

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

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

**August 1, 2024**

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

**Join link:**

<https://eohhs.webex.com/eohhs/j.php?MTID=m717a7091550d6ed7964a55a364df944d>

**Webinar number:**

2534 172 9538

**Webinar password:**

BOP123 (267124 from phones and video systems)

**Join by phone:**

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

+1-650-479-3208 United States Toll

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

**Agenda**

		Item	Page	
8:00	I	CALL TO ORDER		S. Ahmed
8:05	II	APPROVAL OF AGENDA		
8:10	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"><li>Draft of June 6, 2024, Regular Session Minutes</li></ul>		
8:15	IV	REPORTS <ul style="list-style-type: none"><li>Applications approved pursuant to Licensure Policy 13-01</li><li>Monthly report from Probation</li><li>Board Delegated Review pursuant to Licensure Policy 14-02</li><li>PSUD Report-Policy 17-03</li><li>Research Drug Study Report pursuant to Staff Action Policy 18-02</li></ul>		

8:20	V	<b>FLEX</b> <ul style="list-style-type: none"><li>• NABP District 1 &amp; 2 meeting, October 7 – 9, 2024</li><li>• June 12<sup>th</sup> Pharmacy Advisory Committee meeting summary</li><li>• Notice of Opportunity: Selection of Board approved inspectors</li><li>• NABP Resolutions</li><li>• Schedule II Perpetual Inventory</li></ul>																																													
8:30	VI	<b>POLICIES</b> <ul style="list-style-type: none"><li>• Policy 2023-09: Action Level Environmental Monitoring Results</li><li>• Rescission of Policy 2020-01: Pharmacist license reactivation after expiration beyond one renewal cycle</li></ul>																																													
8:45	VII	<b>APPLICATIONS</b> <ul style="list-style-type: none"><li>• Medminder; DS90408 - Petition for Waiver</li><li>• Nimvax; DS90369 – Renovation</li><li>• Crown Colony Pharmacy; DS90247 – Transfer of Ownership</li><li>• LexLab: Wholesale Distributor</li></ul>																																													
9:30	VIII	<b>FILE REVIEW</b> <table><tr><td>1</td><td>CASE-2024-1486</td><td>PHA-2024-0085</td><td>Crown Colony Pharmacy, DS90247</td></tr><tr><td>2</td><td>CASE-2024-1551</td><td>PHA-2024-0087</td><td>CAPS, Inc, NO00053</td></tr><tr><td>3</td><td>CASE-2024-1550</td><td>PHA-2024-0088</td><td>CAPS, Inc, NO00010</td></tr><tr><td>4</td><td>CASE-2024-1668</td><td>PHA-2024-0091</td><td>Walgreens #1851, DS1364</td></tr><tr><td>5</td><td>CASE-2024-1885</td><td>PHA-2024-0114</td><td>Theragnostics, Inc., WD511</td></tr><tr><td>6</td><td>CASE-2024-0994</td><td>PHA-2024-0046</td><td>QuVa Pharma, NO00043</td></tr><tr><td>7</td><td>CAS-2023-0819</td><td>PHA-2024-0064</td><td>Matthew Ward, PH234090</td></tr><tr><td>8</td><td>CAS-2022-1129</td><td>INV100411</td><td>St George Pharmacy Corp., DS90034</td></tr><tr><td>9</td><td>CASE-2023-0826</td><td>PHA-2024-0075</td><td>Lucy Maserejian, PH24058</td></tr><tr><td>10</td><td>CASE-2024-1667</td><td>PHA-2024-0094</td><td>Remedium Pharmacy, DS89943</td></tr></table>				1	CASE-2024-1486	PHA-2024-0085	Crown Colony Pharmacy, DS90247	2	CASE-2024-1551	PHA-2024-0087	CAPS, Inc, NO00053	3	CASE-2024-1550	PHA-2024-0088	CAPS, Inc, NO00010	4	CASE-2024-1668	PHA-2024-0091	Walgreens #1851, DS1364	5	CASE-2024-1885	PHA-2024-0114	Theragnostics, Inc., WD511	6	CASE-2024-0994	PHA-2024-0046	QuVa Pharma, NO00043	7	CAS-2023-0819	PHA-2024-0064	Matthew Ward, PH234090	8	CAS-2022-1129	INV100411	St George Pharmacy Corp., DS90034	9	CASE-2023-0826	PHA-2024-0075	Lucy Maserejian, PH24058	10	CASE-2024-1667	PHA-2024-0094	Remedium Pharmacy, DS89943		
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	<b>IX</b>	<b>11</b>	CASE-2024-1437	PHA-2024-0074	IntegraDose Compounding, NO00054			
		<b>12</b>	CASE-2024-1086	PHA-2024-0048	Rite Aid #10199, DS1996			
		<b>13</b>	CASE-2024-0012	PHA-2024-0018	Prescription Center Pharmacy-University Campus, DS89788			
		<b>14</b>	CASE-2024-0940	PHA-2024-0031	Walgreens #19695, DS90174			
		<b>15</b>	CASE-2024-1224	PHA-2024-0059	Walgreens #17226, DS90222			
		<b>16</b>	CASE-2024-1277	PHA-2024-0069	Walgreens #17637, DS90223			
		<b>17</b>	CASE-2023-0620	PHA-2024-0076	Erika B Andrades, PH232623			
		<b>18</b>	CASE-2023-0620	PHA-2024-0077	Mia Beach, PTT20458			
		<b>19</b>	CASE-2024-0989	PHA-2024-0044	CVS #507, DS89841			
		<b>20</b>	CASE-2024-0071	PHA-2024-0040	CVS #73, DS89858			
		<b>21</b>	CASE-2024-0027	PHA-2024-0025	CVS #7109, DS89836			
		<b>22</b>	CASE-2023-0686	PHA-2023-0246	Coram CVS/ Specialty Infusion Services, DS3601			
<b>11:30</b>	<b>X</b>	<b>EXECUTIVE SESSION</b> The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition, or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, evaluate the Good Moral Character as required for registration for a pending applicant.						
<b>12:00</b>	<b>XI</b>	<b>ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)</b>						
<b>12:30</b>		LUNCH BREAK						
<b>1:00</b>	<b>XII</b>	<b>M.G.L. c. 112, § 65C SESSION</b>						
<b>4:00</b>	<b>XIII</b>	<b>ADJOURNMENT</b>						

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

**MINUTES OF THE GENERAL SESSION**

**Via Remote WebEx Meeting**

**August 1, 2024**

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**Board Members Present**

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

**Board Members Not Present**

Katie Thornell, RPh, MBA President  
Rita Morelli, PharmD, BCACP, RPh, Secretary  
Julie Dorgan, RN

**Board Staff Present**

David Sencabaugh, RPh, 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  
Cheryl Lathum, RPh, PharmD, BCPS, Senior Investigator  
Keith Johnstone, Compliance Officer

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

**CALL TO ORDER 8:07 AM**

A quorum of the Board was present, established by roll call. President-Elect Sami Ahmed chaired the meeting and explained that the Board of Pharmacy was recording the meeting.

