

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

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

August 1, 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 Nahomi Carlisle, Phone: 617-624-5471 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	1	
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of June 27, 2019 Regular Session Minutes • Introduction of Taylor Lee 	4	
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 	20 22 23 24	
8:50	V	POLICIES and ADVISORIES <ul style="list-style-type: none"> • Staff Action Licensure Policy 13-01 • Staff Action Board Delegated Review Policy 14-02 • Joint Policy 2018- 01: Permitted Prescription Changes and Additions • Policy 2019-04: Transfer of Unfilled Prescriptions • Remote Dispensing of Naloxone by a Pharmacy 	25 32 36 38	

9:15	VI	<p>APPLICATIONS</p> <ul style="list-style-type: none"> • Mae Fowler (PTT02755) – Waiver • Conley’s Drug Store (DS2654) – Waivers • Southcoast Pharmacy-Waivers • Norwood Pharmacy – New Community Pharmacy • Partners Pharmacy- New sterile compounding room • Betterlife Pharmacy – New Community Pharmacy • Walgreens 17165 (DS90184) – Change of Manager 	<p>39 42 46 52 68 89 103</p>																																		
10:15	VII	<p>FLEX</p> <ul style="list-style-type: none"> • Pharmacy Advisory Committee Update <ul style="list-style-type: none"> ○ Recommendation 19-01: Policy for Pharmacy Response to Above Action Level Environmental Monitoring Results & Telepharmacy Models • Social Security Number requirements for licensure 	<p>110 111</p>	<p>T. Fensky E. Taglieri S. Sencabaugh</p>																																	
10:45	VIII	<p>TERMINATION OF PROBATION</p> <ul style="list-style-type: none"> • Conley’s Drug Store, DS89731, PHA-2016-0113 		<p>K. Fishman</p>																																	
11:00	IX	<p>FILE REVIEW</p> <table border="1" data-bbox="342 1129 1192 1740"> <tr> <td>1</td> <td>PHA-2018-0088</td> <td>Blue Hill Pharmacy, DS89942</td> </tr> <tr> <td>2</td> <td>PHA-2019-0056</td> <td>CVS #1225, DS1952</td> </tr> <tr> <td>3</td> <td>SA-INV-14992</td> <td>CVS #166, DS3449</td> </tr> <tr> <td>4</td> <td>PHA-2019-0060</td> <td>CVS #8441, DS89794</td> </tr> <tr> <td>5</td> <td>PHA-2019-0059</td> <td>CVS #1955, DS2356</td> </tr> <tr> <td>6</td> <td>SA-INV-14905</td> <td>Tracy Kirkpatrick, PH25994</td> </tr> <tr> <td>7</td> <td>PHA-2019-0035</td> <td>Walgreens #4358, DS2873</td> </tr> <tr> <td>8</td> <td>PHA-2019-0057</td> <td>Walgreens #10128, DS3472</td> </tr> <tr> <td>9</td> <td>PHA-2019-0049</td> <td>Stop & Shop #82, DS3359</td> </tr> <tr> <td>10</td> <td>SA-INV-14965</td> <td>Baystate Pharmacy, DS89896</td> </tr> <tr> <td>11</td> <td>SA-INV-15271</td> <td>AmEx Pharmacy, NO00026</td> </tr> </table>	1	PHA-2018-0088	Blue Hill Pharmacy, DS89942	2	PHA-2019-0056	CVS #1225, DS1952	3	SA-INV-14992	CVS #166, DS3449	4	PHA-2019-0060	CVS #8441, DS89794	5	PHA-2019-0059	CVS #1955, DS2356	6	SA-INV-14905	Tracy Kirkpatrick, PH25994	7	PHA-2019-0035	Walgreens #4358, DS2873	8	PHA-2019-0057	Walgreens #10128, DS3472	9	PHA-2019-0049	Stop & Shop #82, DS3359	10	SA-INV-14965	Baystate Pharmacy, DS89896	11	SA-INV-15271	AmEx Pharmacy, NO00026	<p>112 114 117 120 123 126 129 132 135 137</p>	
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<p>12:00 LUNCH</p>																																					

1:00	X	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.	142	
2:00	XI	M.G.L. c. 112, § 65C SESSION	242	
5:00	XII	ADJOURNMENT		

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

**MINUTES OF THE GENERAL SESSION
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts, 02114
August 1, 2019**

Board Members Present

Andrew Stein, Pharm D, RPh. President
Kim Tanzer, PharmD, RPh. President Elect
Julie Lanza, CPhT, Secretary
Sebastian Hamilton, Pharm D, RPh
Stephanie Hernandez, Pharm D, BCGP, RPh
Patrick Gannon, RPh
Timothy Fensky, RPh (Leaves at 1 PM)
Susan Cornacchio, JD, RN
Michael Godek, RPh

