

COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

March 2, 2017
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

Agenda

Time	#	Item	Contact
8:30	I	CALL TO ORDER	T. Fensky
8:35	II	APPROVAL OF AGENDA Introduction of Intern: Elena Karski	
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of February 2, 2017 Regular Session Minutes	
8:50	IV	APPLICATIONS <ul style="list-style-type: none">• Genoa, Holyoke – New Community Pharmacy• Genoa, Charlestown – New Community Pharmacy• Remedium – Renovation/Expansion	
9:40	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	R. Harris K. Fishman
10:00	VI	FLEX <ul style="list-style-type: none">• Narcan Mobile Initiative	A. Burns

10:30	VII	<p>POLICIES</p> <ul style="list-style-type: none"> • Policy 2017-02: Guidance for Board-Approved pharmacy technician training programs and examinations • Licensure Policy 17-02: Staff Action approval of pharmacy technician training programs and examinations • Amendments to Policy 2015-02: Guideline for pharmacist continuing education requirements • Amendments to Staffing Ratios Policy 	M. Chan D. Sencabaugh
11:00	VIII	<p>REGULATION REVIEW UPDATE</p> <ul style="list-style-type: none"> • 247 CMR 3.00: Personal Registration Requirements • 247 CMR 8.00: Pharmacy Interns and Technicians • 247 CMR 10.00: Disciplinary Proceedings • 247 CMR 16.00: Collaborative Drug Therapy Management 	V. Berg
11:30	IX	<p>COMMENTS ON REGULATIONS</p> <ul style="list-style-type: none"> • 247 CMR 2.00: Definitions • 247 CMR 13.00: Registration requirements and minimal professional standards for nuclear pharmacies. • 247 CMR 14.00: Petition for Waiver 	V. Berg

12:00	X	<p>FILE REVIEW</p> <ol style="list-style-type: none"> 1. PHA-2016-0228, Stop and Shop #21, DS2359 2. PHA-2016-0236, Sleyman Haddad, PH18882 3. PHA-2016-0111- Caring Pharmacy, DS89747 4. SA-INV-9728- CVS #1094, DS1627 5. PHA-2016-0237- CVS #299, DS3596 6. PHA-2016-0157- CVS #166, DS3449 7. PHA-2016-0192- CVS #657, DS89715 8. PHA-2016-0194- CVS #75, DS3535 9. SA-INV-9419- CVS #1876, DS2064 10. PHA-2016-0033- CVS #705, DS3428 11. SA-INV-10002, Walgreens #1233, DS3333 12. PHA-2016-0182- Walgreens #5075, DS2928 13. PHA-2016-0205- Walgreens #6805, DS3246 14. PHA-2016-0227- Rite Aid #10196, DS3170 15. SA-INV-10457- Brigham and Women's Nuclear, NU16 	
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 and notice of a probation violation.</p>	CLOSE D SESSIO N
3:00	XII	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)	CLOSE D SESSIO N

3:30	XIII	M.G.L. c. 112, § 65C SESSION	CLOSE D SESSIO N
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**

March 2, 2017

Board Members Present

Timothy Fensky, R.Ph. President
Susan Cornacchio, JD, RN, Secretary
Michael Godek, R.Ph., President-Elect
Garret Cavanaugh, R.Ph.
Patrick Gannon, R.Ph
Catherine Basile, Pharm D, R.Ph
Andrew Stein, Pharm D, R.Ph.
Ed Taglieri Jr., R.Ph. President (Left at 12:30)
Ali Raja, MD, MBA, MPH
Karen Conley, DNP, RN, AOCN, NEA-BC
William Cox, CPhT

Board Members Not Present

Phillippe Bouvier, R.Ph.
Richard Tinsley, MBA, Med,

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
Michelle Chan, R.Ph. Quality Assurance Pharmacist
Michael Brosnan, 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
Rick Geaney, R.Ph., Investigator
Nathan Van Allen, PharmD, R.Ph.

TOPIC I

CALL TO ORDER

TOPIC I.

CALL TO ORDER 8:30 AM

DISCUSSION: A quorum of the Board was present, established by roll call. President T. FENSKY 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 M. GODEK, seconded by E. TAGLIERI, and voted unanimously to approve the agenda. Executive Director D. SENCABAUGH introduced APPE Intern E. KARSKI, and T. FENSKY asked other interns in the audience to stand up and introduce themselves.

