COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

February 2, 2016 239 Causeway Street ~ Room 417 A&B Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Contact
8:30	Ι	CALL TO ORDER		E. Taglieri
8:35	II	APPROVAL OF AGENDA Introduction of Pharmacy Intern(s)		
8:40	III	 APPROVAL OF BOARD MINUTES Draft of January 5, 2016 Regular Session Minutes 		
8:45	IV	 APPLICATIONS Nimble RX – New Community Pharmacy Cambridge Health Alliance- Cambridge –New Community Pharmacy Cambridge Health Alliance- Malden-New Community Pharmacy Long Term Pharmacy Solutions- Renovation/Expansion Boston Home Infusion- Transfer of Ownership IVG Veterinary Compounding Pharmacy – Renovation/Expansion Target Pharmacy – Transfer of ownership 		
10:00	V	 REPORTS Applications approved pursuant to Licensure Policy 13-01 Monthly Report from Probation 	Reports	R. Harris K. Fishman
10:05	VI	 FLEX SESSION USP <797> Public comment Naloxone Standing Order Update Opioid Misuse and Abuse Advisory 		K. Barnes K. Barnes

10:15	VII	 REGULATIONS and REGULATORY REVIEW 247 CMR 2.00: Definitions 247 CMR 7.00: Wholesale Druggists 247 CMR 9.00: Code of Professional Conduct; Professional Standards for Registered Pharmacists, Pharmacies and Pharmacy Departments 247 CMR 12.00: Restricted Pharmacy 247 CMR 13.00: Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies 247 CMR 14.00: Petition for Waiver 247 CMR 15.00: Continuous Quality Improvement Program 247 CMR 16.00: Collaborative Drug Therapy Management 247 CMR 17.00: Sterile Compounding. Advisory Committee Comments on draft 247 CMR 17.00 		V. Berg H. Engman D. Sencabaugh
12:30		Lunch Break		
1:30	IX	 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. Specifically, the Board will discuss and evaluate the Good Moral Character as required for registration for pending applicants and a petition for reinstatement. 	CLOSED SESSION	
2:30	VIII	 FILE REVIEW PHA-2015-0028, Rite Aid Pharmacy #10166, DS3135 PHA-2015-0120, Nicole S. Henderson, PH27493 PHA-2015-0015, Rite Aid 10128, DS2568 PHA-2015-0125, Irina Berezovskaya, PH25218 SA-INV-7076, Walter Schroeder, PH25422 SA-INV-8515, Atef Ayoub, PH233456 SA-INV-8346, Pharmerica, DS3599 		
3:30	X	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION	
5:00	XI	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

February 2, 2016

Board Members Present

Board Members Not Present

Edmund Taglieri Jr., RPh, MSM, NHA President Timothy Fensky, RPh, FACA President –elect Michael Godek, RPh, Secretary (left meeting at 3:24 p.m.) Phillippe Bouvier, R.Ph. Catherine Basile, Pharm D, RPh Garrett Cavanaugh, RPh Karen Conley, RN, DNP Susan Cornacchio, JD William Cox CPht Patrick Gannon, RPh, MS Dr. Ali Raja, MD, M.B.A., MPH. Andrew Stein, Pharm D, R.Ph. Richard Tinsley, MBA, MEd.,

Board Staff Present

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

TOPIC: I

CALL TO ORDER 8:32 AM

<u>DISCUSSION</u>: A quorum of the Board was present, established by roll call. President E. TAGLIERI chaired the meeting and asked if anyone was recording. Hearing "no", he explained that the Board of Pharmacy was recording the meeting. D. SENCABAUGH introduced APPE student R. LIM from Northeastern University.

TOPIC II.

APPROVAL OF AGENDA

<u>DISCUSSION</u>: Executive Director D. SENCABAUGH informed the Board that the review of a draft "Opioid Advisory", scheduled to take place during Flex Session, was going to be deferred to a future meeting. Board Counsel H. ENGMAN informed the Board that there was no review of 247 CMR section 9 in the Regulations Session.

