

**COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy**

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

November 3, 2015
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Contact
8:30	I	CALL TO ORDER		P. Gannon
8:35	II	APPROVAL OF AGENDA • Pharmacy Intern Introductions		
8:40	III	APPROVAL OF BOARD MINUTES • Draft of September 1, 2015 Regular Session Minutes • Draft of October 6, 2015 Regular Session Minutes		
8:45	IV	APPLICATIONS • Animal Pharm(DS3066)-Relocation • Resident Care Pharmacy(DS3264) - Relocation • Century Pharmacy (DS89877) – Renovation/Expansion • Nimble Pharmacy – New Community Pharmacy		
9:15	V	REPORTS 1. Applications approved pursuant to Licensure Policy 13-01 2. Monthly Report from Probation	Reports	R. Harris K. Fishman
9:20	VI	ADVISORY COMMITTEE UPDATE 1. Update on full committee meeting held October 5, 2015 Present draft policy guidance for Environmental results in the ISO 5 classified space. 2. Update on Abnormal Results sub- committee meeting held October 30, 2015. 3. Topic for Advisory Committee Consideration Shared Pharmacy Services-Telepharmacy		C. Belisle K. Barnes W. Frisch D. Sencabaugh

9:40	VII	FLEX SESSION <ol style="list-style-type: none"> 1. Nomination of Board officers for calendar 2016 2. Board of Registration in Pharmacy regularly scheduled meeting dates for 2016. 3. Pain Management Training CDTM 4. ACPE Accreditation Massachusetts College of Pharmacy and Health Sciences 5. Pharmacy Signage requirements 6. Amendment to M.G.L. c.112,§39C: Long Term Care Pharmacy and Home Fusionist Pharmacy 	D. Sencabaugh V. Berg K. Barnes V. Berg
10:00	VIII	REGULATIONS <u>Proposed new regulation, 247 CMR 21.00: Outsourcing Facilities</u> <u>Proposed amendments to 247 CMR 11.00: Registration Under the Controlled Substances Act (M.G.L. c.94C)</u> <u>Proposed new regulation, 247 CMR 17.00: Sterile Compounding.</u>	V. Berg D. Sencabaugh; K. Barnes; W. Frisch
12:00		LUNCH BREAK	
1:00	IX	FILE REVIEW <ol style="list-style-type: none"> 1. PHA-2015-0090, CVS Pharmacy #1874, DS89741 2. PHA-2015-0142, Neena Lukose, PH23086 3. SA-INV-7085, CVS Pharmacy #488, DS3157 4. SA-INV-7113, CVS Pharmacy #0735, DS2841 5. PHA-2015-0109, CVS #2325, DS2850 6. PHA-2015-0135, Heather Jackman, PH22199 7. PHA-2015-0136, Samuels Pharmacy, DS15095 8. PHA-2015-0137, Peter Lyons, PH19225 9. SA-INV-6870, David Marsh, PH14819 10. SA-INV-8326, Kevin O'Brien, PH17654 	

2:00	X	<p>EXECUTIVE SESSION</p> <p>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>Specifically, the Board will discuss and evaluate the <u>Good Moral Character</u> as required for registration for pending applicants.</p>	CLOSED SESSION
2:30	XI	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)	CLOSED SESSION
3:15	XII	M.G.L. c. 112, 65C SESSION	CLOSED SESSION
5:00	XII	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**

November 3, 2015

Board Members Present

Patrick Gannon, R.Ph., MS, President
Edmund Taglieri, Jr. R.Ph., President-Elect
Timothy Fensky, R.Ph, FACA
Garrett Cavanaugh, R.Ph.
Catherine Basile, Pharm D, R.Ph.
Susan Cornacchio, JD, RN.
William Cox CPhT
Michael Godek, R.Ph.
Karen Conley, DNP, RN
Andrew Stein, Pharm D, R.Ph.
Phillippe Bouvier, R.Ph.

