

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

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

August 2, 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 <ul style="list-style-type: none"> • Intern Introductions 		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of June 7, 2016 Regular Session Minutes 		
8:45	IV	APPLICATIONS <ul style="list-style-type: none"> • Galaxy Pharmacy-Quincy- New Community Pharmacy • Coram/CVS Specialty – Renovation/Expansion • Fisher Healthcare/Fisher Scientific-Wholesale Distributor • US Pharmatrade – Wholesale Distributor • Shire – Wholesale Distributor 		
9:45	V	REPORTS <ul style="list-style-type: none"> • Applications approved pursuant to Licensure Policies 13-01 & 16-01 • Applications approved pursuant to Licensure Policy 14-01 • Monthly Report from Probation • Board Delegated Complaint Review Pursuant to Policy 14-02 	Reports	R. Harris K. Fishman
9:50	VI	FLEX <ul style="list-style-type: none"> • NABP District I & II Meeting 2016, Resolution Recommendations • Amendments to Policy 14-01 • Compounding of Commercially Available Drug Products • Discussion of Board Calendar for 2017 		D. Sencabaugh M. Chan
10:00	VII	REGULATORY REVIEW <ul style="list-style-type: none"> • 247 CMR 2.00: Definitions and Severability • 247 CMR 3.00: Pharmacist Licensure Requirements • 247 CMR 6.00: Licensure of Pharmacies • 247 CMR 8.00: Pharmacy Interns and Technicians • 247 CMR 10.00: Investigations, Complaints and Board Actions • 247 CMR 13.00: Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies • 247 CMR 14.00: Petition for Waiver • 247 CMP 16.00: Collaborative Drug Therapy Management 		V. Berg

11:30	VIII	REGULATIONS <ul style="list-style-type: none"> • 247 CMR 19.00: Hazardous Medications 	W. Frisch M. Chan
12:00		LUNCH BREAK	
1:00	X	FILE REVIEW <ol style="list-style-type: none"> 1. PHA-2016-0043, Maxim Pharmacy, DS3425 2. PHA-2016-0044, Lanvy Vu, PH235417 3. PHA-2016-0007, Walgreens Pharmacy #3337, DS2626 4. PHA-1016-0045, Prerana Patel, PH232475 5. SA-INV-8724, Walgreens Pharmacy #9477, DS89668 6. SA-INV-9336, CVS Pharmacy #1972, DS2498, 7. SA-INV-9418, CVS #166, DS3449 8. SA-INV-9334, Rite Aid #10120, DS3249, 9. SA-INV-8994, Injured Workers Pharmacy, DS89727 10. SA-INV-8903, Stop and Shop Pharmacy #036, DS2360 11. SA-INV-8990, Sullivan's Pharmacy, DS1243 12. SA-INV-8899, St. George Pharmacy, DS90034 	
2:00	XI	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.	CLOSED SESSION
3:00	XII	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION
5:00	XIII	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

August 2, 2016

Board Members Present

Edmund Taglieri Jr., R.Ph, MSM, NHA , President
Timothy Fensky, R.Ph, FACA
President –elect
Michael Godek, R.Ph, Secretary
Phillippe Bouvier, R.Ph.
Karen Conley, RN, DNP
Ali Raja, MD, M.B.A., M.P.H.
Richard Tinsley, MBA, M.Ed. (arrived at 9:02)
Catherine Basile, Pharm D, R.Ph.
Susan Cornacchio, JD
William Cox CPhT (arrived at 8:37)
Andrew Stein, Pharm D, R.Ph.

Board Members Not Present

Patrick Gannon, RPh, MS
Garrett Cavanaugh, R.Ph.

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Vasquez, CPhT, Associate Executive Director
William Frisch, Director of Pharmacy Compliance
Michelle Chan, R.Ph., Quality Assurance Pharmacist
Heather Engman, JD, MPH Board Counsel
Joanne Trifone, R.Ph., Director of Pharmacy Investigations
Richard Harris, Program Analyst
Julienne Tran, PharmD, RPh. Pharmacy Investigator
Greg Melton, JD, R.Ph., Pharmacy Investigator
Vita Palazzolo Berg, JD, Chief Board Counsel
Joanne Trifone, R.Ph. Director of Pharmacy Investigations
Joe Santoro, R.Ph. Contract Investigator
Kimberly Morton, CPhT, Compliance Officer

TOPIC I.

