

COMMONWEALTH OF MASSACHUSETTS

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

January 7, 2014
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Staff Contact
8:30	I.	CALL TO ORDER		
8:35	II.	APPROVAL OF AGENDA		
8:40	III.	<p>EXECUTIVE SESSION 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 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.</p> <p>1. Specifically, the Board will discuss and evaluate the <u>Good Moral Character</u> as required for registration for pending applicants.</p> <p>2. Approval of prior executive session minutes in accordance with M.G.L. ch.30A, § 22(f) for sessions held during the December 3, 2013 meetings.</p>	CLOSED SESSION	
9:45	IV.	M.G.L. c. 112, 65C SESSION	CLOSED SESSION	
11:15	VI.	BREAK		
11:30	VII.	<p>APPROVAL OF BOARD MINUTES</p> <p>Draft Minutes from the December 3, 2013 Meeting of the Board of Registration in Pharmacy, Regular</p>		
11:40	VIII.	<p>REPORTS</p> <p>1. Applications approved pursuant to Licensure Policy 13-01</p>	Reports	M. Cittadino

11:45	IX.	FILE REVIEW 1. SA-INV-4429, Pharmahealth Long Term Care, DS89728 2. PHA-2012-0258, Pharmacy Corp. of America, DS3599 3. PHA-2013-0061, Jeffrey Lynch, PH24722 4. PHA-2013-0072, Richard Mancini, PH22198		
12:50	X.	Lunch		
1:30	XII.	APPLICATIONS 1. Pentec Health, Inc. – Reconsideration of Retail Pharmacy 120 Forbes Boulevard, Mansfield 2. Open Source Pharmaceuticals – Reconsideration of Wholesale Distributor 1208A VFW Parkway, West Roxbury 3. Baxter Healthcare Corporation -Petition for Waiver 26 Wiggins Avenue, Bedford	Applications and supporting documents	M. Cittadino
2:30	XIII.	FLEX SESSION 1. Board Update 2. Review of <i>Licensing Policy 2013-05: Staff Action to Identify License Applications Requiring Good Moral Character Evaluation</i> 3. Walgreen's Delivery Matter 4. Topics for upcoming meetings		
3:00	XIV.	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, January 7, 2014

Board Members Present

Karen Ryle, RPh, President
Patrick Gannon, RPh, MS, President-elect
Edmund Taglieri, RPh, MSM, NHA,
Secretary
Jane F. Franke, RN, MHA
Anthony Perrone, RPh, MD, MBA
Richard Tinsley, MBA, MEd
Joanne Trifone, RPh
Anita Young, RPh, EdD

Board Members Not Present

James DeVita, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Margaret Cittadino, MEd, Associate Director
Heather Engman JD, MPH, Board Counsel
Vita P. Berg, JD, Board Counsel
Cheryl Latham, RPh, PharmD, Investigator
Leo McKenna, RPh, PharmD, QA Coordinator
Samuel Penta, RPh, Investigator Supervisor
William E. Frisch, Jr., RPh, Investigator
Joseph Sceppa, RPh, Consultant

Board Staff Not Present

TOPIC:

I. CALL TO ORDER

DISCUSSION: A quorum of the Board was present. President, K. RYLE chaired the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting.

ACTION: At 8:35 a.m. K. RYLE, President, called the January 7, 2014, meeting of the Board of Registration in Pharmacy to order.

TOPIC:

II. APPROVAL OF AGENDA

DISCUSSION: Board members reviewed the tentative agenda. H. ENGMAN announced that certain items will be deferred to an upcoming meeting (VIII. Applications, #2 Open Source Pharmaceuticals and Home Care).

ACTION: Motion by, A. YOUNG, seconded by P. GANNON, and voted unanimously by roll call to approve the agenda with the above change. K. RYLE: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; P. GANNON: yes; A. PERRONE: yes; R. TINSLEY: yes.

TOPIC:

III. EXECUTIVE SESSION

DISCUSSION: None

ACTION: Motion by E. TAGLIERI seconded by J. FRANKE and passed by unanimous roll call vote to enter into the Executive Session at 8:39 a.m. K. RYLE: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; P. GANNON: yes; A. PERRONE: yes; R. TINSLEY: yes.

EXECUTIVE SESSION (8:39 – 9:00 a.m.; 12:18 – 12:43 p.m., and 3:50 – 3:53 p.m.)

