present. Respondent was not represented by counsel.

Dr. Mikhael and Mr. Meshad were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 465.016(1)(e), FS (2013), by violating Section 893.13 (6)(a), FS (2013).

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

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

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

Motion: by Ms. Glass, seconded by Mr. Philip 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. Glass, seconded by Mr. Philip, to accept the recommendation of the Department. Motion carried.

PSU withdrew motion to assess cost.

DOW-6 Kelly R. Curry, RPT Case No. 2014-14528

Respondent was not present. Respondent was not represented by counsel.

Dr. Mikhael and Mr. Meshad were recused due to participation on the probable cause panel.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 465.016(1)(e), FS (2013-2014) by violating Chapters 893.13(6)(a);893.13(7)(a)(1) and 893.13(7)(a)(9), FS (2013-2014).

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

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

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

Motion: by Dr. Alvarez, 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 Dr. Alvarez, seconded by Ms. Glass to accept the recommendation of the Department. Motion carried.

PSU withdrew motion to assess cost.

DOW-7 Speed II Pharmacy, Inc. Case No. 2014-02099

Respondent was not present. Respondent was not represented by counsel

Dr. Weizer and Ms. Glass were recused due to participation on the probable cause panel. Dr. Mikhael chaired the meeting.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 465.072(1)(q), FS (2013), by failing a lawful order of the department or the board, or failing to comply with a lawfully issued subpoena of the department.

Mr. Witters said the pharmacy was no longer operating.

Motions vacated until Respondent can be properly served.

VOLUNTARY RELINQUISHMENTS

VRs voted on at one time: VR-1, VR- 3, VR-4 , VR-5 , VR-7, VR-8

Motion: by Dr. Fallon, seconded by Dr. Alvarez to accept the above-listed Voluntary Relinquishments as a group. Motion carried.

VR-1 AFM Pharmacy, Inc. Case No. 2014-20076 (PCP Waived)

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

Accepted via group motion.

VR-2 New Vision Medical Supply, Inc. Case No. 2014-06490 (Glass/Meshad)

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

Motion: by Dr. Fallon, seconded by Dr. Alvarez to accept Voluntary Relinquishment. Motion carried.

VR-3 Bird Road Pharmacy & Discount Inc. Case No. 2014-18131 (PCP Waived)

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

Accepted via group motion.

VR-4 Clarissa Jean Hoover, PSI Case No. 2014-18711 (PCP Waived)

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

Accepted via group motion.

VR-5 North Ocean Medical Pharmacy Case No. 2014-17826 (PCP Waived)

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

Accepted via group motion.

VR-6 Ashish J. Patel, R.Ph. Case No. 2012-12916 & Case No. 2012-13364 (Mullins/Mesaros)

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

Motion: by Dr. Fallon, seconded by Dr. Alvarez to accept Voluntary Relinquishments. Motion carried.

VR-7 Mercy Pharmacy Corp. Case No. 2014-18182 (PCP Waived)

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

Accepted via group motion.

VR-8 Jack E. Morgan Jr., R.Ph. Case No. 2015-04470

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

Accepted via group motion.

INFORMALS

I-1 Angel's Touch Pharmacy Discount Case No. 2014-01269

Respondent was not present. Respondent was not represented by counsel

Dr. Weizer and Ms. Glass were recused due to participation on the probable cause panel. Dr. Mikhael chaired the meeting.

Mr. Witters represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: Count one: violation of Section 465.023(1)(c), FS (2013) by violating 64B-16328.1081, Florida Administrative Code. Count two: violating Section 465.023(1)(c), FS (2013) by violating 64B16-28.109, Florida Administrative Code.

Motion: by Dr. Fallon, seconded by Dr. Mesaros to find that respondent was properly served and not disputed facts. Motion carried.

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

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

Motion: by Dr. Fallon, seconded by Dr. Mesaros 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.

