

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

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

May 1, 2025

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

Join link:

<https://eohhs.webex.com/eohhs/j.php?MTID=mfa49dd755ce740ecc2e8748d56cf8404>

Webinar number: 2536 868 7637

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Agenda

8:00		CALL TO ORDER		S. Ahmed
8:05	II	APPROVAL OF AGENDA		
8:10	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">Draft of March 6, 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 14-02		
8:20	V	FLEX <ul style="list-style-type: none">Pharmacy LicensingPharmacy Advisory Committee SummaryRescind - Compounded Preparations from 503B Outsourcing Facilities memo		

8:30	VI	POLICIES <ul style="list-style-type: none"> • Policy 2025-01: Rapid Microbial Methods (Rapid Sterility Testing) • Policy 2022-02: Extended Absence or Departure of a Manager of Record or Designated Pharmacist-in-Charge 		M. Chan
8:40	VII	APPLICATION <ul style="list-style-type: none"> • Trang Pharmacy, DS3581 – New Retail Pharmacy • Vital Care of Cambridge – New Retail Pharmacy • BET Pharm, LLC – New Non-Resident Retail Pharmacy • Empower Pharmacy- Non-Resident Sterile Compounding • Get Relief-Non-Resident Complex Non-Sterile Compounding • Jungle Jim’s Pharmacy - New Non-Resident Retail Pharmacy, New Complex Non-Sterile Compounding, New Sterile Compounding • Louis & Clark #572 – DS2543 – Petition for Waivers • Rush Pharmacy; Non-Resident Sterile Compounding License and Non-Resident Non-Sterile Complex Compounding License 		
10:00	VIII	BOARD STAFF REQUEST FOR EARLY TERMINATION <ul style="list-style-type: none"> • Dominic Regalbuto; PH238864; PHA-2022-0109 		K. Fishman
10:10	IX	REVIEW OF COMPLIANCE AND NOTICE OF PHARMACY CLOSURE <ul style="list-style-type: none"> • Amherst Pharmacy, DS89775; PHA-2022-0018 		K. Fishman
10:20	X	TERMINATION OF STAYED PROBATION DUE TO PHARMACY CLOSURE <ul style="list-style-type: none"> • Walgreens 2781, DS 3468, PHA-2022-0190 		K. Fishman

10:30	XI	FILE REVIEW					
		1	CASE-2024-2817	PHA-2024-0185	Abby Pharmacy, DS90723		
		2	CASE-2024-3796	PHA-2025-0005	Carie Boyd Pharmaceuticals, NO00011		
		3	CASE-2025-0500	PHA-2025-0029	Optum Infusion Services 500, LLC, DS90100		
		4	CASE-2024-3188	PHA-2024-0213	Walgreens #6939, DS3339		
		5	CASE-2024-3187	PHA-2024-0215	Walgreens #5586, DS3042		
		6	CASE-2024-3396	PHA-2024-0220	Walgreens #17728, DS90161		
		7	CASE-2024-3321	PHA-2024-0222	Walgreens #9614, DS3489		
		8	CASE-2024-3640	PHA-2024-0242	Brighton Pharmacy, DS90317		
		9	CASE-2024-3189	PHA-2024-0217	Woodmark Pharmacy of MA, DS89875		
		10	CASE-2024-3388	PHA-2024-0219	CVS #496, DS3580		
		11	CASE-2024-3391	PHA-2024-0224	CVS #1866, DS2956		
		12	CASE-2024-3391	PHA-2024-0225	Kimberly Igo, PH235277		
		13	CASE-2024-3048	PHA-2024-0203	CVS #946, DS3442		
		14	CASE-2024-3048	PHA-2024-0204	Collins Boaitey, PH238704		
		15	CASE-2024-3390	PHA-2024-0227	CVS #1049, DS1716		
		16	CASE-2025-0388	PHA-2025-0027	CVS #7140, DS89720		
11:15	XII	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.					
11:45	XIII	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)					
12:00		LUNCH BREAK					
12:30	XIV	M.G.L. c. 112, § 65C SESSION					
2:00	XV	ADJOURNMENT					

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

May 1, 2025

Board Members Present

Sami Ahmed, PharmD., RPh, BCPS, BCSCP, President
Saad Dinno, RPh, FACP/FACA, President-Elect
Mark Sciaraffa, CPhT, Secretary
Katie Thornell, RPh, MBA
Caryn Belisle, RPh, MBA
John Rocchio, RPh, PharmD
Dr. Richard Lopez, MD
Rita Morelli, PharmD, BCACP, RPh
Delilah Barnes, RPh
Julie Dorgan, RN
Frank Lombardo
Timothy Fensky, RPh

Board Members Not Present

Board Staff Present

Michael Godek, Executive Director
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
Julienne Tran, PharmD, Investigator
Gregory Melton, JD, PharmD, BCPS, Investigator
Keith Johnstone, Compliance Officer
David Sencabaugh
Susan Kim, Pharmacy Intern
Gayatri Ramasubramanian, Pharmacy Intern

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:03 AM

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

Roll call attendance: S. Dinno, yes; M. Sciaraffa, yes; D. Barnes, yes; J. Dorgan, yes; R. Lopez, yes; R. Morelli, yes; J. Rocchio, yes; K. Thornell, yes; S. Ahmed, yes. T. Fensky, yes.

Topic II.

Approval of Agenda

TIME 8:05 AM

Agenda: 04/03/25

DISCUSSION: Deferred: Jungle Jim's Pharmacy
Rush Pharmacy - previously approved by staff action.

