

**7COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy**

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

October 17, 2024

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

Join link:

<https://cohhs.webex.com/cohhs/j.php?MTID=mabec3e2be2c3668d2e790b585ab28a16>

Webinar number:

2536 028 9252

Webinar password:

BOP123 (267124 from phones and video systems)

Join by phone:

+1-617-315-0704 United States Toll (Boston)

+1-650-479-3208 United States Toll

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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

		Item	Page	
8:00	I	CALL TO ORDER		K. Thornell
8:05	II	APPROVAL OF AGENDA		
8:10	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">Draft of September 5, 2024, Regular Session Minutes		
8:15	IV	REPORTS <ul style="list-style-type: none">Applications approved pursuant to Licensure Policy 13-01Monthly report from ProbationBoard Delegated Review pursuant to Licensure Policy 14-02PSUD Report-Policy 17-03Research Drug Study report pursuant to Staff Action Policy 18-02		

8:20	V	FLEX <ul style="list-style-type: none">• URAMP Update• Pharmacist Renewals• Board Staff Update• Vote on Pentec request regarding implantable infusion pumps																						
9:00	VI	POLICIES <ul style="list-style-type: none">• Policy 2024-02: Implantable Infusion Pumps																						
9:15	VII	REGULATIONS <ul style="list-style-type: none">• 247 CMR 13.00: Nuclear Pharmacy Licensure Requirements and Professional Practice Standards																						
9:30	VIII	APPLICATIONS <ul style="list-style-type: none">• Medminder; DS90408 - Petition for Waiver• MBS Pharma Care, Inc. – Change of Business Model• Optum Infusion Services 550, LLC DS90100 – Petition for Waiver• Tarrytown Expocare MA, LLC / DBA Greater Boston Long Term Care Pharmacy– Transfer of Ownership• BILH Home Infusion–New Community Pharmacy• NSCHC Pharmacy – New Community Pharmacy• New England Pharmacy & Wellness-New Community Pharmacy• Brighton Marine Pharmacy – Transfer of Ownership																						
10:30	IX	FILE REVIEW <table><tr><td>1</td><td>CASE-2024-2016</td><td>PHA-2024-0125</td><td>Empower Pharmacy, NO00019</td></tr><tr><td>2</td><td>CASE-2024-1739</td><td>PHA-2024-0108</td><td>Genoa Healthcare, LLC, DS89910</td></tr><tr><td>3</td><td>CASE-2024-1739</td><td>PHA-2024-0109</td><td>Kimberly A. O’Connor, PT11423</td></tr><tr><td>4</td><td>CASE-2024-2497</td><td>PHA-2024-0163</td><td>MBS Pharma Care, Inc., DS89968</td></tr><tr><td>5</td><td>CASE-2024-1730</td><td>PHA-2024-0110</td><td>CVS #735, DS2841</td></tr></table>	1	CASE-2024-2016	PHA-2024-0125	Empower Pharmacy, NO00019	2	CASE-2024-1739	PHA-2024-0108	Genoa Healthcare, LLC, DS89910	3	CASE-2024-1739	PHA-2024-0109	Kimberly A. O’Connor, PT11423	4	CASE-2024-2497	PHA-2024-0163	MBS Pharma Care, Inc., DS89968	5	CASE-2024-1730	PHA-2024-0110	CVS #735, DS2841		
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11:00	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, evaluate the Good Moral Character as required for registration for a pending applicant.		
11:45	XI	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)		
12:00		LUNCH BREAK		
12:30	XII	M.G.L. c. 112, § 65C SESSION		
4:00	XIII	ADJOURNMENT		

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

October 17, 2024

Board Members Present

Katie Thornell, RPh, MBA President
Sami Ahmed, PharmD., RPh, BCPS, BCSCP, President-Elect
Caryn Belisle, RPh, MBA
Dr. Richard Lopez, MD
Sebastian Hamilton, Pharm D, MBA, RPh
John Rocchio, RPh, PharmD
Delilah Barnes, RPh
Mark Sciaraffa, CPhT
Frank Lombardo

Board Members Not Present

Rita Morelli, PharmD, BCACP, RPh, Secretary
Julie Dorgan, RN
Saad Dino, RPh, FACP/FACA

Board Staff Present

Monica Botto, Associate Executive Director
Jacqueline Petrillo, PharmD, RPh, 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
Keith Johnstone, Compliance Officer

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:01 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: S. Hamilton, yes; D. Barnes, yes; J. Rocchio, yes; K. Thornell, yes; S. Ahmed, yes; C. Belisle, yes; Dr. Lopez, yes; M. Sciaraffa, yes; Frank Lombardo, yes.

