COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE BOARD OF REGISTRATION IN PHARMACY January 9, 2025

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

Join link:

https://eohhs.webex.com/eohhs/j.php?MTID=me244cf00d603c2f90beb44353e6a18ad

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 Erin Bartlett, <u>erin.bartlett2@mass.gov</u> 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.

		Item	Page	
8:00	Ι	CALL TO ORDER		S. Ahmed
8:05	II	APPROVAL OF AGENDA		
8:10	III	 APPROVAL OF BOARD MINUTES Draft of December 5, 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 PSUD Report-Policy 17-03 Research Drug Study report pursuant to Staff Action Policy 18-02 		

Agenda

8:20	V	 FLEX Board Staff Update Implementation of new regulations Open Meeting Law, Conflict of Interest, and other reminders for BHPL Board meetings Continuity of Care Guidance for Institutional Sterile Compounding Pharmacies Approval and Authorize the URAMP Operational Plan 	J. Petrillo
9:00	VI	 POLICIES URAMP Operational Policy 24-07 Staff Action Policy Final Draft Rescind Staff Action Policy 17 – 03: Staff Action Policy for Implementation of PSUD Policy 14-02: Board Delegated Review (BDR) Policy 13-01: Licensure Applications and Notices Rescind Policy 16-01: Applications pertaining to Outsourcing Facilities Policy 2023-07: Non-Sterile Compounding Policy 2021-03: License Reinstatement Following Surrender, Suspension, or Revocation Policy 2021-02: Shared Pharmacy Service Models Including Central Fill, Remote Processing, and Telepharmacy Policy 2019-07: Pilot Projects in Pharmacy Practice Policy 2019-02: Automated Dispensing Device Use 	M. Chan
9:30	VII	EMERGENCY AMENDMENTS TO REGULATIONS TOIMPLEMENT SHIELD LAW• 247 CMR 3.00: Pharmacist Licensure Requirements• 247 CMR 6.00: Licensure of Pharmacies• 247 CMR 8.00: Pharmacy Interns and Technicians• 247 CMR 10.00: Disciplinary Proceedings	L. Nelson

3:00	XIV	ADJOURNMENT		
12:45	XIII	M.G.L. c. 112, § 65C SESSION		
12:30	XII	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)		
12:00		LUNCH BREAK		
11:30	XI	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 consider a license reinstatement and to evaluate the Good Moral Character as required for registration for a pending applicant.		
			024-0180 CVS #498, DS3349 024-0181 Catie Zaher El Nabbout, PH233279	
			024-0140 CVS #735, DS2841 024-0180 CVS #498, DS3349	
		5 CASE-2024-2555 PHA-20	024-0156 Long Term Pharmacy Solutions, DS90330	
10:45	X	4 CASE-2024-1739 PHA-20	024-0198 Jennifer Czajka, PH241273	
		3 CASE-2024-2498 PHA-20	DS3503 024-0162 Ellen Sanches, PT26710	
		2 CASE-2024-2498 PHA-20	024-0161 Walgreens #10268,	
		1 CASE-2024-2373 PHA-20	024-0152 Jubilant Radiopharma, NU00022	
		FILE REVIEW		
10:30	IX	CDTM EDUCATIONAL EQU Patricia Ramos-Lazo, PH239 	M. Chan	
		Medication Delivery and Shipping		
10:00	VIII	 Information for Managers of 		
		ADVISORIESBest Practice Recommendation	M. Chan	

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting January 9, 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 Sebastian Hamilton, Pharm D, MBA, RPh Dr. Richard Lopez, MD Rita Morelli, PharmD, BCACP, RPh Julie Dorgan, RN Frank Lombardo

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 Julienne Tran, RPh PharmD, Investigator Keith Johnstone, Compliance Officer David Sencabaugh

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:01 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: Saad Dinno, yes; M. Sciaraffa, yes; C. Belisle, yes; S. Hamilton, yes; D. Barnes; J. Rocchio, yes; R. Lopez, yes; R. Morelli, yes; J. Dorgan, yes; F. Lombardo, yes; K. Thornell, yes; S. Ahmed, yes.

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Draft Minutes General Session: 1/9/25 BOP Approved: 2/6/25 Board Members Not Present Delilah Barnes, RPh Topic II.

