COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE BOARD OF REGISTRATION IN PHARMACY April 3, 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

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

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Stacy Hart, <u>Stacy.Hart@mass.gov</u> or 857-274-1120 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.

Agenua				
8:00	Ι	CALL TO ORDER		S. Ahmed
8:05	II	APPROVAL OF AGENDA		7 milled
8:10	ш	 APPROVAL OF BOARD MINUTES Draft of March 6, 2024, Regular Session Minutes 		
8:15	IV	 REPORTS Applications approved pursuant to Licensure Policy 13-01 Monthly report from Probation Board Delegated Review pursuant to Licensure Policy 14-02 Research Drug Study report pursuant to Staff Action Policy 18-02 		

Agenda

8:20	V	 FLEX Open Meeting Law vote for Pharmacy Advisory Committee Pharmacy Advisory Committee Meeting: April 16, 2025, 10am-11am Recommendation Document 25-01: Rapid Sterility Testing Election of Board member to the meeting Compounded Preparations from 503B Outsourcing Facilities memo FDA memo regarding GLP-1 supply Pharmacy Self-Inspection Requirements (247 CMR 9.19 (21)) 					
			imbursement for Boa	ard Members			
8:45	VI	POLI • Po		legated Review (BDR)		M. Chan
9:00	VII	 APPLICATION CAPS Pharmacy; DS3312 – Petition for Waiver Galaxy Pharmacy-New Retail Pharmacy and Complex Non-Sterile Compounding Jungle Jim's Pharmacy - Non-Resident Retail Pharmacy Manet Pharmacy – New Retail Pharmacy Revive Rx Sterile Compounding License - New Application 					
		FILE No.	REVIEW	Files	Licensee		
		1	CASE-2024-2698	PHA-2024-0177	Walgreens #3151, DS2470		
		2	CASE-2025-031	INV15716	Elsie Preval, PH26271		
		3	CASE-2024-3636	PHA-2024-0244	Jerry May, PH238214		
	VIII	4	CASE-2024-2561	INV13048	Walgreens #17925, DS90150		
		5	CASE-2024-2561	PHA-2024-0228	Melissa Scrima, PH238446		
		6	CASE-2024-2824	PHA-2024-0183	Union Pharmacy, DS90289		
9:45		7	CASE-2024-3050	PHA-2024-0200	Mylyfe Specialty Pharmacy, DS90324		
		8	CASE-2024-3052	PHA-2024-0202	Walgreens #10318, DS89638		
		9	CASE-2024-3047	PHA-2024-0201	CVS #62, DS23814		
		10	CASE-2024-3099	PHA-2024-0206	CVS #240, DS89959		
		11	CASE-2024-3389	PHA-2024-0226	CVS #674, DS1023		
				DITA 0004 0001	CVC //201		
		12	CASE-2024-3316	PHA-2024-0221	CVS #301		
		13	CASE-2024-2785	PHA-2024-0182	CVS #1234, DS3496		
		13 14	CASE-2024-2785 CASE-2024-2818	PHA-2024-0182 PHA-2024-0190	CVS #1234, DS3496 CVS #765, DS2910		
		13	CASE-2024-2785	PHA-2024-0182	CVS #1234, DS3496		

10:30	IX	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.	
11:00	Х	M.G.L. c. 112, § 65C SESSION	
12:30	XI	ADJOURNMENT	

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting April 3, 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 John Rocchio, RPh, PharmD Dr. Richard Lopez, MD Delilah Barnes, RPh Rita Morelli, PharmD, BCACP, RPh Julie Dorgan, RN Frank Lombardo Timothy Fensky, RPh

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 Gregory Melton, JD, PharmD, BCPS, Investigator Keith Johnstone, Compliance Officer David Sencabaugh Susan Kim, Pharmacy Intern Gayatri Ramasubramanian, Pharmacy Intern

TOPICI. Attendance by roll call:

CALL TO ORDER

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.

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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; F. Lombardo, yes; T. Fensky, yes; S. Ahmed, yes.

Draft Minutes General Session: 4/3/25 BOP Approved: 5/1/25 Board Members Not Present Caryn Belisle, RPh, MBA

TIME: 8:01 AM

Topic II.

Approval of Agenda

TIME 8:02 AM

Agenda: 04/03/25

DISCUSSION: Open meeting law vote for Pharmacy Advisory Committee – Deferred CAPS Pharmacy, Petition for Waiver - Withdrawn

ACTION:

Motion by T. FENSKY, 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 03/06/25

Change: Saad Dinno not included in roll call vote

Action: Motion by J. ROCCHIO seconded K. THORNELL and voted to approve the regular session minutes of 3/6/25 with THE noted changes by roll call vote.

Topic IV.

REPORTS

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: R. HARRIS

<u>DISCUSSION</u>: R. Harris reported a total of 47 Resident Change Pharmacist Manager of Record applications, 1 Non-Resident Change Pharmacist Manager of Record application, and 10 Facility Closures that have been approved via Staff Action since the last Board Meeting.

