

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

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

December 6, 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		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of November 1, 2016 Regular Session Minutes 		
8:45	IV	APPLICATIONS <ul style="list-style-type: none"> • Athol Pharmacy, Inc. – New Community Pharmacy • New England Life Care - Woburn – Renovation/Expansion • St. George Pharmacy – New Community Pharmacy • Sullivan’s Pharmacy – Renovation/Expansion • McNabb Pharmacy, Inc. – Transfer of Ownership 		
9:30	V	REPORTS <ul style="list-style-type: none"> • Applications approved pursuant to Licensure Policy 13-01 • Monthly report from probation • Board Delegated Complaint Review pursuant to licensure policy 14-02 	Reports	R. Harris K. Fishman
9:40	VI	POLICIES <ul style="list-style-type: none"> • Policy 16-02: Requirements and procedures for reporting theft or loss of controlled substances to the Board of Registration in Pharmacy 		M. Chan W. Frisch

10:10	VII	REGULATIONS <ul style="list-style-type: none"> • 247 CMR 22.00: Fines 	D. Sencabaugh H. Engman																																			
10:40	VIII	ADVISORY <ul style="list-style-type: none"> • Advisory on staff ratios, dedicated training personnel and pharmacy intern direct supervision. • Sale of Hypodermic Syringes & Needles 	M. Chan																																			
10:50	IX	FLEX SESSION <ul style="list-style-type: none"> • Election of Board officers • Proposed questionnaire of institutional clean rooms • Update on the pharmacist administration of mental health and substance use medication. 	D. Sencabaugh W. Frisch																																			
11:30	X	FILE REVIEW <table border="1"> <tr> <td>1.</td> <td>SA-INV-5884, CVS #844, DS1402, Walpole</td> <td>Vasquez</td> </tr> <tr> <td>2.</td> <td>SA-INV-8119, CVS #2177, DS2723, Georgetown</td> <td>Santoro</td> </tr> <tr> <td>3.</td> <td>PHA-2016-0121, CVS#1111, DS3593, Ware</td> <td>Tran</td> </tr> <tr> <td>4.</td> <td>PHA-2016-0165, CVS #220, DS1722, Marlborough</td> <td>Santoro</td> </tr> <tr> <td>5.</td> <td>SA-INV-9994, CVS #1867, DS89648, Plymouth</td> <td>Morton</td> </tr> <tr> <td>6.</td> <td>SA-INV-9451, Coram CVS Specialty, DS89944, Northborough</td> <td>Melton</td> </tr> <tr> <td>7.</td> <td>SA-INV-7517, Rite Aid #10101 DS2397 Hudson</td> <td>Melton</td> </tr> <tr> <td>8.</td> <td>SA-INV-8090, Rite Aid #10119, DS3117, Lowell</td> <td>Santoro</td> </tr> <tr> <td>9.</td> <td>SA-INV-7312, Rite Aid #10153, DS3613, East Boston</td> <td>Melton</td> </tr> <tr> <td>10.</td> <td>PHA-2016-0123, Rite Aid #10131, DS3095, Amesbury</td> <td rowspan="2">Santoro</td> </tr> <tr> <td>11.</td> <td>PHA-2016-0124, Petrina Sephanides, PH234812</td> </tr> <tr> <td>12.</td> <td>PHA-2016-0117, Rite Aid Pharmacy #10072, DS3217, North Adams</td> <td>Tran</td> </tr> </table>		1.	SA-INV-5884, CVS #844, DS1402, Walpole	Vasquez	2.	SA-INV-8119, CVS #2177, DS2723, Georgetown	Santoro	3.	PHA-2016-0121, CVS#1111, DS3593, Ware	Tran	4.	PHA-2016-0165, CVS #220, DS1722, Marlborough	Santoro	5.	SA-INV-9994, CVS #1867, DS89648, Plymouth	Morton	6.	SA-INV-9451, Coram CVS Specialty, DS89944, Northborough	Melton	7.	SA-INV-7517, Rite Aid #10101 DS2397 Hudson	Melton	8.	SA-INV-8090, Rite Aid #10119, DS3117, Lowell	Santoro	9.	SA-INV-7312, Rite Aid #10153, DS3613, East Boston	Melton	10.	PHA-2016-0123, Rite Aid #10131, DS3095, Amesbury	Santoro	11.	PHA-2016-0124, Petrina Sephanides, PH234812	12.	PHA-2016-0117, Rite Aid Pharmacy #10072, DS3217, North Adams	Tran
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		13	SA-INV-8514, Brigham and Womens Hospital Nuclear Pharmacy, NU15	Melton
		14	SA-INV-9335, Brigham and Womens Hospital Nuclear Pharmacy, NU16	Melton
		15	SA-INV-7443, New England Home Therapies, DS3486	Van Allen
		16	SA-INV-7481, New England Home Therapies, DS3486	Van Allen
		17	SA-INV-8445, New England Home Therapies, DS3487	Van Allen
		18	SA-INV-9997, New England Home Therapies, DS3486	Van Allen
		19	SA-INV-9421, BioRX LLC, DS89763, Woburn	Melton
		20	SA-INV-10104, Amerisourcebergen Drug, WD372, Mansfield	Santoro
		21	PHA-2016-0167, Walgreens Pharmacy #2699, DS2129, Ludlow	Santoro
		22	SA-INV-10229, Community, A Walgreens Pharmacy, DS89805	Santoro
12:30		LUNCH BREAK		

