

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

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

February 1, 2024

The regular session is open to the public by video or phone.

Join link:

<https://eohhs.webex.com/eohhs/j.php?MTID=mbc9513e14c0e797c48d11256b76e6a5b>

Webinar number:

2539 974 7116

Webinar password:

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*If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator **Erin Bartlett**, erin.bartlett2@mass.gov or 857-262-7431 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	
8:00	I	CALL TO ORDER		K. Thornell
8:02	II	APPROVAL OF AGENDA		
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of January 11, 2024, Regular Session Minutes		

8:10	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 • PSUD Report-Policy 17-03 																																						
8:15	V	FLEX <ul style="list-style-type: none"> • Election of a delegate to NABP Annual Meeting 		D. Sencabaugh																																				
8:20	VI	APPLICATIONS <ul style="list-style-type: none"> • Vantive US Healthcare LLC/Baxter Healthcare – Transfer of ownership • Community Care Pharmacy – Transfer of Ownership • Family Health Center of Worcester Pharmacy- New Community Pharmacy • Union Pharmacy Needham – New Community Pharmacy 																																						
9:00	VII	POLICIES <ul style="list-style-type: none"> • Policy 2023-07: Non-Sterile Compounding 		M. Chan																																				
	VIII	REGULATION <ul style="list-style-type: none"> • 247 CMR 3.00: Licensure and Continuing Education Requirements for Individual Pharmacy Professionals 																																						
9:15	IX	FILE REVIEW <table border="1"> <tr> <td>1</td> <td>CASE-2023-0435</td> <td>PHA-2023-0202</td> <td>Medwiz of MA, DS90404</td> </tr> <tr> <td>2</td> <td>CASE-2023-0435</td> <td>PHA-2023-0203</td> <td>Hina Patel, PH</td> </tr> <tr> <td>3</td> <td>CASE-2023-0597</td> <td>PHA-2023-0212</td> <td>Medwiz of MA, DS90404</td> </tr> <tr> <td>4</td> <td>CASE-2023-0560</td> <td>PHA-2023-0199</td> <td>Walgreens #17259, DS90362</td> </tr> <tr> <td>5</td> <td>CAS-2023-1009</td> <td>PHA-2023-0224</td> <td>CVS #517, DS90080</td> </tr> <tr> <td>6</td> <td>CASE-2023-0515</td> <td>PHA-2023-0209</td> <td>CVS #2500, DS3606</td> </tr> <tr> <td>7</td> <td>CAS-2023-0599</td> <td>PHA-2023-0245</td> <td>CVS #38, DS3510</td> </tr> <tr> <td>8</td> <td>CAS-2023-0843</td> <td>PHA-2023-0144</td> <td>CVS #2878, DS3092</td> </tr> <tr> <td>9</td> <td>CAS-2023-1093</td> <td>PHA-2023-0184</td> <td>Coram CVS/ Specialty Infusion Services, DS3601</td> </tr> </table>	1	CASE-2023-0435	PHA-2023-0202	Medwiz of MA, DS90404	2	CASE-2023-0435	PHA-2023-0203	Hina Patel, PH	3	CASE-2023-0597	PHA-2023-0212	Medwiz of MA, DS90404	4	CASE-2023-0560	PHA-2023-0199	Walgreens #17259, DS90362	5	CAS-2023-1009	PHA-2023-0224	CVS #517, DS90080	6	CASE-2023-0515	PHA-2023-0209	CVS #2500, DS3606	7	CAS-2023-0599	PHA-2023-0245	CVS #38, DS3510	8	CAS-2023-0843	PHA-2023-0144	CVS #2878, DS3092	9	CAS-2023-1093	PHA-2023-0184	Coram CVS/ Specialty Infusion Services, DS3601		
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10:15	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 a pending applicant.																																						
11:15	XI	M.G.L. c. 112, § 65C SESSION																																						
12:30	XI	ADJOURNMENT																																						