Board Members Not Present

Carly Jean-Francois, RN, NP
Leah Giambarresi, Pharm D, RPh
Dawn Perry, JD

Board Staff Present

David Sencabaugh, RPh, 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 Investigations
Gregory Melton, Pharm D, JD, RPh Investigator
Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist
Christina Mogni, RPh investigator
Nathan Van Allen, PharmD, RPh, investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:31 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; S. Hamilton, yes; S. Cornacchio, yes; P. Gannon (arrives 8:35 AM); T. Fensky (arrives at 8:47 AM)

Topic II.

Approval of Agenda

TIME 8:34 AM

Agenda August 1, 2019

DISCUSSION:

Change to Agenda:

1. Defer: Termination of Probation: Conley's Drug Store, DS89731, PHA-2016-0113

ACTION:

Motion by M. Godek, seconded by K. Tanzer 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 new office temp staff Taylor Lee.

Topic III

Approval of Board Minutes

TIME: 8:34 AM

Minutes

1. Draft, June 27, 2019 Session Minutes

No noted Changes.

Action:

Motion by A. Stein, seconded S. Hamilton, and voted unanimously to approve the regular session minutes of June 27, 2019 with noted changes.

TOPIC IV

REPORTS

Applications approved pursuant to Licensure Policy 13-01

Time: 8:39 AM

Discussion: E. TAGLIERI noted that there have been twenty-five (25) Change of Managers, seven (7) pharmacy renovations, (1) relocation and nine (9) pharmacy closings.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:39 AM

Discussion: E. TAGLIERI provided the June 1, 2019 – July 25, 2019 Pharmacy Board Probation Monthly Report, which noted that three (3) licensees satisfactorily completed probations. 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: D. SENCABAUGH noted that there were two (2) Board Delegated Review cases heard on July 29, 2019. There was one CE self-disclosure (SA-INV-14964-PH25911) and one CE deficiency of 0.5 CE in NS compounding in 2018 discovered at inspection (SA-INV-15126-PH27443). The staff assignments were reviewed, discipline not warranted and remediation complete. The Board Delegated Review session was attended by A. STEIN as the Board President, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

TOPIC IV **REPORTS**
Above Action Levels Approved by Staff Action 16-04 **Time: 8:39 AM**

Discussion: J. TRAN 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: 8:40 AM**

Discussion: E. TAGLIERI noted that in July 2019, one (1) admission is expected to start on 8/8/19 and there are currently fourteen (14) active participants. One retail chain offer was made to an individual in the PSUD program.

So noted

TOPIC V **Policies and Advisories** **Time: 8:41 AM**

1. Staff Action Licensure Policy 13-01 **Time: 8:41 AM**

Discussion: M. CHAN presented and summarized the changes to Licensing Policy 13-01. Edits include allowing Board staff to approve intern licenses for non-resident interns or pharmacists coming to Massachusetts for residency programs who have not yet passed the MPJE for pharmacist licensure. Additionally, the edits would allow staff to approve applications for non-resident drug stores, institutional sterile compounders, and existing retail pharmacies that engage in sterile compounding and complex non-sterile compounding.

Lastly, the nuclear pharmacy section was removed and any new applications will be handled in the same manner as any new in-state retail compounding pharmacy.

Action: Motion by S. HAMILTON, seconded by K. TANZER, and voted unanimously by those present to approve updates to the policy.

2. Staff Action Board Delegated Review Policy 14-02 **Time: 8:43 AM**

Discussion: M. CHAN presented and summarized the Board Delegated Review (BDR) policy 14-02. The changes allow the BDR group to approve applications for non-resident nuclear pharmacies and non-resident compounding pharmacies and any renovations to these facilities. S. CORNACCHIO requested changes to the waiver petition wording for consistency with the regulations.

Action: Motion by S. HAMILTON, seconded by K. TANZER, and voted unanimously by those present to approve updates to the policy with the noted wording change.

3. Joint Policy 2018-01: Permitted Prescription Changes and Additions **Time: 8:46 AM**

Discussion: M. CHAN presented and summarized changes to Joint policy 2018-01 Permitted Prescription Changes and Additions. The minor change is to clarify that the date written may only be added if omitted, not otherwise edited or changed. It was also suggested to edit the wording under section II to make it clear that patient name changes are intended to prohibit changes to different patients, not spelling or nickname edits.

Action: Motion by K. TANZER, seconded by P. GANNON, and voted unanimously by those present to approve the policy changes with the additional wording change to section II.