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

**Topic II.**  
**Agenda: 8/1/24**

**Approval of Agenda**

**TIME 8:07 AM**

**DISCUSSION:** Applications for Crown Colony Pharmacy and LexLab were withdrawn.

**ACTION:**

Motion by C. Belisle, seconded by D. Barnes and voted unanimously by those present to approve the agenda with the noted changes by roll call vote.

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**Topic III**

**Approval of Board Minutes**

**TIME: 8:09 AM**

**Minutes**

1. Draft 6/6/24

**Change:** No changes

**Action:**

Motion by D. Barnes seconded J. Lopez and voted unanimously to approve the regular session minutes of 6/6/2024 with no noted changes by roll call vote.

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**Topic IV.**

**REPORTS**

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

**TIME: 8:10 AM**

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported a total of 38 Change of MOR applications and 2 facility closures that have been approved via Staff Action since the June 6<sup>th</sup> Board meeting.

So noted.

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**Topic IV.**

**REPORTS**

**Monthly Report from Probation**

**TIME: 8:10 AM**

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto indicated a total of 11 licensees that were given the opportunity to cure, one granted extension, and 5 issuances of final notice since the last Board meeting.

So noted.

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**Topic IV.**

**REPORTS**

**Monthly Report from BDCR pursuant to Policy 14-02**

**TIME: 8:10 AM**

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported 4 Continuing Education deficiency cases, all of which were closed with no discipline warranted, remediation completed. 8 inspectional deficiencies cases had been reported, each issued a reprimand. 4 Controlled Substance losses occurred since the last meeting, each given non-disciplinary stayed probation with terms. Additionally, 2 violations of practice standards were reported, each issued a reprimand. 2 waiver renewal requests have been approved since the last Board meeting.

So noted.

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**Topic IV.**

**REPORTS**

**PSUD report by Staff Action 17-03**

**TIME: 8:11 AM**

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto indicated no new admissions or changes to the PSUD program since the June 6<sup>th</sup> Board meeting. Currently, there are a total of 8 active participants enrolled in the program.

So noted.

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**Topic IV.**

**REPORTS**

**Research Drug Study Report pursuant to Staff Action Policy 18-02**

**TIME: 8:11 AM**

PRESENTED BY: M. CHAN

DISCUSSION: M. Chan reported on 3 pharmacies that are currently participating in research drug studies. In total, there are currently 17 active studies, 5 of which involve investigational drug substances.

So noted.

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**Topic V.**

**FLEX**

**NABP District 1 & 2 meeting, October 7 – 9, 2024**

**TIME: 8:11 AM**

PRESENTED BY: D. SENCABAUGH

DISCUSSION: DAVID SENCABAUGH provided a reminder and encouraged those interested to attend the NABP/AACP District 1 and 2 Meeting being held at Encore Hotel in Everett from October 7, 2024 to October 9 2024.

ACTION: N/A

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**Topic V.****FLEX****June 12th Pharmacy Advisory Committee meeting summary****TIME: 8:12 AM**PRESENTED BY: Sami Ahmed

DISCUSSION: SAMI AHMED summarized the Pharmacy Advisory Committee's meeting held on June 12, 2024, regarding the Installation and administration of compounded sterile drug in implantable infusions pumps. He provided historical context for the request by BORP. He explained that Pentec Health, Inc (DS89913) was issued a pharmacy license in 2014 with restrictions on compounded sterile preparations which may be used in implantable pumps. Pentec Health, Inc requested modification of the restrictions and BORP voted during the March 2024 Board Meeting to refer the matter to the Pharmacy Advisory Committee for input. DAVID SENCABAUGH provided a reminder and encouraged those interested to attend the NABP/AACP District 1 and 2 Meeting being held at Encore Hotel in Everett from October 7, 2024 to October 9 2024.

AHMED described that topics discussed in Pharmacy Advisory Committee's meeting on June 12, 2024 included time at which administration began for implantable infusion pumps, precipitation within the pump, sterility, and patient access limitations. Ultimately, the committee voted to request additional information from Pentec Health, Inc. including a list of compounded sterile preparations that Pentec Health, Inc wished to compound which required modification of the restrictions. In addition, the committee also asserted that a general advisory document for implantable infusion pumps was important to develop to maximize patient safety to address parts of pharmacy practice outside of the jurisdiction of USP <797>.

ACTION: N/A

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**Topic V.****FLEX****Notice of Opportunity: Selection of Board approved inspectors****TIME: 8:16 AM**PRESENTED BY: David Sencabaugh and William Frisch

DISCUSSION: DAVID SENCABAUGH explained in anticipation of promulgation of 247 CMR 6.00 pertaining to the licensing of nonresident pharmacies, sterile compounders, non-sterile compounders, and institutional pharmacies that a notice of opportunity was given during the June 6, 2024 Board Meeting for applications for entities to handle out-of-state inspectors. WILLIAM FRISCH next indicated that two entities, Gates Healthcare Associates, Inc and NABP, applied for approval as inspectors. Frisch then requested that BORP vote to formally accept Gates Healthcare Associates, Inc and NABP as Board approved inspectors with their respective inspection tools.

ACTION: SEBASTIAN HAMILTON motioned to formally accept Gates Healthcare Associates, Inc and NABP as Board approved inspectors with their respective inspection tools. Seconded by SAAD DINO then Board Members present voted unanimously by roll call to approve motion.

**Topic V.****FLEX****NABP Resolutions****TIME: 8:20 AM**

PRESENTED BY: David Sencabaugh and William Frisch

DISCUSSION: DAVID SENCABAUGH requested submission of resolutions by BORP members to present at the NABP/AACP District 1 and 2 Meeting in October 2024. SENCABUGH and WILLIAM FRISCH explained that any resolution would need approval by vote from BORP during the September 2024 Board Meeting. FRISCH suggested that a resolution regarding drugs lost in transit be submitted so NABP may study the issue with a goal of developing strategies to minimize the number of drugs lost in transit.