CALL TO ORDER 8:36 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: Section VI, Amendments to policy 1401 was deferred. Section IX, Staff Ratio Advisory was deferred, and in Section X (Open File) case #12 St. George Pharmacy was deferred.

ACTION:

Motion by W. COX, seconded by M. GODEK, and voted unanimously to approve the agenda (R. TINSLEY had not yet arrived).

Executive Director D. SENCABAUGH introduced APPE students M. NGUYEN, and B. PUN, and Compliance Officer K. MORTON.

TOPIC III.

APPROVAL OF BOARD MINUTES

1. Draft June 7, 2016, Regular Session Minutes

DISCUSSION: None

ACTION:

Motion by M. GODEK, seconded by C. BASILE, and voted unanimously to approve the minutes of the Regular Session from June 7, 2016 (R. TINSLEY had not yet arrived).

P. BOUVIER abstained.

TOPIC IV:

APPLICATIONS

TIME: 8:42-9:50AM

1. Galaxy Pharmacy, Quincy – New Community Pharmacy

RECUSAL: M. GODEK recused himself and was not present during the discussion or vote on this matter.

DISCUSSION: Galaxy Pharmacy was represented by Mr. Kevin Nguyen, Owner/R.Ph. and Mr. Andy Truong, proposed MOR. The representatives answered the Board Member’s questions successfully. W. FRISCH recommended that the pharmacists read draft 247 CMR section 9 (on BOP Website).

ACTION: Motion by K. CONLEY, seconded by, C. BASILE, and voted unanimously in the affirmative to approve the application for a new community pharmacy for Galaxy Pharmacy in Quincy, MA pending correction to the attestation to reflect that they do not currently have licenses in other States, add “moderate” to the type of non-sterile compounding they will be performing, and pending a successful inspection.

2. CORAM / CVS Specialty Renovation/Expansion

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

DISCUSSION: Coram/CVS of Norwood, MA, was represented by Shamir Patel, MOR. Mr. Patel answered the Board’s questions regarding Phase IV of Coram’s clean room renovation plan. Issues regarding environmental monitoring frequency, pass-throughs (a waiver may be necessary), continued use of the temporary set-up beyond what the Board had originally approved, and other issues were addressed to the Board’s satisfaction. Three Action steps were put to a vote:

ACTION 1: Motion by A. STEIN, seconded by T. FENSKY, and voted unanimously in the affirmative to approve Phase IV of Coram’s renovation and expansion plan, pending approval by the Board of the HVAC system, and a successful inspection.

ACTION 2: Motion by T. FENSKY, second by A. STEIN, and voted in the affirmative by all present (Cornacchio recused) except M.GODEK, who OPPOSED, to require environmental testing weekly for the next 4 weeks, then monthly if the weekly tests are below action levels.

ACTION 3: Motion by K. CONLEY, second by A. STEIN and voted unanimously to keep the modular set-up through Phase IV completion.

3. FISHER HEALTHCARE/FISHER SCIENTIFIC Wholesale Distributor

RECUSAL: None

DISCUSSION: Fisher was represented by Steven Bates, Director of Regulatory Affairs. Fisher distributes sterile water for injection for biologic use. Mr. Bates answered questions to the Board’s satisfaction

ACTION: Motion by S. CORNACCHIO, seconded by C. BASILE, and voted unanimously by those present to approve Fisher Healthcare of Agawam, MA’s application as a Wholesale Distributor, pending successful inspection.

4. US PHARMATRADE

Wholesale Distributor

RECUSAL: None

DISCUSSION: Pharmatrade, located in Burlington, MA, was represented by owner Jalal Abbaspour. Pharmatrade is a start-up business, with no existing clients, looking to export drugs from the United States to other countries, processed through a combination office/warehouse in Burlington, MA. Board members and Board staff were left unsure of necessary details to vote on whether to approve the license application, and asked Mr. Abbaspour to provide a more detailed business model, and the matter would be taken up at the next meeting.

ACTION: Motion by T. FENSKY second by M. GODEK, and voted unanimously by those present to defer the matter of Pharmatrade's application as a Wholesale Distributor until next Board meeting, or until a more detailed business model is provided by the owner.

