

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

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

December 5, 2024

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

Join link:

<https://eohhs.webex.com/eohhs/j.php?MTID=m730fld57b4a496e568f7fc93c00794f9>

Webinar number:

2530 971 5628

Webinar password:

BOP123 (267124 from phones and video systems)

Join by phone:

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

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*If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator **Erin Bartlett**, erin.bartlett2@mass.gov or 857-262-7431 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.*

Agenda

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

8:20	V	FLEX <ul style="list-style-type: none">Election of Board Officers<ul style="list-style-type: none">President: Saad Dino, Mark SciaraffaSecretary: Mark Sciaraffa, John RocchioImplementation of new regulations					
8:45	VI	RECONSIDERATIONS <ul style="list-style-type: none">Walgreens 3016- PHA-2022-0047Walgreens 17230- PHA-2021-0119Walgreens 19067- PHA-2022-0073Walgreens 3112- PHA-2021-0111/PHA-2020-0114					
9:00	VII	FILE REVIEW					
		1	CASE-2024-2307	PHA-2024-0145	Carie Boyd Pharmaceuticals, NO00011		
		2	CASE-2024-1667	PHA-2024-0149	Christina Iepure, PH233720		
		3	CASE-2024-2316	PHA-2024-0150	Cardinal Health 414, LLC		
		4	CASE-2024-1609	PHA-2024-0137	CVS #1035, DS1610		
		5	CASE-2024-2137	PHA-2024-0136	CVS #507, DS89841		
9:30	VIII	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 review a request for termination of stayed probation status, consideration of a license reinstatement and to evaluate the Good Moral Character as required for registration for a pending applicant.					
10:00	IX	M.G.L. c. 112, § 65C SESSION					
12:00	X	ADJOURNMENT					

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

December 5, 2024

Board Members Present

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

Board Members Not Present

Saad Dinno, RPh, FACP/FACA

Board Staff Present

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

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:00 AM

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

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

Topic II.

Approval of Agenda

TIME 8:01 AM

Agenda: 12/5/24

DISCUSSION: Move Walgreens Reconsiderations to 65C.

ACTION: Motion by D. Barnes, seconded by M. Sciaraffa and voted unanimously by those present to approve the agenda with the noted change by roll call vote. R. Morelli abstained.

Topic III

Approval of Board Minutes

TIME: 8:02 AM

Minutes

1. Draft 11/7/24

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

Action: Motion by S. Hamilton seconded S. Ahmed and voted to approve the regular session minutes of 11/7/2024 with the noted changes by roll call vote. Abstained: R. Morelli, F. Lombardo, J. Dorgan.

TOIC IV

REPORTS

Applications approved pursuant to Licensure Policy 13-01

TIME: 8:03 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris reported a total of 35 Change Pharmacist Manager of Record applications and 3 facility closures that have been approved by Staff Action since the last Board meeting.

So noted.

Topic IV.

REPORTS

Monthly Report from Probation

TIME: 8:04 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris reported a total of 48 active probation cases, which included 1 licensee that was given the opportunity to cure and 4 successful completions of probation monitoring since the last Board meeting.

So noted.

Topic IV.**REPORTS****Monthly Report from BDCR pursuant to Policy 14-02****TIME: 8:04 AM**

PRESENTED BY: R. HARRIS

DISCUSSION: R. HARRIS indicated a total of 4 CE deficiencies that have been reported, 1 case that was issued a reprimand for inspectional deficiencies, 1 issuance of disciplinary stayed probation for controlled substance loss, 1 CS loss resulting in a reprimand, and 1 waiver approval since the last Board meeting.

So noted.

Topic IV.**REPORTS****PSUD report by Staff Action 17-03****TIME: 8:04 AM**

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris noted several actions within the PSUD program since the last meeting, consisting of 1 inquiry to the PSUD program, 1 mailed application, 1 returned application, and 1 application that was not returned. Additionally, 1 change to the rehab plan with the Substance Abuse Program has been noted since the last Board meeting.

