

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

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

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

Agenda

Time	#	Item	Exhibits	Contact
8:30	I	CALL TO ORDER		E. Taglieri
8:35	II	APPROVAL OF AGENDA Introduction of Intern: Joanna Yen		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of January 5, 2017 Regular Session Minutes • Draft of December 1, 2015 Regular Session Minutes 		
8:50	IV	APPLICATIONS <ul style="list-style-type: none"> • US PharmaTrade – Wholesale Distributor • Genoa/Acton – New Community Pharmacy • Berkshire Community Pharmacy, North Adams – New Community Pharmacy • GE Healthcare – Wholesale Distributor • New England Life Care – Revised Renovation request • Integriscript – Renovation/Expansion 		
9:50	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 • Above Action Levels approved by Staff Action • Board approved CE for 2016 	Reports	R. Harris K. Fishman M. Chan V. Thaker

10:10	VI	FLEX <ul style="list-style-type: none"> Inquiries from July, 2016 to December, 2016 Pharmacy Substance Use Disorder (PSUD) program discussion 	V. Thaker V. Berg	
10:25	VII	POLICIES <ul style="list-style-type: none"> Amendments to Licensure Policy 13-01 Pharmacy Technician reciprocity and training policies 	M. Chan W. Frisch V. Thaker	
10:50	VIII	ADVISORY <ul style="list-style-type: none"> Advisory of Testosterone Days Supply 	W. Frisch M. Chan	
11:10	IX	REGULATION REVIEW UPDATE <ul style="list-style-type: none"> 247 CMR 8.00: Pharmacy Interns and Technicians 247 CMR 16.00: Collaborative Drug Therapy Management 	V. Berg H. Engman	
11:40	X	FILE REVIEW		
		1	PHA-2016-0213- Rite Aid #10189, DS3113 (reconsideration)	Melton
		2	PHA-2017-0002- Rite Aid #10189, DS3113	Melton
		3	PHA-2016-0214 Rite Aid #10198, DS2386	Melton
		4	SA-INV-10594 CAPS of Woburn, DS3312	Melton
		5	PHA-2016-0189 CVS #915, DS3395	Tran
		6	PHA-2016-0190 Omnicare of Northern MA, DS89931	Santoro
		7	PHA-2016-0211 Kimberly Godfrey, PT7891	
		8	PHA-2016-0130 Saigon, DS2696	Horn
		9	PHA-2016-0131- Kiet Ngo, PH19274	
		10	SA-INV-9406 Pentec Health, DS89913	Melton
		11	PHA-2016-0118 Walgreens #4403, DS2805	Geaney
		12	PHA-2016-0119, Matthew Moy, PH27731	
13	PHA-2016-0215 Stop and Shop #12, DS2958	Santoro		

12:30		LUNCH BREAK	
1: 30	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
2:30	XII	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)	CLOSED SESSION
2:45	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**

January 5, 2017

Board Members Present

Timothy Fensky, R.Ph. President
Susan Cornacchio, JD, RN, Secretary
Michael Godek, R.Ph., President-Elect (left 12:30)
Garret Cavanaugh, R.Ph.
Patrick Gannon, R.Ph
Catherine Basile, Pharm D, R.Ph
Andrew Stein, Pharm D, R.Ph.
Phillippe Bouvier, R.Ph.
Richard Tinsley, MBA, Med,
Ed Taglieri Jr., R.Ph. President

Board Members Not Present

Ali Raja, MD, MBA, MPH
Karen Conley, DNP, RN, AOCN,NEA-BC
William Cox, CPhT

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
Cheryl Lathum, PharmD, Senior Investigator

TOPIC I. CALL TO ORDER

TIME: 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 P. GANNON, seconded by M. GODEK, and voted unanimously to approve the agenda.

Executive Director D. SENCABAUGH introduced APPE Intern K. GRIFFITH, and T. FENSKY asked other interns in the audience to stand up and introduce themselves.

TOPIC III.

APPROVAL OF BOARD MINUTES

1. Draft December 6, 2016, Regular Session Minutes

DISCUSSION: R. TINSLEY wanted to be sure the information about 2 Board Members voting for officers by phone in December was included in the minutes (it was.) Also, there was a typo pointed out in bullet #4 that needed correction.