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

**MINUTES OF THE GENERAL SESSION
Via Remote WebEx Meeting
February 1, 2024**

Board Members Present

Katie Thornell, RPh, MBA President
Caryn Belisle, RPh, MBA
Johanna Lopez, MS
Dr. Richard Lopez, MD
Sebastian Hamilton, Pharm D, MBA, RPh
John Rocchio, RPh, PharmD
Sami Ahmed, PharmD., RPh, BCPS, BCSCP
Rita Morelli, PharmD, BCACP, RPh
Delilah Barnes, RPh
Dawn Perry, JD
Mark Sciaraffa, CPhT

Board Members Not Present

Julie Dorgan, RN

Board Staff Present

David Sencabaugh, RPh, Executive Director
Jacqueline Petrillo, PharmD, RPh, JD, Board Counsel
Michael Egan, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh, Quality Assurance Pharmacist
Richard Harris, Program Analyst
Joanna Chow, Program Analyst
Taylor Lee, Office Support Specialist
Joanne Trifone, RPh, Director of Investigations
Gregory Melton, JD, PharmD, BCPS, Investigator
Julienne Tran, RPh PharmD, Investigator
Christina Mogni, RPh, Investigator
Keith Johnston, Compliance Officer
Joshua Kim, Pharmacy Intern

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 AM

A quorum of the Board was present, established by roll call. President Katie Thornell chaired the meeting and explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: C. Belisle, yes; S. Hamilton, yes; D. Barnes; J. Rocchio, yes; M. Sciaraffa, yes; R. Lopez, yes; S. Ahmed, yes; R. Morelli, yes; J. Lopez, yes; D. Perry, yes; K. Thornell, yes.

Topic II.
Agenda: 2/1/24

Approval of Agenda

TIME 8:03 AM

DISCUSSION: The application for Family Health Center of Worcester Pharmacy is deferred.
The application for Union Pharmacy Needham is deferred.

ACTION:

Motion by C. Belisle, seconded by J. Lopez and voted unanimously by those present to approve the agenda with the noted changes by roll call vote.

M. Sciaraffa enters the meeting at 8:04 AM

Topic III

Approval of Board Minutes

TIME: 8:04 AM

Minutes

1. Draft 1/11/24

Change: No changes

Action:

Motion by S. Hamilton seconded D. Barnes and voted unanimously to approve the regular session minutes of 1/11/2024 with no noted changes by roll call vote.

TOIC IV

Reports

Applications approved pursuant to Licensure Policy 13-01

TIME: 8:04 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported a total of 15 Change in MOR applications and 3 facility closures that have been approved via Staff Action since the January 11th Board meeting.

So noted.

Topic IV.

REPORTS

Monthly Report from Probation

TIME: 8:04 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported one licensee that was given the opportunity to cure since the last Board meeting. Currently, there are 16 active probation cases.

So noted.

Topic IV.

REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

TIME: 8:04 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto indicated two cases of controlled substances losses that occurred since the last Board meeting, each of which was issued a reprimand.

So noted.

Topic IV.

REPORTS

PSUD report by Staff Action 17-03

TIME: 8:04 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported 1 new admission to the PSUD program since the January 11th Board meeting with no admissions pending. Currently, there are a total of 8 active participants enrolled in the program.

So noted.

Topic V.

FLEX

Election of a delegate to NABP Annual Meeting

TIME: 8:04 AM

PRESENTED BY: D. SENCABAUGH

DISCUSSION: D. Sencabaugh discussed the need for a Board-appointed delegate to attend the upcoming NABP Annual Meeting held in May. A vote was then conducted to elect a delegate who will represent the MA Board of Pharmacy.

ACTION: A motion was made by C. Belisle to elect J. Rocchio as delegate and K. Thornell as alternate delegate to represent the MA Board of Pharmacy; Seconded by J. Lopez. Then Board Members present voted unanimously by rollcall to approve the motion.

So noted.