Board Members Not Present

Richard Tinsley, MBA, M.Ed. Secretary

Board Staff Present

David Sencabaugh, R.Ph, Executive Director Heather Engman, JD, MPH Board Counsel
David Dunn, R.Ph, Associate Executive Director
Kelly Ann Barnes, JD, R.Ph, Director of Pharmacy QA
William Frisch, R.Ph, Director of Pharmacy Compliance
Richard Harris, Program Analyst
Monica Vasquez, Compliance Officer
Colleen Collins, PharmD, R.Ph. Contract Investigator
Christina Mogni, R.Ph. Investigator
Vita Palazzolo Berg, JD, Chief Board Counsel
James Lavery, JD, Director, Health Professions Licensure

TOPIC: I

CALL TO ORDER

DISCUSSION: A quorum of the Board was present. President P. GANNON opened the meeting at 8:35AM, 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. Quorum was established by a roll call vote: P. GANNON; yes, E. TAGLIERI; yes, T. FENSKY; yes, C. BASILE; yes, M. GODEK; yes, G. CAVANAUGH; yes, S. CORNACCHIO; yes, K. CONLEY; yes, W. COX; yes, A. STEIN; yes, P. BOUVIER; yes.

TOPIC II.

APPROVAL OF AGENDA

Time: 8:36AM

DISCUSSION: D.DUNN informed the Board that the approval for minutes from October 6, 2015 would be deferred to a later meeting.

ACTION: Motion by E. TAGLIERI, seconded by K. CONLEY, and voted unanimously to approve the Agenda with the noted change.

D. SENCABAUGH introduced A. BODZIUCH and V.YOON as the Board's APPE rotation interns. Adriana Bodziuch attends Northeastern University, while Victoria Yoon attends MCPHS University in Boston, MA.

P. GANNON asked for any other interns in the audience to stand up and be recognized.

TOPIC III.

APPROVAL OF BOARD MINUTES

TIME: 8:38

Draft September 1, 2015, Regular Session Minutes

DISCUSSION: none

ACTION: Motion by K. CONLEY, seconded by C. BASILE and voted unanimously to approve the draft regular session minutes from September 1, 2015, with Member T.FENSKY abstaining, since he was not present for that meeting.

TOPIC IV.

APPLICATIONS:

TIME: 8:40

1. Animal Pharm, LLC (DS3066) Community Pharmacy, Relocation Application

DISCUSSION: Animal Pharm, a community pharmacy dedicated to servicing animals, applied for relocation from Scituate, MA to Pembroke, MA.

Animal Pharm was represented by Attorney Paul Garbarini, David Trinks, a 795 compounding consultant, and MOR Kathleen Taylor. Taylor, who is also the owner, explained that the expansion of the pharmacy within a new facility, which is intended to treat “non-food producing” animals, will allow for better access and parking for their clients.

Animal Pharm, which engages in <795> non-sterile complex compounding, requested 3 waivers: (1) waiver for signage (2) to be allowed to limit their service to a limited segment of the public, and (3) exempt them from having to carry all drugs, chemicals, etc.

ACTION: Motion by M. GODEK, seconded by A. STEIN and voted unanimously to approve Animal Pharm’s relocation, including waivers, pending a successful inspection.

TOPIC IV.

APPLICATIONS:

TIME: 8:51

2. Conlin’s “Resident Care Pharmacy” Relocation Methuen, MA

DISCUSSION: Represented by owner Dennis Conlin, Sandra Kalil, RPh Director of Pharmacy, and MOR Linda Waslylak, Conlin’s was seeking approval to relocate from the current location in Methuen, to 380 Merrimack Street in Methuen.

Conlin’s serves Long Term Care homes. They engage in both simple and moderate non-sterile compounding. They requested a waiver for signage exemption. After several questions by Board Members and a suggestion to review proposed draft regulations regarding 247 CMR Section 9 on the Board’s website, a motion was made.