So noted.

Topic IV.

REPORTS

Monthly Report from Probation

PRESENTED BY: R. HARRIS

<u>DISCUSSION</u>: R. Harris indicated 1 licensee that was given a 2nd opportunity to cure and 1 successful completion of probation monitoring since the last report. Currently, there are a total of 43 active cases.

So noted.

TIME: 8:04 AM

TIME: 8:03 AM

Topic IV.

REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris reported 1 reprimand for a regulatory violation, 2 CE discrepancies that have been closed with no discipline warranted; remediation completed, 2 disciplinary stayed probations for controlled substance losses, and 1 reprimand for inspectional deficiencies since the last report.

The Board has approved waiver requests for the following locations: Option Care in both Shelton, CT and Cranston, RI, Bravo Pharmacy in Watertown, MA, Optum Infusion Services in Farmingdale, NY, and Bioscript Infusion Services in Bedford, NH.

So noted.

Topic IV.

REPORTS

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

PRESENTED BY: M. CHAN

DISCUSSION: M. Chan reported a total of 2 pharmacies currently participating in research drug studies. Since the last report, there has been 1 new study and 6 studies that have concluded. Currently, there are 9 active studies involving commercial drug substances and 3 involving investigational drug substances.

So noted.

TOPIC V

FLEX

Open Meeting Law vote for Pharmacy Advisory Committee

Deferred.

Pharmacy Advisory Committee Meeting: April 16, 2025, 10am-11am

- Recommendation Document 25-01: Rapid Sterility Testing
- Election of Board member to the meeting

Presented by: W. FRISCH

Discussion: Board members were asked for a volunteer to present the Recommendation Document to the Advisory Committee at the 4/16/25 meeting.

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TIME: 8:06 AM

TIME: 8:04 AM

TIME: 8:05 AM

Action: Motion by J. DORGAN, seconded by K. THORNELL, and voted unanimously by roll call of those present, for T. FENSKY to present the recommendation document.

Compounded Preparations from 503B Outsourcing Facilities memo

Presented by: W. FRISCH

Discussion: The FDA has proposed "draft" guidance to permit 503A retail pharmacies to dispense compounds obtained from 503B outsourcing facilities. However, since the document clearly states that it is "Not for Implementation", the Board will prohibit 503A retail pharmacies from accepting and redispensing compounds received from 503B outsourcing facilities considering it to be re-dispensing under 247 CMR 9.01(5).

Action: Motion by R. MORELLI, seconded by K. THORNELL, and voted unanimously by roll call of those present, to adopt the memo.

FDA memo regarding GLP-1 supply

Presented by: W. FRISCH

Discussion: Regarding the compounding of copies of commercially available GLP-1 medications, the FDA has announced that the enforcement discretion period for tirzepatide injections has ended, so 503A pharmacies may no longer compound it.

The enforcement discretion period for the compounding of semaglutide injection by 503A pharmacies ends on April 22, 2025, or until the district court decides on the injunction motion, whichever is later.

So noted.

Pharmacy Self-Inspection Requirements (247 CMR 9.19 (21))

Presented by: M. GODEK

Discussion: This regulation requires pharmacies to perform a self-inspection within seven days of any renovation, expansion, relocation, or change of Manager of Record, and at least once per year. The completed self-inspection tool must be retained and readily available for at least two years.

Draft Minutes General Session: 4/3/25 BOP Approved: 5/1/25

TIME: 8:12 AM

TIME: 8:10 AM

TIME: 8:09 AM

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So noted.

TOPIC VI

Policy 14-02: Board Delegated Review (BDR)

Presented by: M. CHAN

Discussion: The edits allow the BDR group to dispose of any losses with a finding of no violation or insufficient evidence, and any Level 1 losses for schedules II -V.

POLICIES

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

Topic VII.	APPLICATION	TIME: 8:54 AM
1. CAPS Pharmacy; DS3312	Petition for Waiver	
Deferred.		

Topic VII.

APPLICATION

TIME: 8:15 AM

TIME: 8:13 AM

2. Galaxy Pharmacy New Retail Pharmacy and Complex Non-Sterile Compounding

<u>REPRESENTED BY</u>: Doan Hung, Thuy Lyn, Christopher Le, Ron Lanton

RECUSAL: NONE

DISCUSSION: We would be the only independent pharmacy left in the area. We want to be able to provide retail and also compounding to the people in the community

Questions:

- What type of compounding are you planning to do at this pharmacy?
 - Complex, non sterile compounding
- T. Fensky: Can you give me an idea of who and how people are going to be trained to do this properly?
 - Currently there is one pharmacist who is trained to complete complex non-sterile compounding, and there are other pharmacists who will complete non sterile and simple compounding who will be trained both in-house and sent out to complete sterile compounding training.
- S. Dinno: Will you be going to the lab location? Or will it be re-done with USP800 and 795?

