

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, July 1, 2014

Board Members Present

Karen Ryle, RPh, President (arrive @ 9 am)
Patrick Gannon, RPh, MS, President-elect
Edmund Taglieri, RPh, MSM, NHA,
Secretary
James DeVita, RPh
Timothy Fensky, RPh
Jane F. Franke, RN, MHA
Anthony Perrone, MD
Joanne Trifone, RPh
Richard Tinsley, MBA, MEd
Anita Young, RPh, EdD

Board Members Not Present

Board Staff Present

David Sencabaugh, RPh, Executive Director
James Lavery, JD, Division Director, DHPL
Heather Engman JD, MPH, Board Counsel
Vita Berg, JD, Chief Board Counsel
Kelly Barnes, JD, RPh, Dir. Quality Assurance
Richard Harris, Administrative Assistant
William Frisch, Jr., RPh, Director of Compliance
Samuel Penta, RPh, Investigator
Anthony Bartucca, RPh, Investigative Consultant
David Dunn, RPh, Investigative Consultant
Christina Moggi, RPh, Investigative Consultant
Joseph Sceppa, Consultant

Board Staff Not Present

Cheryl Latham, RPh, PharmD, Investigator
Leo McKenna, RPh, PharmD, Investigator

TOPIC:

I. CALL TO ORDER

DISCUSSION: A quorum of the Board was present. President-Elect, P. GANNON opened the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. He indicated that the Board was recording the meeting.

ACTION: At 8:32 a.m. P. GANNON, called the July 1, 2014, meeting of the Board of Registration in Pharmacy to order.

TOPIC:

II. APPROVAL OF AGENDA

DISCUSSION: A. YOUNG asked that the NABP Utah Experience be added to the Flex Session.

ACTION: Motion by A. YOUNG, seconded by E. TAGLIERI, and voted unanimously to approve the agenda with the noted changes. K. RYLE was not present for the vote.

TOPIC:

III. EMERGENCY REGULATIONS 8:33-9:35 am

K. RYLE was not present at the start of the discussion.

DISCUSSION: Chief Board Counsel, V. BERG distributed a memo summarizing events and comments received with respect to the Emergency Regulations at 247 CMR 8.05(3) and 9.04(8) regarding Hydrocodone-Only Extended Release Medications that are not in an Abuse Deterrent Form. Ms. BERG advised the Board that a public hearing was held with respect to these emergency regulations on June 13, 2014. Board President Karen Ryle and Board member Anita Young were present for the public hearing, but there was no testimony from the public. Ms. BERG also advised the Board that since the May 6 promulgation of these emergency regulations, the Board of Registration in Medicine (BORIM) had made changes to its corresponding regulations relating to the prescribing of this medication. Ms. BERG made recommendations for specific amendments to the emergency regulations and Board members deliberated as follows:

247 CMR 8.05(3). The recommended change was to eliminate the restriction on pharmacy interns handling of the hydrocodone only medications. Board members concurred with the rationale for this change: (1) that eliminating this restriction may help to alleviate the burden on a pharmacist who is the sole pharmacist on staff, (2) the recognition that the training and experience of interns is substantially greater than that of technicians and (3) that the purpose of the internship is to provide practical experience in the role and function of a pharmacist. While deliberating, however, J. DEVITA raised concerns about the qualifier "approved" in the proposed second sentence of this section. There is no formal approval process in place and the regulations already call for a registered pharmacist preceptor to provide direct supervision. See Action 1 below.

247 CMR 9.04(8)(a). The recommended change was to allow for the hydrocodone only medications to be dispersed in inventory as an alternative to secure in a locked cabinet. This recommendation relied on existing provisions at 247 CMR 6.02(6)(c) and sought to address concerns raised on comments that locked storage may be easier for burglars to identify. Board members deliberated at length. J. TRIFONE raised the concern that dispersal is not a secure method for preventing theft, noting that many robberies are by persons "inside," e.g., employed at the pharmacy. E. TAGLIERI countered that, while diversion is a concern, the manager of a particular pharmacy would benefit from the flexibility of multiple approaches to security. J. TRIFONE and E. TAGLIERI agreed that having a stricter rule for the one drug might be confusing. J. DEVITA noted that in cases of external theft, the result may not be impacted by whether the controlled substances are dispersed or locked, but in the case of internal diversion, dispersal is less secure. W. FRISCH noted that not all dispersal approaches are effective at concealing the location of Schedule II medications, noting that in some pharmacies, they may be "dispersed" in alphabetical order. Board members also commented on the impracticality of dispersal for the period of time after the prescription has been filled but before pick-up. See Action 2 below.