1:30	XI	<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. Specifically, the Board will discuss and evaluate the Good Moral Character as required for registration for pending applicants.</p>	CLOSED SESSION
2:00	XII	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)	CLOSED SESSION
2:30	XIII	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION
5:00	XIV	ADJOURNMENT	

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

**MINUTES OF THE GENERAL SESSION
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts, 02114**

December 6, 2016

Board Members Present

Ed Taglieri Jr., R.Ph. President
Timothy Fensky, R.Ph. President Elect
Garret Cavanaugh, R.Ph.
Susan Cornacchio, JD, RN
Andrew Stein, Pharm D, R.Ph.
Phillippe Bouvier, R.Ph.
Richard Tinsley, MBA, Med,
William Cox, CPhT
Karen Conley, DNP, RN, AOCN, NEA-BC
Ali Raja, MD, MBA, MPH

Board Members Not Present

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

Board Staff Present

David Sencabaugh, R.Ph, Executive Director
Monica Botto, CPhT, Associate Executive Director
Heather Engman, JD, MPH, Pharmacy Board Counsel
William E. Frisch, Jr., R.Ph., Director of Compliance
Christina Mogni, R.Ph., Investigator
Michelle Chan, R.Ph. Quality Assurance Pharmacist
Julienne Tran, PharmD, R.Ph., Investigator
Richard Harris, Program Analyst
Greg Melton, JD, R.Ph., Investigator
Joanne Trifone, R.Ph., Director of Pharmacy Investigations
Joe Santoro, R.Ph. Contract Investigator
Kimberly Morton, CPhT, Compliance Officer
Vishal Thaker, PharmD, Pharmacist

TOPIC I

CALL TO ORDER

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: None

ACTION:

Motion by A. STEIN, seconded by G. CAVANAUGH, and voted unanimously to approve the agenda. (W. COX had not yet arrived.)

TOPIC III.

APPROVAL OF BOARD MINUTES

1. Draft November 1, 2016, Regular Session Minutes

DISCUSSION: none

ACTION:

Motion by K. CONLEY, seconded by G. CAVANAUGH, and voted unanimously to approve the minutes of the Regular Session from November 1, 2016. W. COX had not yet arrived.

TOPIC IV:

APPLICATIONS

TIME: 8:42 am

1. Athol Pharmacy, Inc.

New Community Pharmacy

RECUSAL: N/A

DISCUSSION: Athol was represented by Owner/MOR Keith MacNeil, and R.Ph. Brad Lamberton. They satisfactorily answered the Board Members' questions, indicating that the main reason for the relocation was bigger and better space.

ACTION: Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously in the affirmative to approve the application for the new community pharmacy, Athol Pharmacy, pending successful inspection, and change on their attestation to add "moderate" compounding.

2. New England Life Care, Woburn, MA – Renovation/Expansion

RECUSAL: None

DISCUSSION: Director of Pharmacy Compliance W. FRISCH has been in communication with this pharmacy, and recommended approval of their plan, provided they reduce BUDs (3 days refrigerated maximum) until EM results are received, and provide a containment plan for buffer room during construction,.

ACTION: Motion by K. CONLEY second by P. BOUVIER, and voted unanimously to approve NECL's renovation/expansion plan, with Board recommendations. W. COX had still not arrived.

3. St. Georges Pharmacy – Change of Ownership

RECUSAL: N/A

DISCUSSION: H. ENGMAN presented the fact that St. Georges had previously been approved by the Board, and was open for business, but had a change of ownership prior to opening that needed additional Board approval.

ACTION: Motion by P. BOUVIER, seconded by G. CAVANAUGH, and voted unanimously to approve ownership for St. Georges. W. COX had still not arrived.

4. Sullivan's Health Care – Renovation/Expansion

RECUSAL: T. FENSKY

A.RAJA did not submit a disclosure in time, and had to leave the room. He was not present for discussion or vote on this matter.

DISCUSSION: Sullivan's suffered a leak during the weekend of November 6th, and discovered on Monday November 7th. They immediately ceased compounding and implemented their continuity of care plan. The remediation required a complete "gut", and plans were submitted to the Board. Sullivan's was represented by Paige Barton, MOR, and Brian Marquis, President of "Pharmacerts". Director of Pharmacy Compliance W. FRISCH had reviewed the plans recommended approval of the plans.