D. Perry enters the meeting at 8:07 AM

TOPIC VI

APPLICATIONS

1. Vantive US Healthcare LLC/Baxter Healthcare Transfer of Ownership TIME: 8:08 AM

Represented by: Cheryl Davis, Keegan Chamberlain, Vincent Hanks

Recusal: None

Discussion:

- Pages 27 to 96 of General Session packet
- Transfer of Ownership from Baxter International to Vantive US Healthcare LLC in Bedford
- Phase 1 of a 2 part plan to spin off renal subsidiary to a separate entity
- Closed door pharmacy for dialysis products and supplies only for delivery to the patient's home for self-administration
- The following waivers were requested:
 - 247 CMR 6.02 (2) – equipment and publications

 - 247 CMR 6.02 (4) – sufficient supply of medicinals

 - 247 CMR 6.02 (5) – external signage,

 - 247 CMR 6.02 (6) (d) – separate working alarm

 - 247 CMR 6.02 (6) (e)- floor to ceiling barrier

 - 247 CMR 6.02 (8) (a) – posting of hours of operation

 - 247 CMR 6.02 (8) (b) – hours of operation for prescription department if different than retail store

 - 247 CMR 6.02 (8) (c)- hours of operation of a pharmacy's prescription area if different than non-prescription area.

 - 247 CMR 6.01 (5) (a) (7) – requirement for sink

 - 247 CMR 6.01 (5) (a) (4) – balance

 - 247 CMR 6.01 (5) (a) (5) – equipment for practice of pharmacy

 - 247 CMR 6.02 (5) (a) (1) – copy of list of interchangeable drug products

 - 247 CMR 6.01 (5) (a) (2) – requirement for compendia and updates

 - 247 CMR 9.01 (15) – limiting services

 - 247 CMR 9.01 (16) – shall not refuse to compound

Action: A motion was made by S. Hamilton to approve Vantive US Healthcare’s application for a transfer of ownership with the requested waivers pending a successful inspection; Seconded by C. Belisle then Board Members present voted unanimously by roll call to approve motion.

S. Ahmed enters the meeting at 8:10 AM

2. Community Care Pharmacy Transfer of Ownership TIME: 8:18 AM

Represented by: Junghwa Lee, Laretta Okoye

Recusal: None

Discussion:

- Pages 97 to 114 of General Session packet
- Transfer of Ownership from Community Care Pharmacy Inc owned by Laretta Okoye to Community Care Pharmacy in Dorchester
- Junghwa Lee was the Manager of Record of Community Care Pharmacy Inc. since November 2015 and will be the Owner and Manager of Record of Community Care Pharmacy

Action: A motion was made by S. Ahmed to approve Community Care Pharmacy’s application for a transfer of ownership with the requested waivers pending a successful inspection; Seconded by M. Sciaraffa then Board Members present voted unanimously by roll call to approve motion.

3. Family Health Center of Worcester Pharmacy New Community Pharmacy TIME: 8:02 AM

Deferred

4. Union Pharmacy Needham New Community Pharmacy TIME: 8:02 AM

Deferred

TOPIC VII

POLICIES

Policy 2023-07: Non-Sterile Compounding

Time: 8:22 AM

Presented by: M. CHAN

Discussion: In order to reduce pharmacy barriers to providing compounded medications, the policy addresses certain requirements of USP. For instance, the Board does not intend to enforce the USP

<795> cleaning and sanitizing requirements for pharmacies not engaged in complex non-sterile compounding as long as the pharmacy and equipment are maintained in a clean and sanitary manner. There is a similar provision for temperature monitoring. Also, an allowance was added for pre-measured compounding kits to be documented in the same manner as flavoring agents.

Action: Motion by C. BELISLE, seconded by S. AHMED, and voted unanimously by roll call of those present, to approve the edits to the policy.

TOPIC VIII

REGULATION

247 CMR 3.00: Licensure and Continuing Education Requirements for Individual Pharmacy Professionals **Time: 8:24 AM**

Presented by: M. CHAN and W. FRISCH

Discussion: The proposed change was to eliminate the Pharmacy Technician Trainee license in favor of two tiers of technicians. A "Pharmacy Technician I" would include trainees as well as inventory management persons and others who are not interested in pursuing a Pharmacy Technician II license. The "Pharmacy Technician II" license would be issued to those technicians who have completed training and passed a competency exam or have been licensed elsewhere in the U.S. Essentially, the second tier is equivalent to the current "Pharmacy Technician". Both license tiers will be valid for 2 years and renewable on the licensee's birthdate.

This updated regulation condenses and replaces the current versions of 247 CMR 3.00, 4.00, and 8.00.