Approval of Agenda

TIME 8:04 AM

Agenda: 1/9/25

DISCUSSION: Defer Policy 2021-02: Shared Pharmacy Service Models Including Central Fill, Remote Processing, and Telepharmacy.

ACTION:

Motion by K. Thornell seconded by S. Hamilton and voted unanimously by those present to approve the agenda with the noted change by roll call vote. S. Dinno abstained.

Topic III

Approval of Board Minutes

TIME: 8:04 AM

Minutes

1. Draft 12/5/24

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

Action:

Motion by R. Morelli seconded S. Hamilton and voted to approve the regular session minutes of 12/5/24 with the noted changes by roll call vote. S. Dinno abstained.

ΤΟΙC ΙV

REPORTS

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: R. HARRIS

<u>DISCUSSION</u>: R. Harris reported a total of 38 Change Pharmacist Manager of Record applications and 1 facility closure that have been approved by Staff Action since the last Board meeting.

So noted.

Topic IV.

REPORTS

Monthly Report from Probation

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris indicated no new reports since the last Board meeting.

So noted.

TIME: 8:05 AM

TIME: 8:05 AM

Topic IV.

REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris disclosed that a total of 4 Continuing Education deficiencies were reported since the last meeting, each closed with no discipline warranted. One instance of controlled substance loss was reported and issued a reprimand. One waiver renewal was approved for DS90059 Village Fertility Pharmacy, LLC.

So noted.

Topic IV.

REPORTS

PSUD report by Staff Action 17-03

PRESENTED BY: E. TAGLIERI

DISCUSSION: E. Taglieri indicated a total of 8 participants are actively enrolled in the PSUD program. As of the last report, there have been 3 admissions to the program, 2 discharges, and 1 pending admission. On 12/16/2024, final approval from the Commissioner was granted to launch URAMP, which would allow 21 boards to admit participants. This concludes the last report from PSUD. Quarterly reports will follow from URAMP.

So noted.

Topic IV. REPORTS Research Drug Study report pursuant to Staff Action Policy 18-02

PRESENTED BY: M. CHAN

DISCUSSION: M. Chan reported 3 pharmacies currently participating in drug studies. In total, there are 12 active studies involving commercially available drugs and 5 involving investigational drugs. There have been no new studies since the last report.

So noted.

TOPIC V

1. Board Staff Update

Presented by:

Discussion:

TIME: 8:05 AM

TIME: 8:07 AM

TIME: 8:08 AM

TIME: 8:06 AM

FLEX

Action:

2. Implementation of new regulations

Presented by: Michelle Chan

Discussion: 247 CMR 6, 9, 15, and 20 have been finalized as of 12/6/2024. Section 5 and Section 12 have been rescinded. These new regulatory updates include:

- 247 CMR 6
 - o the licensing of non-resident compounders and institutional sterile compounders
- 247 CMR 9
 - o Practice changes
- 247 CMR 20
 - o Reporting

We began accepting license applications for newly implemented licenses 1.1.2025

So noted.

3. Open Meeting Law, Conflict of Interest, and other reminders for BHPL Board meetings

TIME: 8:11 AM

Presented by: J. Petrillo

Discussion: • Would like to review and discuss this law with Board staff and members.

- Reminders regarding open meeting law.
- o A meeting is considered a deliberation (oral or written),
- o If you are emailing, it is important to not reply all as this may implicate open meeting law
- Conflict of Interest
- o As Board members you are "special employee"

The purpose of conflict of interest law is to prevent the occurrence or appearance of a conflict of ineterest

Board counsel then provided examples of potential conflicts of interest which Board members should avoid.

o If you are found to be in conflict with the conflict of interest law, you can be fined 10,000 dollars.

o If you ever have any questions on this please ask Board Counsel

o If a member knows that a case will be a Conflict of interest, please notify board staff. Ideally this would be done prior to the matter being discussed, but if a matter is being discussed and you realize midway that you have a conflict of interest. Please stop everything and announce this conflict.

So noted.

4. Continuity of Care Guidance for Institutional Sterile Compounding Pharmacies TIME: 8:10 AM

Presented by: Michelle Chan

Discussion: This is a guidance document regarding the use of sterile compounding when one area of the facility is closed, while the other is open to use. This is an informational document, so no vote is needed.

So noted.

5. Approval and Authorize the URAMP Operational Plan

TIME: 8:21 AM

Presented by: Edmund Taglieri, Mark Waksmonski

Discussion: Introduced Mark Waksmonski as the director of URAMP, who provided their background of working in the mental health and medical field.