ACTION: N/A

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**Topic V.****FLEX****Schedule II Perpetual Inventory****TIME: 8:24 AM**

PRESENTED BY: Michelle Chan

DISCUSSION: MICHELLE CHAN provided notice to licensees that allowances under the COVID-19 State of Emergency for pharmacies to perform 15-day perpetual inventory counts for Schedule II controlled substances will end effective October 1, 2024. BORP will then enforce requirements for 10-day counts under 247 CMR 9.01(14). ACTION: N/A

ACTION: N/A

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**TOPIC VI****POLICIES****Policy 2023-09: Action Level Environmental Monitoring Results****Time: 8:25 AM**

**Presented by:** M. CHAN

**Discussion:** A language change was made regarding identification of any growth in an ISO Class 5 area or any action level growth in other ISO Classified areas. This is to be consistent with the language in the draft sterile compounding regulations.

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

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**TOPIC VI****POLICIES****Time: 8:26 AM****Rescission of Policy 2020-01: Pharmacist License Reactivation after Expiration beyond One Renewal Cycle****Presented by:** M. CHAN

**Discussion:** The process to reactivate a pharmacist license has been simplified and instructions have been incorporated into the licensing system and posted on the webpage. The policy is no longer needed.

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

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**TOPIC VII****APPLICATIONS****1. Medminder; DS90408****Petition for Waiver****TIME: 8:24 AM****Represented by:** Erwin Enriquez, Thuan Nguyen**Recusal:** None**Discussion:**

- Medminder [Thuan] is looking to request a waiver for 247 CMR 8.02, to allow for the pharmacy technician to conduct final dispensing and process validation.
- Thuan further explained that an automation software (named DDM-200F) has been installed and implemented which would allow for the fill of multidose cards throughout the pharmacy. This software uses “smart vision” technology to recognize the pills dispensed.
  - Anything that is 100% recognized and filled by the automation software would be sent to a technician for final verification
  - Anything that is not 100% recognized would need to be reviewed by and verified by a pharmacist.
- Thuan also explained that with this waiver approval they hope to have pharmacists spending more time on patient care and to further expand their production speed, safety, and services.
- Board staff explained that a similar pilot project has been brought to The Board before, however the key difference was that the pilot project used Certified Pharmacy Technicians to complete the final verification.

**Questions:**

- Board member asked Board Staff if this automation software would be under the scope of an Automatic Drug Delivery System (ADD or ADDS), and board staff clarified this would not be under the scope of an ADD and that is why this waiver is being requested.
- Will this use certified Pharmacy technicians?
  - No

- Is there a way to bypass the refilling of the cassette [that is loaded into the machine], where a person could bypass the pharmacist verification to load the cassette? No, it will require a pharmacist to verify the cassette and if it has not been verified then the cassette will not be able to be filled until pharmacist verification.
- Is there a way to bypass pharmacist verification for a card which has an error or damaged pill? No there is not a way to bypass it.
- Is it up to the Pharmacy tech to see the defect and determine whether a pharmacist will review? The machine itself would catch that and alert the technician to notify the pharmacist.
- What is the criterion to review for the licensed pharmacy technician? The technician will be using software and, on the screen, it shows which errors need to be resolved. Technicians will be facilitating the card out of the machine onto a table to review the errors noted by the machine and to help rectify the errors and insure they are resolved. All these errors must be resolved before a label can be printed.
- Who places the label? The technician, and the label does not print out until there are no errors or all errors have been resolved.
- Will the machine print one label at a time? Yes, it is based on a barcode scan
- Board member C. Belisle clarified that the vote today is to approve the waiver and that this is not a pilot project. Board member C. Belisle also expressed concern regarding that there is a significant distinction between a certified pharmacy technician versus a pharmacy technician who is not nationally certified.
- Board member M. Sciaraffa concurred with C. Belisle, expressing that this plan may be best suited to have certified pharmacy technicians.
- Board member J. Rocchio expressed that it seems as though a non-certified pharmacy technician would be able to verify and validate considering the technology utilized. J. Rocchio also expressed that the pharmacist supervising should have say as to whether their pharmacy technicians are suitable.
- Board member S. Hamilton concurred with M. Sciaraffa and C. Belisle, citing that there is a reason why we distinguish between a nationally certified pharmacy technician. S. Hamilton further went on to explain that the pharmacy technician career is advancing and that there are higher levels of competency and skill as pharmacy technicians grow and in the role.

**Action:** A motion by C. BELISLE was made to defer this matter until the September 5th, 2024 Board meeting; Seconded by S. HAMILTON and voted unanimously to defer the Petition For Waiver.

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**2. Nimvax; DS90369**

**Renovation**

**TIME: 9:04 AM**

**Represented by:** Anthony Rozzi, Nimit Deocampo

**Recusal:** S. Ahmed

**Discussion:** Attorney Anthony Rozzi explained that during the covid pandemic, this pharmacy was a specialty vaccination clinic. However, now they are looking to expand as a retail pharmacy. Licensee is looking to withdraw all other waivers except for the waiver for the requirement to have the balance.

Board Counsel provided the Board with a short summary regarding the licensee's surrender of their DEA registration, which was initially discussed at the June 6<sup>th</sup>, 2024, meeting.

Questions;

- Are you looking to withdraw all your waivers that were previously granted? Yes, we are
- Do you currently hold a DEA license? No, once approved we will apply for the appropriate DEA licensure
- Can you please explain what is your contingency plan if you would need to close? We have a pending agreement with a nearby pharmacy so that if we need to close, they can still receive care.
- What is your current staffing levels? We have 2 Certified Pharmacy technicians, 1 fulltime pharmacy (Dr. Deocampo), and 1 part time pharmacist. We also have one Pharmacy Intern
- Does the other pharmacy have the same capacity to fulfill prescriptions?
- When talking about a 50-mile radius for delivery, what is your plan if there are packages that come back or are other issues after hours? We are outsourcing the delivery with an organization MedZoomer. The technology allows us to keep track of the deliveries and if someone is not home or the medication cannot be delivered it will come back to the pharmacy.
- Why do you want to be a full-service pharmacy today? We have a lot of patients who are asking us for expanded services. Additionally, as the pandemic is over, we are unable to serve patients. We have no vaccine and with patients asking for more services that has inspired us to start this change in business

**Action:** A motion by D. Barnes was made to approve the renovation application and the removal of all waivers, contingent upon satisfactory inspection; Seconded by S. Hamilton and voted unanimously by roll call to approve the motion.

**Action:** A motion by D. Barnes was made for the approval of a Massachusetts Controlled Substances Registration (MCSR) for Schedules II-VI; Seconded by C. Belisle and voted unanimously by roll call to approve the motion.