ACTION: Motion by R. MORELLI, seconded by M. SCIARAFFA 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: 8:06 AM

Minutes

1. Draft 04/03/2025

Change: None

Action: Motion by M. SCIARAFFA seconded J. DORGAN and voted to approve the regular session minutes of 4/3/25 with the noted changes by roll call vote. C. Belisle abstained.

Topic IV.

REPORTS

Applications approved pursuant to Licensure Policy 13-01

TIME: 8:06 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris reported a total of 41 Resident Change Pharmacist Manager of Record applications, 3 Non-Resident Change Designated Pharmacist in Charge applications, and 7 facility closures that have been approved via Staff Action since the last Board meeting.

So noted.

Topic IV.

REPORTS

Monthly Report from Probation

TIME: 8:07 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris indicated 1 issuance of final notice by Board counsel and 1 successful completion of probation monitoring since the last report. Currently, there are a total of 44 active cases.

So noted.

Topic IV.**REPORTS****Monthly Report from BDCR pursuant to Policy 14-02****TIME: 8:07 AM**PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris noted that a total of 17 Continuing Education discrepancies were reported, all of which have been closed with no discipline warranted. Additionally, 2 regulatory code violations were each issued a reprimand, 1 report of controlled substance loss was issued a year of CS protocol for benzos, and 1 failure to fill a prescription was reported, discipline not warranted. The Board has approved a set of waivers for a residential pharmacy since the last Board meeting.

So noted.

Topic V.**FLEX****Pharmacy Licensing****TIME: 8:08 AM**PRESENTED BY: R. HARRISRECUSAL: NONE

DISCUSSION: R. Harris provided an update on the new license types that have been issued since the beginning of the year. To date, 580 non-resident retail pharmacies, 69 non-resident complex non-sterile compounding pharmacies, 56 non-resident sterile compounding pharmacies, 4 non-resident outsourcing facilities, 28 resident complex non-sterile pharmacies, 18 resident sterile compounding pharmacies, and 24 institutional sterile compounding pharmacies have been issued licenses.

W. Frisch reminded attendees that as of 5/1, all non-resident pharmacies, except for those granted extensions, must now have proper licensure to continue dispensing into MA.

So noted.

T. Fensky enters the meeting at 8:10 AM

Topic V.**FLEX****Pharmacy Advisory Committee Summary****TIME: 8:11 AM**PRESENTED BY: T. FENSKIRECUSAL: NONE

DISCUSSION: T. FENSKI provided a summary for the 4/16 Pharmacy Advisory Committee meeting. Discussion was held regarding the drafted policy provided by Board staff and constructive feedback was given by committee members. Additionally, microbiologists John Walczyk and Francis McAteer provided insights into what pharmacies should focus on when utilizing rapid microbial methods of sterility testing, which is reflected in the updated document.

So noted.

Topic V.

FLEX

Discussion Re: Rescind – Compounded Preparations from 503B Outsourcing Facilities memo

TIME: 8:13 AM

PRESENTED BY: W. FRISCH

RECUSAL: NONE

DISCUSSION: W. Frisch announced that a Board-approved memo prohibiting 503A retailers from purchasing and reselling preparations from 503B outsourcers has since received feedback from compounding and outsourcing organizations that have provided different interpretations regarding FDA guidance on the topic. W. Frisch then requested the Board to rescind the previously approved memo.

ACTION: A motion was made by J. Rocchio, seconded by R. Morelli, voted unanimously by those present to rescind the compounded preparations from 503B Outsourcing Facilities.

TOPIC VI

POLICIES

Policy 2025-01: Rapid Microbial Methods (Rapid Sterility Testing)

TIME: 8:19 AM

Presented by: M. CHAN

Discussion: In order for certain sterile compounded sterile preparations to be released for dispensing, USP <797> requires sterility testing to be performed according to USP <71> or equivalent alternative method. The purpose of this new policy is to outline guardrails for the use of those alternative methods.

With input from the Pharmacy Advisory Committee, the policy outlines general considerations for pharmacies contemplating the use of an alternative method as well as the pharmacy's responsibilities and documentation requirements.

Action: Motion by T. FENSKY, seconded by D. BARNES, and voted unanimously by roll call of those present, to approve the policy.

Policy 2022-02: Extended Absence or Departure of a Manager of Record or Designated Pharmacist-in-Charge

TIME: 8:20 AM

Presented by: M. CHAN

Discussion: Additions and edits to this policy address non-resident Designated PIC absences and departures as well as removes the COVID allowance for an MOR to be Interim Manager of a second pharmacy.

Action: Motion by D. BARNES, seconded by S. DINNO, and voted unanimously by roll call of those present, to approve the updates to the policy.

Topic VII.

APPLICATION

TIME: 8:24 AM

1. Trang Pharmacy, DS3581

New Retail Pharmacy

REPRESENTED BY: Mimi Le

RECUSAL: None

- DISCUSSION: 247 CMR 9.01(15) – A licensee may not refuse to compound simple or moderate non-sterile compounded preparations customary to the community needs except upon extenuating circumstances or by a waiver of Board regulation
- 247 CMR 9.19 (1)(e) – A balance capable of accurately weighing quantities as small as 10 milligrams, which shall be tested and sealed by the state or local sealer of weights and measures at least once each calendar year. All new balances shall have "legal for trade designation"
- 247 CMR 9.19 (1)(f) – the equipment, supplies, and medications necessary to conduct the practice of pharmacy in accordance with the usual needs of the community and scope of practice of the pharmacy

Questions:

- What happens if you get a patient for compounding?
 - We will search for a pharmacy in the area that can do the compounding for the patient.
 - The compounding that we are doing is typically limited to mixing antibiotics with water, and they are usually pediatric patients. We don't see a lot of these patients.
- Have you, Mimi Le, ever been an MOR?
 - I was the Director of Pharmacy since 2007 until approximately 2023. I have been the MOR for this pharmacy since November 2024

ACTION: S. Dinno made a motion to approve the New Retail Pharmacy application with waivers upon completion of successful inspection, Seconded by M. Sciaraffa and voted unanimously by roll call to approve the motion.

