

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

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

**November 7, 2024**

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

**Join link:**

<https://eohhs.webex.com/eohhs/j.php?MTID=mc85fcb4613954ba47cc0c418824562cd>

**Webinar number:**

2536 274 8508

**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 **Erin Bartlett**, [erin.bartlett2@mass.gov](mailto:erin.bartlett2@mass.gov) or 857-262-7431 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.*

**Agenda**

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

8:20	V	<b>FLEX</b> <ul style="list-style-type: none"><li>• Implementation of new regulations</li><li>• Grace period for upcoming non-resident and compounding pharmacy licensure</li><li>• Waiver conversions to new regulatory citations</li><li>• Update on NABP District Meeting</li><li>• Nomination of Board Officers</li><li>• Pharmacy Advisory Committee Summary</li></ul>					
8:30	VI	<b>FILE REVIEW</b>					
		1	CASE-2024-2021	PHA-2024-0127	Walgreens #5755, DS1368		
		2	CASE-2024-2558	PHA-2024-0155	Walgreens #5755, DS1368		
		3	CASE-2024-1612	PHA-2024-0089	Radioisotope Life Sciences, NU00023		
		4	CASE-2024-1926	PHA-2024-0138	Radioisotope Life Sciences, NU00023		
		5	CASE-2024-2445	INV12775	Janice Cohen, PH17856		
		6	CASE-2024-2091	PHA-2024-0132	CVS #1868, DS3518		
9:15	VII	<b>EXECUTIVE SESSION</b> The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition, or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, evaluate the Good Moral Character as required for registration for a pending applicant.					
10:00	VIII	<b>M.G.L. c. 112, § 65C SESSION</b>					
12:00	IX	<b>ADJOURNMENT</b>					

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

**MINUTES OF THE GENERAL SESSION**

**Via Remote WebEx Meeting**

**November 7, 2024**

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**Board Members Present**

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

**Board Members Not Present**

Rita Morelli, PharmD, BCACP, RPh, Secretary  
Frank Lombardo  
Julie Dorgan, RN

**Board Staff Present**

Monica Botto, Associate Executive Director  
Jacqueline Petrillo, PharmD, RPh, JD, Board Counsel  
Michelle Chan, RPh, Quality Assurance Pharmacist  
Richard Harris, Program Analyst  
Joanna Chow, Program Analyst  
Taylor Lee, Office Support Specialist  
Joanne Trifone, RPh, Director of Investigations  
Gregory Melton, JD, PharmD, BCPS, Investigator  
Julienne Tran, RPh PharmD, Investigator  
Keith Johnstone, Compliance Officer

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**TOPIC I. Attendance by roll call:**

**CALL TO ORDER 8:01 AM**

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

Roll call attendance: S. Hamilton, yes; D. Barnes, yes; J. Rocchio, yes; K. Thornell, yes; S. Ahmed, yes; C. Belisle, yes; Saad Dino, yes; M. Sciaraffa, yes.

**Topic II.**

**Approval of Agenda**

**TIME 8:03 AM**

**Agenda: 11/7/2024**

**DISCUSSION:** Defer URAMP presentation and Optum Infusion Services application

**ACTION:**

Motion by M. Sciaraffa, seconded by D. Barnes and voted by those present to approve the agenda with S. Dino abstaining.

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**Topic III**

**Approval of Board Minutes**

**TIME: 8:04 AM**

**Minutes**

1. Draft 10/17/2024

**Change:** Correction: R. Morelli and J. Dorgan were not present

**Action:**

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

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**Topic IV.**

**REPORTS**

**Applications approved pursuant to Licensure Policy 13-01**

**TIME: 8:04 AM**

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris reported a total of 17 Change Pharmacist Manager of Record applications and 1 facility closure that have been approved by Staff Action since the last Board meeting.

So noted.

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**Topic IV.**

**REPORTS**

**Monthly Report from Probation**

**TIME: 8:04 AM**

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris indicated a total of 47 active probation cases, which included 3 licensees given the opportunity to cure and 1 issuance of final notice for discipline. There have been two successful completions of probation monitoring since the last Board meeting.

So noted.

**Topic IV.****REPORTS**

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**Monthly Report from BDCR pursuant to Policy 14-02****TIME: 8:05 AM**

PRESENTED BY: R. HARRIS

DISCUSSION: R. HARRIS disclosed that 2 Continuing Education discrepancies and one inspectional deficiency were reported since the last Board meeting. Additionally, one petition for waiver request has been received and approved.

