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, April 2, 2013

Board Members Present
James T. DeVita, RPh
Karen Ryle, RPh, MS
Joanne Trifone, RPh
Anita Young, RPh, EdD
Edmund Taglieri, RPh, MSM, NHA
Patrick Gannon, RPh, MS

Board Members Not Present
Jane Franke, RN, MHA

Board Staff Present
Madeleine Biondolillo, MD,
Bureau Director, HCSQ
Margaret Cittadino, MEd,
Associate Director
Heather Engman JD, MPH, Board Counsel
Vita P. Berg, Assisting Board Counsel
Samuel Penta, RPh,
Investigator Supervisor
Leo McKenna, RPh, PharmD,
QA Coordinator
William E. Frisch, Jr., RPh,
Investigator
Joseph Sceppa, RPh, Consultant
Cheryl Lathum, RPh, PharmD,
Investigator
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 8:44 a.m. J. DEVITA, President, called the April 2, 2013, meeting of the Board of Registration in Pharmacy to order.

TOPIC:

II. **APPROVAL OF AGENDA**

DISCUSSION: Board members reviewed the tentative agenda and acknowledged that there needed to be changes in the order of agenda items.

ACTION: Motion by, A. YOUNG, seconded by E. TAGLIERI, 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 A. YOUNG, seconded by E. TAGLIERI and passed by unanimous roll call vote to enter into Adjudicatory Session at 8:46 a.m.

ADJUDICATORY SESSION (8:46 – 8:53 a.m.)

TOPIC:

IV. **APPROVAL OF BOARD MINUTES**

March 5, 2013 Regularly Scheduled Meeting
March 5, 2013 Executive Session
March 5, 2013 M.G.L. c. 112, § 65C Session
March 19, 2013 Additional Scheduled Meeting

DISCUSSION: V. BERG presented the minutes of the March 5, 2013 Regularly Scheduled Meeting, March 5, 2013 Executive Session, and March 5, 2013 M.G.L. c. 112, § 65C Session. The Board deferred review of the minutes from the March 19, 2013 Additional Scheduled Meeting, the March 5, 2013 Executive Session and the March 5, 2013, and the M.G.L. c. 112, § 65C Session.

ACTIONS: Motion by J. TRIFONE, seconded by E. TAGLIERI, and voted unanimously to approve the minutes of the March 5, 2013 Regularly Scheduled Meeting.

TOPIC:

V. **REPORTS**

1. **Applications approved pursuant to Licensure Policy 13-01**

DISCUSSION: M. CITTADINO reported that she approved twenty-two (22) applications for Change in Manager of Record, one (1) application for registration as a nuclear pharmacist and one (1) notice of a store closing.

ACTION: So noted.

V. **REPORTS**

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

DISCUSSION: H. ENGMAN reported that no Plans of Correction were reviewed during this period.

ACTION: So noted.

TOPIC:

VI. **POLICY**

1. **Proposed revision to Licensure Policy 13-01**

DISCUSSION: V. BERG presented proposed revision to Licensure Policy 13-01, Staff Action on Licensure Applications and Notices. She noted that the existing policy already helped minimize backlogs by authorizing Board staff to approve and process certain applications or notices concerning individual licensure or changes in the operation of licensed pharmacies. The proposed revision expands this authority to applications for new stores, applications for renovations and expansions and applications for relocation, provided that the applicants meet criteria specified in the policy. Board discussed the language of the proposed revisions and recommended minor adjustments to said revision.
ACTION: Motion by J. TRIFONE, seconded by A. YOUNG, and voted unanimously to approve proposed revisions to Licensure Policy 13-01.

TOPIC:

VI. **POLICY**

2. **Proposed Administrative Policy 13-04**

DISCUSSION: V. BERG presented proposed revisions to Enforcement Policy 13-04, Delegation of Board President Authority. She noted that the proposed revision will permit the Board President to delegate authority conferred on the Board. Specifically, there may be times when the Board President may not be able to act on a matter within his or her authority due to illness, travel, conflict of interest or appearance of conflict of interest. The proposed policy would delegate the Board President's authority to another Board member, in an order of succession established by the policy, upon Board staff's receipt of notice that the Board President cannot act for a period of time, or on a specific matter. The Board discussed the language of the proposed revisions and recommended additional changes to said revision. After the lunch break, V. BERG brought a second version of the policy to the Board for review, incorporating its changes.
ACTION: Motion by P. GANNON, seconded by E. TAGLIERI, and voted unanimously to approve proposed revision to Administrative Policy 13-04 with recommended changes as prepared in version 2.