ACTION: Motion by A. STEIN second by R. TINSLEY, and voted unanimously to approve Sullivan's renovation/expansion plan, and subsequent re-opening pending successful inspection. W. COX had still not arrived.

5. McNabb Pharmacy – Transfer of Ownership

RECUSAL: N/A

DISCUSSION: McNabb Pharmacy was represented by Karen McNabb-Noon. Ms. McNabb-Noon explained that her father had passed away, and that was the reason for the change in ownership. She satisfactorily answered the Board Member's questions, and there was some concern raised relative to compounding hazardous materials.

ACTION: Motion by S. CORNACCHIO second by A. STEIN, and voted unanimously to approve the transfer of ownership, with a request by the Board for an inspection, including inspecting the compounding status. W. COX had still not arrived.

TOPIC V.

REPORTS

Applications Approved Pursuant to Licensure Policy 13-01, 8:58 am

DISCUSSION: R. HARRIS noted that during the past month there have been thirty-five (35) change-of-managers processed, seven (7) closings (Family Pharmacy stores sale to CVS), and eight (8) non-resident outsourcer registrations.

So noted

Board Delegated Review Pursuant to BDCR Policy

There were 9 Board Delegated Review cases heard on November 30, 2016, 1 complaint involved a self-report of CE deficiency, which was dismissed, no discipline warranted – already remediated. 2 other complaints regarding a QRE that had been remediated were also dismissed. 5 cases were referred to the full Board, as they potentially would involve issues that BDCR was not authorized to handle, and 1 case resulted in a consent agreement for resolution of a matter involving a QRE. The Board Delegated Review session was attended by E. TAGLIERI as the Board Member, H. ENGMAN as Board Counsel, W. FRISCH, Director of Pharmacy Compliance, and Executive Director D. SENCABAUGH.

So noted

Report of activities Probation Monitor

DISCUSSION: D. SENCABAUGH (for K.FISHMAN) provided the October 26, 2016 – November 29, 2016, Board of Pharmacy Statistics Report for the Probation monitor, which noted that there are forty (40) licensees on probation, thirty-three (33) satisfactorily completed probation, four (4) licensee did not cure within 30 days, eight (8) given the opportunity to cure, and two (2) notices of further discipline.

So noted

TOPIC VI

POLICIES

Time: 9:01 AM

POLICIES

Time: 9:02 AM

Proposed policy 16-02, Requirements and Procedures for reporting theft or loss of controlled substances to the Board of Registration in Pharmacy

DISCUSSION: Presented by W. FRISCH. The purpose of this update is to build on the original policy by setting forth additional guidance and procedures for reporting any suspected or confirmed reportable loss or theft of controlled substances. The proposed policy also provides guidance on when a loss is considered “reportable” and how a pharmacy should document and track those losses that are not reportable.

The major changes primarily deal with the timeframes for reporting suspected and confirmed losses of controlled substances in Schedule II-VI. Changes to the current reporting form on the Board’s website:

Within one (1) business day of a suspected reportable loss, the pharmacy shall report to the Board by submitting Section A of the *Report of Loss of Controlled Substances* form.

Then, within 30 days of submission of Section A of the *Report of Loss of Controlled Substances* form, licensees are required to submit Section B of the form indicating either a confirmed loss with related documentation or no loss after their investigation. Once a loss has been confirmed and is reportable, registrants must report the loss to the Board within 7 days in accordance with 247 CMR 6.02 (10).

Dedicated email box has been established for licensee reporting. When a report is sent to the email box licensees will receive an auto-reply with further information.

New process will improve the tracking of loss reports and reduce the number of files opened resulting from premature filing of DEA 106 reports by licensees.

ACTION: Motion by A. STEIN, seconded by T. FENSKY and voted unanimously by those present to approve policy 16-02 with additional formatting and language changes. W. COX had still not arrived.

TOPIC VII
REGULATIONS

247 CMR section 22: Fining

Time: 9:12 AM

DISCUSSION: Presented by H. ENGMAN and D. SENCABAUGH. The draft of this section provides the mechanics of how fining will work. Under the statute, registered pharmacists can only be personally fined for CE deficiencies. For pharmacies, a monetary penalty guide will be developed but not included in the regulation so that it can be subject to change. A staff action policy will also be developed to levy fines.

ACTION: No vote today

TOPIC VIII
ADVISORY

Time: 9:17 AM

Advisory on Staff Ratios, dedicated training personnel, and pharmacy intern direct supervision.

DISCUSSION: Presented by M. CHAN. As an update to this advisory that was approved in August, two paragraphs were added to remind pharmacist preceptors to verify that all students, both domestic and foreign, have obtained their Massachusetts intern licenses before the start of the internship. This applies to all practice settings, including hospital pharmacy. It is each individual preceptor's responsibility to ensure their intern has obtained an intern license.

