

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

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

March 7, 2019
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Beth Rabasco, Phone: 617-624-5291 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.

Agenda

Time	#	Item	Page	Contact
8:30	I	CALL TO ORDER		A. Stein
	II	APPROVAL OF AGENDA		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of February 7, 2019 Regular Session Minutes • Introduction of Interns <ul style="list-style-type: none"> ○ Nicole Tusino-MCPHS 		
8:45	IV	REPORTS <ul style="list-style-type: none"> • Applications approved pursuant to Licensure Policy 13-01 • Monthly report from probation • Board Delegated Review pursuant to Licensure Policy 14-02 • Above Action Levels approved by Staff Action 16-04 • PSUD Report-Policy 17-03 		
8:50	V	POLICIES and ADVISORIES <ul style="list-style-type: none"> • Staff Action Policy 13-01(Revision): Licensure Applications and Notices • Policy 2019-01: Shared Pharmacy Service Models Including Central Fill, Central Processing, and Tele-pharmacy 		

9:15	VI	<p>APPLICATIONS</p> <ul style="list-style-type: none"> • Springfield Pharmacy – New Community Pharmacy • Walgreens #16537; DS90079 – Renovation/Expansion • AllCare Plus Pharmacy, DS89984 – Waivers • Walgreens 10673, DS8963 - Change of Manager 														
9:45	VII	<p>FLEX</p> <ul style="list-style-type: none"> • Delegate vote for NABP Treasurer • Circular Letter: Pharmacist Administration of Medications for the treatment of Mental Illness and Substance Use Disorder. • NABP Proposed Resolutions • CVS Loss Prevention Protocol • Greater Lawrence Family Health Center Pharmacies – Medication Buyback Program • 2018 Plan of Correction Report 														
11:00	VIII	<p>FILE REVIEW</p> <table border="1" data-bbox="287 1083 1180 1530"> <tr> <td data-bbox="287 1083 334 1152">1</td> <td data-bbox="334 1083 1180 1152">PHA-2018-0071- Rite Aid #10078- DS90123</td> </tr> <tr> <td data-bbox="287 1152 334 1224">2</td> <td data-bbox="334 1152 1180 1224">PHA-2019-0001- CVS #765- DS2910</td> </tr> <tr> <td data-bbox="287 1224 334 1295">3</td> <td data-bbox="334 1224 1180 1295">SA-INV-14166- Robert Patrie, Jr.- PH237571</td> </tr> <tr> <td data-bbox="287 1295 334 1367">4</td> <td data-bbox="334 1295 1180 1367">PHA-2018-0084- CVS #1230- DS2023</td> </tr> <tr> <td data-bbox="287 1367 334 1438">5</td> <td data-bbox="334 1367 1180 1438">SA-INV-14295- Penny Graves- PT10264</td> </tr> <tr> <td data-bbox="287 1438 334 1530">6</td> <td data-bbox="334 1438 1180 1530">PHA-2018-0072- Williamsburg Pharmacy, Inc- DS2509</td> </tr> </table>	1	PHA-2018-0071- Rite Aid #10078- DS90123	2	PHA-2019-0001- CVS #765- DS2910	3	SA-INV-14166- Robert Patrie, Jr.- PH237571	4	PHA-2018-0084- CVS #1230- DS2023	5	SA-INV-14295- Penny Graves- PT10264	6	PHA-2018-0072- Williamsburg Pharmacy, Inc- DS2509		
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6	PHA-2018-0072- Williamsburg Pharmacy, Inc- DS2509															

1:00	IX	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, to evaluate the Good Moral Character as required for registration for pending applicants.		CLOSED SESSION
2:00	X	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)		CLOSED SESSION
2:30	XI	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION
5:00	XII	ADJOURNMENT		CLOSED SESSION