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### 3. Family Health Center of Worcester Pharmacy

New Community Pharmacy

TIME: 8:02 AM

Deferred

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### 4. Union Pharmacy Needham

New Community Pharmacy

TIME: 8:02 AM

Deferred

**TOPIC VIII.****FILE REVIEW**

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Case #1 / CASE-2024-1486

PHA-2024-0085

Crown Colony Pharmacy, DS90247

Time: 09:57 AM

RECUSAL: NONE

DISCUSSION: C. LATHUM presented and summarized the investigative report that pertained to this matter.

- ID on 4/2/24 for Peggy Tam performing PTT duties while unlicensed. The POC stated a PTT application was submitted for Peggy Tam (on 4/4/24) and she would only work as a cashier until approved.
- MOR Doan indicated PTT Tam was hired on 8/25/23 as a cashier. After a PT left without notice on 2/29/24, PTT Tam began training and started working as a PTT on 3/4/24. MOR Doan alleged he tried to apply for her PTT license prior to training but he was unfamiliar with the new online licensing process and was unsuccessful. After the inspection he contacted BORP staff who assisted in the online process. From 3/9/24-4/16/24, PTT Tam worked approximately 285 hours unlicensed.
- PTT Tam indicated she began performing PTT duties on 3/4/24 which included filling and labeling prescriptions, data entry, accepting written prescriptions and refill requests from patients, establishing and maintaining patient profiles, and faxing refill request to prescriber's offices.
- Going forward, MOR Doan will contact BORP staff immediately for all questions and will ensure all Pharmacy staff are licensed appropriately. MOR Doan, Pharmacist Nguyen and Pharmacist Phan reviewed the current Pharmacy's SOP# G.005 Pharmacy Technician Training and shall comply with all applicable requirements. PTT Tam was issued a PTT license on 04/17/2024.

ACTION: Motion by C. BELISLE, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2024-0085), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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Case #2/CASE-2024-1551

PHA-2024-0087

CAPS, Inc, NO00053

Time: 10:00 AM

RECUSAL: C. BELISLE AND D. BARNES recused and were not present for the vote or discussion in this matter.

DISCUSSION: C. LATHUM presented and summarized the investigative report that pertained to this matter.

- Failure to notify the BORP within 14 days of the 6/21/23-7/31/23 FDA inspection resulting in an FDA-483 issued on 7/31/2023. On 4/4/24, the BORP received notification that CAPS received a Warning Letter on 03/25/2024 related to the inspection. The Warning Letter indicated CAPS ceased distribution of CSPs on 7/14/23 and ceased production on 8/4/23. On 7/14/23 and 8/17/23, CAPS initiated voluntary recalls.
- CAPS Sr. Director O'Keefe asserted CAPS had promptly notified the BORP of the Warning Letter. He acknowledged that CAPS had inadvertently and unintentionally failed to notify the BORP of the FDA inspection. CAPS Sr. Director O'Keefe stated, "This was a regretful oversight and operational gap that

CAPS has addressed with the implementation of a procedure to ensure that the Company adheres to the reporting requirements under 247 CMR 21.09”.

ACTION: Motion by S. HAMILTON, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2024-0087), 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#3/CASE-2024-1550

PHA-2024-0088

CAPS, Inc, NO00010

Time: 10:03 AM

RECUSAL: C. BELISLE AND D. BARNES recused and were not present for the vote or discussion in this matter.

DISCUSSION: C. LATHUM presented and summarized the investigative report that pertained to this matter.

- Failure to notify the BORP within 14 days of a 2/27/23-3/30/23 FDA inspection resulting in a FDA-483 issued on 3/30/23. On 4/3/24, the BORP received notification that CAPS received a Warning Letter on 03/29/2024 related to the inspection. The Warning Letter indicated CAPS had initiated voluntary recalls of CSPs intended or expected to be sterile due to lack of sterility assurance on 4/28/23.
- CAPS Sr. Director O’Keefe asserted CAPS had promptly notified the BORP of the Warning Letter. He acknowledged that CAPS had inadvertently and unintentionally failed to notify the BORP of the FDA inspection and FDA-483. CAPS Sr. Director O’Keefe stated, “This was a regretful oversight and operational gap that CAPS has addressed with the implementation of a procedure to ensure that the Company adheres to the reporting requirements under 247 CMR 21.09”.

ACTION: Motion by R. LOPEZ, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2024-0088), 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

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/CASE-2024-1668

PHA-2024-0091

Walgreens #1851, DS1364

Time: 10:09 AM

RECUSAL: NONE

DISCUSSION: C. LATHUM presented and summarized the investigative report that pertained to this matter.

- Untimely submission of a change in MOR application on 04/19/24 for a change in MOR that occurred on or about 11/21/23 when Current MOR Verelst assumed the role.
- DM Patel and Current MOR Verelst indicated when the paperwork was completed on 11/21/23, the application was sent to an incorrect Walgreens licensing email address. Current MOR Verelst and Former MOR Chhay completed a CS inventory on 11/21/23. Current MOR Verelst discovered the Pharmacy’s license was not updated during a quarterly self-inspection on 4/18/24. He stated he was unaware the email recipient address was incorrect until then. The application was resubmitted then approved on 4/24/24.

- DM Patel and Current MOR Verelst indicated that going forward, they will follow up with the licensing department to ensure receipt of the MOR paperwork and will ensure receipt of the change of MOR paperwork within a week of being sent. Current MOR Verelst will review the BORP website confirming the change of MOR. Current MOR Verelst and Former MOR Chhay reviewed the current Walgreens SOP for the change in MOR in MA to include performing a complete controlled substance inventory by both the incoming MOR and the outgoing MOR.

**ACTION:** Motion by J. ROCCHIO, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0091), Discipline Not Warranted, Remediation Complete.

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Case #5/ CASE-2024-1885

PHA-2024-0114

Theragnostics, Inc., WD511

Time: 10:12 AM

**RECUSAL:** NONE

**DISCUSSION:** C. LATHUM presented and summarized the investigative report that pertained to this matter.

- On 5/23/24, virtual WD Theragnostics notified the BORP of a change of address not reported within 30 days invalidating their CS registration and it was discovered there was an unreported a change of ownership. In a press release dated 6/1/2023, Ariceum announced the acquisition of Theragnostics , Ltd, the parent company of Theragnostics. Ariceum obtained all assets including Nephroscan in partnership with GE Healthcare.
- Sr. Director Block related the corporate offices moved from Braintree to Cambridge on 5/31/24. When the BORP was timely notified, Theragnostics was informed as a virtual WD, they should obtain a MCSR from DCP instead and an application was submitted on 6/20/24. Sr. Director Block contended that although there was a change of ownership last year, neither Theragnostics nor its parent company, Theragnostics Ltd., changed as part of the of ownership. On 6/1/23, Ariceum acquired Theragnostics , Ltd resulting in Theragnostics obtaining a new grandparent owner. He stated, "...Theragnostics was under the sincere impression that the BORP did not require notification for a change in ownership at the grandparent level, which is why Theragnostics never provided any notice of this change".
- On 06/14/2024, Theragnostics initiated an application for a MCSR as a virtual WD. On 06/20/2024, the application was submitted with payment for MCSR number VIR200104. The current address was listed as Cambridge and the "Corporate Name" was listed as "Theragnostics Ltd" in London. On 07/09/2024, MCSR number VIR200104 was issued.