ACTION: Motion by K. CONLEY, seconded by A. STEIN and voted unanimously by those present to approve advisory. W. COX had still not arrived.

Advisory on the Sale of Hypodermic Syringes and Needles

Time: 9:19 AM

DISCUSSION: Presented by M. CHAN. This advisory is based on a recent case where the sale of syringes was refused to a customer. It summarizes the Board's position to support pharmacy efforts to provide clean, sterile syringes and needles to any person of age that requests them. Essentially it is a strong reminder to pharmacists that other than proper photo identification proving age 18 years or older, there are no other requirements or limitations to prevent customers from purchasing syringes and needles.

ACTION: Motion by S. CORNACCHIO, seconded by T. FENSKY and voted unanimously by those present to approve advisory with a change in the third bullet from "shall" to "should". W. COX had arrived and was present for most of the discussion and vote on this matter.

TOPIC IX

FLEX SESSION

9:46 am

TOPIC IX: Flex Session

**Proposed questionnaire of Institutional Clean rooms
Presented by William Frisch**

9:25 am

DISCUSSION: W. FRISCH discussed the details of proposed questionnaire of institutional cleanrooms. Discussed use of tool, to assess sustained compliance and organizing meetings of hospital stakeholders.

TOPIC IX: Flex Session

9:30am

**Update on pharmacist administration of mental health and substance use disorder medications.
Presented by Dave Sencabaugh**

9:35 am Comfort Break

9:46 am Back from Break

TOPIC IX: Flex Session

9:46 am

Election of Board Officers for 2017

Action for President Elect: **Mike Godek** nominated by **Cathy Basile**

Vote: P. GANNON (by phone): Mike. GODEK

E. TAGLIERI: M. GODEK

R. TINSLEY: M. GODEK

K. CONLEY: M. GODEK

M.GODEK (by phone): M GODEK

G. CAVANAUGH: M. GODEK

W. COX: M. GODEK

A. STEIN: M. GODEK

P. BOUVIER: M. GODEK

S. CORNACCHIO: M. GODEK

T. FENSKY: M. GODEK

A. RAJA: M. GODEK

Action for Secretary: **Andy Stein** Nominated by: Kathy Basile

Vote: T. FENSKY, R. TINSLEY, A. STEIN

Action for Secretary: **Susan Cornacchio** Nominated by: **Patrick Gannon**

Vote: P. GANNON, K. CONLEY, S. CORNACCHIO, A. RAJA, P. BOUVIER

Action for Secretary: **Garett Cavanaugh** Nominated by: **Mike Godek**

Vote: M. GODEK (by phone), W. COX, E. TAGLIERI, G. CAVANAUGH

Winner Cornacchio, 5 – 4 – 3

Minutes of the General Session 12/6/2016,
approved January 5, 2017

Topic XI
OPEN SESSION
File Review

TOPIC X

OPEN FILE REVIEW

Time: 9:56 am

Case #1

SA-INV-5884

CVS #844, Walpole DS1402

Time: 10:48 AM

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

DISCUSSION: K.MORTON presented and summarized the investigation report that pertained to these matters.

- Inspectional deficiencies were observed on 12/31/14 during ISP-2439
- Missing lock box sign, out of ratio, dirty compounding equipment, inconsistent BUD's, multiple expired compounding products with no open date.
- Last inspection on 4/25/16 was satisfactory

ACTION: Motion by R.TINSLEY, seconded by W. COX, and voted unanimously by those present, to dismiss SA-INV-5884, no discipline warranted, remediation completed.

Case #2

SA-INV-8119

CVS #2177, Georgetown DS2723

Time: 9:57 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.

- On June 3, 2015, the pharmacy reported a loss of 1392 Lorazepam 0.5mg on or about May 27, 2015
- MOR indicated that the original DEA 106 form was filed on June 4th but was faxed to the DEA office but not to the local police department.
- On June 9, 2015, DEA field agents came to the store and asked for a reconciliation for three additional medications. Losses found included 84 Tramadol 50mg , 890 clonazepam 1mg , 35 hydrocodone/APAP 5/325 and the original loss of 1392 Lorazepam 0.5mg was amended to 1434
- On June 26, 2016, Initial DEA-106 was amended based on the DEA audit findings

Minutes of the General Session 12/6/2016,
approved January 5, 2017

- On July 8, 2015, the pharmacy reported a loss of 404 Clonazepam 0.5mg tablets on or about July 3, 2015
- Camera footage was not reviewed as it was determined that there were no active losses of these medications and film is stored for only fifty five (55) days-Cause of loss could not be determined
- Corrective action per CVS procedures

ACTION: Motion by P.BOUVIER, seconded by G.CAVANAUGH, and voted unanimously by those present, to dismiss SA-INV-8119, no discipline warranted.

Case #3

PHA-2016-0121 CVS #1111, Ware DS3593 Time: 10:00 AM

RECUSAL: S. CORNACCHIO 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.