ACTION: Motion by G. CAVANAUGH, seconded by C. BASILE, and voted unanimously to approve the relocation of Conlin’s Resident Care Pharmacy, with signage waiver, pending amending their application to include moderate non-sterile compounding, and successful inspection.

TOPIC IV.

APPLICATIONS:

TIME: 9:05

3. Century Pharmacy 937 Gorham Street DS89877, Lowell Renovation/Expansion

RECUSAL: T. FENSKY and A. STEIN recused themselves and were not present for the discussion or vote of this matter.

DISCUSSION: Century Pharmacy was represented by MOR David Beck, and Bob Falkum from Gates HealthCare (consultant). The purpose of the expansion would be to increase the space for non-sterile compounding, and to prepare for the final USP 800. Century does engage in non-sterile complex compounding. Discussion centered on the operation of the pharmacy during the period of construction. Since it is in a separate area, there are no expected issues. Director of Pharmacy Quality Assurance for BORIP, Kelly Ann Barnes, wanted to point out that a typo should be struck, so as to be clear that USP 800 is not final.

ACTION: Motion by E. TAGLIERI, seconded by C. BASILE, and voted unanimously to approve the renovation/expansion of Century Pharmacy, and they will contact the Board for an inspection once completed.

TOPIC IV.

APPLICATIONS:

Time: 9:13

Nimble Pharmacy, applying for a new Community Pharmacy, failed to appear, and will need to be scheduled at a future Board Meeting.

TOPIC V. **REPORTS**

Applications Approved Pursuant to Licensure Policy 13-01 Time: 9:15AM

DISCUSSION: R HARRIS noted that during the past month there have been twenty-four (24) Change of Managers and one (1) closing, approved by staff action.

ACTION: So noted

TOPIC V. **REPORTS**

Monthly Report from Probation

9:17AM

DISCUSSION: In the absence of Karen Fishman, Executive Director David Sencabaugh reviewed the report from Probation, covering the period of 10/1/15 – 10/27/15. The report indicated that there were 8 cases of monitored probation that were satisfactorily completed in this time period. Also, there are currently 63 BORIP licenses that are on probation as of 10/17/15.

ACTION: So noted

TOPIC VI.

ADVISORY COMMITTEE UPDATE

Time: 9:19

DISCUSSION: D. SENCABAUGH updated the board on the advisory committee meetings held on October 5 and October 30th.

1. Draft Policy guidance for environmental results in the ISO 5 classified space: Advisory Committee member C. BELISLE updated the board on the Advisory Committee's sub-committee on Abnormal Results work on guidance for registrants in response to abnormal results. C. BELISLE informed the board on the need for compounders to report to the board abnormal results within 24 hours, with additional follow up in 7 days, no compounding of sterile products within the affected ISO 5 PEC, remediation plans, along with the need for repeat environmental monitoring within 30 days. It was noted that the sub-committee will continue to work on guidance for the ISO 7 & 8 spaces but this work will be complicated due to bio-burden of these areas. P. GANNON inquired what would an institution with a single PEC do. There was concern of the length of time it would take for environmental results to be finalized and provided to an institution C. BELISLE indicated that

facilities will need to consider redundancies and have a back-up plan similar is there was a power outage. K. BARNES indicated that a lot of work, debate and careful consideration had gone into the development of the draft policy guidance document and the overarching concern being “what is safe for the citizens of the Commonwealth. K. BARNES reiterated that the guidance document is a policy position. W. FRISCH noted that the guidance document will allow for registrants to be self-directed regarding their POC regarding abnormal results.

2. Update on Abnormal Results Sub-Committee meeting held on October 30.

DISCUSSION: K. BARNES updated the board on the ongoing work of the Abnormal Results Sub-Committee involving the development of a guidance document for registrant encountering abnormal environmental results in the ISO 7 classified space. K. BARNES noted that when the policy position was developed it would be brought back to the board. The key questions that would be addressed by the guidance document would be: (a) when do you stop compounding? (b) what guidance to provide? (c.) trending of abnormal results.