ACTION:

Motion by E. TAGLIERI, seconded by R. TINSLEY, and voted affirmatively to accept, with P.GANNON, C. BASILE, and M. GODEK abstaining, as they were not present at the December 6, 2016 meeting.

TOPIC IV:

APPLICATIONS

TIME: 8:35 am

1. North Amherst Pharmacy New Community Pharmacy

RECUSAL: M. GODEK

DISCUSSION: North Amherst Pharmacy was represented by Brad LeVay, Jr. (proposed MOR), and owner Ioannis Nikitas. They answered the Board members questions to their satisfaction, but it was pointed out that they needed to change their attestation to answer “yes” to performing simple and moderate non-sterile compounding.

ACTION: Motion by P. GANNON, seconded by, G. CAVANAUGH, and voted unanimously in the affirmative to approve the application for the new North Amherst Pharmacy, pending a successful inspection and the change on the attestation.

2. Prescriptions, Inc. – New Community Pharmacy

RECUSAL: None

DISCUSSION: Prescriptions, Inc. was represented by Vashkar Karim, the proposed MOR. Of note, Mr. Karim’s wife is the owner. Executive Director D. SENCABAUGH reminded the Board Members that Mr. Karim had recently been the subject of 2 separate Board cases. The first involved Boston Community Pharmacy, located in Chelsea, MA. Mr. Karim was the owner and MOR of this pharmacy, which had received approval from the Board, and had an successful inspection, resulting in the issuance of a license. However, when Board Investigators went back for a routine inspection, they learned that the pharmacy had never opened, and Mr. Karim had not notified the Board. The second issued involved The Prescription Shoppe in Everett, MA, located at the same address as the proposed “Prescriptions Inc”. Mr. Karim was the owner of that store concurrent with his involvement with Boston Community, and ended up selling his files to Rite Aid. Prior to

the sale, Board Investigators had inspected The Prescription Shoppe, and found a number of significant deficiencies. Board members expressed concern about the proposed pharmacy on that basis.

ACTION: An initial motion by E. TAGLIERI, seconded by P. GANNON to approve the application, was voted 6 – 4 in the negative. A second motion was made by M. GODEK, seconded by C. BASILE to defer the application until the proposed MOR retakes and passes the MPJE, updates his application, and submits a plan for how he will maintain ongoing compliance. That motion was approved unanimously.

3. MedRX Pharmacy – New Community Pharmacy – 9:19 am

RECUSAL: None.

DISCUSSION: MedRX, located in Lawrence, MA, was represented by proposed MOR Edwin Ngaruiya. Mr. Ngaruiya answered the Board's questions to their satisfaction.

ACTION: Motion by E. TAGLIERI, seconded by A. STEIN, and voted unanimously to approve MedRX as a new Community Pharmacy, pending successful inspection.

4. Sale of some existing Rite Aid stores to Freds Pharmacy (through Walgreens) in Massachusetts.

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

DISCUSSION: Walgreens is buying Rite Aid, but FTC mandates have included the sale of 9 Rite Aid locations in Massachusetts, (865 total nationwide), being purchased by a pharmacy company based out of Memphis, TN, known as Freds. Freds currently owns and operates 372 pharmacy locations located in the southern states. The transaction in Massachusetts is likely to occur on or about March 1, 2017. The stores will still be operating under the Rite Aid banner, and use Rite Aid operating Policies & Procedures, for upwards of 30 months after the purchase.

ACTION: Motion by A. STEIN and seconded by P. BOUVIER, and approved unanimously by all to authorize the Executive Director of the Board of Pharmacy to approve the transfer of ownership of the Rite Aid locations to Freds by staff action.

TOPIC V.

REPORTS

Applications Approved Pursuant to Licensure Policy 13-01, 9:32 am

DISCUSSION: R. HARRIS noted that during the past month there have been thirty-seven (37) change-of-managers, and three (3) renovation/expansions.