TOPIC:

IV. M.G.L. c. 112, § 65C SESSION

DISCUSSION: None

ACTION: Motion by E. TAGLIERI seconded by J. TRIFONE and passed by unanimous roll call vote to enter into M.G.L. c. 112, § 65C Session at 9:00 a.m. K. RYLE: yes; P. GANNON: yes; J. TRIFONE: yes; A. YOUNG: yes; E. TAGLIERI: yes; J. FRANKE: yes; A. PERRONE: yes; R. TINSLEY: yes.

M.G.L. c. 112, § 65C SESSION (9:02 a.m. – 12:15 p.m. and 3:53 – 4:33 p.m.)

TOPIC:

V. APPROVAL OF BOARD MINUTES

December 3, 2013 Regularly Scheduled Meeting

DISCUSSION: The review and approval of the minutes of the December 3, 2013 Regularly Scheduled Meeting was deferred to the February meeting.

ACTIONS: So noted.

TOPIC:

VI. REPORTS

1. Applications approved pursuant to Licensure Policy 13-01

DISCUSSION: M. CITTADINO noted that during the past month there have been four (4) changes of manager, nine (9) renovations or expansions, and seven (7) 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 indicated that there were no Plans of Correction to report.

ACTION: So noted.

TOPIC:

VII. FILE REVIEW

1. Pharmahealth Long Term Care (DS89728), SA-INV-4429

DISCUSSION:

W. FRISCH presented the above-referenced matter to the Board. This staff assignment was to investigate the purchasing of alleged contraband drug products distributed by Countrywide Distributors.

Pharmahealth had purchased 5.95% of items from Countrywide since 2008. On August 9, 2013 Board inspectors visited Pharmahealth. Five products were quarantined by investigators. No Countrywide products have been dispensed since July 2013. There is no evidence that Pharmahealth knew or should have known the medications were contraband.

ACTION:

1) Motion by P. GANNON, seconded by J. TRIFONE, and voted unanimously, to close the staff assignment for lack of sufficient evidence.

TOPIC:

VII. FILE REVIEW

2. Pharmacy Corporation of America (DS3599), PHA-2012-0258

3. Jeffrey Lynch (PH24722), PHA-2013-0061

4. Richard Mancini (PH22198), PHA-2013-0071

DISCUSSION:

S. PENTA presented the above-referenced matter to the Board. At the December 2013 meeting of the Board, the matter had been tabled until additional information could be obtained.

As a result of a Board inspection, this Pharmacy Corporation of America in Brockton received a Cease and Desist order from the Board on 12/28/2012.

The Rhode Island Board of Pharmacy notified the MA Board that an inspection of the Warwick facility revealed that at the direction of Jeffrey Lynch (MOR, Brockton) and

Richard Mancini (MOR Warwick), six (6) MA licensed pharmacy technicians from the Brockton PCA prepared sterile products at the Warwick, Rhode Island PCA from 12/28/13 to 1/4/2013 without being licensed in Rhode Island.

The Brockton facility received the compounded sterile products from the Warwick facility, and subsequently dispensed them to a patient.

This is a complex case and the Board was unsure of which compounded products were involved, how it relates to the Cease and Desist order, the sections of 247 CMR, and who made the collective decision to relocate personnel. The Board felt that punishment for Mr. Mancini should mirror that of the Rhode Island Board of Pharmacy.

The underlying facts of these complaints pertain to sterile compounding inspections of November and December 2012. Board members noted that the majority of sterile compounding pharmacies that received a cease and desist notice in late 2012 were offered consent agreements for one year probation; this case is aggravated by the fact that Pharmacia did not properly provide for patient continuity of care and directed technicians to engage in unlicensed practice in Rhode Island.

ACTION:

2. Motion by J. TRIFONE, seconded by J. FRANKE, and voted unanimously, to refer to the Office of Prosecution for the issuance of an Order to Show Cause and to authorize resolution of the matter with a consent agreement for 3-year probation of Pharmacy Corporation of America.

3. Motion by P. GANNON, 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 and to authorize resolution of the matter with a consent agreement for 2-year probation with terms to require a signed attestation of having reviewed 247 CMR, successful completion of 10 live contact hours of continuing education pertaining to pharmacy or drug law/regulations, and successful completion of 10 live contact hours of continuing education pertaining to USP <797> for J. Lynch, the MOR of the Brockton facility. Lynch may continue to serve as manager of record (MOR) while on probation.