Staff noted that the permit information on DOH's website indicates the property is closed.

Department Recommendations: Reprimand with no costs or fines.

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

I-2 Courtney Elizabeth Infanger, RPT Case No. 2014-10146

Respondent was present. Respondent was represented by Attorney Ed Bayo.

Dr. Mikhael and Mr. Meshad were recused due to participation on the probable cause panel.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: violation of Section 456.072(1)(aa), FS (2013).

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

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

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

Motion: by Mr. Philip, 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.

Department Recommendations: Cost of \$710.21 payable over a year and to remain compliant with PRN contract.

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

~~I-3 Jayson Richard Moore, R.Ph Case No. 2014-10494 (Withdrawn)~~

I-4 Melissa Renee Ebokah, R.Ph Case No. 2014-11082

Respondent was present. Respondent was not represented by counsel.

Ms. Glass and Dr. Alvarez were recused due to participation on the probable cause panel.

Mr. Jurich represented the Department and presented the case to the Board. Allegations of the Administrative Complaint: : violation of Section 456.072(1)(k), FS (2014), through violation of section 465.022(11)(a), FS (2014), 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.

Motion: by Mr. Philip, seconded by Dr. Mikhael, to accepts the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

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

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

Motion: by Mr. Philip, seconded by Dr. Mikhael, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Department Recommendations: \$2,000.00 fine payable within 30 days of filling of final order; costs of \$464.00 payable within 90 days of filing of final order; Board approved 12-hour Laws and Rules course to be completed within a year.

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

Lunch Break

Meeting reconvened at 2:17 p.m.

TAB 7 F was taken out of order.

TAB 6: APPLICATIONS REQUIRING BOARD REVIEW- Debra Glass, BPharm, Vice-Chair

A. Pharmacist Intern Applications-

1. Donna Mae Pate, File: 22105 – Tampa, FL

Applicant was present and sworn in. Applicant was represented by Attorney Ed Bayo.

Dr. Ziegler was present and stated Ms. Pate had a current PRN contract and is fully compliant.

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

B. Pharmacist Applications

1. Kye Gooder, File: 42777- Saint Pete Beach, FL

Applicant was present and sworn in. Applicant was not represented by counsel.

Mr. Gooder withdrew his application by endorsement due to not meeting endorsement requirements.

2. Kurt Boesger, File: 44097 – Hampton Beach, GA

Applicant was present and sworn in. Applicant was not represented by counsel.

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

3. John Keyser, File: 45974 – Cincinnati, OH

Applicant was present and sworn in. Applicant was not represented by counsel.

Mr. Keyser requested a continuance, which waives his 90-days, to allow PRN to review his Ohio records. Chair to review PRN determination and staff can issue if approved by chair.

Motion: by Ms. Glass, seconded by Dr. Mesaros, to grant continuance in order for Dr. Ziegler to contact Ohio PRN and get evaluation. Motion carried.

~~4. John Major, File: 43928 (Continued to June Board Meeting)~~

C. Pharmacy Permit Applications

1. RX Unlimited, LLC. File: 22100

Applicant was not present. Applicant was not represented by counsel.

Motion: by Dr. Mesaros, seconded by Dr. Weizer, to resolve all pending discipline in California, notify Board when complete and then appear before the Board for review. Motion carried.

2. ECP Holdings, LLC. File: 22214

Applicant was not present. Applicant was not represented by counsel.

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

The Board made the decision to consider all four PharMEDium applications as a group.

3. PharMEDium Services, LLC. File: 10

4. PharMEDium Services, LLC. File: 11

5. PharMEDium Services, LLC. File: 12

6. PharMEDium Services, LLC. File: 13

Respondent was present and sworn in. Respondent was represented by Counsel Brian Newman.

Dr. Weizer said the company attorney worked with her and Mr. Flynn to resolve questions.

Motion: by Dr. Mesaros, seconded by Ms. Glass, to approve the four applications. Motion carried.