TOPIC:

VII. **APPLICATIONS**

A. **Applications for a New Store**

1. **Brighton Pharmacy**

DISCUSSION: Igor Kuzmin, owner, and Paul Garbarini, attorney, appeared and answered Board members' questions concerning the proposed pharmacy's operations and ability to comply with Board regulations. The pharmacy will be a general retail pharmacy that will only perform basic compounding. Although the pharmacy will be closed on Friday after 7:00 p.m. and Saturdays due to religious observance, Mr. Kuzmin will make himself available by phone when the pharmacy is closed. No waivers are sought.
ACTION: Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously to conditionally approve the application, subject to a successful inspection.

TOPIC:

VII. **APPLICATIONS**

A. **Applications for a New Store**

2. **Belmont Pharmacy**

DISCUSSION: Robert Pavlan, owner and manager of record, appeared and answered Board members' questions concerning the proposed pharmacy's operations and ability to comply with Board regulations. Mr. Pavlan represented that the pharmacy will be an independent community pharmacy with parking available and accessible by public transportation. For after-hour emergencies, Mr. Pavlan will be able to be contacted by phone; he is looking to set up a telephone service. The pharmacy will not be compounding, but will provide delivery and blister pack services. No waivers are sought.

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

TOPIC:

VII. **APPLICATIONS**

A. **Applications for a New Store**

3. **Lowell Community Health Center Pharmacy**

DISCUSSION: M. CITTADINO presented the pharmacy's application for a new store. She noted that the pharmacy is related to Eaton Apothecary but will be operating as a stand-alone pharmacy. No waivers are sought.

ACTION: Motion by P.GANNON, 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**

4. **Easy Care Pharmacy**

DISCUSSION: M. CITTADINO presented the pharmacy's application for a new store. Easy Care pharmacy is part of a chain of pharmacies and the proposed pharmacy represents that this is the final pharmacy that the parent company will be opening. No waivers are sought.

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

TOPIC:

VII. **APPLICATIONS**

B. **Applications for Relocation**

1. **Price Chopper #153**, 2 Worcester Road, Webster (DS2898)

DISCUSSION: M. CITTADINO presented the pharmacy's application for relocation. She noted that it is a relocation of a supermarket, and at the time of the Board meeting, an inspection was needed.

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

TOPIC:

VII. **APPLICATIONS**

C. **Applications for Relocation**

2. **Stat-Care Pharmacy**, 574 Hartford Turnpike, Shrewsbury (DS89676)

DISCUSSION: M. CITTADINO presented the pharmacy's application for relocation. The Board noted that this pharmacy is under common ownership with a pharmacy that is currently subject to probation, but that the discipline in that instance did not warrant denying the relocation of this already existing and compliant pharmacy.

ACTION: Motion by E. TAGLIERI, seconded by J. TRIFONE, and voted unanimously to approve the application.

TOPIC:

VII. **APPLICATIONS**

D. **Applications for Renovation or Expansion**

1. **BioRx LLC**, 266 West Cummings Park, Woburn (DS89763)

DISCUSSION: M. CITTADINO presented the pharmacy's application for expansion. She stated that the compounding pharmacy is in good standing and the expansion would not affect the pharmacy's practice in their clean compounding rooms.

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

TOPIC:

VII. **APPLICATIONS CONTINUED**

E. **Applications for Registration**

1. **Nkemdillim Iffih, Pharmacist**

DISCUSSION: Mr. Iffih appeared and answered Board members' questions concerning his application for a reciprocal license. The Board noted that the applicant has not submitted all information and documentation as requested.

ACTION: The Board deferred action on the application pending receipt of all required documentation.

TOPIC:

VII. **APPLICATIONS CONTINUED**

F. **Applications for Registration**

2. **Dan Ton Nguyen, Pharmacy Intern**

DISCUSSION: M. CITTADINO presented Mr. Nguyen's pharmacy intern application and stated that he submitted two applications, one of which did not report his disciplinary and/or criminal history. Board felt that he did not intentionally omit this information on one of the applications.

