

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

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

September 5, 2024

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

Join link:

<https://eohhs.webex.com/eohhs/j.php?MTID=ma723b5e944c8f04818b3f520958fec31>

Webinar number:

2531 502 5603

Webinar password:

BOP123 (267124 from phones and video systems)

Join by phone:

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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 August 1, 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 17-03		

8:20	V	FLEX <ul style="list-style-type: none"> • NABP District 1 & 2 meeting, October 7 – 9, 2024 <ul style="list-style-type: none"> ○ Round table discussion suggestions ○ Proposed Resolutions ○ Election of a delegate • URAMP Presentation • Upcoming Board Schedule • Board Staff Changes • Schedule II Perpetual Inventory • NABP Resolutions • Pharmacy Advisory Committee Meeting: October 23, 2024 <ul style="list-style-type: none"> ○ Recommendation Document 24-02: Rapid Sterility Testing 		
8:45	VI	POLICIES <ul style="list-style-type: none"> • Policy 2024-03: Ratios, Intern Supervision, and Dedicated Training Personnel • Policy 2024-04: Defective Drug Preparations • Policy 2024-05: Schedules II and III Quantity Limits • Advisory: Environmental Monitoring • Rescind Advisory: Pharmacy Requirement to Maintain Defective Drug Preparation Log 		
9:00	VII	APPLICATIONS <ul style="list-style-type: none"> • Medminder; DS90408 - Petition for Waiver • Optum Infusion Services 550, LLC, DS90100, Petition for Waiver • Community Care Pharmacy; DS100084- Relocation • Brighton Marine Health Center Pharmacy- New Community Pharmacy • UMass Memorial Home Delivery Pharmacy- New Community Pharmacy 		

10:00	VIII	VIOLATION OF PROBATION <ul style="list-style-type: none">CVS 2878; DS3092, PHA-2023-0144					
10:15	IX	FILE REVIEW					
		1	CASE-2024-1782	PHA-2024-0112	New England Life Care, DS3513		
		2	CASE-2024-1611	PHA-2024-0095	Epicur Pharma, NO00051		
		3	CASE-2024-1557	INV10933	IntegriScript, DS89726		
		4	CASE-2024-0067	PHA-2024-0106	Anazao Health Corporation, NO00004		
		5	CASE-2023-0782	PHA-2024-0115	Stop & Shop #782, DS2299		
		6	CASE-2024-1713	PHA-2024-0107	Village Fertility, DS90059		
		7	CASE-2024-1911	PHA-2024-0122	CVS #1871, DS3286		
		8	CASE-2024-1558	PHA-2024-0103	CVS #915, DS3395		
11:15	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, 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

September 5, 2024

Board Members Present

Katie Thornell, RPh, MBA President
Sami Ahmed, PharmD., RPh, BCPS, BCSCP, President-Elect
Rita Morelli, PharmD, BCACP, RPh, Secretary
Caryn Belisle, RPh, MBA
Dr. Richard Lopez, MD
Sebastian Hamilton, Pharm D, MBA, RPh
John Rocchio, RPh, PharmD
Delilah Barnes, RPh
Julie Dorgan, RN
Frank Lombardo

Board Members Not Present

Mark Sciaraffa, CPhT
Saad Dino, RPh, FACP/FACA

Board Staff Present

David Sencabaugh, RPh, 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
Joanne Trifone, RPh, Director of Investigations
Gregory Melton, JD, PharmD, BCPS, Investigator
Julienne Tran, RPh PharmD, Investigator
Cheryl Lathum, RPh, PharmD, BCPS, Senior Investigator
Keith Johnstone, Compliance Officer

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:00 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; R. Lopez, yes; S. Ahmed, yes; R. Morelli, yes; J. Dorgan, yes; K. Thornell, yes.

Topic II.

Approval of Agenda

TIME 8:02 AM

Agenda: 9/5/24

DISCUSSION: Defer URAMP presentation and Optum Infusion Services application

ACTION:

Motion by S. Hamilton, seconded by R. Morelli 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: 8:03 AM

Minutes

1. Draft 8/1/24

Change: No changes

Action:

Motion by D. Barnes seconded J. Rocchio and voted to approve the regular session minutes of 8/1/2024 with no noted changes by roll call vote. Abstained: R. Morelli, K. Thornell, J. Dorgan

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 22 Change in MOR applications and 5 facility closures that have been approved via Staff Action since the last 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 39 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 there were four CE deficiency cases, all of which were closed with no discipline warranted, remediation complete; one loss of controlled substances which was issued a reprimand, and one waiver renewal request have been approved since the last Board meeting.