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

**MINUTES OF THE GENERAL SESSION
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts, 02114
March 7, 2019**

Board Members Present

Andrew Stein, Pharm D, RPh. President
Kim Tanzer, PharmD, RPh. President Elect
Julie Lanza, CPhT, Secretary
Michael Godek, RPh
Sebastian Hamilton, Pharm D, RPh
Stephanie Hernandez, Pharm D, BCGP, RPh
Susan Cornacchio, JD, RN
Carly Jean-Francois, RN, NP
Patrick Gannon, RPh
Leah Giambarresi, Pharm D, RPh
Dawn Perry, JD (leaves at 12:30 PM)

Board Members Not Present

Timothy Fensky, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Associate Executive Director
Heather Engman, JD Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Joanne Trifone, RPh., Director of Pharmacy Investigations
Kimberly Morton, CPhT, Compliance Officer
Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist
Joseph Santoro, RPh Investigator
Christina Moggi, RPh investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:3 AM

A quorum of the Board was present, established by roll call. President A. Stein chaired the meeting and asked if anyone was recording hearing, no one responded. He explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; M. Godek, yes; S. Hernandez (yes);
D. Perry, yes; P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes;
L. Giambarresi, yes.

Topic II.

Approval of Agenda

TIME 8:33 AM

Agenda March 7, 2019

DISCUSSION:

Change to Agenda:

1. Defer flex: CVS Loss Prevention Policy

ACTION:

Motion by M. Godek, seconded by L. Giambarresi and voted unanimously by those present to approve the agenda with noted change.

Dave asks for the Pharmacy Interns to stand and introduce themselves and also introduces the MCPHS Boston Intern: Nicole Tusino.

Topic III

Approval of Board Minutes

TIME: 8:35 AM

Minutes

1. Draft, February 7, 2019 Session Minutes

No noted Changes.

Action:

Motion by M. Godek, seconded L. Giambarresi, and voted unanimously to approve the regular session minutes of February 7, 2019 with noted changes.

TOPIC IV

REPORTS

Applications approved pursuant to Licensure Policy 13-01

Time:8:36 AM

Discussion: M. BOTTO noted that during the past month there have been twenty-three (23) changes of manager on record (MOR), five (5) renovation expansion applications, one (1) relocation application, and one (1) new community pharmacy application approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:36 AM

Discussion: M. BOTTO provided the January 31, 2019 - February 28, 2019, Board of Pharmacy Statistics Report for the Probation monitor, which noted that four (4) licensees satisfactorily completed probations, one (1) was given opportunity to cure, and there are currently thirty-seven (37) licensees on probation.

So noted

TOPIC IV **REPORTS**
Monthly Report from BDR pursuant to Policy 14-02 **Time: 8:39 AM**

Discussion: M.BOTTO noted that there were no Board Delegated Review cases heard prior to the meeting this month.

So noted

TOPIC IV **REPORTS**
Above Action Levels Approved by Staff Action 16-04 **Time: 8:37 AM**

Discussion: K. MORTON noted that one (1) above action level report has been reported since last Board meeting pursuant to Licensure Policy 16-04.

So noted

TOPIC IV **REPORTS**
PSUD Report by Staff Action 17-03 **Time: 8:37 AM**

Discussion: E. TAGLIERI noted that in February 2019, one (1) PSUD applicant was admitted, and there are currently fourteen (14) active participants.

So noted

TOPIC V **Policies and Advisories** **TIME: 8:37 AM**

1. Staff Action Policy 13-01(Revision): Licensure Applications and Notices

Presented by: M. BOTTO

DISCUSSION: This staff action policy allows the Board to review and approve licensure extensions for Pharmacy Technician Trainee licenses.

ACTION: Motioned by L.GIAMBARRESI, seconded by P.GANNON and voted unanimously to approve Staff Action Policy 13-01 (Revision): Licensure Applications and Notices.

2. Policy 2019-01: Shared Pharmacy Service Models Including Central Fill, Central Processing, and Tele-pharmacy **TIME: 8:40AM**

Presented by: W. FRISCH

DISCUSSION: The members of the Board had several concerns with this policy:

- Ratio of pharmacists to technicians in an area completing data entry that is not necessarily inside of a pharmacy.
- Having out of state pharmacies licensed in Massachusetts and having a Massachusetts licensed pharmacist on site.