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

TOPIC:

VII. **APPLICATIONS CONTINUED**

G. **Applications for Registration**

1. **Amber Wayne, Pharmacy Intern**

DISCUSSION: M. CITTADINO presented Ms. Wayne's pharmacy intern

application, which included criminal charges for an OUI in New York in 2010. An official Certificate of Disposition indicated that each of the charges was disposed of.
ACTION: Motion by J. TRIFONE, seconded by K. RYLE, and voted unanimously to approve the application.

LUNCH (10:45– 12:10)

TOPIC:
XIV. **INVESTIGATIVE CONFERENCE**

1. **Pallimed Solutions, Inc., DS3498, PHA-2011-0286**
   DISCUSSION: Jim Nahill, owner and Manager of Record, and John Commisso, attorney, appeared and answered Board members' questions concerning a prescription for HCG which the pharmacy compounded, filled and dispensed, which allegedly caused a patient to have a high-grade fever on three (3) occasions. Mr. Nahill represents that there was a HCG shortage at time the prescription was written the patient's doctor called him to determine whether the pharmacy was able to compound HCG. He also stated that sterility testing was conducted on the stock vials prior to compounding and after the compounded vials had been dispensed to patients. Mr. Nahill attests that the company has received some QRE complaints but he is not aware of any other reactions from the HCG that they have dispensed.
   ACTION: So noted.

TOPIC:
XIV. **INVESTIGATIVE CONFERENCE**

Pallimed Solutions, Inc., DS3498, PHA-2012-0046
Pallimed Solutions, Inc., DS3498, PHA-2012-0045
J. Nahill, PH21521, PHA-2012-0171
DISCUSSION: Jim Nahill, owner and Manager of Record, and John Commisso, attorney, and Michael Costanzo, pharmacist, appeared and answered Board members' questions concerning the lidocaine 18% the pharmacy filled, compounded and dispensed, instead of the prescribed lidocaine 2%, to a 60-year-old and 82-year-old patient. Both patients required a hospital admission after taking the dispensed medication. Mr. Costanzo stated that he was not aware of dialog with a formula resource when formulating the lidocaine. Mr. Nahill represented that the pharmacy did not have an oversight process but one was put into place after this incident.
ACTION: So noted.

TOPIC:
XIV. **INVESTIGATIVE CONFERENCE**

M. Costanzo, PH233143, PHA-2012-0170
M. Costanzo, PH233143, PHA-2012-0167
DISCUSSION: Jim Nahill, owner and Manager of Record, and John Commisso, attorney, and Michael Costanzo, pharmacist, appeared and answered Board members' questions concerning the lidocaine 18% the pharmacy filled, compounded and dispensed, instead of the prescribed lidocaine 2%, to a 60-year-old and 82-year-old patient. Both patients required a hospital admission after taking the dispensed medication. Mr. Costanzo stated that he was not aware of dialog with a formula

resource when formulating the lidocaine. Mr. Nahill represented that the pharmacy did not have an oversight process but one was put into place after this incident.
ACTION: Motion by K. RYLE, seconded by A. YOUNG, and voted unanimously to refer to the Office of Prosecution to issue a stayed probation, for a minimum of one (1) business day, with the requirement that he submit documentation demonstrating completion of continuing education on the topic of Pharmacy Calculations.

TOPIC:
XIV. **INVESTIGATIVE CONFERENCE**

4. **Pallimed Solutions, Inc. DS3498, PHA-2012-0237**
DISCUSSION: Jim Nahill, owner and Manager of Record, and John Commisso, attorney, and Michael Costanzo, pharmacist, appeared and answered Board members' questions concerning its use of sildenafil citrate for human and veterinary prescriptions from a source only intended for veterinary use. Pfizer alleges that Pallimed is compounding sildenafil (Viagra) 50 mg and 100 mg tablets by obtaining sildenafil citrate from an unapproved source of active pharmaceutical ingredient. Mr. Costanzo stated that it was the pharmacy's procedure for purchaser to get approval for an order over a certain amount, such as the one involving sildenafil. He represented that when he brought the sildenafil order to Mr. Nahill for approval, Mr. Nahill told him to sign an agreement with its source to only use the sildenafil. Mr. Nahill, however, denied that he had knowledge of the agreement and that he asked Mr. Costanzo sign it. Mr. Nahill denies that there was any wrong doing in his pharmacy's production of sildenafil.
ACTION: Motion by K. RYLE, seconded by P. GANNON, and voted unanimously to amend the Cease and Desist order issued against the pharmacy to allow dispensing of commercially available sildenafil.