3. Topics for Advisory Committee Consideration Shared Pharmacy Services- Telepharmacy.

DISCUSSION: D. SENCABAUGH updated the board on the work of the advisory committee regarding Shared Pharmacy Services. D. SENCABAUGH reported that the Advisory Committee had reviewed information and after discussion recommended that the board considers regulation regarding shared pharmacy services specific to central fill and central processing. D SENCABAUGH noted that the board should consider these topics at the conclusion of their work on pharmacy regulatory reform mandated by c159 of the Acts of 2014. D. SENCABAUGH thanked board member G. CAVANAUGH for his participation in the shared pharmacy services discussion at the Advisory Committee meeting. D. SENCABAUGH provided the board with an additional request as required by c. 159 for the Advisory Committee to consider, telepharmacy. The board was provided a definition and overview of telepharmacy. The board thought it prudent that the Advisory Committee review and consider telepharmacy

TOPIC VII.

FLEX SESSION

1. Nomination of Board Officers 2016

DISCUSSION: D. SENCABAUGH notified the members of the need for nominations of Board officers for 2016. The board was reminded that it had voted E. TAGLIERI as president –elect at the December 2015 meeting, and that E. TAGLIERI would serve as president in 2016. D. SENCABAUGH informed the board that it would need to seek nominations for the positions of secretary and president –elect, and that the election would take place at the December 1, 2015 meeting.

Secretary:

ACTION: Motion by G. GAVANAUGH, seconded by T. FENSKY to nominate M. GODEK for secretary of the board for 2016.

ACTION: Motion by P. GANNON, seconded by M. GODEK, to nominate S. CORNACCHIO for secretary of the board for 2016

President–elect:

ACTION: Motion by E. TAGLIERI, seconded by P. GANNON to nominate T. FENSKY as president-elect of the board for 2016. There were no other nominations for president-elect.

2. Board of Registration in Pharmacy meeting dates 2016

DISCUSSION: D. SENCABAUGH provided members with the meeting dates for 2016 of note, was the inclusion of extra meeting dates so that members could plan accordingly. Board members noted the May 5 listing as a typo and be corrected to May 3rd. It was also noted that the extra session scheduled for May 17th would conflict with the NABP annual meeting.

ACTION: Motion by E. TAGLIERI, seconded by C. BASILE and voted unanimously to the 2016 meeting calendar with noted corrections.

3. Pain Management CEU Requirements for CDTM Pharmacists

DISCUSSION: V. BERG informed the board that pharmacists working under CDTM agreements that hold a Massachusetts Controlled Substance Registration are required to complete continuing education requirements relative to effective pain management as required by M.G.L. c. 94C s. 18(e). V BERG indicated that board staff would draft a letter to the limited number of pharmacists reminding them of the obligation and the need to provide proof of compliance at renewal.

ACTION: Motion by P. GANNON, seconded by A. STEIN, and voted unanimously to authorize board staff to send a letter to pharmacists with prescriptive authority reminding them of the continuing education requirement.

4. ACPE Accreditation MCPHS University

DISCUSSION: K. BARNES reported to the board her participation at the ACPE accreditation review of MCPHS pharmacy curriculum.

5. Pharmacy Signage Requirements

DISCUSSION: K. BARNES, provided a memo of the pharmacy signage requirements as follow up to the Boards request at the October 6th. meeting. APPE –Intern A. RAFAI was noted for his research and development of the memo.

6. Amendment to M.G.L. c112 39C Long-term Care Pharmacy and Home Infusion Pharmacy

DISCUSSION: V. BERG provided the board with a legislative change that had taken place in c112 39C. In this section the term “fusionist” was replaced with “infusion”

TOPIC VIII

REGULATIONS

1. Proposed new section to 247 CMR 21.00, Registration of Outsourcing Facilities

DISCUSSION: V BERG led the discussion of the proposed new section to 247 CMR.