Currently, PSUD operates under an operationally policy. URAMP would work under a different Operational policy and this request is to ask the Boards to accept and implement URAMP for the BORP.

Action: A motion by S. Hamilton was made to request authorization and approval of URAMP operational policy 24-07; Seconded by M. Sciaraffa and voted unanimously by roll call to approve the motion.

Action: A motion by S. Hamilton was made to rescind operational policy 17-03; seconded by R. Lopez and voted unanimously by roll call to approve the motion.

TOPIC VI

POLICIES

URAMP Operational Policy 24-07 Staff Action Policy Final Draft

TIME: 8:25 AM

Presented by: E. TAGLIERI

Discussion: Allows staff to admit out-of-state licensees. Program is designed for 5 years, but participants may request to graduate at 3 years.

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

Rescind Staff Action Policy 17-03: Staff Action Policy for Implementation of PSUD

TIME: 8:28 AM

Presented by: E. TAGLIERI

Discussion: The URAMP staff action policy replaces the PSUD staff action policy.

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Action: Motion by S. HAMILTON, seconded by R. LOPEZ, and voted unanimously by roll call of those present, to rescind policy 17-03.

Policy 14-02: Board Delegated Review (BDR)

TIME: 8:28 AM

Presented by: M. CHAN

Discussion: Edits were made to allow the group to issue reprimands for reporting non-compliance as well as replace the list of approvable waiver citations with the ones from the new regulations. Proposed edits under New Petitions for Waiver, #4 has an incorrect citation and will be deleted and the citation for #6 will be corrected to 247 CMR 9.19 (14).

Action: Motion by S. HAMILTON, seconded by J. DORGAN, and voted by the majority of those present, to approve edits to the policy. J. ROCCHIO voted against the changes.

Policy 13-01: Licensure Applications and Notices

Presented by: M. CHAN

Discussion: Allows for staff approval of central fill pharmacy petitions and incorporates outsourcer approval conditions from Policy 16-01. Also proposed were edits to the non-resident inspection requirements for staff approval to having evidence of an inspection within the previous 2 years for retail pharmacies and a satisfactory Board inspection within the previous year for compounders.

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

Policy 16-01: Applications Pertaining to Outsourcing Facilities

Presented by: M. CHAN

Discussion: Now that the outsourcing facility requirements have been added to policy 13-01, this policy can be rescinded.

Action: Motion by R. MORELLI, seconded by K. THORNELL, and voted unanimously by roll call of those present, to rescind policy 16-01.

Policy 2023-07: Non-Sterile Compounding

Presented by: M. CHAN

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TIME: 8:31 AM

TIME: 8:33 AM

TIME: 8:34 AM

Discussion: Edits clarify that the pharmacist must evaluate each prescription for a compound to ensure adherence with evidence-based practice. Also added was a reference to the statutory language requiring the prescriber to document the medical need for a compounded preparation.

Action: Motion by S. HAMILTON, seconded by C. BELISLE, and voted by the majority of those present, to approve edits to the policy. J. ROCCHIO and S. DINNO voted against the changes.

Policy 2023-01: Compliance Packaging and Reusable Dose Planners

TIME: 8:36 AM

Presented by: M. CHAN

Discussion: Edits make it clear that policies and procedures must address drug accountability when using compliance packaging, such as when federally controlled substances are removed due to a therapy change.

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

Policy 2021-03: License Reinstatement Following Surrender, Suspension, or Revocation

TIME: 8:37 AM

Presented by: M. CHAN

Discussion: Clarifies that at least 5 years must elapse before reinstatement will be considered and outlines criteria that they Board may consider as part of their review.

Action: Motion by R. MORELLI, seconded by M. SCIARAFFA, and voted unanimously by roll call of those present, to approve edits to the policy.

Policy 2021-02: Shared Pharmacy Service Models Including Central Fill, Remote Processing, and Telepharmacy

DEFERRED

Policy 2019-07: Pilot Projects in Pharmacy Practice

TIME: 8:39 AM

Presented by: M. CHAN

Discussion: Adds requirement for performance metrics to be collected during the pilot.

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

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Policy 2019-02: Automated Dispensing Device Use

Presented by: M. CHAN

Discussion: Clarifies non-resident pharmacy responsibilities and licensure of individuals who may access the machines.