**ACTION:** Motion by S. HAMILTON, seconded by S. DINNO, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0114), No Discipline Warranted, Remediation Complete.

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Case #6/CASE-2024-0994

PHA-2024-0046

QuVa Pharma, NO00043

Time: 10:06 AM

**RECUSAL:** C. BELISLE 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 01-29-2024, QuVa reported to BORP that the facility was issued an FDA Warning Letter on 01-26-2024. The WL described that an inspection from 08-16-2022 to 10-14-2022 revealed drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions and CGMP violations. As a result, FDA issued a Form FDA 483 on 10-14-2022.
- Of note, QuVa failed to notify BORP about the FDA inspection and the Form FDA 483 in a timely manner which QuVa admitted.
- QuVa pledged to ensure full compliance with all BORP reporting requirements going forward. QuVa Pharma's described that a new procedure was implemented to ensure timely notice to BORP about any reportable incident under 247 CMR 21.09.
- In addition, QuVa Pharma explained that the facility submitted a comprehensive response to FDA which addressed the deficiencies described in the Warning Letter and provided a copy to BORP. QuVa also indicated that a 3rd party consultant was engaged to conduct a comprehensive assessment of QuVa's operations with an emphasis on aseptic processing operations.

**ACTION:** Motion by R. LOPEZ, seconded by J. ROCCHIO, and voted unanimously by those present, to refer the matter (PHA-2024-0046), 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 #7/CAS-2023-0819

PHA-2024-0064

Matthew Ward, PH234090

Time: 10:39AM

**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.

- BORP opened a complaint against Former MOR Ward of Wegmans in Chestnut Hill after review of a PHA against the pharmacy and an SA-INV concerning Former MOR Ward during the 03-07-2024 BM after the pharmacy was issued POCs during an RCIs on 06-08-2023 and 09-12-2023 for permitting two staff to work as PTTs without a license then permitting a PTT to work with an expired license, respectively. Wegmans was offered a CA for reprimand during the same meeting.
- MOR Ward initially blamed the violations on issues with the PTT and PT application process in his response to the SA-INV. In addition, he blamed Wegmans for not providing sufficient support. However, MOR Ward explained in his response to the complaint that he was angry at himself when he responded to the SA-INV. He wished that he could take back the response because his words did not reflect his practice professionally.
- Former MOR Ward created a spreadsheet to monitor licensure status on a monthly basis. He already identified a licensing issue at this new practice as an MOR at CVS 1023 and guided a technician to renew their license before expiry. He also completed 10 contact hours of remedial CE in law, ethics, compliance, and safety.

**ACTION:** Motion by S. HAMILTON, seconded by M. SCIARAFA, and voted unanimously by those present, to refer the matter (PHA-2024-0064), 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 #8/CAS-2022-1129

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.

- St. George was indicted on one count each of Medicaid False Claims, Medicaid Reverse False Claims, False Health Care Claims to Private Insurer, Reverse False Health Care Claims to Private Insurer, Excess Charges to MassHealth members, and two counts of Larceny over \$1,200.00. Of note, Owner-MOR Ayoub was also indicted for the same charges. Ultimately, the Office of The Attorney General filed a nolle prosequi (dismissal) on all charges in the cases against St. George and Owner-MOR Ayoub and the cases were closed on July 11, 2023.
- St. George and Owner-MOR Ayoub explained that the indictment stemmed from an audit conducted by Caremark in which inventory shortages due to the pharmacy's inability to produce invoices were uncovered. St. George and Owner-MOR Ayoub acknowledged that the pharmacy's recordkeeping was deficient. St. George and Owner-MOR Ayoub indicated that they were able to prove the majority of disputed claims were in fact prescriptions dispensed to patients by providing patient attestations and signature logs. On the other hand, St. George and Owner-MOR Ayoub admitted that the pharmacy accepted cash payments from MassHealth members for prescription drugs in violation of prohibitions on the acceptance of cash payments for drugs covered by MassHealth in 130 CMR 406.424 but not excessive charges.
- St. George enhanced its inventory processes including recordkeeping for prescription drugs to comply with standards of pharmacy practice and Drug Supply Chain Security Act.

ACTION: Motion by S. HAMILTON, seconded by R. LOPEZ, and voted unanimously by those present, to CLOSE the matter (INV100411), Discipline Not Warranted, Remediation Complete.

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Case #9/CASE-2023-0826

PHA-2024-0075

Lucy Maserejian, PH24058

Time: 10:15 AM

RECUSAL: S. DINNO 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.

- MOR Maserejian was MOR at West Concord Pharmacy during inspections on 01-06-2023 and 12-05-2023 when the pharmacy was cited for staff members practicing without a valid license. The first violation on 01-06-2023 involved a RI licensed pharmacy intern without a Massachusetts intern license. The second violation on 12-05-2023 involved a PTT practicing after her license expired on 11-01-2023.
- MOR Maserejian acknowledged that staff were practicing without valid licenses during both inspections. MOR Maserejian explained that her usual practice was to verify licensure status for every new hire, but she failed to verify Ms. Tosi licensure status. MOR Maserejian then emphasized that the oversight was a first for West Concord Pharmacy.
- MOR Maserejian described that the following corrective cation was implemented to mitigate recurrence of a similar incident. First, Ms. Tosi was required to obtain proper licensing before



returning to work. Next, a new layered policy was implemented which “consisted of multiple checks for licensure upon an employee’s hiring, which would hold the Manager of Human Resources, the MOR of the individual store and... the owners responsible for verifying... licensure of any qualifying employee.” MOR Maserejian added that the licensure status of all pharmacy staff was double-checked, and no further deficiencies were uncovered.

- MOR Maserejian next acknowledged that PTT Gee continued to practice after her license expired despite implementation of the new policy to monitor licensure status. MOR Maserejian indicated that an additional layer was added to the existing policy after violation involving PTT Gee’s license. MOR Maserejian described that “the Manager of Human Resources, the MOR of the individual store and one (or both) of the owners will meet every 6-8 weeks and compare reports of whose license is expiring to ensure compliance with both the Pharmacy’s internal policy and with Massachusetts licensing regulations.”