- Language in the policy may or may not be applicable to standing orders such as immunizations and naloxone.

Board Staff will research other Boards of Pharmacies to see how they handle shared services policy and the challenges for the upcoming Board meeting. Board staff will revise the language in the policy.

ACTION: No action warranted. Deferred 30 days until the next meeting.

TOPIC VI

APPLICATIONS

1. Springfield Pharmacy - New Community Pharmacy

TIME: 9:25 AM

REPRESENTED BY: Alexander Wu

RECUSAL: None

DISCUSSION: Alex Wu, part-owner and proposed Manager of Record for Springfield Pharmacy, has been licensed for 3 years. Springfield Pharmacy will be a retail pharmacy with compliance packaging for group homes, have a delivery option, provide immunizations, and perform simple and moderate compounding. Alex Wu successfully answered the questions from Board members pertaining to experience and activities of the pharmacy.

ACTION: Motion by M. GODEK, seconded by P. GANNON, voted unanimously by those present to approve the application pending a successful inspection.

2. Walgreens #16537, DS90079 - Renovation/Expansion

TIME: 9:36 AM

REPRESENTED BY: Samantha Picking, Kimberly Kim, Johna Tyler

RECUSAL: None

DISCUSSION: During a compliance inspection it was found that construction for a non-sterile compounding room had begun without an application to the Board. Upon this discovery, the construction process was halted. It was stated that a misunderstanding occurred within Walgreens' managerial staff as to the submission of the application.

The compounding room will be used for compounding non-sterile hazardous medications in accordance with USP <800>. The representatives answered questions from Board members regarding training, delivery and quality assurance testing of compounded medications. The representatives were informed of draft regulations that will affect them in the future.

ACTION: Motion by P.GANNON, seconded by K.TANZER, voted unanimously by those present, to approve the application for renovation and expansion pending a successful inspection and the receipt of an updated attestation to perform non-sterile compounding.

3. AllCare Plus Pharmacy, DS89984 - Waivers

TIME: 10:05 AM

REPRESENTED BY: John Leighton

RECUSAL: None

DISCUSSION: AllCare Plus Pharmacy is located in an industrial park and they do not serve the general public. This pharmacy assists patients with obtaining specialty medications for rare medical conditions. The pharmacy obtains the medications directly from the manufacturer and mails or delivers them directly to patients at no cost. As a “closed door” pharmacy, AllCare Plus has applied for four waivers. Waiver #1 is for 247 CMR 6.02 (4) which is to have sufficient medications to serve the general public. Waiver #2 is for 247 CMR 6.02 (5) to have a sign outside indicating that a pharmacy is present. Waiver #3 is for 247 CMR 6.02 (7) waiving a sign with the Manager of Record’s name. Waiver #4 is for 247 CMR 6.02 (8) (a) to post hours of operation.

ACTION: Motion by L. GIAMBARRESI, seconded by P. GANNON voted unanimously by those present, to approve waivers #1, #2, and #4.

ACTION: Motion by M.GODEK seconded by J.LANZA, voted unanimously by those present, to deny waiver #3.

4. Walgreens #10673 - Change of Manager

TIME: 10:15 AM

REPRESENTED BY: Richard Lim Pho

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

DISCUSSION: Richard Lim Pho came before the Board as the new Manager of Record for Walgreens #10673. He is not aware of any incidents or outstanding Plans of Correction at this pharmacy. His pharmacy career began in August 2018, and this will be his first position as Manager of Record. He is PMP registered and immunizes. The Office of Public Protection will visit him at the store with a new educational inspection tool for those who are new to the Manager of Record position.

ACTION: Motion by K. TANZER seconded by P. GANNON voted unanimously by those present, to approve the application.

