

COMMONWEALTH OF MASSACHUSETTS

**NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE
BOARD OF REGISTRATION IN PHARMACY**

May 7, 2013
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

PRELIMINARY AGENDA

Time	#	Item	Exhibits	Staff Contact
8:30	I.	CALL TO ORDER		
8:30	II.	APPROVAL OF AGENDA		
8:30	III.	ADJUDICATORY SESSION	CLOSED SESSION	
9:30	IV.	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION	
9:40	V.	APPROVAL OF BOARD MINUTES 1. March 19, 2013 Additional Scheduled Meeting 2. April 2, 2013 Regularly Scheduled Meeting	Minutes	V. Berg
9:45	VI.	REPORTS 1. Applications approved pursuant to Licensure Policy 13-01 2. Plans of Correction reviewed pursuant to Enforcement Policy 13-02	Reports	M. Cittadino H.Engman
	VII.	APPLICATIONS <i>A. Applications for a New Store</i> 1. Woodmark Pharmacy 69 Hickory Drive 1 st floor, Waltham. 02451-1011 (requesting a waiver) 2. Century Pharmacy 937 Gorham Street, Lowell, MA. 01852 3. St. Vincent Pharmacy 123 Summer Street, Suite 365, Worcester, MA. 01608 4. Pharmahealth Specialty Pharmacy 25 Armory Street, Boston <i>B. Transfer of Ownership</i> 1. Diversified Specialty Pharmacy (DS3575) 1451 Concord Street, Framingham, MA (new owner: Partners of Massachusetts, LLC)	Applications	M. Cittadino

10:00	VII.	APPLICATIONS, CONTINUED <i>C. Applications for Registration</i> 1. Michael Greaves 25 Cherry Ridge, Middlefield, CT 06455 (pharmacist reciprocal licensure application with discipline in another jurisdiction)	Applications	M. Cittadino
11:30	VIII.	LUNCH		
12:00	IX.	FILE REVIEW 1. Pallimed Solutions, Inc. , DS3498, PHA-2011-0286 2. Pallimed Solutions, Inc., DS3498, PHA-2012-0046 3. Pallimed Solutions, Inc., DS3498, PHA-2012-0045 4. Pallimed Solutions, Inc. DS3498, PHA-2012-0237 5. Pallimed Solutions, Inc. DS3498, PHA-2013-0017 6. J. Nahill , PH21521, PHA-2012-0171 7. J. Nahill, PH21521, PHA-2013-0039 8. Pharmahealth Pharmacy , DS, PHA-201 9. Edward Macedo , PH14977, PHA-2013-0035 10. Richard Brisson , PHA15092, PHA-2013-0036 11. Royal Palm Specialty Pharmacy, LLC , DS, PHA-2013-0029 12. Katie Fafalla , PH26808, PHA-2013-0040 13. R. Usta , PH 2333510; PHA-2012-02222 14. M. Christian , PT 11275; PHA-2012-0221 15. L. Holden , PH16717, PHA-2012-0207 16. L. Szeto , PT14243, PHA-2012-0230 17. L. Cincotta , PT13747, PHA-2012-0044 18. K. Howes , PH19966, PHA-2012-0043 19. CVS Pharmacy #938 , DS1505, PHA-2012-0062 20. M. Chagnon , PT11854, PHA-2012-0097 21. C. Gonzalez , PH26121, PHA-2012-0099 22. Prescription Shoppe, Inc. , DS6654, PHA-2012-0092 23. A. LaMonica , PH12804, PHA-2012-0168 24. J. Finnegan , PH16847, PHA-2012-0192 25. H. Patel , PH26555, PHA-2012-0226	Investigation Reports for all complaints listed	S. Penta W. Frisch L. McKenna C. Lathum
3:30	X.	GUIDANCE 1. Chapter 244 of the Acts of 2012: FAQs 2. Chapter 244 of the Acts of 2012: Continuing Education Requirements	Proposed FAQs Proposed Topical Coverage	V. Berg

4:00	XI.	FLEX SESSION <ol style="list-style-type: none"> 1. Items for the next meeting 2. Scheduling of additional meetings prior to next regularly scheduled meeting <ol style="list-style-type: none"> a. Board Delegated Complaint Review b. Plan of Correction Approval 3. Chapter 244 of the Acts of 2012: MPJE 		
5:00	XII.	ADJOURNMENT		

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE REGULARLY SCHEDULED MEETING

239 Causeway Street, Fourth Floor ~ Room 417A

Boston, Massachusetts 02114

Tuesday, May 7, 2013

Board Members Present

James T. DeVita, RPh
Karen Ryle, RPh, MS
Joanne Trifone, RPh
Anita Young, RPh, EdD
Jane Franke, RN, MHA
Edmund Taglieri, RPh, MSM, NHA
Patrick Gannon, RPh, MS