So noted.

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**Topic IV.****REPORTS****PSUD report by Staff Action 17-03****TIME: 8:05 AM**

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris reported one application submission, one approval, and one admission to the PSUD program since the last Board meeting. Currently, there are 9 participants actively enrolled in the program.

So noted.

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**TOPIC V.****FLEX**

- **Implementation of new regulations**

**TIME: 8:06 AM**

**Presented by:** Michelle Chan

**Discussion:** M. CHAN presented how 247 CMR 6.00, 9.00, 15.00, and 20.00 are set to be finalized by the end of the year and the updated inspection tool will be on the website after that occurs. New regulatory updates include licensing of non-resident, compounding, and institutional sterile compounding pharmacies in 247 CMR 6.00, practice changes in 247 CMR 9.00, and reporting in 247 CMR 20.00.

So noted.

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**Topic V.****FLEX**

- **Grace period for upcoming non-resident and compounding pharmacy licensure**

**TIME: 8:06 AM**

**Presented by:** Michelle Chan

**Discussion:** Pending regulations regarding 247CMR 6, 9, 15, and 20 will be finalized by the end of the year.

- Inspection tool with updated citations and language with the work sheets will be provided on the BORP website once the regulations are finalized.
- These updates will include.
  - o Practice changes in 247 CMR 9
  - o A new reporting section in 247 CMR 20
  - o And licensing of nonresident pharmacies, compounding pharmacies, and institutional sterile compounding pharmacies in 247 CMR 6
- Upon promulgation of the new licensing regulations, the Board of registration in Pharmacy (BORP) staff propose a grace period to begin accepting applications as of January 1st, 2025 through March 21st, 2025 to insure timely licensure. After May 1st, 2025 all non-resident and compounding pharmacies must have current and appropriate licensure to dispense any prescription medications, including compounds, to ship into, within, or from the Commonwealth of Massachusetts.

**Action:** S. Hamilton made a motion to accept the proposed grace period as stated by BORP staff. Seconded by D. Barnes and voted unanimously by roll call to approve the motion.

**Topic V.**

**FLEX**

- **Waiver conversions to new regulatory citations**

**TIME: 8:06 AM**

**Presented by:** Michelle Chan

**Discussion:** With the promulgation of the new regs under 247 CMR 6 & 9, common waiver citations based on previous regulations will change. Licensee with these existing waivers will not have to change these citations until they apply for renewal waivers upon expiration.

**Action:** C. Belisle made a motion to recognize the currently issued waiver citation language as the equivalent of the forthcoming changes to the citation language until the time of waiver renewal. Seconded by S. Hamilton and voted unanimously by roll call to approve the motion.

**Topic V.**

**FLEX**

- **Update on NABP District Meeting**

**TIME: 8:09 AM**

**Presented by:** Sami Ahmed

**Discussion:**

- The National Association of Board Pharmacies (NABP) and American Association of Colleges of Pharmacy (AACP) held their annual meeting in Boston/Everett at the Encore Hotel & Casino 10/7 -10/9
- The Next annual meeting will be held in Ft. Lauderdale FL
- The next district 1 and 2 meeting will be held in Philadelphia, PE
- Sami Ahmed provided highlights of the event, noting that hosting of this event was a great success, in particular the ability to meet and dialogue with national colleagues.

So Noted.

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**Topic V.**

**FLEX**

- **Nomination of Board Officers**

**TIME: 8:15 AM**

**Presented by:**

**Discussion:**

- **Discussion: Delilah Barnes nominated Saad Dinno as President.** Seconded by Caryn Belisle and voted unanimously by roll call to nominate Saad Dinno as President.
- **Caryn Belisle nominated Mark Sciaraffa as President.** Seconded by Sami Ahmed and voted unanimously by roll call to nominate Mark Sciaraffa as President.
- **Delilah Barnes nominated Mark Sciaraffa as Secretary.** Seconded by Sebastian Hamilton and voted unanimously by roll call to nominate Mark Sciaraffa as Secretary
- **Caryn Belisle nominated John Rocchio as Secretary.** Seconded by Saad Dinno and voted unanimously by roll call to nominate John Rocchio as Secretary.

So noted.

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**Topic V.**

**FLEX**

- **Pharmacy Advisory Committee Summary**

**TIME: 8:21 AM**

**Presented by:** Sami Ahmed

**Discussion:**

- Met on 10/23/2024.
- W. Frisch started discussion about rapid sterility testing in compounding pharmacies.
  - o Noted that USP797 does not prohibit rapid sterility testing, rather, it requires validation as part of USP1223
- Further discussion was had in the applicability of rapid sterility testing measures and to be compliant with the application of rapid sterility testing, including the understanding of the limitation of rapid sterility testing.