Action: Motion by S. HAMILTON, seconded by R. MORELLI, and voted by the majority of those present, to approve edits to the policy. J. ROCCHIO voted against the changes.

TOPIC VII EMERGENCY AMENDMENTS TO REGULATIONS TO IMPLEMENT SHIELD LAW

TIME: 9:19 AM

- 247 CMR 3.00: Pharmacist Licensure Requirements
- 247 CMR 6.00: Licensure of Pharmacies
- 247 CMR 8.00: Pharmacy Interns and Technicians
- 247 CMR 10.00: Disciplinary Proceedings

Presented by: Lauren Nelson

Discussion: These proposed emergency amendments are to implement and codify the regulations per "An act expanding protections for reproductive and gender affirming care (aka the Shield Law). The statues protect pharmacists, pharmacies, technicians, and inters from disqualification from licensure, and from Board discipline, on the basis of providing, or assisting in providing, reproductive health care services and gender affirming health care services if the services provided would be lawful and consistent with food professional practice in Massachusetts.

247 CMR 3, 6, and 8, would include an additional provision which explains "legally protected Health Care Activity" for each of these license types.

247 CMR 10 includes provision which explains that the provision of reproductive health and gender affirming care, would not be basis for discipline should the practice be considered good care in Massachusetts,

These regulations would follow the process of the emergency regulations procedures and would need to be completed within 90 days.

Does this protect an individual practitioner from being extradited to another state? The Shield law does protect against extradition. These particular regulations do not discuss extradition because it is not in the purview for the BORPs regulations.

Action: A motion by S. Hamilton was made to file the emergency amendments to 247 CMR 3 with the Massachusetts Secretary of State's Office and proceed to a public comment period; seconded by R. Lopez and voted unanimously by roll call to approve the motion

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Draft Minutes General Session: 1/9/25 BOP Approved: 2/6/25 TIME: 8:40 AM

Action: A motion by C. Belisle was made to file the emergency amendments to 247 CMR 6 with the Massachusetts Secretary of State's Office and proceed to a public comment period; seconded by K. Thornell and voted unanimously by roll call to approve the motion

Action: A motion by C. Belisle was made to file the emergency amendments to 247 CMR 8 with the Massachusetts Secretary of State's Office and proceed to a public comment period; seconded by R. Lopez and voted unanimously by roll call to approve the motion

Action: A motion by C. Belisle was made to file the emergency amendments to 247 CMR 10 with the Massachusetts Secretary of State's Office and proceed to a public comment period; seconded by K. Thornell and voted unanimously by roll call to approve the motion

ADVISORIES

TOPIC VIII

Best Practice Recommendations

Presented by: M. CHAN

Discussion: This document was overhauled and updated to include new regulatory citations.

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

Information for Managers of Record

Presented by: M. CHAN

Discussion: The previous document contained general pharmacy practice guidance that has been removed to focus on just the MOR's responsibilities.

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

Medication Delivery and Shipping

Presented by: M. CHAN

Discussion: Changes provide recommendations for frequent losses in transit or shipping.

Action: Motion by S. HAMILTON, seconded by S. DINNO, and voted unanimously by roll call of those present, to approve edits to the advisory.

TIME: 8:49 AM

TIME: 8:47 AM

TIME: 8:48 AM

TOPIC IX CDTM EDUCATIONAL EQUIVALENCY PETITION

• Patricia Ramos-Lazo, PH239821

Presented by: M. CHAN

Discussion: The licensee would like to have her education considered equivalent to the five years of experience as required by statue. Patricia Ramos-Lazo provided the Board with information regarding her experience and training.

Action: Motion by C. BELISLE, seconded by R. MORELLI and voted unanimously by roll call of those present; to approve the petition to participate in the CDTM agreement and her experience meets the educational equivalency required by statue. S. Hamilton Abstained.