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- The ewuipment will stay where it is, it will only change in name.
- Will employees from Galaxy pharmacy be retained?
 - Yes, all employees from Galaxy pharmacy will be moved over to the new location
- What is your plan if your complex non-sterile compounder is unavailable?
 - We transfer the patient to a close by pharmacy who can assist them. However most of the main items we are compounding that are non sterile complex compounding, are non-urgent.

<u>ACTION</u>: D. Barnes made a motion to approve the New Retail pharmacy application upon successful completion of inspection; Seconded by D. Dinno and voted unanimously by those present to approve the motion..

<u>ACTION</u>: D. Barnes Made a motion to approve the Complex Non Sterile Compounding registration upon complete of a satisfactory inspection; Seconded by J. Dorgan and voted unanimously by those present to approve the motion.

Topic VII.

APPLICATION

TIME: 8:35 AM

3. Jungle Jim's Pharmacy Non-Resident Retail Pharmacy

REPRESENTED BY: Andrew Whelan, Ron Fergusion

RECUSAL: NONE

DISCUSSION: We offer both sterile and nonsterile compounding and primarily focus on hormone replacement therapy. On the sterile side, we have helped compound Semaglutide during the shortage for patients.

Questions:

- Do you ship any commercially available products?
 - No, just compounded medications
- Will you be applying for the nonresident sterile and complex licenses?
 - o Yes
- There is some discipline with the OH BOP that we would like further clarified. Specifically there are violations with sterile compounding. Could you further explain?
 - We did not realize that OH required a wholesale license if the manufacturer is FDA licensed. One of the wholesalers had a license pending at the time of inspection by the OH BOP. Because we did not check or retain the needed information, we were cited.
- Referring to the matter in 2019, could you please clarify what happened?
 - In March 2019, there were some law changes, and we were unfortunately slow to adopt those changes. After that inspection, we got everything updated and moving forward hired a Consultant and a Chief Compliance Officer to further help. We did a major rework because of our policies and learn from this incident.
- I see that there was an issue of selling patient specific dangerous drugs to an unlicensed entity? Could you explain that?

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- We sent the hormone compounded pellets to the physicians office, and the law at the time was that we could not send patient specific medication to the physicians office. Since this occurred, the law has changed so that you can do so now. Additionally, we no longer engage in that practice as 503B pharmacies can provide that service at a cheaper cost.
- What is your current license status in Ohio?
 - Active and in good standing.
- In that same agreement there were some alarming USP797 violations. Could you speak to those and how you will prevent this from happening again?
 - Thia happened because initially had out Pellet press outside of the clean room. However, once OH law changed, we moved our pellet press into the clean room.
- Under allegations under 1a -c there are things such as, cleaning only occurring with non sterile rubbing alcohol, not using gloves and other things. Have you updated your policies since?
 - Yes we have, we follow all UPS 797 guidelines
- Do you have a current acceptable inspection?
 - We do. And we will be having an NABP style inspection April 28th, as that was the soonest on could be completed.

<u>ACTION</u>: T. Fensky Made a motion to defer the matter until after the April 28th NABP style inspection; seconded by S. Dinno and voted unanimously by those present to approve the motion.

Topic VII.APPLICATIONTIME: 8:32 AM

4. Manet Pharmacy New Retail Pharmacy

REPRESENTED BY: John Awad

RECUSAL: NONE

DISCUSSION: Currently BMC, is operating the pharmacy, and we are working to set up Manet Pharmacy so that once BMC leaves the health pharmacy there will not be a gap in care.

Question:

- Will the plan be to retain the same staff?
 - Yes, we will be absorbing the same staff. We will be keeping the same Manager of Record

<u>ACTION</u>: J. Rocchio made a motion to approve the application for the New Retail Pharmacy upon completion of a successful inspection. Seconded by T. Fensky and voted unanimously by those present to approve the motion.

Topic VII.

APPLICATION

5. Revive Rx Sterile Compounding License New Application

<u>REPRESENTED BY</u>: Kimberline, Johnathan

RECUSAL: NONE

DISCUSSION: BORP staff provided a summary that the licensee is returning to the board after the previous meeting to allow for follow-up regarding procedures around lyophilization, scan RDI, and a letter received from the FDA. We have received documents from the Revive team since then.

The presenters explained that the Lyophilization process changes the properties physically where it increases the shelf life. This process has been around for some time, and we have internal sterility data which supports the increased shelf-life.

Massachusetts law states that all licensees need to follow USP guidelines. Are you willing to stick with USP guidelines for Massachusetts?

<u>ACTION</u>: R. Lopez made a motion to approve the license upon receipt of documentation stating the intent to conform with the BUD expirations for Category 3 CSPs; S. Ahmed Seconded the motion and voted by roll call as follows: S. Dinno Nay, M. Sciaraffa Nay, D. Barnes Nay, J. Dorgan Ay, T. Fensky Ay, F. Lombardo Nay, R. Lopez Ay, R. Morelli ay, J. Rocchio ay, K Thornell Ay, S. Ahmed ay. (Ay = 7, Nay = 4)

TOPIC VIII.