ACTION:

1. Motion by P. GANNON, seconded by, C. BASILE, and voted unanimously to approve the agenda with the noted changes.

TOPIC III. APPROVAL OF BOARD MINUTES

1. Draft January 5, 2016, Regular Session Minutes

DISCUSSION: None

ACTION:

2. Motion by P. GANNON, seconded by, C. BASILE, and voted unanimously to approve the minutes of the General Session from January 5, 2016.

TOPIC IV:APPLICATIONSTIME: 8:36AM-9:10AM

1. Nimble Rx, New Community Pharmacy 8:36AM

<u>DISCUSSION</u>: Nimble Pharmacy, which had been before the Board in January, but was deferred with the Board requesting additional information and recommending an apprearance from the MOR candidate, did not have any representatives in attendance, and was therefore deferred. Board staff was asked to reach out to them and reschedule just one more time.

3.

4. <u>ACTION:</u> None Taken by the Board_

2. Cambridge Health Alliance – Cambridge, MA New Community Pharmacy 8:37AM

<u>DISCUSSION</u>: Cambridge Health Alliance was represented by Operations Manager Joel Itzkowitz, Quyen Luong, MOR candidate for the Malden location (see #3 below), and Michele Ortiz MOR, candidate for the Cambridge location.

Mr. Itzkowitz described them as free standing pharmacies that are Health Safety Net Providers, who already own and operate one retail pharmacy at Cambridge Hospital. The representatives were able to satisfy all the board member concerns, including enrolling and the utilization of the PMP, performing self-inspections, being certified immunizers planning to administer flu shots, and after-hours coverage.

It was noted by Board Member T. FENSKY that they needed to add "moderate" compounding to their application, since they planned to compound Miracle Mouthwash, etc.

Director of Pharmacy Compliance requested that they contact HCQ, make sure there are no issues with their locations.

5.

6. <u>ACTION:</u> Motion by P. GANNON, seconded by, C. BASILE, and voted unanimously, to approve the application for this New Community Pharmacy, pending successful inspection, and correcting the paperwork around Moderate NS Compounding and training attestations.

7. M. GODEK had recused himself since both MOR candidates were former Walgreen Pharmacy employees, and was not present during the discussion or vote on this matter.

8.

3. Cambridge Health Alliance – Malden, MA New Community Pharmacy 8:37AM

<u>DISCUSSION</u>: combined with discussion for number 2 (see above)

9. <u>ACTION:</u> Motion by P. GANNON, seconded by, C. BASILE, and voted unanimously, to approve the application for this New Community Pharmacy, pending successful inspection, and correcting the paperwork around Moderate NS Compounding and training attestations.

10. M. GODEK had recused himself since both MOR candidates were former Walgreen Pharmacy employees, and was not present during the discussion or vote on this matter.

4. Long Term Pharmacy

<u>DISCUSSION</u>: Long Term Pharmacy Solutions had no representative in attendance. Director of Pharmacy Compliance Bill Frisch Advised the Pharmacy Board members that he had reviewed their renovation plans, and was comfortable. They are planning to shut down during renovations and will re-test / re-certify before starting back up._

11. <u>ACTION:</u> Motion by M. GODEK, seconded by, C. BASILE, and voted unanimously, to approve the renovation of Long Term Pharmacy Solutions. T.FENSKY had recused himself and was not present for the discussion or voting on this matter.

12.**5. Boston Home InfusionTransfer of Ownership8:36AM**

<u>DISCUSSION</u>: Boston Home Infusion was represented by MOR Rachel Gallagher, Attorney Paul Garbarini, 797 Compounding Consultant David Trinks, and VP of Operations for PromptCare, Ms. Kathy Pawlke. PromptCare is the purchaser.

MOR Gallagher has been with Boston Home Infusion for 7 years, the last three of which while serving as MOR. She has performed a yearly gap analysis, and Director of Pharmacy Compliance B. FRISCH said they have been inspected regularly, twice last year without any issues. This will be the 4th pharmacy owned by PromptCare, the other three located in New Jersey, Long Island, and in Pennsylvania.