The new section set forth the requirements for the registration for resident and non resident outsourcing facilities. V. BERG informed the board that new section was a result new statutory language recently enacted as part of the FY 16 budget calling for the board to

register outsourcing facilities. V. BERG reminded the board that c.159 of the Acts 2014 had been silent on the issue of outsourcing facilities and this new legislation sought to address that fact. V. BERG informed the board that the regulation presented closely mirrored the statutory language with little room for the board’s interpretation or structural changes necessary. V. BERG assured board members that prior to licensure the outsourcing facility would need to be registered with the FDA as an 503B outsourcing facility. V. BERG updated regarding the use of a provisional licensure category that would allow for a facility to get up and running so it could be evaluated under dynamic conditions. The Board was made aware that an outsourcing facility operating under a provisional license would not be allowed to ship product into or out of the commonwealth. V. BERG informed the board that the licensed facility must be in good standing with the FDA and if not the board could take swift action against the board issued license. After a brief discussion and noting that the language in the proposed new regulation was aligned with the statute P. GANNON called for a vote on the matter.

ACTION: Motion by K. CONLEY, seconded by P. BOUVIER and voted unanimously to approve the proposed draft new regulation 247 CMR 21:00; Outsourcing Facilities, and to schedule a public hearing and comment period for the new draft regulation.

2 Proposed draft amendments to 247 CMR section 11.00; Registration under the Controlled Substances ACT.

DISCUSSION: V. BERG led the discussion on the draft proposed changes to 247 CMR 11:00. V. BERG noted for the board that as part of EO 562 regulatory review the draft changes sought to streamline section 11:00 by moving definition to the to be developed 247 CMR 2:00, and rescinding section 11.13 “Record and Inventories” as duplicative with federal regulations. The additional draft proposed changes were the incorporation of the regulatory language necessary allowing for licensure of in state outsourcing facility to obtain a Massachusetts Controlled Substance Registration.

ACTION: Motion by E. TAGLIERI, seconded by C. BASILE, and voted unanimously to approve the revisions and additions to draft proposed amendments to 247 CMR 11:00 and to schedule a public hearing and send out for public comment.

3. Proposed new section 247 CMR 17:00: Sterile Compounding

DISCUSSION: The discussion continued on the 247 CMR 17:00 Sterile Compounding. K. BARNES and W, FRISCH facilitated the discussion. The discussed began on the new draft regulation involving compounding robotics. At the end of the robotics discussion the board was informed that this marked the conclusion of the new content.

K. BARNES informed the board of the process in preparation for the evening meeting scheduled for November 24th. K. BARNES noted that comments from previous board meetings, stakeholders, would be reviewed and incorporated where appropriate. The proposed draft regulation would then be cross walked with the NABP and Board Audit tools; with the goal of providing the board with a finished document for a final review at the upcoming meeting. D. SENCABAUGH noted that the draft regulation in many cases met the standards proposed in the recent draft of USP <797>. P GANNON invited members of the public to provide feedback on section 17:00 in order for the best possible regulation to be developed and provided for public comment.

TOPIC IX

FILE REVIEW:

PHA-2015-0090; CVS Pharmacy 1874, DS89741 TIME:10:45

RECUSAL: S. CORNACCHIO recused, and was not present for the discussion or vote on this matter. (Interns Yoon and Bodziuch recused also)

DISCUSSION: M. VASQUEZ presented and summarized the investigative report pertaining to this matter. On May 21, 2014, February 2, 2015, and June 3, 2015, inspections at this location yielded multiple supervisory ratio deficiencies. Since the ratio deficiencies continued over multiple inspection dates, the Board decided to issue a Reprimand on the DS license.

ACTION: Motion by T. FENSKY, seconded by K. CONLEY, and voted unanimously by those present to refer the matter to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter with a consent agreement for a REPRIMAND for CVS #1874, DS 89741.

TOPIC IX.

