

# COMMONWEALTH OF MASSACHUSETTS

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

April 7, 2015  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

### Agenda

Time	#	Item	Exhibits	Contact
8:30	I	<b>CALL TO ORDER</b>		
8:35	II	<b>APPROVAL OF AGENDA</b>		
8:40	III	<b>APPROVAL OF BOARD MINUTES</b> 1. Draft January 6, 2015 Regular Session Minutes 2. Draft February 3, 2015 Regular Session Minutes 3. Draft March 3, 2015 Regular Session Minutes 4. Draft March 24, 2015 Regular Session Minutes		
8:45	IV	<b>APPLICATIONS</b> 1. MBS Pharma Care, Inc. – New Community Pharmacy 2. Pharma Blue Pharmacy- New Community Pharmacy 3. St. George Pharmacy- New Community Pharmacy 4. Conlin’s Pharmacy- Renovation/Expansion 5. Community Care Pharmacy- Relocation 6. Lohxa- Wholesale Distributor		
9:30	V	<b>REPORTS</b> Applications approved pursuant to Licensure Policy 13-01 Report of activities pursuant to Board Delegated Complaint Review Policy 14-02	Reports	R. Harris D. Sencabaugh
9:35	VI	<b>REGULATIONS:</b> Proposed amendments to 247 CMR 9.00: Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments.		H. Engman
11:45		<b>LUNCH BREAK</b>		

12:45	VII.	<b>FILE REVIEW</b> <ol style="list-style-type: none"> <li>1. PHA-2013-0007, CAPS Pharmacy, DS3312</li> <li>2. PHA-2013-0060, Yu Cheung, PH24284</li>   <li>3. PHA-2014-0200, Pharmahealth, DS3473</li> <li>4. PHA-2014-0204, Phamahealth, DS89728</li> <li>5. PHA-2014-0206, Pharmahealth, DS3056</li> <li>6. PHA-2014-0207, Pharmahealth, DS3214</li>   <li>7. SA-INV-6648, Fresenius Medical Care North America, DS2969</li>   <li>8. PHA-2014-0141, America's Compounding Center, DS3530</li>   <li>9. SA-INV-5456, Boston Home Infusion, DS2623</li> </ol>		
1:30	VIII.	<b>M.G.L. c 112, 65C Session</b>	CLOSED SESSION	
2:30	IX.	<b>EXECUTIVE SESSION</b> 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.  Specifically, the Board will discuss and evaluate the <u>Good Moral Character</u> as required for registration for pending applicants and notice of violation of probation.	CLOSED SESSION	
3:00	X.	<b>FLEX SESSION</b> <ol style="list-style-type: none"> <li>1. Pain Management Fact Sheet</li> <li>2. Introduction of Pharmacy Interns: Michele Jennings, Dahea Lee</li> <li>3. Advisory Committee Update: March 27<sup>th</sup> meeting recap Abnormal Results</li> </ol>	OPEN SESSION	D. Sencabaugh T. Fensky
3:30	XI.	<b>M.G.L. c. 112, 65C SESSION</b>	CLOSED SESSION	
4:30	XII.	<b>ADJUDICATORY SESSION</b>	CLOSED SESSION	
5:00	XIII.	<b>ADJOURNMENT</b>		

**COMMONWEALTH OF MASSACHUSETTS  
BOARD OF REGISTRATION IN PHARMACY**

**MINUTES OF THE REGULARLY SCHEDULED MEETING  
239 Causeway Street, Fourth Floor Room 417A  
Boston Massachusetts, 02114**

**April 7, 2015**

**Board Members Present**

Patrick Gannon, RPh, MS, President  
Edmund Taglieri Jr., RPh, MSM, NHA  
President-elect  
Catherine Basile, Pharm D, RPh  
Garrett Cavanaugh, RPh  
Karen Conley, RN, DNP  
Susan Cornacchio, JD  
William Cox CPht  
Timothy Fensky, RPh, FACA  
Michael Godek, RPh

**Board Members Not Present**

Richard Tinsley, MBA, MEd.,  
Secretary

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
David Dunn, RPh, Associate Executive Director  
Heather Engman, JD, MPH Board Counsel  
Kelly Ann Barnes, JD, RPh, Director of Pharmacy  
Quality Assurance  
William Frisch, RPh, Director of Pharmacy Compliance  
Richard Harris, Program Analyst  
Christina Mogni, Investigator  
Monica Vasquez, Compliance Officer  
Colleen Collins, PharmD, RPh. Contract Investigator

**TOPIC: I**

**CALL TO ORDER**

**DISCUSSION:** A quorum of the Board was present. President P.GANNON chaired the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. P. GANNON also announced that the Board was recording the meeting.