TAB 7: LICENSURE ISSUES

A. Request for Payment Extension

1. Donna Marie Fulton, PS 29339 – Tampa, FL

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

Motion: by Dr. Mikhael, seconded by Dr. Fallon, to accept request for payment extension with equal payments being made over a 12-month period.

Motion carried.

B. Petition for Termination of Probation

1. Florida Solutions Pharmacy, PH 21697 – Hialeah, FL

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

Representative present- Eugene Delgado

Motion: by Dr. Fallon, seconded by Mr. Adams, to accept termination of probation. Motion carried.

2. HVVP RX, LLC PH 25159 – Seminole, FL

Respondent was present and sworn in by the court reporter. Respondent was represented by Attorney Dan Musca.

Present: Vikas Ghiya

Mr. Musca said the P&E permit had been turned in.

Motion: by Ms. Glass, seconded by Dr. Fallon, to accept termination of probation. Motion carried.

3. RPH Solution, Inc., PH 19484 – Dade City, FL

Respondent was present and sworn in by the court reporter. Respondent was represented by Attorney Ed Bayo.

Present: Haresh Patel

Motion: by Dr. Mikhael, seconded by Mr. Adams, to accept request for termination of probation upon completion of successful inspection. Motion carried.

4. Haresh C. Patel, PS 30906-

Respondent was present and sworn in by the court reporter. Respondent was represented by Attorney Ed Bayo.

Motion: by Dr. Mesaros, seconded by Mr. Adams, to accept termination of probation upon completion of a 12-hour Laws and Rules course and copy of passing inspection. Motion carried.

C. Early Termination of Probation

1. Infupharma, PH 23566 – Hollywood, FL

Respondent was present and sworn in by the court reporter. Respondent was represented by Attorney Ed Bayo.

Present: Michael Rizo

Motion: by Dr. Weizer, seconded by Dr. Fallon, to reject early termination of probation. Motion carried.

2. Monika Girgis, R.Ph. PS 38789

Respondent was present and sworn in by the court reporter. Respondent was represented by Attorney Ed Bayo.

Dr. Ziegler was present and stated Ms. Girgis was in complete compliance.

Motion: by Dr. Mesaros, seconded by Ms. Glass, to accept early termination of probation upon successful exit interview with PRN and termination of contract. Motion carried.

D. Modification to Final Order

1. Lincourt Compounding Center, PH 24418 – Clearwater, FL

Respondent was present and sworn in by the court reporter. Respondent was represented by Attorney Marcus Hasbun.

Representatives present: Katherine Nielsen, PDM for compounding pharmacy, and Louis Ladson, PDM of retail pharmacy

Lincourt representatives said they planned to apply for a sterile compounding license. They were told they had met the first prong, understanding the requirements for sterile compounding. Lincourt's application had expired and they are required to reapply.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to accept modification of Final Order. Motion carried.

E. Motion to Vacate Final Order

1. Maksim Yermakov PS 48324 – Plantation, FL

Respondent was present and sworn in by the court reporter after lunch at 2:17 p.m. and case was taken out of order. Respondent was represented by Attorney Greg Ross.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to reject vacating the Final Order. Motion carried.

G. Petition for Reinstatement

1. Richard Alonso, PS 39780- Tampa, FL

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

Mr. Alonso stated that neither his attorney, Monica Rodriguez, nor Dr. Pomm were able to attend the meeting and that he could no longer pay Ms. Rodriguez.

Mr. Alonso requested a continuance.

Dr. Weizer granted the continuance until an attorney and Dr. Pomm can be present. Motion carried.

Dr. Weizer opened the floor to public comments.

Mr. Parrado asked the Board to re-examine Rule 64B16-27.831.

Motion: by Dr. Fallon, seconded by Ms. Glass to adjourn the meeting. Motion carried.

Meeting was adjourned at 4:19 p.m.

DRAFT