13. <u>ACTION:</u> Motion by C. BASILE, seconded by, M. GODEK, and voted unanimously, to approve the transfer of ownership for this community pharmacy. Board Member T. FENSKY had recused himself and did not take part in the discussion or the voting on this matter

14.

6. IVG Veterinary Compounding Center Renovation / Expansion 8:55AM

<u>DISCUSSION</u>: IVG was represented by MOR Justin McDowell and Ms. Celine Rosas who manages the company on the business side. McDowell has been MOR since their 2013 opening, and reported having been an MOR elsewhere previously.

Director of Pharmacy Compliance W. FRISCH indicated that the renovations being proposed by IVG are the result of a previous inspection, during which it was determined that they were not properly set-up to handle hazardous materials. They are renovating in hopes to become compliant with USP <800> ahead of the 2018 deadline. IVG only compounds 4 items, and not often. They are currently compounding under USP's low-volume exception, but this renovation will move their compounding are to an entirely different suite within their building.

15.

16. <u>ACTION:</u> Motion by P. GANNON, seconded by A. STEIN, and voted unanimously, to approve the renovation of IVG Veterinary Compounding Center.

17.

7. Target PharmacyTransfer of Ownership9:05AM

<u>DISCUSSION</u>: Executive Director D. SENCABAUGH reported that CVS/Pharmacy is purchasing 39 Target Pharmacy locations, and will be operating them as CVS Pharmacies inside Target. They reported that the pharmacies are being transitioned to operate under CVS Policies and Procedures. 18.

19. <u>ACTION:</u> Motion by R. TINSLEY, seconded by C. BASILE and voted unanimously, to approve the transfer of ownership for the 39 Target Pharmacies to CVS Pharmacy. Board Member S. CORNACCHIO had recused herself and was not present for the discussion or voting on this matter.

20. 21.

TOPIC V.

REPORTS

Applications Approved Pursuant to Licensure Policy 13-01

<u>DISCUSSION</u>: R. HARRIS noted that during the past month there have been thirty-five (35) change of managers, and five (5) closings since the last Board meeting. <u>ACTION</u>: So noted

Report of activities Probation Monitor

<u>DISCUSSION</u>: D. SENCABAUGH provided the January 1, 2016 – January 26, 2016, Board of Pharmacy Statistics Report for the Probation monitor, which noted that: there are 57 licenses on probation (57) licensees on probation, seven (7) satisfactorily completed probation, two (2) licensee did not cure within 30 days, and two (2) given the opportunity to cure.

ACTION: So noted

TOPIC VI.

Flex Session

1. USP <797> Public Comment

DISCUSSION: K BARNES updated the Board on comments to USP <797> that she and Director of Compliance W. FRISCH had submitted on the Board's behalf as instructed at the January 5th meeting. Board members were provided the comments for review.

2. Naloxone Standing Order Update

DISCUSSION: K. BARNES updated the Board on the changes to the Naloxone Standing Order to include the new auto injector product. K. BARNES noted that the changes would be posted to the example standing order information on the Board's website. M. CHAN was recognized for her work in updating the policy.

TOPIC VII: REGULATIONS

TIME: 9:20AM-12:30PM

Proposed amendments to 247 CMR 2.00: Definitions

DISCUSSION: D. SENCABAUGH and H. ENGMAN provided the overview to the members drawing the distinction between regulatory review as required by Executive Order 562 and Regulatory Reform. Board members were informed that the definitions they were to consider were changes to the current regulation as required by regulatory review. The new draft proposed changes incorporated definitions that resided in various sections of 247 CMR to improve reference and readability of the regulation. The document was displayed on the screen for the members and the audience to view. H. ENGMAN reviewed the proposed changes line by line capturing board members comments in track changes. It was noted that section 2.00 would come back to the board members as there will be many new terms as a result of the new sections approved by the board. ACTION: Motion by K. CONLEY, seconded by P. BOUVIER, and voted unanimous to approve the proposed amendments section 247 CMR 2.00: Definitions, and proceed with the EO562 process and if substantive changes are not required by the administrative process, send the proposed amendments to 247 CMR 2.00: Definitions out for public comment and hearing.