247 CMR 9.04(8)(c). K. RYLE joined the meeting and discussion at this point. There were three recommended changes to this section. The first was to delete the reference to BORIM regulations in order to remove what had become a circular

regulatory reference following BORIM's amendments to its own regulations. The second was to substitute the phrase "have failed" with "are inadequate," so that the Board's regulation will align with amendments to BORIMs regulations. The third change was to insert an exception to the requirement that the prescriber and patient enter into a Pain Management Treatment Agreement where the prescriber has determined that such agreement was not clinically indicated due to the severity of the patient's medical conditions. This change was likewise recommended in order that the Board's regulations would align with BORIM's regulations. K. RYLE and A. PERRONE expressed concern that prescribers would develop form versions or prescription pad versions of the Letter of Medical Necessity. They discussed whether a new letter should be required with each prescription and if not, in which circumstances an earlier letter would suffice. Board members agreed that a *new* letter with each prescription should be provided and kept with the prescription. They noted that since prescribers should be monitoring for patient for changes indicative of substance abuse activity, that the requirement is not unlike other medications where proof of compliance with blood testing needs to accompany the prescription in order for it to be dispensed. See Action 3 below.

247 CMR 9.04(8)(e). K. RYLE proposed an additional topic to the list of required counseling provisions: signs and symptoms of an acute overdose, to be inserted as item 9. Board members agreed with this addition. Board members also considered whether item 8 was appropriate: action to be taken in the event of a missed dose. Noting Hydrocodone-Only Extended Release medications are prescribed for pain, and that normally, pain medications are prescribed as needed, Board members considered whether there would be special instructions for a "missed" dose. Given the concerns for overdose if two doses are taken too closely together in time, Board members decided that it would be prudent to leave this in so that there would be discussion between pharmacists and patients. See Action 4 below.

ACTIONS:

- Action 1: Motion by J. DEVITA, seconded by J. TRIFONE and voted unanimously to strike the word "approved" from the proposed second sentence in 247 CMR 8.05(3), but to otherwise adopt the amendments as recommended.
- Action 2: Motion by A. Young, seconded by J. FRANKE, and voted unanimously to reject the proposed amendments to 247 CMR 9.04(8)(a), such that the provision will remain as promulgated on May 6, 2014.
- Action 3: Motion by J.DEVITA, seconded by J. FRANKE, and voted unanimously to adopt all three amendments to 247 CMR 9.04(8)(c) as recommended and also to insert the word "new" in front of the first instance of "Letter of Medical Necessity" in that subsection.
- Action 4: Motion by P. GANNON, seconded by J. FRANKE, and voted unanimously to insert "9. signs and symptoms of an acute overdose" into 247 CMR 9.04(8)(e) and also to correct the reference in the first sentence of this section, so that it reads "written warning supplied in accordance with 247 CMR 9.04(8)(d)."
- Action 5: Motion by A. YOUNG, seconded by E. TAGLIERI, and voted unanimously, to promulgate permanent regulations at 247 CMR 8.03(5) and 9.04(8) as amended by the Board's earlier votes at this meeting.

TOPIC:

IV. APPLICATIONS

Application for a New Community Pharmacy

9:37 am

1. Village Pharmacy, 355 Bear Hill Road, Suite B, Waltham, MA

RECUSAL: T. FENSKY recused himself and was not present during the discussion or vote for this matter.

DISCUSSION: MOR, Julia Narowski; Owner, Stuart Levine, and Compliance Manager, David Brass presented this application for a new pharmacy.

Village Pharmacy is owned by and is a completely separate entity from Village Fertility Pharmacy (DS89658, 355 Bear Hill Road, Waltham). Mr. Levine indicated that Village Fertility Pharmacy is recognized by pharmacy benefit manager Medco-Express Scripts as a specialty pharmacy and will not allow them to bill for non-specialty prescriptions.

Village Pharmacy will be open from 1 am to 7 pm Monday through Friday (emergency phone # posted & on prescription labels); will have shared patient profiles, but separate controlled substance registrations and inventory/purchasing.