5. SHIRE

Wholesale Distributor

RECUSAL: None

DISCUSSION: Shire, located in Lexington, MA, presented before the Board on June 7, 2016, and was asked to provide a more detailed business model. Since no product will pass through their facility, they are a "virtual wholesaler". Board Counsel H. ENGMAN has since had discussion with Shire, who provided the requested business model, and feels that a reasonable interpretation gives us the authority to approve the license

ACTION: Motion by R. TINSLEY second by C. BASILE, and voted unanimously by those present to approve Shire's application as a Wholesale Distributor, pending correction of their address on their application to 95 Hayden Ave in Lexington, amending the drug selection (Vyvanse), and pending a 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 forty-one (41) change-of-managers, and six (6) renovation/expansions, and two (2) closings.

Applications Approved Pursuant to Licensure Policy 14-01

Four (4) Pharmacy Technicians, three (3) Pharmacists, and one (1) pharmacist were approved for licensure pursuant to Licensure Policy 14-01

Board Delegated Review Pursuant to BDCR Policy

There were 2 Board Delegated Review cases heard on July 28, both involving self-reports of CE deficiencies. Both were satisfactorily remediated and the Staff Assignments were closed with no discipline warranted. The Board Delegated Review session was attended by E. TAGLIERI as the Board Member, H. ENGMAN as Board Counsel, W. FRISCH as Director of Pharmacy Compliance, and Executive Director SENCABAUGH.

ACTION: So noted

Report of activities Probation Monitor

DISCUSSION: D. SENCABAUGH, (for K. FISHMAN) provided the May 27, 2016 – July 25, 2016, Board of Pharmacy Statistics Report for the Probation monitor, which noted that: there are fifty-three (53) licensees on probation, twenty-five (25) 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 **FLEX SESSION**

TOPIC VI (taken out of order) **FLEX SESSION** **Time: 10:35 am**

Discussion: Resolutions due to NABP 20 days prior to NABP meeting which will be before next Board meeting 8/30/16.

Board members made a motion to submit the following 3 resolutions at the NABP District I and District II Meeting 2016:

- Veterinary Compounding both patient specific and for Office Use
- Medication Disposal Programs (best practices)
- Packaging Modelssafe packaging for single dose and multi-dose, labeling, co-mingling

ACTION: Motion by A STEIN second by P. BOUVIER, and voted unanimously by those present to approve the topics listed to move forward to the NABP/AACP

District I + II meeting in September.

TOPIC VI **FLEX SESSION** **Time: 10:45 am**

Memorandum - Compounding of Commercially Available Drug Products

Discussion: Board Quality Assurance Pharmacy Michelle Chan read the proposed memorandum to Board members.

ACTION: Motion by K. CONLEY second by C. BASILE, and voted unanimously by those present to approve the memo, and to post the memo on our website, and to send it to our distribution list recipients.

TOPIC VI **FLEX SESSION** **Time: 10:50 am**

Discussion of Board Calendar 2017 (Thursdays?)

Presented by Rick Harris

- Advantage Packets
- Advantage Posting
- Advantage fixing last minute issues

Discussion:

Board members had a concern about when the packets would be delivered. Board staff stated no change in the mailing date of packets (i.e. members would have packet prior to weekend). 2017 meeting schedule will be presented at next Board meeting.

NO VOTE NECESSARY

TOPIC VII **REGULATIONS** **TIME: 10:06 am**

TOPIC VII: (taken out-of-order)

REGULATIONS

Presented by V. BERG

V.BERG presented to the board the proposed revisions of regulations in accordance with Executive Order 562 (EO562). The proposed revisions were reviewed by the Department of Public Health (DPH), the Executive Office of Health and Human Service (EHS) and Executive Office of Administration and Finance (ANF). At each stage of review, further edits to the proposed revisions were added. During May and June 2016, ANF approved the proposed revisions as edited through the review process. V. BERG began the discussion by mentioning that 247 CMR 5.00 and 247 CMR 12.00 are to be rescinded. 247 CMR 7.00 was not reviewed because it has been voted to remain as is.