TOPIC VII

FLEX

1. Delegate vote for NABP Treasurer

TIME: 10:19 AM

PRESENTED BY: D. SENCABAUGH

RECUSAL: None

DISCUSSION: There are two candidates for NABP treasurer. Their resumes have been distributed to the Board members for review and a vote at the next Board meeting.

So noted

2. Circular Letter: Pharmacist Administration of Medications for the Treatment of Mental Illness and Substance Use Disorder **TIME: 8:39 AM**

PRESENTED BY: M. CHAN

RECUSAL: None

DISCUSSION: This circular letter issued by the Drug Control Program provides details on the training, specific drugs that may be administered, and other requirements in order to administer these drugs.

So noted

3. NABP Proposed Resolutions **TIME: 10:22AM**

PRESENTED BY: D. SENCABAUGH

RECUSAL: None

DISCUSSION: Board members asked to consider new resolutions to bring forward to the district meeting on September 19, 2019 in Burlington, Vermont.

So noted

4. CVS Loss Prevention Protocol

DEFERRED

5. Greater Lawrence Family Health Center Pharmacies - Medication Buyback Program **TIME: 10:24AM**

PRESENTED BY: Diane Martin, Alicia Modestino, Tina Starnier, Alicia Mam DaCunha

RECUSAL: None

DISCUSSION: Representatives from Greater Lawrence Family Health Center Pharmacies would like to conduct a randomized control trial to test the effectiveness of information and/or financial incentives to having patients bring back unused opioids to the pharmacy. Any patient picking up a prescription for a 14-day supply or less will be included. At the point of sale, the patient will receive an information card informing them about return of the drugs and/or financial incentive depending on the pharmacy

location. When a patient brings back unused opioids, the pharmacist will log the patient's information, visually make an estimate on how many tablets there are and identify the medication. Without handling the used prescription, the pharmacist will unlock the medication return kiosk located outside of the pharmacy space, instruct the patient to drop the medication in, and lock the kiosk again. The trial is compliant with both DEA and DEP regulations. The members of the Board asked extensive questions regarding employee safety, security, and removal of the drugs from the kiosk. It was recommended for them to track drugs on the PMP list to see if patients bring those back as well. The trial is expected to last for 1 year and the representatives are enthusiastic to bring statistics back to the Board in 6 and 12 months. The pilot does not contain any regulatory conflicts and no action was required.

So noted

6. 2018 Plan of Correction Report

ME: 11:13 AM

PRESENTED BY: K. MORTON

RECUSAL: None

DISCUSSION: A comprehensive report including plan of correction data from 2016, 2017 and 2018 was presented. In the past year, there has been a downward trend in issuing plans of correction and an increase in compliance. Controlled substance records remain the largest compliance issue.

So noted

TOPIC VIII

FILE REVIEW

Case #1

PHA-2018-0071

Rite Aid #10078, DS90123

Time: 11:17AM

RECUSAL: NONE

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- Timely RLCS of #389 clonazepam 1 mg tablets on or about 08/15/2018 and #100 oxycodone/acetaminophen 10/325 mg on or about 11/05/2018 but failed to submit Appendix I response for both losses.
- The loss of clonazepam was discovered during a cycle count. An investigation was conducted including a search of all shelves and performing exact counts of all clonazepam. Security footage was reviewed but was not helpful based on the camera locations. MOR LaRoche and loss prevention concluded the medication may have been discarded in the trash.
- The loss of oxycodone/apap 10/325mg was discovered during the reconciliation of the perpetual inventory on 11/3/18 after the receipt of a CII order. MOR LaRoche received in the CII order on 10/31/18. MOR LaRoche alleged that she received 5x100 instead of 6x100 as indicated on the invoice.

Security footage was reviewed by loss prevention and showed nothing suspicious. MOR LaRoche requested additional cameras be installed in the pharmacy.