TOPIC III.

APPROVAL OF BOARD MINUTES

Draft February 2, 2017, Regular Session Minutes

DISCUSSION: None

ACTION:

Motion by K. CONLEY, seconded by C. BASILE, and voted affirmatively to accept, with P.GANNON, and A. RAJA abstaining, as they were not present at the February 2, 2017 meeting.

TOPIC IV:

APPLICATIONS

TIME: 8:34 am

1. Genoa, Holyoke New Community Pharmacy

RECUSAL: None

DISCUSSION: Genoa was represented by Jason Kan, Director of Pharmacy Operations, and Kim Stafford, R.Ph., proposed MOR of Charlestown. They answered the Board members' questions to their satisfaction. They applied for 6 waivers, which are the same waivers that were approved for their other three facilities 247 CMR 6.02(5), 9.01(15), 6.01(5)(a) (8), 9.01(16), 6.01 (5)(a)(4), and 6.02 (4).

ACTION: Motion by P. GANNON, seconded by, C. BASILE, and voted unanimously in the affirmative to approve the application for the new Genoa Pharmacy in Holyoke, with waivers, pending a successful inspection. S. CORNACCHIO had not arrived.

2. Genoa, Charlestown – New Community Pharmacy

RECUSAL: None

DISCUSSION: Genoa was represented by Jason Kan, Director of Pharmacy Operations, and Kim Stafford, R.Ph., proposed MOR. They answered the Board members' questions to their satisfaction. They applied for 6 waivers, which are the same waivers that were approved for their other three facilities 247 CMR 6.02(5), 9.01(15), 6.01(5)(a) (8), 9.01(16), 6.01 (5)(a)(4), and 6.02 (4). W. FRISCH emphasized the importance of patient "Freedom of Choice", since the pharmacy will be located in the same building as a group home (upstairs), and the patients are currently receiving their pharmacy services from elsewhere.

ACTION: Motion by P. GANNON, seconded by, W. COX, and voted unanimously in the affirmative to approve the application for the new Genoa Pharmacy in Charlestown, with waivers, pending a successful inspection. S. CORNACCHIO had not arrived.

3. Remedium Pharmacy – Renovation/Expansion – 8:44 am

RECUSAL: None.

S. CORNACCHIO arrived at 8:47 am

DISCUSSION: Remedium suffered a fire and related water damage last month. Board staff, including: W. Frisch, M. Chan, and N. VAN ALLEN, reviewed the plan for construction for a new pharmacy space to be located in another unit of the same complex, planned to be used until the damaged area can be repaired. Remedium was represented by Attorney Paul Garbarini, Consultant David Trinks, and MOR Christine Iepure, to answer questions. They reported that current patients have been referred to other pharmacies, until they can back up and running.

Director of Compliance W. FRISCH reported to Board Members that, prior to the fire, Remedium had been inspected and several significant deficiencies had been identified, and needed to be corrected with a POC. Frisch just wanted to make sure that the deficiencies were addressed in the new set-up.

ACTION: Motion by M. GODEK, seconded by P. GANNON, and voted unanimously to approve Remedium's plan for renovation and expansion.

TOPIC V.

REPORTS

Applications Approved Pursuant to Licensure Policy 13-01, 8:50 am

DISCUSSION: R. HARRIS noted that during the past month there have been fifty-one (51) change-of-managers, four (4) renovation/expansions, and one (1) relocation approved by staff.

ACTION: So noted

Report of activities Probation Monitor

DISCUSSION: D. SENCABAUGH (for K.FISHMAN) provided the February 1, 2017 – February 20, 2017, Board of Pharmacy Statistics Report for the Probation monitor, which noted that there are forty-four (44) licensees on probation, thirty-five (35) satisfactorily completed probation, one (1) extension granted, eight (8) licensees given the opportunity to cure, four (4) licensee did not cure within 30 days, and two (2) notices of further discipline.

ACTION: So noted

Board Delegated Review Pursuant to BDCR Policy

There were 12 Board Delegated Review (all Staff Assignments) cases heard on February 27, 2017. All 12 were self-reports of CE deficiency, and all 12 had successfully remediated. The Board Delegated Review session was attended by T. FENSKY as the Board Member, H. ENGMAN as Board Counsel, W. FRISCH, Director of Pharmacy Compliance, and Executive Director D. SENCABAUGH.