**ACTION:** AT 8:30AM P.GANNON, called the April 7, 2015, meeting of the Board of Registration in Pharmacy to order. Quorum was established by roll call, P. GANNON; yes, E.TAGLIERI; yes, C.BASILE; yes, G.CAVANAUGH; yes, K. CONLEY; yes, S. CORNACCHIO; yes, W. COX; yes, T.FENSKY; yes, M. GODEK; yes.



TOPIC II.

**APPROVAL OF AGENDA**

DISCUSSION: Associate Executive Director D.DUNN informed the Board that applicant MBS Pharma Care, Inc., had requested that their application to Operate and Manage a New Community Drug Store be deferred to a future meeting. It was also noted that File Review cases PHA-2013-0007; CAPS Pharmacy, and PHA-2013-0060 would be moved to M.G.L. c 122, 65C Session.

ACTION: Motion by K. CONLEY, seconded by T. FENSKY, and voted unanimously to approve the agenda with the noted changes.

TOPIC III.

**APPROVAL OF BOARD MINUTES**

1. Draft January 6, 2015, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by E.TAGLIERI, seconded by M.GODEK and voted unanimously to approve the Draft January 6, 2015, Regular Session Minutes.

2. Draft February 3, 2015, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by C. BASILE, seconded by T. FENSKY and voted unanimously to approve the Draft February 3, 2015, Regular Session Minutes.

3. Draft March 3, 2015, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by M. GODEK, seconded by C. BASILE and voted unanimously to approve the Draft March 3, 2015, Regular Session Minutes.

4. Draft March 24, 2015, Regular Session Minutes

DISCUSSION: None

ACTION: Motion by K.CONLEY, seconded by C. BASILE, and vote unanimously to approve the Draft March 24, 2015. Regular Session Minutes.

TOPIC IV.

**IV. APPLICATIONS**

8:36

**2. PharmBlue Pharmacy New Community Pharmacy 163 Pleasant St. Attleboro**

DISCUSSION: Pharm Blue was represented by two associates from Integrated Pharmacy Services, Victor Fournier, and Benjamin Sturm, who applied as Manager of Record (MOR). Initially, PharmBlue had submitted a waiver to “not compound”, but withdrew the waiver when Board members and staff pointed out that using compounding “kits” was still compounding. Sturm is registered with PMP and does not plan to immunize at this point in time. Sturm has been a MOR previously, in Hyannis, MA.



ACTION: Motion by M. GODEK, seconded by, C. BASILE, and voted unanimously, to approve the license for this community pharmacy, pending successful inspection.

TOPIC IV.  
**APPLICATIONS**

**3. St George Pharmacy New Community Pharmacy, 435 Furnace St., Marshfield**

DISCUSSION: Atef Ayoub appeared before the Board for this license back in September, 2012, but due to landlord issues, never opened. Pharmacist Ayoub, a first-time MOR, satisfactorily answered the Board's questions about "after hours" coverage, physical footprint, compounding of hazardous drugs, drug security, and delivery.

ACTION: Motion by E. TAGLIERI, seconded by C. BASILE, and voted unanimously, to approve the license for this community pharmacy, pending successful inspection, and pending staff approval of a documented plan for delivery.

TOPIC IV:  
**APPLICATIONS**

**4. Conlin's Pharmacy Renovation / Expansion 30 Lawrence St., Methuen**

DISCUSSION: MOR Sandra Kalil, and consultant Ernie Gates appeared on behalf of Conlin's Pharmacy application. Conlin's Pharmacy is engaged in all 3 levels of <795> non-sterile compounding. The Board reviewed the plans, and Board Member Fensky suggested that they build out in accordance with the likelihood of what USP 800 will require. Conlin's representatives assured the Board that there is enough space to accommodate any likely USP 800 requirements.

ACTION: Motion by T. FENSKY, seconded by E. TAGLIERI, and voted unanimously, to approve the renovation and expansion plans for this pharmacy, pending successful inspection.