MOR Narowski indicated that Village Pharmacy will not engage in compounding sterile or non-sterile pharmaceuticals, and requests waivers from the following requirements:

- a. 247 CMR 6.01 (5)(a)4: A balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually.
- b. 247 CMR 6.01 (5)(d)(1): A pharmacy must provide a designated consultation area, with signage stating "Patient Consultation Area", designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area must be accessible by a patient from the outside of the prescription dispensing.
 - The rooms in the Patient Counseling Area will be shared with Village Fertility Pharmacy.
- c. 247 CMR 6.02 (4): The pharmacy or pharmacy department shall maintain on the premises at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed medications in accordance with the usual needs of the community.
- d. 247 CMR 6.02 (5): A pharmacy or pharmacy department shall have a reasonably-sized sign affixed to the main entrance of the business or otherwise installed in an easily observable area outside the premises, identifying the presence of a pharmacy or pharmacy department.
 - A reasonably-sized (in terms of need) compliant sign will be placed on the entrance to the pharmacy department door.
- e. 247 CMR 6.02 (8)(a): The hours of operation shall be prominently posted at all consumer entrances to the pharmacy and, in the case of a pharmacy department, the hours shall also be posted at all consumer entrances to the retail store and at the pharmacy department;
 - The hours of operation will be posted at the shared entrance to the pharmacies.
- f. 247 CMR 9.01 (15): Unless otherwise provided for by law, a pharmacist shall not limit his or her services to a particular segment or segments of the general public.
 - Village Pharmacy would specialize in servicing fertility patients.
- g. 247 CMR 9.07 (3)(c): (c) A sign of not less than 11 inches in height by 14 inches in width shall be posted in a conspicuous place, adjacent to the area where prescriptions are dispensed, informing customers of their rights, pursuant to 247 CMR 9.07 and to M.G.L. c. 94C, § 21A, to counseling by a pharmacist where their prescription was filled. Said sign shall read, in letters not less than ½ inch in height: "Dear patients, you have the right to know about the proper use of your medication and its effects. If you need more information please ask the pharmacist."
 - The sign and verbiage will be consistent with that of Village Fertility Pharmacy.

It was noted that Village Pharmacy did not request a waiver from 247 CMR 9.01(16) (A pharmacist shall not refuse to compound customary pharmaceutical preparations except upon

extenuating circumstances). MOR Narowski indicated that she would amend the application to include the additional waiver request.

In response to the Board's concern for the Village Fertility Pharmacy compounding areas during construction, Mr. Levine agreed to send a containment strategy to the Board for their approval.

Board members noted Village Fertility Pharmacy is owned and operated by the Village Pharmacy applicants. Board members expressed concern that Village Fertility Pharmacy may attempt to avoid probation by opening the new Village Pharmacy. **ACTION:** Motion by R. TINSLEY, seconded by, J. TRIFONE, and voted unanimously to approve the Village Pharmacy's Application for a New Community Pharmacy and to grant requested waivers so long as the following conditions are met: (1) applicant submits a revised waiver request; (2) Village Pharmacy enters into a consent agreement for probation that will terminate at the same time as the Village Fertility Pharmacy probationary term; (3) Village Pharmacy provides a construction plan and containment strategy; (4) Village Pharmacy successfully passes an inspection.

BREAK 10:00 – 10:12 am

TOPIC:

IV. APPLICATIONS

Application for a New Community Pharmacy

10:12 am

2. Southcoast Specialty Pharmacy, 206 Mill Road, Fairhaven, MA

RECUSAL: P. GANNON recused himself and was not present during the discussion or vote for this matter.

DISCUSSION: Scott Flanagan, Director of Ambulatory Pharmacy Operations presented this application for a new pharmacy. Proposed MOR, Susan Kvilhaug was unable to be present.

Southcoast Specialty Pharmacy will be a for-profit entity within a non-profit corporation and will be located in an oncology building, adjacent to a full retail pharmacy. It plans to dispense a limited group of specialty medications that are not available at regular community pharmacies. The pharmacy will not engage in sterile or non-sterile compounding. There will not be walk-in patients.

The application contained the following five (5) waiver requests:

- a. 247 CMR 6.01 (5)(a)4: A balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually.
 - The proposed pharmacy will not engage in any form of compounding.
- b. 247 CMR 6.01 (5)(d)(1): A pharmacy must provide a designated consultation area, with signage stating "Patient Consultation Area", designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area must be accessible by a patient from the outside of the prescription dispensing.
 - Since the pharmacy will be closed to the public, there will be no walk-in traffic. Space is available to counsel patients receiving outpatient infusions. A written offer to counsel (by phone) accompanies each medication dispensed.
- c. 247 CMR 6.02 (5): A pharmacy or pharmacy department shall have a reasonably-sized sign affixed to the main entrance of the business or otherwise installed in an easily observable area outside the premises, identifying the presence of a pharmacy or pharmacy department.