ACTION: So noted

TOPIC VI.**FLEX****TIME: 10:01 AM****Narcan Mobile Initiative**

DISCUSSION: Representing the Narcan Mobile Initiative was founder of End Mass Overdose, Allison Burns, Apothecare Pharmacy Fellow Elizabeth (Lilly) Travis, Apothecare director of pharmacy Geoffrey Peterson, and Apothecare owner Rudy Dajie. The initiative is to provide naloxone to underserved communities at local functions. They would provide naloxone as well as extensive education regarding opioid use. They answered the Board members questions to their satisfaction and clarified some information regarding the proposed pilot program for a mobile Narcan program. H.ENGSMAN requested the Board vote on this issue next month after research into whether any waivers are necessary, is completed.

ACTION: no action warranted

TOPIC VII.**POLICIES****TIME: 8:51AM****Amendment: 8:51 AM****Amendment to Policy 2015-02: Guideline for pharmacist continuing education requirements.**

DISCUSSION: Presented by M. CHAN and V. THAKER. Policy 2015-02 was originally approved May 5, 2015 and is now being updated to provide a comprehensive overview of all CE requirements including the new immunization CE requirement.

ACTION: Motion by K. CONLEY, seconded by C. BASILE and voted unanimously to approve the amendments to Policy 2015-02.

New: 8:57 AM**Policy 2017-01: Guidance for Board-approved pharmacy technician training programs and examinations.**

DISCUSSION: Presented by M. CHAN. Policy 2017-01 outlines the approval criteria for both pharmacy technician training programs and exams. The requirements were adapted from the ASHP guidelines as well as 247 CMR 8.02 and will serve to provide more consistent training criteria and exam content across programs. As we are looking to make this a more self-directed process, the process would now include a yearly checklist and attestation that the criteria have been met. After initial review and approval, an audit of materials would occur at least once every 5 years. Completion of an approved training program is in lieu of the 500 hours of experience.

ACTION: Motion by A. STEIN, seconded by K. CONLEY and voted unanimously to approve Policy 2017-01.

New: 9:00 AM**Licensure Policy 17-02: Staff Action approval of pharmacy technician training programs and examinations.**

DISCUSSION: Presented by M. CHAN. Staff action policy 17-02 authorizes the Director of Pharmacy Compliance or his designee to manage the review and approval of pharmacy technician programs and exams in accordance with Policy 2017-01 and 247 CMR 8.02.

ACTION: Motion by A. STEIN, seconded by W. COX and voted unanimously to approve Policy 17-02.

Clarify: 9:00 AM
Staffing Ratio Policy

DISCUSSION: D. SENCABAUGH notes the regulations regarding the current preceptor to intern ratio may not be applicable to the academic setting. The matter is being deferred to the next Board meeting to allot time on discussion of a waiver process in the setting of educational purposes or possible writing of an advisory document.

ACTION: None warranted.

TOPIC VIII.

Regulation Review Update

TIME: 10:27 AM

247 CMR section 3:00 Personal Registration Requirements

DISCUSSION: V. BERG noted that there were no changes to the proposed revisions from the Board meeting January 5, 2017, so suggested to submit drafts for post-public hearing administrative review, and if approved, promulgate the regulations.

ACTION: None

247 CMR section 8.00 Pharmacy Interns and Technicians

DISCUSSION: V. BERG proposed to adopt the further changes to the proposed revisions to 247 CMR 8.00 as set forth in the updated draft.

ACTION: Motion by P.GANNON, seconded by, M.GODEK and voted unanimously in the affirmative to approve the edits to 247 CMR section 8:00 and adopt the changes and proceed with administrative review and promulgation.

247 CMR section 10:00 Disciplinary Proceedings

TIME: 10:42

DISCUSSION: V. BERG noted that there were no changes to the proposed revisions from the Board meeting January 5, 2017, so suggested to submit drafts for post-public hearing administrative review, and if approved, promulgate the regulations.

ACTION: None

247 CMR section 16:00

DISCUSSION: V. BERG proposed to change the “grandfathering: date in 247 CMR 16.02 (1)©1 to “June 30, 2017” with no further changes to the other proposed revisions.

ACTION: Motion by P.GANNON, seconded by, C.BASILE and voted unanimously in the affirmative to approve the edits to CMR section 16:00.

TOPIC IX.