So noted

Board Delegated Review Pursuant to BDCR Policy

There were 10 Board Delegated Review (all Staff Assignments) cases heard on January 3rd, 2017. 8 were about self-reports of a CE deficiency, and 2 involved customer grievances. They had all been satisfactorily remediated and the files were closed with no discipline warranted. The Board Delegated Review session was attended by T. FENSKY as the Board Member,

H. ENGMAN as Board Counsel, M. CHAN, QA Pharmacist (for W. FRISCH, Director of Pharmacy Compliance), and Executive Director D. SENCABAUGH.

ACTION: So noted

Report of activities Probation Monitor

DISCUSSION: D. SENCABAUGH (for K.FISHMAN) provided the November 30, 2016 – January 3, 2017, Board of Pharmacy Statistics Report for the Probation monitor, which noted that there are forty (40) licensees on probation, thirty-four (34) satisfactorily completed probation, eight (8) licensees given the opportunity to cure, four (4) licensee did not cure within 30 days, eight (8) given the opportunity to cure, and two (2) notices of further discipline.

ACTION: So noted

TOPIC VI

POLICIES

Time: 9:35 AM

Proposed Recommended Response to Above Action Level Environmental Monitoring Results

DISCUSSION: Presented by Michelle Chan and William Frisch

Guideline for sterile compounding with regards to above action level EM. Document was passed around to Board members to review. Questions were raised with regards to how long the documentation should be kept on site, as well as the legal aspects, i.e. peer review protection. Members agreed that it gave good guidance and roadmap for pharmacies to use. Board Members agreed to just leave as guidance with some adjustments.

ACTION: Motion by P. GANNON, seconded by A. STEIN and voted unanimously to approve Above Action Level Environmental Monitoring Results pending recommendations.

Collection of Social Security Numbers and Department of Revenue Suspensions

Time: 11:41 AM

DISCUSSION: Presented by V. BERG

Clarification of staff action policy with regards to SS numbers required to issue license. Will not issue license without SSN to enforce child support issue

- Can suspend license if non-compliant with child support
 - If person doesn't have SSN (i.e. foreign), can submit affidavit
 - Can get initial license without SSN, but cannot renew without one
- 1.

ACTION: Motion by P. GANNON, seconded by M. GODEK and voted unanimously to approve Collection of Social Security Numbers and Department of Revenue Suspension.

PSUD – Deferred

Conflict of Interest and Board Member Indemnification

Time: 10:30 AM

DISCUSSION: Presented by V. BERG

Definitions of statutory conflict of interest and appearance of bias were summarized as well as options for the board members if they find themselves in either position. Members can either recuse themselves or file a disclosure. "Rule of necessity" was clarified as a limited exception to recusal if quorum could not be reached.

ACTION: No action today.

TOPIC VII

REGULATIONS

Time: 11:41AM

247 CMR 3: Personnel Registration Requirements

DISCUSSION: Presented by V. BERG

No further changes were made to this section.

ACTION: Motioned by M. GODEK, seconded by C. BASILE and voted unanimously to approve 247 CMR section 3 Personnel Registration Requirements for promulgation pending recommendations.

247 CMR 8: Pharmacy Interns and Technicians

Time: 12:00 PM

DISCUSSION: Presented by V. BERG

ACTION: No action today.

247 CMR 10: Disciplinary Proceedings

Time: 11:46 PM

DISCUSSION: Presented by V. BERG

No further changes were made, submit for review

ACTION: Motioned by M. GODEK, seconded by E. TAGLIERI JR and voted unanimously to approve 247 CMR section 10 Disciplinary Proceedings for promulgation pending recommendations.

247 CMR 16: Collaborative Drug Therapy Management

Time: 12:00 PM

DISCUSSION: Presented by V. BERG

Changes to current collaborative drug therapy management requirements were discussed. The proposed regulation grandfathered in pharmacists who have already entered into a collaborative agreement. Questions were raised whether a PharmD alone was sufficient for entering into collaborative practice agreement. Point was made that non-physician prescribers do not need 5 years of practice before prescribing under supervising prescriber.

ACTION: Motion by M. GODEK, seconded by A. STEIN and voted unanimously to defer 247 CMR 16 to the February board meeting.

