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

# NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE BOARD OF REGISTRATION IN PHARMACY March 6, 2025

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

#### Join link:

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

**Webinar number: 2536 868 7637** 

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#### Agenda

		Item	Page	
8:00	I	CALL TO ORDER		S. Ahmed
8:05	II	APPROVAL OF AGENDA		
8:10	III	<ul> <li>APPROVAL OF BOARD MINUTES</li> <li>Draft of February 6, 2024, Regular Session Minutes</li> </ul>		
8:15	IV	<ul> <li>REPORTS</li> <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> </ul>		

8:20	V	<ul> <li>FLEX</li> <li>Board member changes</li> <li>NABP annual meeting election of delegates</li> <li>Guaifenesin with Codeine Memo</li> <li>Licensing Update</li> <li>Open Meeting Law- 940 CMR 29.00</li> </ul>	
8:45	VI	<ul><li>POLICIES</li><li>Policy 14-02: Board Delegated Review (BDR)</li></ul>	M. Chan
9:00	VII	EMERGENCY AMENDMENTS TO REGULATIONS TO IMPLEMENT 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
9:10	VIII	REVIEW OF COMPLIANCE/VIOLATION OF CONSENT AGREEMENT  • Carbone, Domenico PH16514 – Docket No PHA-2023-0142	K. Fishman
9:20	IX	<ul> <li>APPLICATION</li> <li>Vantive US Healthcare LLC – New Retail Pharmacy</li> <li>Option Care – Sterile Compounding License</li> <li>Revive Rx (NDSNE97431SC) Sterile Compounding License - New Application</li> <li>Galaxy Pharmacy; DS90257- Relocation</li> </ul>	

	X	FILE REVIEW					
		1	CASE-2024-3749	INV15492	Grant LaPierre, PH239985		
		2	CASE-2024-2654	PHA-2024-0174	Medwiz of Mass, LLC, DS90404		
		3	CASE-2024-3753	PHA-2025-0007	Kenny Correia, PH232913		
		4	CASE-2024-2625	PHA-2024-0176	Genoa Healthcare LLC, DS90412		
		5	CASE-2024-2823	PHA-2024-0184	Springfield Pharmacy, DS90286		
		6	CASE-2024-2827	PHA-2024-0189	Walmart 10-5448, DS89911		
		7	CASE-2024-3186	PHA-2024-0214	Walgreens #4729, DS2878		
10:00		8	CASE-2024-3051	PHA-2024-0197	Prescription Center Pharmacy, DS89916		
		9	CASE-2025-0282	PHA-2025-0018	ProRx, LLC, NO10087		
		10	CASE-2024-2559	PHA-2024-0169	Walgreens #10401, DS3553		
		11	CASE-2024-2697	PHA-2024-0172	Southcoast Pharmacy, DS89872		
		12	CASE-2024-2499	PHA-2024-0159	Wal-Mart 10-2903, DS2966		
		13	CASE-2024-2499	PHA-2024-0160	Deepa Singh, PT15474		
		14	CASE-2024-2496	PHA-2024-0164	CVS #1015, DS1534		
		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,					
11:00	XI	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.					
12:00	XII	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)					
12:15		LUNCH BREAK					
12:45	XIII	M.G.L. c. 112, § 65C SESSION					
3:00	XIV	ADJOURNMENT					

### COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

## MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting March 6, 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
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
Julienne Tran, PharmD, Investigator
Gregory Melton, JD, PharmD, BCPS, Investigator
Keith Johnstone, Compliance Officer
David Sencabaugh
Susan Kim, Pharmacy Intern
Gayatri Ramasubramanian, Pharmacy Intern

#### **Board Members Not Present**

Caryn Belisle, RPh, MBA Rita Morelli, PharmD, BCACP, RPh

Topic I. Attendance by roll call:

CALL TO ORDER TIME 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: T. Fensky, yes; D. Barnes, yes; J. Rocchio, yes; K. Thornell, yes; S. Ahmed, yes; R. Morelli, no; C. Belisle, no; J. Dorgan, yes; Dr. Lopez, yes; Frank Lombardo, yes

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Topic II. Approval of Agenda TIME 8:03 AM

Agenda: 03/06/25

**DISCUSSION: None** 

**ACTION:** Motion by D. BARNES, seconded by K. THORNELL 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: 8:04 AM

#### **Minutes**

1. Draft 2.6.2025

Change: No changes

Action: Motion by K. THORNELL seconded R. LOPEZ and voted to approve the regular session minutes of

02/06/2025 with no noted changes by roll call vote. T. Fensky abstained.