FILE REVIEW:

1. PHA-2015-0142; Neena Lukose , PH23086 TIME: 10:48

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

DISCUSSION: M. VASQUEZ presented and summarized the investigative report that

pertained to this matter. As a companion to PHA-2015-0090; CVS Pharmacy 1874, MOR Neena Lukose PH23086 was deemed responsible for the ratio deficiencies found at that pharmacy, and as such the Board voted to take action.

ACTION: Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously by those present, to refer the matter to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter with a consent agreement Stayed Probation for Neena Lukose, PH23086, with terms to require her to attest to having read and understood 247 CMR, specifically sections 6, 8, 9, and 15, Board staff was also required to send an Advisory Letter on staffing ratios.

TOPIC IX
FILE REVIEW

2. SA-INV-7085 CVS Pharmacy #488 DS3157 TIME: 10:55

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

DISCUSSION: M. VASQUEZ presented and summarized the investigation report that pertained to these matters. Vasquez reported that CVS #488 submitted a “self-report” on the loss of #84 oxycodone 10 tablets.

Initially, it was thought that there may have been a dispensing error at the root of the matter, whereby a patient would have received more than the prescribed amount. However, patients were contacted and all indicated they received the correct amount, and security footage showed nothing to the contrary.

The MOR implemented a corrective action plan that involves double counting on all C-II prescriptions, going forward.

ACTION: Motion by C. BASILE, seconded by E. TAGLIERI, and voted unanimously by those present, to close the staff assignment with no discipline warranted since remediation was complete.

TOPIC IX
FILE REVIEW

3. SA-INV-7113; CVS Pharmacy #735 , DS2841 TIME: 10:55AM

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

DISCUSSION: M. VASQUEZ presented and summarized the investigative report that pertained to this matter. Evidence indicates that the licensee reported a loss of schedule II controlled substances that was discovered during the perpetual count. The license reported that their investigation was inconclusive and that patients receiving the medications had been contacted in an attempt to retrieve an over dispensing. Company policy and procedures were followed and an appropriate plan of correct was submitted to limit future occurrences.

ACTION: Motion by M. GODEK, seconded by C. BASILE and voted unanimously to close investigation SA-INV-7113 with no violation.

TOPIC IX
FILE REVIEW

4. PHA-2015-0109; CVS Pharmacy #2325, DS285 TIME: 10:57AM

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

DISCUSSION: M. VASQUEZ presented and summarized the investigative report that pertained to this matter. Evidence indicates that a complaint was opened as a result of repeat inspectional deficiencies

related to noncompliance with staffing ratios. It was also noted that during the investigation that the MOR was deficient one (1) continuing education credit.

ACTION: Motion by T.FENSKY, seconded by C. BASILE, and voted unanimously, to refer the matter to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for the reprimand of CVS Pharmacy's #2325 drugstore license and for board staff to provide a board advisory letter on staffing ratios.

TOPIC IX

FILE REVIEW

5. PHA-2015-0135; Heather Jackman, PH22199

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

DISCUSSION: M. VASQUEZ presented and summarized the investigative report that pertained to this matter. Evidence indicates that a complaint was opened as a result of repeat inspectional deficiencies related to noncompliance with staffing ratios that the MOR was found responsible for. It was also noted that during the investigation that the MOR was deficient one (1) continuing education credit.

ACTION: Motion by T.FENSKY, seconded by C. BASILE, and voted unanimously, to refer the matter to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter with a consent agreement for a non-disciplinary stayed probation with terms to include attest to the reading and understanding of 247 CMR sections 6, 8, 9,15, and provide proof of completion of three (3) contact hours of pharmacist continuing education hours over and above the twenty hours (20) required for renewal in 2015.

TOPIC IX.

FILE REVIEW

6.PHA-2015-0136; Samuels Pharmacy, DS15095 TIME: 11:01

DISCUSSION: M. VASQUEZ presented and summarized the investigative report that pertained to this matter. Evidence indicates that a complaint was opened as a result of inspectional deficiencies related to disrepair, sanitation, refrigeration, security, and lack of a CQI program. W. FRISCH noted that ownership has made strides to improve the physical plant and the MOR had submitted a satisfactory POC. W. FRISCH noted that a follow up inspection conducted in July of 2015 demonstrated substantial compliance. The board was concerned that if the store was not monitored closely that it could back slide. W. FRISCH noted that the store would be closely monitored and scheduled for a re-inspection in the near future.