Board Members Not Present

Board Staff Present

James Lavery,
Division Director, DHPL
Margaret Cittadino, MEd,
Associate Director
Heather Engman JD, MPH, Board Counsel
Vita P. Berg, Board Counsel
Samuel Penta, RPh,
Investigator Supervisor
Leo McKenna, RPh, PharmD,
QA Coordinator
William E. Frisch, Jr., RPh,
Investigator
Cheryl Lathum, RPh, PharmD,
Investigator Joel Kanter, Consultant
Joseph Sceppa, RPh, Consultant
Louis Dell'Olio, RPh,
Director, SOPS
Erin Belitskus, Program Coordinator
Carissa Prosnitz, Paralegal

Board Staff Not Present

TOPIC:

I. CALL TO ORDER

DISCUSSION: A quorum of the Board was present.

ACTION: At 8:36 a.m. J. DEVITA, President, called the May 7, 2013, meeting of the Board of Registration in Pharmacy to order.

TOPIC:

II. APPROVAL OF AGENDA

DISCUSSION: Board members reviewed the tentative agenda. J. DEVITA suggested changing the order of the items to facilitate discussion of related items and to facilitate board member recusals. These changes included ordering IX.15 before IX.14, and moving VII.4 to after IX.8 through IX.10. V. BERG also added to Flex Session an update with respect to the Cease and Desist issued to Pawtucket Pharmacy.

ACTION: Motion by, A. YOUNG, seconded by K. RYLE, and voted unanimously to approve the agenda with changes in the order of the agenda items.

TOPIC:

III. ADJUDICATORY SESSION

DISCUSSION: None

ACTION: Motion by J. TRIFONE, seconded by A. YOUNG and passed by unanimous roll call vote to enter into Adjudicatory Session at 8:40 a.m.

ADJUDICATORY SESSION (8:40 – 9:04 a.m.)

TOPIC:

IV. M.G.L. c. 112, § 65C SESSION

DISCUSSION: None

ACTION: Motion by P. GANNON seconded by E. TAGLIERI and passed by unanimous roll call vote to enter into M.G.L. c. 112, § 65C Session at 9:04 a.m.

M.G.L. c. 112, § 65C SESSION (9:04 – 9:26 a.m.)

TOPIC:

V. APPROVAL OF BOARD MINUTES

A. March 19, 2013 Additional Scheduled Meeting

DISCUSSION: V. BERG presented the minutes of the March 19, 2013 Additional Scheduled Meeting

ACTIONS: Motion by J. TRIFONE, seconded by P. GANNON, and voted unanimously to approve the minutes of the March 19, 2013 Additional Scheduled Meeting

TOPIC:

V. APPROVAL OF BOARD MINUTES

B. April 2, 2013 Regularly Scheduled Meeting

DISCUSSION: V. BERG presented the minutes of the April 2, 2013 Regularly Scheduled Meeting. Board members noted changes that needed to be made on the second page of the proposed minutes.

ACTIONS: Motion by J. TRIFONE, seconded by P. GANNON, and voted unanimously, but with J. FRANKE abstaining, to approve the minutes of the April 2, 2013 Regularly Scheduled Meeting, with changes.

TOPIC:

VI. REPORTS

1. Applications approved pursuant to Licensure Policy 13-01

DISCUSSION: M. CITTADINO noted that there were four (4) new community pharmacy, one (1) community pharmacy relocation, twenty-four (24) change of manager, four (4) renovation or expansion, and three (3) store closing applications which were approved.

ACTION: So noted.

VI. REPORTS

2. Plans of Correction reviewed pursuant to Enforcement Policy 13-02

DISCUSSION: H. ENGMAN reported that there were seven (7) Plans of Correction submitted and approved.

ACTION: So noted.

TOPIC:

VII. APPLICATIONS

A. Applications for a New Store

1. Woodmark Pharmacy, 69 Hickory Drive, Waltham, MA

DISCUSSION: Jennifer Chin, Manager of Record, and J. Cuzzupoli, co-owner, presented the pharmacy's application for a new store and answered the questions of the Board. The proposed MOR provided the board with a brief history of her prior experience, which includes practice in long term care and hospital settings as well as prior MOR experience. The pharmacy intends to work with long-term care facilities as a closed-door pharmacy and as a pharmacy consultant. The pharmacy does not plan to perform sterile compounding, but will instead refer such prescriptions to a different pharmacy. Mr. Cuzzupoli advised that the owner of the pharmacy is an LLC that also owns skilled nursing facilities located outside of Massachusetts. Board members recommended that the pharmacy submit a request for waiver of board regulations pertaining to signage and to operate as a closed pharmacy. Board members also cautioned that the proposed pharmacy could not redistribute the medications referred to a third party, such as the sterile compounded medications, but rather should leave the dispensing of such medications to be handled directly by the pharmacy preparing them.