Regulation Review Update

TIME: 10:40 AM

247 CMR section 2:00 Definitions

TIME: 10: 42

DISCUSSION: V.BERG proposed that some of the definitions listed in 247 CMR section 2:00 are no long applicable to the most current regulations. It was proposed that the current definitions should be edited so that they are applicable to current regulations.

ACTION: No vote necessary.

247 CMR section 13:00 Registration Requirements and minimal professional standards for nuclear pharmacies

DISCUSSION: V. BERG proposed the changes to 247 CMR 13:00 and proposed that the Board staff will consult with the Massachusetts Department of Public Health Radiation Control Program and NABP to evaluate any other suggested changes and then return with the recommendations.

ACTION: No vote necessary.

247 CMR section 14:00 Petition for Waiver

DISCUSSION: V. BERG proposed the changes to 247 CMR 13:00 and proposed that the Board staff will consult with the Massachusetts Department of Public Health Radiation Control Program and NABP to evaluate any other suggested changes and then return with the recommendations.

ACTION: Motion by P.GANNON, seconded by, A.STEIN and voted unanimously in the affirmative to approve CMR section 14:00 and send out for administrative review and promulgation.

TOPIC X

OPEN FILE REVIEW

TIME: 09:13 AM

Case #1

PHA-2016-0228

Stop and Shop #21, DS2359

Time: 09:13 AM

RECUSAL: NONE.

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

- On September 26, 2016, during a retail compliance inspection (ISP-6030), OPP Investigator identified an individual designated as a PTT with greater than 1000 hours without an extension granted by the board (actual hours 1987)
- MOR indicate that multiple attempts were made over several months to have the PTT attend a training class and delays were caused by class availability and inability of the PTT to travel to training location

- On August 29, 2016, Board staff received notice from the Professional Credential Service that PTT applied for the pharmacy technician registration with 1200 hours (actual hours 1694)
- MOR Indicated that PTT was refrained from performing duties on September 26, 2016 until confirmation of her registration on or about October 10, 2016
- MOR indicated that PTT hours will be monitored utilizing the corporate policy and at the store level the MOR will utilizing a monthly review process to track technicians in training (corporate policy provided)

ACTION: Motion by P.GANNON, seconded by C.BASILE and voted unanimously by those present to DISMISS (PHA-2016-0228), No Discipline Warranted and to obtain a copy of their Corporate Action Plan.

Case #2

PHA-2016-0236

Sleyman Haddad, PH18882

Time: 09:16 AM

RECUSAL: NONE

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

- On September 26, 2016, during a retail compliance inspection (ISP-6030), OPP Investigator identified an individual designated as a PTT with greater than 1000 hours without an extension granted by the board (actual hours 1987)
- MOR indicate that multiple attempts were made over several months to have the PTT attend a training class and delays were caused by class availability and inability of the PTT to travel to training location
- On August 29, 2016, Board staff received notice from the Professional Credential Service that PTT applied for the pharmacy technician registration with 1200 hours (actual hours 1694)
- MOR Indicated that PTT was refrained from performing duties on September 26, 2016 until confirmation of her registration on or about October 10, 2016
- MOR indicated that PTT hours will be monitored utilizing the corporate policy and at the store level the MOR will utilizing a monthly review process to track technicians in training (corporate policy provided)

ACTION: Motion by M.GODEK, seconded by C.BASILE, and voted unanimously by those present, to refer the matter (PHA-2016-0236) 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 STAYED PROBATION with special terms to read and attest to 247 CMR 8.00 and the Advisory on New Managers of Record (AKA MOR Checklist).

Case #3

PHA-2016-0111

Caring Pharmacy, DS89747

Time: 9:17 AM

RECUSAL: NONE

DISCUSSION: M.BROSNAN presented and summarized the investigative report that pertained to these matters.

- On June 13, 2016, a routine compliance inspection (ISP-5117) was completed and multiple deficiencies were observed. Two of these deficiencies were repeated from the previous inspection ISP-3108 conducted on November 16, 2015.
- The Biennial Inventory for Schedule II Controlled Substances was not readily retrievable during this inspection. (Repeat deficiency from ISP-3108)
- DEA 222 forms for reverse distribution of controlled substances were not readily retrievable during this inspection. (Repeat deficiency from ISP-3108.)
- Schedule II through VI prescriptions were improperly separated and filed.
- Scheduled II prescriptions were not properly cancelled by the dispensing pharmacist.
- Standard Operating Procedures (SOPs) for non-sterile compounding were not readily retrievable.
- Quality Related Events (QREs) were not properly documented as part of the pharmacy's Continuous Quality Improvement (CQI) Program.
- Two unlicensed adults (MOR's parents) accessed a basement living room area through the pharmacy.
- The Manager of Record submitted a response and documentation including policies properly remediating all deficiencies.
- A satisfactory retail compliance inspection (ISP-5770) was subsequently conducted on August 16, 2016