TOPIC IV:  
**APPLICATIONS**

**5. Community Care Pharmacy Relocation of Community Pharmacy  
2100 Dorchester Ave., Dorchester**

DISCUSSION: Owner Laretta Okoye appeared before the Board along with MOR Justin Bloc, seeking approval to relocate their traditional retail pharmacy from Mansfield, MA to Dorchester, MA, specifically in the lobby of Carney Hospital. In addition to the traditional pharmacy practice, Community Care is planning to offer "opt-in" bedside delivery to discharged patients, starting first with cardiology patients, then expanding to the entire patient population. Okoye and Bloc answered the Board's questions about drug security, both at the location and during the transfer of controlled substances from Mansfield to Dorchester, where their wholesaler, HD Smith will have a role. They are planning to immunize. They had intended to submit a waiver to compound, but changed their minds based on satisfying the community need, particularly pediatric patients being



discharged from the hospital, as pointed out by Director of Quality Assurance, K. BARNES.

ACTION: Motion by M. GODEK, seconded by C. BASILE, and voted unanimously, to approve the relocation, pending updated compounding attestation approval of the Drug Control Program, policy and procedures for bed-side delivery, and successful inspection.

TOPIC IV:  
**APPLICATIONS**

**6. Lohxa Wholesale Distributor 600 Main Street, Suite A, Worcester**

DISCUSSION: Lohxa was represented by owner partners Kreshnik Loxha (President) and Hans Meireles (Vice President). The plan is to perform repackaging of non-sterile bulk drugs into unit dose for hospital use, using syringes, blister packs, and cups. Kreshnik will be the only pharmacist at start-up, but explained that he has a brother attending pharmacy school now, and will likely join the staff upon graduation and licensure next year. Board members seemed concerned about drug security, based on the location, but Lohxa stated that security has been addressed with cameras and motion sensors, as well as building security in place from 9PM – 3AM. Board Director of Pharmacy Compliance W. FRISCH explained that the State would coordinate an inspection along with DEA.

ACTION: Motion by E. TAGLIERI, seconded by K. CONLEY, and voted 6 – 3 to approve the license, pending evidence of proper registration with the DEA and FDA, and pending successful inspection by the Board and DEA. Members M. GODEK, T. FENSKY, and G. CAVANAUGH opposed.

TOPIC V.  
**REPORTS**

**Applications Approved Pursuant to Licensure Policy 13-01**

DISCUSSION: R HARRIS noted that during the past month there have been eleven (24) change of managers, and one (1) pharmacy closure, and one (1) renovation/expansion.

ACTION: So noted

**Report of activities pursuant to Board Delegated Complaint Review Policy 14-02**

DISCUSSION: D.SENCABAUGH reported that on March 27, 2015, a Board Delegated Complaint Review was held, during 19 files were reviewed. Seven (7) were self-reported CEU deficiencies, six (6) were QRE-related, two (2) involved consumer grievances, and four (4) were complaints. In all, 18 files were closed, and 1 required discipline. Board member T. FENSKY was the Board member present at the March 27, 2015, Board Delegated Complaint Review session.

ACTION: So noted

---

BREAK

TIME: 9:37AM- 9:49AM



---

**TOPIC VI:  
REGULATIONS**

**TIME: 9:49AM-11:41AM**

Draft Proposed Amendments to 247 CMR 9.00: Code of Professional Conduct; Professional Standards for Registered Pharmacist, Pharmacies, and Pharmacy Departments.

DISCUSSION: At 9:49 AM, the Board continued its discussion on 247 CMR 9.00 beginning at proposed 9.15 "Pharmacy Operations", subsection 15, Posting of Hours of Operation". The draft proposed regulation was displayed on the screen for Board members and the audience to view. Executive Director D. SENCABAUGH read line-by-line, stopping for Board Members' feedback, while Board Counsel H. ENGMAN captured Board Members concerns and changes to the Draft document via track changes on the screen for Board members and the audience to view. The Board discussion concluded at the end of 247 CMR, skipping a few sections as "placeholders" for the next meeting (9.08, Patient Specialty Packaging.) Board Director of Quality Assurance K. BARNES gave an overview the section, while Board member T. FENSKY's contribution was noted. Board President P. GANNON ended the session at 11:41, when members broke for lunch.