ΤΟΡΙϹ Χ	FILE REVIEW	
Case #1 / CASE-2024-2373 PHA-2024-0152	Jubilant Radiopharma, NU00022	Time: 09:15 AM

RECUSAL: NONE

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

- •Jubilant was cited during a nuclear compliance inspection on July 30, 2024 for multiple inspectional deficiencies including failures to notify BORP about construction of a new cleanroom space, report an above action level event, and to properly identified organisms isolated during environmental monitoring, and insanitary conditions including rust/rust stains, peeling flooring, and accumulation of particulate matter behind a PEC.
- MOR Cone submitted a POC on behalf of the pharmacy. Significantly, MOR Cone pledged that the new cleanroom space and new PEC would not be used until BORP approved the renovation/expansion and proper certifications were obtained. In addition, he pledged to submit the required renovation/expansion application for review and approval by BORP. MOR Cone also pledged to remediate insanitary conditions cited during the inspection including removal, repair, or replacement of worn equipment and flooring. Lastly, MOR Cone pledged to adopt BORP Policy 2023-09.
- In response to the complaint, MOR Cone acknowledged Jubilant's failures to notify BORP about construction of a new cleanroom space, report an above action level event, and to properly identified organisms isolated during environmental monitoring, and insanitary conditions. He reiterated his pledges in Jubilant' s POC. He also confirmed completion remediation of insanitary condition involving rust/rust stains, peeling flooring, and accumulation of particulate matter behind a PEC. He also indicated that Jubilant had adopted BORP Policy 2023-09 and integrated the policy into work instructions.

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<u>ACTION</u>: Motion by C. BELISLE, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2024-0152), 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-2024-2498 PHA-2024-0161

Walgreens #10268, DS3503

Time: 09:31 AM

RECUSAL: NONE

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

- On 08/13/2024, Investigator Murray discovered during an RCI at WAG 10268 that Technician Sanches was working after her license expired on December 26, 2023. In turn, he cited the pharmacy and issued a POC based partly on the expired license.
- MOR Kass acknowledged that Technician Sanches worked after her license expired and that violation was due to confusion that her national certification "was misunderstood as a valid license" when she was hired.
- POC/CA: MOR Kass indicated that Technician Sanches renewed her license on 08/14/2024. He added that "proper procedure and credentials needed when hiring a pharmacy technician" were reviewed. MOR Kass next acknowledged that he was responsible for ensuring all pharmacy staff were properly licensed including pharmacy technicians as MOR.
- Technician Sanches acknowledged that she practiced after her license expired. She then apologized for her oversight. She explained that she mixed up the expiration date for her national certification with her Massachusetts technician license expiration date. She emphasized that she did not intentionally work after her license expired.
- CA: Technician Sanches indicated that she renewed her technician license. She then pledged that she would "continue to keep it up to date as to not practice with an expired license again." Technician Sanches explained that she paid additional attention to license details since the incident especially now that she held multiple licensures.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0161), 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-2024-2498					
PHA-2024-0162	Ellen Sanches, PT26710	Time: 09:35 AM			

RECUSAL: NONE

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

• On 08/13/2024, Investigator Murray discovered during an RCI at WAG 10268 that Technician Sanches was working after her license expired on December 26, 2023. In turn, he cited the pharmacy and issued a POC based partly on the expired license.

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- MOR Kass acknowledged that Technician Sanches worked after her license expired and that violation was due to confusion that her national certification "was misunderstood as a valid license" when she was hired.
- POC/CA: MOR Kass indicated that Technician Sanches renewed her license on 08/14/2024. He added that "proper procedure and credentials needed when hiring a pharmacy technician" were reviewed. MOR Kass next acknowledged that he was responsible for ensuring all pharmacy staff were properly licensed including pharmacy technicians as MOR.
- Technician Sanches acknowledged that she practiced after her license expired. She then apologized for her oversight. She explained that she mixed up the expiration date for her national certification with her Massachusetts technician license expiration date. She emphasized that she did not intentionally work after her license expired.
- CA: Technician Sanches indicated that she renewed her technician license. She then pledged that she would "continue to keep it up to date as to not practice with an expired license again." Technician Sanches explained that she paid additional attention to license details since the incident especially now that she held multiple licensures.