2. 247 CMR. 7.00: Wholesale Druggist

DISCUSSION: H. ENGMAN informed the members that due to the in pending changes required by the DQSA Act it was the recommendation that Section: 7.00 remain as is.

ACTION: Motion by P. BOUVIER, seconded by C. BASILE, and voted unanimous to retain 247 CMR7.00: Wholesale Druggist, and proceed with the EO562 process

3. 247 CMR 12.00: Restricted Pharmacy

DISCUSSION: H. ENGMAN referred Board members to a memo provided by DPH recommending the rescission of section 12:00, Restricted Pharmacy. It was noted that the Board does not issue restricted licenses and that facilities have the ability to request a waiver of regulations should the need arise. ACTION: Motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimous to approve the rescission of section 247 CMR 12.00: Restricted Pharmacy, and proceed with the EO562 process and if substantive changes are not required by the administrative process, send the proposed amendments to 247 CMR 12.00 Restricted Pharmacy and send out for public comment and hearing.

4. 247 CMR 13.00 Registration Requirements and Minimal Standards / Nuclear

DISCUSSION: H. ENGMAN informed the members of the technical changes to section 13:00 that were meant to improve readability and to make terminology consistent with other sections of 247 CMR. K. BARNES informed the members that section 13.00 will be address later on in regulatory reform. The changes where displayed on the screen for members and the audience to view; members comments were captured in track changes.

ACTION: Motion by P. GANNON, seconded by C. BASILE, and voted unanimous to approve the amendments to section 247 CMR 13.00: Registration Requirements and Minimal Standards / Nuclear, and proceed with the EO562 process and if substantive changes are not required by the administrative process, send the proposed amendments to 247 CMR Registration Requirements and Minimal Standards / Nuclear Pharmacy and send out for public comment and hearing.

5. 247 CMR 14.00: Petition for Waiver

DISCUSSION: H. ENGMAN noted the proposed changes to the Waiver Process. The changes where displayed on the screen for members and the audience to view; members comments were capture in track changes. The notable change is that granted waiver of board regulation would have a 5 year term and licensee would need to reapply at that time.

It was proposed that all waivers granted prior to June 30, 2012 will expire on the 5 year anniversary. The Board members were concerned with the work load that could impact staff. It was noted that staff need to have a starting point in order get licensee with waivers on a similar starting point.

ACTION: Motion P. BOUVIER, seconded by P. GANNON, and voted unanimous to approve the amendments of section 247 CMR 14.00: Petition for Waiver, and proceed with the EO562 process and if substantive changes are not required by the administrative process, send the proposed amendments to 247 CMR 14.00 Petition for Waiver and send out for public comment and hearing.

6. 247 CMR 15.00: Continuous Quality Improvement

DISCUSSION: H. ENGMAN informed members of the changes to section 15.00. The noted changes were the movement of the definitions to section 247 CMR 2.00 and the relocation of section 15.05 into 247 CMR 20.00 Mandatory Reporting. The changes where displayed on the screen for members and the audience to view; members comments were captured in track changes.

ACTION: Motion P. GANNON, seconded by C. BASILE, and voted unanimous to approve the amendments of section 247 CMR 15.00: Continuous Quality Improvement, and proceed with the EO562 process and if substantive changes are not required by the administrative process, send the proposed amendments to 247 CMR 15.00 Continuous Quality Improvement and send out for public comment and hearing.

7. 247 CMR 16.00: Collaborative Drug Therapy Management

DISCUSSION: H. ENGMAN noted for the members the technical changes and organizational improvements to the readability to section 16.00. The changes where displayed on the screen for members and the audience to view; members comments were captured in track changes.

ACTION: Motion by P. GANNON, seconded by C. BASILE, and voted unanimous to approve the amendments to 247 CMR 16.00: Collaborative Drug Therapy Management, and proceed with the EO562 process and if substantive changes are not required by the administrative process, send the proposed amendments to 247 CMR 16.00: Collaborative Drug Therapy Management out for public comment and hearing.