ACTION: Motion by C.BASILE, seconded by M.GODEK, and voted unanimously by those present, to DISMISS PHA-2016-0111, No Discipline Warranted, Remediation Complete and to send a copy of the Advisory on New Managers of Record (AKA MOR Checklist).

Case #4

SA-INV-9728

CVS #1094, DS1627

Time: 9:20 AM

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

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

- On May 6, 2016, CVS Pharmacy #1094 reported an unknown loss of 847 tablets of lorazepam 1mg was discovered on April 26, 2016. The report was amended on January 3, 2017 and the loss was adjusted to 774 tablets.
- CVS Loss Prevention and MOR Joseph Makosiej conducted an internal investigation and found no evidence of diversion. MOR Makosiej attributed the loss to inaccurate dispensing and improper handling of returns & damages.
- POC included retraining of staff on proper procedures for dispensing, returns, and damages

ACTION: Motion by A.STEIN seconded by C.BASILE, and voted unanimously by those present, to CLOSE SA-INV-9728 due to No Discipline Warranted, Remediation Complete.

Case #5

PHA-2016-0237

CVS #299, DS3596

Time: 9:22 AM

BORP Agenda:
March 2, 2017

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

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

- On November 19, 2016 OPP received a RLCS of unknown loss of #1,315 clonazepam 0.5mg tablets
- Loss was identified through a controlled substance reconciliation report
- A Retail Compliance Inspection (ISP-5431) at CVS Pharmacy #299 was completed by Investigator Paul Seed on August 1, 2016 with deficiencies noted including refrigerator temperatures out of range, expired CII not included in the perpetual inventory and interim MOR did not perform controlled substance inventory.
- Reported a prior loss of #5,039 diazepam 5mg tablets reported loss on 5/26/2015

ACTION: Motion by G.CAVANAUGH, seconded by M.GODEK, and voted unanimously by those present, to refer the matter (PHA-2016-0237) 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 STAYED PROBATION with special terms to include all strengths of benzodiazepines to be kept on a perpetual log (exact count) and reconciled every 10 days for 6 months as well as performing an exact count controlled substance inventory within 60 days.

Case #6

PHA-2016-0157

CVS#166, DS3449

Time: 9:33 AM

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

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

- On June 16, 2016 OPP received a RLCS #802 zolpidem 10mg tablets
- Investigation did not uncover a reason for the loss. drug was counted daily and reconciled weekly for a period of 4 weeks
- Of note- including this loss of #802 tablets, CVS #166 has reported unknown losses of #2,715 tablets since May 2015 (of which #1913 tablets were benzodiazepines)
- A Retail Compliance (ISP- 5919) inspection was completed on September 23, 2016 with deficiencies noted such scales not sealed, expired product on shelves, freezer needing defrosting, insulin fridge disorganized, compounding issues including unsanitary compounding area, product labels with a one year BUD, and temperature log recording issues. A satisfactory plan of correction was submitted, and a follow up inspection completed December 5, 2016 with no deficiencies noted.

ACTION: Motion by P.GANNON, seconded by K.CONLEY, and voted unanimously by those present, to refer the matter (PHA-2016-0157) 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 STAYED PROBATION with special terms to include all strengths of zolpidem containing products and benzodiazepines to be kept on a perpetual log (exact count) and reconciled every 10 days for 6 months as well as performing an exact count controlled substance inventory within 60 days.

Case #7

PHA-2016-0192

CVS #657, DS89715

Time: 9:36 AM

BORP Agenda:
March 2, 2017

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

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

- On August 22, 2016, CVS #657 reported an unknown loss of 1,734 tablets of tramadol 50mg that occurred on August 5, 2016. MOR Kristiana Papa was notified of the loss by the corporate PMP program on August 5, 2016. An internal investigation was initiated at that time by the Loss Prevention Team and no evidence of diversion was found.

- MOR Papa's POC included additional cycle counts and increased vigilance when reviewing record keeping to identify losses more quickly. Staff was retrained on proper procedures for returns, damages, and double counting federally controlled substances.