Topic IV REPORTS

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: R. HARRIS

<u>DISCUSSION</u>: R. Harris reported a total of 27 Change Pharmacist Manager of Record applications and 5 facility closures that have been approved via Staff Action since the last Board meeting.

**TIME: 8:05 AM** 

**TIME: 8:05 AM** 

So noted.

Topic IV. REPORTS

**Monthly Report from Probation** 

PRESENTED BY: R. HARRIS

<u>DISCUSSION</u>: R. Harris indicated a total of 2 licensees that were given a 2<sup>nd</sup> opportunity to cure and 1 successful completion of probation monitoring since the last report. Currently, there are a total of 42 active cases.

So noted.

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Topic IV. REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: R. HARRIS

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

So noted.

Topic V. FLEX

Board Member Changes TIME: 8:05 AM

**TIME: 8:05 AM** 

PRESENTED BY: M. GODEK

<u>DISCUSSION</u>: M. Godek announced S. Hamilton's departure from the Board, giving thanks for his years of service and dedication to the profession. Succeeding S. Hamilton is T. Fensky, who has previously served on the Board and comes from a background of operations compliance, compounding, and who had previously served as the president of NABP.

So noted.

Topic V. FLEX

NABP Annual Meeting Election of Delegates TIME: 8:06 AM

PRESENTED BY: M. GODEK

**RECUSAL: NONE** 

<u>DISCUSSION:</u> M. Godek led discussion in appointing a delegate and an alternate delegate to represent the Massachusetts Board of Pharmacy at the upcoming NABP Annual Meeting from May 13<sup>th</sup> through May 16<sup>th</sup>, 2025. The meeting will take place in Fort Lauderdale, FL.

<u>ACTION:</u> Motion by J. ROCCHIO, seconded by T. FENSKY, voted unanimously by those present to appoint S. DIINO as the delegate and K. THORNELL as the alternate delegate for the 121<sup>st</sup> NABP Annual Meeting.

Topic V. FLEX

Guaifenesin with Codeine Memo TIME: 8:06 AM

PRESENTED BY: W. FRISCH

**RECUSAL:** NONE

<u>DISCUSSION</u>: W. Frisch presented a memo in which he discusses the issue of pharmacies not stocking Guaifenesin with Codeine for a multitude of reasons, including theft and supply chain issues. As a result,

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these facilities are not meeting the needs of the community. Upon receipt of a valid prescription, the pharmacist must reach out to the prescriber for an alternative product or for the medication to be provided by another means in a timely manner.

<u>ACTION:</u> Motion by T. FENSKY, seconded by K. THORNELL, voted unanimously by those present to adopt the memo for posting on the Board website.

Topic V. FLEX

Licensing Update TIME: 8:06 AM

PRESENTED BY: R. HARRIS

**RECUSAL: NONE** 

<u>DISCUSSION:</u> R. Harris disclosed that as of March 4<sup>th</sup>, 2025, 385 non-resident licenses have been issued by the Board across 42 states. This includes retail and compounding facility license types. Approvals issued via Staff Action will be incorporated into the 13-01 report moving forward.

W. Frisch indicated that a large volume of the submitted inspection reports are not up to Board standards, causing a delay in processing. The March 31<sup>st</sup> deadline for applications is rapidly approaching, and those applying from out-of-state are encouraged to submit their applications as soon as possible to allow for timely processing.

So noted.

Topic V. FLEX

Open Meeting Law- 940 CMR 29.00 TIME: 8:09 AM

PRESENTED BY: J. PETRILLO

**RECUSAL: NONE** 

<u>DISCUSSION</u>: J. Petrillo provided an update on the status of the Open Meeting Law in which meetings are to be conducted remotely. The proposed measures per 940 CMR 29.00 expire on March 31<sup>st</sup> of 2025. If no further action by the governor or legislature is made to extend this order, all meetings that fall under the law will need to resume to live, in-person meetings. The Bureau has begun preparation for inperson meetings in the event that the order is not extended.

If meetings need to be conducted in-person, authority must be granted for Board members to potentially work remotely. A member of a public body is allowed to participate remotely in a meeting if and only if physical attendance would be unreasonably difficult as per the statutory requirement. If a physical quorum of the body, including the Chair or otherwise authorized individual, is not met, other members may not participate remotely for that corresponding meeting.