ACTION: Motion by E. TAGLIERI, seconded by P. GANNON and voted unanimously to conditionally approve the application subject to a successful inspection and submission of appropriate request for waivers.

TOPIC:

VII. APPLICATIONS

A. Applications for a New Store

2. Century Pharmacy, 937 Gorham Street, Lowell, MA

DISCUSSION: Christina Iepure, Manager of Record, Lilia Bepalko, owner, and Attorney Garbarini presented the pharmacy's application for a new store and answered the questions of the Board. The proposed MOR has been licensed as a pharmacist since 2011 and has served as MOR at a Boston area pharmacy under common ownership with the proposed pharmacy since February 2012. She advised that patients from the Lowell area are currently seeking services at the Boston area

pharmacy, and that the proposed pharmacy in Lowell is intended to better serve that patient population. Multiple language information will be made available as appropriate to the patient population. The proposed pharmacy plans to dispense medications in multi-drug "blister" packaging, with the exception of medications subject to frequent dosage changes. The proposed pharmacy does not require regulatory waivers. It does not have plans to conduct immunizations.

ACTION: Motion by J. FRANKE, seconded by P. GANNON, and voted unanimously to conditionally approve the application subject to a successful inspection.

BREAK (10:37– 10:45)

TOPIC:

VII. APPLICATIONS

A. Applications for a New Store

3. St. Vincent Pharmacy, 125 Summer St., Ste. 365, Worcester, MA

DISCUSSION: Joseph Sawicki, Manager of Record, and Stuart Kersky, consultant, presented the pharmacy's application for a new store and answered the questions of the Board. The proposed MOR described his experience, which includes both serving clinical pharmacy at St. Vincent's and prior MOR experience. The proposed pharmacy will be located in a part of the hospital building but will operate as a general retail pharmacy open to the public. The proposed MOR advised that the hospital pharmacy will be available to patients for after hours emergencies. The pharmacy will refer patients for specialty pharmaceuticals that are not typically available at a general pharmacy. It does not have plans to conduct immunizations.

ACTION: Motion by J. TRIFONE, seconded by E. TAGLIERI, and voted unanimously to conditionally approve the application, subject to a successful inspection.

TOPIC:

VII. APPLICATIONS

A. Applications for a New Store, 25 Amory Street, Boston, MA

4. Pharmahealth Specialty Pharmacy, 25 Amory St., Boston, MA

DISCUSSION: NB: Discussion and action concerning this item was conducted in conjunction with File Review items IX.8-IX.10, which are complaints involving pharmacies owned by corporations that share common ownership. The proposed store is located in the AIDS Action Community Center and does not intend to perform sterile compounding. C. LATHUM presented to the Board her observations during a site-visit of the proposed location. Evidence indicates that another pharmacy within the common ownership (located in Fairhaven) has been dispensing medications out of the proposed pharmacy's space. Board members expressed strong reservations against approving this application given the observations during the site-visit, coupled also with evidence concerning the truthfulness of owners' representations to the Board in connection with the complaints at IX.8-IX.10.

ACTION 1: Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously to deny approval of the application.

ACTION 2: Motion by J. TRIFONE, seconded by A. YOUNG, and voted

unanimously to open a staff assignment on the Fairhaven store's dispensing operations out of the proposed store.

TOPIC:

VII. APPLICATIONS

B. Transfer of Ownership

1. **Diversified Specialty Pharmacy**, 1451 Concord St. Framingham, MA (DS3575)

DISCUSSION: M. CITTADINO presented the pharmacy's application for transfer of ownership. She noted that there were no changes to the pharmacy.

ACTION: Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously to approve the application.

TOPIC:

VII. APPLICATIONS

C. Applications for Registration

2. **Michael Greaves**, 25 Cherry Ridge, Middlefield, CT

DISCUSSION: M. CITTADINO presented Mr. Greaves' application for registration by reciprocity based on licensure in Connecticut. The applicant has prior disciplinary history in CT, consisting of his voluntary surrender of licensure based on misconduct relating to substance abuse. Board members noted his CT license has been restored to good standing, but sought more recent evaluation of his recovery status.

ACTION: Motion by P. GANNON, seconded by K. RYLE, and voted unanimously to conditionally approve the application, subject to the recommendations from an MRPS evaluation.