**ACTION:** Motion by D. BARNES, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2024-0075) 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-2024-1667

PHA-2024-0094

Remedium Pharmacy, DS89943

Time: 10:19 AM

**RECUSAL:** NONE

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

- PTT Lisa Witham was observed during an RCI on 04/22/2024 working after her license expired on July 11, 2022.
- MOR Cristina Iepure explained that a misunderstanding between state licensure and national certification was the root cause of the violation. Of note, BORP previously voted to offer a consent agreement for reprimand during the 12/01/2022 Board Meeting for the same violation after a different PTT was permitted to work after their license expired.
- CA: First, PTT Witham was barred from working in the pharmacy until she renewed her license. Next, all pharmacists were trained on requirements for state licensure versus credentials such as national certification issued by nongovernmental certification bodies. In addition, MOR Iepure indicated that “the hiring process will add an extra step of printing the licenses and this step will NOT be delayed until copies of the licenses are put on the wall.” Lastly, MOR Iepure reiterated that she updated Remedium’s standard operating procedures to emphasize requirements to verify state licensing regardless of national certification status.

**ACTION:** Motion by J. ROCCHIO, seconded by S. HAMILTON, and voted unanimously by those present, to defer the vote on this matter (PHA-2024-0094) until the 65C session. A second motion was made by R. LOPEZ, and seconded by S. HAMILTON, and voted unanimously by those present, to open a complaint on MOR Iepure (PH233720).

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Case #11/ CASE-2024-1437

PHA-2024-0074

IntegraDose Compounding, NO00054

Time: 10:23 AM

RECUSAL: NONE

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

- On 03/25/2024, IntegraDose untimely notified BORP that FDA inspected the facility between 02/12/2024 and 03/01/2024 then issued an FDA Form 483 on 03/01/2024. FDA noted eight observations in the FDA Form 483 including failing to conduct root cause analyses when batches failed to pass quality standards and the failure to ensure an aseptic environment.
- IntegraDose Compliance Manager Goree acknowledged that IntegraDose failed to notify BORP within 14 days of the FDA inspection and FDA Form 483. CM Goree explained that “IntegraDose had incorrectly documented the timeframe for notification of a FDA inspection and issuance of the 483 resulting in the failure to notify within the 14-day timeframe as required ...”
- CM Goree indicated that “IntegraDose has updated our process for notification to ensure timely notification in the future.” IntegraDose also provided a copy of the facility’s final plan of correction submitted to FDA regarding the FDA Form 483. However, FDA had yet to close-out the FDA Form 483 as of 06/26/2024.

ACTION: Motion by S. HAMILTON, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0074) 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-2024-1086

PHA-2024-0048

Rite Aid #10199, DS1996

Time: 10:26 AM

RECUSAL: NONE

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

- During a retail compliance inspection (ISP30659-RCCOM) conducted on 02/01/2024, the Investigator observed that the Pharmacy was not engaging in simple and moderate compounding.
- Senior Specialist (SS) Deborah Hurley provided a response indicating that Rite Aid wanted to request a waiver and/or exemption from dispensing compounded medications because they were not able to meet the requirements to continue compounding at our retail locations.
- On 04/03/2024, SS Hurley communicated with the BORP Executive Director (ED) David Sencabaugh via email correspondence. She wanted to withdraw the request for a waiver/exemption in regard to the compounding requirement. The pharmacists have been counseled as follows: If a patient requests a medication which requires compounding and they do not have the ingredients in stock to prepare it – the patient will be advised that we do not have the required ingredients to prepare the medication and they will be referred to the nearest compounding pharmacy.
- SS Hurley indicated that if any signs were posted indicating that we do not compound – they were removed.

ACTION: Motion by R. LOPEZ, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0048), Discipline Not Warranted, Remediation Complete.

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Case #13/ CASE-2024-0012

PHA-2024-0018 Prescription Center Pharmacy-University Campus, DS89788 Time: 10:28 AM

RECUSAL: NONE

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

- During a retail compliance inspection conducted on 12/20/2023, the Investigator noted insanitary conditions of mold growth on two refrigerators.
- MOR Glennon indicated that all medications stored in the refrigerator were damaged out and reverse distributed and all 10 prescriptions affected were reprocessed. Refrigerators have been removed from pharmacy for disposal and two new refrigerators have been delivered.
- In the Policy titled, "3.3.3 Retail Pharmacy Out of Range Medication in Refrigerator and/or Freezer", under the Maintenance Schedule, it stated that the units will be cleaned once monthly during review of outdating medications, or sooner if the unit is visibly dirty. A checklist will be maintained containing the date the unit was last cleaned and when the maintenance was last performed.
- MOR Glennon indicated that the team members are expected to clean and document that all items stored in all three refrigerators in the pharmacy were removed and all trays and walls were wiped down during the first week of each month. MOR will follow up and confirm this is done monthly. MOR and Prescription Center staff will work diligently to be sure that all refrigerators are cleaned and maintained appropriately.

ACTION: Motion by R. LOPEZ, seconded by C. BELISLE, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0018), Discipline Warranted, Remediation Complete.

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Case #14/CASE-2024-0940

PHA-2024-0031

Walgreens #19695, DS90174

Time: 10:30 AM

RECUSAL: NONE

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

- During a retail compliance inspection conducted on 01/08/2024, drug was observed stored in unlicensed space and unlicensed practice of a staff member was observed.
- MOR Eisenbiegler indicated that the freezer containing vaccine that was stored outside of licensed space was moved into the Pharmacy on 01/08/2024 and will remain in the Pharmacy to stay in compliance with Board regulations.
- MOR Eisenbiegler noted that Ms. Mullins was unlicensed at the time of the inspection noting that she had previously applied for a PTT license but it had not yet been granted. She was removed from the pharmacy department and did not resume pharmacy technician duties until her application was approved on 01/09/2024. The MOR indicated that Ms. Mullins was hired on 12/07/2023 and began

the onboarding process outside the pharmacy. Ms. Mullins entered the pharmacy starting on 12/26/2023, worked 46 hours until she was removed from the department during the inspection on 01/08/2024.

- MOR Eisenbiegler indicated that the freezer was moved to within the pharmacy on 01/08/2024 and will remain in the pharmacy to stay in compliance with BOP regulations. Additionally, she will verify all newly hired employees have active licensure prior to entering the pharmacy and will review licensure for existing employees monthly.