Action: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by roll call of those present, to forward the document for administrative review and approval to hold a public hearing.

TOPIC IX

FILE REVIEW

Case #1 /CASE-2023-0435

PHA-2023-0202

Medwiz of MA, DS90404

Time: 08:35 AM

RECUSAL: NONE

DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to this matter.

- During a retail compliance inspection (ISP-22126) on 08/31/2023, it was found that an unlicensed employee was handling medications in the controlled substance room.
- MOR Patel indicated PTT Bando's start date with the MedWiz company was on 06/30/2019 and she only worked at the Pharmacy in Massachusetts on 8/31/2023 from 9am to 12pm. According to Current MOR Patel, PTT Bando was organizing the paperwork in the controlled substance room and was not handling medications and she was supervised at all times. She was removed promptly from the Pharmacy once it was ascertained that she didn't have the proper credentials.

- MOR Patel indicated that she started working with Medwiz on 08/14/2023 and was new to the organization.
- MOR Patel indicated that all approved team member’s certifications are posted and they have key card access to permit them into the control room. No one else is permitted access to this room.
- PTT Frimet was licensed with BORP on 10/02/2023.

ACTION: Motion by S. AHMED, seconded by S. HAMILTON, and voted unanimously by those present, to combine the matter (PHA-2023-0202), with PHA-2023-0217, and refer 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 #2/CASE-2023-0435

PHA-2023-0203

Hina Patel, PH26095

Time: 08:35 AM

RECUSAL: NONE

DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to this matter.

- During a retail compliance inspection (ISP-22126) on 08/31/2023, it was found that an unlicensed employee was handling medications in the controlled substance room.
- MOR Patel indicated PTT Bando’s start date with the MedWiz company was on 06/30/2019 and she only worked at the Pharmacy in Massachusetts on 8/31/2023 from 9am to 12pm. According to Current MOR Patel, PTT Bando was organizing the paperwork in the controlled substance room and was not handling medications and she was supervised at all times. She was removed promptly from the Pharmacy once it was ascertained that she didn’t have the proper credentials.
- MOR Patel indicated that she started working with Medwiz on 08/14/2023 and was new to the organization.
- MOR Patel indicated that all approved team member’s certifications are posted and they have key card access to permit them into the control room. No one else is permitted access to this room.
- PTT Frimet was licensed with BORP on 10/02/2023.

ACTION: Motion by R. LOPEZ, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2023-0203), 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#3/CAS-2023-0597

PHA-2023-0212

Medwiz of MA, DS90404

Time: 08:37 AM

RECUSAL: NONE

DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to this matter.

- On 09/13/2023, Board staff notified OPP that during the processing of Kyle Brantley’s PT application it was discovered that she had been working in the pharmacy without a PTT license.
- MOR Patel related that Ms. Brantley was first hired on 07/10/2023 for a pharmacy technician position with a job function as a “toter.” In this role, Ms. Brantley would place filled prescriptions into their

designated bin, stage for delivery, and ensuring all medication packages and packing list are placed into a delivery bag and sealed. This included bagging the medications.

- Ms. Brantley had initially applied for the incorrect license type of PT instead of PTT. During the eLX transition, the MOR instructed her to apply again, and the MOR thought she was in the process of obtaining a license. According to the MOR, Ms. Brantley worked packaging medication for 1 day then was transitioned back to the delivery function when it was discovered she did not have a PTT license.
- It was determined that Ms. Brantley worked 332.4 hours unlicensed.
- MOR Patel indicated that team members in transition of a license can only package medications for delivery. The MOR physically verifies the tech trainee license status on Massachusetts Board of Pharmacy website before they train team members on the rest of our workflow and immediately post the license on our license board.

ACTION: Motion by S. AHMED, seconded by D. PERRY, and voted unanimously by those present, to combine the matter (PHA-2023-0212), with PHA-2023-0202, and refer 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 #4

/CAS-2023-0560
PHA-2023-0199 Walgreens #17259, DS90362 Time: 08:43 AM

RECUSAL: NONE

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to this matter.