247 CMR 2.00 Definitions
Presented by V. BERG

TIME: 10:10am

V. BERG noted grammatical and stylistic changes throughout. Definitions regarding to nuclear pharmacy are to remain in section 13. The definition for “Good Standing” was clarified to identify the types of license statuses that would not be considered in good standing. The definition of “outsourcing facility” mirrors the definition provided by statute M.G.L. c. 112, § 36 E. Definition of MassHealth was amended to support 16.02(1)(f)3. Severability provisions were inserted in regulations for all boards in the division.

ACTION: Motion by K. CONLEY, seconded by M. GODEK, and voted unanimously by those present to APPROVE the revisions of the regulation and authorize Board staff to publish the proposed revisions for public comment in accordance with M.G.L. c. 30A and schedule a public hearing.

247 CMR 3.00 Personal Registration Requirements
Presented by V. BERG

TIME: 10:11am

V. BERG noted grammatical and stylistic changes throughout. The term “license” is substituted for “registration” for consistency throughout the board’s own regulations and across the division.

ACTION: Motion by M. GODEK, seconded by C. BASILE, and voted unanimously by those present to APPROVE the revisions of the regulation and authorize Board staff to publish the proposed revisions for public comment in accordance with M.G.L. c. 30A and schedule a public hearing.

247 CMR 6.00 Registration, Management and Operation of a Pharmacy or Pharmacy Department
Presented by V. BERG

TIME: 10:15am

V. BERG noted grammatical and stylistic changes throughout. Edits of 6.13(3) are intended to clarify. K. CONLEY suggests to strike “by mail” out in 6.13(3) and that further distinction be made between transferring of prescriptions between pharmacies and notifying patients.

ACTION: Motion by T. FENSKY, seconded by C. BASILE, and voted unanimously by those present to DEFER the revisions of the regulation.

247 CMR 8.00 Pharmacy Interns and Technicians

TIME: 10:17am

Presented by V. BERG

V. BERG noted grammatical and stylistic changes throughout. The term “license” is substituted for “registration” for consistency throughout the board’s own regulations and across the division. V. BERG suggests an edit substituting “intern” with “technician” at 8.01(15) be rejected and be reversed back to “technician”.

ACTION: Motion by M. GODEK, seconded by T. FENSKY, and voted unanimously by those present to APPROVE the revisions of the regulation and authorize Board staff to publish the proposed revisions for public comment in accordance with M.G.L. c. 30A and schedule a public hearing after reverting “intern” back to “technician” at 8.01 (15).

247 CMR 10.00 Disciplinary Proceedings

TIME: 10:20am

Presented by V. BERG

V. BERG noted grammatical and stylistic changes throughout. 10.04(8) adds a provision that nothing in 9.00 limits other governmental agencies from enforcing their laws against a licensee. 10.06 (3) adds language setting a 30 day limitation period on how long another Board member or staff member make act on behalf of the Board Chair or Executive Director due to incapacity, without further direction from the Board. The changes correspond to changes made throughout all boards' regulations as this is intended to be a uniform section across the division.

ACTION: Motion by M. GODEK, seconded by T. FENSKY, and voted unanimously by those present to APPROVE the revisions of the regulation and authorize Board staff to publish the proposed revisions for public comment in accordance with M.G.L. c. 30A and schedule a public hearing.

247 CMR 13.00 Registration Requirements and Minimal Professional Standards for Nuclear Pharmacies
Presented by V. BERG TIME: 10:25am

V. BERG noted grammatical and stylistic changes throughout. The term "license" is substituted for "permit" for consistency throughout the board's own regulations and across the division. 13.03(2) combines all items required to be on a nuclear pharmacy applicant's premises. 13.03(7) specifies that nuclear pharmacies must comply with regulations and guidance of the United States Nuclear Regulatory Commission and the United States Food and Drug Administration.

ACTION: Motion by C. BASILE, seconded by T. FENSKY, and voted unanimously by those present to APPROVE the revisions of the regulation and authorize Board staff to publish the proposed revisions for public comment in accordance with M.G.L. c. 30A and schedule a public hearing.

247 CMR 14.00 Petition for Waiver TIME: 10:26am Presented by V. BERG

V. BERG noted grammatical and stylistic changes throughout.

ACTION: Motion by K. CONLEY, seconded by C. BASILE, and voted unanimously by those present to APPROVE the revisions of the regulation and authorize Board staff to publish the proposed revisions for public comment in accordance with M.G.L. c. 30A and schedule a public hearing.