So Noted.

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**TOPIC VI****FILE REVIEW**

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Case #1 /CASE-2024-2021

PHA-2024-0127

Walgreens #5755, DS1368

Time: 08:25 AM

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

- Loss of #60 amphetamine salt combo 10mg tablets attributed to an unknown loss discovered on or about 06/10/2024.
- MOR Hariz noted that the loss was discovered during the weekly bin reconciliation. The prescription was placed in the ready bin but was not found there. The patient was called but noted that he never picked it up.
- They were unable to check the video footage of the ready bin since the prescription was on the delete list for 5 days and no one notified the MOR or the staff pharmacist.
- MOR Hariz indicated that they would review standing operating procedures (SOPs) with all team members on how to file bags properly in the correct bins and how to ring out patients at the register. Spot checks the ready BINs every now and then to check that all Schedule II ready prescriptions are still there and reinforce security measures with the team.

ACTION: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by those present, to consolidate the matter (PHA-2024-0127) with PHA-2024-0155. A second motion was made by C. BELISLE, seconded by D. BARNES, to refer the consolidated 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.

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Case #2/CASE-2024-2558

PHA-2024-0155

Walgreens #5755, DS1368

Time: 08:26 AM

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

- Failure to timely submit final loss report of #60 amphetamine salt combo 10mg tablets attributed to an unknown loss discovered on or about 06/10/2024.
- Interim MOR Agyiri noted that they were not the MOR at the time of the loss. It was noted that former MOR Hariz who is on leave forgot to submit the appendix on time.
- Interim MOR Agyiri indicated that they are aware of the requirements and will ensure all the appropriate steps will be followed moving forward.

ACTION: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by those present, to consolidate the matter (PHA-2024-0155) with PHA-2024-0127. A second motion was made by C. BELISLE, seconded by D. BARNES, to refer the consolidated 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.

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RECUSAL: NONE

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

- During a USP <825> Nuclear Compliance inspection conducted on 4/12/2024, Board Investigators noted that the licensee failed to report an Above Action Level (AAL) event to the BORP and also had unlicensed staff working to clean the interior ISO 5 PEC.
- The Pharmacy had a cumulative count of 9 CFUs in the ISO 7 positive area, surface sample during their semi-annual recertification EM.
- MOR Mah indicated that the failure to report of the AAL to the Board was due to a misinterpretation and incorrect facility implementation of BORP Policy 2023-09. However, he was educated on the cumulative counts from the investigators during the inspection.
- In regard to the unlicensed employee, MOR Mah noted that the root cause of this event was the result of high personnel turnover, staffing shortages, and the critical timing required to prepare and deliver radiopharmaceuticals. However, he noted that the employee, Mr. Perez completed the general cleaning and disinfecting duties including the outside of the ISO 5 PECs, walls, floors, and ceilings and noted that he did not clean the ISO classified areas independently.
- MOR Mah noted that the Pharmacy will continue to perform in-house monthly EM utilizing their updated EM record, trend the appropriate results and disclose above action level (AAL) EM results accordingly.
- Effective 05/14/2024, they have implemented local corrective actions to include an updated internal EM form requiring the cumulative totals in each ISO classified environment to be recorded at the time of EM results documentation. He submitted a signed attestation to having reviewed Policy 2023-09 and trained the employees on the new procedures.

ACTION: Motion by S. AHMED, seconded by D. BARNES, and voted unanimously by those present, to consolidate the matter (PHA-2024-0089) with PHA-2024-0138. A second motion was made by D. BARNES, seconded by C. BELISLE, to refer the consolidated 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 #4

/CASE-2024-1926

RECUSAL: NONE

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

- On 5/30/2024, the Pharmacy disclosed above action level results identified in their ISO 5 PEC including 1 CFU of Aspergillus sp. and 1 CFU of Pseudomonas sp. The Pharmacy ceased compounding within the affected PEC, as required. INV11747 was opened to further investigate Pharmacy actions and confirm adherence to policy 2023-09.