So noted.

Topic IV.

REPORTS

PSUD report by Staff Action 17-03

TIME: 8:04 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto indicated one inquiry since the last Board meeting. Currently, there are a total of 8 active participants enrolled in the program.

So noted.

Topic V.

FLEX

NABP District 1 & 2 meeting, October 7 – 9, 2024

Time: 8:04 AM

- Round table discussion suggestions
- Proposed Resolutions
- Election of a delegate
-

Presented by: D. SENCABAUGH, W. FRISCH

Discussion: A resolution has been proposed for NABP to establish a task force to study and develop effective strategies to minimize the incidence of medications lost in transit.

Action: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by roll call of those present, to approve and submit the resolution.

Discussion: R. MORELLI and S. AHMED were nominated as delegates to vote on the Board's behalf at the meeting.

Action: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by roll call of those present, for R. MORELLI to be the Board's delegate with S. AHMED as the alternate.

URAMP Presentation

Time: 8:10 AM

Deferred

Topic V.

FLEX

Upcoming Board Schedule

Time: 8:10 AM

Presented by: D. SENCABAUGH

Discussion: The October 2024 meeting has been changed to October 17, 2024 and the 2025 meeting dates were proposed.

Action: Motion by S. HAMILTON, seconded by D. BARNES, and voted by roll call of those present, for R. MORELLI to be the Board's delegate with S. AHMED as the alternate. F. LOMBARDO abstained from the vote.

Board Staff Changes

Time: 8:12 AM

Presented by: D. SENCABAUGH, M. BOTTO

Discussion: Executive Director David Sencabaugh is retiring from his position. The job listing will be posted this week. He will be staying on part-time to assist with the transition to his successor.

So noted.

Pharmacy Advisory Committee Meeting: October 23, 2024

Time: 8:17 AM

- Recommendation Document 24-02: Rapid Sterility Testing

Presented by: D. SENCABAUGH

Discussion: This meeting will be held to obtain Advisory Committee guidance on rapid sterility testing in order to develop guidelines for sterile compounding pharmacies.

Action: Motion by R. MORELLI, seconded by D. BARNES, and voted unanimously by roll call of those present, to approve the Recommendation Document.

Action: Motion by S. HAMILTON, seconded by R. MORELLI, and voted unanimously by roll call of those present, for S. AHMED to represent the Board at the meeting.

TOPIC VI

POLICIES

Policy 2024-03: Ratios, Intern Supervision, and Dedicated Training Personnel Time: 8:20 AM

Presented by: M. CHAN

Discussion: The Board has previously voted to combine regulatory sections 3, 4, and 8 into one section: 247 CMR 3.00, but the ratios were not incorporated. They will eventually be moved to 247 CMR 9.00 which addresses pharmacy practice. In the interim, ratios have been added to this policy as well as updates to supervisory ratios regarding vaccine supervision.

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

Policy 2024-04: Defective Drug Preparations

Time: 8:22 AM

Presented by: M. CHAN

Discussion: The change from an advisory to this policy was made to clearly indicate to licensees that the defective drug requirements are mandatory.

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

Policy 2024-05: Schedules II and III Quantity Limits

Time: 8:23 AM

Presented by: M. CHAN

Discussion: Changes have been made to reflect the recent update to state law. Schedules II and III prescriptions may be filled for a 90-day supply for:

1. drugs for the treatment of opioid use disorder, such as buprenorphine products;
2. any non-opioids in Schedules II and III, such as stimulants and testosterone; and
3. implantable infusion pumps.

All other Schedule II and III medications (e.g., opioids) may only be filled for a maximum 30-day supply and there is no longer a need to verify diagnoses for narcolepsy, Attention Deficit Disorder ("ADD"), or Attention Deficit/Hyperactivity Disorder ("ADHD").