<u>ACTION:</u> Motion by R. LOPEZ, seconded by J. ROCCHIO, voted unanimously by those present to authorize remote participation by Board members at any and all public meetings conducted by the Board of Registration in Pharmacy pursuant to 940 CMR 29.10.

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TOPIC VI POLICIES

Policy 14-02: Board Delegated Review (BDR)

Presented by: M. CHAN

**Discussion:** Edits clarify the time frame for a "late" mandatory report for which the BDR group may issue a reprimand. Also now permitted are issuance of approval of certain waivers including compounding and veterinary resources as well as approval of Controlled Substance Registration (CSR) drug schedule amendments.

**TIME: 8:25 AM** 

**TIME: 8:27 AM** 

Also added was the authorization to approve resident compounding pharmacies that are not in good standing as long as the sanctions have resulted from violations that do not impact patient safety.

Lastly, the Loss of Controlled Substance section was edited to clarify that the BDR group can address other losses, not just Level 1.

**Action:** Motion by D. BARNES, seconded by F. LOMBARDO, and voted unanimously by roll call of those present, to approve the edits to the policy.

#### TOPIC VII EMERGENCY AMENDMENTS TO REGULATION TO IMPLEMENT 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

Presented by: L. NELSON

**Discussion:** The emergency amendments have undergone a public hearing where no comments were submitted.

**Action:** Motion by T. FENSKY, seconded by M. SCIARAFFA, and voted unanimously by roll call of those present, to approve the post-comment emergency amendments for 247 CMR 3.00, 6.00, 8.00, and 10.00 and file for promulgation.

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#### Topic VIII. REVIEW OF COMPLIANCE/VIOLATION OF CONSENT AGREEMENT

Carbone, Domenico PH16514 – Docket No PHA-2023-0142

Presented by: K. Fishman

**Discussion:** Entered in into a Non-disciplinary 6 month styed probation on May 2024, and had until November 2024 to complete the ND-probation requirements. The reason for this agreement was regarding the failure to complete their CEs for 2021-2022 licensing year.

**TIME: 8:30 AM** 

The total amount of credits he had to complete was 50.75. This was for the lack of completing CEUs for 2021, 2022, and 2023. The Licensees CPE monitor shows that the licensee has not completed their remedial CEs, and the complain-ant has not completed any of their 2024 CEs.

**Action:** T. Fensky made a motion that the licensee violated their consent agreement, second by R. Lopez and voted unanimously by roll call to approve the motion.

- T. Fensky made a motion to lift the stay and extend the probation through March 2026 to include special terms of 2024 CEs for a total of 70.75 CES to be completed, with a 1/3rd of the CES to be completed in 3 months, 2/3rds to be completed within 6 months, and the remainder to be completed by the end of the extension; Seconded by R. Lopez and voted unanimously by roll call to approve the motion.
- T. Fensky made a motion to immediately suspend the licensee's license, seconded by D. Barnes and voted unanimously by roll call to approve the motion.

Topic IX: APPLICATION

1. Vantive US Healthcare LLC New Retail Pharmacy TIME: 8:58 AM

**Presented by:** Vince Hanks

**Recusal:** 

**Discussion:** We are a home dialysis pharmacy and only dispense the products that a patient may need to perform dialysis at home. We have no drugs, just devices and supplies for home dialysis. Cardinal Health Stores our solutions. Nothing is being housed at the address for Vantive.

#### Question:

- Are you able to handle same day requests?
- o We are able to get an order our same day or next day.

#### Waivers:

247 CMR 9.01(15) 247 CMR 9.19(1)(a) 247 CMR 9.19(1)(b)

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247 CMR 9.1.9(1)(e) 247 CMR 9.19(1)(f) 247 CMR 9.19(1)(I) 247 CMR 9.19(10) 247 CMR 9.19(14) 247 CMR 9.19(16)(a) 247 CMR 9.21(5)

**Action:** D. Barnes made a motion to approve the New retail Pharmacy application with waivers pursuant to a successful inspection, seconded by K. Thornell and voted unanimously by roll call of members present to approve the motion.

#### 2. Option Care

**Sterile Compounding License** 

TIME: 9:05 AM

Presented by: Brier Olsen

Recusal:

**Discussion:** We operate as a 503A compounding pharmacy and make patient specifics medications. We've been at this location for approximately 10 years and are applying in-line with the new Board regulations.

**Action:** T. Fensky made a motion to approve the Sterile Compounding license application, seconded by J. Rocchio and voted unanimously by roll call to approve the motion.

