COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

March 7, 2024
The regular session is open to the public by video or phone.

Join link:
https://eohhs.webex.com/eohhs/j.php?MTID=m08d1586bb5b2fbd14dff530bb139de9c
Webinar number:
2530 182 1885
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
Access code: 253 018 21885

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

Agenda

Time	#	Item	Page	
8:00	**I**	**CALL TO ORDER**		K. Thornell
8:02	**II**	**APPROVAL OF AGENDA**		
8:05	**III**	**APPROVAL OF BOARD MINUTES** • Draft of February 1, 2024, Regular Session Minutes		
8:10	**IV**	**REPORTS** • Applications approved pursuant to Licensure Policy 13-01 • Monthly report from Probation • Board Delegated Review pursuant to Licensure Policy 14-02 • PSUD Report-Policy 17-03		

8:30	**V**	**RECONSIDERATIONS** • CVS Pharmacy #26; DS2912; PHA-2023-0104 • CVS Pharmacy #23; DS90049; PHA-2022-0108		M. Egan
8:45	**VI**	**REVIEW OF COMPLIANCE** • Blue Hill Pharmacy, License No. DS89942 - PHA-2022-0122		K. Fishman
9:00	**VII**	**APPLICATIONS** • Blue Hill Pharmacy; DS89942 - Change Pharmacy Hours of Operation • CVS/Specialty; DS3416 – Renovation • BMC Pharmacy at South Boston – New Community Pharmacy • BILH Pharmacy 41 Mall Rd, Burlington– New Community Pharmacy • Bravo Pharmacy; DS89981 – Relocation • Nephron Sterile Compounding Center, LLC - Non-Resident Outsourcing		

10:00	**VIII**	**FILE REVIEW**					
		1	CAS-2022-1376	PHA-2022-0207	Nephron SC, Inc, NO00036		
		2	CAS-2023-0867	PHA-2023-0170	SOFIE, NU00021		
		3	CAS-2023-1092	PHA-2024-0013	SOFIE, NU00021		
		4	CASE-2023-0564	PHA-2024-0014	SOFIE, NU00021		
		5	CASE-2023-0453	INV8186	BWH Nuclear Pharmacy, NU16		
		6	CASE-2023-0754	INV8849	BWH Nuclear Pharmacy, NU16		
		7	CASE-2023-0762	PHA-2023-0265	Walgreens #5445, DS2964		
		8	CAS-2023-0522	PHA-2023-0234	Imad Haidardiab, PH24533		
		9	CASE-2023-0630	PHA-2023-0236	Walgreens #17531, DS90420		
		10	CASE-2023-0559	PHA-2023-0216	Walgreens #15390, DS89867		
		11	CASE-2023-0691	PHA-2023-0249	Tufts Medicine Infusions Services, DS90378		
		12	CASE-2023-0423	PHA-2023-0177	Fresenius Kabi Compounding, RO00002		
		13	CAS-2023-1127	PHA-2023-0195	Michael Martin, PH19637		
		14	CASE-2023-0509	PHA-2023-0232	Walgreens 4966, DS2924		
		15	CASE-2023-0398	INV8069	Paul R Casale, PT23845		
		16	CASE-2023-0557	PHA-2023-0198	Market 32, DS2526		
		17	CASE-2023-0690	INV8698	Paul Rohde, PH15575		
		18	CASE-2023-0657	PHA-2023-0238	McNabb Pharmacy, DS90087		
		19	CASE-2023-0408	PHA-2023-0243	Walgreens #7063, DS3238		
		20	CASE-2023-0440	PHA-2023-0244	Walgreens #17545, DS90127		

		21	CASE-2023-0625	PHA-2023-0237	Walgreens #5756, DS3252	
		22	CASE-2023-0688	PHA-2023-0248	New England Life Care, DS90241	
		23	CASE-2023-0621	PHA-2023-0218	ProCare LTC, DS90042	
		24	CASE-2023-0485	PHA-2023-0225	CAPS, DS3312	
		25	CASE-2023-0689	PHA-2023-0247	Partners of MA, DS3419	
		26	CASE-2023-0587	PHA-2023-0201	Amherst Pharmacy, DS89775	
		27	CASE-2023-0518	PHA-2023-0233	CVS #1531, DS89663	
		28	CASE-2023-0685	PHA-2023-0255	CVS #11131, DS99287	
		29	CASE-2023-0561	PHA-2023-0257	CVS #4200, DS89646	
		30	CASE-2023-0491	PHA-2023-0208	CVS #17589, DS90006	
		31	CASE-2023-0516	PHA-2023-0210	CVS #1238, DS2058	
		32	CASE-2023-0543	PHA-2023-0258	CVS #1002, DS3060	
		33	CASE-2023-0483	PHA-2023-0226	CVS #1852, DS3462	
		34	CAS-2023-0819	PHA-2023-0145	Wegman Food Market, Inc, DS89914	
		35	CAS-2023-0819	INV8500	Matthew Ward, PH234090	
		36	CASE-2023-0567	PHA-2023-0200	CVS #2201, DS2770	
11:30		**LUNCH BREAK**				
12:00	**IX**	**EXECUTIVE SESSION** The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition, or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, to review a petition for reinstatement; review a consent agreement for participation in PSUD and to evaluate the Good Moral Character as required for registration for a pending applicant**.**				
1:00	**X**	**ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)**				
1:15	**XI**	**M.G.L. c. 112, § 65C SESSION**				
4:00	**XII**	**ADJOURNMENT**				

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION
Via Remote WebEx Meeting
March 7, 2024

Board Members Present
Katie Thornell, RPh, MBA, President
Sami Ahmed, PharmD., RPh, BCPS, BCSCP, President-Elect
Caryn Belisle, RPh, MBA
Johanna Lopez, MS
Dr. Richard Lopez, MD
Sebastian Hamilton, Pharm D, MBA, RPh
Delilah Barnes, RPh
Mark Sciaraffa, CPhT
Julie Dorgan, RN
Saad Dinno, RPh, FACP/FACA
John Rocchio, RPh, PharmD

Board Members Not Present
Rita Morelli, PharmD, BCACP, RPh
Dawn Perry, JD

Board Staff Present
David Sencabaugh, RPh, Executive Director
Monica Botto, Associate Executive Director
Jacqueline Petrillo, PharmD, RPh, JD, Board Counsel
Michael Egan, 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
Christina Mogni, RPh, Investigator
Keith Johnstone, Compliance Officer
Ali Al Juboori, Pharmacy Intern

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 AM
A quorum of the Board was present, established by roll call. President Katie Thornell chaired the meeting and explained that the Board of Pharmacy was recording the meeting.

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

Topic II. **Approval of Agenda** **TIME 8:06 AM**
Agenda: 3/7/24

DISCUSSION: No Changes

ACTION:
Motion by S. Hamilton, seconded by J. Lopez and voted unanimously by those present to approve the agenda by roll call vote.

Topic III **Approval of Board Minutes** **TIME: 8:07 AM**

Minutes
1. Draft 2/1/24

Change: No changes

Action:
Motion by S. Hamilton seconded D. Barnes and voted to approve the regular session minutes of 2/1/2024 with no noted changes by roll call vote. Abstained: S. Dinno

---

Topic IV. **REPORTS**

Applications approved pursuant to Licensure Policy 13-01 **TIME: 8:07 AM**

PRESENTED BY**:** M. BOTTO

DISCUSSION: M. Botto reported a total of 47 Change in MOR applications and 9 facility closures that have been approved via Staff Action since the February 1st Board meeting.

So noted.

Topic IV. **REPORTS**

Monthly Report from Probation **TIME: 8:07 AM**

PRESENTED BY**:** M. BOTTO

DISCUSSION: M. Botto reported 25 active probation cases since the February 1st Board meeting. 1 licensee was given the opportunity to cure, and 1 licensee was issued final notice by Board counsel.

So noted.

Topic IV. **REPORTS**

Monthly Report from BDCR pursuant to Policy 14-02 **TIME: 8:08 AM**

PRESENTED BY**:** M. BOTTO

DISCUSSION: M. Botto indicated 2 inspectional deficiencies that were reported since the last Board meeting, each of which was issued a reprimand. 18 CE were reported deficiencies, all closed with discipline not warranted, remediation complete. 1 waiver request has been approved since the last meeting.