LUNCH (11:16– 12:09)

TOPIC:

IX. FILE REVIEW

1. **Pallimed Solutions, Inc.** (DS3498), PHA-2011-0286
2. **Pallimed Solutions, Inc.** (DS3498), PHA-2012-0045
3. **Pallimed Solutions, Inc.** (DS3498), PHA-2012-0046
4. **Pallimed Solutions, Inc.** (DS3498), PHA-2012-0237
5. **Pallimed Solutions, Inc.** (DS3498), PHA-2013-0017
6. **J. Nahill** (PH21521), PHA-2012-0171
7. **J. Nahill** (PH21521), PHA-2013-0039

DISCUSSION: All seven complaints were considered as a group for purposes of authorization of commencing disciplinary proceedings, or in the alternative, resolving the pending complaints through a consent agreement. H. ENGMAN presented an update on the complaints and cease and desist order against the above-referenced cases. Per the cease and desist order, the pharmacy is restricted from conducting sterile compounding, and from compounding sildenafil. She noted that there were no USP <795> compounding violations seen on the most recent inspection conducted by investigators. L. McKENNA and S. PENTA presented their observations during an inspection on March 20-22, 2013. They noted that no action had yet been taken on many of the deficiencies observed during the November 19-20 inspection. The observations during the March 20-22 Board inspection included the discovery of 56

vials (9 different products) with visible particulate matter, deviation reports without root-cause analyses or corrective/ preventative actions, inappropriate use of a lyophilizer, inappropriate use of sterilizing filters, multiple inappropriate activities in the ante and buffer areas, and lack of supporting data for extending beyond-use dates (BUDs) as well as lack of a non-resident license in 9 states to which product was shipped. Board members discussed the Board's role as Pallimed's "home state" of licensure, noting that other states receiving shipments from Pallimed may be relying on the Board's actions. Board members considered not only the evidence of observed regulatory violations, but also the appropriateness of Pallimed's proposed corrective actions. Board members also discussed the dual role of James Nahill as both MOR and owner and his ability and/or willingness to perform due diligence.

ACTION 1: Motion by J. DEVITA, seconded by K. RYLE, and voted unanimously to consolidate the complaints against Pallimed and to refer them to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaints by a consent agreement for probation for a minimum of three years, but deferred discussion on the specific monitoring terms to be included in such agreement pending further recommendations.

ACTION 2: Motion by J. DEVITA, seconded by J. TRIFONE to consolidate the complaints against James Nahill and to refer them to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaints by a consent agreement for suspension of licensure for six months followed by probation for a minimum of three years, but deferred discussion on the specific monitoring terms to be included in such agreement pending further recommendations. Motion passed with K. RYLE opposed, but all other members in favor.

TOPIC:

IX. FILE REVIEW

8. **Pharmahealth Specialty Pharmacy** (DS3056), PHA-2013-0013
9. **Edward Macedo** (PH14977), PHA-2013-0035
10. **Richard Brisson** (PH15092), PHA 2013-0036

DISCUSSION: All three complaints were considered as a group. C. LATHUM and B. FRISCH presented the above-referenced matters to the Board. Richard Brisson holds an ownership interest in the pharmacy and Edward Macedo serves as MOR. Both individuals represented to Board investigators during an inspection in December, and attested in writing, that Pharmahealth had ceased sterile compounding practice. A second inspection was conducted in February after the Board received information that Pharmahealth was in fact engaged in sterile compounding. At the second inspection, investigators observed current sterile compounding practice and non-compliance with <797> including no documentation of media fill tests, monthly surface testing, or training. Investigators spoke with Pharmahealth employees who advised that management instructed them to proceed with sterile compounding. Board members expressed alarm that the conduct involves not merely noncompliance, but deliberate misrepresentation and attempts at deception for the purpose of evading oversight.

ACTION 1: Motion by J. DEVITA, seconded by E. TAGLIERI, and voted unanimously for Board staff to conduct a re-inspection and complete a USP <795> audit. The motion further called for the Board to refer the complaint against Pharmahealth Specialty Pharmacy to the Office of Prosecution for the issuance of an

order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaint by a consent agreement for probation for a minimum of three years, but deferred discussion on the specific monitoring terms to be included in such agreement pending further recommendations. Motion passed with all members in favor.

ACTION 2: Motion by E. TAGLIERI, seconded by J. FRANKE to refer the complaint against Edward Macedo to prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaint by a consent agreement for suspension of licensure for one year followed by probation for a minimum of three years, but deferred discussion on the specific monitoring terms to be included in such agreement pending further recommendations. Motion passed with all members in favor.

ACTION 3: Motion by J. DEVITA, seconded by E. TAGLIERI to refer the complaint against Richard Brisson to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, commencement of settlement negotiations for resolution of the complaint by a consent agreement for suspension of licensure for one year followed by probation for a minimum of three years, but deferred discussion on the specific monitoring terms to be included in such agreement pending further recommendations. Motion passed with all members in favor.