#### 3. Revive Rx (NDSNE97431SC) Sterile Compounding License - New Application TIME: 9:09 AM

**Presented by**: Kimberly Chukwurah, Johnathan Rekieta **Recusal**:

**Discussion:** We are a 503 a pharmacy located in Houston, Texas that dispenses sterile, non-sterile, and commercial medications.

#### Questions:

- How is the testing of 250 or more products done effectively?
- o We test batches of 208, and it is sampled per USP standards. Environment sampling is also completed, then a cleaning of the ISO 5 hood, and then another batch of 208 us complete. Once that second batch is completed, additional sampling is completed.
- Once all the samples are then taken from the lot, all of them are tested accordingly. If any of the units come back with unfavorable results, the entire lot is disposed of.
- o A lot may be up to 1000 units, and if any batch comes back with an issue the entire lot of up to 1000 units will be disposed.
- What products are undergoing scan RDI, and are you relying on that for Release testing? Do you have method suitability test for each CSP formulation undergoing that test?

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- o We do [have method suitability testing], Our third party lab thatwe use for scan RDI requires suitability testing.
- o I am not aware of any product that is not using scan RDI.
- o Method suitability is used for each CSP formulation
- Will you be aligning with UPS BUD assignments?
- o Yes
- Licensee was asked for a description of the lyophilizer process at this facility, and provided board staff with a step-by-step process of lyophilization. Staff are trained on this process.
- What is the mix of business?
- o Health & wellness, hormone replacement therapy, weight loss (GLP-1s and other drugs), urology and we also dispense medication
- Why do you want licensure in Massachusetts?
- o We are seeking licensure because we have a significant amount of provider who treat Massachusetts patients

**Action:** T. Fensky made a motion to defer the matter, seconded by S. Dinno and voted unanimously by roll call to approve the motion.

4. Galaxy Pharmacy; DS90257

Relocation

**TIME: 9:32 AM** 

Presented by: Ron Lanton, Hung Doan, Christopher Le

**Recusal:** 

**Discussion:** Requesting to relocate the pharmacy to a more suitable location. This was initially supposed to be an asset transfer, though board staff noted that this appears to be a sale/transfer of ownership.

The licensee attempted to submit a relocation and new pharmacy application, but after submitting the relocation application, was unable to submit the application because the online system would not accommodate both. Board counsel explained that the Board would need to receive the new pharmacy application before the relocation could be considered.

Board staff explained they will work on the back end to allow the licensee can submit the transfer of ownership application.

**Action:** D. Barnes made a motion to defer the relocation application, seconded by M. Sciaraffa, and voted unanimously by roll call to approve the motion.

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Topic X FILE REVIEW

Case #1 / CASE-2024-3749

INV15492 Grant LaPierre, PH239985 Time: 10:16 AM

**RECUSAL: NONE** 

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

- Repeat CE deficiency; previously deficient 14.5 CEs (including 2 law) in 2021; remediated in 2022
- In 2024, the licensee self-reported another CE deficiency in 2023.
- Short 8.75 CES in 2023; Remediated in 2024.
- Short 1.5 CEs in 2024; Remediated in 2025.

<u>ACTION</u>: Motion by D. BARNES, seconded by M. SCIARAFFA, and voted unanimously by those present, to CLOSE the matter (INV15492), No Discipline Warranted, Remediation Complete.

Case #2/ CASE-2024-2654

PHA-2024-0174 Medwiz of Mass, LLC, DS90404 Time: 10:18 AM

**RECUSAL: NONE** 

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

- On 08/31/2024, OPP received a complaint alleging that the Pharmacy outsources the data entry of
  prescriptions to unlicensed teams in the Philippines, that mistakes are not tracked or trended, and
  that the international team uses VPN connections that make it appear that they are in the United
  States. The complaint also alleged that unlicensed technicians are allowed to issue emergency kit
  withdrawals from any schedule of medication.
- On 09/05/2024, Investigator Murray conducted a site visit and confirmed that data entry does occur in the Philippines, but other processes are conducted in Foxboro.
- On 09/05/2024, the Pharmacy agreed to cease use of all staff outside of the United States.
- Former MOR Brunette responded that prescriptions received via fax or not transmitted directly into the pharmacy operating system were data entered by technicians in the Philippines. Technicians in the Philippines also entered insurance information but not any clinical information. Additionally, technicians in the Philippines provided backup support to the primary call center located within the United States. They would route calls to a pharmacist, answer non-clinical questions, and notate in the call log if a refill was needed. Lastly, technicians in the Philippines reentered internal data entry errors that were routed via an internal error queue.
- All data entry functions, including re-entered items from the internal error queue, were verified by a
  Massachusetts registered pharmacist and reviewed for duplicate therapy, drug interactions, allergies,
  and appropriateness of dose. All clinical clarifications were conducted by a Massachusetts registered
  pharmacist who contacted nursing staff directly. All dispensing functions were conducted at the
  Pharmacy in Massachusetts by registered technicians or trainees and verified by a Massachusetts
  registered pharmacist.