---

**LUNCH BREAK**

**TIME: 11:41AM-12:45PM**

---

**TOPIC VII.  
OPEN FILE REVIEW**

**1. PHA-2013-0007, CAPS Pharmacy, DS3312**

DISCUSSION: None

ACTION: Matter moved to M.G.L c. 112, 65C Session

**2. PHA-2013-0060, Yu Cheung, PH24284**

DISCUSSION: None

ACTION: Matter moved to M.G.L c. 112, 65C Session


**3. PHA-2014-0020, Pharmahealth, DS3473**

**4. PHA-2014-0204, Pharmahealth, DS89728**

**5. PHA-2014-0206, Pharmahealth, DS3056**

**6. PHA-2014-0207, Pharmahealth, DS3214**

The four (4) Pharmahealth files were presented and summarized by C. MOGNI, and heard simultaneously:



- PharmaHealth Specialty (parent company) admitted to shipping completed patient prescriptions to prescriber offices for dispensing to patients and supplying pre-printed order forms for specialty meds.
  - There was an out of court settlement with the DEA for violating 21 CFR §1306.21 (a) for \$20,000.
  - Pharmahealth Pharmacies DS3056 and DS3214 were closed 12/17/2014.
  - Inventory manifests indicated the transfer of drug stock from the Pharmahealth Pharmacy Fairhaven location to other PharmaHealth locations.
  
  - Pharmahealth Pharmacy DS3473 MOR Brien reported that no pre-printed (logo) prescription blanks had been used since he was named MOR (11/2013), and only 2 prescriptions had been delivered to a physician's office, both for emergency situations.
  
  - Considering this and the fact that two (2) of the four (4) Pharmahealth Pharmacy locations were now closed, the Board took the following actions:
3. Pharmahealth, DS3473, PHA-2014-0200 N. Dartmouth (closed)  
ACTION: Motion by E. TAGLIERI, seconded by T. FENSKY, and voted unanimously to dismiss the complaint due to insufficient evidence. K.CONLEY and, G.CAVANAUGH, were not present for the vote of this matter.
  
  4. Pharmahealth, DS89728, PHA-2014-0204 Fairhaven  
ACTION: Motion by E. TAGLIERI, seconded by C. BASILE, and voted unanimously to refer the matter to the office of prosecution for the issuance of an order to show cause, and authorizing a consent agreement to settle the matter with one (1) year probation and a statement by the MOR, attesting to have read and understood M.G.L. Chapter 94C. Also, requiring Policies and Procedures addressing relevant sections of 94C, removal of any signage referring to delivering prescriptions to physician's offices, and discontinuing the use of the company logo on any pre-printed forms used for prescribing of prescriptions.
  
  5. Pharmahealth, DS3056, PHA-2014-0206 New Bedford (closed)  
ACTION: Motion by E. TAGLIERI, seconded by T. FENSKY, and voted unanimously to dismiss the complaint due to insufficient evidence.
  
  6. Pharmahealth, DS3214 PHA-0207-0207 New Bedford (closed)  
ACTION: Motion by E. TAGLIERI, seconded by K. CONLEY, and voted unanimously to dismiss the complaint due to insufficient evidence.
  
  7. **Fresenius Medical Care North America, DS2969, SA-INV-6648**  
Investigation report Presented and summarized by C. MOGNI  
DISCUSSION: A staff assignment was opened as a result of a March 2012, Class I recall initiated by Fresenius. The recall involved product manufactured in an FDA registered facility. Investigation initiated to see if any of the affected products was dispensed by the Massachusetts licensed pharmacy. Investigators were able to view quarantined product but did not receive documentation from Fresenius. W. Frisch





informed the Board that this was an FDA matter. H.ENGMAN agreed indicating that the matter involved manufacturing processes overseen by the FDA and was outside of the Board's jurisdiction.

ACTION: Motion by P. GANNON, seconded by M.GODEK and voted unanimously to close the staff assignment with no violation noted.

**8. America's Compounding Center, DS3530, PHA-2014-0141**

Investigation report Presented and summarized by C. COLLINS

DISCUSSION: The complaint was opened as a result of a notification by a national Pharmacy Benefits Management (PBM) organization alleging the dispensing of medications to patients outside of Massachusetts without possessing the required non-resident pharmacy license. The PBM did notify the Board of Pharmacy in each of the non-resident states. Missouri opened two (2) complaints against ACC as a result of the notification. ACC indicated that they have corrected all licensing issues, and the issue was the result of an oversight by pharmacy staff. ACC indicates that has modified its policy and procedures to prevent a reoccurrence of this issue.

ACTION: Motion by T. FENSKY, seconded by C.BASILE and voted unanimously to dismiss the complaint with discipline not warranted.

**9. Boston Home Infusion, DS2623**

**SA-INV-5456**

Investigation report Presented and summarized by: W. FRISCH

DISCUSSION: The Staff Assignment was opened as the result of a mandatory report of an Abnormal Result. The abnormal result was reported by the licensee as result of environmental monitoring in the Ante Room. MOR Gallagher preformed a root cause analysis, along with swift and successful remediation of the abnormal result along with monthly environmental monitoring. W. FRISCH noted that Boston Home Infusion has now relocated to a state of the art facility.