TOPIC XIII

SPEAKER

Time: 10:42 AM

DISCUSSION: Bureau Director Jim Lavery introduced DPH COMMISSIONER Dr. Monica Bharel. The Commissioner met and thanked Board members, first giving them an overview on her background and personal history. Board members and staff took turns introducing themselves as well. The Commissioner talked about the mission of DPH, focusing on efforts to positively impact the opioid crisis and resulting overdoses. She highlighted the new PMP (MassPAT) Program, and how she views it as a great tool to combat the opioid crisis. Dr. Bharel opened the floor to the Board Members, asking if they had any concerns or questions for her.

TOPIC IX

ADVISORY

Time:

DEFERRED

TOPIC X

OPEN FILE REVIEW

Case #1

PHA-2016-0155

Rite Aid #10063, DS3009

Time: 10:04 AM

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

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

- OPP received notification that Rite Aid #10063 had a loss of #427 alprazolam 2mg tablets. Rite Aid monitored the supply of the medication for several months, reviewed audit of prescriptions.
- The Pharmacy indicated that they ordered three bottles of #100 tablets, and received three bottles of #500 tablets, and that one of the bottles may have been thrown in the trash. Board members discussed the fact that a loss due to being thrown in the trash is becoming a common reason for loss.
- MOR Stanczak indicated that correction plan includes the medication being moved to a more visible area for the Pharmacist, back count completed when dispensed to a patient and the minimum quantity of the medication is kept in stock.
- Further covert routine counts have been performed since the original loss with no further discrepancies noted.
- A Retail Compliance inspection (ISP-5513) was completed on July 7, 2016 with no deficiencies noted.

ACTION: Motion by P.GANNON, seconded by E.TAGLIERI and voted unanimously by those present to refer the matter to the Office of Prosecution for the issuance of an Order to Show Cause and to authorize a Consent Agreement for Stayed Probation with special terms to include all strengths of alprazolam, later amended to all benzodiazepine products, to be kept on a perpetual log (exact count) and reconciled every 10 days until the next

biennial inventory or 6 months, whichever is greater. Any significant loss encountered needs to be reported to the Board.

Case #2

PHA-2016-0128

Rite Aid #10161, DS3144

Time: 10:16AM

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

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

- On May 16, 2016 during ISP-5266, OPP Inspector observed a technician trainee at 1341 hours.
- The MOR indicated that the deficiency in monitoring the training was due to a lack of record keeping at the store level. Another factor that delayed registration was the financial burden to the technician
- The plan of corrective action indicated that the MOR would monitor all technician trainees to make sure that they start to study and take technician exam at 500 hours.
- MOR also indicated that there would be a discussion with the trainee early in their training process regarding the registration cost, the importance of being a registered technician, and the repercussions of not becoming registered within the 1000-hour limitation.
- Retail Compliance Inspections, (ISP-5722) conducted on July 17, 2016 and (ISP-5873) conducted on December 5, 2016 were both deemed satisfactory with no deficiencies.

ACTION: Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present, to DISMISS PHA-2016-0128, with no discipline warranted.

Case #3

PHA-2016-0129

Ngoc T. Nguyen, PH27662

Time: 10:17 AM

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

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

- On May 16, 2016 during ISP-5266, OPP Inspector observed a technician trainee at 1341 hours.
- The MOR indicated that the deficiency in monitoring the training was due to a lack of record keeping at the store level. Another factor that delayed registration was the financial burden to the technician
- The plan of corrective action indicated that the MOR would monitor all technician trainees to make sure that they start to study and take technician exam at 500 hours.

- MOR also indicated that there would be a discussion with the trainee early in their training process regarding the registration cost, the importance of being a registered technician, and the repercussions of not becoming registered within the 1000-hour limitation.

- Retail Compliance Inspections, (ISP-5722) conducted on July 17, 2016 and (ISP-5873) conducted on December 5, 2016 were both deemed satisfactory with no deficiencies.