- Deficiency on 10/3/23 for storage of COVID vaccine for immediate administration in 20 unlabeled, pre-drawn syringes next to a dirty sink with a commercial dehumidifier draining into it. The dehumidifier had been in place for 2 weeks. MOR Kebede provided Pfizer Medical Information which states COVID vaccine in unpreserved single dose vials may be stored up to 12 hours at room temperature but microbial risk must be considered. MOR Kebede salvaged the pre-drawn syringes. All vaccines are no longer drawn up or stored in the area near the sink.
- MOR Kebede contended the pre-drawn vaccines were in a segregated tote. He filled them in anticipation of a high volume of vaccines expected that day and had not yet placed them in the refrigerator. Once informed of the microbial risk, he salvaged the vaccines. He resumed administering vaccines using a newly drawn-up syringe prepared at a different location for immediate administration. MOR Kebede stated he was the only staff member who practiced pre-drawing vaccine in syringes on that day and occasionally during the week prior to the inspection.
- Forty vaccines were administered by MOR Kebede during his shift. Four patients received vaccine in pre-drawn syringes prior to the inspection. These patients were contacted with no adverse effects reported.
- MOR Kebede posted a notice on the wall near the sink advising against vaccine preparation or temporary placement of syringes in that area. MOR Kebede reviewed the Walgreens policies and procedures for COVID-19 vaccine storage and handling.

ACTION: Motion by C. BELISLE, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0199), 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.

RECUSAL: J. ROCCHIO and D. PERRY recused and were not present for the vote or discussion in this matter.

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to this matter.

- ID on 7/14/23 for an unmonitored refrigerator containing vaccines and medications. Investigator Brosnan directed the Pharmacy to quarantine the contents until documentation from the manufacturer confirmed they were safe and effective. The POC stated manual temperature logs were started immediately and a TempAlert node was installed 8/3/23. Documentation showed 90 vaccines stored in the unmonitored refrigerator were administered.
- Senior Analyst Furtado indicated the refrigerator was installed on 6/15/23 and use of it for refrigerated products began on 6/16/23. She stated the TempAlert team assessed the incident and had no product integrity concerns as the refrigerator was in good working condition with no documented disruptions. When the old refrigerator was replaced with a medical-grade one, the TempAlert device was taken with it. The new refrigerator has a built-in manual thermometer with a digital readout.
- MOR Kerr stated, "From a product integrity standpoint, there is no reason to believe a temperature excursion event has occurred in RX Cooler 4 as this was a new medical grade fridge being used with no confirmed disruptions in power to the fridge and attestation that temperatures were monitored twice daily during the gap in TempAlert data". MOR Kerr and Pharmacist Godek acknowledged there was a period of 4 weeks with no manual or electronic temperature logs for the refrigerator.
- The following information was requested but not provided: if refrigeration temperatures were monitored prior to use; a list of the contents of the refrigerator; supporting evidence confirming the safety and effectiveness of the products; and follow-up with patients/prescribers.
- The Pharmacy team is aware to document twice daily temperature readings on the TempAlert website. MOR Kerr and Pharmacist Godek signed and dated policies ROPP-052388 Routine Temperature Monitoring and Drug Product Storage and ROPP-046268 Cold Chain Product Storage confirming review.

ACTION: Motion by D. BARNES, seconded by J. LOPEZ, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0224), 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.

RECUSAL: J. ROCCHIO and D. PERRY recused and were not present for the vote or discussion in this matter.

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to this matter.