REPRESENTED BY: Brook Rezendes, Dave Adams, Summer Bosarge

RECUSAL: T. Fensky

DISCUSSION: Waivers:

- 247 CMR 9.18(6) – A pharmacy shall have a designated patient consultation area, with signage stating "Patient Consultation Area", designed to provide adequate privacy for confidential visual and auditory patient counseling. The private consultation area shall be accessible by a patient from the outside of the prescription dispensing area without having to traverse a stockroom or the prescription dispensing area.
- 247 CMR 9.01(15) – A licensee may not refuse to compound simple or moderate non-sterile compounded preparations customary to the community needs except upon extenuating circumstances or by a waiver of Board regulation
- 247 CMR 9.19 (1)(e) – A balance capable of accurately weighing quantities as small as 10 milligrams, which shall be tested and sealed by the state or local sealer of weights and measures at least once each calendar year. All new balances shall have "legal for trade designation"
- 247 CMR 9.19 (1)(f) – the equipment, supplies, and medications necessary to conduct the practice of pharmacy in accordance with the usual needs of the community and scope of practice of the pharmacy

Questions:

- Will the infusion/sterile compounding suite be within the currently provided footprint in the board package or will it be in a new space?
 - The area we are applying for licensure is in a different wing of the building.
- What is your business model?
 - This is a specialty pharmacy that won't be doing traditional oral medicine. This will be an infusion pharmacy.
- How will patients get the medication?
 - Medication will be delivered to the patient's home. We have policies and procedures in place to insure that the medications are shipped and stored properly
 - There will also be nurses/caregivers at the home who will be assisting the
- Have you, Summer Bosarge, been an MOR in the state of Massachusetts?
 - Yes, I have been the MOR at many locations including chain pharmacies and worked in sterile compounding as well.

ACTION: C. Belisle made a motion to approve the application with the submitted waivers upon successful inspection; Seconded by M. Sciaraffa and voted unanimously by roll call to approve the motion. T. Fensky recused.

3. BET Pharm, LLC**New Non-Resident Retail Pharmacy****TIME: 8:44 AM****REPRESENTED BY: : Micah Cheak****RECUSAL:** None**DISCUSSION:** See Board Packet

- Can you speak to previous discipline?
 - The policy of the previous pharmacist in charge was to allow for technicians to open the pharmacy and to do administrative work. Since I, Micah, have taken over this practice has been discontinued
 - The action regarding misbranding was due to the use of an autopopulation issue where our BUDs were autopopulated but it didn't always consider that some of the ingredients used would expire prior to the BUD. This practice of autopopulating BUDs has been discontinued.
 - The 3rd action, was regarding a matter with California regarding misbranding. We would label things as LA, Long Acting, but felt it was misbranding because we did not have FDA approval that the items were long acting, however we disagreed with this distinction because the FDA does not approve compounded medications.
- Does your pharmacy dispense commercially manufactured medications?
 - We typically only have manufactured items that we do. We typically service equine patients, and we have only dispensed 2 antibiotic medications but those are the only ones we have shipped since I have been at this pharmacy
- Do you only do veterinary compounding?
 - Yes, only veterinary

ACTION: C. Belisle made a motion to approve the New Non-resident Retail Pharmacy Application; Seconded by M. Sciaraffa and voted unanimously by roll call to approve the motion

4. Empower Pharmacy**Non-Resident Sterile Compounding****TIME: 9:01 AM****REPRESENTED BY: Shane Ernst, Jordan Cuccia, Justin Hagland****RECUSAL:** None**DISCUSSION:** See Board packet

Questions:

- Can you give me background on how you plan to do comply with USP guidelines of testing 250, considering you can do up to 20,000 units in a lot?
 - We plan to do break down the larger lots into sub-lots for testing purposes.
- You all were recently issued an FDA 483, can you tell me how you plan to rectify that 483 and the observations noted?
 - The FDA's interpretation of insanitary guidance is stricter than USP 797 guidelines. We are now working to comply with the FDA's guidance

- The FDA also found our disinfectant procedure regarding stopper bowls to be insufficient as the FDA views autoclaving to be the only acceptable procedure. We are making changes to comply with this as well. to be not compliant with their guidance.
- Are you doing category 2 or 3 sterile compounding?
 - Category 2
- Are you complying with USP 797?
 - Yes
- How often are you doing Environmental monitoring
 - ISO5 is sampled daily where as others such as ISO7 and ISO8 is sampled every 2 weeks.
- How often do you perform competencies on your compounding stuff
 - Every three months
- What is your current recall infrastructure?
 - Our Pharmacy management system is able to identify the lot that a patient's medication was from and we will be able to notify the patients and the Mass BORP
- Have you ever had to do a recall?
 - Yes we've had to recall at the batch level before.
- Do you plan on shipping in GLP1s while they have been removed from the FDA shortage list?
 - No, we will not be shipping commercial copies of GLP-1s

ACTION: C. Belisle made a motion to approve the application for Non-resident sterile compounding application; Seconded by M. Sciaraffa and voted unanimously by roll call to approve the motion.