- MOR LaRoche attested to confirming review of perpetual inventories, cycle counts, biennial inventories, and inventory reports for 3 months prior to the loss date until the current date and that the perpetual inventory is reconciled at least every 10 days.
- Review of the perpetual inventory indicated reconciliation had occurred on 10/27/2018 then on 11/07/2018 and that the discrepancy was discovered when a prescription was being filled on 11/02/2018 which contradicts the response.
- Amerisource Bergen was contacted and it was confirmed that 6x100 oxycodone/acetaminophen 10/325mg tablets were sent in the order, no other customers reported receiving an additional 100 tablets, and they had no discrepancies in their inventory.
- CA: All CIII-CV medications are required to be double counted prior to being dispensed. The trash receptacle was moved away from the dispensing area. The Pharmacy District Manager discussed the failure to follow procedures for controlled substance order acceptance with MOR LaRoche. Pharmacists are now required to open delivery totes to ensure receipt of all controlled substances. CIIs are immediately segregated and checked in or locked into the safe until the pharmacist is able to check them in. MOR LaRoche received written disciplinary action for two significant unexplained losses.
- Former DS3471 has 3 prior controlled substance losses with one resulting in a reprimand (PHA-2017-0126) and an inspection (ISP-10871) conducted on 11/02/2018 was deemed satisfactory.

ACTION: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2018-0071) 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 PROBATION for a period of one year, with terms to include conducting an exact count CS inventory for all scheduled 3-5 medications within 30 days, and a monthly exact count of all benzodiazepines for a period of 12 months.

Case #2

PHA-2019-0001

CVS #765, DS2910

Time: 11:23 AM

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

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- Converted from SA-INV-14155 on 01/09/2019
- On 10/22/18, an untimely RLCS of #5 fentanyl 100 mcg patches on 9/17/18 was reported as an unknown loss.
- MOR O'Hearn identified the loss during the reconciliation of the perpetual inventory.
- Only one prescription had been dispensed since the last reconciliation and MOR O'Hearn contacted the patient who confirmed receipt of the correct quantity.
- Perpetual inventory, dispensing reports, purchase invoices and video footage were reviewed by CVS Loss Prevention, but the reason for the loss could not be determined.
- CA: CVS Corporate indicated pharmacists were retrained to double count all controlled substances prior to dispensing and all loss prevention policies and procedures were reviewed; MOR O'Hearn will ensure RLCS documents are submitted timely.
- On 01/10/2019, the Pharmacy was notified that SA-INV-14155 had been converted to a complaint.

- On 01/28/2019, CVS Regulatory Affairs responded that there is no additional information to provide for this matter.

ACTION: Motion by M. GODEK, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0001) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #3

SA-INV-14166

Robert Patrie, Jr, PH237571

Time: 11:26 AM

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

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- 08/17/2018 - CVS #257 in Pittsfield entered into a Consent Agreement for Probation for losses of controlled substances which occurred prior to MOR Patrie's tenure as MOR.
- 08/29/2018 - retail compliance inspection was conducted with deficiencies cited resulting in probation violations for submission of an untimely POC, failure to reconcile the perpetual inventory, numerous missing temperature log recordings, missing CPR certifications, and administration of a vaccine by Pharmacist Naginewicz with an expired CPR card.
- 10/14/2018 - probation violation was heard at the Board of Pharmacy meeting and the Board voted to open a staff assignment on the MOR of CVS #257.
- 11/28/2018 - MOR Patrie was notified of the staff assignment.
- 01/09/2019 - MOR Patrie and CVS Regulatory Affairs provided a response. MOR Patrie indicated there had been a lot of turnover of pharmacy staff at CVS 257 in the past year. The submission of an untimely POC was due to a misunderstanding of the POC process. Prior to the inspection, the expired CII's had not been reconciled so MOR Patrie initiated the use of a paper perpetual inventory to reconcile expired CII's. Pharmacist Naginewicz had forgotten to renew his CPR and only administered the one vaccine observed during the inspection. No additional vaccines were administered until his CPR was reinstated on 09/22/2018. No response was given regarding the refrigeration temperature readings.
- Temperature logs for 09/01/2018 to 01/09/2019 showed a total of 34 missing entries and 99 temperature excursions with only one documented action.
- Numerous requests were made for the Temp Alert electronic refrigeration temperature readings, records of alerts from the Temp Alert system, and any corresponding documentation of action from CVS Regulatory Affairs which were not provided and are not available at store level.
- MOR Patrie indicated he sets reminder alerts to perform benzodiazepine counts to comply with the probation agreement. MOR Patrie has re-trained staff on refrigeration temperatures with the correct temperature range. Temperature excursions recorded after 01/09/2019 to 01/22/2019 included documented action.

