

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

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

May 3, 2016
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

Agenda

Time	#	Item	Exhibits	Contact
8:30	I	CALL TO ORDER		E. Taglieri
8:35	II	APPROVAL OF AGENDA Introduction of Pharmacy Interns		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of April 5, 2016 Regular Session Minutes 		
8:45	IV	APPLICATIONS <ul style="list-style-type: none"> • Bouvier Pharmacy – Transfer of Ownership • Greater Lawrence Family Health Center-Transfer of Ownership • Shire US, Inc.- Wholesale Distributor • Anawan Pharmacy, LLC- New Community Pharmacy • Coram CVS/Specialty Infusion Services – Petition for Waiver • CVS/Specialty Infusion Services – Renovation/Expansion • Prescott Pharmacy – New Community Pharmacy 		
9:45	V	REPORTS <ul style="list-style-type: none"> • Applications approved pursuant to Licensure Policy 13-01 • Monthly Report from Probation 	Reports	R. Harris K. Fishman
9:50	VI	REGULATIONS <ul style="list-style-type: none"> • Proposed amendments; 247 CMR 4.00: Personal Registration Renewal; Continuing Education Requirement • Proposed new regulations, 247 CMR 19.00: Hazardous Drugs • Ch. 52 of the Acts of 2016 (Substance Use Rehabilitation Program) 		V. Berg W. Frisch M. Chan V. Berg

11:00	VII	<p>FILE REVIEW</p> <ol style="list-style-type: none"> 1. SA-INV-7661 CVS Pharmacy #1056, DS1646 2. SA-INV-7660 CVS Pharmacy #166, DS3449 3. SA-INV-7721 CVS Pharmacy #299, DS3596 4. PHA-2015-0173 CVS Pharmacy #0026, DS2912 5. SA-INV-8123 Winchendon Family Pharmacy, DS89843 6. PHA-2015-0073 Sullivan's Pharmacy, DS1243 7. SA-INV-8973 Greater Lawrence Health Center, DS89840 	
12:00		LUNCH BREAK	
1:00	VIII	<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 Good Moral Character as required for registration for pending applicants and a petition for reinstatement.</p>	CLOSED SESSION
2:00	IX	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)	CLOSED SESSION
2:10b	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**

May 3, 2016

Board Members Present

Edmund Taglieri Jr., R.Ph, MSM, NHA
President
Timothy Fensky, R.Ph, FACA
President –elect
Garrett Cavanaugh, R.Ph. (arrived 9:06am)
Karen Conley, RN, DNP
Ali Raja, MD, M.B.A., M.P.H.(arrived at 1:00)
Patrick Gannon, RPh, MS
Richard Tinsley, MBA, M.Ed.
Phillippe Bouvier, R.Ph.
Susan Cornacchio, JD
William Cox CPhT (arrived at 8:40)
Andrew Stein, Pharm D, R.Ph.

Board Members Not Present

Catherine Basile, Pharm D, R.Ph.
Michael Godek, R.Ph, Secretary

Board Staff Present

David Sencabaugh, RPh, Executive Director
William Frisch, Director of Pharmacy Compliance
Michelle Chan, R.Ph., Quality Assurance Pharmacist
Heather Engman, JD, MPH Board Counsel
Sam Leadholm, JD, Board Counsel
Richard Harris, Program Analyst
Monica Vasquez, CPhT, Compliance Officer
Julienne Tran, PharmD, RPh. Pharmacy Investigator
Christina Mogni, R. Ph., Pharmacy Investigator
Cheryl Latham, Pharm D., R.Ph., Senior Investigator
Greg Melton, JD, R.Ph., Pharmacy Investigator
Vita Palazzolo Berg, JD, Chief Board Counsel
Karen Fishman, Probation Monitor

TOPIC: I

CALL TO ORDER 8:32 AM

DISCUSSION: 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.

TOPIC II.

APPROVAL OF AGENDA

DISCUSSION: The open file review on Winchendon Family Pharmacy will be deferred.

ACTION:

Motion by P. GANNON, seconded by, K. CONLEY, and voted unanimously to approve the agenda (G. CAVANAUGH and A. RAJA had not yet arrived).

TOPIC III.

APPROVAL OF BOARD MINUTES

1. Draft April 5, 2016, Regular Session Minutes

DISCUSSION: None

ACTION:

Motion by P. BOUVIER, seconded by, W. COX, and voted to approve the minutes of the General Session from April 5, 2016, 6 yes, 2 (A. RAJA, G. CAVANAUGH) not present for vote, 2 absent, and 3 (P.GANNON, K. CONLEY, and R. TINSLEY) abstained, as they did not attend the 4/5/16 meeting.