247 CMR 16.00 Collaborative Drug Therapy Management TIME: 10:27am

Presented by V. BERG

V. BERG notes references to "continuing education units" are eliminated or simplified to "continuing education" for consistency with 247 CMR 4.00.

ACTION: Motion by C. BASILE, seconded by W. COX, and voted unanimously by those present to APPROVE the revisions of the regulation and authorize Board staff to publish the proposed revisions for public comment in accordance with M.G.L. c. 30A and schedule a public hearing.

247 CMR 19.00 Hazardous Medications TIME: 10:54am
Presented by W. FRISCH and M. CHAN

W. FRISCH states that he will not be seeking a vote by the Board today but only seeks guidance from the Board regarding 247 CMR 19.00. A draft is expected to be voted on for the next Board meeting. Proposed changes include: A clarification of continuity of care in the case of power outage without a generator; the addition of a section that defines "non-shedding" to be similar to 247 CMR 17. 19.05(17) add a requirement of negative compounding rooms built after 2018 to be a minimum of 725 sq ft. 19.07(11) address redundancy with stating 247 CMR 17. 19.07(18) "prohibited" proposed to be changed to "unless otherwise stated by the Board... opportunity to waiver". 19.09(15) remove "closest sink". 19.10 (11) addressing decontamination after any "interruption of power".

ACTION: NONE TAKEN.

TOPIC: X FILE REVIEW

I. Open File Review Cases 1-11

I. Open File Review

Case #1

PHA-2016-0043

Maxim Pharmacy, DS3425

TIME: 11:13 am

RECUSAL: N/A

DISCUSSION: G. MELTON presented and summarized the investigation report:

- Pharmacy had a repeated inspectional deficiency on August 10, 2015 and December 21, 2015 due to problems with immunizations and improper refrigeration.
- August 12, 2015 inspection several out of range temperatures below 36 affecting 19 products. Pharmacy called the manufacturers for recommendations on product viability. Four products were destroyed. Purchased new refrigerator and 2 electronic thermometers as part of the plan of correction.
- December 21, 2015 – Log for only 1 of 2 refrigerators. Immunizations, insulin, ophthalmic, and other products were affected. 222 patients and 60 providers were required to be contacted with potential problems with efficacy. No harm reported at this time but requires monitoring for vaccine failures, etc.
- Former MOR Vu has left the company and currently works in California
- Retail Compliance Inspection (ISP-4978) was deemed satisfactory on 3-30-16

ACTION: Motion by C. BASILE, seconded by M. GODEK, 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 by a consent agreement for REPRIMAND.

Case #2

PHA-2016-0044

Lanvy Vu, PH235417

TIME: 11:13 am

RECUSAL: N/A

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

- Pharmacy had a repeated inspectional deficiency on August 10, 2015 and December 21, 2015 due to problems with immunizations and improper refrigeration.
- August 12, 2015 inspection several out of range temperatures below 36 degrees affecting 19 products. Pharmacy called the manufacturers for recommendations on product viability. Four products were destroyed. Purchased new refrigerator and 2 electronic thermometers as part of the plan of correction.
- December 21, 2015 – Log for only 1 of 2 refrigerators. Immunizations, insulin, ophthalmic, and other products were affected. 222 patients and 60 providers were required to be contacted with potential problems with efficacy. No harm reported at this time but requires monitoring for vaccine failures, etc.
- Former MOR Vu has left the company and currently works in California
- Retail Compliance Inspection (ISP-4978) was deemed satisfactory on 3-30-16

ACTION: Motion by C. BASILE, seconded by M. GODEK, 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 by a consent agreement for REPRIMAND.

Case #3

PHA-2016-0007

Walgreens Pharmacy #3337, DS2626

TIME: 11:21 am

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

DISCUSSION: J. TRAN presented and summarized the investigation report that pertained to these matters.

- Pharmacy had inspectional deficiencies on August 13, 2015 and November 9, 2015 due to improper pharmacist support staff ratios, emergency CII prescriptions without a hard copy and unsanitary conditions. Pharmacy support staff being out of ratio was repeated.
- It appeared that the pharmacy had approximately 69 hours of non-compliance on 39 separate days.
- MOR Patel stated that in May 2015, 3 pharmacy technicians resigned and going forward, she now has 4 certified pharmacy technicians, 2 registered technicians and 3 pharmacy technician trainees. Two of the trainees are in the process of becoming registered with one going to classes to be certified.