ACTION: Motion by P. GANNON, seconded by D. PERRY, and voted unanimously by those present, to hold an investigative conference with MOR and CVS Corporate, including the supervisor for CVS #257 in Pittsfield.

Case #4

PHA-2018-0084

CVS #1230, DS2023

Time: 11:38 AM

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

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

- RLCS- #70 oxycodone 15mg tablets due to a suspected dispensing error. No prior reported losses.
- Variance of 70 tablets of oxycodone 15mg was discovered while conducting a perpetual inventory count on October 19, 2018.
- Patient was contacted but denied receiving extra tablets, so a dispensing error could not be confirmed.
- MOR reviewed video footage and noted that it did not reveal any evidence of diversion or gross violation of current policy.
- MOR Etti indicated that he has retrained the pharmacists on proper procedures to ensure accurate quantities are dispensed. In addition, the MOR reviewed all baseline loss prevention procedures with his entire staff, specifically those that prevent drug diversion.
- A retail compliance inspection (ISP-11298) on January 10, 2019 was conducted with no deficiencies noted.

ACTION: Motion by M. GODEK, seconded by K. TANZER, and voted unanimously by those present, to refer the matter (PHA-2018-0084) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #5

SA-INV-14295

Penny Graves, PT10264

Time: 11:40 AM

RECUSAL: NONE

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

- Technician Graves failed to obtain final verification from a pharmacist for two prescriptions for the same patient that she filled with the wrong drug, buspirone 10mg tablets, instead of the correct drug, baclofen 10 mg tablets.
- Technician Graves error was discovered during the investigation of a complaint against Green Street Pharmacy filed on behalf of the patient by his DDS licensed group home. The prescriptions were dispensed on the same day with a supply sent to the patient's group home and another supply to the patient's day program. Both prescriptions were filled incorrectly.
- MOR's internal investigation showed that only Technician Graves' initials were on both prescriptions as the person responsible for filling and he concluded that she failed to have the prescriptions verified by a pharmacist before sending them to the group home. He provided images of the prescriptions with only Technician Graves' initials.
- Technician Graves was unable to recall any specific details of the incident but did not dispute the incident as described by the MOR.
- CA: Technician Graves read 247 CMR 15.00 for remediation. She also indicated that she was forced to stop working and retire suddenly due to health issues. She does not plan to work any longer due to her illness and allowed her technician license to expire.

ACTION: Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present, to CLOSE the matter (SA-INV-14295), No Discipline Warranted, Remediation Complete.