4. Policy 2019-04: Transfer of Unfilled Prescriptions **Time: 8:50 AM**

Discussion: M. CHAN presented and summarized changes to policy 2019-04, the Transfer of Unfilled Prescriptions. It has come to our attention that the policy unintentionally restricted the transfer of unfilled electronic schedule VI prescriptions. Edits were made to allow those transfers to be made in the same fashion as paper, fax or oral unfilled CVI.

Action: Motion by M. GODEK, seconded by S. HERNANDEZ, and voted unanimously by those present to approve updates to the policy.

5. Policy: Remote Dispensing of Naloxone by a Pharmacist **Time: 8:55 AM**

Discussion: M. CHAN presented and summarized new policy 2019-05 Dispensing Naloxone from a Remote Location. Under this policy, pharmacies would be able to dispense naloxone from locations other than their licensed pharmacy space. In order to do this, the policy outlines requirements for privacy, technology, labeling, and security. The policy only addresses naloxone dispensing by pharmacies as the Board does not have authority over other naloxone distribution activities by non-pharmacy individuals or groups.

Action: Motion by S. HERNANDEZ, seconded by T. FENSKY, and voted unanimously by those present to approve the new policy.

TOPIC VI	APPLICATIONS	
1. Mae Fowler (PTT02755)	Waiver	Time: 8:58 AM

REPRESENTED BY: N/A

RECUSAL: N/A

DISCUSSION: A pharmacy technician in training license extension was submitted by Mae Fowler (license number PTT02755). An additional letter was submitted on her behalf by pharmacy manager Donna Gorka detailing request for extension. States that Fowler does not perform pharmacy technician duties and simply bags and rings out medications.

ACTION: Motion by T. FENSKY, seconded by M. GODEK, and voted unanimously by those present to approve and extend the waiver for the pharmacy technician in training license for one year.

2. Conley's Drug Store DS2654

Waivers

Time: 8:59 AM

REPRESENTED BY: Alex Doyle (RPh), Richard Doyle (owner), Andrew Pszeny (RPh)

RECUSAL: N/A

DISCUSSION: Conley's Drug Store is requesting a waiver for 247 CMR 9.01 (5) which states that a pharmacist shall not limit his or her services to a particular segment or segments of the general public unless otherwise provided for by law. The pharmacy fills both simple and complex non-sterile products and are changing their business model to focus on the compounded products.

The pharmacy compounds complex non-sterile preparations for both hazardous and non-hazardous drugs. They are currently renovating their pharmacy to comply with USP <800>.

ACTION: Motion by T. FENSKY, seconded by S. HERNANDEZ, and voted unanimously by those present to approve waiver.

3. Southcoast Pharmacy

Waivers

Time: 9:02 AM

REPRESENTED BY: N/A

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

DISCUSSION: Southcoast received two renewals for waivers last month. Waiver #1 was for 247 CMR 9.01 (16) that states a pharmacist shall not refuse to compound customary pharmaceutical preparations. Southcoast pharmacy has explained to the Board that it does not and will not engage in any form of sterile or non-sterile compounding. Waiver #2 was in regards to 247 CMR 6.02 (4) that states the pharmacy shall maintain on the premises a sufficient variety and supply of medicinal chemicals and preparations. Southcoast pharmacy states that they engage only in the dispensing of specialty medications which are of limited manufacturer distribution, limited coverage by PBM formulary, or those involving an extra degree of monitoring.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present to renew the two waivers.

4. Norwood Pharmacy New community pharmacy

Time: 9:04 AM

REPRESENTED BY: Sejal Patel (MOR), Oleg Urim (owner), Falgun Patel. Falgun Patel is additional owner; however, he was not present. Attorney Paul Gabarini was present.

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

DISCUSSION: Attorney Garbarini noted that Pharmacists Sejal Patel and Oleg Urim are applying to open a new pharmacy. Sejal Patel was a previous MOR in NH for Rite Aid pharmacy. Representatives agreed to register with PMP. They stated that they will be immunizing at the pharmacy. As far as compounding, they will be doing simple to moderate preparations. Pharmacy will have a camera system and close monitoring 24/7. A. STEIN recommended for Falgun Patel to get a pharmacy technician in training license. M. GODEK reminded the applicants that a PTT license is necessary in order to work in the pharmacy. Pharmacy will offer delivery as well as serve community nursing homes. P. GANNON asked what the protocol will be in the event of an illness and stated that a pharmacist will need to be on call during nights and weekends.

ACTION: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by those present to approve application for new pharmacy upon successful inspection.