So noted.

Topic IV. **REPORTS**

PSUD report by Staff Action 17-03 **TIME: 8:08 AM**

PRESENTED BY**:** M. BOTTO

DISCUSSION: M. Botto reported 1 new admission to the PSUD program since the last Board meeting, with one successful completion and discharge from the program. Currently, there are 8 active participants enrolled in the program.

So noted.

J. Rocchio leaves the meeting at 8:18 AM

V. **RECONSIDERATIONS** **TIME: 8:19am**

- **CVS Pharmacy #26; DS2912; PHA-2023-0104**

Presented by: Michael Egan
Recusal: None

Discussion: MICHAEL EGAN described that BORP voted to consolidate this matter cases with cases which were previously consolidated PHA-2022-0062 & PHA-2022-0108. However, CVS #26 entered into consent agreement to resolve the previously consolidated PHA-2022-0062 & PHA-2022-0108 before PHA2023-0104 was consolidated into the previously consolidated cases. EGAN then provided an extensive description of the matters including the category of drugs. He also provided an comprehensive overview of different disciplinary actions that BORP may take to resolve PHA-2023-0104 including hybrid consent agreements.

Action: SEBESTIAN HAMILTON motioned to separate PHA-2023-0104 from the previously consolidated PHA-2022-0062 & PHA-2022-0108; CARYN BELISLE seconded; Board members present then voted by roll call to unanimously to approve the motion. Next, SEBESTIAN HAMILTON motioned to refer the matter (PHA-2023-0104) 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 one-year period of probation with terms to include the controlled substance loss protocol for all tramadol-containing products; Seconded by DELILAH BARNES; Board members then voted unanimously by those present approve the motion. Of

note, JOHN ROCCHIO left the meeting at 8:18am prior to presentation and deliberation of the reconsideration of PHA-2023-0104.

VI. RECONSIDERATIONS TIME: 8:18am

- **CVS Pharmacy #23; DS90049; PHA-2022-0108**

Presented by: Michael Egan
Recusal: None

Discussion: MIOCHAEL EGAN described that BORP voted during the June 2, 2022 Board Meeting to consolidate then authorize resolution of PHA-2022-0062 & PHA-2022-0108 involving losses of 365 phenobarbital 16.2mg tablets and 100 oxycodone-acetaminophen 10-325mg tablets, respectively, by a consent agreement for a one-year period of probation with terms including controlled substance loss protocol. However, the terms for the controlled substance protocol was mistakenly left out of the consent agreement the controlled substance protocol when the pharmacy entered into the agreement on May 18, 2023. EGAN noted that the pharmacy did not have any "red flag issues" during the period of probation so far. Therefore, EGAN requested that BORP vote adopt the consent agreement as signed as resolution for PHA-2022-0062 & PHA-2022-0108.

Action: SEBESTIAN HAMILTON motioned to rescind the BORP vote on June 2, 2022 to authorize resolution of PHA-2022-0062 & PHA-2022-0108 by a one-year period of probation with terms to include the controlled substance loss protocol and authorize the consent agreement entered into by CVS Pharmacy #23 on May 18, 2023 as resolution of the matter; Seconded by DELILAH BARNES; Board members then voted unanimously by those present approve the motion.

VI. REVIEW OF COMPLIANCE TIME: 8:33am

- **Blue Hill Pharmacy, License No. DS89942 - PHA-2022-0122**

Presented by: Karen Fishman
Recusal: None

Discussion: RON LANTON attorney for Blue Hill was present. VICTORIA OKEKE, MOR & Owner, was present by speaker phone through LANTON. KAREN FISHMAN reported that Blue Hill was in violation of a consent agreement for probation for a three-year period entered into effective November 23, 2023 to resolve PHA-2022-0122 & CAS-2022-0664 (See Consent Agreement pp 26 to 30 Board Packet). Specifically, on Wednesday, January 17, 2024, at approximately 12:15pm, and again at 12:30pm, a Board inspector went to the pharmacy to perform a retail inspection, however, the pharmacy was closed. Regular business hours for the pharmacy are posted as Monday through Friday from 12:00pm to 4:00pm. JACQUELINE PETRILLO then interceded on behalf of BORP to clarify that the authorized hours of operation on January 13, 2024 were 12:00pm to 5:00pm Monday through Friday. FISHMAN next described that Blue Hill was closed during regular business hours. She noted that the incident was a repeat violation and the same violation in the consent agreement. OKEKE responded that construction

around her pharmacy caused a delayed opening on January 17, 2024. OKEKE indicated that she owned the building where Blue Hill was located but the building did not include parking.

Action: SEBESTIAN HAMILTON motioned to find that Blue Hill was in violation of the consent agreement entered into effective November 13, 2023; Seconded by CARYN BELISLE; Board members then voted unanimously by those present approve the motion. SEBESTIAN HAMILTON next motioned to modify the terms of the consent agreement entered into effective November 13, 2023 by Blue Hill to include a term requiring that the pharmacy must be opened and always staffed by a licensed pharmacist during regular posted business hours; Seconded by CARYN BELISLE; Board members then voted unanimously by those present approve the motion.

VII: APPLICATIONS

1. Blue Hill Pharmacy; DS89942 Change Pharmacy Hours of Operation TIME 8:11am

Represented by: Victoria Okeke, MOR & Owner & Ron Lanton, Attorney for Blue Hill
Recusal: None

Discussion: RON LANTON requested clarification as to hours od operation currently on record with BORP. JACQUELINE PETRILLO responded that the most recent hours of operation on record were 12:00pm to 5:00pm. SEBASTIAN HAMILTON inquired as to reason for the reduction in hours off operation. VICTORIA OKEKE indicated that she wished to reduce the hours of operation so she may begin delivery of prescriptions to patients earlier in the day. SAMI AHMED inquired about the impact of reduced hours of operation may have on the community. OKEKE explained that she did not have foot traffic in the pharmacy so the community would not be impacted. PETRILLO interceded and addressed OKEKE. PETRILLO conveyed that she wished to be "crystal clear" to avoid future misunderstandings that OKEKE must have a licensed pharmacist in the pharmacy and the pharmacy must be opened to public during the approved hours of operation on record with BORP. OKEKE acknowledged that she understood.

Action: SEBESTIAN HAMILTON motioned to approve the application for change in hours of operation to 12:00pm to 4:00pm Monday through Friday (See Application pp 39 to 40 in Board Packet); JOHN ROCCHIO seconded; Board members present then voted by roll call to unanimously to approve the motion.

---

2. CVS/Specialty; DS3416 Renovation TIME 8:54am

Represented by: Kim Morese, MOR, Jennifer DiMauro, Director of Professional Practice, Benjamin DiMarco, Attorney fo CVS
Recusal: None

Discussion: KIM MORESE provided a comprehensive overview of the planned phases of renovation at CVS/Specialty. She added that CVS would remain open during the renovation by performing construction during off-hours. CARYN BELISLE inquired whether a registered pharmacist would be

onsite at all times during construction. MORESE confirmed a registered pharmacist would be on site during construction. WILLIAM FRISCH requested that BORP require presentation of a certificate of occupancy and a successful renovation inspection upon completion of renovation as part of the approval of the application for renovation.

Action: SEBESTIAN HAMILTON motioned to approve CVS/Specialty's application renovation pending presentation of a certificate of occupancy and a successful renovation inspection upon completion of renovation; CARYN BELISLE seconded; Board members present then voted by roll call to unanimously to approve the motion.

---

3. BMC Pharmacy at South Boston **New Community Pharmacy** **TIME: 8:59 AM**

Represented by: Gerry & Robert Miranda
Recusal: S. Hamilton

Discussion:

Here today for a new pharmacy application. We are submitting an application to open a new pharmacy at South Boston. CVS provided a notice to leave their South Boston location and BMC would like to take over pharmacy operations to provide continuity of care to the patients at South Boston Community Health Center. Our goal is to have this pharmacy operate like a retail pharmacy and minimize patient disruptions. We don't plan to change the hours; we plan to have 2 pharmacist and 3 techs working the hours. We plan to have security monitoring and temperature monitoring. Our goal is to minimize care issues access to South Boston patients. CVS will be leaving on April 12th, and the network infrastructure (such as IT and security) over the weekend, and BMC to resume operations by Friday (April 19th).