- On December 7, 2015, the pharmacy reported a loss of 175 Suboxone 8/2mg SL films on or about December 7, 2015.
- LP investigated and the drug was counted daily and reconciled weekly for a period of 8 weeks with no variance.
- MOR indicated that the loss may be attributed miscounts and improper handling/processing of outdates or damages over the two year period of the reconciliation and no suspicious activity on video surveillance.
- MOR indicated that he has reviewed all baseline loss prevention procedures with the staff, specifically those that prevent drug diversion.

ACTION: Motion by A.STEIN, seconded by G.CAVANAUGH, and voted unanimously by those present, to dismiss, PHA-2016-0121, no discipline warranted.

Case #4

PHA-2016-0165 CVS #220, Marlborough DS1722 Time: 10:01 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.

- Inspectional deficiencies were observed on May 23, 2016 during ISP-5009.

- Observed: supervisory ratios 1:5

Corrective Action: CVS objects-the two trainees were providing ancillary duties and wearing tags that identified their roles

- Observed: improper identification of pharmacy technician and pharmacy trainee with the appropriate name tags

Corrective Action: CVS objects, trainees were not in training and wearing tags that appropriately represented the work they performed “pharmacy sales associate”

- Observed: Power of Attorney on file at store did not have a signature matching the name printed

Corrective Action: Corporate licensing department assisted in correcting the POA on file with MOR

- Observed: Sink clogged –Previously discussed on 1/27/2016 ISP-4533

Corrective Action: Sink repaired

- MOR indicated that she reviewed supervisory ratios with the staff to ensure continued compliance and that staff members have name tags that accurately reflect their roles. MOR will be the only person to distribute name tags to ensure that they are worn by the appropriate team members

- DS was reprimanded in 2015 for inspectional deficiencies.

ACTION: Motion by K.CONLEY, seconded by W.COX, and voted unanimously by those present, to dismiss, PHA-2016-0165, no discipline warranted, and to send the advisory on staffing ratios as well as the MOR checklist to the DS.

Case #5

SA-INV-9994

CVS #1867, Plymouth

DS89648

Time: 10:18AM

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

DISCUSSION: K.MORTON presented and summarized the investigation report that pertained to these matters

- On June 7, 2016, the pharmacy reported a loss of 697 Tramadol 50mg tablets on or about May 31, 2016.

- LP ruled out active losses or diversion. They reviewed cycle counts, biennial inventories, staffing schedules, and inventory reports for the applicable time period and were unable to identify the reason for the loss

Minutes of the General Session 12/6/2016,
approved January 5, 2017

- Corrective action includes monitoring balance on hand modification reports, ordering, and cycle count activity, double count all controlled medication prior to dispensing to reduce any miscounts, only the pharmacist on duty will double check all controlled substances most commonly dispensed and prescriptions in the waiting bin to accurately count all medications & reviewed all baseline loss prevention procedures with the staff.
- A Retail Compliance inspection (ISP- 5599) at CVS Pharmacy #1867 was completed on June 28, 2016 with no deficiencies noted.

ACTION: Motion by T.FENSKY, seconded by W.COX, and voted unanimously by those present, to close, SA-INV-9994, due to insufficient evidence, with the issuance of a Board approved advisory letter.

Case #6

SA-INV-9451 Coram CVS Specialty, Northborough DS89944 Time:10:21AM

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

- On March 17, 2016, Coram properly notified the Board of abnormal results.
- Compounding ceased and never restarted after consult with outside engineer.
- Coram chose to close the site and surrendered its license on April 8, 2016 rather than remediate.

ACTION: Motion by G.CAVANAUGH, seconded by K.CONLEY, and voted unanimously by those present, to close, SA-INV-9451, no discipline warranted.

TOPIC: XI

I. Open File Review Cases 7-12

Case #7

SA-INV-7517

Rite Aid #10101, DS2397

TIME: 10:22 AM

RECUSAL: G. CAVANAUGH recused and was not present for the discussion or vote in this matter.

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

- On April 27, 2015 a burglary resulted in multiple losses of controlled substances.
- The burglars disabled the alarm by cutting all telephone wires and entered through a hole cut in the roof.

- Controlled substances were stolen from the waiting for pick-up medication and the security cabinet for hydrocodone products.
- The Schedule II safe was tampered with but not accessed.
- The Pharmacy was repaired and a wireless backup for the alarm system was installed.

ACTION: Motion by K. CONLEY, seconded by T. FENSKY and voted unanimously by those present to close SA-INV-7517, with no violation.

Case #8

SA-INV-8090

Rite Aid #10119, DS3117

TIME: 10:23 AM

RECUSAL: G. CAVANAUGH recused and was not present for the discussion or vote in this matter.