<u>ACTION</u>: Motion by C. BELISLE, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2024-0162), 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-2024-1739 PHA-2024-0198

Jennifer Czajka, PH241273

Time: 09:36 AM

RECUSAL: NONE

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

- On 05/20/2024, Inv. Brosnan discovered during an RCI at Genoa that PT Kimberly O'Connor was practicing after her license expired on October 30, 2023. BORP initially opened complaints against Genoa and PT O'Connor which were reviewed during the 10/17/2024 BM. At that time, BORP voted to offer CAs for reprimand to Genoa and PT O'Connor to resolve the corresponding complaints. BORP then voted opened a complaint against MOR Czajka for permitting PT O'Connor to practice with an expired license.
- According to MOR Czajka, she assumed the role of MOR at Genoa on 04/08/2024. This was her first time as MOR since she was licensed on 11/29/2022. She was not aware that Technician O'Connor was working with an expired license until the inspection. She conducted a "staff licensing audit" after she was hired. At that time, she discovered that Technician O'Connor's license was not posted in the pharmacy.
- MOR Czajka requested a copy of Technician O'Connor's license on several occasions. However, Technician O'Connor failed to produce a copy despite MOR Czajka's multiple requests but confirmed orally that she had an active license but was waiting for a copy in the mail.
- CA: Technician O'Connor's employment was terminated on 06/18/2024. MOR Czajka confirmed that she was now "fully trained and educated on Genoa's Pharmacy and Staff Licensure policy and procedure as well as Massachusetts state pharmacy rules and regulations..." which she was not when the inspection occurred.

• MOR Czajka added that Genoa trained her "to access and verify a health profession license through Mass.gov's online license verification platform." Lastly, MOR Czajka described that Optum, Genoa's parent company, reinforced to pharmacy staff that the company covered renewal fees for licenses required for their jobs.

<u>ACTION</u>: Motion by K. THORNELL, seconded by S. DINNO, and voted unanimously by those present, to refer the matter (PHA-2024-0198), 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-2024-2555		
PHA-2024-0156	Long Term Pharmacy Solutions, DS90330	Time: 09:40 AM

RECUSAL: NONE

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

- Failure to submit a final loss report within 21 days.
- On 12/09/2024, the MOR sent the final loss report .
- On 06/11/2024, a visiting nurse called the Pharmacy to report that a prescription for morphine ER 15mg tablets was not delivered to the patient.
- MOR reviewed the video footage and discovered that the package was brought to the courier waiting area, and given to the driver, but the driver did not record the handover or reconcile the number of packages against the manifest.
- Going forward, the MOR indicated that the process of reconciling packages with the courier was completely changed and turned into an electronic system. A barcode scanning system was implemented to ensure each package is reconciled once handed over to the courier. All pharmacy personnel and the courier/drivers were trained on this process by 06/30/2024.
- MOR is now aware that a final report submission is required.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2024-0156), 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-2024-2371		
PHA-2024-0140	CVS #735, DS2841	Time: 09:42 AM

<u>RECUSAL</u>: 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.

- An unknown loss of #30 hydrocodone-homatropine 5-1.5mg tablets discovered on 06/17/2024 while completing perpetual inventory count.
- MOR Quttas suspects the bottle may have been thrown in the trash with an empty bottle. MOR Quttas indicated that video footage was reviewed from 06/07/2024 through 06/17/2024 which did not show anything out of the ordinary.

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• MOR Quttas indicated that the Loss Prevention policy and procedures have been reviewed with the Pharmacy Team.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to CONSOLIDATE the matter (PHA-2024-0140), with PHA-2022-0079. A second motion was made by S. HAMILTON, 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 #7/ CASE-2024-2783		
PHA-2024-0180	CVS #498, DS3349	Time: 09:46 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 09/04/2024, Investigator Seed discovered during an RCI that Pharmacist El Nabbout permitted PTT McCracken to perform drug utilization review and provide counseling on a new prescription by providing her with her pharmacist credentials.
- Investigator Seed next described that "[PTT McCracken] says that [Pharmacist El Nabbout] said she could do the DURs she felt comfortable with and enter [Pharmacist El Nabbout's] credential.
 [Pharmacist El Nabbout] admits she gave [PTT McCracken] her credentials to use for the DURs that were 'the easy ones.' "
- MOR Mielnicki acknowledged that Pharmacist El Nabbout permitted PTT McCracken to counsel a patient during the inspection on September 4, 2024. She explained that Pharmacist El Nabbout's act deviated from standard protocol at CVS 498 which required "all counseling and Drug Utilization Reviews are to be performed by the pharmacist on duty and that no sharing of credentialing is allowed." MOR Mielnicki added that Pharmacist El Nabbout was not a staff pharmacist at CVS 498.
- MOR Mielnicki indicated that "after this incident, my staff pharmacists and technicians were retrained on not only the policies and procedures within CVS, but also on 247 CMR 9.07."
- Pharmacist El Nabbout also submitted a response in which she wrote, "On September 4, 2024, I permitted a pharmacy technician trainee to provide counseling to a patient. I was giving vaccinations, and I had written down for the technician what to convey to the patient and told her to get me from the vaccination room in case the patient had additional questions. The prescription in question was a cross sensitivity on a repeat medication that the patient had before and was familiar with. I apologize and will not let this happen again."