The Hours of operation do not plan to change the hours of operation (M-F 9am to 5:30pm and Saturday 9am -1pm), with 2 pharmacists and 3 technician staffing. We also plan to have the appropriate temperature and security monitoring once this pharmacy opens. We want to make sure patients have access to care due to CVS leaving this pharmacy.

When the BMC South Boston pharmacy, we are anticipating a gap of service for 60 days because of stock. In order to alleviate this issue, BMC would like to implement a depot model for the first 60-90 days in order to have the stock, until all necessary contracts are in place. On page 2, the exec summary, BMC will plan to use the BMC Shapiro pharmacy to fill and courier prescriptions at the South Boston location. If the patient wants a same day pick up, they will transfer the prescription to another pharmacy. There will be a notice that also explains that next day pick up is available for pick up from the South Boston location. Once next day pick up is confirmed, the BMC Shapiro pharmacy will use a 3rd party courier which will have totes (sealable) that have the medications, and a manifest to be within the tote. It will be taken by the courier to South Boston from Shapiro Pharmacy. When the scripts arrive, normal corrections and review will occur at the South Boston location (i.e. verification, data entry, etc…). They will then be able to pick up the medications from the South Boston location.

Question:

- Is there a communication going to the patients who use this pharmacy before this transition?

    - Yes there is a plan for South Boston Community Health Center, to communicate to their patients that this change is coming
- What about non-South Boston Community Center folks?
    - There will be outdoor signage. There is a plan in place to have CVS notify and send people notice of their closure. BMC will also be receiving patient and prescription info and will be able to outreach
- Will there be a licensed pharmacy at the south Boston location at all the hours of operations during the depot model?
    - Yes
- Will the courier deliveries be batch deliveries?
    - Batch deliveries.
- And will payment/signature be done at the South Boston location ?
    - it will be collected at the South Boston location. It will all, however, funnel back to and be under the license at the Shapiro pharmacy during the depot time frame.
- What is the plan if the prescription is canceled or not picked up? Is there a plan to reverse distribute to Shapiro?
    - We will plan to have the same process to reverse distribute and will follow the standard operating procedures of BMC Shapiro pharmacy.
- Will there be a manifest to confirm the items of reverse distribution?
    - Yes
- Will the courier be using this for controlled substances and refrigerated items?
    - Courier will be the same, however We will have tamper evident tape on the controlled substances.
- How would you handle a walk in with a written script?
    - We have a pharmacy network so we can take that script and upload it to complete data entry and process through the Shapiro pharmacy. If a patient needs it that same day, then we will have to have them sent to another pharmacy as previously mentioned (until the depot timeframe is over)

Action: A motion was made by D. Barnes to approve the New Pharmacy application for BMC at the South Boston location upon successful inspection; Seconded by J. Lopez then Board members present voted unanimously by roll call to approve the motion.

---

4. BILH Pharmacy 41 Mall Rd, Burlington New Community Pharmacy TIME: 9:20 AM

Represented by: Leah Giambarresi & Mary Caban
Recusal:

Discussion: There is a clinic pharmacy that is located at this facility, and, as a result of various mergers and acquisitions, in order to provide more complete care for our patients who may have a different prescriber that is not part of the Lahey network due to the limitations of the clinic license. We want to be able to service all of our patient's needs but we will be open and willing to serve any community member.

The applicants are still waiting for approval from HCQ to convert from a clinic to retail space

- To clarify, there already is an established pharmacy that is servicing patients, but there is a population within the group that can't be serviced because they go through a specialist and you're now trying to provide service for everybody?
    - We currently operate under a clinic license, and we are only allowed to fill prescriptions from a prescribed who is in the Lahey system. The goal of this is to fill all of the prescriptions for our patients.
- You're a clinic pharmacy, but your primary function is dispensing medication, not refilling automated dispensing and other hospital pharmacy uses?
    - Correct, there is a separate clinic in-patient pharmacy that does this. This pharmacy is primarily filling employee, dependent of employee, and patient outpatient prescriptions.
- What is the current plan for the change over from the clinic purchased inventory to transition retail the inventory?
    - We've already worked with Board staff behind the scenes and came up with a plan to transition from the inventory that is satisfactory with everyone
- And the DEA license?
    - We will be getting a new retail DEA license as well.

Action: A motion made by S. Hamilton to approve the application for the New Pharmacy as submitted, pending confirmation from Health Care Quality and upon successful inspection; Seconded by S. Ahmed the Board Members present voted unanimously by roll call to approve the motion, with M. Sciaraffa being unable to provide vote due to technical difficulties.

---

5. Bravo Pharmacy; DS89981 **Relocation** **TIME: 9:27 AM**

Represented by: David Trinks, Dmitry, and Eris Karnaxha
Recusal:

Discussion: Relocating form JP to Watertown. The lease is expiring and the current space is not ideal for clientele. This will also allow for parking, better patient access, and is generally a better space for the clients. Eris Karnaxha confirmed he is MOR, Dmitry is owner.

- The relocation will also include a non-sterile compounding expansion space?
    - The already do compounding up to USP 800. This area will include non hazardous complex compounding.
- Mentioned that parking is going to be increasing patient access, but the location change form Jamaica Plain to Watertown is significant, will this impact their access?
    - Most of our patients receive their medication via mail as they are elderly. We started testing this to some extent and patients appreciate the elevated service and we have been engaging patients on what would work best for them as well.
- Once you move to Watertown you'll still be providing shipping and services?
    - It's a nicer and safer building and we do not plan on limiting services at all.
- Will your whole prescription area be secure?
    - Yes, access will only be for the pharmacy staff

Action: A motion was made by S. Hamilton to approve the relocation application for Bravo Pharmacy pending successful inspection upon relocation; Seconded by C. Belisle, then Board members present voted unanimously by roll call to approve the motion.

---

6. Nephron Sterile Compounding Center, LLC Non-Resident Outsourcing TIME: 9:38 AM

Represented by: Chris Fortier, April Reed, Tosin Adelakun, Lori Leeshun, Christin Stewart
Recusal: Mark, Sami, Caryn

Discussion: Nephron pharmaceutical corporation has 2 divisions, one is a generic drug corporation where we make inhaled respiratory products, the other is a 503b facility. This is regarding our licensure relating to the naming of Nephron and our FEI numbers.

Back in 2016, Nephron SC and Nephron SCC were separated into two FEI numbers, and the FDA then recommended we merge those two FEI numbers. In February in 2022, the FDA said that we should split those FEI numbers back to Nephron SC and Nephron SCC. When we applied for licensure outsourcing [with MA], it is currently in your system as Nephron SC under one FEI number. In discussion with the Board in January, it was suggested that we relinquish our outsourcing license and then reapply under Nephron SC and a separate FEI number for the outsourcing facility.

Board counsel noted that "This is simple matter of the wrong entity holding the wrong licensure and we requested that they correct that mistake. "

Action: A motion by S. Hamilton to approve the Non-resident outsourcing application as submitted with the required correction; Seconded by J. Lopez, then Board members present voted unanimously by roll call to approve the motion.

TOPIC IX FILE REVIEW

Case #1 /CAS-2022-1376
PHA-2022-0207 Nephron SC, Inc, NO00036 Time: 10:03 AM

RECUSAL: S. AHMED, C. BELISLE, and M. SCIARAFFA 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.

- FDA conducted a drug manufacturer inspection at Nephron SC, Inc. during March and April 2022 then issued a Form 483 followed by a Warning Letter. Violations cited in the Warning Letter included (1) the failure to thoroughly investigate any unexplained discrepancy or failure of a batch or any of its components to meet any of its specifications, whether or not the batch has already been distributed. (2) the failure to establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, and that include validation of all aseptic and sterilization processes, (3) the failure to establish an adequate system for monitoring

environmental conditions in aseptic processing areas, (4) violations of requirements for Field Alert Reporting concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in distributed drug products.