- d. 247 CMR 6.02 (7): A pharmacy or a pharmacy department shall conspicuously display, in legible letters not less than one inch high, over, on or adjacent to the main entrance of the pharmacy or pharmacy department, the name of the pharmacist Manager of Record who is responsible for the management and operation of the pharmacy or pharmacy department.
- e. 247 CMR 6.02 (8)(a): The hours of operation shall be prominently posted at all consumer entrances to the pharmacy and, in the case of a pharmacy department, the hours shall also be posted at all consumer entrances to the retail store and at the pharmacy department.
 - c, d, and e: The proposed pharmacy will be closed to public traffic. All required licenses and notifications will be posted within the interior pharmacy space. Existing signage in the Center for Cancer Care building informs patients of the retail Southcoast Pharmacy in the adjoining building.

Board members suggested two additional waiver requests, to which Mr. Flanagan agreed and will submit an amended application.

- 1. 247 CMR 6.02 (4): The pharmacy or pharmacy department shall maintain on the premises at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed medications in accordance with the usual needs of the community.
- 2. 247 CMR 9.01(16): A pharmacist shall not refuse to compound customary pharmaceutical preparations except upon extenuating circumstances.

ACTION: Motion by E. TAGLIERI, seconded by, R. TINSLEY, and voted unanimously to approve the Southcoast Specialty Pharmacy Application for a New Community Pharmacy, conditioned upon receipt of non-sterile compounding attestation, attestation that MOR is familiar with 247 CMR and a successful inspection at which the proposed MOR, Susan Kvilhaug, would be present.

TOPIC:

IV. APPLICATIONS

Renovation/Expansion Update

10:23 am

3. CVS Pharmacy #2162 @ Children’s Hospital, 300 Longwood Ave., DS2687

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

DISCUSSION: Executive Director SENCABAUGH received an update letter from CVS indicating that, because of a major hospital renovation, they would be moving from the Children’s Hospital lobby on the first floor to the second floor. They expect to occupy the new space (without compounding) mid-July. Renovations for a new non-sterile compounding area are expected to be completed in mid-September.

ACTION: So noted.

TOPIC:

IV. APPLICATIONS

Waiver Request Not to Compound

10:26 am

4. Little’s HSC Pharmacy, 109 Eagle Street, North Adams, MA, DS2551

DISCUSSION: Quality Assurance Director, K. BARNES presented a Petition for Waivers from David Dupree, MOR of Little’s HSC Pharmacy. Little’s HSC Pharmacy has decided not to engage in non-sterile compounding (USP <795>). Pharmacy personnel will assist patients in locating a local pharmacy that can meet their compounding needs. Mr. Dupree requested the following three (3) waivers to 247 CMR:

- a. 247 CMR 6.01 (5)(a)4: A balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually.
- b. 247 CMR 6.02 (4): The pharmacy or pharmacy department shall maintain on the premises at all times a sufficient variety and supply of medicinal chemicals and preparations which are necessary to compound and dispense commonly prescribed medications in accordance with the usual needs of the community.
- c. 247 CMR 9.01(16): A pharmacist shall not refuse to compound customary pharmaceutical preparations except upon extenuating circumstances.

ACTION: Motion by A. YOUNG, seconded by, P. GANNON, and voted unanimously to approve Little's HSC Pharmacy three (3) Waiver Requests.

TOPIC:

IV. APPLICATIONS

Application for a New Wholesale Distributor 10:29 am

5. Sobi/Cardinal Health, Waltham, MA

DISCUSSION: Board Counsel, H. ENGMAN discussed an application for wholesale distributor license from Sobi, a division of Cardinal Health. The Sobi facility in Waltham is an office; as Sobi would be a virtual wholesaler and would not maintain inventory. Medication (non-federally controlled; MA Schedule VI) would be shipped from facilities in Europe directly to the customer.

Although two (2) licenses have been issued to virtual wholesalers, the Board expressed concerns about the inability to inspect a physical facility and many of the functions that wholesalers perform (e.g., drug pedigree).

It was noted that guidelines for virtual wholesalers might be available from NABP's Verified-Accredited Wholesale Distributors (VAWD) program.

Board members had several questions for the applicant which could not be answered from the papers submitted. The board members wanted additional information on the business model and business plan. Board members expressed disappointment that applicant did not appear at the board meeting. Board members agreed that representatives for Sobi need to be present for future discussions.

ACTION: Motion by J. DEVITA, seconded by, R. TINSLEY, and voted unanimously to table consideration until a future meeting when applicant can attend meeting an answer questions.

TOPIC:

IV. APPLICATIONS

Application for Relocation of a Community Pharmacy 10:43 am

6. Omnicare of Northern Massachusetts (formerly known as North Shore Pharmacy Services), Wakefield, MA, DS3458

DISCUSSION: Anthony Linardos (current MOR), Stephen Rappa and Bill Irvin presented this application for a new pharmacy. Michael Tapley (proposed MOR) was not present. Omnicare must leave their current Wakefield location by August 31, 2014 because it was unable to renew its lease. They propose moving to a larger (50,000 ft²) facility at 2 Technology Drive in Peabody.