5. Get Relief Non-Resident Complex Non-Sterile Compounding TIME: 9:24 AM

REPRESENTED BY: Dennis Rudolph, Saed Sadry, Lindsay Wall, Wendy Scoffield

RECUSAL: None

DISCUSSION: See Board Packet

Questions:

- What do you compound at your pharmacy
 - We compound a product called Solamyn that is a combination of cetirizine and famotadine that is usually used for chronic diarrhea. We also compound GLP-1 in a suspension formulation. We offer about 7 products in total
- I am concerned about the product "Solamyn" as it appears to be a commercially available copy.
 - While these products are commercially available separately, we feel that at the concentration level and formulation, it is not available to the public.
 - This is based on a study from physicians (Gastroenterologists) in Mississippi where they found that the compounded formulation has been effective and helping their patients who have not had success in treating their diarrhea in the past.
- Is that study published data?

- It is not published at this point.
- Is it an investigational product?
 - It is not being used under research study.
- What data is being used by these physicians to use this compound?
 - They are using the data in from their Gastroenterologist practice in Jackson Mississippi. There are about 20 doctors in the practice, and Dr. Holgan(sp?) is doing the primary data collection in the practice.
 - We are not currently providing the medicine to them however, as we are still getting our license for Mississippi
- Would this medication be dispensed through the doctor's office?
 - No we would need a prescription
- How does the medication get to the patients
 - It is shipped directly to the home.
- Have you developed a plan of Correction in response to the August inspectional deficiencies?
 - Yes we have responded to all of them and have since had a state board inspection and had no issues.
 - I can provide you with the responses
- Is there a telehealth aspect to this?
 - Yes there is.
- Are you currently shipping to Massachusetts?
 - No. When this was an open state we had a couple patients that we shipped to, but we would not be able to continue shipping without approval.
- How do you confirm a Dr/Patient relationship?
 - All of that information is provided in the prescription and then we proceed with the compounding of the medication.

ACTION: K. Thornell made a motion to defer the matter; Seconded by M. Sciaraffa and voted unanimously by roll call to approve the motion.

6.	Jungle Jim's Pharmacy	New Non-Resident Retail Pharmacy	TIME: 8:21 AM
		New Complex Non-Sterile Compounding	
		New Sterile Compounding	

REPRESENTED BY:

RECUSAL:

DISCUSSION: **DEFERRED**

ACTION:

TIME: 8:21 AM

REPRESENTED BY:

RECUSAL:

DISCUSSION:

DEFERRED

ACTION:

8. Rush Pharmacy

Non-Resident Sterile Compounding License

TIME: 8:21 AM

Non-Resident Non-Sterile Complex Compounding License

REPRESENTED BY:

RECUSAL:

DISCUSSION:

DEFERRED

ACTION:

Topic VIII. BOARD STAFF REQUEST FOR EARLY TERMINATION

TIME: 10:20 AM

- **Dominic Regalbuto; PH238864; PHA-2022-0109**

Presented by: K. Fishman

Recusals: None

Discussion:

The licensee entered a 23-month suspension agreement on July 17, 2024, with the earliest release date being July 17, 2026.

- The agreement stemmed from out-of-state discipline in New York (January 28, 2022) for supervising unlicensed drug compounding and practicing pharmacy with gross negligence.
- The licensee paid a \$2,500 fine and received a two-year suspension (23 months stayed) and probation in New York.

Board Considerations:

- The Massachusetts agreement required compliance with standard terms and remedial continuing education. The licensee met these requirements except for timely license renewal, which was impossible due to the suspension.
- The licensee does not live or work in Massachusetts and has no intention of returning.
- Board staff believe monitoring probation serves no public good, as probation is meant for those working toward unrestricted status.

Recommended Action:

- Terminate probation and mark the license as expired.
- Caryn asked for clarification: If the board approves early termination, does this prohibit the individual from applying for a license again and going through the process as described?
- Karen clarified that early termination does not prevent future licensing applications, and the licensee could apply before July 2026 if he chooses.
- Compliance and Probation – Jacque: The licensee has been substantially compliant with terms, except for timely renewal of his license.
- License Reinstatement – Tim and Jacque: If the licensee wants to get his license back, he must go through the reinstatement process and retake the MPJE. He cannot simply pay a fee online to reinstate the license.

Action: Motion by D. BARNES, seconded by J. DORGAN, voted unanimously by roll call to terminate the licensee’s probationary status, convert the license to expired, and close the case, in accordance with the board’s recommendation regarding Docket # PHA-2022-0109, considering the licensee’s substantial compliance, inability to renew due to suspension, and lack of intention to return to practice in Massachusetts.

TOPIC IX: REVIEW OF COMPLIANCE AND NOTICE OF PHARMACY CLOSURE TIME: 10:29 AM

- **Amherst Pharmacy, DS89775; PHA-2022-0018**

Presented by: K. Fishman

Recusals: None

Discussion: Case PHA-2022-0018 – Probation & Closure

- Probation Agreement: One-year probation started December 14, 2023, due to USP<795> violations, controlled substance and record-keeping deficiencies. The earliest release date was December 14, 2024.
- Compliance Review: The licensee met terms except full compliance with laws and regulations.
 - April 29, 2024: Pharmacy failed to open during scheduled hours due to flood damage.
 - October 31, 2024: John Nikitas (manager & owner) planned reopening for November 18, 2024, but failed to do so and did not notify board staff.
 - January 8, 2025: Board inspector found the pharmacy still closed.

Inspection & Violation Notice:

- January 22, 2025: A violation notice was issued for failing to operate, as flood-related signage remained posted. Attempts to reach Mr. Nikitas failed.

Legal & Closure Process:

- February 2025: Licensee retained attorney Bill Kennedy.
- March 4, 2025: Confirmed pharmacy was closed during January inspection.
- March 11, 2025: Attorney explained closure due to financial losses.
- March 17, 2025: Nikitas submitted required closure documentation.
- April 10, 2025: License status changed to out of business.