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- Technicians in the Philippines logged into the MedWiz operating system through Citrix via a VPN to provide a secure connection.
- The Pharmacy does track quality-related events.
- Only licensed nurses are authorized to remove any medication in the BD MedBank system. Only a Massachusetts registered pharmacist is authorized to approve the removal of a controlled medication.
- Currently, remote staff are in another MedWiz Pharmacy or work from home in the United States.

<u>ACTION</u>: Motion by M. SCIARAFFA, seconded by J. DORGAN, and voted unanimously by those present, to REFER the matter (PHA-2024-0174), 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-2024-3753

PHA-2025-0007 Kenny Correia, PH232913 Time: 10:22 AM

RECUSAL: NONE

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

- During December 2024, BORP received a notification from the NABP's Clearinghouse that Pharmacist
  Correia was disciplined by RI BOP. Specifically, Pharmacist Correia entered into a consent order with
  RI BOP effective November 21, 2024 to resolve a board investigation concerning his failure to
  complete 2023 annual CE requirements discovered during a routine audit. Pharmacist Correia was
  reprimanded and required to complete an additional 10 contact hours of CE beyond RI BOP's annual
  requirements.
- In turn, BORP audited Pharmacist Correia's annual CE for the 2021-2022 and 2023-2024 renewal cycles. In total, Pharmacist Correia was deficient 4 contact hours of CE in any format or topic in 2021 and 10 contact hours of CE in any format or topic in 2023. Of note, Pharmacist Correia remediated the 2021 and 2023 deficiencies in 2022 and 2024, respectively.
- Pharmacist Correia explained that he misunderstood that CE was required on an annual basis every calendar year regardless of renewal cycles.
- CA: Pharmacist Correia indicated that he would change in his practice moving forward "to ensure that CEs are annual (vs biannual)."

<u>ACTION</u>: Motion by J. ROCCHIO, seconded by S. DINNO, and voted unanimously by those present, to DISMISS the matter (PHA-2025-0007), No Discipline Warranted, Remediation Complete.

Case #4/ CASE-2024-2625

PHA-2024-0176 Genoa Healthcare LLC, DS90412 Time: 10:23 AM

**RECUSAL: NONE** 

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

• On August 29, 2024, Investigator Brosnan issued Genoa a POC during an RCI after he observed pharmacy staff handing "a multi-dose vial of polio vaccine... to an associated clinic's nurse to be administered to a patient outside by the nurse outside of the pharmacy.10 The [multi-dose vial of

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polio vaccine] was then returned to the pharmacy and placed back in the pharmacy's refrigerator for storage.".

• CA: The multi-dose vial of polio vaccine was destroyed. No medication will be accepted into stock in the pharmacy once it has been dispensed per Genoa policy and in accordance with Massachusetts rules and regulations. Clinic staff have been informed that they will need to dispose of any unwanted medications per their own policies. All pharmacy staff have been coached and trained regarding the above incident to ensure compliance with state rules and regulations and Genoa's policy and procedure to mitigate any future incidents. In addition, vaccines are only dispensed pursuant to a patient specific prescription.

<u>ACTION</u>: Motion by D. BARNES, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0176), 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-2024-2823

PHA-2024-0184 Springfield Pharmacy, DS90286 Time: 10:25 AM

**RECUSAL: NONE** 

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

- Investigators Brosnan and Seed were dispatched on September 11, 2024 to conduct a retail compliance inspection at Springfield after PMP notified BORP that Springfield was not reporting PMP prescriptions. Investigators Brosnan and Seed audited a total of 564 prescriptions filled by Springfield during three five-day periods in January 2024, March 2024, and September 2024, respectively, which were required to be reported to PMP. The audit revealed that Springfield reported only approximately 72% (407/564) of prescriptions required to be reported to PMP during that period.
- In addition, Investigators Brosnan and Seed observed that physical descriptions and NDC on multidrug-single dose compliance packaging did not match the drug actually dispensed to the patient. Of note, the drug was correct, but the details recorded on labeling and in patient prescription profile were inaccurate. In addition, BUD for compliance packaging was 90-days which was more than 60-day permitted.
- CA: MOR Wu contacted his software vendor to correct the issues with PMP reporting. He also submitted missing data to PMP. In addition, he corrected the assigned BUD in his software system. Furthermore, he indicated that he would cull outdated drug selections from the pharmacy's software according to availability. Lastly, MOR Wu pledged to monitor PMP, BUD, and NDC for issues going forward.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0184), 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-2024-2827