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

Presented by: M. CHAN

Discussion: As with similar documents, a language change was made regarding identification of any growth in an ISO Class 5 area or any action level growth in other ISO Classified areas. After the completion of renovations or HVAC shutdown, a recommendation was added to reduce or limit BUDs until EM results within action levels have been received.

Action: Motion by D. BARNES, seconded by C. BELISLE, and voted unanimously by roll call of those present, to approve the edits to the advisory.

Rescission of Advisory: Pharmacy Requirement to Maintain Defective Drug Preparation Log
Time: 8:29 AM

Presented by: M. CHAN

Discussion: Now that Policy 2024-04 has been approved, the advisory is no longer needed.

Action: Motion by S. HAMILTON, seconded by R. MORELLI, and voted unanimously by roll call of those present, to rescind the advisory.

TOPIC VII

APPLICATIONS

1. Medminder; DS90408 - Petition for Waiver

TIME: 8:30 AM

Represented by: Thuan Nguyen & Erwin Enriquez

Recusal: None

Discussion: MedMinder is submitting a request to have PV2 to be more streamlined through a workflow which now include automation called VBM.

- The VBM automation uses a “Smart Vision” system to take a picture of what is filled in multi-dosage packaging to visually verify the prescription. What is not able to be verified by the system will be verified by a pharmacist.
- Accuracy data collected since April 2024 has shown that this system is 99.7% accurate for prescription verification.
- The request is to allow for the use of Certified Pharmacy Technicians (CPhTs) to help with the final verification (also called “blister checkout”) to scan the cards that the automated system produces and can flag the pharmacist if anything needs to be approved by the Pharmacist.
- MedMinder appeared before the board last month and has implemented the change to use nationally certified CPhTs in this application.
- Board staff suggested that licensee amend their waiver language for more detailed language as follows - “limited waiver of 247CMR8.04 (4)(e), which would allow for licensed certified pharmacy technicians to conduct final dispensing process validation when using the VPM

multi medication adherence packaging machine, after the pharmacist has reviewed the prescription and checked the stock cassettes. Pharmacist must randomly perform at least a 5% verification check of the adherence parts. All other workflow processes not using the specified automation will require 100% pharmacist verification.”

- Board counsel requested that The Board defer their vote on this matter until after additional matters regarding MedMinder are discussed and resolved later today.

Questions:

- D. Barnes: What made you select for the usage of CPhTs to complete this final verification instead of a Pharmacy Intern (PI) or recent Pharmacist graduate that is not yet licensed as a pharmacist?
 - MedMinder: we are open to the idea, but we wanted to establish this waiver based on our current staff.
- D. Barnes: What is your pharmacist is doing clinically that is different than a pharmacist in another setting dealing with similar issues? What makes your situation so unique?
 - The average age of our patients are 66 years old, they tend to have 3 or more chronic conditions, and they take approximately 13.5 medications on average. A lot of them live at home. Our goal is to keep them healthy in the home.
 - Every month we have the opportunity to do a PV1 and clinical check when we fill the multidose cards. We also work to keep our clients compliant with their medications, though we do complete med-reconciliations at times when needed. Approximately 3% of our patients are hospitalized monthly, and when they need that transition of care we complete those med-recs to ensure that the patients can be home.
 - If we can reduce the amount of time pharmacists are spending to complete medication verification for each pill cup, they will have more time to complete MtMs and to complete vaccination clinics to more holistically treat our patients.
- R. Morelli: Who is responsible for an error that occurs? The Pharmacist or the CPhT?
 - If it is a matter where the cassette is broken, the operations team would be responsible.
- J. Rocchio made a statement suggesting that the BORP makes a policy for matters similar to this, as this has already been a pilot project.
- S. Hamilton expanded on this, stating that many of these questions have been asked prior when the pilot project was originally running and the BORP was amenable to the project after discussion at that time. Particularly, S. Hamilton echoed that this would allow for Pharmacists to “operate at the top of their license.”

Action: A motion by S. Hamilton, seconded by S. Ahmed, and voted unanimously by roll call to defer the matter until later this afternoon.