RECUSAL: NONE

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

- During an inspection, investigator discovered that an expired product, coal tar solution, was used on two occasions to prepare compounded non-sterile preparations (CNSPs) of a topical gel dispensed on separate occasions to the same patient.
- Patient was notified of the error. Patient reported no harm or decreased efficacy observed using compound prepared with expired product.
- MOR identified that the same pharmacist used the expired coal tar solution on two separate occasions to prepare compounded prescriptions. MOR reported that the expired product was replaced in December 2017 and used to properly prepare the same compound for the same patient in December 2017. The same pharmacist then used the expired product in March 2018 & June 2018 to prepare the same compound for the same patient. MOR also noted that the pharmacist wrote expiration dates of November 2017 in the compounding logs for the prescriptions prepared in 2018.
- The pharmacist who prepared the compounds with the expired product recalled in his statement that two opened bottles of coal tar solution (one expired and one unexpired) were stored in the compounding area on March 2018. He then indicated that he didn't know which bottle he used but he did record the lot and expiration date for the expired product. He next denied using the expired product in the June 2018 compound because the expired product was quarantined in the expired drug section of the pharmacy. He explained that he was in a rush and copied information in the March 2018 entry for the June 2018 entry.
- CA: MOR implemented new procedures to identify short-dated products (< 3 months) in the compounding area, place short-date warnings on the products to alert staff, order replacements for the short-dated products, and quarantine the short-dated product once replacement arrives.
- In addition, MOR implemented new procedures for the pharmacy's "Defective Drug Log" by integrating the log requirements with the pharmacy's CQI process. Thus, standard operating procedure now requires that any event involving a defective drug must also be investigated as a QRE according to the pharmacy's CQI program.
- RPh responsible for error completed 2 hours of CEs in patient safety, 3 hours of CE's in non-sterile compounding, and read 247 CMR 15 as part of the overall remediation plan.

ACTION: Motion by M. GODEK, seconded by K. TANZER, and voted unanimously by those present, to DISMISS (PHA-2018-0072), No Discipline Warranted, Remediation Complete.

Topic IX
Read by A. Stein

EXECUTIVE SESSION

Time: 11:46 AM

DISCUSSION:

ACTION: At 11:45 AM President A. Stein read the statement on reasons for Executive Session.

D. Perry leaves meeting at 12:30 PM

Topic IX: Executive Session Call to Order: Time: 12:55 PM
By: A. Stein

ACTION: Motion by P. Gannon, seconded by K. Tanzer, and voted unanimously by roll call to call the March 7, 2019 meeting of the Executive Session to order.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; M. Godek, yes; S. Hernandez (yes); P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes.

Topic X: Adjudicatory Session (M.G.L. ch 30A § 18) Time: 11:50 AM

DISCUSSION: None

ACTION: President A. Stein request a motion to enter Adjudicatory Session.

At 11:50 AM P. Gannon, seconded by K. Tanzer and voted unanimously by all those present to enter Adjudicatory Session:

Topic XI: M.G.L. 65 C #1 Time: 11:52 AM

DISCUSSION: None

ACTION: President A. Stein request a motion to enter M.G.L 65 c Session.

At 11:52 AM P. Gannon, seconded by S. Hernandez and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

Topic XII ADJOURNMENT OF MEETING TIME: 1:15 PM

ACTION: Motion by L. Giambarresi seconded by M. Godek, and voted unanimously by those present, to adjourn from General Session.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 3/7/19 General Session
2. Draft Minutes of the 2/7/19 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on probation
5. Report on Board Delegated Complaint Review to licensure policy 14-02
6. Report on Above Action Levels approved by Staff Action 16-04
7. Report on PSUD 17-03
8. Staff Action Policy 13-01 (Revision): Licensure Applications and Notices
9. Policy 2019-01: Shared Pharmacy Service Models Including Central Fill, Central Processing and Tele-pharmacy
10. Applications: Springfield Pharmacy New Community Pharmacy
11. Applications: Walgreens #16537; DS90079 Renovation/Expansion
12. Applications: AllCare Plus Pharmacy, DS89984 Waivers
13. Applications: Walgreens 10673, DS8963 Change of Manager
14. Circular Letter: Pharmacist Administration of Medications for the treatment of Mental Illness and Substance Use Disorder
15. Greater Lawrence Family Health Center Pharmacies- Medication Buyback Program
16. 2018 Plan of Correction
17. PHA-2018-0071 Rite Aid #10078 DS90123
18. PHA-2019-0001 CVS #765 DS2910
19. SA-INV-14166 Robert Patrie, JR PH237571
20. PHA-2018-0084 CVS #1230 DS2023
21. SA-INV-14295 Penny Graves PT10264
22. PHA-2018-0072 Williamsburg Pharmacy, INC DS2509

Respectfully Submitted,
Julie Lanza, CPhT, Secretary