8. 247 CMR 17.00: Sterile Compounding

DISCUSSION: D. SENCABAUGH provided and overview of the process. Board members were updated on the events that have occurred since they approved section 17.00 on November 24th. The approved section was provided to the Advisory Committee for review and comment on December 11, 2015. On January 22nd the committee met and their in a public forum which they review draft new section 17.00 section by section with their comments captured via track changes. D. SENCABAUGH reminded the board that the Board has been many hours carefully considering the draft new section and the desire was to work through the recommendation of the committee today so the document can move forward to administrative review and public comment. The committee selected E. KASTANGO to present the committee's recommendations to the board. Advisory Committee member K. BELISE attended the meeting and was provided the courtesy assisting Mr. Kastango during the discussion session. The board was provided a spreadsheet detailing the one hundred and eleven (111) sections the committee had offered comment on. K. BARNES and W. FRISCH reviewed all the committee commentations of the review seventy eight (78) sections where Board Staff agreed with recommendations of the committee. E. TAGLIERI encouraged members expedite the process and accept the recommendations of the Advisory Committee that were supported by Board Staff.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously to accept changes to 247 CMR 17.00: Sterile Compounding, as recommended by the Advisory Committee with Board Staff recommendation of "neutral" or "support".

The Board then took under consideration the remaining thirty three (33) sections section by section. Advisory committee representatives and Board Staff provide rational on each of their respective recommendation. The voted on each of the thirty three sections accepting three additional committee recommendations. It was voted by the board that the more restricted standard should prevail and provided for public comment.

ACTION: Motion P. GANNON, seconded by T. FENSKY, and voted

unanimous to approve the amendments of section 247 CMR 17.00: Sterile Compounding, and proceed with the EO562 process and if substantive changes are not required by the administrative process, send the proposed new section 247 CMR 17.00 Sterile Compounding and out for public comment and hearing.

TOPIC VIII.

OPEN FILE REVIEW

W. FRISCH introduced the newest Investigator, JULIENNE TRAN.

1. PHA-2015-0028, Rite Aid #10166 DS3135

RECUSAL: G. CAVANAUGH and W. COX recused themselves and were not present for the discussion or vote on this matter. M. GODEK had left the meeting early and was not present either.

<u>DISCUSSION</u>: C. MOGNI presented and summarized the investigation (for C. LATHUM) report that pertained to this matter. The evidence indicates that OPP compliance initially investigated this pharmacy (August 2014) after a tornado hit Revere and caused damage. They noted some repeat inspectional deficiencies during a subsequent compliance inspection. Deficiencies included; discrepancies in labeling of vials on the

3:50 PM

shelves,<795> compounding, supervisory ratios, stained ceiling tiles, missing Rx subsequent to emergency dispensing of a C-II, inconsistency of signing daily logs. Since the deficiencies were noted, the pharmacy has submitted a comprehensive and accepted plan of correction.

<u>ACTION:</u> Motion by P. GANNON, seconded by C. BASILE and voted unanimously by those present, to dismiss the complaint against Rite Aid #10166, No Discipline Warranted (remediation complete.)

2. PHA-2015-0120, Nicole Henderson PH27493

RECUSAL: G. CAVANAUGH and W. COX recused themselves and were not present for the discussion or vote on this matter. M. GODEK had left the meeting early and was not present either.

<u>DISCUSSION</u>: C. MOGNI presented and summarized the investigation (for C. LATHUM) report that pertained to this matter. The evidence indicates that OPP compliance initially investigated this pharmacy (August 2014) after a tornado hit Revere and caused damage. They noted some repeat inspectional deficiencies during a subsequent compliance inspection. Deficiencies included; discrepancies in labeling of vials on the shelves,<795> compounding, supervisory ratios, stained ceiling tiles, missing Rx subsequent to emergency dispensing of a C-II, inconsistency of signing daily logs. Since the deficiencies were noted, the pharmacy has submitted a comprehensive and accepted plan of correction.

<u>ACTION</u>: Motion by C. BASILE, seconded by T. FENSKY and voted unanimously by those present, to dismiss the complaint against Nicole Henderson MOR Rite Aid #10166, No Discipline Warranted (remediation complete.)