• Investigators Murray and Tran conducted a retail compliance inspection (ISP-4896) on 4/14/16 with no deficiencies noted.

ACTION: Motion by T. FENSKY, seconded by C. BASILE 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 by a consent agreement for REPRIMAND.

Case #4

PHA-1016-0045

Prerana Patel, PH232475

TIME: 11:21 am

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

DISCUSSION: J. TRAN presented and summarized the investigation report that pertained to these matters.

- Pharmacy had inspectional deficiencies on August 13, 2015 and November 9, 2015 due to improper pharmacist support staff ratios, emergency CII prescriptions without a hard copy and unsanitary conditions. Pharmacy support staff being out of ratio was repeated.
- It appeared that the pharmacy had approximately 69 hours of non-compliance on 39 separate days.
- MOR Patel stated that in May 2015, 3 pharmacy technicians resigned and going forward, she now has 4 certified pharmacy technicians, 2 registered technicians and 3 pharmacy technician trainees. Two of the trainees are in the process of becoming registered with one going to classes to be certified.
- Investigators Murray and Tran conducted a retail compliance inspection (ISP-4896) on 4/14/16 with no deficiencies noted.

ACTION: Motion by T. FENSKY, seconded by C. BASILE 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 by a consent agreement for REPRIMAND with reading and attesting to reviewing 247 CMR 6, 8, 9, and 15.

Case #5

SA-INV-8724

Walgreens Pharmacy #9477, DS89668

TIME: 11:24 am

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

DISCUSSION: J. TRAN presented and summarized the investigation report that pertained to these matters.

- The Office of Public Protection received a submission of a DEA 106 form that they had a loss of #79 oxycodone 5mg tablets at Walgreens Pharmacy #9477.
- MOR indicated the loss oxycodone 5mg #79 tablets was discovered on a weekly perpetual inventory.
- Contributing factors may include handling of multiple controlled and returning products into the safe after use. The 79 tablet variance of oxycodone 5mg tablets represented a 0.81% loss of inventory.

Remediation: MOR Walgreen's policies were reviewed.

- The Pharmacist on Duty given a final written warning for poor handling of the controlled medications. Security camera was moved to cover the controlled substance cabinet.
- Protocols that all controlled medications need to be returned back to the safe upon usage was reinforced.
- Additionally, remaining tablets within bottle had to be counted and recorded on the outside of all controlled medication bottles once used.
- Investigator Horn conducted a retail compliance inspection (ISP-5665) on July 14, 2016 with no deficiencies noted.

ACTION: Motion by C. BASILE, seconded by K. CONLEY, and voted unanimously by those present, to CLOSE SA-INV-8724, with no discipline warranted, remediation complete.

Case #6

SA-INV-9336

CVS Pharmacy #1972, DS2498

TIME: 11:30 am

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

DISCUSSION: M. NGUYEN presented and summarized the investigation report that pertained to these matters.

- Unknown Loss of #1104 Diazepam 5mg tablets.
- CVS Loss Prevention completed investigation with negative results for diversion.

ACTION: Motion by M. GODEK, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE SA-INV-9336, with no discipline warranted, remediation complete.

Case #7

SA-INV-9418

CVS Pharmacy #166, DS3449

TIME: 11:34 am

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

DISCUSSION: J. SANTORO presented and summarized the investigation report that pertained to these matters.

- Office of Public Protection received notification that CVS #166 had a loss of #779 lorazepam 0.5mg tablets. Representing approximately 0.86% loss of inventory. The loss was discovered during periodic review of controlled substance reconciliation reports. The CVS Loss Prevention Team opened an investigation into the matter and the drug was counted daily and reconciled weekly for a period of 4 weeks.
- Video footage revealed no evidence of suspicious behavior or breach in P&P. Stores ordering and inventory process were reviewed for indications of diversion (excessive ordering, inventory adjustments, etc)
- The plan of corrective action indicated that the MOR will monitor Balance on Hand (BOH) modification reports, ordering, and cycle count activity in sufficient detail to quickly identify and prevent drug count discrepancies or diversion. This incident as well as baseline loss prevention procedures were reviewed with staff.