ACTION: Motion by A.STEIN seconded by C.BASILE, and voted unanimously by those present, to refer the matter (PHA-2016-0192) 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 STAYED PROBATION with special terms to include all strengths of tramadol containing products to be kept on a perpetual log (exact count) and reconciled every 10 days for 6 months as well as performing an exact count controlled substance inventory within 60 days.

Case #8

PHA-2016-0194

CVS #75, DS3535

TIME: 9:37 AM

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

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

- On September 2, 2016, CVS #75 reported an unknown loss of 100 tablets of oxycodone-acetaminophen 5-325mg that occurred on August 18, 2016. The loss was discovered by MOR Saroun Chhoeun during weekly reconciliation of CII's. An internal investigation was initiated that included the CVS Loss Prevention Team and uncovered no evidence of diversion. Video showed that the bottle was likely thrown in the trash.
- MOR Chhoeun's POC included additional cycle counts and increased vigilance when reviewing record keeping to identify losses more quickly. Staff was retrained on proper procedures for returns, damages, and double counting federally controlled substances.

ACTION: Motion by M.GODEK, seconded by P.GANNON and voted unanimously by those who were present to refer the matter to the office of prosecution for the issuance of an order to show cause and to authorize reprimand with the conditions of providing evidence of staff retraining on inventory procedures.

Case #9

SA-INV-09419

CVS #1876, DS2064

TIME: 9:39 AM

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

DISCUSSION: R.GEANEY presented and summarized the investigative report that pertained to these matters.

- On 4/14/16 a routine inspection (ISP-5104) was conducted and a larger than normal number of invoices for various NDCs of testosterone cypionate 200mg/ml were observed.

- In comparing invoices to dispensing reports and on hand balances at the pharmacy it seemed as if there was a loss of approximately 14 X 10ml vials of testosterone cypionate 200mg/ml.
- Pharmacy supervisor Colleen Klaus partnered with Loss Prevention manager Eric Spatola to investigate the discrepancy.
- Reconciliation reports were provided by Regulatory Affairs department which showed that there was no discrepancy in the number of vials ordered, received dispensed and actual balance on hand.
- Some of the invoices that were being questioned showed product being ordered but it was never shipped and/or received by the pharmacy due to a backorder by the manufacturer.

ACTION: Motion by M.GODEK, seconded by P.GANNON and voted unanimously by those who were present to close the staff assignment as there was no violation.

Case #10

PHA-2016-0033

CVS #705, DS3428

TIME: 9:40 AM

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

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

- During a routine retail compliance inspection on February 23, 2016, the pharmacy dispensed testosterone, a schedule III medication, for more than a thirty-day supply.
- MOR Tumuna indicated on two separate occasions in February 2015 and August 2015, a patient was dispensed a 10mL vial of testosterone cypionate for a 1 month supply because the 1mL vial was not available.
- Verifying Pharmacist Hakim indicated that he verified a testosterone prescription with a 10mL vial for a 30 day supply because the 1mL testosterone vial was not available due to manufacturer backorder and informed the patient that the vial is only good for 30 days once the vial was punctured.
- Verifying Pharmacist Huynh may have verified that testosterone prescription correctly that day but someone other than me may have switched out the product due to workflow processes. She indicated that contributing factors include: accountability issues, miscalculation of dosage, oversight of quantity on drug product, product scan bypassed, mismatched prescription to same drug product while checking under intense pressure. She no longer works for CVS unrelated to this incident.
- MOR Tumuna indicated that she reviewed this incident with all staff members and the proper dispensing of CII and CII medications to prevent a similar event in the future.
- MOR submitted 2 CEs in law for all staff involved including signed attestations of 247 CMR 15.

ACTION: Motion by A.STEIN, seconded by P.GANNON and voted unanimously by those who were present to dismiss the complaint, no discipline warranted. The matter was remediated.

Case #11

SA-INV-10002

Walgreens #1233, DS3333

TIME: 9:43 AM

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

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

- During a routine retail compliance inspection on June 8, 2016 it was determined the pharmacy dispensed testosterone for more than 30-day supply.