Topic II.

Approval of Agenda

TIME 8:03 AM

Agenda: 10/17/24

DISCUSSION: Brighton Marine Pharmacy deferred

ACTION:

Motion by D. Barnes, seconded by Dr. Lopez and voted unanimously by those present to approve the agenda with the noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:12 AM

Minutes

1. Draft 9/5/2024

Change: No changes.

Action:

Motion by S, Hamilton seconded M. Sciaraffa and voted to approve the regular session minutes of 9/5/2024 with no noted changes by roll call vote.

Topic IV.

REPORTS

Applications approved pursuant to Licensure Policy 13-01

TIME: 8:12 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris reported a total of 45 Change Pharmacist Manager of Record applications and 7 facility closures that have been approved by Staff Action since the last Board meeting.

So noted.

Topic IV.

REPORTS

Monthly Report from Probation

TIME: 8:13 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris indicated a total of 46 active probation cases, including 1 opportunity to cure and 1 second opportunity to cure. There has been one successful completion of probation monitoring since the last Board meeting.

So noted.

Topic IV.

REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

TIME: 8:14 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported a total of 2 Continuing Education deficiencies and 3 inspectional deficiencies since the last Board meeting. Additionally, 8 petition for waiver requests had been received and approved.

So noted.

Topic IV.

REPORTS

PSUD report by Staff Action 17-03

TIME: 8:14 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris reported 1 returned PSUD application since the September 5th Board meeting. There are currently 8 participants actively enrolled in the program.

So noted.

Topic IV.

REPORTS

Research Drug Study Report pursuant to Staff Action Policy 18-02

TIME: 8:14 AM

PRESENTED BY: M. CHAN

DISCUSSION: M. Chan reported on 3 pharmacies currently participating in research drug studies. There are currently 17 active studies, 5 of which involve investigational drug substances.

So noted.

Topic V.

FLEX

• **URAMP Update**

TIME: 8:15 AM

Presented by: Edmund Taglieri, PSUD Supervisor, Jonathan Dillon, BHPL Director of Policy, Gillian Coffey, BHPL Health Comm Manager, Sophia Emidy, BHPL Intern,

Discussion: EDMUND TAGLIERI introduced JOHNATHAN DILLON. DILLION provided an overview of BHPL's Unified Rehabilitation and Monitoring Program (URAMP). DILLION explained that URAMP was being established in accordance with Chapter 177 of the Acts of 2022, An Act Addressing Barriers to Care for Mental Health. The ACT required BHPL to establish a confidential, voluntary program for monitoring the rehabilitation of health care professionals licensed by BHPL who seek support for their mental health or substance use, or who are referred to the program by a licensing board. URAMP will replace BORP's PSUD and other all other BHPL Substance-Use Disorder Programs. DILLON indicated that URAMP was expected

launch before the end of 2024. DILLON provided an overview of differences between BOP's PSUD Program and URAMP including shorter times to return to practice and overall program length. DILLON advised that URAMP will seek a vote from BOP to accept the changes in URAMP compared to BOP's PSUD Program upon finalization of the program and prior to launch.

Action: None

Topic V.

FLEX

- **Pharmacist Renewals**

TIME: 8:48 AM

Presented by: Richard Harris

Discussion: RICHARD HARRIS notified licensees and public that all pharmacist licenses issued by BOP were due for renewal on or before December 31, 2024. HARRIS then notified licensees and public that BHPL implemented a new online platform for renewal of all licenses including pharmacist licenses. HARRIS explained that the platform was already available on BHPL's website at <https://healthprofessionlicensing.mass.gov/login-register> and encouraged licensees to register for an account. He explained that the renewal process was now online only and renewal reminders would be sent by email only. He described that licensees would be able to print registration cards and process other administrative actions such as name or address changes on the platform once registered for an account. He also described that the platform provided a tutorial on use. HARRIS added that BHPL eLicensing Staff and BOP Staff would be available to help answer questions about renewals during usual BHPL business hours.