PHA-2024-0189 Walmart 10-5448, DS89911 Time: 10:28 AM

**RECUSAL: NONE** 

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

- On August 17, 2024, Walmart 10-5448 submitted an initial report of loss of 1 testosterone cypionate injection 200mg/ml-1ml vial which was inadvertently discarded into the trash on August 15, 2024.
- Walmart 10-5448 then failed to submit a final report of loss within 21 days of submission of the initial report of loss. Ultimately, Walmart 10-5448 submitted a final report of loss on October 11, 2024 after a request by BORP as part of the notice of complaint for this matter.
- Of note, Walmart 10-5448 provided video evidence which supported with the pharmacy's contention that the loss was caused by inadvertent discard.

<u>ACTION</u>: Motion by M. SCIARAFFA, seconded by J. DORGAN, and voted unanimously by those present, to REFER the matter (PHA-2024-0189), 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-2024-3186

PHA-2024-0214 Walgreens #4729, DS2878 Time: 10:30 AM

**RECUSAL: NONE** 

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

- On October 17, 2024, WAG 4729 submitted a final report (RLCS10474) of an unknown loss of 120 oxycodone 15mg tablets discovered on September 21, 2024. According to the loss report, MOR Jin discovered 120 oxycodone 15mg tablets were missing while conducting weekly Schedule II perpetual inventory. At that time, MOR Jin launched an internal investigation of the incident which included review of surveillance video. MOR Jin indicated that the investigation proved unsuccessful at finding the missing drugs or determining a reason for the loss.
- CA: MOR Jin described that "to prevent this from occurring again, we have implemented a back count on every control from the safe. The oxycodone 15 mg tablets will be continuously counted daily for the next two months to ensure accuracy and safety of the medication. Return to stock controls will be taken care of with utmost priority, placed into the safe and logged correctly. Reassessment of how effective these measures were will be evaluated after 2 months."

<u>ACTION</u>: Motion by K. THORNELL, seconded by R. LOPEZ, and voted unanimously by those present, to REFER the matter (PHA-2024-0214), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #8/CASE 2024 2051

Case #8/CASE-2024-3051

PHA-2024-0197 Prescription Center Pharmacy, DS89916 Time: 10:33 AM

**RECUSAL**: NONE

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

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- An unknown loss of 100 hydromorphone 8mg tablets discovered on September 4, 2024. Pharmacist
  Bell discovered a 100-tablet bottle of hydromorphone 8mg tablets was missing from a controlled
  substance shipment received on September 4, 2024 while securing the shipment in the pharmacy's
  Pyxis safe on the same day after receipt. In turn, a search of the pharmacy was conducted but the
  missing hydromorphone was not found. MOR Grady indicated that the wholesale distributor was also
  contacted, and the distributor confirmed that the missing hydromorphone was shipped.
- MOR Grady next indicated that video footage captured by the pharmacy's surveillance cameras was
  reviewed with UMASS Memorial Medical Center's police chief. MOR Grady reported that no
  suspicious activity or diversion was observed. However, Pharmacist Bell was captured deviating from
  standard process for receiving. Specifically, she verified the contents of the totes used by the
  wholesale distributor to securely ship controlled substances to PCP with stickers included in the totes
  rather than the shipment invoice.
- MOR Grady indicated that Pharmacist Bell was given a written warning. MOR Grady then indicated that the receiving policy was updated, and staff were trained on the updated process.