Action: Motion by S. DINNO, seconded by D. BARNES, voted unanimously by roll call to close the case for Amherst Pharmacy (DS89775; PHA-2022-0018) and consider whether violations during probation warrant a formal complaint against John Nikitas, in accordance with the board's recommendation.

• Walgreens 2781, DS 3468, PHA-2022-0190

Recusals: None

- The store has closed, and the license status is out of business.
- Staff action authority is needed to close the state probation agreement without a board vote

Action: Motion by K. THORNELL, seconded by T. FENSKY, voted unanimously by roll call to terminate the stayed probation agreement for Walgreens 2781 (DS 3468; PHA-2022-0190) due to pharmacy closure and update the license status to out of business, in accordance with staff action authority.

Time: 10:49 AM

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

- During a retail compliance inspection conducted on 09/12/2024, it was observed that licensee changed their hours of operation without properly notifying the BORP.
- MOR Shenouda claimed he submitted the change in hours application on or about May 2024. He later provided Investigator Brosnan documentation that he submitted the Pharmacy Change in Hours of Operation to the pharmacy.admin@mass.gov email on 04/25/2024.
- As there was no record of it in the BORP's licensing system he resubmitted the application (DSHO1000024) on 09/12/2024 to change his pharmacy hours to be open on Tuesday, Thursday and Saturday, only 24 hours per week, due to financial circumstances. During the days off from the Pharmacy, he would have to work full-time elsewhere to pay his operating expenses at his Pharmacy.
- On 3/25/25 Board staff approved the application (DSHO1000024) submitted on 09/12/2024. "

ACTION: Motion by C. BELISLE, seconded by J. ROCCHIO, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0185), No Violation.

Case #2/ CASE-2024-3796

PHA-2025-0005

Carie Boyd Pharmaceuticals, NO00011

Time: 10:51 AM

RECUSAL: NONE

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

- On 12/27/2024, Carie Boyd notified BORP about receipt of an FDA Warning Letter issued on 12/17/2024. FDA described in the Warning Letter that the facility underwent an FDA inspection between May 26, 2024 and June 21, 2024 which resulted in the issuance of an FDA Form 483. Carie Boyd then submitted a corrective action in response to the FDA Form 483 which FDA deemed deficient and issued a Warning Letter. FDA indicated in the Warning Letter that adulterated compounded drug products, unapproved compounded new drug products, and misbranded drug products were observed during the aforementioned inspection.
- Carie Boyd responded by submitting a copy of the facility's response to the Warning Letter. The response highlighted correct action taken by Carie Boyd to remediate deficiencies described in the Warning Letter and provide additional data to support the evaluation of the corrective action taken by the facility. Of note, FDA had not closed out the matter as of 03/17/2025.

ACTION: Motion by T. FENSKY, seconded by R. MORELLI, and voted unanimously by those present, to CONSOLIDATE the matter (PHA-2025-0005) with PHA-2024-0145. A second motion was made by T. FENSKY, seconded by S. DINNO, and voted unanimously by those present, to refer the matters 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-2025-0500

PHA-2025-0029

Optum Infusion Services 500, LLC, DS90100

Time: 10:51 AM

RECUSAL: NONE

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

- Optum failed to submit annual sterile compounding data. However, Optum ceased compounding in October 2023 then decommissioned its cleanroom with approval from BORP due to a business decision. Optum reported sterile compounding data every 6 months until decommissioning in October 2024.

ACTION: Motion by R. MORELLI, seconded by K. THORNELL, and voted unanimously by those present, to DISMISS the matter (PHA-2025-0029), No Violation.

Case #4/CASE-2024-3188

PHA-2024-0213

Walgreens #6939, DS3339

Time: 10:56 AM

RECUSAL: NONE

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

- On 10/17/2024, WAG 6939 submitted a final report an unknown loss of 100 oxycodone 10mg tablets discovered during reconciliation of the perpetual inventory on 09/2282024. Of note, WAG 6939 did not submit all of the supplemental information required for unknown losses.
- MOR Saadallah and WAG Asset Protection conducted an extensive search of the pharmacy including the ready bins and the hazardous waste bins. In addition, the perpetual log and activity reports were compared for “missed scripts, sales, receipts, or claims that were not recorded in the perpetual.” Also, patients who recently were dispensed oxycodone 10mg tablets were contacted to confirm quantities dispensed were accurate. Lastly, surveillance video was reviewed and revealed “nothing noteworthy to report that could answer where the missing drugs went.”
- CA: MOR Saadallah wrote, “Since the loss occurred, we have conducted daily inventory counts for oxycodone 10mg for the last 45 days and have continuous monitoring of counts multiple times per week. A back count is conducted and verified in the system each time this product or similar narcotics are dispensed. Empty bottles are now placed in the verification tote for the pharmacist to review before disposal.”
- In addition, Asset Protection noted that “the pharmacy will be counting Oxycodone 10mg every day for the next 30 until November 3, 2024 and will report any discrepancies immediately. On November 1, 2024 there has been no other discrepancies noted.”

ACTION: Motion by R. LOPEZ, seconded by J. DORGAN, and voted unanimously by those present, to refer the matter (PHA-2024-0213), 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-2024-3187

PHA-2024-0215

Walgreens #5586, DS3042

Time: 10:58 AM

RECUSAL: NONE

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

- On 10/18/2024, WAG 5586 submitted a final report of unknown losses of 56 Adderall XR 20mg capsules and 56 amphetamine mixed-salts 10mg tablets discovered on 10/04/2024. MOR Harenberg attributed the losses to “an operational error at the point of sale.”
- MOR Harenberg explained that the patient was sold a prescription for a non-federally controlled substance on 09/30/2024 but left the pharmacy with three prescriptions in total including the Adderall XR and amphetamine mixed-salts prescriptions due to an error scanning by the cashier. However,

“[he] attempted to review the video but there is not a good angle to confirm if the medication was dispensed.” In addition, patient denied receiving the Adderall XR and amphetamine prescriptions.