Action: None

Topic V.

FLEX

- **Board Staff Update**

TIME: 8:04 AM

Presented by: James G. Lavery, BHPL Director

Discussion: JAMES LAVERY presented DAVID SENCABAUGH with a Commissioner's Certificate and a Governor's Certificate awarded for his outstanding service to the Commonwealth as Executive Director of the Board of Registration in Pharmacy.

Action: None

Topic V.

FLEX

• **Vote on Pentec request regarding implantable infusion pumps**

TIME: 8:59 AM

Presented by: Michelle Chan

Discussion: MICHELLE CHAN requested that BORP vote to grant approval of a request from Pentec to be released from the requirement to obtain scientific evidence for each compounded sterile preparation used in Medtronic infusion pumps that are implanted in the body and slowly infuse CSPs from the reservoir (which is at body temperature) for up to 90 days in light of anticipated launch of BORP Policy 2024-02: Implantable Infusion Pumps covering CSPs used in such devices.

Action: CARYN BELISLE motioned grant approval to the request from Pentec to be released from the requirement to obtain scientific evidence for each compounded sterile preparation used in Medtronic infusion pumps; Seconded by SAMI AHMED then Board Members present voted unanimously by roll call to approve motion.

TOPIC VI

POLICIES

Policy 2024-03: Ratios, Intern Supervision, and Dedicated Training Personnel **TIME: 8:52 AM**

Presented by: M. CHAN

Discussion: As discussed with the Advisory Committee, a policy has been drafted regarding the infusion of compounded sterile drugs with extended infusion times via implanted pumps. Licensees must assess documentation that has been obtained from either relevant and reliable sources or through direct testing in order to assure that such compounded sterile preparations maintain their stability at the applicable temperature and compatibility for the full duration of the infusion. The policy details were discussed with Board members C. BELISLE and S. AHMED prior to the meeting.

Action: Motion by S. HAMILTON, seconded by J. ROCCHIO, and voted unanimously by roll call of those present, to approve the new policy.

TOPIC VII

REGULATIONS

TIME: 8:55 AM

247 CMR 13.00: Nuclear Pharmacy Licensure Requirements and Professional Practice Standards

Presented by: M. CHAN

Discussion: Since edits were last brought before the Board in 2022, a most significant change was made to remove the requirement for the separate nuclear pharmacist license and defer nuclear pharmacist qualifications to the nuclear regulations at 105 CMR 120.526: Training for an Authorized Nuclear Pharmacist. The federal Nuclear Regulatory Commission (NRC) has extensive requirements for pharmacist training and those requirements are outlined in 105 CMR 120.526.

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 VIII

APPLICATIONS

1. Medminder; DS90408 - Petition for Waiver

TIME: 8:58 AM

Represented by:

Recusal: None

Discussion: This is being brought forth as an FYI to the public regarding the previous vote in the September closed session.

Medminder was approved for a Limited waiver for 247 CMR 8.04 (4) (e) that would allow for a licensed certified pharmacy technician to conduct final dispensing process validation when using the VBM® multi-medication adherence packaging machine after the pharmacist has reviewed the prescription and checked the stocked cassettes. Pharmacists must randomly perform 10% verification check of the adherence cards. All other workflow processes not using the specified automation will require 100% pharmacist verification. Data submission every 3 months.

Action: None

F. Lombardo left the meeting

2. MBS Pharma Care, Inc.

Change of Business Model

TIME: 9:00 AM

Represented by: Injy Botros

Recusal: None

Discussion: Applying for a change in business model, along with some waivers (see below).

We have been open as a close door pharmacy and are looking to transition to an opendoor pharmacy to the public and would like to remove some of the waivers.