FILE REVIEW

Case #1/ CASE-2024-2698 PHA-2024-0177

Walgreens #3151, DS2470

Time: 09:31 AM

RECUSAL: NONE

<u>DISCUSSION</u>: J. TRIFONE presented and summarized the investigative report that pertained to this matter.

- Report Loss of Controlled Substances (RLCS) on 08/14/2024 of #100 morphine sulfate IR 15mg tablets, reportedly due to a dispensing error.
- MOR Montville indicated that the camera footage confirmed the prescription was double counted for #168 by the filling technician, then the pharmacist added a full manufacturer bottle of #100 tablets to the amber vial.
- MOR Montville identified the pharmacy staff involved in this incident. He identified the staff members involved in the production and verification of the prescription were: Pharmacist Ines Mbami, Pharmacist Arwa Sabri and Pharmacy Technician Trainee (PTT) Fabricio Filho. None of the staff involved in the incident provided a statement and Pharmacist Sabri is on a leave of absence.
- MOR Montville indicated that he reviewed with the staff the proper policy and procedure for dispensing of controlled substances. All staff were counseled, and the conversation was documented.

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• MOR Montville submitted a signed attestation from the staff involved (except for Pharmacist Sabri) in the incident that they have reviewed 247 CMR 15, Continuous Quality Improvement (CQI) Program. Pharmacist Mbami submitted CE documentation for 2 CEs in patient safety.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0177), 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-2025-0031		
INV15716	Elsie Preval, PH26271	Time: 09:34 AM

RECUSAL: NONE

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

- On December 31, 2024, Pharmacist Preval requested an extension for completion of CE requirements. Upon review, Pharmacist Preval was deficient 1 contact hour of CE in immunizations in 2023 and 14.25 contact hours of CE in 2024 including 2 contact hours in pharmacy law and 1 contact hour in immunizations. In turn, Pharmacist Preval completed remediation in 2025.
- Of note, BORP previously opened a staff-assignment investigation (SA-INV-16032) in 2020 and a complaint (PHA-2011-0053) in 2011 against Pharmacist Preval for failing to complete CE. BORP ultimately dismissed both matters.

<u>ACTION</u>: Motion by T. FENSKY, seconded by S. DINNO, and voted unanimously by those present, to CLOSE the matter (INV15716), No Discipline Warranted, Remediation Complete.

Case #3/ CASE-2024-3636		
PHA-2024-0244	Jerry May, PH238214	Time: 09:36 AM

RECUSAL: NONE

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

- On 12/09/2024, Pharmacist May notified BORP that he entered into a consent agreement for disciplinary action with the LA BOP effective 11/20/2024 requiring him to pay a \$5,000.00 fine and \$250.00 administrative fee to resolve a complaint against his Louisiana pharmacist license.
- According to details provided by LA BOP, Pharmacist May was PIC at WP Pharma Labs of Dallas, TX between 03/31/2022 and 03/31/2024 when it dispensed "approximately 606 prescriptions of compounding products into Louisiana that failed to conform to the minimal standards of acceptable pharmacy practice. Specifically, these products were compounded with unapproved bulk drug substances that are not eligible for human compounding." Significantly, Pharmacist May acknowledged that the consent agreement was considered disciplinary action against his Louisiana pharmacist license by LA BOP.
- Pharmacist May explained that WP Pharma Labs "followed the case law and legal advice that allowed compounding with bulk drug substances that had been nominated to the FDA for use in compounding" prior to FDA's "Interim Policy on Compounding Using Bulk Drug Substances in

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December 2023." WP Pharma Labs then "voluntarily ceased compounding with any of substances not allowed under that Policy."

<u>ACTION</u>: Motion by D. BARNES, seconded by J. DORGAN, and voted unanimously by those present, to refer the matter (PHA-2024-0244), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #4/ CASE-2024-2561		
INV13048	Walgreens #17925, DS90150	Time: 09:38 AM
<u>RECUSAL</u> : NONE		