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

- On August 11, 2015 OPP received a report of a loss of #5 hydrocodone 7.5/325 mg tablets on or before July 25, 2015
- The MOR indicated that the loss was discovered by a pharmacist during the weekly CII count
- The loss was believed to be the result of a dispensing error
- The Pharmacy District Manager was notified and the patient was finally reached but was unwilling to bring the medication back to verify the error
- A plan of correction indicated that all CII prescriptions are now double counted and back counted before returning to safe and the procedures for dispensing controlled substances and baseline loss prevention were reviewed with staff.

ACTION: Motion by T. FENSKY, seconded by K. CONLEY and voted unanimously by those present to close SA-INV-8090 due to insufficient evidence.

Case #9

SA-INV-7312

Rite Aid #10153, DS3613

TIME: 10:25 AM

RECUSAL: G. CAVANAUGH recused and was not present for the discussion or vote in this matter.

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

- On November 14, 2014 a loss of multiple controlled substances was reported.
- The loss was traced back to a delivery missing two totes that were signed as received by MOR Winnie Yee.
- The Rite Aid Asset Protection (AP) team was able to obtain video of the delivery and two totes were missing according to the invoice.
- MOR Yee admitted that she signed the paperwork but did not reconcile with the physical inventory.
- The AP team was able to watch the remaining totes being opened and stocked in the pharmacy.
- Those totes did not contain controlled substances.

- The out of state distributor was notified of the missing totes.
- The totes were never found.
- MOR Yee received a final notice of discipline and staff was trained on the proper way to receive inventory.

ACTION: Motion by R. TINSLEY, seconded by W. COX and voted unanimously by those present to close SA-INV-7312 with no discipline warranted.

Case #10

PHA-2016-0123

Rite Aid #10131 DS3095

TIME: 10:28 AM

RECUSAL: G. CAVANAUGH recused and was not present for the discussion or vote in this matter.

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

- Inspectional deficiency was found on April 29, 2015
- A technician trainee was found to be greater than 1000 hours with total hours worked as 2,910 hours
- The technician became registered on May 31, 2015
- The technician hours were incorrectly calculated because of a coding issue.
- Plan of correction included reviewing technician hours on a weekly basis
- A retail compliance inspection was completed on September 29, 2016 with no deficiencies noted.

ACTION: Motion by R. TINSLEY, seconded by K. CONLEY and voted unanimously by those present to dismiss PHA-2016-0123, with no discipline warranted, remediation complete.

Case #11

PHA-2016-0124

Petrina Sephanides, PH234812

TIME: 10:28 AM

RECUSAL: G. CAVANAUGH recused and was not present for the discussion or vote in this matter.

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

- Inspectional deficiency was found on April 29, 2015
- A technician trainee was found to be greater than 1000 hours with total hours worked as 2,910 hours
- The technician became registered on May 31, 2015
- The technician hours were incorrectly calculated because of a coding issue.
- Plan of correction included reviewing technician hours on a weekly basis
- A retail compliance inspection was completed on September 29, 2016 with no deficiencies noted.

ACTION: Motion by A. STEIN, seconded by R. TINSLEY and voted unanimously by those present to dismiss PHA-2016-0124, with no discipline warranted, remediation complete.

Case #12

PHA-2016-0117

Rite Aid #10072, DS3217

TIME: 10:30 AM

RECUSAL: G. CAVANAUGH recused and was not present for the discussion or vote in this matter.

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

- Report of loss of controlled substances -- #14 Subutex 8 mg, #56 Suboxone 2mg/0.5 mg film, #7 Suboxone 2mg/0.5mg tablets, #7 Suboxone 12mg/3mg film and #62 zolpidem 10mg tablets due to undetermined reasons
- A trusted MOR from another store was brought in overnight to perform physical medication counts and MOR Wolf was instructed to covertly perform routine cycle counts.
- Former MOR Backman noted that the losses occurred due to dispensing error in a chaotic working environment, new pharmacists who could not keep up with the work and the incorrect NDC's chosen during data entry
- Former MOR Backman did not report to work on his last day to perform the controlled substance inventory.
- A Retail Compliance (ISP-5512) inspection at Rite Aid Pharmacy #10072 was completed by Michael Brosnan on July 8, 2016 with a deficiency noted that a technician was observed counseling a patient.

ACTION: Motion by T. FENSKY, seconded by S. CORNACCHIO, and voted unanimously by those present to dismiss PHA-2016-0117 with no discipline warranted.

Case #13. Brigham and Women's Nuclear Pharmacy; NU15; SA-INV-8514

- Ali Raja and Karen Conley recused themselves from this matter and were not present for the discussion or vote.
- G. Melton presented and summarized the investigation report.
- Motion by A. Stein, seconded by R. Tinsley, and voted unanimously to close the staff assignment noting there was no violation.

Case #14. Brigham and Women's Nuclear Pharmacy; NU15; SA-INV-9335

- Ali Raja and Karen Conley recused themselves from this matter and were not present for the discussion or vote.
- G. Melton presented and summarized the investigation report.
- Motion by A. Stein, seconded by R. Tinsley, and voted unanimously to close the staff assignment noting there was no violation.