ACTION: Motion by P. GANNON, seconded by C.BASILE, and voted unanimously by those present, to refer the matter to the Office of Prosecution for the issuance of an Order to Show Cause and to authorize a Consent Agreement for Stayed Probation with special terms to include having the licensee attest to reading 247 CMR 8 as well as the Rite Aid Corporate Technician Training Policies.

Case #4

PHA-2016-0213

Rite Aid #10189, DS3113

Time: 10:19 AM

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

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

- OPP received notification that Rite Aid #10189 had a loss of #100 oxycodone 10mg tablets. Loss was identified during weekly inventory count. • Internal investigation found that Verification Pharmacist Nguyen was fixing a data entry error for a prescription for a quantity of 120 entered as 220. He poured the extra 100 tablets into another vial that he intended to return to stock and labeled it with the incorrect prescription label.

- In addition, video surveillance showed that the safe was left unlocked and opened and that technicians were accessing the safe.

- Former MOR Leach searched through trash and found empty stock bottles, which would correspond to 220 tablets accidentally prepared and no vial of the missing medication.

- Rite Aid disciplined Pharmacist Nguyen.

- Former MOR Leach became MOR temporarily until a new MOR was identified. She indicated that the store lacked continuity with staff pharmacists.

- New MOR Rosenbach has extensive experience in the retail setting. She is from the area and has worked in the area as a pharmacist. She pointed out that she was the 3rd MOR in a year and the store has suffered due to the lack of continuity.

ACTION: Motion by A.STEIN, seconded by P.GANNON, and voted unanimously by those present, to refer the matter (PHA-2016-0213) 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 a REPRIMAND.

Case #5

PHA-2016-0204 CVS #1972, DS2498

Time: 11:30 AM

RECUSAL: S. CORNACCHIO and K.GRIFFITH 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.

- Loss of #95 dextroamphetamine-amphetamine 5mg and #67 methylphenidate 20mg tablets identified during weekly CII inventory.
- Dextroamph-Amphet 5mg was reconciled on 3/6 and 3/16/16, loss noted on 3/16/16 reconciliation. No Rx's recorded as dispensed during this timeframe.
- There was a math error on data entry for Methylphenidate 20mg that was corrected but still showed a discrepancy of -67 tablets.
- A full investigation did not reveal any evidence of diversion or gross evidence of violation of P&P, an explanation of the loss was not uncovered.
- Plan of correction indicated that the store is now counting, back counting, and marking bottles with back counts to make sure all inventories match.
- Inventory is returned to safe as soon as possible after the prescription is dispensed.
- A new process for entering the perpetual inventory into the computer system is now being handled by weekend staff.

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

Case #6

PHA-2016-0183 CVS #1085, DS89689

Time: 11:36 AM

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

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

- Loss of #1530mL of Iophen-C NR Liquid 100mg-10mg/5ml and a loss of #825 alprazolam 0.5mg tablets were reported
- Suspected loss of Iophen-C was identified via controlled substance reconciliation report, daily counts completed, AIM (Assisted inventory management) system for suspicious ordering, reconciliation were completed for several months and variances small in comparison to volume of scripts dispensed. Loss believed to be result of product lost during normal course of dispensing
- Reconciliation of the 2015 biennial revealed a suspected loss of #825 alprazolam 0.5mg with daily counts completed and it was concluded the loss was unknown
- Going forward store will review BOH (balance on hand) modification reports, ordering, and cycle count activity in sufficient detail to quickly identify and prevent drug count discrepancies or diversion. The staff has been reminded to double count all controlled medication prior to dispensing to reduce any miscounts

ACTION: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously by those present, to refer the matter to the office of 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 perpetual inventory Iophen-C and all alprazolam products for 6 months or next biennial.

Case #7

SA-INV-10401

CVS #615, DS3493

Time: 11:38 AM

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

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

- Loss of #1387ml Iophen-C 100mg-10mg/5ml
- Reconciliation completed 5/1/15-2/22/16 was 1,948ml loss, another count on 3/2/16 was completed for 5/1/15-3/2/16 showed loss of 1,082ml and final reconciliation done from 5/1/15-4/23/16 showed a final variance of 1,387 ml
- MOR indicated loss is due to excess poured when dispensing, loss of a couple mLs the pharmacist pours out to measure drug volume
- Security camera footage was not reviewed because time period for loss could not be determined

ACTION: Motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously by those present to open complaint.