BREAK (2:00–2:25)

TOPIC:
XIII. **FILE REVIEW**

1. **R. Usta, PH233510; PHA-2012-02222**
2. **M. Christian, PT11275; PHA-2012-0221**
3. **L. Holden, PH16717, PHA-2012-0207**
4. **L. Szeto, PT14243; PHA-2012-0230**
8. **L. Cincotta, PT13747; PHA-2012-0044**
9. **K. Howes, PH19966; PHA-2012-0044**
10. **CVS Pharmacy #938 in North Attleboro, MA, DS1505; PHA-2012-0062**
11. **M. Chagnon, PT11854; PHA-2012-0097**
12. **C. Gonzalez, PH26121; PHA-2012-0099**

RECUSAL: Recusal by at least one Board member was appropriate in each of these complaints, but recusal would have left the Board without a quorum.
ACTION: Discussion and action deferred to a subsequent Board meeting.

TOPIC:
XIII. **FILE REVIEW**

5. **Sedell's Pharmacy, DS3318; PHA-2011-0303**
DISCUSSION: B. FRISCH made a presentation to the Board on this matter. During a compliance inspection of Sedell's Pharmacy conducted on October 26, 2011

inspectors observed numerous improper practices. Observations included containers of improperly labeled and unlabeled medications in inventory, containers of outdated/expired medications commingled with active stock, failure to redact patient information on return-to-stock containers, improperly labeled compounding ingredients, use of drug refrigerator freezer compartment for storage of food, failure to maintain refrigeration logs, failure to maintain the sink and shelving in a clean and sanitary manner, failure to maintain medications in inventory in a manner calculated to prevent accidental misuse (e.g., internal and external compounding ingredients commingles on same shelf), failure to maintain documentation in accordance with federal and state laws. Evidence from the investigation indicates that although Registrant Sterling held the position of the Manager of Record for the pharmacy, he was frequently absent from the pharmacy for extended periods.

ACTION: Motion by J. DEVITA, seconded by P. GANNON and voted unanimously to refer this complaint for prosecution with authorization to enter into a consent agreement for probation for 90 days with terms to be completed during the period of probation. These terms shall include a requirement that the pharmacy replace the Manager of Record within 60 days of the agreement effective date and that the pharmacy shall submit with its application for change of manager of record an affidavit signed by the proposed new Manager of Record averring the he or she has read 247 CMR 6.00, et. seq., and understands his or her obligations as a Manager of Record. The terms of the vote also included provision that board staff shall conduct an inspection of the pharmacy 60 days after the approval of the new Manager of Record.

TOPIC:

XIII. **FILE REVIEW**

6. **R. Sterling, PH14543; PHA-2011-0304**

DISCUSSION: B. FRISCH made a single presentation to the Board for on this matter. During a compliance inspection of Sedell's Pharmacy conducted on October 26, 2011 inspectors observed numerous improper practices. Observations included containers of improperly labeled and unlabeled medications in inventory, containers of outdated/expired medications commingled with active stock, failure to redact patient information on return-to-stock containers, improperly labeled compounding ingredients, use of drug refrigerator freezer compartment for storage of food, failure to maintain refrigeration logs, failure to maintain the sink and shelving in a clean and sanitary manner, failure to maintain medications in inventory in a manner calculated to prevent accidental misuse (e.g., internal and external compounding ingredients commingles on same shelf), failure to maintain documentation in accordance with federal and state laws. Evidence from the investigation indicates that although Registrant Sterling held the position of the Manager of Record for the pharmacy, he was frequently absent from the pharmacy for extended periods.

ACTION: Motion by J. TRIFONE, seconded by E. TAGLIERI and voted unanimously to refer this complaint for prosecution with authorization to enter into a consent agreement for reprimand of the Registrant's license, on the condition that the Registrant first resign from the position of Manager of Record at Sedell's Pharmacy in Lakeville, DS 3318, and that the Registrant agree that he will not apply for or accept a position as Manager of Record at any pharmacy registered by the Board until such time as he takes and passes the MPJE with a score of 75% (MPJE to be taken after the effective date of the agreement).