<u>ACTION</u>: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2024-0180), 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. A second motion was made by C. BELISLE, seconded by S. HAMILTON, and voted by those present (S. HAMILTON was off screen and did not vote) with the exception of NAY votes by S. DINNO and F. LOMBARDO, to open a complaint on Pharmacy Technician Trainee McCracken (PTT102325).

Case #8/ CASE-2024-2783 PHA-2024-0181

Catie Zaher El Nabbout, PH233279

Time: 09:52 AM

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<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 09/04/2024, Investigator Seed discovered during an RCI that Pharmacist El Nabbout permitted PTT McCracken to perform drug utilization review and provide counseling on a new prescription by providing her with her pharmacist credentials.
- Investigator Seed next described that "[PTT McCracken] says that [Pharmacist El Nabbout] said she could do the DURs she felt comfortable with and enter [Pharmacist El Nabbout's] credential.
 [Pharmacist El Nabbout] admits she gave [PTT McCracken] her credentials to use for the DURs that were 'the easy ones.' "
- MOR Mielnicki acknowledged that Pharmacist El Nabbout permitted PTT McCracken to counsel a patient during the inspection on September 4, 2024. She explained that Pharmacist El Nabbout's act deviated from standard protocol at CVS 498 which required "all counseling and Drug Utilization Reviews are to be performed by the pharmacist on duty and that no sharing of credentialing is allowed." MOR Mielnicki added that Pharmacist El Nabbout was not a staff pharmacist at CVS 498.
- MOR Mielnicki indicated that "after this incident, my staff pharmacists and technicians were retrained on not only the policies and procedures within CVS, but also on 247 CMR 9.07."
- Pharmacist El Nabbout also submitted a response in which she wrote, "On September 4, 2024, I permitted a pharmacy technician trainee to provide counseling to a patient. I was giving vaccinations, and I had written down for the technician what to convey to the patient and told her to get me from the vaccination room in case the patient had additional questions. The prescription in question was a cross sensitivity on a repeat medication that the patient had before and was familiar with. I apologize and will not let this happen again."

<u>ACTION</u>: Motion was made by S. HAMILTON, to DISMISS the matter (PHA-2024-0181). The motion failed as there was no second. Another motion was made by C. BELISLE, seconded by R. MORELLI, and voted by those present with one NAY vote by S. HAMILTON, to refer the matter (PHA-2024-0181), 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 XI:

Executive Session Call to Order:

Time: 8:29 AM

By: President S. Ahmed 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 XII:

DISCUSSION: None

<u>ACTION</u>: President S. Ahmed request a motion to enter 65C.

At 11:08 a.m. S. Hamilton seconded by S. Dinno and voted unanimously by all those present to enter Adjudicatory Session by roll call vote.

Topic XIII:65C Sessions MGL c. 112 section 65CTime: 11:15 AM

<u>DISCUSSION</u>: None ACTION: President S. Ahmed request a motion to enter 65C.

At 11:15 a.m. M. Sciaraffa seconded by J. Dorgan and voted unanimously by all those present to enter M.G.L. chapter 65 c Session by roll call vote.

Lunch 12:00PM-12:30PM

Topic XIV:

ADJOURMENT OF MEETING

TIME: 1:23 PM

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

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. General Session Agenda 1.9.2025
- 2. Draft Minutes December 5, 2024
- 3. Licensure Policy 13-01
- 4. PSUD Report Policy 17-03
- 5. Research Drug Study Report Staff Action Policy 18-02
- 6. Continuity of Care Guidance for Intuitional Sterile Compounding Pharmacies
- 7. URAMP Operational Policy 24-07
- 8. Staff Action Policy 17093: Staff Action Policy for Implementation of PSUD
- 9. Policy 14-02: Board Delegated Review
- 10. Policy 13-01: Licensure Applications and Notices
- 11. Policy 16-01: Applications pertaining to Outsourcing Facilities
- 12. Policy 2023-07: Non-Sterile Compounding