- MOR Harenberg described that he and the front store manager “had a discussion with the technician about the importance of verifying information fully and reviewed correct policy and procedure for working the register in the pharmacy” as corrective action.

ACTION: Motion by T. FENSKY, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0215), 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 #6/ CASE-2024-3396

PHA-2024-0220

Walgreens #17728, DS90161

Time: 11:00 AM

RECUSAL: NONE

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

- On 11/05/2024, WAG 17728 submitted a final report of loss of 35 oxycodone 10mg tablets due to inadvertent discard on 10/13/2024. According to the reports, a patient arrived on 10/15/2024 to pick-up a prescription for 35 oxycodone 10mg tablets. However, staff were unable to locate the prescription. During the subsequent investigation of the loss, surveillance video was reviewed which revealed that Pharmacist Zhang inadvertently discarded a prescription for 35 oxycodone 10mg tablets in a trash receptacle on 10/13/2024. Of note, patient’s prescription was filled without delay in therapy.
- CA: MOR Covino described that she “provided coaching to my team members and moved trash away from verification area” as corrective action.

ACTION: Motion by D. BARNES, seconded by M. SCIARAFFA, and voted unanimously by those present, to REFER the matter (PHA-2024-0220), 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-2024-3321

PHA-2024-0222

Walgreens #9614, DS3489

Time: 11:02 AM

RECUSAL: NONE

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

- On 10/09/2024, WAG 9614 submitted an initial report of unknown loss of 29 amphetamine mixed-salts 20mg tablets discovered on 10/07/2024 during a back-count while filling a prescription on October 7, 2024. MOR Ogbodo initiated an investigation including review of surveillance video and

confirmation of quantity dispensed to patients. Ultimately, MOR Ogbodo indicated that he was unable to determine a reason for the loss.

- WAG 9614 then failed to submit a final report of loss.
- CA: (1) Ensuring a timely return of products to the safe after each fill, (2) Ensure triple count of all C2 products during prescription filling and a back count of C2 products for which the manufacture package quantity is 100 or less, (3) Pharmacist must review delete list daily to identify and retrieve any C2 prescription on the list.

ACTION: Motion by M. SCIARAFFA, seconded by R. LOPEZ, and voted unanimously by those present, to REFER the matter (PHA-2024-0222), 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/CASE-2024-3640

PHA-2024-0242

Brighton Pharmacy, DS90317

Time: 11:04 AM

RECUSAL: NONE

DISCUSSION: K. JOHNSTONE presented and summarized the investigative report that pertained to this matter.

- During a retail compliance inspection conducted on 12/04/2024 at Brighton Pharmacy, Investigator Van Allen observed that on 12/24/2023, a DEA 106 was filed about a break-in that occurred at the Pharmacy on 12/23/2023. Multiple Schedule II stimulant and opioid medications were stolen. No RLCS was submitted to the BORP.
- On 12/05/2024, a plan-of-correction was received. MOR Kuzman stated that the RLCS was submitted to the BORP. BORP records indicate it was received on 12/05/2024.
- On 01/02/2025, MOR Kuzman responded that all staff attested to reviewing policies and procedures about the proper storage and handling of controlled substances and Board Policy 2022-01.
- MOR Kuzmin also stated that Schedule II substances are now stored in a separate, securely locked cabinet, expired Schedule II substances are stored in the safe, and the keys for the safe are stored in a separate, secure location far away from both storage areas.

ACTION: Motion by C. BELISLE, seconded by R. MORELLI, and voted unanimously by those present, to REFER the matter (PHA-2024-0242), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #9/CASE-2024-3189

PHA-2024-0217

Woodmark Pharmacy of MA, DS89875

Time: 11:07 AM

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

DISCUSSION: K. JOHNSTONE presented and summarized the investigative report that pertained to this matter.

- During a retail compliance inspection on 10/24/2024, Investigator Murray observed Jack Andrew Liebersen performing technician duties without a pharmacy technician or technician-in-training license.
- He obtained a Massachusetts PTT license on 10/29/2024.
- MOR Diebolt stated that at the time of the inspection, Jack Liebersen had applied for a PTT license, but it had not yet been approved by the Board. He was sent home and did not return until after the PTT license was issued.
- Corrective action includes tracking all staff licenses weekly, sending email reminders to all employees of upcoming license expirations (within 60 days), electronic time-keeping of technician trainee hours, and only hiring candidates that are appropriately licensed.

ACTION: Motion by T. FENSKY, seconded by D. BARNES, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0217), No Discipline warranted, remediation complete.

Case #10/ CASE-2024-3388

PHA-2024-0219

CVS #496, DS3580

Time: 11:10 AM

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

DISCUSSION: K. JOHNSTONE presented and summarized the investigative report that pertained to this matter.