ACTION: Motion by T.FENSKY, seconded by M. GODEK, and voted unanimously, to refer the matter to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter with a consent agreement for the reprimand of Samuels Pharmacy's drugstore license.

TOPIC IX.

FILE REVIEW

7. PHA-2015-0137; Peter Lyons, PH19225

DISCUSSION: M. VASQUEZ presented and summarized the investigative report that pertained to this matter. Evidence indicates that a complaint was opened as a result of inspectional deficiencies related to disrepair, sanitation, refrigeration, security, lack of a CQI program that the MOR was found to be responsible for. W. FRISCH noted that ownership has made strides to improve the physical plant and the MOR had submitted a satisfactory POC. W. FRISCH noted that a follow up inspection in July of 2015 demonstrated substantial compliance. The board was concerned that if the store was not monitored closely that it could back slide. W. FRISCH noted that the store would be closely monitored and scheduled for a re-inspection in the near future.

ACTION: Motion by T.FENSKY, seconded by M. GODEK, and voted unanimously, to refer the matter to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter with a consent agreement for the reprimand of Peter Lyons' pharmacist license conditioned on the prior receipt of attestation to reading 247 CMR sections 6,9,15, and the completion of two (2) contact hours of pharmacist continuing education in the area in pharmacy law that will be in addition to the requirement for pharmacist continuing education for during the renewal cycle.

**TITLE XI
FILE REVIEW**

8. SA-INV-6870; David Marsh, PH14819

DISCUSSION: M. VASQUEZ presented and summarized the investigative report that pertained to this matter. Evidence indicates that an investigation was opened due to a self-report of a deficiency of pharmacist continuing education requirement. M VASQUEZ noted that the licensee had submitted continuing education contact hours to remediate the deficiency.

ACTION: Motion by C. BASILE, seconded by A. STEIN, and voted unanimously to close investigation SA-INV-6870 with no discipline warranted remediation complete.

**TITLE XI
FILE REVIEW**

9. SA-INV-8326; Kevin O'Brien, PH17654 TIME: 11:10

DISCUSSION: M. VASQUEZ presented and summarized the investigative report that pertained to this matter. Evidence indicates that an investigation was opened due to a self-report of a deficiency in pharmacist continuing education requirement. M VASQUEZ noted that the licensee had submitted continuing education contact hours to remediate the deficiency.

ACTION: Motion by M. GODEK, seconded by C. BASILE, and voted unanimously to close investigation SA-INV-8326 with no discipline warranted remediation complete.

TOPIC XI

M.G.L. c112, 65C Session:

DISCUSSION: P. GANNON notifies audience that the board will meet in closed session for the remainder of the day.

ACTION: At 11:24AM motion by T.FENSKY, seconded by C. BASILE and voted unanimously to enter into M.G.L. c. 112, 65C session.

ACTION: At 11:53AM motion by T. FENSKY, seconded by C. BASILE and voted unanimously to exit M.G.L. c.112, 65C session

LUNCH 11:54AM to 12:59PM

**TOPIC X
EXECUTIVE SESSION**

DISCUSSION: P. GANNON called the session to order.

ACTION: At 12:59PM motion by, seconded by and voted unanimously by a roll call vote, P. GANNON; yes, E. TAGLIERI; yes, T. FENSKY; yes, C. BASILE; yes, M. GODEK; yes, G. CAVANAUGH; yes, S. CORNACCHIO; yes, K. CONLEY; yes, W. COX; yes, A. STEIN; yes, P. BOUVIER; yes.