- Pharmacy actions taken included initiating an investigation utilizing internal procedures and documentation including RCA and CAPA, conducting a triple clean of the PEC with a sporicidal agent, and resampling the work surface of the PEC to verify effectiveness.
- Further review of the pharmacy's remediation plan and corrective actions identified that they were non-adherent to BORP policy 2023-09 due to undisclosed organisms observed within their other ISO classified spaces (*Alternaria* sp and *Candida* sp.) which would require repeat sampling.
- On 07/10/2024, the Pharmacy acknowledged the omitted fungal isolates. The Pharmacy provided an amended disclosure form but required remediation was not conducted.
- On 07/17/2024, Board Staff voted to elevate the investigation to a complaint against the pharmacy license for non-adherence to Board Policy 2023-09.
- On 09/10/2024. The Investigator review of the provided documentation showed that resampling of all air and surface monitoring locations was conducted by Pharmacy staff on 07/16/2024 and did not identify any growth. Additional routine surface sampling was conducted on 08/16/2024 with no growth identified.
- Pharmacy corrective actions included updates to internal procedures for environmental monitoring to ensure adherence to BORP Policy 2023-09 including cumulative count of identified organisms and staff attestations that they understood the contents and requirements of the policy. Additional updates to procedures were made on 09/13/2024 to identify all growth to confirm presence of highly pathogenic organisms such as gram-negative rods, fungal isolates and coagulase positive staphylococcus as samples are reviewed by Pharmacy employees rather than in association with a qualified microbiology professional.

**ACTION:** Motion by S. AHMED, seconded by D. BARNES, and voted unanimously by those present, to consolidate the matter (PHA-2024-00138) with PHA-2024-0089. A second motion was made by D. BARNES, seconded by C. BELISLE, to refer the consolidated 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.

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Case #5/CASE-2023-2445  
INV12775

Janice Cohen, PH17856

Time: 08:36 AM

**RECUSAL:** NONE

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

- On August 3, 2024, Pharmacist Cohen reported to BORP that she was unable to complete annual CE for 2023. Pharmacist Cohen later indicated that she was required to complete topic specific CE in sterile compounding and complex non-sterile compounding during 2021, 2022, and 2023. Consequently, Pharmacist Cohen was deficient 25 contact hours including 5 contact hours in live format, 6 contact hours in sterile compounding, and 5 contact hours in non-sterile compounding from 2021 through 2023.
- Pharmacist Cohen wrote, "My explanation for the reason I was deficient in ceu's is that the past couple of years I've had a lot going on in my life and I lost track of my completing my ce requirements. I sincerely apologize, Please do not suspend my license to practice." In addition, Pharmacist Cohen remediated her CE deficiencies on a 1:1 basis in 2024 and acknowledged that remedial CE cannot be

used to satisfy any other CE requirements including 2024 annual requirements. Of note, Pharmacist Cohen previously failed to complete annual CE requirements during 2015.

ACTION: Motion by S. HAMILTON, seconded by R. LOPEZ, and voted unanimously by those present, to elevate the matter (INV12775), to a complaint.

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Case #6/ CASE-2024-2091  
PHA-2024-0132

CVS #1868, DS3518

Time: 08:39 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 06/26/2024, medication and immunization supplies were observed stored in unlicensed space.
- MOR Brosco indicated that all the stored products in that area have been removed.
- She noted that going forward all supplies will be kept in the Pharmacy and brought to the immunization room when needed to administer immunizations.

ACTION: Motion by S. AHMED, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0132), 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.

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**Topic VII:** **Executive Session Call to Order:** **Time: 8:42 AM**

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

**Action:** Motion by M. SCIARAFFA, seconded by S. HAMILTON, voted unanimously by roll call to enter executive session #1.

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

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**Topic VIII:** **65C Sessions MGL c. 112 section 65C** **Time: 9:22 AM**

DISCUSSION: None

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

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

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**Topic IX:** **ADJOURNMENT OF MEETING** **TIME: 9:53 AM**

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

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EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 11/7/2024 General Session
2. Draft Minutes of the 10/17/2024 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Monthly Report from Probation
5. Report on Board Delegated Complaint Review to licensure policy 14-02
6. Report on PSUD 17-03
7. Memorandum on non-resident and compounding pharmacy licensure
8. Memorandum on waiver conversions to new regulatory citations
9. PHA-2024-0127 Walgreens #5755, DS1368
10. PHA-2024-0155 Walgreens #5755, DS1368
11. PHA-2024-0089 Radioisotope Life Sciences, NU00023
12. PHA-2024-0138 Radioisotope Life Sciences, NU00023
13. INV12775 Janice Cohen, PH17856
14. PHA-2024-0132 CVS #1868, DS3518