Case #15. New England Home Therapies; DS3486; SA-INV-7443

- N. Van Allen presented and summarized the investigation report, noting the pharmacy is currently going through a renovation.
- Motion by W. Cox, seconded by G. Cavanaugh, and voted unanimously to close the staff assignment noting there was no violation.

Case# 16. New England Home Therapies; DS3486; SA-INV-7481

- N. Van Allen presented and summarized the investigation report.
- Motion by W. Cox, seconded by T. Fensky, and voted unanimously to close the staff assignment noting there was no violation.

Case #17. New England Home Therapies; DS3486; SA-INV-8445

- N. Van Allen presented and summarized the investigation report.
- Motion by W. Cox, seconded by G. Cavanaugh, and voted unanimously to close the staff assignment noting there was no violation.

Case #18. New England Home Therapies; DS3486; SA-INV-9997

- N. Van Allen presented and summarized the investigation report and noted the most recent inspection in November 2016 was successful.
- Motion by W. Cox, seconded by K. Conley, and voted unanimously to close the staff assignment noting there was no violation.

Case #19

SA-INV-9421

BioRX LLC, DS89763

TIME: 10:40AM

DISCUSSION: G. MELTON presented and summarized the investigation report that pertained to this matter.

- On April 29, 2016, BioRx properly reported abnormal (above action level environmental monitoring) results. Compounding was ceased.
- Proper remediation was completed per consultation with the Board Staff.
- Compounding was resumed with reduced BUD. Repeat EM results were within action limits and normal operations resumed with Board Staff approval.

ACTION: Motion by P. BOUVIER, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE SA-INV-9421, with no violation.

Case #20

SA-INV-10104

Amerisourcebergen Drug, WD372

TIME: 10:41AM

DISCUSSION: J. SANTORO presented and summarized the investigation report that pertained to this matter.

- The Board received a reported loss of controlled substances (RLCS) of #100 Methadone HCL 10mg tablets on or about June 09, 2016. The loss was discovered during the daily inventory cycle count.
- A full investigation did not reveal evidence of diversion or violation of policy.
- Standard operating procedures were followed which included an immediate search of the area as well as previous days trash.
- The Compliance Manager indicated that daily controlled cycle counts will continue to be conducted for the purpose of providing early detection of any inventory variance.

- Corrective action was not issued based on the investigative findings showing all processes and SOP's were followed.

ACTION: Motion by P. BOUVIER, seconded by G. CAVANAUGH, and voted by majority by those present, to CLOSE SA-INV-10104, with insufficient evidence. T. FENSKY and A. STEIN opposed the motion.

Case #21

PHA-2016-0167

Walgreens Pharmacy #2699, DS2129

TIME: 10:47AM

DISCUSSION: J. SANTORO presented and summarized the investigation report that pertained to this matter.

- This matter relates to inspectional deficiencies observed on March 31, 2016 ((ISP-5004).
- OPP Inspector observed that the daily freezer temperature recorded on the temperature log was a consistent -8.3 degrees F since January 2015 and did not change when OPP Inspector took the thermometer and probe out of the freezer and left at room temperature.
- OPP Inspector observed vaccines stored in said freezer have been dispensed and administered and that the manufacturer should be contacted to determine if they can guarantee safety of the vaccines despite unreliable temperatures.
- Corrective actions: the freezer probe was re-calibrated and vaccines stored in that freezer were immediately quarantined. Patients and their primary care provider were notified and 15 out of the 79 patients that had received vaccinations were re-vaccinated at no charge. Insurances claims were reversed and co-pays were returned to patients.
- OPP Inspector also observed purified water dispensers were dirty and one of the dispensers had had 95mls of standing water. As a corrective action the purified water dispensers and area around the dispensers were emptied, cleaned, and tips replaced.
- A compliance inspection conducted on August 31, 2016 was satisfactory.

ACTION: Motion by T. FENSKY, seconded by G. CAVANAUGH, and voted unanimously by those present, to refer the matter (PHA-2016-0167) to the Office of Prosecution, for an order to show cause (OTSC) and authorize a consent agreement for a REPRIMAND.

Case #22

SA-INV-10229

Community, A Walgreens Pharmacy, DS89805

TIME: 10:49AM

DISCUSSION: J. SANTORO presented and summarized the investigation report that pertained to this matter.

- The Board staff received a referral from the Board of Registration in Nursing with allegations that Community Pharmacy (Walgreens) accepted unwanted, previously dispensed medications and then sent them to third world countries. The medications were placed in a donation box located in the lobby (Boston Living Center?).
- MOR indicated that the extent of involvement consisted of providing information to interested parties regarding the availability of the donation box and because Community

Minutes of the General Session 12/6/2016,
approved January 5, 2017

Pharmacy has a shipping and receiving department, along with packaging materials, offered to box, and ship medications to AFA (Aid for AIDS) in N.Y. City. The shipping area is located outside of the pharmacy blueprint.