SUSPEND EXECUTIVE SESSION

DISCUSSION: None

ACTION: At 1:07PM motion by T. FENSKY, seconded by A. STEIN , and voted unanimously by roll call vote to suspend Executive Session; P. GANNON; yes, E. TAGLIERI; yes, T. FENSKY; yes, C. BASILE; yes, M. GODEK; yes, G. CAVANAUGH; yes, S. CORNACCHIO; yes, K. CONLEY; yes, W. COX; yes, A. STEIN; yes, P. BOUVIER; yes.

TOPIC XI.

ADJUDICATORY SESSION:

DISCUSSION: P. GANNON called the session to order.

ACTION: At 1:08PM motion by M. GODEK, seconded by G. CAVANAUGH, and voted unanimously to enter into Adjudicatory Session.

TOPIC XII

M.G.L. c.112, 65C Session

DISCUSSION: P. GANNON called the session to order.

ACTION: At 1:33PM motion by E. TAGLIERI, seconded by P. BOUVIER to re-enter M.G.L. c 112, 65C Session.

TOPIC X

EXECUTIVE SESSION

DISCUSSION: P. GANNON called the session to order.

ACTION: At 2:19PM motion by E. TAGLIERI, seconded by P. GANNON and voted unanimously by roll call vote to re-enter Executive Session; P. GANNON; yes, E. TAGLIERI; yes, T. FENSKY; yes, C. BASILE; yes, M. GODEK; yes, G. CAVANAUGH; yes, S. CORNACCHIO; yes, K. CONLEY; yes, W. COX; yes, A. STEIN; yes, P. BOUVIER; yes.

TOPIC XIV

M.G. L. c112, 65C Session

DISCUSSION: P. GANNON called the session to order.

ACTION: At 2:28PM motion by E. TAGLIERI, seconded by C. BASILE, and voted unanimously to re-enter M.G.L. c 112, 65C Session.

TOPIC XII.

ADJOURNMENT

DISCUSSION: None

ACTION: At 3:10PM motion by T. FENSKY, seconded by A. STEIN, and voted unanimously to adjourn the meeting.

Exhibits used during the meeting

1. Draft Agenda for the General Session of the Regularly Scheduled Meeting November 3, 2015.
2. Draft General Session Minutes September 1, 2015.
3. Application for Expansion / Relocation of Animal Pharm DS3066
4. Application for Expansion / Relocation of Resident Care Pharmacy DS3264

5. Application for Expansion / Relocation of Century Pharmacy DS 89877
6. Application to Operate and Manage a New Community Drugstore, Nimble Pharmacy.
7. Report of Applications approved pursuant to licensure policy 13-01
8. Report from Probation Monitor
9. Draft proposed new regulation to 247 CMR 21.00: Outsourcing Facilities
10. Draft proposed new regulation to 247 CMR 21.00: Outsourcing Facilities with track changes
11. Draft proposed amendments to 247 CMR 11.00: Registration Under the Controlled Substances Act (M.G.L. c. 94C)
12. Draft proposed amendments to 247 CMR 11.00: Registration Under the Controlled Substances Act (M.G.L. c. 94C) with track changes
13. Draft proposed new regulation 247 CMR 17.00: Sterile Compounding
14. Draft proposed new regulation 247 CMR 17.00: Sterile Compounding with track changes.
15. Investigation report in the matter of CVS Pharmacy #1874, PHA-2015-0090
16. Investigation report in the matter of Neena Lukose, PHA-2015-0142.
17. Investigation report in the matter of CVS Pharmacy #488, SA-INV-7085.
18. Investigation report in the matter of CVS Pharmacy #734, SA-INV-7113.
19. Investigation report in the matter of CVS Pharmacy 2325, PHA-2015-0109.
20. Investigation report in the matter of Heather Jackman, PHA-2015-0135.
21. Investigation report in the matter of Samuels Pharmacy, PHA-2015-0136.
22. Investigation report in the matter of Peter Lyons, PHA-2015-0137.
23. Investigation report in the matter of David Marsh, SA-INV-6870.
24. Investigation report in the matter of Kevin O'Brien, SA-INV-8326.