4. Motion by P. GANNON, 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 and to authorize resolution of the matter with a consent agreement, consistent with that of the Rhode Island Board of Pharmacy for R. Mancini (MOR of the Brockton facility), namely a 2-year stayed suspension; a 2-year period of probation with terms to include not serving as an MOR, successful completion of 10 contact hours of continuing education pertaining to pharmacy or drug law/regulations, and successful completion of 10 contact hours of continuing education pertaining to USP <797>.

LUNCH (12:47 – 1:25 p.m.)

TOPIC:

VIII. APPLICATIONS

A. Reconsideration of Retail Pharmacy

1. Pentec Health, Inc., 120 Forbes Road, Mansfield, MA

DISCUSSION: L. McKENNA presented the Pentec Health application to the Board for reconsideration after he conducted a re-inspection prior to licensure. Pentec proposes to compound high-risk level sterile CSPs from nonsterile powders (e.g., baclofen) for combination with other medications and installation into intrathecal pumps. The issue is that Pentec assigns a 3-day BUD prior to the instillation of the CSP into a Medtronic pump (start of the infusion). However, the infusion may continue for 90 or 180 days (based on whether non-sterile or sterile drugs were used). Jessica Pauline (proposed MOR) indicated that Pentec is the largest distributor of infusions for MS patients and have a 10 year history of dispensing these products (33,000 prescriptions dispensed) for MS and other patients. She indicated that because the combinations and concentrations vary, no stability or sterility studies have been done.

The Board expressed concern that no stability or sterility studies have been done to assure that the combination is both compatible and stable for the maximum length of the infusion.

ACTION: Motion by J. FRANKE, seconded by R. TINSLEY, and voted unanimously to approve the application pending successful inspection and receipt of affidavit from Jessica Pauline stating that Pentec will not compound unapproved CSPs or unapproved combinations of CSPs unless and until it obtains scientific evidence demonstrating that the CSPs maintain their stability and sterility for the entire time they are present in the infusion pump.

TOPIC:

VIII. APPLICATIONS

B. Reconsideration of Wholesale Distributor

1. Open Source Pharmaceuticals, 1208A VW Parkway, West Roxbury, MA

DISCUSSION: None

ACTION: Postponed per applicant request.

TOPIC:

VIII. APPLICATIONS

C. Petition for Waiver

1. Baxter Healthcare Corporation, 26 Wiggins Avenue, Bedford, MA

DISCUSSION: Baxter Healthcare Corporation warehouse in Bedford includes an enclosed area from which pallets of peritoneal dialysis solutions are delivered to patients' homes. Although peritoneal dialysis solutions are formulated by the manufacturer and no compounding occurs on site, they are considered legend drugs and the area has been licensed a retail pharmacy (DS2892). The packages of dialysis solution are huge, very heavy, and can only be moved by forklift. Because of the size and weight of items, unlicensed personnel have been assembling the medications for dispensing. This operation is unlike a retail pharmacy in that it is not open to the general public and limits the prescriptions dispensed to commercially-prepared peritoneal dialysis solutions. Given the limited nature of the business, Fredrick

Frankhauser, MOR, submitted twelve (12) waivers to 247 CMR for consideration of the Board:

1. 247 CMR 6.01 (5)(a)(2)(a)-(d): Require maintenance of references
2. 247 CMR 6.01 (5)(a)(4) and (5): Maintenance of a balance
3. 247 CMR 6.01 (5)(a)(8): Book or recording sales of controlled substances
4. 247 CMR 6.01 (5)(a)(9): Book for recording sales of alcoholic beverages
5. 247 CMR 6.02 (2): Maintenance of sufficient equipment and publications
6. 247 CMR 6.02 (4): Sufficient supply of product to dispense and compound
7. 247 CMR 6.02 (5): Maintenance of a sign
8. 247 CMR 6.02 (6)(d) and (e): Security requirements
9. 247 CMR 6.02 (8)(a) through (c) inclusive: Posting hours of operation
10. 247 CMR 6.02 (9)(a): Pharmacist be on duty at all times when the pharmacy is open
11. 247 CMR 9.01 (15): Shall not limit services to a particular segment of the general public
12. 247 CMR 9.01 (16): Shall not refuse to compound customary pharmaceutical preparations

ACTION: Motion by J. TRIFONE, seconded by, E. TAGLIERI, and voted unanimously to approve waiver requests 1-9 and 11-12. The motion further requested that Mr. Frankhauser resubmit waiver request #10 with additional detail to include the assurance that no prescription medication would leave the pharmacy without verification by the registered pharmacist on duty.