So noted.

TOPIC V**FLEX****1. K. THORNELL was thanked for her exemplary service as president in 2024.****TIME: 8:07 AM**

2. Election of Board Officers**TIME: 8:09 AM**

Presented by: K. THORNELL

Discussion: The final vote for Board officers for 2025 was held.

Action: Vote by roll call by the majority of those present for S. DINNO to be President-Elect for 2025.

Action: Vote by roll call by the majority of those present for M. SCIARAFFA to be Secretary for 2025.

TOPIC V**FLEX****3. Implementation of new regulations****TIME: 8:13 AM****Presented by:** M. CHAN

Discussion: Regulations at 247 CMR 6, 9, 15, and 20 will be promulgated tomorrow, December 6th meaning that they will be final and in effect.

These updates include practice changes in 247 CMR 9.00, a new reporting section at 247 CMR 20.00, and the licensing of non-resident pharmacies, compounding pharmacies, and institutional sterile compounding pharmacies in 247 CMR 6.00.

As the Board voted last month, applications for the new license types will begin to be accepted as of January 1st, 2025. Information has been distributed through several channels to our current licensees as well as to the institutions and non-resident pharmacies. Licensing information can be found on the Board's homepage under Recent news & announcements.

So noted.

TOPIC VI**RECONSIDERATIONS**

- **Walgreens 3016- PHA-2022-0047**

TIME: N/A**Presented by:****Recusal:****Discussion:**

Deferred to 65C

TOPIC VI.**RECONSIDERATIONS**

- **Walgreens 17230- PHA-2021-0119**

TIME: N/A**Presented by:****Discussion:**

Deferred to 65C

TOPIC VI.**RECONSIDERATIONS**

- Walgreens 19067- PHA-2022-0073

TIME: N/A

Presented by:

Recusal:

Discussion:

Deferred to 65C

TOPIC VI.**RECONSIDERATIONS**

- Walgreens 3112- PHA-2021-0111/PHA-2020-0114

TIME: N/A

Presented by:

Recusal:

Discussion:

Deferred to 65C

TOPIC VII**FILE REVIEW**

Case #1/2024-2307

PHA-2024-0145

Carie Boyd Pharmaceuticals. NO00011

Time: 08:14 AM

RECUSAL: NONE

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

- During July 2024, BORP was notified by NABP's Clearinghouse that Carie Boyd was disciplined by the Ohio Board of Pharmacy (OH BOP). Specifically, Carie Boyd entered into a settlement agreement for discipline with OH BOP effective June 25, 2024 to resolve allegations that the facility sold dangerous drugs, including controlled substances, on June 15, 2023 and June 21, 2023 to an unlicensed entity. Carie Boyd agreed to accept a written reprimand from OH BOP and pay a \$250.00 fine to resolve the matter. Carie Boyd then failed to notify BORP about the OH BOP discipline within 14 days.
- Carie Boyd acknowledged failing to report the OH BOP discipline because the facility was not aware of the requirement. Carie Boyd then disclosed that the facility also failed to report an FDA inspection between May 26, 2024 and June 21, 2024 which resulted in the issuance of a Form 483 on June 21, 2024 for the same reason.
- CA: 247 CMR 21.09 was added to Carie Boyd's reporting policy

ACTION: Motion by S. AHMED, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0145), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #2/CASE-2024-1667

PHA-2024-0149

Cristina Iepure, PH233720

Time: 08:17 AM

RECUSAL: NONE

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

- Cristina Iepure was MOR of Remedium Pharmacy when the pharmacy was cited for inspectional deficiencies for permitting PTT to practice after their license expired during separate retail compliance inspections on April 22, 2024 and July 20, 2022.
- CA: MOR Iepure indicated that she revised Remedium's existing standard operating procedure for staff licensure and provided a copy for reference. Next, MOR Iepure indicated that she enrolled in Pharmacy Audit Assistance Service National's PAAS Vault used to track employee licenses to assist in monitoring license status of pharmacy staff going forward. Lastly, MOR Iepure indicated that the PTT with the expired license during the April 22, 2024 inspection was terminated from employment on July 12, 2024.