Waivers to be rescinded:

247 CMR 9.01(15)

247 CMR 6.02(5)

Action: Sebastian Hamilton made a motion to approve the application and to rescind the two waivers, pending a successful inspection. Seconded by S. Ahmed and voted unanimously by roll call to approve the motion

3. Optum Infusion Services 550, LLC DS90100**Petition for Waiver****TIME: 9:05 AM****Represented by:** Laurie Donovan**Recusal:** C. Nelson

Discussion: I am here because Optum has made the business decision to discontinue compounding. This location will plan to continue to provide non-compounded medicines. Licensee is also applying for waivers (see below)

247 CMR 9.01(15)

247 CMR 6.02 (4)

Per C. Belisle: Once they decommission the clean room it will still be a licensed space. What is the plan to use that space?

There isn't a plan at this time, but we are planning to re-use this space. W. Frisch also added that any changes to the space will need an application.

Action: Motion by D. Barnes to approve the change in business model with waivers, seconded by Dr. Lopez and voted unanimously by roll call to approve the motion

4. Tarrytown Expocare MA, LLC / DBA Greater Boston Long Term Care Pharmacy**Transfer of Ownership****TIME: 9:11 AM****Represented by:** Ernessa Brawley, Iman Badawy, Michael Wessenberg**Recusal:** None

Discussion: Tarrytown Expocare is looking to buy and operate Greater Boston Long Term Care Pharmacy.

Action: Motion by K. Thornell to approve the transfer of ownership application pending successful inspection, Seconded by S. Hamilton and voted unanimously by roll call to approve the motion.

5. BILH Home Infusion**New Community Pharmacy****TIME: 9:26 AM****Represented by:** Scott Shepard, Neil Gilchrist**Recusal:** None

Discussion: BILH is expecting to open this location in two phases. Phase 1 will be providing limited services and an RN will be administering the infusions at the patient's home. After 12 months, BILH is looking to move to Phase 2 once the cleanroom is ready for use.

Requested waivers are as follows:

247 CMR 9.01 (15)
247 CMR 9.01 (16)
247 CMR 6.01 (5) (d)
247 CMR 9.07 (3) (c)
247 CMR 6.02(4)

Action: Motion by C. Belisle to approve the new community pharmacy application with waivers upon successful inspection; Seconded by D. Barnes and voted unanimously by roll call to approve the motion.

6. NSCHC Pharmacy New Community Pharmacy TIME: 9:17 AM

Represented by: Maribelle Ellhoury, Ryan Ribeiro-Rodriguez, John Awad
Recusal: Rocchio

Discussion: NSCHC is looking to open a new community pharmacy and planning to take over from a local CVS that is leaving. NSCHC also asked for a temporary pharmacy in order to provide continuity of care during this time.

Action: Motion by D. Barnes to approve the new community pharmacy application upon two successful inspections; Seconded by S. Ahmed and voted unanimously by roll call to approve the motion.

7. New England Pharmacy & Wellness New Community Pharmacy TIME: 9:31 AM

Represented by: Sepideh Amirifeli, Farshad Ghobbeh
Recusal: Rocchio

Discussion: New England Pharmacy and Wellness is looking to provide Medication Therapy Management (MTM) and Blood Pressure monitoring services to the community.

Action: Motion by J. Rocchio to approve the New Community Pharmacy application contingent upon a successful inspection; seconded by M. Sciaraffa and voted unanimously by roll call to approve the motion. F. Lombardo abstained.