ACTION: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2024-0031), 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 #15/CASE-2024-1224

PHA-2024-0059

Walgreens #17226, DS90222

Time: 10:32 AM

RECUSAL: NONE

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

- On 02/26/2024, Investigator Brosnan conducted a retail compliance inspection at Walgreens #17226 and observed that the change of MOR application was not filed when the former MOR departed on or around 01/28/2024.
- Current MOR Calcagno wrote that Former MOR Nambaru's last day at the Pharmacy was 01/28/2024 and an interim MOR application was completed by corporate on 01/29/2024 and approved on 02/01/2024. On 03/04/2024, a new MOR application for Current MOR Calcagno to serve as full-time MOR was submitted. Walgreens was notified on 03/19/2024 that it was approved.
- Per eLX, an interim MOR application was submitted and approved on 01/30/2024 naming the interim MOR as Michael Calcagno and a new MOR application was submitted on 03/05/2024 and approved on 03/18/2024.
- In the response dated 03/29/2024, MOR Calcagno stated "I have reviewed the Board rules regarding the change of MOR to ensure an understanding of the process."

ACTION: Motion by R. LOPEZ, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0059), 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 #16/CASE-2024-1277

PHA-2024-0069

Walgreens #17637, DS90223

Time: 10:35 AM

RECUSAL: NONE

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

- During a retail compliance inspection conducted on 03/07/2024, the Investigator observed that a change in the MOR application had not been filed since the previous MOR went on leave in early November 2023.
- Interim Choi indicated that Current MOR Danehey went out on a leave of absence on 11/16/2023 which was expected to last 2 weeks, but it was extended.
- An interim MOR was not put in place until 01/09/2024, 54 days after Current MOR Danehey's LOA began, in violation of BP 2022-02. A controlled substance inventory was completed by Interim MOR Choi and Pharmacist Hua at that time.
- As of this report, BORP records indicate that Interim MOR Choi has served as MOR for greater than 100 days as BORP has not been notified that Current MOR Danehey has returned from her LOA as required by Board Policy 2022-02.
- On 06/27/2024, Board staff reached out to the MOR and informed that MOR Danehey returned from her leave on 05/28/2024.

**ACTION:** Motion by S. HAMILTON, seconded by J. ROCCHIO, and voted unanimously by those present, to consolidate the matter (PHA-2024-0069) with PHA-2021-0118. A second motion was made by J. ROCCHIO, seconded by S. HAMILTON, 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.

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Case #17/CASE-2023-0620

PHA-2024-0076

Erika B Andrades, PH232623

Time: 10:45 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.

- These complaints were opened during 04/04/2024 Board Meeting after review of PHA-2023-0219 against CVS 2339 in Chicopee, MA regarding the discovery during an RCI that MOR Andrades permitted PTT Beach to administer approximately 286 vaccines (COVID-19, influenza, pneumococcal, zoster, RSV, TDAP, MMR, HPV) when PTTs were not authorized to do so. BORP voted to offer a CA for reprimand to CVS 2339 then opened the complaints against MOR Andrades and PTT Beach.
- MOR Andrades indicated that she relied on word of mouth from the former MOR at CVS 2339 and PTT Beach when she vetted PTT Beach's licensure. She indicated that CVS listed PTT Beach as a pharmacy technician and PTT Beach was not prevented from doing immunization training. Therefore, MOR Andrades contended that she "saw no reason to question [PTT Beach's] status."
- CA: MOR Andrades pledged to verify the licensure status of any technician interested in becoming an immunizer prior to start of immunization training
- PT Beach asserted that she and the former MOR at CVS 2339 submitted an application for licensure by reciprocity because she was licensed in CT as a PT. Thus, she believed she was licensed as a pharmacy technician not a trainee.
- Of note, MOR Andrades and PTT Beach did not provide any documentation to support the contention that a licensure by reciprocity was submitted to BORP. In addition, PTT Beach did not submit an application for licensure as a Massachusetts pharmacy technician until 10/16/2023 after the RCI was

conducted according to BORP records. Furthermore, PTT Beach began to administer vaccinations on 09/13/2023 well after MOR Andrade was appointed MOR on 07/15/2023.

ACTION: Motion by R. LOPEZ, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0076), 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 #18/CASE-2023-0620

PHA-2024-0077

Mia Beach, PTT20458

Time: 10:48 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.

- These complaints were opened during 04/04/2024 Board Meeting after review of PHA-2023-0219 against CVS 2339 in Chicopee, MA regarding the discovery during an RCI that MOR Andrade permitted PTT Beach to administer approximately 286 vaccines (COVID-19, influenza, pneumococcal, zoster, RSV, TDAP, MMR, HPV) when PTTs were not authorized to do so. BORP voted to offer a CA for reprimand to CVS 2339 then opened the complaints against MOR Andrade and PTT Beach.
- MOR Andrade indicated that she relied on word of mouth from the former MOR at CVS 2339 and PTT Beach when she vetted PTT Beach's licensure. She indicated that CVS listed PTT Beach as a pharmacy technician and PTT Beach was not prevented from doing immunization training. Therefore, MOR Andrade contended that she "saw no reason to question [PTT Beach's] status."
- CA: MOR Andrade pledged to verify the licensure status of any technician interested in becoming an immunizer prior to start of immunization training
- PT Beach asserted that she and the former MOR at CVS 2339 submitted an application for licensure by reciprocity because she was licensed in CT as a PT. Thus, she believed she was licensed as a pharmacy technician not a trainee.
- Of note, MOR Andrade and PTT Beach did not provide any documentation to support the contention that a licensure by reciprocity was submitted to BORP. In addition, PTT Beach did not submit an application for licensure as a Massachusetts pharmacy technician until 10/16/2023 after the RCI was conducted according to BORP records. Furthermore, PTT Beach began to administer vaccinations on 09/13/2023 well after MOR Andrade was appointed MOR on 07/15/2023.

ACTION: Motion by D. BARNES, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0077), 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 #19/CASE-2024-0989

PHA-2024-0044

CVS #507, DS89841

Time: 10:49 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.

- During a retail compliance inspection on 01/23/2024, the Investigator observed that there was no interim Manager named, or a Change in MOR application was not submitted to the Board and the failure to report a change in their hours of operation.
- The POC stated that temporary sign with the current MOR's name was created and posted until the permanent sign is received. The hours were modified during the immunization season due to a staffing shortage. The store has since returned to normal hours of operation. A CS inventory was completed and sent to CVS corporate on 01/28/2024.
- DL Patel indicated that Former MOR Hsu was the MOR when he first came to work in the district. In November 2023, Former MOR Amin was placed there as the staff pharmacist and Former MOR Hsu was sent to another store to be trained as a MOR and then return to her role as MOR of CVS #507 once trained.
- Former MOR Amin indicated that the MOR and District Leader will work together to ensure the required inventories and paperwork are completed and submitted to the BOP in accordance with regulations.
- Former MOR Amin was replaced on 05/12/2024. A Change in MOR application was submitted and approved by BORP.