- In addition, Nephron SC, Inc was not registered with FDA as a human drug compounding outsourcing facility under Section 503B of the Federal FD&C Act as required for BORP registration as an outsourcing facility.
- CA: Nephron SC, Inc. summarized that independent third party, Lachman Consultant Services, Inc., was hired to provide on-site support to Nephron SC, Inc. in the form of "assessments, interim control recommendations, remediation plan, participated in steering committee dedicated to ensuring a compliant and effective manufacturing and quality system, communications plan, escalation plan, protocols, and protocol reports (where warranted), batch record review, post-market drug assessment, and real-time operational and quality oversight."
- Nephron SC, Inc. further provided a status update on implementation of the facility's corrective action plan submitted to FDA in response to the Warning Letter which asserted that all items were closed. However, FDA indicated that the deficiencies described in the Warning Letter remained open pending confirmation during additional inspections in the future.

ACTION: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2022-0207), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #2/CAS-2023-0867
PHA-2023-0170 SOFIE, NU00021 Time: 10:06 AM

RECUSAL: NONE

DISCUSSION: N. VAN ALLEN presented and summarized the investigative report that pertained to this matter.

- On 6/20/23, 7/21/23, and 8/22/23, SOFIE submitted timely disclosures of above action level environmental results pursuant to Board Policy 2019-08 (Now 2023-09). The excursions were located within their ISO 5 Designated Hot Cell (DHC) which provides both operator protection from radiation and a clean environment for preparing sterile compounds.
- The 7/21/23 disclosure was identified as "Too Many CFUs to count" which would qualify as a significant loss of control under BORP Policy requiring additional steps to be taken including initiating recall procedures, notifying prescribers, conducting adverse event surveillance, and engaging a microbiology professional for assessment.
- The Pharmacy conducted investigations into the root cause of each incident and determined that the cause was likely due to "Operator Error" from dropping sampling plates during the incubation process. The root cause led the Pharmacy to determine that the identified excursion was not a "significant loss of control" and therefore did not conduct the requirements of the policy.
- No adverse events have been reported.
- Pharmacy corrective actions included review of subsequent environmental sampling and cleaning activities. This review did not identify additional contamination and led the Pharmacy to determine those routine procedures for monitoring and cleaning remediated the identified excursion

successfully. These routine procedures include daily environmental monitoring of the ISO 5 DHC, daily cleanings with germicidal agents, and weekly cleanings with sporicidal agents.

- Additional corrective actions included retraining operators with handling sampling plates, and cleaning procedures.
- Since the opening of this complaint the Pharmacy has submitted three (3) additional Disclosures of Above Action Level Environmental Results citing insufficient cleaning of the ISO 5 DHC and operator error with inadvertent dropping of sampling plates as the initial root cause. They were all remediated successfully.

ACTION: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to CONSOLIDATE the matter (PHA-2023-0170), with PHA-2024-0013 and PHA-2024-0014. A second motion was made by S. HAMILTON, and seconded by C. BELISLE, to refer the consolidated matters to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 12 to 18 months, with special terms to include the following:

i. Comply with all laws and regulations governing the practice of nuclear pharmacy.

ii. Immediately upon the Effective Date appoint a local full time Interim Manager of Record until June 30, 2024, at which time a permanent on-site MOR shall be appointed. The Regional Director of Operations shall be on site every three (3) weeks for a minimum of one (1) week at a time until the new permanent MOR is in place, and for an additional six (6) months to mentor the new MOR.

iii. Engage a qualified third-party authorized nuclear pharmacist with operational and regulatory expertise in nuclear pharmacy and USP <825> to assess all clean room procedures including, but not limited to, staff training & competency, hand hygiene & garbing, aseptic technique, cleaning & disinfecting, environmental sampling procedures, and policies & procedures. The Licensee shall provide a written report to the Board within one-hundred, twenty (120) days of the Effective Date to include an assessment & recommended corrective actions and Licensee's action plan and timeline for implementing said corrective actions.

iv. Engage a qualified third-party microbiologist or similarly qualified professional (e.g., industrial hygienist, infection control professional, etc.) to conduct an assessment of environmental control and testing procedures to address multiple reports of "operator failure." The Licensee shall submit a written report to the Board within one-hundred, twenty (120) days of the Effective Date to include an assessment & recommended corrective actions and Licensee's action plan and timeline for implementing said corrective actions.

v. Perform quarterly gloved thumb/fingertip sampling for all radiopharmaceutical compounding/preparation personnel for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.

vi. Perform quarterly media fill qualification for all radiopharmaceutical compounding/preparation personnel for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.

vii. Perform quarterly qualification for all radiopharmaceutical compounding/preparation personnel on cleaning & disinfecting procedures for all ISO-classified area including the DHC for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.

viii. Submit an attestation to the Board demonstrating that all radiopharmaceutical compounding/preparation personnel have read and reviewed Licensee's policies & procedures on material transfer processes (prior to and within the clean room suite) to assure adherence to the company policy within thirty (30) days of the Effective Date.

ix. Submit an attestation to the Board demonstrating that all nuclear pharmacy staff have read and reviewed the Board's Advisory on Pharmacy Requirement to Maintain Defective Drug Preparation Log and associated reporting requirements within 30 days of the Effective Date.

x. Submit an attestation to the Board demonstrating that all nuclear pharmacy staff have read and reviewed the Board Policy 2023-09: Action Level Environmental Monitoring Results within 30 days of the Effective Date.

Case#3/CAS-2023-1092
PHA-2024-0013 SOFIE, NU00021 Time: 10:13 AM

RECUSAL: NONE

DISCUSSION: N. VAN ALLEN presented and summarized the investigative report that pertained to this matter.

- On 8/7/2023, BORP received a disclosure of defective drug preparation from SOFIE, a dual licensed FDA manufacturer and state licensed radiopharmacy, regarding a failed sterility test for a batch of manufactured study drug Pylarify which was dispensed in patient specific doses and administered to patients across New England including MA.
- A Site Visit (ISP-21904) was conducted on 8/8/2023 to determine the extent of error and review and collect documents related to the facilities actions and continued compliance to the regulations.
- In discussions with Pharmacy staff, the sterility sample was taken from a batch of manufactured drug on 7/26/2023. The positive sample was identified on 7/31/2023 and reported in a timely fashion as required. Retest of the sample was negative for growth. Sterility results are retrospective in nature due to the short beyond use date of radiopharmaceuticals.
- All communication to patients and providers was conducted by the study sponsor as noted in the pharmacy quality assurance agreement. The Pharmacy did not conduct this action as required by MGL c112 s39D€ and BORP Advisory.
- The Pharmacy's initial investigation determined that the likely cause of contamination was during material handling in either the sterility testing, material transfer, or final product vial preparation.
- An FDA Field Alert Report was submitted by the study sponsor. No adverse events have been reported as result of the drug administration.
- Initial corrective actions included retraining of staff in aseptic technique, material transfer, gowning integrity, and principles of microbiology.
- Initial investigation was elevated to complaint on 1/17/2024 for which response to investigator inquiries was received 2/14/2024.
- The Pharmacy response described corrective actions including updated policies and procedures and quality assurance agreement with study sponsor to ensure the Pharmacy directly communicates with providers and patients.
- Additional corrective and preventative actions include narrowing gaps in operational staffing to better address training, sterility assurance, and investigations. Also, the Pharmacy has initiated a third party review with a qualified nuclear pharmacist to assess the overall operation.