TOPIC:

XIII. **FILE REVIEW**

7. **C. Sedell, PH24364; PHA-2011-0177**

DISCUSSION: B. FRISCH presented the matter to the Board. The evidence gathered during the investigation supports the allegations as follows: The Registrant was employed as a pharmacist at Sedell's Pharmacy in Lakeville. A patient contacted the Registrant claiming that he was unable to access clonazepam previously dispensed at Sedell's in Assonet. The Registrant dispensed tablets in a quantity less than the full amount of the prescription, in a prescription bottle with no label, and without contacting the physician for a new order. Board members discussed the matter and reasoned that the evidence appeared to be sufficient to commence disciplinary proceedings for improper practice, but not supportive of participation in diversion.
ACTION: Motion by K. RYLE, seconded by A. YOUNG and voted unanimously to refer this complaint for prosecution with authorization to enter into a consent agreement for reprimand, on the condition that the Registrant first submit documentation demonstrating completion of 2 contact hours in pharmacy law continuing education (live), which the Registrant may not count towards fulfillment of his continuing education requirements for license renewal.

TOPIC:

XI. **GUIDANCE**

1. **§244 of the Acts of 2012: FAQs**

DISCUSSION: Board members reviewed the FAQ on §244 of the Acts of 2012 drafted by J. TRIFONE and discussed revisions needed including (1) clarification on the meaning of "only" as it relates to "prescribed by a physician"; (2) adding May 1, 2013 onward where there are start dates; and, (3) accessing PMP online. She also discussed a matrix she created that includes a table of definitions and language from the PMP website. M. BIONDLILLO indicated that she would forward the FAQs and table to DPH Drug Control Program staff with oversight over PMP so that they may review and comment prior to finalization.
ACTION: So noted.

TOPIC:

XVI. **FLEX SESSION**

1. **Items for the Next Meeting**

DISCUSSION: Board discussed adding the following items to the agenda for the May 7, 2013 regularly scheduled meeting:

- Continuing Education requirements on §244 of the Acts of 2012
- The recommendations of the Special Commission on the Oversight of Compounding Pharmacies
- Communicating to the public regarding non-FDA compounded sterile products

ACTION: None.

TOPIC:

XVI. **FLEX SESSION**

2. **Scheduling of Additional Meetings Prior to Next Regularly Scheduled Meeting**

DISCUSSION: The Board felt there was no need to schedule an additional meeting before the regularly scheduled May meeting.
ACTION: None.

TOPIC:

XVI. **FLEX SESSION**

3. **Chapter 244 of the Acts of 2012: MPJE**

DISCUSSION: J. TRIFONE and K. RYLE volunteered to update questions on the MPJE to reflect the changes created by Chapter 244 of the Acts of 2012.

ACTION: None.

TOPIC:

XVI. **FLEX SESSION**

4. **DEA Conference: Pharmacy Diversion Awareness**

DISCUSSION: The Board discussed the recommendations made by the DEA about coordinating with the DEA taskforce and addressing risks associated with non-approved drug products.

ACTION: So noted.

TOPIC:

XVI. **ADJOURNMENT**

DISCUSSION: None

ACTION: Motion by E. TAGLIERI, seconded by A. YOUNG, and voted unanimously to adjourn at 4:10 p.m.

LIST OF EXHIBITS USED DURING THE MEETING

1. Report of Applications approved pursuant to Licensure Policy 13-01
2. Proposed Administrative Policy 13-04, Delegation of Board President Authority
3. Proposed Revisions to Licensure Policy 13-01, Staff Action on Licensure Application and Notices
4. Application to Manage and Operate a New Community Pharmacy: Good Health Pharmacy, Inc.
5. Application to Manage and Operate a New Community Pharmacy: Belmont Pharmacy, Inc.
6. Pharmacy Intern Licensure Application with report of prelicensure Good Moral Character Review for D. Nguyen
7. Pharmacist Reciprocal Licensure Application with report of prelicensure Good Moral Character Review for N. Iffih
8. Investigation Report re: Pallimed Solutions, Inc., DS3498, PHA-2011-0286
9. Investigation Report re: Pallimed Solutions, Inc., DS3498, PHA-2012-0046; M. Costanzo, PH233143, PHA-2012-0170
10. Investigation Report re: Pallimed Solutions, Inc., DS3498, PHA-2012-0045; J. Nahill, PH21521, PHA-2012-0171; M. Costanzo, PH233143, PHA-2012-0167
11. Investigation Report re: Pallimed Solutions, Inc. DS3498, PHA-2012-0237
12. National Association of Boards of Pharmacy March 11, 2013 Request for Comments
13. Draft Chapter 244 of the Acts of 2012 FAQs

Respectfully submitted,

Vita Palazzolo Berg, Assisting Board Counsel