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

- On 08/02/2024, WAG 17925 reported to BORP that Former MOR Scrima was terminated as MOR at WAG 17925 after she failed to properly conduct an annual control substance count on 06/11/2024. WAG 17925 indicated that surveillance video captured over several days including 06/11/2024 was reviewed which revealed Former MOR Scrima did not complete a physical annual CII inventory count despite attesting to doing so. In addition, a pharmacy technician who worked on 06/11/2024 reported that she did not observe Former MOR Scrima complete a physical count.
- Former MOR Scrima admitted that she did not conduct a physical annual count on 06/11/2024 despite attesting that she did so. She explained that she did not understand the seriousness of attesting to doing so when she did not actually complete the count.
- Former MOR Scrima indicated that she scheduled the annual count on several prior occasions with extra staff to ensure the safe operation of the pharmacy. However, Walgreens Corporate cancelled her counts then with less than 24 hours' notice required her to complete the count.
- Former MOR Scrima was unable to schedule extra staff due to the short notice and was left with only one technician and one trainee as staff. She also explained that she had completed reconciliations over the weekend so she believed that the annual count that she attested to completing on 06/11/2024 was accurate based on those prior reconciliations.
- Former MOR Scrima pledged that "she will certainly refuse an employer's request to sacrifice level of care to a patient versus following to the letter State and Federal requirements pertaining to her work as a pharmacist" going forward. She also pledged that "despite being a large source of her family's income she would unquestionably resign her position if she is ever given such choice in the future."

<u>ACTION</u>: Motion by R. MORELLI, seconded by D. BARNES, and voted unanimously by those present, to CLOSE the matter (INV13048), No Violation.

Case #5/ CASE-2024-2561 PHA-2024-0228 Melissa Scrima, PH238446 <u>RECUSAL</u>: NONE

Time: 09:42 AM

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

- On 08/02/2024, WAG 17925 reported to BORP that Former MOR Scrima was terminated as MOR at WAG 17925 after she failed to properly conduct an annual control substance count on 06/11/2024. WAG 17925 indicated that surveillance video captured over several days including 06/11/2024 was reviewed which revealed Former MOR Scrima did not complete a physical annual CII inventory count despite attesting to doing so. In addition, a pharmacy technician who worked on 06/11/2024 reported that she did not observe Former MOR Scrima complete a physical count.
- Former MOR Scrima admitted that she did not conduct a physical annual count on 06/11/2024 despite attesting that she did so. She explained that she did not understand the seriousness of attesting to doing so when she did not actually complete the count.
- Former MOR Scrima indicated that she scheduled the annual count on several prior occasions with extra staff to ensure the safe operation of the pharmacy. However, Walgreens Corporate cancelled her counts then with less than 24 hours' notice required her to complete the count.
- Former MOR Scrima was unable to schedule extra staff due to the short notice and was left with only one technician and one trainee as staff. She also explained that she had completed reconciliations over the weekend so she believed that the annual count that she attested to completing on 06/11/2024 was accurate based on those prior reconciliations.
- CA: Former MOR Scrima pledged that "she will certainly refuse an employer's request to sacrifice level of care to a patient versus following to the letter State and Federal requirements pertaining to her work as a pharmacist" going forward. She also pledged that "despite being a large source of her family's income she would unquestionably resign her position if she is ever given such choice in the future."

<u>ACTION</u>: Motion by D. BARNES, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0228), 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-2024-2824		
PHA-2024-0183	Union Pharmacy, DS90289	Time: 09:43 AM

RECUSAL: NONE

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

- During a retail compliance inspection on 09/16/2024, Investigator Geaney observed Annesther Prezeau performing technician duties without a Massachusetts technician license. She was licensed as a technician in Florida.
- She obtained a Massachusetts PT license on 09/30/2024.
- MOR Qin stated that she was hired as a cashier/clerk but did input 3 prescriptions prior to being licensed as a PT in MA.
- Once monthly, MOR Qin will ensure all staff are appropriately licensed. All staff are required to renew their license no later than one week prior to its expiration.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by M. SCIARAFFA, and voted unanimously by those present, to REFER the matter (PHA-2024-0183), 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-2024-3050		
PHA-2024-0200	Mylyfe Specialty Pharmacy, INC, DS90324	Time: 09:45 AM

RECUSAL: NONE

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

- On 10/04/2024, Investigator Brosnan conducted a retail compliance inspection at the Pharmacy. He observed that there were no medications stored within the Pharmacy except naloxone and flushes. Prescriptions were processed remotely at the Mylyfe in Enfield, Connecticut.
- BORP Policy 2021-02 in effect at the time required that a pharmacy planning to serve as a central fill pharmacy for other pharmacies must file a petition to the Board and receive the Board's approval prior to engaging in any central filling activities.
- Policy 2021-02 stated "Until the final promulgation of 247 CMR 6.00 (Licensure of Pharmacies) that will require non-resident licensure, the Board does not intend to take enforcement action with respect to shared pharmacy services occurring in a non-resident pharmacy on behalf of a Massachusetts located pharmacy." The Pharmacy interpreted this to mean that Board approval requirement for a central fill pharmacy was not in effect until after the final promulgation of the new regulations.
- Mylyfe Specialty Pharmacy, Inc (DS90324, Issued: 06/09/2020)) underwent a change of ownership and was restructured. It is no longer in business as of 01/13/2025.
- The new pharmacy is Mylyfe Specialty Pharmacy, LLC (DS100220, Issued 01/14/2025)
- Closed pharmacy Mylyfe Specialty Pharmacy, Inc and new pharmacy Mylyfe Specialty Pharmacy, LLC listed the same address at 1111 Elm Street, Suite 12 in West Springfield. The MOR stayed the same for the new licensee.