BREAK (2:07 – 2:15)

TOPIC:

IX. FILE REVIEW

11. **Royal Palm Specialty Pharmacy** (DS89765), PHA-2013-0029

12. **Katie Fafalla** (PH26808), PHA-2013-0040

DISCUSSION: Both complaints were considered and discussed together. C. LATHUM presented the above-referenced case to the Board. On January 15, 2013, during an inspection, investigators observed violations of pharmacy laws and regulations, including: (1) failing to comply with USP <795> standards for non-sterile compounding, (2) failing to provide for an arrangement and storage of drugs that is calculated to preventing their accidental misuse; and, (3) providing practitioners with prescription blanks that refer to Royal Palm Pharmacy. Specifically, in relation to USP <795>, the facility was unable to provide documentation of training and testing, storage, environmental monitoring, quality control, and multiple standard operating procedures (SOPs). It was observed that it did not meet the requirements for the storage and disposal of hazardous compounds, and was unable to provide policies. C. LATHUM also noted that Royal Palm Specialty Pharmacy has another pending complaint against it for a serious compounding error where the former MOR missed a step in titrating a compound. In both open cases the pharmacy failed to implement the Plan of Correction (POC) for deficiencies. Katie Fafalla is the current MOR and was present during the January 15, 2013 inspection of the pharmacy. Ms. Fafalla become MOR in September 2012 and was not employed at the pharmacy when the titrating error occurred.

ACTION 1: Motion by J. DEVITA, seconded by P. GANNON, and voted unanimously to refer to the Office of Prosecution to be consolidated and prosecuted together with PHA-2011-0309. The motion further authorized, in the alternative,

resolution of the complaint by consent agreement as previously authorized for PHA-2011-0309.

ACTION 2: Motion by E. TAGLIERI, seconded by P. GANNON, and voted unanimously to refer the complaint to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, resolution of the complaints by a consent agreement for stayed probation for six (6) months, with terms requiring the MOR to be in compliance with the January 2013 POC within that time.

TOPIC:

IX. FILE REVIEW

13. **R. Usta** (PH233510), PHA-2012-0222

RECUSAL: E. TAGLIERI recused himself and was not present during the discussion or vote of this matter.

DISCUSSION: XXXXX presented the above-referenced case to the Board. The Board received a report that the registrant reported to work in an impaired state and was stopped by co-workers from working. Her employment was terminated. The Registrant submitted to a toxicology screen which was positive only for medications that were prescribed for her.

ACTION: Motion by J. TRIFONE, seconded by P. GANNON, and voted unanimously to conditionally dismiss the complaint, subject to the recommendations from an MRPS evaluation

TOPIC:

IX. FILE REVIEW

14. **M. Christian** (PT11275), PHA-2012-0021

RECUSAL: J. DEVITA recused himself and was not present during the discussion or vote of this matter.

DISCUSSION: C. LATHUM presented the above-referenced case to the Board. On August 26, 2012 CVS Pharmacy submitted to the Board an initial notification of a significant loss or theft of controlled substances. Ms. Christian admitted that she diverted prescription medications on multiple occasions. Her employment was terminated. The licensee did not respond to the complaint filed against her.

ACTION: Motion by A. YOUNG, seconded by E. TAGLIERI, and voted unanimously to refer the complaint to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, resolution of the complaint by a consent agreement for the permanent voluntary surrender of licensure.

TOPIC:

IX. FILE REVIEW

15. **L. Holden** (PH16717), PHA-2012-0207

RECUSAL: J. TRIFONE recused herself and was not present during the discussion or vote of this matter.

DISCUSSION: V. BERG presented the above-referenced case to the Board. Ms. Holden voluntarily surrendered her license upon allegations that she diverted prescription drugs, prior to the Board's consideration of the complaint.

ACTION: Motion by K. RYLE, seconded by J. FRANKE, and voted unanimously to authorize resolution of the complaint by a consent agreement for the voluntary surrender of licensure with terms permitting reinstatement provided that the registrant

successfully complete the MPRS program and otherwise complies Board policy for reinstatement.

TOPIC:

IX. FILE REVIEW

16. L. Szeto (PT14243), PHA-2012-0230

RECUSAL: J. DEVITA recused himself and was not present during the discussion or vote of this matter.

DISCUSSION: V. BERG presented the above-referenced case to the Board. On August 30, 2012 CVS pharmacy submitted an initial notification of a significant loss or theft of a controlled substance. Ms. Szeto diverted prescription drugs which resulted in her termination from employment. The licensee submitted a voluntary surrender agreement, dated November 9, 2012, along with her original laminated license prior to consideration of the complaint by the Board.

ACTION: Motion by E. TAGLIERI, seconded by P. GANNON, and voted unanimously to ratify the submitted voluntary surrender agreement.