- ID on 8/15/23 for refrigeration temperature excursions without documented actions. RxCooler 3 recorded 52°F on 7/24/23; RxCooler 6 recorded 50°F on 7/29/23; and RxCooler 2 recorded 27°F and 51°F on 8/13/23. The keep and discard lists were requested for each refrigerator but not all medications were identified in the response.
- MOR Dumond received the alert for RxCooler 3 which contained prescriptions for pick-up on 7/24/23. The refrigerator door was not closed fully. He reviewed the storage information for the medications and deemed them safe. Although he logged into SmartSense and closed the alert, he failed to log the incident in the correct field. The excursion lasted 1 hour, 30 minutes.
- Pharmacist Nguyen addressed the 7/29/23 excursion which lasted 13 hours. The door was not closed. He reviewed the storage information for the medications and deemed them safe. Although he logged into SmartSense and closed the alert, he failed to log the incident in the correct field.
- MOR Dumond addressed the 8/13/23 excursions which last 7 hours, 31 minutes and 1 hour, 30 minutes. He was notified of the alerts at the start of his shift. The medications had been mKoved to another refrigerator. He submitted in a workorder. Corporate notified him 5 medications were at risk from the excursions and 5 patients were contacted. Two responded and were re-dispensed medications. Of note, all 5 medications were dispensed after 8/15/23.
- Pharmacy staff and floaters are to ensure compliance with twice daily temperature monitoring. Quarantine protocols for excursions were reviewed along with the importance of ensuring refrigerator doors are closed. The Pharmacy staff were re-educated to respond to excursion calls as soon as they are received. A checklist was added at each station to secure refrigerators before closing shifts. The Pharmacy staff provided a signed statement confirmed the review of policies and procedures for the appropriate storage of refrigerated medications and vaccines including the action policy for excursions.

ACTION: Motion by D.BARNES, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2023-0209), 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 #7/CASE-2023-0599

PHA-2023-0245

CVS #38, DS3510

Time: 08:58 AM

RECUSAL: J. ROCCHIO and D. PERRY recused and were not present for the vote or discussion in this matter.

DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to this matter.

- Formerly SA-INV-22167, elevated to this complaint via staff action.
- On 04/28/2023, it was observed during an inspection that the Pharmacy had automated pharmacy systems (APS) located outside of the pharmacy. The pickup lockers were not in use at the time, and it was confirmed with BORP staff that there was no renovation request submitted to BORP.
- In the initial renovation request on 09/12/2022, the Pharmacy requested renovations for updates to the pharmacy shelves and countertops while adding an immunization/consultation room.
- On 06/05/2023, Board Staff received another renovation application for the lockers.
- On 07/14/2023, Investigator Seed conducted a site visit (ISP-21713) to inspect the renovations requested for the lockers and immunization room. The inspection was satisfactory.

- On 08/18/2023, MOR Eljadidi indicated that the renovation request was sent to the Board on 6.2.23 for the lockers. She noted that the store is not live with Rx lockers and are waiting to get official approval from the Board before turning them on.
- In response to the complaint, MOR Eljadidi indicated that CVS Store 38 had lockers approved by the MA BOP and enabled on 11/14/23.

ACTION: Motion by S. AHMED, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2023-0245), 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 #8/CAS-2023-0843

PHA-2023-0144

CVS #2878, DS3092

Time: 09:00 AM

RECUSAL: J. ROCCHIO and D. PERRY recused and were not present for the vote or discussion in this matter.

DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to this matter.

- RLCS- a loss of #387 suboxone 8mg/2mg films on or about 04/20/2023 due to an unknown loss.
- MOR Loura escalated the electronic balance on hand (eBOH) for suboxone 8mg/2mg films with a variance of 404 films. She was instructed to complete daily loss prevention initiated counts and review of inventory showed one large negative cycle count of -375 on 01/27/2023.
- Between 04/19/2023 and 05/09/2023, the variance remained around 404. On 05/15/2023, the variance dropped and there were no active signs of diversion within the last 90 days so it was decided to request a final reconciliation and close the investigation. The Pharmacy submitted an amended final loss report to reflect the variance drop to 387 tablets.
- The DEA completed an audit on 07/07/2023 and found additional losses to include #240 lorazepam 1mg tablets which is an unknown loss and #31 morphine ER 25mg tablets due to a dispensing error.
- MOR Loura indicated that the loss Prevention policy and procedures will be reviewed with the Pharmacy Team to prevent future losses. This includes diligent inventory management. Pharmacy staff attested to review of CVS' "Pharmacy Colleague Asset Analytics and Insights/Drug Diversion" policy.

ACTION: Motion by C.BELISLE, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0144), 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, for a period of 1 year, with special terms to include the CS Loss Protocol for all Suboxone products and all Benzodiazepines.

D. Perry leaves the meeting at 9:00 AM

RECUSAL: J. ROCCHIO, D. PERRY and J. TRIFONE recused and were not present for the vote or discussion in this matter.