- MOR indicated that the pharmacists dispensed these prescriptions on multiple occasions between 3/2016-9/2016
- 1ml vial was on backorder and dispensed the 10ml vial to avoid therapy disruption
- MOR reinforced with staff that the day supply cannot exceed 30 days for a schedule III medication, asked staff to read MGL Chapter 94C Section 23(d), used it as a monthly discussion topic, and bright yellow placards were placed around the pharmacy that state "CIII, no more than 30-day supply"
- Both pharmacists involved completed 2CE's in law & attested to reading 247 CMR 15, CQI program

ACTION: Motion by P.GANNON, seconded by A.STEIN and voted unanimously by those who were present to close the staff assignment with no discipline warranted.

Case #12

PHA-2016-0182

Walgreens #5075, DS2928

TIME: 9:44 AM

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

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

- On November 18, 2015, Walgreens #5075 reported an unknown loss of 100 capsules of amphetamine mixed salts 30mg ER occurred on November 17, 2015. MOR Huan Vu discovered the loss during the weekly reconciliation on November 12, 2015.
- An internal investigation was conducted involving MOR Vu, the Pharmacy District Manager, and Asset Protection. They were unable to determine a reason for the loss but ruled out diversion
- Staff was retrained to back-count inventory prior to dispensing and to receive controlled substance shipments by scanning each piece electronically & physically matching the pieces to the hard copy invoice after scanning.
- Of note, MOR Vu wished for the BORP to consider that he has not had another significant loss since this incident in November of 2015.

ACTION: Motion by A. STEIN, seconded by C.BASILE and voted unanimously by those who were present to refer the matter to the office of prosecution for the issuance of an order to show cause and to authorize reprimand.

Case #13

PHA-2016-0205

Walgreens #6805, DS3246

TIME: 9:45 AM

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

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

- RLCS #100 Oxycodone 5mg tablets at Walgreens Pharmacy #6805 on or about November 12, 2015.
- MOR Le indicating that the loss was discovered on November 12, 2015 while completing a weekly narcotic reconciliation inventory. The pharmacy staff and asset protection team reviewed perpetual inventories, cycle counts, biennial inventories, and inventory reports for the time period of the loss, as well as three months prior to the loss and were unable to find any reason for the loss.
- Corrective action includes emphasizing to staff that a Registered Pharmacist must put controlled drugs back into the locked safe immediately after filling the prescription and a Registered Pharmacist must put controlled drugs into the locked safe immediately after receiving shipment. This will reduce the likelihood of medications being misplaced or stolen.

- A Retail Compliance (ISP- 4567) inspection at Walgreens Pharmacy #6805 was completed on January 25, 2016 with no deficiencies noted.

ACTION: Motion by A. STEIN, seconded by C.BASILE and voted unanimously by those who were present to refer the matter to the office of prosecution for the issuance of an order to show cause and to authorize reprimand.

Case #14

PHA-2016-0227

Rite Aid #10196, DS3170

TIME: 9:47 AM

RECUSAL: W. COX and G. CAVANAUGH recused and were not present for the discussion or vote on this matter.

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

- On January 20, 2016, Rite Aid #10196 reported an unknown loss of 178mL of hydrocodone-homatropine 5-1.5mg/5mL oral syrup were discovered lost on November 11, 2015.
- PDM Daniel M. Maloof conducted an internal investigation and was unable to determine the cause of the loss but did not suspect diversion. MOR Jacqueline Almeida believed the bottle was somehow accidentally thrown in the trash.
- MOR Almeida described and provided records that the weekly physical inventory was logged as 178mL from the last date a prescription was dispensed on October 13, 2015 until the discovery of the loss on November 11, 2015. In addition, the counts were recorded by three different pharmacists including MOR Almeida.

ACTION: Motion by A. STEIN, seconded by P.GANNON and voted unanimously by those who were present to refer the matter to the office of prosecution for the issuance of an order to show cause and to authorize reprimand.

Case #15

SA-INV-10457

Brigham and Women's Nuclear, NU16

TIME: 9:49 AM

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

DISCUSSION: N. VAN ALLEN presented and summarized the investigative report that pertained to these matters.

- On October 28, 2016, a disclosure was filed for failed HEPA filter integrity tests. Specifically, 9 of 23 HEPA filters failed this test (6 in the Board of Pharmacy licensed space).
- All filters were replaced and tested successfully.
- Environmental monitoring was conducted post installation identifying organisms of concern. Remediation was initiated including a monthly cleaning and repeat sampling. BUDs of sterile preparations do not exceed 12 hours.
- Repeat sampling showed minor contamination within the classified spaces. Remediation continued until corrective action was deemed appropriate with no additional contamination.
- Normal compounding activities resumed on January 24, 2017

ACTION: Motion by A. STEIN, seconded by P.GANON and voted unanimously by those who were present to close the staff assignment, with no discipline warranted. The matter was remediated.