5. Partners Pharmacy

New Sterile Compounding Room

TIME: 9:12 AM

REPRESENTED BY: Jody Fenelon (Director of compliance), Derek Corriveau (Owner of pharmacy), and Brian McGonigle (MOR)

RECUSAL: NONE

DISCUSSION: Representatives of Partners Pharmacy are seeking an application for a modular compound room. They are doing low-medium risk compounds for a long-term care facility. The compounding area is segregated with demising wall to separate from pharmacy production. Representatives stated that the pharmacy will be using Critical Point for didactic training and Simplifi for tracking of cleaning production. EM monitoring will be completed monthly. There is a closed connection and unclosed ducted unit. There is a pass-through buffer that leads to the anteroom. They discussed one (1) return with a smoke study to decrease contamination.

ACTION: Motion by T. FENSKY, seconded by S. HERNANDEZ, and voted unanimously by those present to approve renovation application pending a successful inspection

6. Betterlife Pharmacy

New Community Pharmacy

TIME: 9:20 AM

REPRESENTED BY: Loc Do (Owner and MOR)

RECUSAL: NONE

DISCUSSION: Loc Do has worked prior as registered pharmacist in NH for three years. This new pharmacy will be his first time sitting as manager. The pharmacy plans to do simple to moderate compounding and is considering blister packaging. As business expands, do is considering adding a clerk. Applicant understands that the clerk will need to have (at minimum) a pharmacy technician in training license. He plans on registering with PMP in MA. Applicant holds a current immunization and CPR license. Pharmacy is located in a plaza with connecting businesses. For security, cameras will be operating. The pharmacy will be using Pioneer Rx software to process prescriptions. As far as consulting, Do has contacted Northeast Pharmacy for basic policy and procedure guidance. Do states that after hours, call forwarding will be made possible to his cell phone in the case of emergencies.

ACTION: Motion by S. HAMILTON, seconded by K. TANZER, and voted unanimously by those present to approve application pending a successful inspection.

7. Walgreens 17165 DS90184 Change of Manager

TIME: 9:32 AM

REPRESENTED BY: Dorothy Nguyen, MOR

RECUSAL: NONE

DISCUSSION: Dorothy Nguyen came before the Board as the new Manager of Record for Walgreens #17165 in Cambridge. This will be her first time as MOR. She has been a registered pharmacist in MA for two (2) years. Board recommended that she request previous history of the store from supervisor. She is registered with PMP and for immunizations. Store is relatively low volume and has a budget of one (1) pharmacist and one (1) technician.

ACTION: Motion by S. HAMILTON, seconded P. GANNON, and voted unanimously by those present to approve the application.

TOPIC VII

FLEX

Time: 9:55 AM

1. Pharmacy Advisory Committee Update

Time: 9:55 AM

Recommendation 19-01: Policy for Pharmacy Response to Above Action Level Environmental Monitoring Results and Telepharmacy Models

Discussion: E. TAGLIERI, T. FENSKY, and W. FRISCH summarized the Advisory Committee discussions. Much of the conversation focused on response to Above Action Levels including product recalls and variable responses to contaminant levels. No conclusions or recommendations were finalized. W. FRISCH stated that a clear policy is needed for licensees to react to excursions in a self-directed way to protect public safety. W. FRISCH and M. CHAN will develop a policy to bring forth in the next few months.

There was also some limited discussion regarding shared services. The Advisory Committee did not support the use of off-site technicians without direct pharmacist supervision.

The technology check technician advisory was presented to the Advisory Committee who agreed that this was useful guidance.

So noted.

2. Social Security Number requirements for licensure

Time: 10:12 AM

Discussion: D. SENCABAUGH summarized the federal requirement that all applicants for pharmacy licenses (pharmacist, pharmacy technician, pharmacy intern, etc.) must have a social security numbers. Licenses may no longer be issued without social security numbers.

The only exception would be an applicant currently living outside of the U.S. However, a social security number is required to renew that license.

So noted.

TOPIC VIII

TERMINATION OF PROBATION

DEFERRED

TOPIC IX

FILE REVIEW

Case #1

PHA-2018-0088

Blue Hill Pharmacy, DS89942

Time: 10:20 AM

RECUSAL: NONE

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

- Complaint was opened on December 28, 2018 as a result of the Pharmacy not being open for business during posted business hours and failure to implement a plan of correction.
- Prior to the complaint, The BORP opened a staff assignment (SA-INV-10879) for not being open for business on multiple days during posted business hours and calls made to the MOR went unanswered.
- BORP voted unanimously to close staff assignment (SA-INV-10879), Discipline Not Warranted, Remediation Complete. The remediation included: If a delivery requires a pharmacist it will be delivered before opening or after closing and there will be a pharmacist cell phone number posted on the door in the case of an emergency.
- On November 28, 2018, Investigator Richard Geaney was unable to perform an inspection due to the Pharmacy being closed.
- MOR Okeke indicated that she was late opening the Pharmacy on 11/28/18 due to a family medical emergency in which she had to be at the hospital.
- MOR Okeke indicated that she plans to hire a part-time pharmacist who would cover for her if she couldn't be in the pharmacy during business hours. Her immediate plan is to make all deliveries

between the hours of 5:00pm-7:00pm to accommodate her patient's needs for person to person counseling. She indicated that her future plan is to hire a dedicated delivery person who can make deliveries during work hours.