<u>ACTION</u>: Motion by M. SCIARAFFA, seconded by J. DORGAN, and voted unanimously by those present, to REFER the matter (PHA-2024-0197), 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 #9/ CASE-2025-0282

PHA-2025-0018 ProRx, LLC, NO10087 Time: 10:35 AM

**RECUSAL: NONE** 

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

- FDA Form 483 on 08/02/2024 as result of an FDA inspection conducted between 07/15/2024 and 08/02/2024.
- Upon review, PRORX failed to notify BORP about the Warning Letter. On the other hand, PRORX submitted a copy of the aforementioned FDA Form 483 on 12/06/2024 as part of the facility's application for licensure which was approved on 12/10/2024.
- Of note, FDA described in the Warning Letter that PRORX produced drugs which violated the United States Food, Drug, and Cosmetic Act (FDCA). FDA noted that drug products produced by PRORX failed to meet the conditions of section 503B of the FDCA required for registration during the inspection.
- FDA also noted additional FDCA violations including adulterated drug products caused by failure to meet Current Good Manufacturing Practice (CGMP), unapproved new drug products, and misbranded drug products. Furthermore, the Warning Letter noted that parts of corrective action implemented after the FDA inspection and issuance of the Form 483 were deficient.
- CA: "ProRx LLC was acquired by a new group of owners after the FDA inspection, 483, and 483 response occurred. Since the acquisition the new ownership has been diligent in onboarding more staff, conducting ongoing training, and implementing thorough compliance measures..." Compliance Manager Harris also provided a copy of PRORX's response to FDA addressing the Warning Letter.

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<u>ACTION</u>: Motion by K. THORNELL, seconded by T. FENSKY, and voted unanimously by those present, to REFER the matter (PHA-2025-0018), 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 #10/ CASE-2024-2559

PHA-2024-0169 Walgreens #10401, DS3553 Time: 10:38 AM

**RECUSAL**: NONE

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

- On 08/15/2024, an OPP Investigator discovered that the MOR listed no longer worked for Walgreens and indicated that no interim was named, nor was a permanent MOR appointed.
- Healthcare Supervisor DeLeo and District Manager Johnson indicated that MOR Munene was terminated on 04/20/2024. They had been unsuccessful in filling the MOR position and had a series of interim MORs in place. They did not realize that an electronic MOR application was required and had only emailed the board when they placed an interim MOR.
- Current MOR Sarn took over the role of MOR at the Pharmacy on 12/05/2024.

<u>ACTION</u>: Motion by T. FENSKY, seconded by M. SCIARAFFA, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0169), No Violation.

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Case #11/ CASE-2024-2697

PHA-2024-0172 Southcoast Pharmacy, DS89872 Time: 10:40 AM

**RECUSAL: NONE** 

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

- Unknown loss of #100 mixed amphetamine salts 5mg tablets discovered on 08/03/2024 during the perpetual inventory count.
- The MOR suspects that a full bottle of mixed amphetamine salts 5mg tablets ended up in the trash bin, which was previously located beneath the Schedule 2 safe.
- The previous perpetual inventory on 07/27/2024 had no discrepancies. Following the perpetual inventory on 08/03/2024, it was reported to be short by 100 tablets. There was no additional dispensing or purchasing of the product in question between the two listed inventory dates.
- MOR Wojtasinski indicated that the trash bin has since then been relocated away from the Schedule 2 safe, retraining of the staff while handling of Schedule 2 drugs during inventory occurred, and preliminary discussions have occurred to increase video surveillance in the area.

<u>ACTION</u>: Motion by D. BARNES, seconded by M. SCIARAFFA, and voted unanimously by those present, to REFER the matter (PHA-2024-0172), 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 #12/CASE-2024-2499

PHA-2024-0159 Wal-Mart 10-2903, DS2966 Time: 10:41 AM

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**RECUSAL: NONE** 

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

- During a retail compliance inspection conducted on 08/08/2024, the Investigator observed Pharmacy Technician (PT) Singh working in the licensed pharmacy space with an expired license.
- Former MOR Barbone indicated that on 06/24/2024 he realized that PT's Singh's license was expiring on 07/11/2024 during the Pharmacy's internal quarterly compliance inspection. He indicated that he informed PT Singh's that she had to renew her license. PT Singh was on a LOA from 07/02/2024 until 08/06/2024. Additionally, he noted that he was on vacation from 07/31/2024 until 08/12/2024 and did not realize that PT Singh had not renewed her license before returning to work.
- PT Singh worked with an expired license for approximately 8 hours from 07/11/2024 through 08/08/24.
- Former MOR Barbone said that he would audit the PT licenses each month for 3 months and verification audits went to the Director. The Director would then complete the quarterly audit of the pharmacy licenses.
- PT Singh indicated that she was out of the country from 06/30/2024 through 08/07/2024. She did not realize that her license was expired but did renew on 08/14/2024. She indicated going forward that she will put a reminder on her phone for renewal.