This Omnicare location services approximately 18,000 of the 40,000 nursing home beds in MA. The facility would install modular clean rooms with new laminar flow hoods, and would compound only low and medium-risk level sterile products.

ACTION: Motion by J. DEVITA, seconded by, J. TRIFONE, and voted unanimously to

approve the Omnicare of Northern MA relocation application, contingent on receipt of a written transition plan, a patient continuity of care plan, and a successful inspection.

BREAK 11:00 – 11:06 am

TOPIC:

V. APPROVAL OF BOARD MINUTES

11:07 am

1. June 3, 2014 Regular Session of the Board

DISCUSSION: One minor change was made to the June 3, 2014 draft minutes.

ACTION: Motion by J. TRIFONE, seconded by E. TAGLIERI, and voted unanimously to approve the minutes of the June 3, 2014 of the Regular Session of the Board with the minor change.

T. FENSKY and J. FRANKE abstained from voting.

TOPIC:

VI. REPORTS

11:09 am

1. Applications Approved Pursuant to Licensure Policy 13-01

DISCUSSION: R. HARRIS distributed a July 1, 2014 report which noted the two (2) new community pharmacies, twenty-two (22) change of managers, one (1) certificate of fitness, and one (1) renovation that had been approved pursuant to Licensure Policy 13-01.

ACTION: So noted.

2. Applications Approved Pursuant to Licensure Policy 14-01

DISCUSSION: R. HARRIS distributed a July 1, 2014 report which noted the good moral character application for a pharmacist that had been approved pursuant to Licensure Policy 14-01.

ACTION: So noted.

3. Board Delegated Complaint Review Pursuant to Policy 14-02

DISCUSSION: D. SENCABAUGH distributed a report which noted that on June 17, 2014, forty-two (42) Board Delegated cases were reviewed. The Board member present was P. GANNON. There were twenty-one (21) cases of CE deficiencies which resulted in authorized consent agreements for stayed probation, fifteen (15) closed staff assignments or dismissed complaints, two (2) consent agreements for pharmacies, two (2) cases closed pending receipt of CE evidence, and two (2) diversion-related cases referred to the full Board.

ACTION: So noted.

TOPIC:

IX. M.G.L. c. 112 §65C SESSION

11:10 am

DISCUSSION: None

ACTION: At 11:10 a.m., motion by P. GANNON, seconded by J. FRANKE, and voted unanimously to enter into M.G.L. c. 112 65C Session.

LUNCH 12:00 – 1:04 pm

TOPIC:

VII. FLEX SESSION

1:04 pm

1. Automated Pharmacy Systems Joint Guidelines: Policy 2010-02

J. DEVITA distributed a copy of *Joint Guidelines for the Use of Automated Pharmacy Systems for the Storage and Dispensing of Schedule VI Controlled Substance Prescriptions in Pharmacies*. The Guidelines were developed by the Board, Drug Control Program, and Division of Health Care Quality.

Mr. DEVITA discussed the use of these devices for refill prescriptions and continuation of therapy. Board members expressed concern about security and access. Mr. DEVITA agreed to develop a list of pharmacies that use these devices. This will be an agenda item for the September meeting.

ACTION: So noted.

2. Board Update: Introductions

1:15 pm

Executive Director D. SENCABAUGH:

- Introduced Casey Minicucci and Kirty Shah, pharmacy interns from Northeastern University and MCPHS respectively,
- Welcomed Timothy Fensky (introduced earlier) as the newest member of the Board,
- Congratulated E. TAGLIERI who was reappointed to the Board, and
- Announced that Christina Mogni had been moved from contracted Investigator to a permanent Board Investigator.

3. Scope of Practice

1:17 pm

DISCUSSION: Director of Quality Assurance, K. BARNES distributed a memo noting the lack of detail in 247 CMR on the scope of practice for pharmacists and pharmacy technicians. The memo, co-authored by Pharmacy Intern, Casey Minicucci, included NABP's definition of a pharmacist's scope of practice as well as definitions from contiguous states. H. ENGMAN indicated that definitions, once approved, could become part of definitions mandated in the pending pharmacy bill. Board members encouraged Ms. BARNES to draft a policy on scope of practice issues.

ACTION: So noted.