- MOR has since ceased shipping to AFA and the Boston Living Center has taken on the responsibilities.
- On October 7, 2016, OPP conducted a satisfactory retail compliance inspection (ISP-6096) where no deficiencies were observed.

ACTION: Motion by A. STEIN, seconded by G. CAVANAUGH, and voted unanimously by those present, to CLOSE SA-INV-10229, with no violation.

TOPIC XII

Adjudicatory Session

DISCUSSION: None

ACTION: At 11:02 pm, on a motion by T. FENSKY, seconded by W. COX, the members voted unanimously to enter into Adjudicatory session.

TOPIC XIII.

M.G.L. c. 65C Session

DISCUSSION: None

ACTION: At 11:22 pm motion by K. CONLEY, seconded by T. FENSKY and voted unanimously to enter into M.G.L. c. 65C Session.

TOPIC XI

Executive Session

DISCUSSION: None

ACTION: At 1:53 pm President Taglieri called for a motion to enter Executive Session: 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, S. CORNACCHIO yes, A. STEIN: yes G. CAVANAUGH: yes; W. COX; yes K. CONLEY; yes, R.TINSLEY; yes, A. RAJA; yes

TOPIC XIII.

M.G.L. c. 65C Session

DISCUSSION: None

ACTION: At 2:23 pm motion by T. FENSKY, seconded by G. CAVANAUGH and voted unanimously to re-enter into M.G.L. c. 65C Session.

TOPIC XIV.

ADJOURNMENT OF MEETING

DISCUSSION: NONE

ACTION: At 4:22 pm motion by G. CAVANAUGH, seconded by K. CONLEY, and voted unanimously to adjourn the meeting.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda for the November 1, 2016, regularly scheduled meeting of the Board of Registration in Pharmacy.
2. Draft November 1, 2016 Open Session Minutes.
3. Application for New Community Pharmacy Athol Pharmacy, Inc.
4. Application for Renovation / Expansion New England Life Care, Woburn
5. Application for Change of Ownership, St. Georges Pharmacy
6. Application for Renovation/Expansion Sullivan's Pharmacy
7. Application for Transfer of Ownership, McNabb Pharmacy
8. Report of Applications approved pursuant to licensure policy 13-01
9. Report from Probation Monitor 10/26/2016 –11/29/2016
10. Board Delegated Compliant Review report 11/30/2016
11. Draft Proposed Policy 16-02, Requirements and Procedures for Reporting Theft or Loss of Controlled Substances to the Board of Registration in Pharmacy.
12. Draft proposed regulation 247 CMR 22:00: Fining
13. Draft Advisory on Staff Ratios, dedicated training personnel, and pharmacy intern direct supervision.
14. Draft Advisory on the sale of hypodermic syringes and needles
15. Draft 247 CMR section 22.00 Fining
16. Investigation report in the matter of CVS #844, DS1402,SA-INV-5884
17. Investigation report in the matter of CVS #2177, Georgetown, DS2723,SA-INV-8119
18. Investigation report in the matter of CVS #1111, Ware, DS3593,PHA-2016-0121
19. Investigation report in the matter of CVS #220, Marlborough, DS1722,PHA 2016-0165
20. Investigation report in the matter of CVS #1867, Plymouth,SA-INV-9994
21. Investigation report in the matter of Coram CVS Specialty, DS89944,SA-INV-9451
22. Investigation report in the matter of Rite Aid #10101, DS3117, SA-INV-7517
23. Investigation report in the matter of Rite Aid #10119, DS3117, SA-INV-8090
24. Investigation report in the matter of Rite Aid #10153, DS3613, SA-INV-7312
25. Investigation report in the matter of Rite Aid #10131, DS3095, PHA-2016-0123
26. Investigation report in the matter of Petrina Sephanides, PH2384812, PHA-2016-0124
27. Investigation report in the matter of Rite Aid #10072, DS3217, PHA-2016-0117
28. Investigation Report – Brigham and Women's Nuclear Pharmacy; NU15; SA-INV-8514
29. Investigation Report – Brigham and Women's Nuclear Pharmacy; NU15; SA-INV-9335
30. Investigation Report – New England Home Therapies; DS3486; SA-INV-7443
31. Investigation Report – New England Home Therapies; DS3486; SA-INV-7481
32. Investigation Report – New England Home Therapies; DS3486; SA-INV-8445

33. Investigation Report – New England Home Therapies; DS3486; SA-INV-9997
34. Investigation Report – BioRX, LLC, DS89763; SA-INV-9421
35. Investigation Report – Amerisourcebergen; WD372; SA-INV-10104
36. Investigation Report – Walgreens Pharmacy #2699, DS2129; PHA-2016-0167
37. Investigation Report – Community, A Walgreens Pharmacy; DS89805; SA-INV-10229

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