<u>ACTION</u>: Motion by J. ROCCHIO, seconded by J. DORGAN, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0200), No Discipline Warranted.

Case #8/ CASE-2024-3052		
PHA-2024-0202	Walgreens #10318, DS89638	Time: 09:48 AM

RECUSAL: NONE

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

- On 09/13/2024, during a retail compliance inspection, Investigator Seed observed a multi-dose vial of Typhim with a vial cap missing and a punctured stopper.
- The vaccine was confirmed to be administered to one patient by MOR Benincaso, but it is not a routine vaccine that pharmacists are authorized to administer.
- The physician was informed of the vaccine administration.

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- The patient experienced no adverse effects.
- MOR Benincaso reviewed the list of approved vaccines with staff and removed the Typhim vaccine from inventory.
- MOR Benincaso attested to having reviewed 247 CMR 15 Continuous Quality Improvement in its entirety and completed 2 CEs as remediation.

<u>ACTION</u>: Motion by J. ROCCHIO, seconded by T. FENSKY, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0202), No Discipline Warranted, Remediation Complete.

Case #9/ CASE-2024-3047		
PHA-2024-0201	CVS #62, DS23814	Time: 09:55 AM

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

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

- On or about 10/08/2024, BORP received a call from PTT Courtney who reported having unknowingly worked with a PTT license that expired on 09/05/2024.
- A PTT renewal application was approved the same day. A PT registration was issued on 10/18/2024.
- MOR Xuan responded that PTT Courtney worked as a cashier and conducted no technician duties while his PTT license was expired.

<u>ACTION</u>: Motion by T. FENSKY, seconded by K. THORNELL, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0201), No Violation.

Case #10/ CASE-2024-3099		
PHA-2024-0206	CVS #240, DS89959	Time: 09:56 AM

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

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

- During a 10/15/2024 RCI, Investigator Geaney issued a POC to CVS 240 for failing to comply with minimum supervisory ratios after he discovered 1 pharmacist was supervising 2 interns and 3 technicians who were not nationally certified (1:5 ratio). Significantly, Investigator Geaney previously cited the pharmacy for supervisory violations during a 03/18/2024 RCI in which he discovered 1 pharmacist supervising 2 technicians who were not nationally certified and 2 PTTs (1:4 ratio). Of note, licensees involved in the inspections on 10/15/2024 were different from those on the 03/18/2024 inspection.
- MOR McPhillips explained that she scheduled extra staff on the morning of the October 15, 2024 inspection in anticipation of receipt of a "Warehouse delivery (usually 20 totes) in addition to Cardinal." MOR McPhillips next described processing the warehouse delivery and Cardinal order on such a day "usually takes two technicians out of workflow for many hours (4-5 hours)."
- CA: MOR McPhillips indicated that she emphasized the importance of compliance with minimum supervisory ratios with staff with special attention paid to CVS 240's lead technicians to monitor

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ratios. MOR McPhillips also indicated that she instructed extra staff scheduled in anticipation of the warehouse delivery "to pivot to other projects/learning modules that do not involve patient care on the computer" in times of delayed delivery.

• In addition, MOR McPhillips indicated that CVS 240 technicians were becoming or planning to become nationally certified, and a former technician was licensed as an intern. MOR McPhillips described that the addition of national certificated technicians and interns would expand supervisory ratios which would help support CVS 240's high-volume vaccination services.

<u>ACTION</u>: Motion by D. BARNES, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2024-0206), 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 #11/ CASE-2024-3389		
PHA-2024-0226	CVS #674, DS1023	Time: 09:59 AM

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

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

- On 11/08/2024, Investigator Murray discovered manufacturer stock bottles of methylphenidate ER 40mg capsules containing 5 capsules, amphetamine mixed salts ER 10mg capsules containing 4 capsules, and amphetamine mixed salts 10mg tablets containing 7 tablets stored in an unlocked cabinet behind the pharmacist's workstation.
- MOR Yu explained that the aforementioned stock bottles of methylphenidate and amphetamine were from a medication disposal kiosk which was overflowing. She described that she set the stock bottles aside with the intention of disposing of the bottles once the kiosk was emptied. MOR Yu then explained that she did not store the bottles in the CVS 674's safe because the drugs were not part of the pharmacy's inventory.
- MOR Yu wrote, "Moving forward, I have instructed staff pharmacist [Ghu] to leave the box in the cabinet and to not bring any drugs from the disposal to be stored in the pharmacy. We will keep all drugs from disposal in the disposal cabinet, and on weekends we will check the disposal level."