4. Discussion of Wholesale Distributors and VAWD Accreditation

1:20 pm

DISCUSSION: D. SENCABAUGH opened a discussion on the NABP's Verified-Accredited Wholesale Distributors (VAWD) program. K. RYLE indicated that the NABP survey process was quite lengthy and that only a few national wholesalers have been accredited (e.g., Cardinal, McKesson, H.D. Smith, Amerisource Bergen). One of the benefits is the non-accreditation status of those secondary and tertiary wholesalers who inappropriately profit during drug shortages. Members agreed that additional information should be obtained and the topic presented at the September meeting.

ACTION: So noted.

5. NABP Utah Experience

1:25 pm

DISCUSSION: A. YOUNG reported on her recent attendance at the 6-day NABP conference at the University of Utah. Over 300 pharmacists attended. Speakers were all individuals in recovery from dependencies on illicit and licit drugs, including alcohol. Ms. Young attended AA & NA sessions. Attendance costs for some were offset by \$1,500 grants. This is the last year that the University of Utah will host the conference.

She will send out save-the-date notices for the October 15th NABP meeting in Williamsburg, VA.

ACTION: So noted.

TOPIC:

VIII. FILE REVIEW

1. PHA-2014-0172, **Westminster Pharmacy**, Westminster, DS1710 **1:30 pm**

DISCUSSION: This complaint was presented by S. PENTA.

As a result of a January 16, 2014 retail and <795> compliance survey, Board investigators noted major deficiencies which included lack of adherence to posted hours, no consultation signs, not including outdated controlled substances as part of the perpetual inventory, and broken hinges on the safe door. Non-sterile compounding deficiencies included a lack of written policies and procedures (including CQI), outdated compounded products, non-compliant sink and refrigerator, lack of hot water, preparing sterile eye drops for veterinary use without a laminar flow hood, inappropriate sterile filter, and other unsafe and unsanitary conditions. The facility had submitted an attestation indicating compliance with USP <795> criteria.

Westminster Pharmacy voluntarily agreed to cease non-sterile compounding, referring current patients to Boulevard Pharmacy and to refer patients requiring sterile compounding to out-of-state pharmacies. A voluntary recall is in process.

The Board suggested that local veterinarians be polled for possible adverse events related to compounded products by Westminster Pharmacy.

A plan of correction, due 15 days after the June 16th survey) has not been received.

ACTION: Motion by P. GANNON, seconded by A. YOUNG, and voted unanimously to issue a Notice to Cease and Desist all sterile and non-sterile compounding and in the alternative to authorize an agreement to refrain from all sterile and non-sterile compounding. The matter will be brought back to the board once investigators receive the pharmacy's plan of correction.

TOPIC:

VIII. FILE REVIEW

2. SA-INV-5280, **Hopkinton Drug**, 52 Main St., Hopkinton, DS8191 **2:00 pm**

DISCUSSION: This staff assignment was presented by D. DUNN.

On January 17, 2014, the Board received a self-report of abnormal results in compliance with 247 CMR 6.15 (7). The report by Pharmetric Laboratory indicated evidence of endotoxin in an anticipatory lot of sterile papaverine HCl/phentolamine mesylate (30/0.5 mg/mL). Although Hopkinton Drug conducted a comprehensive root cause analysis, a specific cause could not be identified. They have implemented a robust plan of correction. No patients received any medication from the lots in question.

Hopkinton Drug has indicated that they plan to cease sterile compounding.

ACTION: Motion by J. TRIFONE, seconded by P. GANNON, and voted unanimously, to close the staff assignment on **Hopkinton Drug** with no violation.

TOPIC:

VIII. FILE REVIEW

3. SA-INV-5537, **Johnson Compounding & Wellness Center**, Waltham, DS3579 **2:03 pm**

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

DISCUSSION: This staff assignment was presented by C. MOGNI.

The Board received a self-report of abnormal results in compliance with 247 CMR 6.15 (7) describing a sub-potent lot of naltrexone 1.5 mg capsules. Analytical Research Laboratories reported a potency of 1.25 mg (83%) determined by HPLC. A thorough root cause analysis identified the problem as not taking into account the 12.28% water content. Five of the six patients that received the sub-potent product were contacted and received a replacement order. Three unsuccessful attempts were made to contact the 6th patient. All prescribers were notified of the sub-potent naltrexone capsules. An extensive plan of correction has been conducted, and included retraining and testing of all personnel. Two pharmacists will review each certificate of analysis.
ACTION: Motion by A. YOUNG, seconded by J. DEVITA, and voted unanimously, to close the staff assignment on **Johnson Compounding and Wellness Center**, with discipline not warranted.

TOPIC:

VIII. FILE REVIEW

4. SA-INV-5455, **Walgreens Infusion Services**, Southborough, DS3584 **2:15 pm**

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

DISCUSSION: This staff assignment was presented by S. PENTA.