ACTION: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to CONSOLIDATE the matter (PHA-2024-0013), with PHA-2023-0170 and PHA-2024-0014. A second motion was made by S. HAMILTON, and seconded by C. BELISLE, to refer the consolidated matters to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a

consent agreement for PROBATION for a period of 12 to 18 months, with special terms to include the following:

i. Comply with all laws and regulations governing the practice of nuclear pharmacy.

ii. Immediately upon the Effective Date appoint a local full time Interim Manager of Record until June 30, 2024, at which time a permanent on-site MOR shall be appointed. The Regional Director of Operations shall be on site every three (3) weeks for a minimum of one (1) week at a time until the new permanent MOR is in place, and for an additional six (6) months to mentor the new MOR.

iii. Engage a qualified third-party authorized nuclear pharmacist with operational and regulatory expertise in nuclear pharmacy and USP <825> to assess all clean room procedures including, but not limited to, staff training & competency, hand hygiene & garbing, aseptic technique, cleaning & disinfecting, environmental sampling procedures, and policies & procedures. The Licensee shall provide a written report to the Board within one-hundred, twenty (120) days of the Effective Date to include an assessment & recommended corrective actions and Licensee's action plan and timeline for implementing said corrective actions.

iv. Engage a qualified third-party microbiologist or similarly qualified professional (e.g., industrial hygienist, infection control professional, etc.) to conduct an assessment of environmental control and testing procedures to address multiple reports of "operator failure." The Licensee shall submit a written report to the Board within one-hundred, twenty (120) days of the Effective Date to include an assessment & recommended corrective actions and Licensee's action plan and timeline for implementing said corrective actions.

iv. Perform quarterly gloved thumb/fingertip sampling for all radiopharmaceutical compounding/preparation personnel for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.

vi. Perform quarterly media fill qualification for all radiopharmaceutical compounding/preparation personnel for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.

vii. Perform quarterly qualification for all radiopharmaceutical compounding/preparation personnel on cleaning & disinfecting procedures for all ISO-classified area including the DHC for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.

viii. Submit an attestation to the Board demonstrating that all radiopharmaceutical compounding/preparation personnel have read and reviewed Licensee's policies & procedures on material transfer processes (prior to and within the clean room suite) to assure adherence to the company policy within thirty (30) days of the Effective Date.

ix. Submit an attestation to the Board demonstrating that all nuclear pharmacy staff have read and reviewed the Board's Advisory on Pharmacy Requirement to Maintain Defective Drug Preparation Log and associated reporting requirements within 30 days of the Effective Date.

x. Submit an attestation to the Board demonstrating that all nuclear pharmacy staff have read and reviewed the Board Policy 2023-09: Action Level Environmental Monitoring Results within 30 days of the Effective Date.

Case #4

/CASE-2023-0564

PHA-2024-0014 SOFIE, NU00021 Time: 10:16 AM

RECUSAL: NONE

DISCUSSION: N. VAN ALLEN presented and summarized the investigative report that pertained to this matter.

- On 9/12/2023, BORP received a disclosure of defective drug preparation from SOFIE, a dual licensed FDA manufacturer and state licensed radiopharmacy, regarding an out of specification radiochemical purity result for a batch of manufactured study drug Pylarify which was dispensed in patient specific doses and administered to patients across New England including MA.
- The licensee described the event to have no impact on patient safety or be a public health hazard but rather relate to patients experiencing excess bone uptake of free F18 and resulting scans to be less effective and increase risk of false results. The incident directly affected 2 patients on 8/25/2023 and 8/28/2023 (a total of 4 doses).
- A notice of investigation (INV8446) was sent to the Pharmacy on 10/19/2023 and response received on 11/08/2023. The response indicated that an investigation was conducted and determined that the final product vial was not diluted to the final concentration after end of synthesis which caused degradation of the product. This was not noticed by the Quality Control operator or releasing Pharmacist for which 34 patient specific doses were then dispensed and administered to patients.
- An FDA Field Alert Report was submitted on behalf of the Pharmacy by the study sponsor.
- Review of submitted documents showed that the excess bone uptake was reported to the Pharmacy on 08/30/2023 and was attributed to altered biodistribution of the drug. The Pharmacy did not consider this to be a defective drug at that time. On 9/5/2023, the Pharmacy investigation determined that the radiochemical purity was not properly integrated and then reported 7 days later 9/12/2023 per MGL c112 s39D(e).
- Initial investigation was elevated to this complaint on 1/17/2024 for which response to investigator inquiries was received 2/14/2024.
- The Pharmacy's response to the complaint described their short-term and long-term actions to help ensure that batches are not erroneously released with improper radiochemical purity. These changes include adjustments to release responsibilities, additional training and qualification for the Facility Manager, and documentation responsibilities to ensure proper radiochemical peak integration.
- Additional corrective actions included updates to production and quality control standard operating procedures clarifying time limits for dilution and mixing of the final product vial, changes to chromatography methodology and analysis improving accuracy. The Pharmacy acquired more chromatography and shielding equipment to minimize impact of nearby radiation from dose packaging and testing.
- The Pharmacy also conducted an internal review of their operation and identified several corporate level changes including expanding the training department, improving documentation or exception reporting, and investigations. They also initiated a third-party consultant review with a local nuclear pharmacist experienced in Nuclear Pharmacy operations.

ACTION: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to CONSOLIDATE the matter (PHA-2024-0014), with PHA-2023-0170 and PHA-2024-0013. A second motion was made by S. HAMILTON, and seconded by C. BELISLE, to refer the consolidated matters to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 12 to 18 months, with special terms to include the following:

ii. Comply with all laws and regulations governing the practice of nuclear pharmacy.

ii. Immediately upon the Effective Date appoint a local full time Interim Manager of Record until June 30, 2024, at which time a permanent on-site MOR shall be appointed. The Regional Director of Operations shall be on site every three (3) weeks for a minimum of one (1) week at a time until the new permanent MOR is in place, and for an additional six (6) months to mentor the new MOR.

v. Engage a qualified third-party authorized nuclear pharmacist with operational and regulatory expertise in nuclear pharmacy and USP <825> to assess all clean room procedures including, but not limited to, staff training & competency, hand hygiene & garbing, aseptic technique, cleaning & disinfecting, environmental sampling procedures, and policies & procedures. The Licensee shall provide a written report to the Board within one-hundred, twenty (120) days of the Effective Date to include an assessment & recommended corrective actions and Licensee's action plan and timeline for implementing said corrective actions.

iv. Engage a qualified third-party microbiologist or similarly qualified professional (e.g., industrial hygienist, infection control professional, etc.) to conduct an assessment of environmental control and testing procedures to address multiple reports of "operator failure." The Licensee shall submit a written report to the Board within one-hundred, twenty (120) days of the Effective Date to include an assessment & recommended corrective actions and Licensee's action plan and timeline for implementing said corrective actions.

vi. Perform quarterly gloved thumb/fingertip sampling for all radiopharmaceutical compounding/preparation personnel for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.

vi. Perform quarterly media fill qualification for all radiopharmaceutical compounding/preparation personnel for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.

vii. Perform quarterly qualification for all radiopharmaceutical compounding/preparation personnel on cleaning & disinfecting procedures for all ISO-classified area including the DHC for the term of probation and provide a summary of all results to the Board, including corrective actions for any failed tests.

viii. Submit an attestation to the Board demonstrating that all radiopharmaceutical compounding/preparation personnel have read and reviewed Licensee's policies & procedures on material transfer processes (prior to and within the clean room suite) to assure adherence to the company policy within thirty (30) days of the Effective Date.

ix. Submit an attestation to the Board demonstrating that all nuclear pharmacy staff have read and reviewed the Board's Advisory on Pharmacy Requirement to Maintain Defective Drug Preparation Log and associated reporting requirements within 30 days of the Effective Date.

x. Submit an attestation to the Board demonstrating that all nuclear pharmacy staff have read and reviewed the Board Policy 2023-09: Action Level Environmental Monitoring Results within 30 days of the Effective Date.

Case #5/CASE-2023-0453
INV8186 BWH Nuclear Pharmacy, NU16 Time: 10:27 AM

RECUSAL: C. BELISLE and S. AHMED recused and were not present for the vote or discussion in this matter.

DISCUSSION: N. VAN ALLEN presented and summarized the investigative report that pertained to this matter.