- MOR Okeke indicated that once her plan is in place she will request a change in hours to 10:00am-5:00pm. MOR Okeke has subsequently hired a part-time delivery person. MOR Okeke noted that she has implemented call forwarding services so that calls will be forwarded to her cell phone in an event that she had to step out of the pharmacy.

ACTION: Motion by S. HAMILTON, seconded by S. HERNANDEZ, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0088), No Discipline Warranted, Remediation Complete, pending receipt of documents/SOPS requested at the Investigative Conference on 6/27/19.

Case #2

PHA-2019-0056

CVS #1225, DS1952

Time: 10:23 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 April 26, 2019, CVS Drug Loss Program sent the BORP staff an untimely notification of a loss of #501 lorazepam 1mg tablets on or about March 11, 2019. An investigation concluded on April 8, 2019 that it was considered an unknown loss.
- The loss was discovered on March 15, 2019 while filling a script for lorazepam 1mg tablets. MOR noted that on March 11, 2019 a bottle of #500 lorazepam 1mg tablets was received in the order, checked in, and left in a tote until it could be placed into its usual location in stock.
- Cameras were viewed to determine where the bottle was placed but the tote was placed in an area of the pharmacy that is not visible to the cameras. Asset Protection Leader (AP), Brian New, reviewed the video footage, and indicated that it was inconclusive.
- AP New conducted behavioral analysis interviews on the three technicians who worked on the day of delivery and did not get any admission from them. He suspects that the bottle was either misplaced and unable to locate or thrown away by mistake.
- On June 7, 2019, Senior Consultant, Pharmacy Regulatory Affairs (SC), Kelsey White sent an email informing this OPP Investigator that there was an oversight on their part and the continuation letter was only sent to the DEA on April 12, 2019.
- MOR Mathieu indicated that the CVS Pharmacy Employee Loss Prevention/Drug Diversion Policy has been reviewed with the Pharmacy staff. The Pharmacy team is to check in controls immediately upon receiving and put away to avoid any issues in the future. All Controls will be left in their sealed totes/bags until they are ready to be checked in and opened in an area of the pharmacy that is in clear view of cameras, either at the production or verification bench. The team was coached and verbally counseled to ensure this process does not fail in the future.
- CVS Pharmacy #1225 has no prior reported losses. A retail compliance inspection (ISP-11708) conducted at CVS#1225 on 03/07/2019 was deemed satisfactory.

ACTION: Motion by M. GODEK, seconded by P. GANNON, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0056), No Discipline Warranted, Remediation Complete, pending

attestation that MOR and Staff PH have read Board Policy 2018-05: *Requirements and Procedures for Reporting Theft or Loss of Controlled Substances*.

Case #3

SA-INV-14992

CVS #166, DS3449

Time: 10:35 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 April 12, 2019, the BORP staff received an untimely report of a loss of #327 carisoprodol 350mg tablets on or before February 12, 2019
 - The loss was discovered as part of a CVS Loss Prevention initiated drug count on 2/12/2019 and MOR noted that the loss may have been missed during the May 1, 2018 biennial count.
 - Video surveillance was reviewed throughout various dispensing's of the medication in question and no oddities or evidence of diversion were discovered on camera.
 - In response to the untimely RLCS, MOR indicated that letters of continuation were submitted to the Board on March 13, 2019, and April 11, 2019 as the loss was still being investigated.
 - This OPP Investigator along with the Compliance Officer reviewed the email inbox used for the submission of RLCS forms and there were no emails received in this email inbox for CVS #166 during this time period.
 - In response to this event, all Pharmacy staff have completed training modules regarding proper handling of controlled substances. Pharmacy Staff have been coached on baseline procedures as they pertain to safeguarding the integrity of the controlled substance inventory. MOR indicated that there is a zero tolerance for personal items in the pharmacy and that policy will be reinforced.
 - MOR will continue to be observant and utilize all tools available to her to ensure warehouse and outside vendor orders placed and received are appropriate to dispensing levels.
- Shelves have been re-organized; cycle counts will be continued weekly for system prompted cycle counts and signed off by the pharmacist and the pharmacy manager will complete the monthly count used for BOP and Loss Prevention. There will be a weekly review of BOH modification and order adjustment reports to work in tandem to help better identify any inventory areas of concern and help to prevent further losses.