2. Optum Infusion Services 550, LLC, DS90100

Petition for Waiver

TIME:

DEFERRED

TOPIC VII

APPLICATIONS

3. Community Care Pharmacy; DS100084

Relocation

TIME: 8:50 AM

Represented by: Ron Lanton & Junghwa Lee

Recusal: None

Discussion: After the closure of Carney Hospital, we moved to another location and did not have enough time to prepare everything. As such, we were recommended by Board staff to request waivers for the sign and other items, and to run this pharmacy as a closed-door pharmacy and then open to the public when available.

- The only waiver being requested at this time is for signage.
- Board Counsel reminded the representatives that once the sign for the store is complete, to reach out to BORP so that the waiver for a sign can be repealed and that the licensee can resume operation as an open-door pharmacy.
 - Board Counsel also re-iterated that the licensee will need to comply with all laws, rules, and/or regulations regarding pharmacy practice.
- Finally, Board Counsel stated that Board inspectors have already been to this location and the licensee has passed inspection. She also expressed that this happened quickly due to the Carney Hospital closure and that the waiver is for the sign as there was not enough time to change the signage.
- Requested waiver is for the following:
 - 247 CMR 6.02(5) states: "A pharmacy or pharmacy department shall have a reasonably-sized sign affixed to the main entrance of the business or otherwise installed in an easily observable area outside the premises, identifying the presence of a pharmacy or pharmacy department."

Action: A motion was made by S. Hamilton, seconded by D. Barnes, and voted unanimously by roll call to approve the relocation application with waiver.

4. Brighton Marine Health Center Pharmacy

New Community Pharmacy

TIME: 8:57 AM

Represented by: James Germano & Susan Brown

Recusal: None

Discussion: Currently, this hospital clinic pharmacy was operated a department under St. Elizabeth's license for US family health Plan. Since St. Elizabeth's is being sold to Boston Medical Center (BMC). And This pharmacy will not be a part of BMC.

- We are hoping to apply for a retail pharmacy license to "break away" from the current situation and operate the pharmacy for US family Health plan members, which works as an alternative to TRICARE and will be servicing veterans.
- Due to the pharmacy not being in a government owned building, the licensee must first apply for a license through the state BORP before obtaining a DEA license, even though they only intend to service TRICARE health plan patients.

- The licensee will no longer be providing medication to clinic sites in accordance with the law/regulation now that they are looking to no longer be affiliated with St. Elizabeths or BMC.

Waivers requested are as follows:

- 247 CMR 9.01(15)
- 247 CMR 9.01(16)
- 247 CMR 6.04(2)

Questions:

- Board staff asked for confirmation if the licensee still intends to compound. J. Germano explained that they have a low volume of compounding requests and that they only do simple compounding.

Action: A motion was made by S. Hamilton, seconded by R. Lopez, and voted unanimously by roll call to approve the application with waivers upon a successful inspection.

5. UMass Memorial Home Delivery Pharmacy New Community Pharmacy TIME: 9:06 AM

Represented by: David Mangan, Jackie Breeds

Recusal: None

Discussion: We are looking to open a Home Delivery Pharmacy. Initially, what we are looking to do is open a retail pharmacy that will allow us to also provide home delivery services. We have no waivers at this time, but there may be waivers to come at a forthcoming time.

- This pharmacy will operate as a typical retail pharmacy.

Questions:

- D. Barnes: In the blueprints, there is discussion of an infusion room. Will that not be a part of the pharmacy?
 - D Mangan: With this location we are looking to leverage future services. There is a lot that we are looking and/or exploring to do with this building in the future but at this time we are only looking at pursuing the retail pharmacy.
- Board counsel confirmed with the licensee that if they wanted to use an infusion space different licensure will be needed. Mangan went on to explain that their team is aware and will plan to apply for the appropriate licensure but that these plans are over 1 year away and that at this time, UMASS Memorial is only applying for the pharmacy licensure.

Action: A motion was made by S. Hamilton, seconded by R. Morelli, and voted unanimously by roll call to approve the application as written upon successful inspection.

TOPIC VIII

VIOLATION OF PROBATION

• **CVS 2878; DS3092, PHA-2023-0144**

Time: 9:39 AM

Presented by: Karen Fishman

Recusals: J. Rocchio

Discussion: • Licensee entered into a stayed probation agreement for a period of one year in May of 2024. This was due to a violation (PHA-2023-0144) unknown loss of #887 suboxone 8mg-2mg discovered April 2023, with additional losses of #240 Lorazepam 1mg tablets & #31 Morphine ER 25mg tablets.

o Note: The Morphine loss was found to be a dispensing error.