Case #8

SA-INV-10376

Walgreens #4729, DS2878

Time: 3:16 PM

RECUSAL: NONE

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

- A known loss of #90 generic Adderall 20mg on August 19, 2016
- Two pharmacists determined that the customer's license was not acceptable
- Customer grabbed the license and the prescription from the counter and fled the scene with the #90 tablets of generic Adderall
- On August 20, 2016, a police report was completed by an Officer at the Norwood Police Department
- MOR indicated that video footage was turned over to the Norwood Police Department as part of their larger investigation into fake prescriptions
- MOR informed all staff members to be away from arm's reach when dispensing controlled substances and conducted training on how to identify fake scripts without elements of tamper resistance

ACTION: Motion by P. GANNON, seconded by A. STEIN, and voted unanimously by those present, to close SA-INV-10376, no violation.

Case #9

The Medicine Shop; DS2793; SA-INV-9992

- C. Lathum presented and summarized the investigation report, noting that the pharmacy achieved adequate remediation.

- Motion by P. Gannon, seconded by A. Stein, and voted unanimously to close the staff assignment with no discipline warranted, noting the pharmacy achieved adequate remediation.

Case #10

Standard Pharmacy; DS3454; SA-INV-10103

- J. Santoro presented and summarized the investigation report, noting that the pharmacy achieved adequate remediation.
- Motion by P. Bouvier, seconded by C. Basile, and voted unanimously to close the staff assignment with no discipline warranted, noting the pharmacy achieved adequate remediation.

Case #11

Lenox Village Pharmacy; DS3344; SA-INV-9452

- G. Melton presented and summarized the investigation report, noting that the pharmacy achieved adequate remediation.
- Motion by P. Bouvier, seconded by C. Basile, and voted unanimously to close the staff assignment with no discipline warranted.

Case #12

Balboni's Drug Store; DS1287; SA-INV-10112

- P. Seed presented and summarized the investigation report.
- Motion by A. Stein, seconded by P. Gannon, and voted unanimously to close the staff assignment, with no discipline warranted, noting the pharmacy achieved adequate remediation.

Case #13

SA-INV-10111 Shattuck Pharmacy, DS22507 Time: 3:28 PM

RECUSAL: NONE

DISCUSSION: P. SEED presented and summarized the investigation report that pertained to these matters.

- On July 11, 2016 OPP investigators performed a U.S. Consumer Product Safety Commission inspection
- 3 of 120 filled prescriptions in the will call area did not comply with the Poison Prevention Packaging Act (PPA). The 3 prescriptions were filled without child-resistant packaging
- MOR educated staff on importance of compliance with PPA and provided a form customers will complete to request non child-resistant packaging

ACTION: Motion by P. BOUVIER, seconded by C. BASILE, and voted unanimously by those present, to close SA-INV-10111, no discipline warranted.

Case #14

SA-INV-10115 Oldens Pharmacy, DS2017 Time: 3:28 PM

RECUSAL: NONE

DISCUSSION: P. SEED presented and summarized the investigation report that pertained to these matters.

- On June 7,2016 OPP investigators performed a U.S. Consumer Product Safety Commission inspection
- 39 of 458 filled prescriptions in the will call area did not comply with the Poison Prevention Packaging Act (PPA).
- CPSC requested a written response from the MOR
- MOR indicates a recent software change did not transfer non-safety cap information. Staff was re-trained, intake forms for new patients includes a safety cap question, software system updated to display non child-resistant packaging requests print on patient receipt.

ACTION: Motion by P. BOUVIER, seconded by P.GANNON, and voted unanimously by those present, to close SA-INV-10115, no discipline warranted.

Case #15

SA-INV-10114 Andrews Pharmacy, DS1429

Time: 3:29 PM

RECUSAL: NONE

DISCUSSION: P. SEED presented and summarized the investigation report that pertained to these matters.