ACTION: Motion by P. GANNON, seconded by K. TANZER, and voted unanimously by those present, to elevate the matter (SA-INV-14992) to a complaint, and refer the matter to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of one year, with special 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 carisoprodol containing products, benzodiazepines, tramadol containing products, gabapentin and zolpidem for 12 months, staff retraining in the areas of inventory management, prescription production, and waiting bin management within 30 days and increased store visits from the Pharmacy Supervisor or Loss Prevention at least once every 30 days to validate and sign off on the BOH report cover page.

Case #4

PHA-2019-0060

CVS #8441, DS89794

Time: 10:40 AM

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

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

- Untimely RLCS on 5/8/19 of an unknown loss of #100 amphetamine salts 15 mg tablets discovered during the reconciliation of the perpetual inventory on 4/1/19.
- The internal investigation did not reveal the cause of the loss but MOR Leavitt (Eskildsen) proposed the bottle of #100 amphetamine salts 15 mg tablets “may have unintentionally been thrown away in error”. Video was reviewed with no evidence of theft or diversion.
- Orders for 1x100 amphetamine salts 15 mg were received on 3/27/19 and 4/1/19 but were not immediately put into the CII safe and were left on the bench near the pharmacist.
- The area around the bench and some of the trash were searched but other trash bins had been removed from the Pharmacy and brought to the dumpsters. MOR Leavitt (Eskildsen) indicated contributing factors included a cluttered work space and trash bins located near the bench where medication could be knocked off into the trash.

CA: All loss prevention policy and procedures were reviewed with the pharmacy team including diligent inventory management and bag/smock checks, as well as ensuring all stock bottles are empty before discarding in the trash. All pharmacists were retrained on the proper check in procedure for controlled substance deliveries, as well as the proper procedures for double counting all CII prescriptions prior to dispensing. MOR Leavitt (Eskildsen) stated they are ensuring that medication is immediately put away after being checked in and not placing medication totes in the bench location where medication could be inadvertently discarded. The pharmacy bench was thoroughly cleaned and organized to eliminate any clutter.

ACTION: Motion by S. HERNANDEZ, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0060) 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

PHA-2019-0059

CVS #1955, DS2356

Time: 10:44 AM

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

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

- Untimely RLCS on 5/8/19 for unknown loss of #60 amphetamine salts 30mg tablets on 4/5/19 discovered while conducting a back count after filling a prescription.
- The BOH after the last prescription was filled on 4/1/19 was correct. Internal investigation included counts of all NDCs of amphetamine salts with no discrepancies noted, search of the pharmacy shelves and CII safe, review of back counts documented on hard copies and review of video footage which didn't reveal any pilferage or diversion. The reason for the loss was not determined. No theory was provided as to the cause of the loss.

- CA: All applicable policies and procedures pertaining to controlled substances were reviewed with the pharmacy team including weekly perpetual inventory counts, double counting CII, back counting CII with a comparison to balance on hand quantities in the perpetual inventory, checking in CII medication orders, and ensuring the safe is not left open and unsupervised while filling or checking in CII. Pocket checks for any pharmacy personnel leaving the pharmacy will be performed.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0059) 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 #6

SA-INV-14904

Tracy Kirkpatrick, PH25994

Time: 10:46 AM

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

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

- Pharmacist Kirkpatrick was the pharmacist-in-charge of Tri-Coast Pharmacy in FL which was inspected by the FDA in 2016 with a subsequent voluntary recall on 11/17/2016 of all CSPs prepared between 05/17/2016 and 11/17/2016 due to a concern of a lack of sterility assurance. On 4/14/17, the FL DOH suspended the pharmacy's license.
- On 6/7/17, FL BOP heard complaints for the pharmacy and Pharmacist Kirkpatrick who had signed variance/incident reports dated 10/12/2016 indicating contaminated lots of CSPs were discovered and allegedly disposed of with no supporting documentation. The Pharmacy's license was revoked, and Pharmacist Kirkpatrick received no discipline.
- 4/11/2019 BORP received notification Pharmacist Kirkpatrick that on 3/12/2019 an informal resolution was negotiated with the Alabama Board of Pharmacy for discipline for one violation for failure to discharge her obligations as supervising pharmacist or pharmacist-in-charge of Tri-Coast Pharmacy, a fine of \$5,000 and to not reapply for or seek reinstatement of her license to practice pharmacy in the State of Alabama.
- Investigations were opened by the Arkansas, Arizona, Georgia, and Oregon Boards of Pharmacy based on the discipline issued by Alabama, but no other discipline was issued for Pharmacist Kirkpatrick.