**ACTION:** Motion by S. HAMILTON, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2024-0044), 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 #20/CASE-2024-0071

PHA-2024-0040

CVS #73, DS89858

Time: 10:51 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.

- Unknown loss of #461 clonazepam 1mg tablets on 12/15/2023 discovered via corporate controlled substance monitoring.
- MOR DeRosa indicated that in April 2023 he became the MOR, and the Pharmacy was in complete disarray. He indicated that there were inventory issues across the board, staff shortages, and poor engagement from the team. He noted that multiple pharmacists were filling in the Pharmacy.
- The MOR noted that he could not locate the medication bottle and notified the loss prevention team. The team had him complete daily counts on all clonazepam 1mg bottles for about 3 weeks without any further loss.
- MOR DeRosa indicated that they continue to drive CVS policy and procedures on our filling process as well as training an inventory specialist to head this moving forward.
- On 05/06/2024, they retracted their DEA 106 report indicating that they located the missing medication resulting in no loss.

**ACTION:** Motion by R. LOPEZ, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0040), No Violation.

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Case #21/CASE-2024-0027

PHA-2024-0025

CVS #7109, DS89836

Time: 10:54 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.

- During a retail compliance inspection conducted on 11/14/2023, it was observed that a Rx Cooler 1 had experienced a temperature excursion for a period of 13 hours and 30 minutes, with a high of 51.4 F, without any documentation of action taken in response to the excursion.
- MOR Son indicated that the temperature excursion occurred on September 29, 2023. He noted that the refrigerator was working but the door was left ajar. No medication in the refrigerator was deemed unsafe for continual use that needed to be damaged/returned. Two medications (insulin degludec and etonogestrel vaginal) were dispensed to patients. MOR Son noted that he called the patients who did not want replacements.
- MOR Son indicated that in future instances of temperature excursions, the pharmacist on duty is to observe, document, and notify MOR about the excursions to ensure appropriate procedures. All staff have been educated on temperature excursion vigilance.

ACTION: Motion by D. BARNES, seconded by M. SCIARAFFA, and voted unanimously by those present, to refer the matter (PHA-2024-0025), 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 #22/CASE-2023-0686

PHA-2023-0246

Coram CVS/ Specialty Infusion Services, DS3601

Time: 10:56 AM

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

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

- During a USP <797> compliance inspection (ISP-30013) on 10/24/2023, the Investigator observed that the licensee had extensive contamination and insanitary issues, not compliant with USP guidelines.
- The Investigators found visible contamination and rust on various pieces of equipment, and within the room.
- On 10/24/2023, the Pharmacy voluntarily suspended compounding and informed the staff not to ship any finished products made on this day with a continuity care plan put in place.
- On 11/21/2023, Investigators Nathan Van Allen and Michael Brosnan conducted a site-visit (ISP-30071) at the Pharmacy to assess Cleanroom A, reviewed the interior cleanroom and the current state of operation and remediation was completed. On 11/22/2023, compounding would resume in cleanroom side A only.
- On 04/30/2024, Investigators Nathan Van Allen, Paul Seed, and John Murray conducted a <797> inspection (ISP-30032) in response to re-open the negative pressure room (NPR) in Suite A. A POC was issued for PEC certification reports and Employee HD training.
- On 05/06/2024, the Pharmacy was approved to start compounding in the NPR.



ACTION: Motion by D. BARNES, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0246), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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**Topic X:** **EXECUTIVE SESSION Call to Order:** **Time: 10:59 AM**

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

**Action:** Motion by S. HAMILTON, seconded by R. LOPEZ, and Board Members present voted unanimously by roll call to approve motion.

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

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**Topic XI:** **ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)** **Time: 11:22 AM**

DISCUSSION: None

ACTION: President-Elect S. Ahmed request a motion to enter 65C.

At 11:22 A.M. S. HAMILTON, seconded by S. DINNO and voted unanimously by all those present to enter Adjudicatory session by roll call vote.

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**Topic XII:** **65C SESSIONS MGL c. 112 section 65C** **Time: 11:46 AM**

DISCUSSION: None

ACTION: President-Elect S. Ahmed request a motion to enter 65C.

At 11:46 A.M. S. HAMILTON, seconded by R. LOPEZ and voted unanimously by all those present to enter 65C by roll call vote.

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**Lunch 12:00 PM to 12:30 PM**

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**Topic XIII:** **ADJOURNMENT OF MEETING** **TIME: 3:00 PM**

**ACTION:** Motion by S. HAMILTON seconded by S. DINNO and voted unanimously by all those present to adjourn the meeting by roll call vote.

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## **EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING**

1. Draft Agenda of the 8/1/2024 General Session
2. Draft Minutes of the 6/6/2024 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on Board Delegated Complaint Review to licensure policy 14-02
5. PSUD Report by Staff Action 17-03
6. Research Drug Study Report Pursuant Staff Action Policy 18-02
7. Documents regarding Notice of Opportunity
8. Policy 2023-09: Action Level Environmental Monitoring Results
9. Rescission of Policy 2020-01: Pharmacist license reactivation
10. Health Care Pharmacy- New Pharmacy Application
11. Medminder Petition for Waiver DS90408
12. Nimvax – Renovation application DS90369
13. PHA-2024-0085 Crown Colony Pharmacy DS90247
14. PHA-2024-0087 CAPS, Inc NO00053
15. PHA-2024-0088 CAPS, INC NO00010
16. PHA-2024-0091 Walgreens #1851, DS1364
17. PHA-2024-0114 Theragnostics, WD511
18. PHA-2024-0046 QuVa Pharma, NO00043
19. PHA-2024-0064 Matthew Ward, PH234090
20. INV100411 St. George Pharmacy, DS90034
21. PHA-2023-0075 Lucy Maserejian, PH24058
22. PHA-2024-0094 Remedium Pharmacy, DS89943
23. PHA-2024-0074 IntegraDose Compounding, NO00054
24. PHA-2024-0048 Rite Aid #10199, DS1996
25. PHA-2024-0018 Prescription Center Pharmacy, DS89788
26. PHA-2024-0031 Walgreens #19695, DS90174
27. PHA-2024-0059 Walgreens #17226, DS90222
28. PHA-2024-0069 Walgreens #17637, DS90223
29. PHA-2024-0076 Erika B Andrades, PH232623
30. PHA-2024-0077 Mia Beach, PTT20458
31. PHA-2024-0044 CVS #507, DS89841
32. PHA-2024-040 CVS #73, DS89858
33. PHA-2024-0025 CVS #7109, DS89836
34. PHA-2024-026 Coram CVS/Specialty Infusion Services, DS3601