TOPIC IV:

APPLICATIONS

TIME: 8:36-9:25AM

1. SHIRE – Wholesale Distributor

DISCUSSION: Shire was represented by Ms. Hadas Artzi. Originally, Shire had applied to be a Virtual Manufacturer, but this is not a license currently offered in MA. Since they do not take custody of any product in the State, they do not fall into our existing WD license category. After some discussion, Board Counsel H. ENGMAN stated that she needed more information on the Shire business model before making any recommendations to the Board about whether they should be licensed by the Board, and in what category.

ACTION: Motion by K. CONLEY, seconded by, R. TINSLEY, and voted unanimously in the affirmative to defer the application to the June 7, 2016 meeting.

2. BOUVIER PHARMACY Transfer of Ownership

RECUSAL: P. BOUVIER and S. CORNACCHIO recused and were not present during discussion or voting on this topic.

DISCUSSION: Bouvier Pharmacy was not represented in this matter. This was a simple transfer of ownership.

ACTION: Motion by R. TINSLEY, seconded by T. FENSKY, and voted unanimously to approve the transfer of stock ownership for Bouvier Pharmacy.

3. GREATER LAWRENCE FAMILY HEALTH CENTER Transfer of Ownership

DISCUSSION: Greater Lawrence Family Health Center (GLFHC) was represented by AVP Operations, Diane Martin. Ms. Martin explained that this clinic wants to open this pharmacy on site, similar to their other locations, where they can service their patients in a retail capacity. Director of Pharmacy Compliance W. FRISCH asked Ms. Martin to make sure BHCSQ is aware and in approval as well.

ACTION: Motion by R. TINSLEY, seconded by T. FENSKY, and voted unanimously to approve the transfer of ownership for Greater Lawrence Community Health Center from Progressive Pharmacy Solutions.

4. ANAWAN PHARMACY New Community Pharmacy

DISCUSSION: Anawan Pharmacy was represented by Eric Johnson (co-owner and proposed MOR) and Richard Ploude (co-owner and staff pharmacist). The two representatives answered all of the Board Member's questions, to their satisfaction.

ACTION: Motion by R. TINSLEY, seconded by W. COX, and voted unanimously to approve the application for Anawan Pharmacy, pending a successful Board of Pharmacy inspection.

CORAM/CVS Petition for Waiver

CORAM/CVS Renovation / Expansion

RECUSAL: S. CORNACCHIO recused and was not present during discussion or voting on this topic.

DISCUSSION: Coram/CVS was represented for both matters by MOR Shamir Patel, and Attorney Joseph Lavino. The Petition for Waiver regarding the regulation requiring a scale was requested because Coram has no need for one in this business model.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously to approve the petition for waiver.

DISCUSSION: Coram/CVS addressed the Board seeking approval for Phases II and III of their renovation/expansion plan. After questioning by the Board Members and a statement by W. FRISCH, who explained that he had undergone extensive discussion with CORAM/CVS regarding these matters, the Board moved to approve the process.

ACTION: Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously to approve the Phase II and Phase III renovation plans, pending successful inspections.

7. PRESCOTT PHARMACY New Community Pharmacy

DISCUSSION: Prescott Pharmacy was represented in this matter by proposed MOR Renee Collins, Consultant David Trinks, and Attorney Paul Garbarini. The three representatives answered all of the Board Member's questions regarding this Long Term Care Pharmacy, to their satisfaction.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously to approve the application for Prescott Pharmacy, pending successful inspection.

TOPIC V. REPORTS

Applications Approved Pursuant to Licensure Policy 13-01

DISCUSSION: R. HARRIS noted that during the past month there have been nineteen (19) change-of-managers, two (2) renovation/expansions, two (2) closings, eight (8) outsourcing facilities, and one (1) new community pharmacy since the last Board meeting.

ACTION: So noted

Report of activities Probation Monitor

DISCUSSION: D. SENCABAUGH, (for K. FISHMAN) provided the March 26, 2016 – April 26, 2016, Board of Pharmacy Statistics Report for the Probation monitor, which noted that: there are fifty-two (52) licensees on probation, twenty (20) satisfactorily completed probation, three (3) licensee did not cure within 30 days, five (5) given the opportunity to cure, and two (2) notices of further discipline.