• This matter being brought to discussion today due to a new violation. Specifically, there was a new unknown loss of regarding the loss of #526 Lorazepam 0.25mg tablets discovered in June 2024.

• On June 26th, K. Fishman submitted a notice of violation to the licensee for failing to submit their first attestation to the probation department. While an attestation of retraining was received on July 8th, however no attestation of drug counts for June was received.

• On July 9th, a second notice of violation was issued regarding the loss of #526 Lorazepam 0.5mg tablets. The notice gave the registrant time to respond by July 19th, but no response was received.

• Additionally, on the attestation for September, the attestation was not signed within 48 hours of the count being completed. Rather it was signed within 72 hours.

Brief Statement provided by N. Brand of CVS

• N. Brand has recently become an overseer for Board of Pharmacy responses for CVS as senior counsel. Regarding the delay in responding to Ms. Fishman's notice of violation, that was an oversight on the part of legal and not the [Licensee].

• An AP investigation took place, interviews were conducted, and video footage was reviewed. While it was not 100% confirmed to the reason of the loss, this loss [from June 2024] appears to be an accidental discard of the medicine and there is no evidence to show this is was a diversion in this case.

Recommendation by K. Fishman

• Lift the stay and place the licensee on disciplinary probation for one year or to extend the stayed probation by one year.

Question:

• C. Belisle: Does the current consent agreement include terms to count suboxone only, or benzodiazepines in general?

o The terms include that licensee must conduct an exact count and reconciliation on all buprenorphine containing products and all benzodiazepines.

Action: A motion was made by D. Barnes, seconded by S. Hamilton, voted to unanimously by roll call to lift the stay and to place the licensee on disciplinary probation and to extend the probation by 1 year.

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 BORP 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 BORP'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.

- BORP 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.

Case #7/CASE-2024-1911

PHA-2024-0122

CVS #1871, DS3286

Time: 09:50 AM

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.

Case #8/CASE-2024-1558

PHA-2024-0103

CVS #915, DS3395

Time: 09:52 AM

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: 10:13 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 S. AHMED, 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.

Topic XI: **ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)** **Time: 10:22 AM**

DISCUSSION: None

ACTION: President K. Thornell request a motion to enter Adjudicatory.

At 10: 22 S. HAMILTON seconded by D. Barnes and voted unanimously by all those present to enter Adjudicatory Session by roll call vote.

Topic XII: **65C Sessions MGL c. 112 section 65C** **Time: 10:35 AM**

DISCUSSION: None

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

At 10:35 a.m. S. Hamilton seconded by D. Barnes and voted unanimously by all those present to enter M.G.L. chapter 65 c Session by roll call vote.

Topic XIII: **ADJOURNMENT OF MEETING** **TIME: 2:48 PM**

ACTION: Motion by S. Hamilton seconded by J. Dorgan 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 9/5/2024 General Session
2. Draft Minutes of the 8/1/2024 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. 2025 Board Meeting Calendar
8. Submission of District Resolutions to NABP
9. PAC Recommendation Document 24-02
10. Policy 2024-03: Rations, Intern Supervision and Dedicated Training Personnel
11. Policy 2024-04: Defective Drug Preparations
12. Policy 2024-05: Schedules II and III Quantity Limits
13. Advisory: Environmental Monitoring
14. MedMinder Pharmacy: Petition for waiver

15. Community Care Pharmacy- Relocation application
16. Brighton Marine Health Center Pharmacy – New Community Pharmacy application
17. UMass Memorial Home Delivery Pharmacy – New Community Pharmacy application
18. Violation of Probation: CVS 2878
19. Nimvax-Renovation Application
20. PHA-2024-0112 New England Life Care, DS3513
21. PHA-2024-0095 Epicur Pharma, NO00051
22. INV10933 IntegriScript, DS89726
23. PHA-2024-0106 Anazao Health Corporation, NO00004
24. PHA-2024-0115 Stop & Shop #782, DS2299
25. PHA-2024-0107 Village Fertility, DS90059
26. PHA-2024-0122 CVS #1871, DS3286
27. PHA-2024-0103 CVS #915, DS3395