- On 8/25/23, BORP received a timely disclosure of an above action level result from BWH Nuclear Pharmacy; microbial excursions described as “too many to count” from routine EM conducted on 8/15/23.
- The excursions were identified as 12 surface samples from ISO 7 spaces. These samples were observed to be stored on their side within the incubator with visible contamination on interior of storage bag and growth on media surfaces.
- Due to the expansive nature of the identified contamination, BWH Nuclear voluntarily suspended compounding on 08/25/23 until further evaluation and remediation of the observed deficiencies.
- A Site Visit (ISP-30004) and Nuclear Compliance inspection (ISP-30001) was conducted on 8/29/23.
- Observed deficiencies included delamination of paint on PEC used for compounding radiopharmaceuticals, lack of didactic environmental monitoring training for staff members.
- The Pharmacy conducted a root cause analysis which identified mishandling and storage of media by pharmacy staff as likely cause though described various facility issues requiring attention as potential contributors including handwashing sink and residue buildup on radiopharmaceutical packaging.
- After review of submitted documents and remedial actions taken by the Pharmacy, BWH Nuclear resumed compounding on 9/5/23.
- The Pharmacy submitted a response and corrective actions on 9/20/23 which addressed all identified deficiencies including training of staff, adjustment to policy and procedures, cleaning and disinfection, and environmental resampling per the Pharmacy policy.
- A final response to INV8186 was received on 11/1/23 and reiterated pharmacy RCA, CAPA and other related actions. All actions and submitted documents appear to be compliant with the standards and current BORP Policy 2023-09.

ACTION: Motion by D. BARNES, seconded by S, HAMILTON, and voted unanimously by those present, to CLOSE the matter (INV8186), Discipline Not Warranted, Remediation Complete.

Case #6/CASE-2023-0754
INV8849 BWH Nuclear Pharmacy, NU16 Time: 10:31 AM

RECUSAL: C. BELISLE and S. AHMED recused and were not present for the vote or discussion in this matter.

DISCUSSION: N. VAN ALLEN presented and summarized the investigative report that pertained to this matter.

- On or about 11/21/2023, BORP received a self-disclosure of abnormal results from BWH Nuclear (NU16) regarding a questionable discoloration suggestive of growth on the underside of the sink located in ISO classified space.
- Included in the disclosure, the MOR stated the Pharmacy voluntarily ceased compounding on 11/16/2023 and transferred prescription orders to local and regional suppliers.
- A Site Visit (ISP-30077) was conducted on 12/6/23 to assess remedial efforts including sealing off the sink with plastic to act as containment, increased frequency of environmental monitoring in gowning SEC to identify possible sources.
- The Pharmacy proposed use of a temporary sink located approximately 25 feet and 2 doorways outside of the classified spaces to conduct handwashing activities. Investigator observed proposed room to

have contamination concerns including wooden casework and shelves along with visibly stained laboratory countertop not meeting the USP <825> standard requirement for "clean space."

- The Pharmacy responded to the plan of correction issued at the 12/6/2023 site visit and included relocation of supplies, removal of wooden wall shelving, and installed stainless steel table.
- Additionally, they wrapped the sink and wooden casework in heavy duty plastic sheeting and sealed to floor and walls to act as containment barrier.
- A reinspection Site Visit (ISP-30090) conducted on 1/8/2024 verifying the elements of the submitted plan of correction were conducted. Additional requests were made of licensee in which they agreed to implement including installation of portable HEPA filters in the temporary handwashing room and control corridor to decrease bioburden, increased cleaning frequency, restriction of foot traffic to only necessary personnel, and increased gloved fingertip sampling of compounding staff to ensure adherence to changes in policy.
- The Pharmacy agreed to the additional requests and once completed resumed compounding on 1/23/2024.
- A renovation application was submitted on 1/29/2024.

ACTION: Motion by R. LOPEZ, seconded by J. LOPEZ, and voted unanimously by those present, to CLOSE the matter (INV8849), Discipline Not Warranted, Remediation Complete.

Case #7/CASE-2023-0762
PHA-2023-0265 Walgreens #5445, DS2964 Time: 10:36 AM

RECUSAL: NONE

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

- On November 17, 2023, WAG 5445 submitted a final report of an unknown loss, 40 Oxycontin 10mg tablets, discovered on November 1, 2023. Former MOR Fenton later retracted the report of loss. She indicated that "while reviewing additional video footage we found that the pharmacist overcounted a prescription. The patient has been contacted and requested to return the additional tablets. The DEA 106 will be retracted." WAG 5445 confirmed that Pharmacist Sirard overcounted the prescription and the error was documented in accordance with 247 CMR 15.00. As corrective action, Pharmacist Sirard implemented new practices when dispensing controlled substances in regard to counting and verifying procedures.

ACTION: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0265), Discipline Not Warranted, Remediation Complete.

Case #8/CAS-2023-0522
PHA-2023-0234 Imad Haidardiab, PH24533 Time: 10:38 AM

RECUSAL: NONE

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

- During September 2023, NABP notified BORP that MI BOP imposed a fine and placed Pharmacist Haidardiab's Michigan license on probation to resolve a complaint for incompetence, negligence, and technical violations of the Michigan PHC.
- According to the CS&O for matter, Pharmacist Haidardiab was fined $10K and his Michigan license was placed on probation for two-years effective 09-24-2023 with requirements for periodic reviews of his practice of pharmacy and completion of 10 contact hours of CE in pharmacy law.
- Pharmacist Haidardiab was disciplined because he was co-owner/PIC of a pharmacy which was cited during an inspection for multiple violations including temperature monitoring, patient counseling, and lack of technician policies and procedures. A follow-up interview revealed that several patients at the pharmacy were dispensed promethazine or promethazine with codeine syrup on a long-term basis. Pharmacist Haidardiab was unable to provide diagnosis codes for any of the prescriptions during the interview.
- In addition, 1,745,370mL of promethazine syrup were purchased by the pharmacy between 03-01-2020 and 06-30-2022 while only 283,172mL were dispensed during the same timeline. Pharmacist Haidardiab explained that he gave most of the promethazine to another Michigan pharmacy to donate to Lebanon but did not keep records of the transactions.
- Pharmacist Haidardiab explained in his response to the complaint that his "primary goals in this matter [was] to effectively voluntarily forfeit his Massachusetts pharmacist license without being subject to adverse consequences affecting his Michigan license." He indicated that he left Massachusetts in 2002 to practice pharmacy in Michigan and thought he was required to renew his Massachusetts license to maintain his Michigan license. He has since learned that he did not need to renew his Massachusetts license so planned to allow his Massachusetts license to lapse.
- Pharmacist Haidardiab also offered to retire his Massachusetts pharmacist license, but he was unsure whether he was eligible. Alternatively, Pharmacist Haidardiab pleaded that any disciplinary action taken by BORP "be limited to probation concurrent" with the Michigan Consent Order and Stipulation.

ACTION: Motion by D. BARNES, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2023-0234), 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 PROBATION to align with the Michigan BOP's probation.

Case #9/CASE-2023-0630
PHA-2023-0236 Walgreens #17531, DS90420 Time: 10:43 AM

RECUSAL: NONE

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

- On October 20, 2023, Investigator Geaney observed "[an] unlicensed person [Trisha Exantus] in the pharmacy - technician trainee registration submitted 10/3/2023, not listed - working in pharmacy" during an RCI. He then observed "Pfizer COVID vaccine prefilled and stored next to sink unlabelled [sic] in an amber vial". Accordingly, Investigator Geaney issued a plan of correction (POC) to the pharmacy based partly on the above-described violations.
- POC/CA: WAG 17531's MOR notified all pharmacy staff that the prefilling of syringes of vaccine was no longer permitted. She indicated that managers and pharmacist would monitor for compliance. Next, the MOR indicated that the unlicensed staff member, Ms. Exantus, was removed from the

pharmacy until she applied for and obtained a PTT license. The unlicensed staff member was also reminded "to inform managers on actions related to licensing." Lastly, "managers created a sheet detailing staff members' license statuses and expiration dates, to be regularly checked and updated to prevent issue from happening in the future." Of note, the unlicensed staff was issued a PTT license on October 25, 2023.