ACTION: So noted

TOPIC VI

REGULATIONS

TIME: 9:35 am

247 CMR 4.00 Proposed Amendments to 247 CMR 4.00 Personal Registration/Renewal; CE

Presented by Vita Berg

DISCUSSION: Immunization CE's. suggested 1 CE for 2-yr cycle. Also, with CDTM R.Ph.-prescribing, R.Ph. needs additional CE's.

1st Vote: Vote to submit proposed changes highlighted in blue for executive order 562, promulgate, and file within a few weeks.

ACTION: At 9:37 am motion by P. GANNON, seconded by R. TINSLEY, and voted unanimously to approve the proposed amendments to 247 CMR 4.00

E. TAGLIERI: yes, T. FENSKY; yes, W. COX; yes, G. CAVANAUGH: yes, CORNACCHIO: yes, P. BOUVIER: yes, A. STEIN: yes, R. TINSLEY: yes, P. GANNON: yes, K. CONLEY; yes

2nd Vote: Since NC Dental ruling, to submit this change to the commissioner under executive order for approval, since it adds requirements that are recognized as having anti-competitive potential (individual must possess knowledge to be able to administer.)

ACTION: At 9:38 A. STEIN, seconded by R. TINSLEY, and voted unanimously to approve the proposed amendments to 247 CMR 4.00

E. TAGLIERI: yes, T. FENSKY; yes, W. COX; yes, G. CAVANAUGH: yes, CORNACCHIO: yes, P. BOUVIER: yes, A. STEIN: yes, R. TINSLEY: yes, P. GANNON: yes, K. CONLEY; yes

TOPIC VI **REGULATIONS** **TIME: 10:05 am**
247 CMR 19.00 **Proposed New Regulations-Hazardous Drugs** **TIME: 10:05**
Presented by: W. FRISCH, M. CHAN

DISCUSSION: W. Frisch led the discussion. Board members were informed the presentation will be a discussion of changes and no vote will be needed. W. Frisch also informed the Board there will be a meeting with T. FENSKY and A. STEIN for input, and to finalize the section 19. M. Chan captured all board member input in track changes displayed on the screen for board members and the audience to view. It was the consensus of the members that only highlighted sections and changes would be reviewed.

ACTION: None at this time.

TOPIC VI **Chapter 52 of the acts of 2016** **TIME: 9:39 am**
Presented by: Vita Berg

DISCUSSION: This is now the formal substance abuse rehabilitation program. Substance abuse issue is currently referred to MPRS; one concern of MPRS is that the program doesn't have free standing authority. The new statutory language uses the same model (with certain changes), as the Nursing Board. It is finally clear that this is for Pharmacists, Interns, and Technicians. The intended start up period will be June, 2016. There will be a full-time pharmacist coordinator of a Committee consisting of 7 members. Three (3) will constitute quorum. The Board will need to decide if they are expecting abstinence only, or will they allow therapy that includes the use of Suboxone or methadone, as example. Also the Board will need to decide how to handle non-compliance of program if allowed in the program. R. TINSLEY voiced concern all Boards will have different programs. V. BERG stated that the policies have to be implemented according to law.

ACTION: None at this time

TOPIC VII

FILE REVIEW

Case #1

SA-INV-7661 CVS Pharmacy #1056, DS1646

TIME: 10:47 am

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.

- OPP received a DEA 106 report regarding a loss of #1,116 alprazolam 1mg tablets at CVS Pharmacy #1056 located in Lowell, MA
- The form indicated the reason for the loss was unknown.
- Upon further investigation, it was discovered that an inaccurate count was provided for the initial inventory number used in the reconciliation.
- CVS's loss prevention has since concluded that there is no loss of Alprazolam 1mg at this store. They withdrew the DEA 106 form previously submitted and submitted a clarifying letter to the Board of Pharmacy and DEA on June 2, 2015 stating that no loss occurred.

ACTION: Motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously by those present, to CLOSE SA-INV-7661, no violation.

Case #2

SA-INV-7660

CVS Pharmacy #166, DS3449

TIME: 10:55 am

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.

- OPP received a DEA 106 report regarding a loss of #3,949 lorazepam 0.5mg tablets at CVS #166 in Worcester, MA.
- The form indicated the reason for the loss was unknown
- The drug was counted for a period of 10 weeks without a single tablet variance. The counting process revealed no variance and the DVR review showed no evidence of apparent diversion
- In the course of the investigation it was discovered that there was not an active loss of lorazepam.
- It was ultimately discovered that the original count used to reconcile Lorazepam 0.5 was an inaccurate count conducted during a change of manager inventory on 5/15/2014.
- This store does not have any active losses of Lorazepam.
- The initial reported loss of 3,949 tablets of Lorazepam 0.5mg is now adjusted to a positive 40 tablets after completing the reconciliation of this drug going back to the biennial inventory of 2013.
- The original DEA 106 submitted for this matter has been withdrawn, with a clarifying letter sent to both the DEA and the Massachusetts Board of Pharmacy.
- Extensive corrective action submitted.