TOPIC:

IX. FILE REVIEW

17. L. Cincotta (PT13747), PHA-2012-044

RECUSAL: J. DEVITA recused himself and was not present during the discussion or vote of this matter.

DISCUSSION: V. BERG presented the above-referenced case to the Board. The Board received a report alleging that Ms. Cincotta requested and received from a pharmacist K. Howes Schedule VI prescription medications, including two (2) Pro-Air inhalers and a generic Z-Pak without valid prescriptions while both she and the pharmacist were employed at CVS. The licensee admitted to receiving the above-referenced medications without valid prescriptions and signed a promissory note to pay restitution to the pharmacy.

ACTION 1: Motion by A. YOUNG, seconded by E. TAGLIERI, and voted unanimously to refer the complaint to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, resolution of the complaint by a consent agreement for the voluntary surrender of licensure.

FURTHER DISCUSSION: After discussion of related complaint PHA-2012-0043, the Board reopened discussion of this matter. Board members expressed concerns about the parity of sanctions.

ACTION 2: Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously to rescind the consent agreement authorization in the previous vote and to authorize instead resolution of the complaint by a consent agreement for a reprimand.

TOPIC:

IX. FILE REVIEW

18. K. Howes (PH19966), PHA-2012-0043

RECUSAL: J. DEVITA recused himself and was not present during the discussion or vote of this matter.

DISCUSSION: V. BERG presented the above-referenced case to the Board. The Board received and reviewed a report alleging that Ms. Howes provided two (2) Schedule VI prescription medications to an employee, L. Cincotta, without valid

prescriptions while employed at CVS. The licensee admitted to providing the medications to the employee without valid prescriptions. There are two (2) prior complaints against the licensee; one which involve a QRE dosage issue a second which involves CE deficiencies.

ACTION: Motion by A. YOUNG, seconded by J. FRANKE and voted unanimously to refer the complaint to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, resolution of the complaint by a consent agreement for a reprimand, condition on the licensee's prior completion of two (2) continuing education credits on pharmacy law.

TOPIC:

IX. FILE REVIEW

- 19. **CVS # 938** (DS1505), PHA-2012-0062
- 20. **M. Chagnon** (PT11854), PHA-2012-0097
- 21. **C. Gonzalez** (PH26121), PHA-2012-0099

RECUSAL: J. DEVITA recused himself and was not present during the discussion or vote of this matter.

DISCUSSION: The Board considered the facts of these three complaints together as they arise from the same incident. The Board received and reviewed a complaint against CVS # 938 which alleges that the pharmacy failed to fill/ dispense a prescription properly. Specifically, it is alleged that CVS incorrectly filled/ dispensed a prescription for Doxycycline 100 mg with Doxepin 100mg, resulting in adverse drug effects and hospitalization for the patient. The pharmacy attributed the error to incorrect data entry and a failure to notice the error when it verified the prescription. PT Chagnon, who has no prior complaints, made a transcription error during prescription drop off. Pharmacist Gonzalez missed the error during the quality assurance process. Moreover, no adverse effects were flagged for the medication.

ACTION 1: Motion by K. RYLE, seconded by J. TRIFONE, and voted unanimously to refer the complaint against the pharmacy (CVS #938) to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, resolution of the complaint by a consent agreement for stayed probation, with terms requiring that the pharmacy report the incident to ISMP and submit a POC detailing how it will avoid incorrectly filling/ dispensing medications in the future.

ACTION 2: Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously to refer the complaint against M. Chagnon to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, resolution of the complaint by stayed probation, with terms requiring completion of two (2) CE credits on medication errors.

ACTION 3: Motion by A. YOUNG seconded by J. FRANKE, and voted unanimously to refer the complaint against C. Gonzalez to the Office of Prosecution for the issuance of an order to show cause. The motion further authorized, in the alternative, resolution of the complaint by stayed probation, with terms requiring completion of two (2) CE credits on medication errors

TOPIC:

IX. FILE REVIEW

- 22. **Prescription Shoppe, Inc.** (DS1505), PHA-2012-0062
- 23. **A. LaMonica** (PH12804), PHA-2012-0168

RECUSAL: K. RYLE recused herself and was not present during the discussion or

vote of this matter.

DISCUSSION: The Board discussed the facts of these two complaints together as they arise from the same events. W. FRISCH and S. PENTA presented the above-referenced case to the Board. The Board received an "Arrest Report" from Massachusetts State Police regarding the arrest of A. LaMonica II in December 2011. This individual is not a registrant of the Board, but is an employee of the registrant Prescription Shoppe and the grandson of the registrant and MOR of the pharmacy, A. LaMonica. The Report alleges that numerous controlled substances were located during a search of the younger Mr. LaMonica's vehicle that he claimed came from said pharmacy. Based on the foregoing, the DEA was notified about the incident and conducted an administrative inspection warrant at the pharmacy on May 10, 2012. Based on audits performed DEA inspectors discovered a number of statutory and regulatory deficiencies in the areas of controlled substances accountability and pharmacy security. It was learned on the date of the inspection that the owner was in the process of trying to sell the pharmacy business and it was subsequently sold in the days following. Registrant and MOR A. LaMonica had also suffered a stroke and was no longer physically able to serve as MOR, although he continued to work at the pharmacy part time. Board members expressed concerns about his ongoing ability to practice.