BREAK (3:17 – 3:23 p.m.)

TOPIC:

IX. FLEX SESSION

1. Board Update

- a. Status of Licenses: M. Cittadino indicated that there have been problems with the software that maintains information on licenses. The issues have been corrected. She asked that any questions relative to the status of licenses be directed to Lau Kwan. Ms. Kwan will reprint licenses if necessary.
- b. USP <795> Attestations: Board staff member, Carolyn Reid is entering the data from all of the attestations into a spreadsheet.

2. Review of Licensure Policy 14-01: Staff Action to Identify License Applications requiring Good Moral Character evaluation

DISCUSSION: V. BERG distributed a revised draft of proposed licensure policy 14-01 (previously numbered 13-05). The policy attempts to identify those areas where no discretion of the Board would be necessary.

The Board suggested that "third party processing agents" be replaced with the actual name of the company (Professional Credentialing Services/PCS). They also recommended that the position(s) of designated staff be included.

ACTION: Motion by E. TAGLIERI, seconded by, A. YOUNG, and voted unanimously to approve Licensure Policy 14-01: Staff Action to Identify License Applications requiring Good Moral Character evaluation, with the noted changes.

3. Walgreens Delivery Matter

RECUSAL: J. TRIFONE recused herself and was not present during the discussion or votes for these matters.

DISCUSSION: D. Sencabaugh and W. Frisch indicated the AIDS Community Action Center, at 75 Armory Street in Boston has had a relationship with MOM's pharmacy, located on the premises. MOM's pharmacy closed in 2012 and through 2013 PharmaHealth provided prescription courier services from a Fairhaven facility. PharmaHealth was denied an application for a new community pharmacy on this site. Walgreens is proposing to build a pharmacy in the MOM's pharmacy location, which is adjacent to the AIDS Action Committee to service these patients. Walgreens will be coming to the Board with a waiver request or a delivery service until the new pharmacy is built and operational.

ACTION: So noted.

4. Topics for Upcoming Meetings

- a. CPE Monitor and Statements of credit; guidance to registrants,
 - b. Bob Hallisey will be invited to discuss the MPRS program,
 - c. Blister pack packaging; compilation of best practices; possible newsletter article,
 - d. Impact of interruptions during the filling of prescriptions,
 - e. Counseling: most patients decline; it is an opportunity for the pharmacist to review medications with a patient, especially elderly or pediatric patients,
 - f. Manager of Record's role in determining staff fitness for duty,
 - g. Possible scholarship to attend district meetings of the Board.
- Board members are encouraged to forward additional topics to D. Sencabaugh or M. Cittadino.
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TOPIC:

TEMPORARY ADJOURNMENT

DISCUSSION: None

ACTION: Motion by P. GANNON, seconded by E. TAGLIERI, and voted unanimously to temporarily adjourn at 3:50 p.m. and return to Executive Session.

TOPIC:

X. ADJOURNMENT

DISCUSSION: None

ACTION: Motion by A. YOUNG, seconded by A. PERRONE, and voted unanimously to adjourn at 4:33 p.m.

LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the January 7, 2014 Regularly Scheduled Meeting.
2. Applications approved pursuant to Licensure Policy 13-01, December 2013 – January 2014
3. Investigative Report in the Matter of PharmaHealth Long Term Care, DS89728, SA-INV-4429
4. Investigative Report in the Matter of Pharmacy Corp off America, DS3599, PHA-2012-0258; Jeffrey Lynch, PH24722, PHA-2013-0061, Richard Mancini, PH22198, PHA-2013-0072.
5. Application for approval reconsideration of a retail pharmacy: Pentec Health, Inc.
6. Medical Device Recall: Medtronic SynchroMed II Implantable Drug Infusion Pump and SynchroMed EL Implantable Drug Infusion Pump
7. Application for waiver: Baxter Healthcare Corporation, DS2892
8. Proposed Licensure Policy 14-01, Staff Action to Identify Individual Registration Applications requiring Good Moral Character evaluation

Respectfully submitted,

Edmund Taglieri, RPh, MSM, NHA, Secretary