The Board received a self-report of abnormal results in compliance with 247 CMR 6.15 (7) describing a colony of gram-negative rod (*pseudomonas* spp.). On February 11, 2014 Air Systems Technology performed environmental monitoring. The positive sample was taken from the door during dynamic work conditions. Subsequent reports to the Board described a thorough root cause analysis and plan of correction, including relocating the lint-free towels or hand drying and removal of the electric hand dryer. The facility is developing plans for new ante and clean rooms.

ACTION: Motion by E. TAGLIERI, seconded by P. GANNON, and voted unanimously, to close the staff assignment on **Walgreens Infusion Services**, with no violation.

TOPIC:

VIII. FILE REVIEW

5. SA-INV-4389, **Baystate Home Infusion & Respiratory Services**, DS3300 **2:08 pm**

R. TINSLEY stepped out for some of the discussion of this matter.

DISCUSSION: This staff assignment was presented by A. BARTUCCA.

The Board received a self-report of abnormal results in compliance with 247 CMR 6.15 (7) describing environmental contaminants related to primary and secondary engineering controls. Between 5/31/13 and 9/4/13 there were 5 instances of surface contaminants, each followed by changes in cleaning practices to address the cause. The facility does not compound high-risk level compounds, chemotherapy, or TPN. Since 9/4/13 there have not had any reportable events and the facility continues to do monthly environmental monitoring.

On October 3, 2013, a Board re-inspection was satisfactory. A corrective action plan listed nine (9) changes to be implemented by October 18, 2013, and another six (6) additional improvements to be implemented by December 1, 2013.

A re-inspection in May, 2014 confirmed completion of the corrective action plan.

ACTION: Motion by K. RYLE, seconded by P. GANNON, and voted unanimously, to close the staff assignment on **Baystate Home Infusion & Respiratory Services**, with discipline not warranted. A recommendation for enhanced viable and non-viable monitoring for the next six months will be sent to MOR, Bryan Stadnicki.

TOPIC:

VIII. FILE REVIEW

6. SA-INV-3690, **Preferred Pharmacy Solutions (PPS)**, Haverhill, DS3542 **2:11 pm**

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

DISCUSSION: This staff assignment was presented by A. BARTUCCA.

On April 1, 2013, the Board received an anonymous complaint that unregistered and uncertified personnel had access to narcotics to fill prescriptions.

MOR Anthony Rizzo indicated that the individual in question is Elizabeth Lopez, a pharmacist technician trainee was hired on January 16, 2013 and has been training under the direct supervision of a pharmacist and had been allowed access to the access to the controlled drug room.

According to 247 CMR 8.05 (2): *Under the supervision of a pharmacist:*

(a) *a pharmacy technician may assist in transporting of Schedule II controlled substances;*

(b) *a certified pharmacy technician may assist in the transporting and handling of Schedule II controlled substances; provided, the pharmacist has approved the certified pharmacy technician or pharmacy technician to assist the pharmacist in the handling or transporting of Schedule II controlled substances, in accordance with 247 CMR 8.05(2) and as evidenced by written policies and procedures to be followed in the pharmacy*

On March 19, 2014, MOR Rossi submitted an updated PPS policy (2/28/14) which included that only MA Board registered technician that have been nationally certified (PTCB, NHA) are allowed to work in the controlled drug room under the direct supervision of a pharmacist.

At a March 24, 2014 inspection, Board investigators reviewed position descriptions, policies (*Inventory of Controlled Substances, Controlled Substance Prescription Filling*), and attestations of training.

ACTION: Motion by P. GANNON, seconded by J. DEVITA, and voted unanimously, to close the staff assignment on **Preferred Pharmacy Solutions**, with discipline not warranted and to accept the plan of correction.

TOPIC:

VIII. FILE REVIEW

7. SA-INV-4785, **Walgreens Pharmacy #4393**, Beverly, DS2882 **2:18 pm**

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

DISCUSSION: This staff assignment was presented by S. PENTA.

As a result of a general inspection, the Board alleges that Walgreens Pharmacy #4393 failed to conduct pharmacy operations in accordance with 247 CMR 9.01, USP <795>, and 247 CMR 6.02. Specifically, Board investigators observed multiple compounded products of hazardous and non-hazardous powders without the use of a powder hood; an incorrect mask was used for compounding powdered APIs; lack of a dedicated sink; use of a soiled and rusted sink, an automated dispensing machine (ADM) with visible powder contamination, and multiple soiled ceiling tiles in the pharmacy dispensing area.

This pharmacy is a large volume, regional compounding center for Walgreens.