ACTION 1: Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously to dismiss the complaint against Prescription Shoppe, Inc. as the pharmacy business is under new ownership.

ACTION 2: Motion by E. TAGLIERI, seconded by J. FRANKE, and voted unanimously to rescind the previous vote and defer action on the complaint against Prescription Shoppe, Inc. until the Board obtains more information.

ACTION 3: Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously to defer action on the complaint against A. LaMonica until the Board obtains more information.

TOPIC:

IX. FILE REVIEW

24. J. Finnegan (PH16847), PHA-2012-0192

DISCUSSION: V. BERG presented the above-referenced case to the Board. J. Finnegan entered into a Consent Agreement on June 22, 2011, requiring him to (1) complete 90 CE credits, including thirty (30) hours of live CEs and 12 hours of law CEs, and (2) pass the Multistate Pharmacy Jurisprudence Examination. The Board informed Mr. Finnegan by mail on September 26, 2012 that a complaint was opened against him as he failed to comply with the 2011 Consent Agreement.

ACTION: Motion by J. DEVITA, seconded by E. TAGLIERI, and voted unanimously to refer the complaint to the Office of Public Protection for the issuance of an order to show cause. The motion further authorized, in the alternative, resolution of the complaint by a consent agreement for a voluntary surrender of licensure.

TOPIC:

IX. FILE REVIEW

25. H. Patel (PH26555), PHA-2012-0226

DISCUSSION: C. LATHUM presented the above-referenced case to the Board. The Board was notified that H. Patel received a reprimand on his license in North Carolina, effective February 21, 2012. The NC discipline was based on an error in the

preparation of a morphine solution for a terminally ill patient, where the dosage actually prepared exceeded both the dose prescribed and normal therapeutic doses. Board members determined that its actions should be consistent with the actions of the NC Board.

ACTION: Motion by J. TRIFONE, and seconded by P. GANNON, to refer the complaint to the Office of Public Protection for the issuance of an order to show cause. The motion further authorized, in the alternative, resolution of the complaint by a consent agreement for a reprimand.

TOPIC:

X. GUIDANCE

1. **Chapter 244 of the Acts of 2012: FAQs**
2. DISCUSSION: Members of the Board determined that a discussion on §244 of the Acts of 2012: FAQs is deferred to a subsequent meeting as there was a further postponement of the regulation's effective date.

ACTION: None.

TOPIC:

X. GUIDANCE

3. **Chapter 244 of the Acts of 2012: CE Requirements**

DISCUSSION: V. BERG and K. RYLE submitted a memorandum on the continuing education requirement established by Chapter 244 of the Acts of 2012. Board members reviewed and discussed the proposed outline of topics that need to be covered for a continuing education course to be considered to fulfill the Chapter 244 requirement that pharmacists obtain training on the use of the Prescription Monitoring Program.

ACTION: Motion by K. RYLE, seconded by A. YOUNG, and voted unanimously to adopt the topical parameters detailed in the memorandum.

TOPIC:

XI. FLEX SESSION

1. **Items for the Next Meeting**

DISCUSSION: Board members discussed outlining the commission's recommendation on pharmacy compounding for a future meeting.

ACTION: None.

TOPIC:

XI. FLEX SESSION

- 2a. **Board Delegated Complaint Review**

DISCUSSION: M. CITTADINO requested that Board members volunteer for the monthly Board Delegated Complaint Review. Board members discussed the amount of time devoted to the Review and their desire to determine the schedule in advance.

ACTION: None.

TOPIC:

XI. FLEX SESSION

- 2b. **Plan of Correction Approval**

DISCUSSION: M. CITTADINO requested that Board members volunteer for the monthly Plan of Correction Approval. Board members discussed the amount of time

devoted to the Review and their desire to determine the schedule in advance.

ACTION: None.

TOPIC:

X. FLEX SESSION

3. Chapter 244 of the Acts of 2012: MPJE

DISCUSSION: Board members acknowledged and thanked members K. RYLE and J. TRIFONE for reviewing and updating MPJE questions for consistency with changes in the law resulting from the passage of Chapter 244 of the Acts of 2012.

ACTION: So noted.