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

- Investigator Stephen Horn was dispatched to Coram to conduct a site on August 2, 2023 and August 3, 2023 after Coram requested to be permitted to move drugs to a refrigerated trailer because a walk-in refrigerator was malfunctioning. Investigator Horn discovered that extended and continuous periods of temperature excursions above 10° C (50° F) with maximum temperatures of approximately 14.6° C (58.3° F) had occurred since July 11, 2023.
- Significantly, Investigator Horn learned that Coram dispensed prescription drugs to patients including compounded sterile preparations deemed substandard because the drugs were stored in the malfunctioning walk-in refrigerator during the above-described periods of extended and continuous temperature excursions. He requested that Coram quarantine those drugs until confirmation of suitability for use from manufacturers was obtained. Investigator Horn then requested that Coram determine whether the use of any of those drugs posed a risk to patients then notify patient and physicians accordingly. In addition, Coram was permitted to use the refrigerated trailer for a short period while the walk-in refrigerator was repaired.
- POC/CA: Coram indicated that the walk-in refrigerator was “cleaned and sanitized. We monitored the temp to make sure it was maintained. Then we moved the drugs (that we had the data to return to fridge) into the walk-in cooler. We have been monitoring the temp since then and everything looks good so far.” Coram added that the walk-in would be scheduled to be cleaned and organized monthly and as needed.
- Coram indicated that inventory in the walk-in refrigerator was quarantined at the time of the inspection pending confirmation of suitability for use. Coram described that corresponding drug manufacturers were contacted “to determine the stability of the drug product.” She indicated that “product with verified data from the manufacture as being stable was placed back into inventory and segregated from other drugs being stored... Product which could not be verified was discarded and labeled as ‘Do Not Use.’ ” In addition, patient outreach was conducted, and drugs were replaced or physicians were notified that patient’s drug was compromised.

ACTION: Motion by S. HAMILTON, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0184), 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.

Topic X:**Executive Session Call to Order:****Time: 9:07 AM**

By: President K. Thornell reads the executive session language and requests a motion to enter executive session.

Action: Motion by C. BELISLE, seconded by S. HAMILTON, and Board Members present voted unanimously by roll call to approve motion. Roll call attendance:

Roll call attendance: Roll call attendance: C. BELISLE, yes; D. BARNES; yes; J. ROCCHIO, yes; M. SCIARAFFA, yes; R. LOPEZ, yes; S. AHMED, yes; R. MORELLI, yes; K. THORNELL, yes; S. HAMILTON, yes; J. LOPEZ, yes.

Topic XI:**65C Sessions MGL c. 112 section 65C****Time: 9:45 AM**

DISCUSSION: None

ACTION: President K. Thornell request a motion to enter 65C.

At 9:45 A.M. J Lopez, seconded by D. Barnes and voted unanimously by all those present to enter 65C by roll call vote.

Topic XII:**ADJOURNMENT OF MEETING****TIME: 10:37 AM**

ACTION: Motion by S. Hamilton seconded by D. Barnes and voted unanimously by all those present to adjourn the meeting by roll call vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 2/1/24 General Session
2. Draft Minutes of the 1/11/24 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Monthly report from Probation
5. Report on Board Delegated Complaint Review to licensure policy 14-02
6. Report on PSUD 17-03
7. Vantive US Healthcare LLC – Transfer of Ownership application
8. Policy 2023-07: Non-Sterile Compounding
9. 247 CMR 3.00: Licensure and Continuing Education Requirements for Individual Pharmacy Professionals
10. PHA-2023-0202 Medwiz of MA, DS90404
11. PHA-2023-0203 Hina Patel, PH
12. PHA-2023-0212 Medwiz of MA, DS90404
13. PHA-2023-0199 Walgreens #17259, DS90362
14. PHA-2023-0224 CVS #517, DS90080

15. PHA-2023-0209 CVS #2500, DS3606
16. PHA-2023-0245 CVS #38, DS3510
17. PHA-2023-0144 CVS #2878, DS3092
18. PHA-2023-0184 Coram CVS/ Specialty Infusion Services, DS3601

Respectfully Submitted,
Rita Morelli, Secretary