- On 12/09/2024, CVS Pharmacy #496 submitted an amended final RLCS concluding that the loss of #29 lisdexafetamine 40 mg capsules was due to a dispensing error by MOR Hogan on 09/23/2024.
- On 10/16/2024, MOR Hogan discovered that #29 capsules of lisdexafetamine 40 mg were missing during a perpetual inventory reconciliation.
- On 12/02/2024, the patient confirmed receiving an extra #29 capsules on 09/23/2024.
- MOR Hogan stated that contributing factors were lack of staff during the shift when the dispensing error occurred, lack of back counting the particular bottle during the fill process, and lack of manual counting during the two subsequent state counts.
- Pharmacists Elswesey and Pharmacist Hoang reportedly did not physically count the lisdexafetamine 40mg capsules during the "state counts" conducted on 09/29/2024 and 10/04/2024, respectively.
- MOR Hogan completed 2 remedial CEs in medication safety and attested to reviewing 247 CMR 15, Continuous Quality Improvement Program.
- MOR Hogan and staff attested to reviewing all policies for the proper storage and handling of controlled substances.

ACTION: Motion by R. MORELLI, seconded by F. LOMBARDO, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0219), No Discipline Warranted.

Case #11/CASE-2024-3391

PHA-2024-0224

CVS #1866, DS2956

Time: 11:12 AM

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

DISCUSSION: K. JOHNSTONE presented and summarized the investigative report that pertained to this matter.

- During a retail compliance inspection conducted on 11/06/2024 at CVS Pharmacy #1866, Investigator Van Allen observed repeat deficiencies from a previous inspection conducted on 12/26/2023. Specifically, expired Schedule II controlled substances were not reconciled every 10 days, evidence of pharmacy technicians' current registrations was not readily available, and pharmacy technicians/trainees were not wearing name tags.
- On 12/03/2024, a plan-of-correction was received that stated expired Schedule II controlled substances would be reconciled, all registrations would be readily available, and staff would wear name tags.
- On 01/03/2025, MOR Igo responded that all staff attested to having reviewed current policies and procedures about reconciliation of the perpetual inventory and the wearing of name tags.
- On 01/03/2025, in response to the complaint opened on her license, Former MOR Igo stated that proper procedures were reviewed with the overnight pharmacists, technicians who were not wearing name tags were counseled, and the technicians have been instructed to place a copy of their licenses/relevant documents into the Regulatory Box. Former MOR Igo will monitor monthly.

ACTION: Motion by T. FENSKY, seconded by R. LOPEZ, and voted unanimously by those present, to CONSOLIDATE the matter (PHA-2024-0224) with PHA-2024-0021. A second motion was made by T. FENSKY, seconded by S. DINNO, and voted unanimously by those present, to refer the consolidate matters 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 #12/CASE-2024-3391
PHA-2024-0225

Kimberly Igo, PH235277

Time: 11:16 AM

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

DISCUSSION: K. JOHNSTONE presented and summarized the investigative report that pertained to this matter.

- During a retail compliance inspection conducted on 11/06/2024 at CVS Pharmacy #1866, Investigator Van Allen observed repeat deficiencies from a previous inspection conducted on 12/26/2023. Specifically, expired Schedule II controlled substances were not reconciled every 10 days, evidence of pharmacy technicians' current registrations was not readily available, and pharmacy technicians/trainees were not wearing name tags.
- On 12/03/2024, a plan-of-correction was received that stated expired Schedule II controlled substances would be reconciled, all registrations would be readily available, and staff would wear name tags.
- On 01/03/2025, MOR Igo responded that all staff attested to having reviewed current policies and procedures about reconciliation of the perpetual inventory and the wearing of name tags.
- On 01/03/2025, in response to the complaint opened on her license, former MOR Igo stated that proper procedures were reviewed with the overnight pharmacists, technicians who were not wearing

name tags were counseled, and the technicians have been instructed to place a copy of their licenses/relevant documents into the Regulatory Box. MOR Igo will monitor monthly

ACTION: Motion was made by T. FENSKY, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2024-0225), 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 #13/CASE-2024-3048

PHA-2024-0203

CVS #946, DS3442

Time: 11:17 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.

- During a retail compliance inspection conducted on 10/10/2024, Investigator Seed observed a non-licensed cashier at the drive-thru conducting a drug utilization review (DUR) using a pharmacist's credentials.
- When questioned by Investigator Seed, the cashier admitted that when prompted on the screen at the drive-thru he entered Pharmacist Boaitey's credentials which were written on a piece of paper. He stated that he did not write the credentials down. He explained that they were at the drive-thru when he arrived.
- MOR Swalec indicated that a contributing factor was that the DUR warning system causes many DURs to be resolved at the point of sale of the prescription rather than beforehand during data entry verification.
- Pharmacist Boaitey indicated that he was taking a verbal prescription from a doctor's office when the cashier informed him of a DUR. He admitted that he wrongfully provided his credentials to the cashier to avoid a hold-up at the drive-thru.
- MOR Swalec indicated that all staff have been retrained and that only a pharmacist can resolve DUR prompts.
- Pharmacist Boaitey indicated that he will not be sharing credentials any longer.

ACTION: Motion by R. MORELLI, seconded by R. LOPEZ, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0203), No Discipline Warranted.

Case #14/ CASE-2024-3048

PHA-2024-0204

Collins Boaitey, PH238704

Time: 11:20 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.

- During a retail compliance inspection conducted on 10/10/2024, Investigator Seed observed a non-licensed cashier at the drive-thru conducting a drug utilization review (DUR) using a pharmacist's credentials.

- When questioned by Investigator Seed, the cashier admitted that when prompted on the screen at the drive-thru he entered Pharmacist Boaitey's credentials which were written on a piece of paper. He stated that he did not write the credentials down. He explained that they were at the drive-thru when he arrived.
- MOR Swalec indicated that a contributing factor was that the DUR warning system causes many DURs to be resolved at the point of sale of the prescription rather than beforehand during data entry verification.
- Pharmacist Boaitey indicated that he was taking a verbal prescription from a doctor's office when the cashier informed him of a DUR. He admitted that he wrongfully provided his credentials to the cashier to avoid a hold-up at the drive-thru.
- MOR Swalec indicated that all staff have been retrained and that only a pharmacist can resolve DUR prompts.
- Pharmacist Boaitey indicated that he will not be sharing credentials any longer."