<u>ACTION</u>: Motion by D.BARNES, seconded by K. THORNELL, and voted unanimously by those present, to REFER the matter (PHA-2024-0159), 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-2024-2499

PHA-2024-0160 Deepa Singh, PT15474 Time: 10:44 AM

**RECUSAL: NONE** 

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

- During a retail compliance inspection conducted on 08/08/2024, the Investigator observed Pharmacy Technician (PT) Singh working in the licensed pharmacy space with an expired license.
- Former MOR Barbone indicated that on 06/24/2024 he realized that PT's Singh's license was expiring on 07/11/2024 during the Pharmacy's internal quarterly compliance inspection. He indicated that he informed PT Singh's that she had to renew her license. PT Singh was on a LOA from 07/02/2024 until 08/06/2024. Additionally, he noted that he was on vacation from 07/31/2024 until 08/12/2024 and did not realize that PT Singh had not renewed her license before returning to work.
- PT Singh worked with an expired license for approximately 8 hours from 07/11/2024 through 08/08/24.
- Former MOR Barbone said that he would audit the PT licenses each month for 3 months and verification audits went to the Director. The Director would then complete the quarterly audit of the pharmacy licenses.

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• PT Singh indicated that she was out of the country from 06/30/2024 through 08/07/2024. She did not realize that her license was expired but did renew on 08/14/2024. She indicated going forward that she will put a reminder on her phone for renewal.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by D. BARNES, and voted unanimously by those present, to REFER the matter (PHA-2024-0160), 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-2024-2496

PHA-2024-0164 CVS #1015, DS1534 Time: 10:45 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 site visit conducted 08/08/2024, the Investigator observed a pharmacy technician trainee working without a name badge which was a repeat deficiency.
- On 05/23/2024, 05/31/2024, 07/02/2024, and 08/05/2024, the complainant, indicated that the majority of the Pharmacy staff were not wearing name badges when he visited the Pharmacy.
- MOR Vu indicated that during the August site visit floater PTT Cajuste, was not wearing a name badge. There was a long line when he came in for the shift and MOR Vu stated that she did not check his name badge. However, she made him a name badge when it was discovered he needed one.
- MOR Vu said, going forward, she has all staff leave name tags in the pharmacy at the end of shifts. When floaters come to the Pharmacy, she prepares name tags in advance.

<u>ACTION</u>: Motion by M. SCIARAFFA, seconded by J. DORGAN, and voted unanimously by those present, to REFER the matter (PHA-2024-0164), 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 X: ADJOURMENT OF MEETING TIME: 12:30 PM

ACTION: Motion by J. ROCCHIO 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. March 6, 2025 Agenda
- 2. February 6, 2025 Board Minutes
- 3. Licensure Policy 13-01 Report
- 4. Monthly Probation Report
- 5. Guaifenesin with Codeine memo
- 6. Policy 14-02: Board Delegated Review (BDR)
- 7. Emergency Amendments to Regulations to Implement Shield Law
  - a. 247 CMR 3.00: Pharmacist Licensure Requirements

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- b. 247 CMR 6.00: Licensure of Pharmacies
- c. 247 CMR 8.00: Pharmacy Interns and Technicians
- d. 247 CMR 10.00: Disciplinary Proceedings
- 8. Review of Compliance/Violation of Consent Agreement
- 9. Vantive US Healthcare LLC- New Retail Pharmacy application
- 10. Option Care-Sterile Compounding application
- 11. Revive RX-Sterile Compounding application
- 12. Galaxy Pharmacy Relocation application
- 13. INV15492 Grant LaPierre
- 14. PHA-2024-0174-Medwiz of Mass, LLC
- 15. PHA-2025-007- Kenny Correia
- 16. PHA-2024-0176 Genoa Healthcare, LLC
- 17. PHA-2024-0184 Springfield Pharmacy
- 18. PHA-2024-0189 Walmart 10-5448
- 19. PHA-2024-0214 Walgreens 4729
- 20. PHA-2024-0197 Prescription Center Pharmacy
- 21. PHA-2025-0018 ProRx, LLC
- 22. PHA-2024-0169 Walgreens 10401
- 23. PHA-2024-0172 Southcoast Pharmacy
- 24. PHA-2024-0159 Wal-Mart 10-2903
- 25. PHA-2024-0160 -Deepa Singh
- 26. PHA-2024-0164 CVS 1015

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