8. Brighton Marine Pharmacy Transfer of Ownership TIME: 9:31 AM

DEFERRED

F. Lombardo entered the meeting

TOPIC IX**FILE REVIEW**

Case #1 /CASE-2024-1782

PHA-2024-0112

New England Life Care, DS3513

Time: 09:31 AM

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

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

- On 05/28/2024, a <797> compliance inspection was conducted with inspectional deficiencies observed as follows:
 - o NELC did not send out viable surface sampling to an external laboratory for identification. Specifically, 2 CFU in ISO 8 in March 2024.
 - o A RCA and CAPA were not conducted on a report of 10 CFU of coryneform bacillus in ISO 7 in January 2024.
 - o Label did not use the term Beyond Use Date (BUD) and was confusing.
 - o The HD storage room did not have a certificate confirming at least 12 air changes per hour (ACPH).
 - o HEPA filter pass-thru was not tested for leaks and air flow.
 - o Dispatch® disinfectant towels expired on 02/10/2024.
- Plan of Correction (POC) was received on 06/19/2024 as follows:
 - o All monthly surface samples with a CFU>0 will be sent to an external laboratory for identification.
 - o Documentation of a RCA and CAPA that were conducted on 01/08/24 was submitted.
 - o Prescription label clarified to include, "Discard Unused Drug By."
 - o On 06/02/2024, HD room certified under operational conditions and room found to have 71 ACPH as well as a satisfactory HEPA filter leak scan test (no leaks detected) and a down flow velocity profile was conducted.
 - o HD storage room and HEPA filtered pass-thru will be recertified every 6 months.
 - o All drug and cleaning products will be checked monthly for expiration dates.
- In response to this complaint, MOR Tedesco reiterated the corrective action submitted in the POC.

ACTION: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2024-0112), 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-2024-1611

PHA-2024-0095

Epicur Pharma, NO00051

Time: 09:38 AM

RECUSAL: NONE

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

- On 04/16/ 2024, Epicur notified BORP about a Warning Letter issued by FDA on 04/02/2024. The Warning Letter highlighted the Epicur's failure to meet conditions required to register as an FDA outsourcing facility, production of adulterated and misbranded drugs, and inadequate corrective

action observed during an FDA inspection between 09/26/2023 and 10/25/2023 which resulted in the issuance of a FDA Form 483. Of note, Epicur previously notified BORP about the FDA inspection and FDA Form 483.

- Epicur indicated that several outside experts were retained to fully address each concern described in the FDA Warning Letter. According to Epicur, those experts agreed that the warning letter was likely only issued because Epicur failed to update FDA on the progress of the corrective action plan in response to the FDA Form 483. Attorney Juliano added that FDA did not request updates and Epicur was unaware of the expectation.
- CA: Epicur explained that “many of the issues within the warning letter have already been fully addressed, as our commitment tracker within our FDA response indicated. Addressing the remaining issues has begun, which includes a comprehensive assessment of operations. This comprehensive assessment is being headed by industry expert Pramod Sharma, whose qualifications are attached to this email.” A copy of the commitment tracker was provided for reference. In addition, Epicur was now periodically updating FDA on the progress of corrective action.

ACTION: Motion by S. AHMED, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2024-0095), 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/CASE-2024-1557

INV10933

IntegriScript, DS89726

Time: 09:40 AM

RECUSAL: NONE

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

- On 04-05-2024, Investigators Brosnan and Seed while conducting an SCI observed pharmacy staff using an orbital shaker located in the anteroom outside of the ISO Class 5 PEC to complete reconstitution of daptomycin before adding the reconstituted drug to the final container for the CSP. Ultimately, Investigators Brosnan and Seed issued a plan of correction (POC) based partly on the reconstitution of the daptomycin outside of ISO 5 Class PEC using an orbital shaker. Followed by, BORP opening an investigation.
- In summary, MOR Kowal argued that the reconstitution of daptomycin outside the PEC using the orbital shaker was analogous to permitted removal of reconstituted vials from a PEC after entry or puncture as long as conditions for storage were according to PI under USP <797>. He also asserted that “BUDs for CSPs are based primarily on factors that affect the achievement and maintenance of sterility.’ When any vial is punctured only in ‘ISO Class 5 or cleaner air,’ aside from any specific ‘chemical and physical stability properties of the drug and/or its formulation,’ as detailed in the section 14.2.”
- However, he was unable to provide any references for the use of the orbital shaker when compounding daptomycin to consider any “specific ‘chemical and physical stability properties of the drug and/or its formulation” other than his compounders have never mentioned an issue. In addition, he contacted the manufacturer who also did not have any references to support use of orbital shakers to reconstitute. Lastly, he did not create SOPs for use of orbital shakers for CSPs.

- MOR Kowal indicated that the orbital shaker was removed from the pharmacy and would no longer be used to compound sterile preparations going forward.