3. PHA-2015-0015, Rite Aid Pharmacy #10128, DS2568 TIME: 3:55 PM

RECUSAL: G. CAVANAUGH and W. COX recused themselves and were not present for the discussion or vote on this matter. M. GODEK had left the meeting early and was not present either.

DISCUSSION: C. MOGNI (for C. LATHUM) presented and summarized the investigation report that pertained to this matter. The evidence indicates that OPP compliance investigated noted multiple and repeat inspectional deficiencies during unannounced compliance inspections conducted in July 2014 & January 2015. Multiple inspectional deficiencies were noted on each visit; the repeat deficiencies included missing name tags, stained ceiling tiles, dirt in several areas of the pharmacy, perpetual inventory not reconciled every 10 days, and other items. There were extensive Plans of Correction (POCs) submitted and a follow-up inspection in August 2015 showed no deficiencies.

ACTION: Motion by E. TAGLIERI, seconded by P. GANNON, and voted unanimously by those present, to dismiss the complaint against Rite Aid #10128, no discipline warranted (remediation complete.)

4. PHA-2015-0125, Irina Berezovskaya, PH25218

RECUSAL: S. CORNACCHIO recused herself and was not present for the discussion or vote on this matter. DISCUSSION: C. MOGNI (for C. LATHUM) presented and summarized the investigation report that pertained to this matter. The evidence indicates that OPP compliance investigated noted multiple and repeat inspectional deficiencies during unannounced compliance inspections conducted in July 2014 & January 2015. Multiple inspectional deficiencies were noted on each visit; the repeat deficiencies included missing name tags, stained ceiling tiles, dirt in several areas of the pharmacy, perpetual inventory not reconciled every 10 days, and other items. Also, there were some BUD (beyond use dates) above USP <795> without stability data. There were extensive Plans of Correction (POCs) submitted and a follow-up inspection in August 2015 showed no deficiencies.

ACTION: Motion by C. BASILE, seconded by A. STEIN, and voted unanimously by those present, to dismiss the complaint against Irina Berezovskaya, of Rite Aid #10128, no discipline warranted (remediation complete.)

5. SA-INV-7076, Walter Schroeder, PH25422

RECUSAL: M. GODEK had left the meeting and was not present for the discussion or vote on this matter. DISCUSSION: M. VASQUEZ presented and summarized the investigation report that pertained to this matter. The evidence indicates that the licensee self-reported a CE deficiency of fourteen contact hours for 2014.

TIME: 3:57

TIME: 9:45AM

TIME: 9:16AM

Schroeder stated he had taken the courses, but had not completed the evaluations and therefore was not given the credit. The licensee submitted proof of fourteen additional contact hours in 2015 to apply to 2014, including PMP, live, and law requirements.

ACTION: Motion by P. GANNON, seconded by K. CONLEY, and voted unanimously by those present to close staff assignment SA-INV-7076, discipline not warranted (remediation complete.)

6. SA-INV-8515, Atef Ayoub, PH233456 TIME: 3:59

RECUSAL: M. GODEK had left the meeting and was not present for the discussion or vote on this matter. DISCUSSION: M. VASQUEZ presented and summarized the investigation report that pertained to this matter. The evidence indicates that the licensee self-reported a CE deficiency of thirteen contact hours for 2013. The licensee submitted proof of twenty-two additional contact hours in 2015 to apply toward the 2013 deficiency, including live, and law requirements necessary.

ACTION: Motion by A. STEIN, seconded by C. BASILE, and voted unanimously by those present to close staff assignment SA-INV-8515, discipline not warranted (remediation complete.)

7. SA-INV-8346; Pharmerica, DS3599

RECUSAL: M. GODEK had left the meeting and was not present for the discussion or vote on this matter. DISCUSSION: C. Collins presented and summarized the investigation report that pertained to this matter. The evidence indicates that Pharmacy Quality Assurance received a report of an Abnormal Result (1cfu mold) isolated from the ante room on September 25, 2015. Pharmerica remediated appropriately and follow-up Environmental Monitoring all noted to be below USP <797> action levels.