BORP Agenda:
March 2, 2017

TOPIC XI

EXECUTIVE SESSION

DISCUSSION: None

ACTION: At 10:51 pm President T. FENSKY read the statement on reasons for Executive Session. At 2:03, he called for a motion to enter Executive Session: Motion by P. GANNON, seconded by C. BASILE 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, A. STEIN: yes G. CAVANAUGH: yes; R.TINSLEY; yes, P. GANNON; yes (M. GODEK, who attended from opening until lunch, was not present.)

TOPIC XII

Adjudicatory Session

DISCUSSION: None

ACTION: At 11:06 pm, on a motion by W. COX, seconded by M. GODEK, the members voted unanimously to enter into Adjudicatory session.

TOPIC XIII.

M.G.L. c. 65C Session

DISCUSSION: None

ACTION: At 11:24 pm motion by E. TAGLIERI, seconded by C. BASILE and voted unanimously to enter into M.G.L. c. 65C Session.

TOPIC XIV.

ADJOURNMENT OF MEETING

DISCUSSION: NONE

ACTION: At 2:13 pm motion by M. GODEK, seconded by C. BASILE, and voted unanimously to adjourn the meeting. P. GANNON left meeting at 2:10 pm.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 3/2/2017 General Session
2. Draft Minutes of the 2/2/2017 Meeting
3. Draft Above Action Level Staff Action Policy
4. Application of Genoa Pharmacy, New Community Pharmacy, Holyoke
5. Application of Genoa Pharmacy, New Community Pharmacy, Charlestown
6. Application of Remedium Pharmacy – for Renovation/Expansion
7. Policy # 2015-02: Guidelines for Pharmacist Continuing Education Requirements
8. Policy # 2017-02: Guidance for Board-Approved Pharmacy Technician Training Programs and Examinations
9. Staff Action Policy Licensure Policy 17-02, allowing staff action approval of pharmacy technician training programs and examinations
10. Attestation of Compliance with Requirements for Board Approved Pharmacy Technician Training Programs Checklist
11. Report on applications Approved Pursuant to Licensure Policy 13-01
12. Report of activities Probation Monitor 2/1/17 – 2/20/2017
13. Report of Board Delegated Review Session from 2/27/2017
14. Memo to the Board of Pharmacy from Vita Berg, Chief Board Counsel regarding 247 CMR 3.00, 8.00, 10.00, and 16.00
15. 247 CMR section 8.00 with track changes
16. 247 CMR section 8.02 clean copy incorporating proposed revisions
17. Summary Comments on draft 247 CMR 13.00 and 247 CMR 14.00
18. Draft 247 CMR section 8 Pharmacy Interns and Technicians

19. Narcan Mobile Pilot Program Petition for Approval
20. Investigation report in the matter of PHA-2016-0228 Stop & Shop #21, DS2359
21. Investigation report in the matter of PHA-2016-0236 Sleyman Haddad, PH18882
22. Investigation report in the matter of PHA-2016-0111 Caring Pharmacy, DS897747
23. Investigation report in the matter of SA-INV-9728 CVS#1094, DS1627
24. Investigation report in the matter of PHA-2016-0237, CVS #299, DS3596,
25. Investigation report in the matter of CVS #166, DS3449, PHA-2016-0157
26. Investigation report in the matter of CVS #657, DS897515, PHA-2016-0192
27. Investigation report in the matter of CVS #75, DS3535, PHA-2016-0194
28. Investigation report in the matter of CVS #1876, DS2064, SA-INV-9419
29. Investigation report in the matter of CVS #705, DS3428, PHA-2016-0033
30. Investigation report in the matter of Walgreens, DS3333, SA-INV-10002
31. Investigation report in the matter of Walgreens, DS2928, PHA-2016-0182
32. Investigation report in the matter of Walgreens, DS3246, PHA-2016-0205
33. Investigation report in the matter of Rite Aid, DS3170, PHA-2016-0227
34. Investigation report in the matter of Brigham & Womens Nuclear, NU16, SA-INV-10457

Respectfully submitted by:

S. CORNACCHIO, R.Ph.
Secretary