ACTION: Motion by P. GANNON, seconded by K. CONLEY, and voted unanimously by those present, to CLOSE SA-INV-7660, no violation.

—

Case #3

SA-INV-7721

CVS Pharmacy #299, DS3596

TIME: 10:57 am

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.

- DEA 106 report regarding a loss of #5,039 Diazepam 5mg tablets at CVS Pharmacy #299 (DS3596 Issued on 06/06/2008, No prior complaints) in Worcester, MA.
- The form indicated the reason for the loss was unknown.
- The drug was counted for a period of 6 weeks without a single tablet variance. The store's DVR system was also analyzed and available pertinent footage was reviewed. The counting process revealed no variance and the DVR review showed no evidence of apparent diversion.
- Regional Diversion Manger Chris Ivanoski ran several reconciliations using two 2013 physical inventory counts and the 2014 physical inventory. The physical inventory conducted on 2/18/2013 encompassed the 2013 biennial and present and only showed a slight variance.
- This confirmed the Diazepam 5mg count on the 2013 biennial was a "bad" count. The discovery changed the count variance from #5,039 Diazepam 5mg tablets to 300 tablets.
- Extensive corrective action submitted.

ACTION: Motion by P. GANNON, seconded by W. COX, and voted unanimously by those present, to CLOSE SA-INV-7721, no violation.

Case #4

PHA-2015-0173

CVS Pharmacy #26, DS2912

TIME: 10:58 am

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

DISCUSSION: G. MELTON presented and summarized the investigation report that pertained to these matters.

- Routine inspection in July 2015 found inspectional deficiencies involving Supervisory Ratios, Refrigeration, and Immunizations.
- Follow up inspection in September 2015 found repeat inspectional deficiencies involving Supervisory Ratios, Refrigeration, and Immunizations.
- Additional inspection on November 2015 was satisfactory.
- Change in MOR prompted request for additional information from January 2016 to March 2016 to monitor status of pharmacy revealed inspectional deficiencies related original repeated deficiencies that opened the investigation.
- Repeat inspection in April 2016 was satisfactory.

ACTION: Motion by P. GANNON, seconded by R. TINSLEY, and voted unanimously by those present, to DISMISS PHA-2015-0173, no discipline warranted, remediation complete.

Case #5

SA-INV-8123 Winchendon Family Pharmacy, DS 89843

This case was deferred

Case #6

PHA-2015-0073

Sullivan's Pharmacy, DS1243

TIME: 11:01 am

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

DISCUSSION: C. LATHUM presented and summarized the investigation report that pertained to these matters.

- April 16, 2015 Site Visit (ISP-3094):
 - Registrant failed to comply with United States Pharmacopoeia (USP) Sterile Compounding Standards <797>, in violation of 247 CMR 9.01(3). Specifically, on January 22, 2015:
 - a. The clean room certification was conducted under “static” conditions with only the sampling technician present;
 - b. Environmental monitoring was conducted under “static” conditions;
 - c. Ante room did not meet requirement of 20 ACPH;
 - d. Differential pressure from the ante room to the pharmacy could not be measured under the door and reading was taken from magnehelic gauge;
 - e. Airflow measurements for the buffer room HEPA filter could not be accurately measured due to the placement of the Isolator directly in front of the filter;
 - f. HEPA filter air was introduced at the wall and not at the ceiling as required by USP <797>.
 - Plan of Correction to ISP-3094:
 - Voluntarily ceased sterile compounding on April 16, 2015. The Pharmacy's clean rooms were recertified and environmental monitoring was conducted under dynamic, operating conditions on April 17, 2015. The Pharmacy resumed compounding on April 24, 2015.
 - May 6, 2015 Inspection (ISP-3129): No deficiencies.
 - February 11, 2016 Inspection (ISP-4549): No deficiencies.
 - Additional POC (January 5, 2016 and March 11, 2016):
Pharmacy will cease using BSC and will exclusively use CACI. Pharmacy will submit plan for renovation to address air flow and location of HEPA filters and returns.
- ACTION: Motion by A. STEIN, seconded by P. BOUVIER, and voted unanimously by those present, to Dismiss PHA-2015-0073 with no discipline warranted (remediation complete).