<u>ACTION</u>: Motion by R. MORELLI, seconded by T. FENSKY, and voted unanimously by those present, to REFER the matter (PHA-2024-0226), 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-2024-3316 PHA-2024-0221 CVS #301, DS89652

Time: 10:02 AM

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

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

- On October 23, 2024, CVS 301 submitted a final report of loss of 200 amphetamine mixed salts 30mg tablets. According to the report, 200 amphetamine mixed salts 30mg tablets were lost in transit on October 4, 2024 when an order received from a wholesale druggist "was found to be missing two bottles."
- However, MOR Chiodi admitted that Pharmacist "did not check-in the order in real time (driver left the building)" during a retail compliance inspection according to OPP Investigator Van Allen." Of note, MOR Chiodi indicated that the wholesale druggist who shipped the order to CVS 301 refused to issue a credit for the missing amphetamine. Lastly, MOR Chiodi did not submit any further evidence to support his contention that the drug was lost in transit.
- MOR Chiodi indicated that "the pharmacy will continue to follow CVS protocol when receiving controlled substance orders to ensure we receive all drugs that are on the receiving paperwork. If tampering is identified the pharmacist will refuse the order" as corrective action to mitigate recurrence of a similar incident.

<u>ACTION</u>: Motion by T. FENSKY, seconded by M. SCIARAFFA, and voted unanimously by those present, to REFER the matter (PHA-2024-0221), 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-2024-2785		
PHA-2024-0182	CVS #1234, DS3496	Time: 10:04 AM

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

<u>DISCUSSION</u>: J. TRIFONE presented and summarized the investigative report that pertained to this matter.

- During a retail compliance inspection on 09/04/2024, an investigator observed a PTT administering a vaccine.
- MOR Le indicated that once realized PTT Brown refrained from administering vaccines immediately.
- MOR Le indicated that he did not see the immunizer communications from corporate on the eligibility requirements for immunizers in 2023 when he became MOR. He did ask his staff of their interest in becoming an immunizer and a few technicians agreed including PTT Brown. Shortly after, he received an email from corporate which indicated that PTT Brown's immunizer status was "good to go" and thought it was an indication that she was qualified to become an immunizer. She proceeded to complete her immunization training and CPR certification in September of 2023.
- PTT Brown administered 719 vaccinations while licensed as a PTT. She was since licensed as a PT on 11/06/24.
- MOR Le indicated that he understands the immunizer requirements now and will evaluate the technicians to make sure they are appropriately licensed and complete the mandatory trainings to qualify them to immunize. He will also be more diligent in reviewing corporate communications and regulatory requirements and sharing that information with his team.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by M. SCIARAFFA, and voted unanimously by those present, to REFER the matter (PHA-2024-0182), 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 #14/ CASE-2024-2818 PHA-2024-0190 CVS #765, DS2910

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

<u>DISCUSSION</u>: J. TRIFONE presented and summarized the investigative report that pertained to this matter.

- During a retail compliance inspection conducted on 9/19/2024, the Investigator observed a Pharmacy Technician using a pharmacist's credentials to provide patient counseling and/or DUR. Specifically, PT Atkinson admitted to the Investigator that she entered Pharmacist Gaddis' credentials to resolve the DUR. Pharmacist Gaddis told the Investigator at the time of the inspection that she did not provide PT Atkinson with her credentials to complete the DUR on her own.
- Also, during the inspection, the investigator observed a total of 11 prefilled syringes containing vaccine, with needles attached, in the refrigerator with no expiration dates assigned.
- MOR Alhassany indicated that the team's overwhelming workload and pressure that came with the immunization season attributed to this incident.
- Pharmacist Gaddis indicated that early on Thursday morning, 09/19/2024, it was a very busy day during flu season. PT Atkinson was in the process of a transaction when a DUR stop occurred which required a pharmacist's credentials. She counseled the patient from afar and allowed her PT to enter in her credentials and proceed to help the next patient.
- PT Atkinson provided the same account as Pharmacist Gaddis.
- Both PT Atkinson and Pharmacist Gaddis indicated that they would not repeat this incident again.
- MOR re-educated his team so that only a Pharmacist can perform DURs and needles should only be attached to syringes prior to administration.

<u>ACTION</u>: Motion by F. LOMBARDO, seconded by T. FENSKY, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0190), No Discipline Warranted, Remediation Complete.

Case #15/ CASE-2024-2818		
PHA-2024-0191	Amy Gaddis, PH240910	Time: 10:10 AM

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

<u>DISCUSSION</u>: J. TRIFONE presented and summarized the investigative report that pertained to this matter.

- During a retail compliance inspection conducted on 9/19/2024, the Investigator observed a Pharmacy Technician using a pharmacist's credentials to provide patient counseling and/or DUR. Specifically, PT Atkinson admitted to the Investigator that she entered Pharmacist Gaddis' credentials to resolve the DUR. Pharmacist Gaddis told the Investigator at the time of the inspection that she did not provide PT Atkinson with her credentials to complete the DUR on her own.
- Also, during the inspection, the investigator observed a total of 11 prefilled syringes containing vaccine, with needles attached, in the refrigerator with no expiration dates assigned.
- MOR Alhassany indicated that the team's overwhelming workload and pressure that came with the immunization season attributed to this incident.