ACTION: Motion by S. AHMED, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0236), 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 #10/CASE-2023-0559
PHA-2023-0216 Walgreens #15390, DS89867 Time: 10:46 AM

RECUSAL: NONE

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

- On 10-5-2023, WAG 15390 MOR reported that an unknown loss of 60 amphetamine mixed salts 10mg tablets occurred at the pharmacy on 9-5-2023. The MOR indicated that the loss was first discovered on 09-13-2023. He then described that a prescription 60 amphetamine mixed salts 10mg tablets was filled on 09-05-2023. However, the prescription was not sold according to point-of-sale records and staff were unable to locate the prescription in the pharmacy.
- Of note, the MOR did not submit supplemental information for unknown losses as required. In addition, the MOR did not notify BORP about the loss until 09-29-2023 which was not within 7 days of discovery 09-13-2023 as required.
- Ultimately, the MOR retracted the loss after he was notified about this complaint. He then explained that a PTT was captured on video failing to scan one of two prescriptions for the same patient at point-of-sale. The prescription that was not scanned was determined to be the missing amphetamine prescription. However, WAG 15390 was unable to provide copies of the surveillance video due to technical issues.
- CA: "(1) Reviewed the process of selling with prescriptions with technicians, (2) Back-count all C2 medication when filling, (3) Be more careful when putting away prescriptions."

ACTION: Motion by C. BELISLE, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0216), 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 #11/CASE-2023-0691
PHA-2023-0249 Tufts Medicine Infusions Services, DS90378 Time: 10:48 AM

RECUSAL: D. SENCABAUGH

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

- On October 31, 2023, Investigators Brosnan and Seed observed insanitary conditions during a SCI at Tufts as follows: (1) Water leaking from the anteroom sink onto the anteroom floor, (2) Rust and contaminated standing water accumulating on the bottom floor structure of the sink, (3) Gaps between pipes and walls of plumbing under anteroom sink, (4) The plexiglass attached to sides of sink was broken or cracked, (5) Seam separation at the entry door on buffer room side, (6) Several areas where the paint has chipped away on walls, door and window jambs of anteroom and buffer room, (7) Dust or debris observed in an EdgeGard PEC in a return slot under deck, (8) Rust on clean room chairs, (9) Dust transferred to a wipe from back of Baker SterilGard PEC.
- At that time, Tufts agreed to cease compounding and activate its COC plan until remediation of the deficiencies listed in ISP30018-SCCOM and confirmation by repeat environmental monitoring with results within acceptable limits after completion of remediation. In addition, Tufts was issued a POC.
- CA/POC: MOR Hall submitted a POC dated November 6, 2023 outlining action taken to remediate the deficiencies listed in ISP30018-SCCOM. Next, MOR Hall notified Investigators Brosnan and Seed on November 15, 2023 that the results of environmental monitoring conducted after completion of remediation were within acceptable limits. Investigators Brosnan and Seed then reinspected Tufts and confirmed that remediation was completed, and environmental monitoring results performed after the remediation were within acceptable limits on November 16, 2023. At that time, MOR Hall was notified that "based on our [Investigators Brosnan and Seed] reinspection today, EM and Recertification performed and submitted, and the remediation of all items previously identified, we have no objections to [Tufts] resuming sterile compounding operations."

ACTION: Motion by J. LOPEZ, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0249), 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 #12/CASE-2023-0423
PHA-2023-0177 Fresenius Kabi Compounding, RO00002 Time: 10:52 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.

- During August 2023, BORP was notified by FDA that FKC underwent an outsourcing facility inspection between January 30, 2023 and March 6, 2023. During the inspection, FDA observed two instances of conditions deemed objectionable and issued an FDA-483 based on those observations. The first observation involved "procedures designed to prevent microbiological contamination of drug products purporting to be sterile [were] not established, written and followed." The second observation involved "the accuracy, sensitivity, specificity and reproducibility of test methods [was] not established."
- FKC failed to notify BORP within 14 days that FDA conducted the outsourcing facility inspection and failed to notify BORP within 14 days that FDA issued the FDA-483.
- SVP McEniry explained that FKC was not aware of the requirements for reporting FDA inspections or FDA-483s to BORP.
- CA: SVP McEniry described that "our internal SOP for Regulatory inspections, FSS-SOP-0013, will be updated to include BORP notification of any FDA Form 483 or related documentation." In addition, SVP McEniry described CA implemented as a result of the inspection and FDA-483. In summary, new

standard operating procedures for cleaning PECs were implemented which prohibited staff from leaning inside hoods when cleaning. Instead, staff were required to use a reaching tool to clean areas inside the hood when areas were out of reach.

- Next, standard operating procedures for sterility testing of vancomycin products were immediately revised to require that products be tested in-house only. FKC indicated that staff were also prohibited from using the third-party laboratory which performed the sterility testing deemed inadequate by FDA for vancomycin products between June 11, 2021 and January 30, 2023.

ACTION: Motion by D. BARNES, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0177), 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/CAS-2023-1127
PHA-2023-0195 Michael Martin, PH19637 Time: 10:56 AM

RECUSAL: NONE

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

- During August 2023, BORP learned from NABP's Clearinghouse that Pharmacist Martin entered into a consent order for discipline with GA BOP effective April 24, 2023 in which he agreed to pay a $5,000.00 fine after The Medicine Shoppe in Dallas, Georgia was cited for inspectional deficiencies involving CNSPs during inspections on September 22, 2020 and August 8, 2022 when he was MOR.
- The deficiencies on September 22, 2020 included improper beyond-use dates (BUDs), failure to maintain complete and accurate compounding records, failure to maintain appropriate training records, failure to use appropriate garb, incomplete compounding log records, incomplete master formulation records, and lack of standard operating procedures specific to the pharmacy.
- The deficiencies on August 8, 2022 included lack of documentation of final verification by a pharmacist, compounding records lacked required information such as lot numbers, expirations dates, and quantities for ingredients, incomplete training records, lack of standard operating procedures specific to the pharmacy, and compounding of cytotoxic products without proper training or protective equipment.
- Pharmacist Martin wrote in response to the complaint, "…I do not contest the findings from the Georgia Drug Inspector from Sept 2020. The claims against us, with the exception of protective clothing, are all due to inadequate record keeping. I would like to point out that we did have a record keeping system on our pharmacy software system that allowed us to fill our compounded prescriptions accurately and repeatably, but not in total compliance with the USP record keeping requirements… Due to the consent order from the Georgia Board of Pharmacy we decided to suspend compounding permanently."

ACTION: Motion by J. LOPEZ, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2023-0195), 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-2023-0509
PHA-2023-0232 Walgreens 4966, DS2924 Time: 11:00 AM

RECUSAL: NONE

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

• An unknown loss of #40 hydrocodone/acetaminophen 7.5mg/325mg tablets discovered during the weekly perpetual inventory on 08/26/2023.
• It was noticed that the count of hydrocodone/acetaminophen 5/325mg was 40 tablets over and that hydrocodone/acetaminophen 7.5/325mg was 40 tablets short.
• All patients that filled either strength in the suspected time frame were contacted to assess if incorrect medication was dispensed and waited on callbacks. It was noted that video was reviewed with no suspicions of theft, diversion or dispensing errors observed.
• However, the MOR attributes the loss is due to a medication error due to the similarity in the tablets, in which either the tablets were returned to the wrong stock bottle or incorrect stock bottle being used.
• The MOR indicated that moving forward all pharmacists will be checking in Schedule II substances on a clutter free bench. Staff was be coached to not distract the pharmacists as he/she is counting controlled substances.

ACTION: Motion by S. AHMED, seconded by J. DORGAN, and voted unanimously by those present, to refer the matter (PHA-2023-0232), 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 #15/CASE-2023-0398
INV8069 Paul R Casale, PT23845 Time: 11:03 AM

RECUSAL: NONE

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

• During an inspection on 08/08/2023, it was observed that pharmacy technician (PT) Paul Casale was practicing with an expired license at Union Pharmacy.
• PT Casale responded that he renewed his license during a previous inspection in June 2022 when Investigator Geaney informed him his license had expired on 07/04/2021.
• PT Casale was provided instructions on how to renew his license.
• Per eLX, a PT License renewal application submitted on 11/15/2023 was approved on 12/06/2023 for PT Casale.