ACTION: Motion by P. GANNON, seconded by T.FENSKY, to close the staff assignment with discipline not warranted

TOPIC X.

**Flex Session**

**TIME: 1:12PM**

1. Pain Management Fact Sheet, D.SENCABAUGH reviewed the fact sheet developed by DPH, resulting from, Chapter 244 acts of 2012, Section 5. D. SENCABAUGH made the Board aware that the Pain Management pamphlets need to be dispensed with each CII-CIII prescriptions dispensing. The Board was made aware that the pamphlet would be posted on the Board's website and sent out on distribution list.

2. Introduction of Pharmacy Interns: Michelle Jennings and Dahea Lee

3. Advisory Committee Update: T. FENSKY provided a recap of the March 27<sup>th</sup> meeting of the Pharmacy Advisory committee informing the Board of the formation of a subcommittee to address a decision tree on the handling of Abnormal Results and when a pharmacy should cease compounding activities.



TOPIC VIII.

**M.G.L. c. 65C Session**

DISCUSSION: P.GANNON noted that the Board would not return to open session following closed session.

ACTION: Motion by M. Godek, seconded by E. TAGLIERI, and voted unanimously at 1:24PM to enter into M.G.L. c. 65C Session.

ACTION: Motion by T. FENSKY, seconded by M. GODEK, and voted unanimously at 3:07PM to exit M.G.L. c. 65C Session

TOPIC IX.

**EXECUTIVE SESSION:**

DISCUSSION: None

ACTION: Motion by P. GANNON, seconded by T.FENSKY, and voted unanimously by roll call at 3:07PM to enter into Executive Session. P. GANNON; yes, E.TAGLIERI; yes, C.BASILE; yes, G.CAVANAUGH; yes, K. CONLEY; yes, S. CORNACCHIO; yes, W. COX; yes, T.FENSKY; yes, M. GODEK; yes.

TOPIC XI.

**Return to M.G.L. c. 65C Session**

DISCUSSION: None

ACTION: Motion by P.GANNON, seconded by T.FENSKY and voted unanimously at 3:36PM to return to M.G.L. c. 65C Session. K.CONLEY was not present for the vote on this matter.

TOPIC XII.

**ADJUDICATORY SESSION**

DISCUSSION: NONE

ACTION: Motion by M. GODEK, seconded by T.FENSKY, and voted unanimously at 4:34PM to enter into Adjudicatory session.

TOPIC XIII.

**ADJOURNMENT OF MEETING**

DISCUSSION: NONE

ACTION: Motion by C. BASILE , seconded by T.FENSKY, and voted unanimously at 4:33PM to adjourn

LIST OF EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft January 6, 2015 Regular Session Minutes.
2. Draft February 3, 2015 Regular Session Minutes.
3. Draft March 3, 2015, Regular Session Minutes.



4. Draft March 24, 2015 Regular Session Minutes.
5. Application to Manage and Operate a New Community Pharmacy: Pharm Blue Pharmacy.
6. Application to Manage and Operate a New Community Pharmacy: St. George Pharmacy.
7. Application for a Renovation / Expansion Request for Board Approval: Conlin's Pharmacy.
8. Application for a Relocation of a Community Pharmacy: Community Care Pharmacy.
9. Application to Operate as a Wholesale Distributor: Lohxa.
10. Report of Applications approved pursuant to Licensure Policy 13-01.
11. Report of activities pursuant to Board Delegated Compliant Review Policy 14-02.
12. Draft proposed amendments to 247 CMR 9.00: Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies, and Pharmacy Departments.
13. Draft proposed amendments to 247 CMR 9.00: Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies, and Pharmacy Departments with track changes.
14. Investigative report in the matter of Pharmahealth ,DS3473, PHA-2014-0200.
15. Investigative report in the matter of Pharmahealth, DS89728, PHA-2014-0204.
16. Investigative report in the matter of Pharmahealth, DS3056, PHA-2014-0206.
17. Investigative report in the matter of Pharmahealth, DS3214, PHA-2014-0207.
18. Investigative report in the matter of Fresenius Medical Care North America, DS2969, SA-INV-6648.
19. Investigative report in the matter of America's Compounding Center, DS3530, PHA-2014-0141.
20. Investigative report in the matter of Boston Home Infusion, DS2623, SA-INV-5456.
21. DPH Pain Management Fact Sheet.

Respectfully submitted by:  
Richard Tinsley, MBA. MEd.



---