ACTION: Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present, to CLOSE the matter (SA-INV-14905), No Discipline Warranted.

Case #7

PHA-2019-0035

Walgreens #4358, DS2873

Time: 10:52 AM

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

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

- During a retail compliance inspection (ISP-11646) conducted on 02/26/2019, a DEA 06 was observed for a loss of #47 oxycodone 15 mg tablets on or about 11/21/2018 with no BORP RLCS available.
- In response to the POC, MOR Huynh stated the Walgreens District Manager had instructed her to withdraw the DEA 106 because #47 oxycodone 15 mg tablets were not a significant loss as was less than 10%.
- In response to the complaint, MOR Huynh stated the loss was discovered during the reconciliation of the perpetual inventory. The pharmacy was searched for a misplaced bottle, oxycodone prescriptions filled for the week were checked to determine if any had been not logged or mis-logged, controlled substance recordkeeping was reviewed for accuracy, and security footage was reviewed. Only one prescription had been dispensed and the patient, who had received a dispensing for #630 tablets, was contacted and she stated there was no over-dispensing.
- MOR Huynh stated that an open bottle of oxycodone may not have been marked as opened and was counted as a full bottle during inventory.
- CA: Pharmacy staff has been instructed to remove all caps for CII during inventory so that we have an accurate count of unopened bottles. Pharmacy staff were reminded to double count all narcotics. Policies regarding controlled substance inventory were reviewed with the pharmacy staff.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2019-0035), 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 REPRIMAND, and to send an Advisory on 21 CFR §1301.76 *Other security controls for practitioners* regarding factors to consider when determining a significant loss.

Case #8

PHA-2019-0057

Walgreens #10128, DS3472

Time: 10:55 AM

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

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

- PCS notified BORP an application for a pharmacy technician license for Brandi Estridge was received on 4/15/19 that indicated she had worked 2,156 hours as a pharmacy technician in training at Walgreens Pharmacy 10128.
- Current MOR Chappel indicated on 4/8/19, the front store manager discovered that Ms. Estridge was over her hours. Current MOR Chappel had not assumed the role of MOR when the application was submitted and cannot speak to how it was overlooked.
- Ms. Estridge was started work at the Pharmacy on 2/17/18 and documentation provided showed she had worked 2,255 hours as of 4/8/19.

CA: Current MOR Chappel will be tracking all technician in training hours on a physical log kept in the pharmacy for employees to enter their hours worked following each shift worked and will verify the information on a bi-weekly basis in Kronos. The expiration date for all technician licenses will also be tracked to ensure renewal. Ms. Estridge was issued a Pharmacy Technician in Training license (PTT00034) on 04/11/2018 and a Pharmacy Technician license (PT24686) on 05/06/2019.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2019-0057) 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 REPRIMAND.

Case #9

PHA-2019-0049

Stop & Shop #82, DS3359

Time: 10:57 AM

RECUSAL: NONE

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

- Untimely RLCS on 9/14/18 for #40 oxycodone 15mg tablets on 8/16/18 discovered during the reconciliation of the perpetual inventory.
- MOR Kryzyzewski indicated the loss was due to Pharmacist Stephen inadvertently discarding a stock bottle containing #40 tablets while filling a prescription which S&S confirmed by review of the security footage.
- Pharmacist Stephen acknowledged filling a prescription on 8/16/18 for #120 oxycodone 15mg tablets then discarding the stock bottle in the trash.

CA: MOR Kryzyzewski reinforced with staff the importance of maintaining accurate controlled substance records and reviewed all policies and procedures related to controlled substances with staff; emphasis was placed on immediately CII stock bottles to the safe after performing a back count; Pharmacist Stephen reviewed S&S's 'Perpetual Schedule II Inventory' policy, focusing on the back-count procedure; Pharmacist Stephen received a formal write up.

ACTION: Motion by M. GODEK, seconded by P. GANNON, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0049), No Discipline Warranted, Remediation Complete.

Case #10

SA-INV-14965

Baystate Pharmacy, DS89896

Time: 11:00 AM

RECUSAL: NONE

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

- Inspectional deficiencies for a site visit (ISP-11190) on 12/21/18 as a follow up to a report to the PMP for a prescription for 1,400 oxycodone/apap 5/325mg tablets which was determined to be a prescription created as a transfer of medication between Baystate locations.
- In the POC, the Pharmacy indicated that the transfer of controlled substances will no longer be processed as prescriptions in the computer system with P&P provided.
- During a retail inspection (ISP-10273) on 4/12/19, the transfer of CVI medications between 5 Baystate locations (3 retail and 2 clinics) by creating prescriptions in the computer was still occurring.
- POC and response to staff assignment indicated Baystate considered the process as a creation of an electronic medication requisition and not the creation of a prescription. The intention of the process

was to fulfill an immediate patient need or for inventory control. Inventory was transferred between retail and 340B inventories from retail and clinic locations.