Case #7

SA-INV-8973

Greater Lawrence Health Center, DS89840

TIME: 11:06 am

DISCUSSION: G. MELTON presented and summarized the investigation report that pertained to these matters.

- Two Trainees exceeded trainee hrs
- Performance improvement initiative by GLFHC to have cashiers become registered pharmacy technicians
- Technicians were coded as Technicians in Training resulting in miscommunications and miscalculations of hours.

ACTION: Motion by A. STEIN, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE SA-INV-8973, no discipline warranted (already remediated).

**TOPIC IX:
REGULATIONS**

TIME: 10:26am

247 CMR 19.00 New Section-Hazardous Medications

TOPIC VIII

EXECUTIVE SESSION:

DISCUSSION: None

ACTION: at 1:09PM motion by K. CONLEY, seconded by A. RAJA, and voted unanimously by roll call to enter into Executive Session: E. TAGLIERI; yes, T. FENSKY; yes, G. CAVANAUGH; yes, P. BOUVIER; yes, P. GANNON; yes, S. CORNACCHIO; yes, W. COX; yes, A. RAJA; yes, R. TINSLEY; yes. K. CONLEY; yes
A. STEIN was not in the room for the vote.

TOPIC XII.

ADJUDICATORY SESSION: at 11:09am, motion by P. GANNON, seconded by R. TINSLEY, and voted unanimously to enter Adjudicatory Session: E. TAGLIERI; yes, T. FENSKY; yes, G. CAVANAUGH; yes, P. BOUVIER; yes, P. GANNON; yes, S. CORNACCHIO; yes, W. COX; yes, A. RAJA; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN; yes

TOPIC XIII.

M.G.L. c. 65C Session

DISCUSSION: None

ACTION: At 11:12 am motion by R. TINSLEY, seconded by G. CAVANAUGH and voted unanimously to enter into M.G.L. c. 65C Session. E. TAGLIERI; yes, T. FENSKY; yes, G. CAVANAUGH; yes, P. BOUVIER; yes, P. GANNON; yes, S. CORNACCHIO; yes, W. COX; yes, A. RAJA; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes

TOPIC XIII.

M.G.L. c. 65C Session

DISCUSSION: None

ACTION: At 2:22 am motion by P. GANNON, seconded by A. STEIN and voted unanimously to enter into M.G.L. c. 65C Session again. E. TAGLIERI; yes, T. FENSKY; yes, G. CAVANAUGH; yes, P. BOUVIER; yes, P. GANNON; yes, S. CORNACCHIO; yes, W. COX; yes, A. RAJA; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes

TOPIC XIV.

ADJOURNMENT OF MEETING

DISCUSSION: NONE

ACTION: At 3:20PM motion by T.FENSKY, seconded by P.GANNON, and voted unanimously to adjourn the meeting.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda for the May 3, 2016, regularly scheduled meeting of the Board of Registration in Pharmacy.
2. Draft April 5, 2016 Open Session Minutes.
3. Application to Transfer Ownership Greater Lawrence Family Health Center
4. Application to Renovate and Expand, Coram/ CVS DS3601, Norwood, MA. and waive 247 CMR 6.01(3)
5. Application as Wholesale Distributor, Shire
6. Application to Transfer Ownership Bouvier Pharmacy
7. Application for New Community Pharmacy, Anawan Pharmacy
8. Application for New Community Pharmacy, Prescott Pharmacy
9. Report of Applications approved pursuant to licensure policy 13-01

10. Report from Probation Monitor 3/26/2016 – 4/26/2016
11. Draft proposed new regulation 247 CMR 4:00: Personal Registration Renewal; continuing education requirements
12. Draft proposed new regulation 247 CMR 19.00: Hazardous Drugs
13. Chapter 52 of 2016: An act relative to substance abuse, treatment, education and prevention
14. Investigation report in the matter of CVS 1056 DS1646, SA-INV-7661
15. Investigation report in the matter of CVS 166, DS3449, SA-INV-7660
16. Investigation report in the matter of CVS 299, DS3596, SA-INV-7721
17. Investigation report in the matter of CVS 026, DS2912, PHA-2015-0173
18. Investigation report in the matter of Sullivan’s Pharmacy, DS1243, PHA-2015-0073.
19. Investigation report in the matter of Greater Lawrence Health Center, DS89840, SA-INV-8973

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