ACTION: Motion by C. BASILE, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE SA-INV-9418, with no discipline warranted, remediation complete.

Case #8

SA-INV-9334

Rite Aid #10120, DS3249

TIME: 11:36 am

RECUSAL: N/A

DISCUSSION: J. SANTORO presented and summarized the investigation report that pertained to these matters.

- The Office of Public Protection received a report of an unknown loss of 504 alprazolam 1mg tablets representing approximately 4.1% of yearly total.
- Asset Protection District Manager conducted interviews with the entire pharmacy staff. After interviewing all staff, any suspicions of diversion were ruled out and concluded that 500 tabs may have been thrown into trash.
- The plan of corrective action indicated that cameras were installed, and after the initial loss, there were no additional losses. Technicians were questioned on the procedures for checking in orders and dispensing medications. Actions were taken to lock up all doses of alprazolam and have a periodic count along with a reduction of inventory amounts of controlled substances for easier handling, counting, and detection.

ACTION: Motion by C. BASILE, seconded by K. CONLEY, and voted unanimously by those present, to CLOSE SA-INV-9334, with no discipline warranted, remediation complete.

Case #9

SA-INV-8994

Injured Workers Pharmacy, DS89727

TIME: 11:40 am

RECUSAL: W. FRISCH and K.CONLEY recused and were not present for the discussion or vote on this matter.

DISCUSSION: J. SANTORO presented and summarized the investigation report that pertained to these matters.

- The Office of Public Protection received notification from Injured Workers Pharmacy within the mandated 7 days for disciplinary action and proposed settlement agreement from the state of Hawaii. This was a result of their failure to report disciplinary action against them from other states (Colorado, Alabama and Louisiana) in 2011 within the required 30 days.
 - Board requested additional information regarding the disciplinary action taken against Injured Workers Pharmacy in 2011.
 - The plan of corrective action indicated that an Excel spreadsheet was developed to record the expiration dates of state licenses and prescription monitoring renewals. Injured Workers Pharmacy will apply for licenses and renewals at least 60 days in advance. Injured Workers Pharmacy Officers and Pharmacist-in-Charge will receive a weekly license update report. Two additional attorneys and a paralegal were hired to assist and monitor license and reporting process.
- ACTION: Motion by R. TINSLEY, seconded by C. BASILE, and voted unanimously by those present, to CLOSE SA-INV-8994, no violation.

Case #10

SA-INV-8903

Stop & Shop Pharmacy #036, DS2360 TIME: 11:42 am

RECUSAL: N/A

DISCUSSION: J. SANTORO presented and summarized the investigation report that pertained to these matters.

- The Office of Public Protection received a report of an unknown loss of #100 oxycodone 10mg tablets during routine weekly inventory. An investigation with a thorough search and review of video footage revealed no suspicious activity, evidence of diversion or violations of policy. Attention was given to an invoice for oxycodone 10mg 4x100 received prior to the loss.
- The plan of corrective action indicated that policy and procedures related to controlled substances inventory and receiving were discussed with the entire staff. A designated and contained area was developed for the receiving area, free of clutter and distractions. A three month reconciliation of DEA 222 forms against the perpetual inventory was conducted and revealed no further discrepancies.

ACTION: Motion by A. STEIN, seconded by P. BOUVIER, and voted unanimously by those present, to CLOSE SA-INV-8903, with no discipline warranted, remediation complete.

Case #11

SA-INV-8990

Sullivan's Healthcare, DS3335

TIME: 11:27 am

RECUSAL: M. GODEK, T. FENSKY, and R. TINSLEY recused and were not present for the discussion or vote on this matter.

DISCUSSION: G. MELTON presented and summarized the investigation report that pertained to these matters. Above action level environmental monitoring:

- 1 Actionable Result: ISO Class 8 Air Sampling
- 1 cfu/400mL (2.5 cfu/m³) Trichophyton (fungal) sp. in ante room (sample code A6)

January 19, 2016 – January 28, 2016

- Remedial cleaning was performed
- Ante Room Retest samples collected on January 20, 2016
- All Beyond Use Dates (BUD) were lowered from 14 days to 5 days
- Compounding Aseptic Containment Isolator (CACI) only was utilized for preparing Compounded Sterile Products (CSP)

January 28, 2016

- CACI only was utilized for preparing CSP
- Received results indicating Test Report (Ante Room Retest) for sample date January 20, 2016 within USP action levels BUD returned to 14 days and continue to only utilize CACI under negative pressure for preparing CSP

ACTION: Motion by P. BOUVIER, seconded by C. BASILE, and voted unanimously by those present, to CLOSE SA-INV-8990, no violation.