<u>ACTION</u>: Motion by P. GANNON, seconded by C. BASILE and voted unanimously by those present to dismiss SA-INV-8346, no violation.

<u>TOPIC IX.</u> **EXECUTIVE SESSION:** <u>DISCUSSION</u>: None <u>ACTION</u>: at 1:48PM motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by roll call to enter into Executive Session: E. TAGLIERI; yes, T. FENSKY; yes, M. GODEK; yes, P. Bouvier, yes, C. BASILE; yes, G. CAVANAUGH; yes, S. CORNACCHIO; yes, K. CONLEY; yes, W. COX; yes, P. GANNON, yes A. RAJA; yes, A. STEIN; yes, R. TINSLEY; yes.

TOPIC XI.

M.G.L. c. 65C Session

DISCUSSION: None

<u>ACTION</u>: At 4:01PM motion by P. GANNON, seconded by T. FENSKY and voted unanimously to enter into M.G.L. c. 65C Session. M. GODEK was not present for the discussion or vote on this matter.

TOPIC XIII.

ADJOURMENT OF MEETING

DISCUSSION: NONE

<u>ACTION</u>: At 4:45PM motion by E. TAGLIERI, seconded by P. GANNON, and voted unanimously to adjourn the meeting.

LIST OF EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 22. Draft Agenda for the February 2, 2016, regularly scheduled meeting of the Board of Registration in Pharmacv.
- 23. Draft January 5, 2016 Open Session Minutes.
- 24. Application to Operate and Manage a New Community Drugstore, Nimble Pharmacy.
- 25. Application to Operate and Manage a New Community Drugstore, Cambridge Health Alliance Cambridge, MA
- 26. Application to Operate and Manage a New Community Drugstore, Cambridge Health Alliance Malden, MA
- 27. Application for Expansion / Renovation of Long Term Pharmacy DS3184
- 28. Application for Transfer of Ownership of Boston Home Infusion DS89953
- 29. Application for Expansion / Renovation of IVG Veterinary Pharmacy DS89887
- 30. Application for Transfer of Ownership of Target Pharmacies to CVS Pharmacy
- 31. Report of Applications approved pursuant to licensure policy 13-01
- 32. Report from Probation Monitor
- 33. Comments to United States Pharmacopia (USP) Expert Committee, January 31, 2016
- 34. 13. Draft proposed amendments to 247 CMR 2.00: Definitions
- 35. 14. Draft proposed amendments to 247 CMR 7.00: Wholesale Druggists
- 36. 15. Draft proposed amendments to 247 CMR 12.00: Restricted Pharmacy

16. Draft proposed amendments to 247 CMR 13.00: Registration Requirements and Minimal 37. Professional Standards for Nuclear Pharmacies.

- 38. 17. Draft proposed amendments to 247 CMR 14.00: Petition for Waiver
- 39. 18. Draft proposed amendments to 247 CMR 15.00: Continuous Quality Improvement Program
- 40. 20. Draft proposed amendments to 247 CMR 16.00: Collaborative Drug Therapy Management
- 41. 21. Draft proposed new regulation 247 CMR 17.00: Advisory Committee Comments on Sterile Compounding proposed 247 CMR 17.00 with track changes.
- 22. Investigation report in the matter of Rite Aid Pharmacy #10166, PHA-2015-0028 42.
- 43. 23. Investigation report in the matter of Nicole S. Henderson, PHA-2015-0120.
- 44. 24. Investigation report in the matter of Rite Aid Pharmacy #10128, PHA-2015-0015
- 45. 25. Investigation report in the matter of Irina Berezovskaya, PHA-2015-0125.
- 46. 26. Investigation report in the matter of Walter Schroeder, SA-INV-7076.
- 27. Investigation report in the matter of Atef Ayoub, SA-INV-8515. 47.
- 48. 28. Investigation report in the matter of Pharmerica, SA-INV-8346.
- 49.
- 50.

Respectfully submitted by: M. GODEK, R.Ph.