ACTION: Motion by C. BELISLE, seconded by R. LOPEZ, and voted unanimously by those present, to CLOSE the matter (INV10933), No Violation.

Case #4

/CASE-2024-0067
 PHA-2024-0106 Anazao Health Corporation, NO00004 Time: 09:35 AM

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

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

- Anazao failed to renew the facility's non-resident outsourcing registration in a timely manner after the registration expired on 12/31/2023 until BOP Staff reached out to inquire about the facility's status on 01/10/2024 . In addition, Anazao shipped drugs into MA on 23 occasions during the period when facility's registration was lapsed including testosterone (CIII) on 10 occasions.
- Anazao explained that licensing personnel relied too much on renewal reminders from state boards instead of proactively tracking renewal dates. Those shortcomings combined with the recent changes in the BOP's process for renewals and notifications resulted in Anazao's failure to renew the facility's registration in a timely manner.
- CA: (1) A spreadsheet would be used to proactively track renewals going forward, (2) Licensing personnel would meet weekly with general counsel to discuss upcoming renewals, questions, and any issues, and (3) a paralegal was assigned to independently developing and maintain a master spreadsheet of licenses and renewal deadlines to remind and otherwise assist in proactively addressing renewals.

ACTION: Motion by J. ROCCHIO, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2024-0106), 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 #5/CASE-2023-0782
 PHA-2024-0115 Stop & Shop #782, DS2299 Time: 09:44 AM

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

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

- BOP opened this complaint during the 06/06/2024 BM after review of INV8911 concerning an inadvertent discard of 126 eszopiclone 2mg tablets discovered on 11/02/2023. An internal investigation revealed that "two stock bottles containing a total of #126 tablets were inadvertently discarded during a dispensing that occurred on 10/3/2023." Of note, loss was attributed to clutter in the product dispensing workplace which did not comply with internal policies.

- Surveillance video was provided which staff at S&S 782 used to confirm the inadvertent discard of two bottles of drug into a recycle bin on 10/03/2023. Staff then monitored over the next two days to ensure the discard was not a ruse. Ultimately, the recycle bin was removed from the pharmacy and disposed of per usual course of business on 10/05/2023. Thus, staff determined that no diversion occurred.
- CA: (1) Maintaining a clean workspace throughout the day, such as keeping open stock bottles separate from empty ones to ensure proper disposal. Empty stock bottles are placed into a separate basket for disposal on a separate counterspace. (2) All discarded and recycled medication bottles will have the cap removed. This will be checked prior to throwing anything out to avoid inadvertently mixing in any of the bottles that should be returned to stock. (3) Additionally, night-time organizing of counters and workspace has been added as a daily task. This will help to reduce clutter. (4) Any stock bottles will be returned to the shelf in a timely manner and not collecting a large quantity of bottles at any given time. (5) Reporting identified discrepancies in a timely manner. (6) Adhering and following all Stop and Shop policies regarding controlled substances, as well as federal and state laws.

ACTION: Motion by R. MORELLI, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0115), No Discipline Warranted.

Case #6/CASE-2024-1713

PHA-2024-0107

Village Fertility, DS90059

Time: 09:47 AM

RECUSAL: NONE

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

- On May 3, 2024, Investigator Murray discovered during a site visit that Village was dispensing Fluarix prescriptions issued for office stock to various locations of local fertility clinic. In addition, Investigator Murray discovered that an unlicensed staff member was packaging prescriptions for shipment.
- Village asserted the unlicensed staff member was working as a pharmacy clerk and his duties included “packing pre-assembled, pre-labelled, and pre-checked totes of medication for mailing” which did not require licensure by BORP.
- POC/CA: First, Village ceased selling the Fluarix vials at issue and removed the drug from inventory then re-training pharmacy personnel and updating its prescription processing policy and procedure.
- Village’s “procedure for prescription intake and medication dispensing verification to ensure that the prescription is for the legitimate medical need of a specific, individual patient and not being supplied for office use as a bulk drug order.” Village affirmed that all pharmacists were trained on the updated policy.
- Village indicated that the unlicensed staff member obtained licensure as a PTT shortly after the inspection. Village also confirmed that “all pharmacy personnel licenses and facility permits [were] up to date and posted in the pharmacy in compliance with the relevant law and regulations.” In addition, a new process for onboarding to prevent recurrence of a similar situation.