ACTION: Motion was made by R. LOPEZ , seconded by J. DORGAN, and voted unanimously by those present, to refer the matter (PHA-2024-0204), 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 #15/CASE-2024-3390

PHA-2024-0227

CVS #1049, DS1716

Time: 11:21 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.

- CVS 1049 was issued a POC during an RCI on 11/12/2024 for failing to comply with minimum supervisory ratios (1:3 technicians w/no CPhT). This was a repeat inspectional deficiency which previously led to issuance of POC during an RCI on 05/02/2024 (1:4 technicians w/only 1 CPhT).
- CA: Former MOR Davidov described that "currently there is 1 technician waiting on an exam date to take the PTCB exam and another technician studying to become nationally certified." Former MOR Davidov then pledged " to monitor and adjust schedules to meet requirements for rph/tech ratio."
- Of note, most recent RCI on 02/13/2025 was satisfactory and no POC was issued.

ACTION: Motion by D. BARNES, seconded by J. DORGAN, and voted unanimously by those present, to REFER the matter (PHA-2024-0227), 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 #16/ CASE-2025-0388

PHA-2025-0027

CVS #7140, DS89720

Time: 11:23 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 01/09/2025, CVS 7140 submitted a final report of unknown losses of 872 gabapentin 100mg capsules and 530 gabapentin 300mg capsules discovered on 12/23/2024 while completing cycle counts. MOR Costa notified the area DL and AP. She then initiated an internal investigation including review of invoices, dispensing logs, and gabapentin prescriptions issued for large quantities. Ultimately, she “did not identify any discrepancies or a reason for the loss.”
- Of note, MOR Costa indicated that she found reconciliation difficult because gabapentin was not check-in by a physical count because the drug was not a federally controlled substance.
- MOR Costa indicated that she “implemented weekly cycle counts of all strengths of gabapentin since the loss was discovered” as corrective action to mitigate recurrence of a similar incident. MOR Costa then conveyed that “there have been no discrepancies since this has been implemented.”

ACTION: Motion by C. BELISLE, seconded by T. FENSKY, and voted unanimously by those present, to REFER the matter (PHA-2025-0027), 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, with special terms to include the CS Loss Protocol for all gabapentin products.

Topic XII: **Executive Session Call to Order:** **TIME: 11:27 AM**

By: President S. Ahmed reads the executive session language and requests a motion to enter executive session.

Action: Motion by J. DORGAN, seconded by M. SCIARAFFA, voted unanimously by roll call to enter executive session #1.

Topic XIII: **Adjudicatory Session** **TIME: 12:30 PM**

DISCUSSION: None

ACTION: President S. Ahmed request a motion to enter Adjudicatory Session.

At 12:32 PM R. LOPEZ seconded by M. SCIARAFFA and voted unanimously by all those present to enter the Adjudicatory Session by roll call vote.

Lunch 12:33 PM – 01:05 PM

Topic XIV: **65C Sessions MGL c. 112 section 65C** **TIME: 01:27 PM**

DISCUSSION: None

ACTION: President S. Ahmed request a motion to enter M.G.L 65 c Session.

At 01:27 PM J. DORGAN seconded by R. LOPEZ and voted unanimously by all those present to enter M.G.L. chapter 65 C Session by roll call vote.

Topic XV:

ADJOURNMENT OF MEETING

TIME: 03:33 PM

ACTION: Motion by S. AHMED seconded by K. THORNELL and voted unanimously by those present, to adjourn the meeting by roll call vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. May 1, 2025, Agenda
2. April 3, 2025, Board Minutes
3. Licensure Policy 13-01 Report
4. Monthly Probation Report
5. BDR Licensure Report pursuant Policy 14-02
6. Policy 2025-01: Rapid Microbial Methods (Rapid Sterility Testing)
7. Policy 202-02: Extended Absence or Departure of a Manager of Record of Designated Pharmacist-in Charge
8. Trang Pharmacy-New Retail Pharmacy
9. Vital Care of Cambridge- New Retail Pharmacy
10. BET Pharm, LLC: Non-Resident Retail Pharmacy
11. Empower Pharmacy: Non-Resident Sterile Compounding
12. Get Relief: Non-Resident Complex Non-Sterile Compounding
13. Jungle Jim's Pharmacy: Non-Resident Retail Pharmacy, Complex Non-Sterile Compounding, Sterile Compounding.
14. Louis & Clark #572: Petitions for Waiver
15. Dominic Regalbuto; PHA-2022-0109
16. Amherst Pharmacy; PHA-2022-0018
17. Walgreens 2781; PHA-2022-0190
18. PHA-2024-0185, Abby Pharmacy
19. PHA-2025-0005; Carie Boyd Pharmaceuticals
20. PHA-2025-0029; Optum Infusion Services 500
21. PHA-2024-0213; Walgreens #6939
22. PHA-2024-0215; Walgreens #5586
23. PHA-2024-0220; Walgreens #17728
24. PHA-2024-0222; Walgreens #9614
25. PHA-2024-0242; Brighton Pharmacy
26. PHA-2024-0217; Woodmark Pharmacy of MA
27. PHA-2024-0219; CVS #496
28. PHA-2024-0224; CVS #1866
29. PHA-2024-0225; Kimberly Igo
30. PHA-2024-02023; CVS #946
31. PHA-2024-0204; Collins Boaitey
32. PHA-2024-0227; CVS #1049
33. PHA-2025-0027; CVS #7140