- On July 15,2016 OPP investigators performed a U.S. Consumer Product Safety Commission inspection
- 2 of 273 filled prescriptions in the will call area did not comply with the Poison Prevention Packaging Act (PPA).
- MOR indicated initiating policies to assure compliance. The pharmacy staff was educated on importance of safety closures. All prescriptions will have a safety closure unless a non child-resistant packaging is requested.

ACTION: Motion by P. GANNON, seconded by A.STEIN, and voted unanimously by those present, to close SA-INV-10114, no discipline warranted.

Case #16

SA-INV-9920 CAPS Pharmacy, DS3312

Time: 3:30 PM

RECUSAL: NONE

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

- On July 26,2016 CAPS notified BORP of abnormal result involving (+) fungi growth on a cart in the cleanroom from EM completed on 7/5/16.
- A delay in reporting occurred due to email notification of the actionable result to a CAPS staff member on vacation
- Remediation was completed as part of standard operating procedures (weekly cleaning & sanitization of the entire cleanroom and equipment including carts and weekly EM testing with no actionable results)
- Cart 4 was retested on 7/26, 7/27, and 7/28 and results were negative for growth
- CAPS corrective action included requiring verbal and written confirmation of results by telephone and email from the lab with notification to two separate staff members

ACTION: Motion by C. BASILE, seconded by E.TAGLIERI, and voted unanimously by those present, to close SA-INV-9920, no violation.

TOPIC XI

EXECUTIVE SESSION

DISCUSSION: None

ACTION: At 1:09 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 3:38 pm, on a motion by E. TAGLIERI, seconded by A. STEIN, the members voted unanimously to enter into Adjudicatory session.

TOPIC XIII.

M.G.L. c. 65C Session

DISCUSSION: None

ACTION: At 3:49 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 5:05 pm motion by T. FENSKY, seconded by M. GODEK, and voted unanimously to adjourn the meeting.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 1/5/2017 General Session
2. Draft Minutes of the 12/6/2016 Meeting
3. Draft Above Action Level Staff Action Policy
4. Application of North Amherst Pharmacy, New Community Pharmacy
5. Application of Prescriptions, Inc. – New Community Pharmacy
6. Application of MedRX Pharmacy – New Community Pharmacy
7. Memo from Vita Berg to the Board Members Titled “Collection of Social Security Numbers and Department of Revenue Suspensions”
8. Powerpoint from Vita Berg to the Board Members Titled “Conflict of Interest and Board Member Indemnification”
9. Report on applications Approved Pursuant to Licensure Policy 13-01
10. Report of activities Probation Monitor 11/30/16 – 1/3/2017
11. Report of Board Delegated Review Session from 1/3/2017
12. Draft 247 CMR section 3 Personnel Registration Requirements
13. Draft 247 CMR section 8 Pharmacy Interns and Technicians
14. Draft 247 CMR 10 Disciplinary Proceedings
15. Draft 247 CMR 16 Collaborative Drug Therapy Management
16. Investigation report in the matter of PHA-2016-0155 Rite Aid #10063, DS3009

17. Investigation report in the matter of PHA-2016-0128 Rite Aid #10161, DS3144
18. Investigation report in the matter of PHA-2016-0129 Ngoc T. Nguyen, PH27662
19. Investigation report in the matter of PHA-2016-0213 Rite Aid #10189, DS3113
20. Investigation report in the matter of CVS #1972, DS2498, PHA-2016-0204
21. Investigation report in the matter of CVS #1085, DS89689, PHA-2016-0183
22. Investigation report in the matter of CVS #615, DS3493, SA-INV-10401
23. Investigation report in the matter of Walgreens #4729, DS2878, SA-INV-10376
24. Investigation report in the matter of Balboni's Drug Store, DS1287, SA-INV-10112
25. Investigation report in the matter of Shattuck Pharmacy, DS22507, SA-INV-10111
26. Investigation report in the matter of Oldens Pharmacy, DS2017, SA-INV-10115
27. Investigation report in the matter of Andrews Pharmacy, DS1429, SA-INV-10114
28. Investigation report in the matter of CAPS Pharmacy, DS3312, SA-INV-9920

Respectfully submitted by:

S. CORNACCHIO, R.Ph.
Secretary