ACTION: Motion by D. BARNES, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2024-0107), 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 recused and was not present for the vote or discussion in this matter.

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

- On June 4, 2024, CVS 1871 submitted a final report of an unknown loss of 512 tramadol 50mg tablets discovered on May 23, 2024 via the corporate controlled substance monitoring. CVS 1871 indicated that the cause of the loss was unable to be determined despite an exhaustive internal investigation.
- CA: "All Loss Prevention policy and procedures have been reviewed with the Pharmacy Team to prevent future losses. This includes diligent inventory management."

ACTION: Motion by D. BARNES, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2024-0122), 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 1 year with the Controlled Substance Loss Protocol for all tramadol containing products.

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

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

- BORP received a consumer complaint from a veterinarian which indicated that on or about 03/23/2024, that the Pharmacist demanded the doctor's DEA number for a prescription of gabapentin.
- Investigator Van Allen contacted the Pharmacy and spoke with Pharmacist Wallace for additional information. Pharmacist Wallace indicated that the prescription was phoned in and was not filled so the provider called the prescription into another pharmacy. Pharmacist Wallace indicated that he could not locate the veterinarian in the dispensing system using the provider's name or the license number to enter the new provider into the system.
- The MOR sent a job aid for adding a prescriber and in the event a Prescriber record cannot be located through a store prescriber search or advance/central prescriber search in RxConnect, Pharmacy Teams should add a new prescriber record and a NPI or DEA is not required to perform a prescriber search.
- The MOR reviewed the job aid with the staff pharmacists and the pharmacists have signed the document to acknowledge they understand the proper procedure to add a new vet into the dispensing system. Ensuring that all information is inputted correctly and appropriately is one of the most important parts of the job and is taken very seriously.

ACTION: Motion by D. BARNES, seconded by S. HAMILTON, and voted unanimously by those present, with the exception of a NAY vote by K. THORNELL, to refer the matter (PHA-2024-0103), 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: 10:15 AM**

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

Action: Motion by S. HAMILTON, seconded by R. LOPEZ, voted unanimously by roll call to enter executive session #1.

Roll call attendance: D. Barnes, yes; C. Belisle, yes; S. Hamilton, yes; F. Lombardo, yes; R. Lopez, yes; J. Rocchio, yes; S. Ahmed, yes; M. SCIARAFFA.

Topic XI: **65C Sessions MGL c. 112 section 65C** **Time: 10:48 AM**

DISCUSSION: None

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

At 10:48 a.m. S. Ahmed seconded by S. Hamilton and voted unanimously by all those present to enter M.G.L. chapter 65 c Session by roll call vote.

Topic XII: **ADJOURNMENT OF MEETING** **TIME: 12:15 PM**

ACTION: Motion by D. Barnes seconded by M. Sciaraffa and voted unanimously by those present, to adjourn from General Session by roll call vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 10/17/2024 General Session
2. Draft Minutes of the 9/5/2024 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. Research Drug Study report pursuant to Staff Action Policy 18-02
8. Pentec request regarding implantable infusion pumps
9. Policy 2024-02: Implantable Infusion Pumps
10. 247 CMR 13.00: Nuclear Pharmacy Licensure Requirements and Professional Practice Standards
11. Medminder: Petition for Waiver
12. MBS Pharma Care request for a change of business model
13. Optum Infusion Services: Petition for Waiver
14. Tarrytown Expocare/DBA Greater Boston Long Term Care: Transfer of Ownership
15. BILH Home Infusion: New Community Pharmacy
16. NSCH Pharmacy: New Community Pharmacy
17. New England Pharmacy and Wellness: New Community Pharmacy
18. PHA-2024-0125: Empower Pharmacy
19. PHA-2024-0108: Genoa Healthcare
20. PHA-2024-0109: Kimberly O'Conner
21. PHA-2024-0163: MBS Pharma Care
22. PHA-2024-0110: CVS 735