ACTION: Motion by C. BELISLE, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2024-0149), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #3/CASE-2024-2316

PHA-2024-0150

Cardinal Health 414, NU11

Time: 08:19 AM

RECUSAL: NONE

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

- On July 26, 2024, Investigator Allen discovered during an NCI that Cardinal 414 failed to report an ongoing temperature excursion from May 17, 2024 to June 19, 2024 due to a malfunctioning HVAC system. Cardinal explained that BUDs were reduced to 12 hours, no blood labeling products were prepared, HVAC ultimately was repaired. According to temp logs, temps reached max of 27.5°C during the affected period. Temperatures normalized after HVAC was repaired.
- MOR argued that "BORP Policy 2023-09 defines action level environmental monitoring results as non-viable air as well as viable air and surface meeting or exceeding the criteria outlined in the policy. None of these describe the temperature of ISO classified areas." MOR next argued that BORP Policy 2023-09 Section 1 "directs pharmacists to notify the Board by using the 'Action Level Environmental Monitoring Results reporting form.' The currently posted version of this form (Revised 10/27/23) does not include a field noting a temperature excursion."

ACTION: Motion by R. LOPEZ, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2024-0150), 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-2024-1609

PHA-2024-0137

CVS #1035, DS1610

Time: 08:21 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.

- On March 28, 2024, CVS 1035 submitted a final report of loss of a manufacturer stock bottle which contained 500 lorazepam 0.5mg tablets during transit on March 19, 2024. CVS 1035 indicated that the drug was expected in a delivery received on March 18, 2024 but was not found in the tote. However, CVS 1035's "check-in delivery" details documented that the lorazepam was received. Furthermore, the wholesale druggist did not have any discrepancies.
- CVS 1035's internal investigation included a search of pharmacy and review of surveillance video which did not reveal "anything out of the ordinary."
- CA: 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."

ACTION: Motion by D. BARNES, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0137), 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-2024-2137

PHA-2024-0136

CVS #507, DS89841

Time: 08:24 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.

- Loss of #211 alprazolam 2mg tablets discovered on 06/22/2023 but was not reported to BORP by the Pharmacy. DEA discovered the unreported loss during a DEA audit and notified BORP on 06/26/2024.
- The loss was first discovered on CVS' prescription drug monitoring report.
- Upon review of video footage, it was observed that the pharmacist filled a prescription and placed the stock bottle in the trash instead of the shelf. The end of the day trash activities did not show suspicious activity. As a result, the loss was determined to be an accidental disposal of the medication.
- In response to this complaint, CVS Regulatory Affairs wrote that after further review of the Alprazolam 2mg loss (#211 tablets) loss, it was deemed as an insignificant loss and not reported.

ACTION: Motion by C. BELISLE, seconded by D. BARNES, and voted unanimously by those present, to consolidate the matter (PHA-2024-0136) with PHA-2024-0002. A second motion was made by C. BELISLE, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter, to the

Topic VIII:

Executive Session Call to Order:

TIME: 8:29 AM

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

ACTION: Motion by R. MORELLI, seconded by J. DORGAN, 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; R. Morelli, yes; J. Dorgan, yes; F. Lombardo, yes.

Topic IX:

65C Sessions MGL c. 112 section 65C

TIME: 10:27 AM

DISCUSSION: None

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

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

Topic X:

ADJOURNMENT OF MEETING

TIME: 11:46 AM

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

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 12/5/2024 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. PHA-2024-0145; Carie Boyd Pharmaceuticals NO00011
8. PHA-2024-0149; Christina Iepure PH233720
9. PHA-2024-0150; Cardinal Health 414, LLC
10. PHA-2024-0137; CVS 1035, DS1610
11. PHA-2024-0136; CVS #507; DS89841