- CA: The P&P was revised to include all medications and the practice was suspended.

ACTION: Motion by M. GODEK, seconded by J. LANZA, and voted by most present, for an Investigative Conference to be scheduled to further discuss the matter with the MOR and any individual(s) involved in pharmacy decision making within the corporation. Board Members K. TANZER and P. GANNON voted in opposition to the motion.

Case #11

SA-INV-15271

AmEx Pharmacy, NO00026

Time: 11:12 AM

RECUSAL: NONE

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

- SA-INV was opened after FDA issued a 483 to AmEx Pharmacy in Melbourne, FL. (503b) on May 31, 2019.
- FDA inspected the Pharmacy from April 15, 2019 to May 31, 2019 and observed numerous system issues such as conditions for environmental monitoring, cleaning and disinfection, procedures for preventing contamination of drug products, lack of validation of aseptic and sterilizations methods, quality assurance, and complaint handling (#287 since 2016). Complaints included, “floaters, plunger not advancing, fibers found on needle, eye inflammation, loss of visual acuity)
- Additional observations were made regarding deficiencies in systems for determining expiration date, identification of incoming products, training and onboarding of new staff, container closure testing, aseptic procedures, protective apparel, labeling, and retention of reserve samples.
- FDA requested the firm to recall all products within expiry. AmEx Pharmacy declined to do so stating their products are sterile and safe within a press release.
- SA letter was provided to MOR Christina Buhrman requesting further detail into their decision to not recall. MOR cited that they have no sterility testing failures, endotoxin failures, certification testing failures, and microbiological excursions that would dictate the product sent to MA were contaminated.
- The case is still under review. Information forwarded to BHCSQ and BORIM.

ACTION: NONE taken at this time, as the matter was brought before the Board for informational purposes at this time, and is still pending investigation.

Topic X

EXECUTIVE SESSION

Time: 11:17 AM

Read by A. Stein

DISCUSSION:

ACTION: At 11:16 AM President A. Stein read the statement on reasons for Executive Session.

Topic X: **Executive Session Call to Order:** **Time: 11:37 AM**
By: A. Stein

ACTION: Motion by K. Tanzer, seconded by P. Gannon, and voted unanimously by roll call to call the August 1, 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; S. Hamilton, yes; S. Cornacchio, yes; P. Gannon, yes; T. Fensky, yes.

Topic XI: **M.G.L. 65 C #1** **Time: 11:21 AM**

DISCUSSION: None

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

At 11:21 AM P. Gannon, seconded by J. Lanza and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

Topic XII **ADJOURNMENT OF MEETING** **TIME: 1:43 PM**

ACTION: Motion by S. Hamilton, seconded by T. Fensky, 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 8/1/19 General Session
2. Draft Minutes of the 6/27/19 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): Licensure Applications and Notices (update)
9. Staff Action Board Delegated Review policy 14-02 (Update)
10. Joint Policy 2018-01: Permitted Prescription Changes and Additions (update)
11. Policy 2019-04: Transfer of Unfilled Prescriptions
12. Policy Remote dispensing of Naloxone by a Pharmacy
13. Applications: Mae Fowler PTT02755 Waiver
14. Applications: Conley's Drug Store (DS2654) Waivers
15. Applications: Southcoast Pharmacy Waivers
16. Applications: Partners Pharmacy; New Sterile Compounding Room
17. Applications: Betterlife Pharmacy New Community Pharmacy
18. Applications: Walgreens 17164 (DS90184) Change of Manager

19. PHA-2018-0088 Blue Hill Pharmacy, DS89942
20. PHA-2019-0056 CVS #1225, DS1952
21. SA-INV-14992 CVS #166, DS3449
22. PHA-2019-0060 CVS #8441, DS89794
23. PHA-2019-0059 CVS #1955, DS2356
24. SA-INV-14905 Tracy Kirkpatrick, PH25994
25. PHA-2019-0035 Walgreens #4358, DS2873
26. PHA-2019-0057 Walgreens #10128, DS3472
27. PHA-2019-0049 Stop & Shop #82, DS3359
28. SA-INV-14965 Baystate Pharmacy, DS89896
29. SA-INV-14927 Cornerstone Health Solutions, DS90083

Respectfully Submitted,
Julie Lanza, CPhT, Secretary