TOPIC:

X. FLEX SESSION

4. Pawtucket Pharmacy, DS

DISCUSSION: V. BERG and H. ENGMAN updated the Board about an inspection at Pawtucket Pharmacy that resulted in the issuance of a Cease and Desist. The inspection was initiated due to the probation monitor's concerns that the pharmacy was non-compliant with its probation agreement. Per the terms of that agreement, the pharmacy was prohibited from sterile compounding practice and was required to complete appropriate disposal of certain hazardous substances on its premises. Investigators observed that the pharmacy was continuing to engage in sterile compounding and had not followed through with disposal requirements. Board members expressed concerns that the pharmacy had thus far failed to comply with its agreement with the Board in a manner that poses ongoing immediate danger to the public health safety and welfare. Board members considered whether the cease and desist was sufficient, and determined that a full summary suspension was more appropriate under the circumstances. Board members requested that staff monitor the shut down of the pharmacy to ensure continuity of care for patients.

ACTION: Motion by E. TAGLIERI, seconded by J. FRANKE, and voted unanimously to refer to the Office of Prosecution for issuance of an Order of Summary Suspension.

TOPIC:

XVI. ADJOURNMENT

DISCUSSION: None

ACTION: Motion by K. RYLE, seconded by J. DEVITA, and voted unanimously to adjourn at 5:04 p.m.

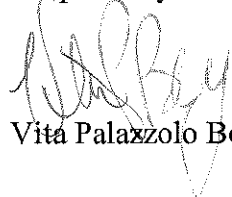
LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the May 7, 2013 Regularly Scheduled Meeting.
2. Proposed Minutes of the March 19, 2013 Additional Scheduled Meeting
3. Proposed Minutes of the April 2, 2013 Regularly Scheduled Meeting
4. Report of Applications approved pursuant to Licensure Policy 13-01
5. Report of Plans of Correction reviewed pursuant to Enforcement Policy 13-02
6. Application to Manage and Operate a New Community Pharmacy: Woodmark Pharmacy
7. Application to Manage and Operate a New Community Pharmacy: Century Pharmacy
8. Application to Manage and Operate a New Community Pharmacy: St. Vincent

Pharmacy

9. Application to Manage and Operate a New Community Pharmacy: Pharmahealth Specialty Pharmacy
10. Application for Transfer of Ownership of Community Pharmacy: Diversified Specialty Pharmacy
11. Pharmacist Reciprocal Licensure Application with report of prelicensure Good Moral Character Review for Michael Greaves
12. Investigation Report re: Pallimed Solutions, Inc. (DS3498), PHA-2011-0286
13. Investigation Report re: Pallimed Solutions, Inc. (DS3498), PHA-2012-0237
14. Investigation Report re:
 - a. Pallimed Solutions, Inc. (DS3498), PHA-2012-0045
 - b. James Nahill (PH21521); PHA-2012-0171
 - c. Michael James Constanzo (PH233143); PHA-2012-167
15. Investigation Report re:
 - a. Pallimed Solutions, Inc. (DS3498), PHA-2012-0046
 - b. Michael James Constanzo (PH233143); PHA-2012-170
16. Investigation Report re:
 - a. Pharmahealth Pharmacy (DS3065), PHA-2013-0013;
 - b. Edward Macedo (PH14977), PHA-2013-0035;
 - c. Richard Brisson (PH15092), PHA-2013-0036
17. Investigation Report re:
 - a. Royal Palm Specialty Pharmacy (DS89765), SA-INV-3209;
 - b. Katie Fafalla (PH26808), PHA-2013-0040
18. Investigation Report re: R. Usta (PH233510), PHA-2012-0222
19. Investigation Report re: M. Christian (PT11275), PHA-2012-0021
20. Investigation Report re: L. Holden (PH16717), PHA-2012-0207
21. Investigation Report re: L. Szeto (PT14243), PHA-2012-0230
22. Investigation Report re: L. Cincotta (PT13747), PHA-2012-0044
23. Investigation Report re: K. Howes (PH19966), PHA-2012-0043
24. Investigation Report re:
 - a. CVS # 938 (DS1505), PHA-2012-0062;
 - b. M. Chagnon (PT11874), PHA-2012-0097;
 - c. C. Gonzalez (PH26121), PHA-2012-0099
25. Investigation Report re: Prescription Shoppe Inc. (DS6654), SA-INV-2718
26. Investigation Report re: A. LaMonica (PH12804), PHA-2012-0168
27. Correspondence to J. Finnegan dated September 26, 2012 regarding PHA-2012-0192;
28. Investigation Report re: H. Patel (PH2655), PHA-2012-0226
29. Memorandum regarding the continuing education requirement established by Chapter 244 of the Acts of 2012

Respectfully submitted,



Vita Palazzolo Berg, Assisting Board Counsel