MOR Christina Muniz responded that: a powder hood is not required as hazardous APIs are no longer used; the personnel interviewed by the investigators were new and identified the wrong mask to the investigators; personnel protective equipment has been ordered (including ventilator masks and gowns); the sink has been replaced; more

frequent cleaning rotation of the ADM, and ceiling tiles are being replaced. Inspector PENTA plans a follow-up focused USP <795> inspection and plans to check with other states as to when to use powder hoods (e.g., not just for hazardous APIs). ACTION: Motion by J. FRANKE, seconded by E. TAGLIERI, and voted unanimously, to close the staff assignment on **Walgreens Pharmacy #4393**, with discipline not warranted.

TOPIC:

X. EXECUTIVE SESSION

2:38 pm to 4:30 pm

DISCUSSION: The Board will meet in Executive Session as authorized pursuant to (M.G.L. c. 30A, §21(a)(1) for the purpose of discussing the reputation, character, physical condition or mental health, rather than the professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Board chair announced the meeting would not reconvene in open session.

1. Specifically, the Board will discuss and evaluate the Good Moral Character as required or registration or pending applicants.
2. Approval of prior executive session minutes in accordance with M.G.L. c. 30A, §22(f) for the session held on June 3, 2014

ACTION: At 2:38 p.m., motion by A. YOUNG, seconded by P. GANNON, and voted unanimously by roll call to enter Executive Session.

K. RYLE: yes; P. GANNON: yes; E. TAGLIERI: yes; J. DEVITA: yes; T. FENSKY: yes; J. FRANKE: yes; A. PERRONE: yes; R. TINSLEY: yes; J. TRIFONE: yes; A. YOUNG: yes.

TOPIC:

IX. M.G.L. c. 112 §65C SESSION

4:30 pm

DISCUSSION: None

ACTION: At 4:30 p.m., motion by P. GANNON, seconded by J. TRIFONE, and voted unanimously to return to M.G.L. c. 112 65C Session.

TOPIC:

XI. ADJUDICATORY SESSION (M.G.L. c. 30A, §18)

5:33 pm

DISCUSSION: None.

ACTION: At 5:33 p.m., motion by P. GANNON, seconded by J. FRANKE, and voted unanimously to enter into Adjudicatory Session.

TOPIC:

IX. M.G.L. c. 112 §65C SESSION

5:36 pm

DISCUSSION: None

ACTION: At 5:36 p.m., motion by P. GANNON, seconded by J. TRIFONE, and voted unanimously to return to M.G.L. c. 112 65C Session.

TOPIC:

XII. ADJOURNMENT

6:45 pm

DISCUSSION: None.

ACTION: At 6:45 p.m., motion by A. YOUNG, seconded by A. PERRONE, and voted unanimously to adjourn.

LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the July 1, 2014 Regularly Scheduled Meeting
2. Memo of July 1, 2014, Emergency Regulations regarding Hydrocodone-Only Extended Release Medications that are not in an Abuse Deterrent Form
3. Draft Minutes of the June 3, 2014 Regularly Scheduled Meeting of the Board
4. Applications approved pursuant to Licensure Policy 13-01, July 1, 2014
5. Good Moral Character Applications approved pursuant to Licensure Policy 14-01, July 1, 2014
6. Board Delegated Complaint Reviews pursuant to Policy 14-02, June 17, 2014
7. Joint Guidelines for the Use of Automated Pharmacy Systems for the Storage and Dispensing of Schedule VI Controlled Substance Prescriptions in Pharmacies, 2010-02
8. Memo, Pharmacy Scope of Practice in Massachusetts: Technicians and Pharmacists
9. Application to Manage and Operate a New Community Pharmacy, Village Pharmacy
10. Application to Manage and Operate a New Community Pharmacy, Southcoast Specialty Pharmacy
11. Petition for a Waiver of the Provisions of 247 CMR, Little's HSC Pharmacy
12. Application for a Relocation of a Community Pharmacy, Omnicare of Northern Massachusetts (former North Shore Pharmacy Services)
13. Investigative Report in the Matter of Hopkinton Drug, DS8191, SA-INV-5280
14. Investigative Report in the Matter of Johnson Compounding and Wellness Center, DS3579, SA-INV-5537
15. Investigative Report in the Matter of Walgreens Infusion Services, DS3584, SA-INV-5455
16. Investigative Report in the Matter of Baystate Home Infusion & Respiratory Services, DS3300, SA-INV-4389
17. Investigative Report in the Matter of Preferred Pharmacy Solutions, DS3542, SA-INV-3690
18. Investigative Report in the Matter of Walgreens Pharmacy #4393, DS2882, SA-INV-4785

Respectfully submitted,

Edmund Taglieri, RPh, MSM, NHA, Secretary