TOPIC XI

EXECUTIVE SESSION

DISCUSSION: None

ACTION: At 2:00 pm motion by T. FENSKY, seconded by W. COX and voted unanimously by roll call to enter into Executive Session. E. TAGLIERI; yes,

T. FENSKY; yes, P. BOUVIER; yes, C. BASILE; yes, S. CORNACCHIO; yes,
W. COX; yes, A. RAJA; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes
M. GODEK: yes

At 2:47 pm motion by C. BASILE seconded by M.GODEK, and voted unanimously by roll call to adjourn Executive session. E. TAGLIERI; yes,

T. FENSKY; yes, C. BASILE; yes, P. BOUVIER; yes, S. CORNACCHIO; yes,
W. COX; yes, A. RAJA; yes, R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes M. GODEK: yes

TOPIC XII.

M.G.L. c. 65C Session

DISCUSSION: None

ACTION: At 1:10 pm motion by A. STEIN, seconded by C. BASILE and voted unanimously to enter into M.G.L. c. 65C Session. E. TAGLIERI; yes,

T. FENSKY; yes, P. BOUVIER; yes, C. BASILE; yes, S. CORNACCHIO; yes,
W. COX; yes, , R. TINSLEY; yes. K. CONLEY; yes, A. STEIN: yes M. GODEK: yes
A. RAJA was not in the room at the time.

At 2:02 PM motion by C. BASILE, seconded by M. GODEK, and voted unanimously to adjourn M.G.L. 65 C.

TOPIC XIII.

ADJOURNMENT OF MEETING

DISCUSSION: NONE

ACTION: At 2:48 pm motion by P. BOUVIER, seconded by R. TINSLEY, and voted unanimously to adjourn the meeting.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda for the August 2, 2016, regularly scheduled meeting of the Board of Registration in Pharmacy.
2. Draft June 7, 2016 Open Session Minutes.
3. Application for New Community Pharmacy Galaxy Pharmacy (Quincy)
4. Application for Renovation and Expansion Coram/CVS HealthCare Norwood
5. Application for Fisher Scientific - Wholesale Distributor
6. Application for US Pharmatrade – Wholesale Distributor
7. Application for Shire – Wholesale Distributor
8. Report of Applications approved pursuant to licensure policy 13-01
9. Report of Application information pursuant to licensure policy 16-01
10. Report from Probation Monitor 5/27/2016 – 7/25/2016
11. Board Delegated Compliant Review report 7/28/2016
12. Applications approved to Licensure Policy 14-01
13. Draft Board memorandum on Compounding Commercially Available Products
14. Draft proposed new regulation 247 CMR 19.00: Hazardous Drugs
15. Memo from Board Counsel on Regulatory Review: 247 CMR, sections 2.00, 3.00, 6.00, 8.00, 10.00, 13.00, 14.00, and 16.00
16. Investigation report in the matter of Maxim Pharmacy, DS3425, PHA-2016-0043
17. Investigation report in the matter of Lanvy Vu, PH235417, PHA-2016-0044
18. Investigation report in the matter of Walgreens Pharmacy, DS2626, PHA-2016-0007
19. Investigation report in the matter of Prerana Patel, PH232475, PHA-2016-0045
20. Investigation report in the matter of Walgreens Pharmacy, DS89668, SA-INV-8724
21. Investigation report in the matter of CVS Pharmacy #1972, DS2498, SA-INV-9336
22. Investigation report in the matter of Rite Aid #10120, DS3249, SA-INV-9334
23. Investigation report in the matter of Injured Worker's Pharmacy, DS89727, SA-INV-8994
24. Investigation report in the matter of Stop & Shop Pharmacy, DS2360, SA-INV-8903
25. Investigation report in the matter of Sullivan's Pharmacy, DS1243, SA-INV-8990

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