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- Pharmacist Gaddis indicated that early on Thursday morning, 09/19/2024, it was a very busy day during flu season. PT Atkinson was in the process of a transaction when a DUR stop occurred which required a pharmacist's credentials. She counseled the patient from afar and allowed her PT to enter in her credentials and proceed to help the next patient.
- PT Atkinson provided the same account as Pharmacist Gaddis.
- Both PT Atkinson and Pharmacist Gaddis indicated that they would not repeat this incident again.
- MOR re-educated his team so that only a Pharmacist can perform DURs and needles should only be attached to syringes prior to administration

<u>ACTION</u>: Motion by T. FENSKY, seconded by R.LOPEZ, and voted unanimously by those present, to REFER the matter (PHA-2024-0191), 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-2024-2818		
PHA-2024-0192	Natasha Atkinson, PT29355	Time: 10:11 AM

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

<u>DISCUSSION</u>: J. TRIFONE presented and summarized the investigative report that pertained to this matter.

- During a retail compliance inspection conducted on 9/19/2024, the Investigator observed a Pharmacy Technician using a pharmacist's credentials to provide patient counseling and/or DUR. Specifically, PT Atkinson admitted to the Investigator that she entered Pharmacist Gaddis' credentials to resolve the DUR. Pharmacist Gaddis told the Investigator at the time of the inspection that she did not provide PT Atkinson with her credentials to complete the DUR on her own.
- Also, during the inspection, the investigator observed a total of 11 prefilled syringes containing vaccine, with needles attached, in the refrigerator with no expiration dates assigned.
- MOR Alhassany indicated that the team's overwhelming workload and pressure that came with the immunization season attributed to this incident.
- Pharmacist Gaddis indicated that early on Thursday morning, 09/19/2024, it was a very busy day during flu season. PT Atkinson was in the process of a transaction when a DUR stop occurred which required a pharmacist's credentials. She counseled the patient from afar and allowed her PT to enter in her credentials and proceed to help the next patient.
- PT Atkinson provided the same account as Pharmacist Gaddis.
- Both PT Atkinson and Pharmacist Gaddis indicated that they would not repeat this incident again.
- MOR re-educated his team so that only a Pharmacist can perform DURs and needles should only be attached to syringes prior to administration

<u>ACTION</u>: Motion by T. FENSKY, seconded by F. LOMBARDO, and voted unanimously by those present, to REFER the matter (PHA-2024-0192), 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 IX:

Executive Session Call to Order:

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

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

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

Topic X:

65C Sessions MGL c. 112 section 65C

TIME: 09:56 AM

DISCUSSION: None

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

At 09:56 AM M. SCIARAFFA seconded by S. DINNO and voted unanimously by all those present to enter M.G.L. chapter 65 C Session by roll call vote.

Topic XI:

ADJOURMENT OF MEETING

TIME: 11:52 AM

ACTION: Motion by M. SCIARAFFA seconded by T. FENSKY and voted unanimously by those present, to adjourn the meeting by roll call vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. April 3, 2025, Agenda
- 2. March 6, 2025, Board Minutes
- 3. Licensure Policy 13-01 Report
- 4. Monthly Probation Report
- 5. BDR Licensure Report pursuant Policy 14-02
- 6. Research Drug Study Report Pursuant to Staff Action Policy 18-02
- 7. Policy 14-02: Board Delegated Review (BDR)
- 8. PAC recommendation document 25-01: Rapid Sterility Testing
- 9. Compounded Preparations from 503B Outsourcing Facilities memo
- 10. FDA memo regarding GLP-01
- 11. Policy 14-02: Board Delegated Review
- 12. Galaxy Pharmacy application for a new pharmacy
- 13. Jungle Jim's Pharmacy- New non-resident retail pharmacy application
- 14. Revive Rx Non-Resident Sterile Compounding new application
- 15. Manet Pharmacy-new retail pharmacy application

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Draft Minutes General Session: 4/3/25 BOP Approved: 5/1/25 TIME: 09:07 AM

- 16. PHA-2024-0177: Walgreens 3151
- 17. INV15716: Elsie Preval
- 18. PHA-2024-0244: Jerry May
- 19. INV13048: Walgreens 17925
- 20. PHA-2024-0183: Union Pharmacy
- 21. PHA-2024-0200: MyLyfe Specialty Pharmacy
- 22. PHA-2024-0202: Walgreens 10318
- 23. PHA-2024-0201: CVS 62
- 24. PHA-2024-0206: CVS 240
- 25. PHA-2024-0226: CVS 674
- 26. PHA-2024-0221: CVS 301
- 27. PHA-2024-0182: CVS 1234
- 28. PHA-2024-0190: CVS 765
- 29. PHA-2024-0192: Amy Gaddis
- 30. PHA-2024-0192: Natasha Atkinson