ACTION: Motion by C. BELISLE, seconded by J. LOPEZ, and voted unanimously by those present, to ELEVATE the matter (INV8069), to a complaint.

Case #16/CASE-2023-0557
PHA-2023-0198 Market 32, DS2526 Time: 11:05 AM

RECUSAL: NONE

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

- During a retail compliance inspection conducted on 10/04/2023, vaccine was observed stored in refrigerators located in unlicensed space.
- MOR Showalter indicated that during the COVID-19 pandemic, the need for refrigerator space for vaccine storage increased dramatically. To meet the increased storage needs additional refrigerator/freezer units were purchased. MOR Showalter indicated that due to the design of the Pharmacy, there was no immediate safe way to add additional refrigeration/freezer units to the dispensing area.
- The newly purchased refrigerators were therefore placed in the Pharmacy's counseling/immunization room which they believed was licensed space. Additionally, MOR Showalter noted that Epi-pens for immediate use were also stored in unlicensed space in lieu of continually having to be brought to and from the area.
- The MOR indicated that as corrective action they ordered a full-size refrigerator for the dispensing area with an expected delivery on October 30, 2023. Plans to redesign the pharmacy to allow for a full-size refrigeration unit are underway and will be provided to the Board once ready. Patients will be directed to nearby pharmacies for immunizations that can no longer be stocked or stored given space constraints in the dispensing area.
- Investigator Brosnan conducted a site visit on 02/26/2024 and confirmed a new refrigerator is in the Pharmacy and is operational.

ACTION: Motion by D. BARNES, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0198), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #17/CASE-2023-0690
INV8698 Paul Rohde, PH15575 Time: 11:08 AM

RECUSAL: NONE

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

- Repeat CE deficiencies of 5 CEs for 2022 self-reported on 11/3/23. Pharmacist Rodhe had recently reviewed his CPE Monitor and realized the deficiency. He alleged he had completed CEs with Pharmacy Times that were not posted. In 2021, Pharmacist Rohde self-reported deficiencies for 2017, 2018, and 2019 of 8 CEs total. At that time he stated he retired in 2010 but his license was not formally retired. He was provided with a copy of an Application for Retired License Status along with 247 CMR 3.04 Licensure Retirement.
- Pharmacist Rodhe failed to remediate his CE deficiencies for 2022 by 12/31/2023 having completed only 8 CEs in 2023.
- On 1/4/24, Pharmacist Rodhe was asked to clarify if he would be renewing his license or pursuing a retired pharmacist license and was provided with 247 CMR 3.12 Pharmacist Retirement. He responded he was still considering the option of a retired Pharmacist license. Since his license was expired, Pharmacist Rohde was informed that 5 of 13 CEs completed in 2023 would be considered as remediation of his 2022 deficiency. He was provided with a copy of an Application for Retired License Status.

• Pharmacist Rohde acknowledged that 5 CEs completed in 2023 would be used as remediation. A review of his 2021 CPE Monitor should 27.5 CEs were completed but 8 CEs were for remediation of his previously reported deficiencies. On 1/9/24, he was notified that 1 of 13 CEs from 2023 would be used as remediation for 2021.

ACTION: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by those present, to CLOSE the matter (INV8698), Discipline Not Warranted, Remediation Complete.

Case #18/CASE-2023-0657
PHA-2023-0238 McNabb Pharmacy, DS90087 Time: 11:12 AM

RECUSAL: NONE

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

• Inspectional deficiency on 10/23/2023 for storage of vaccines, epinephrine and needles/syringes in a vaccination room.
• MOR McNabb Noon alleged when she appeared at the 1/9/2020 BORP meeting, a renovation including the vaccination room was approved. She claimed that during the renovation inspection on 08/02/2022, the Investigators stated as long as the vaccine was locked while not in use, vaccines, epinephrine and needles/syringes could be stored there and they proceeded to use the room as such. Note, there is no documentation of said conversation. Pharmacist Cormier, Pharmacist Newcomb, and CPhT Tesini echoed MOR McNabb Noon's statement.
• The Pharmacy's policy Prescription Medication Storage was revised on 12/5/2023 which specified all prescription medications including vaccines, epinephrine, and needles/syringes will be stored in the locked Pharmacy space.
• MOR McNabb Noon stated, "In response, we moved the vaccinations to the retail stock medication refrigerator behind the counter, in the Pharmacy Space. Epinephrine and needles/syringes were moved to [sic] stock area in the Pharmacy Space and are no longer kept in the locking vaccination room. These items are only brought to the vaccination room for each individual vaccination given". MOR McNabb Noon, Pharmacist Cormier, Pharmacist Newcomb, and CPhT Tesini provided a signed and dated statement confirming review of the Pharmacy's policies and procedures for the storage requirements of prescription medications and needles/syringes.

ACTION: Motion by S. AHMED, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0238), 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 #19/CASE-2023-0408
PHA-2023-0243 Walgreens #7063, DS3238 Time: 11:15 AM

RECUSAL: NONE

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

• Complaint the Pharmacy refused to fill a veterinary prescription without the prescriber's DEA number. The office manager stated the DEA has cautioned them to not provide a DEA number without a valid

reason since the vet's state license number can be used instead. He confirmed this with the prescriber and called back the Pharmacy. He was informed they could not process the prescription using a coupon without the DEA number.
• Former MOR Dabek confirmed the DEA number was requested in order to bill the prescription using a coupon. If a prescription is processed as cash, the DEA number is not needed, which is what the team members should have done.
• Pharmacist McAuliffe stated a hardcopy prescription was presented with a coupon. She adjudicated the prescription and received a 3rd party rejection stating the DEA number was required for billing with the coupon. She informed the customer she needed to contact the office. She called the vet's office, but the office staff were unable to find the DEA number. She was told the office manager would look for it and they'd call the Pharmacy back.
• CPhT Sullivano spoke with the office manager who informed her the DEA number was not needed and refused to provide it. She told him the customer would have to pay full price. He told her to have the customer fill the prescription at CVS. CPhT Dutton spoke with the prescriber who stated the DEA informed them not to give out their DEA number.
• Former MOR Dabek advised Pharmacy staff that DEA numbers for CVI vet prescriptions are not required and not to contact prescribers to request them. Prescriptions with coupons requiring DEA numbers will be billed as cash. Pharmacy staff confirmed review of the corrective action.

ACTION: Motion by D. BARNES, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0243), No Violation.

Case #20/CASE-2023-0440
PHA-2023-0244 Walgreens #17545, DS90127 Time: 11:17 AM

RECUSAL: NONE

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

• Refusal to fill a veterinary prescription without the prescriber's DEA number. When Former MOR Lam was informed a DEA number is not required for non-controlled medications and that the state license number can be used to confirm the veterinarian's identity, he claimed there was no way for him to do that. Former MOR Lam refused to dispense the medications and was alternatively provided with the Complainant's DEA number.
• Former MOR Lam alleged the prescriber and canine patient were unfamiliar to him and he was exercising his professional judgement to verify the prescriber's information to ensure the prescriptions for #7 enalapril 2.5mg, #7 furosemide 20mg, and #5 spironolactone were legitimate. He stated, The information I attempted to collect was solely for verification purposes and has nothing to do with whether the prescriber can or cannot prescribe non-control medications. Once I was able to verify the prescriber, all three medications were dispensed without issue. I understand that a DEA number is not required from a veterinarian when attempting to fill a veterinary prescription…".
• A copy of Walgreens Prescriber Management & Registration Job Aid was provided which indicated the state license number for a veterinarian is required. DEA numbers are required for controlled substances.
• Pharmacist Lam stated, "…moving forward I will not use a DEA number as part of the standard verification process of a veterinarian". A statement signed by the Pharmacy staff was submitted

attesting to review of the MA Veterinary Medical Association Frequently Asked Questions - Prescriptions. The Pharmacy staff stated the guidelines will be followed going forward.

ACTION: Motion by S. HAMILTON, seconded by J. LOPEZ, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0244), Discipline Not Warranted, Remediation Complete.

Case#21/CASE-2023-0625
PHA-2023-0237 Walgreens #5756, DS3252 Time: 11:20 AM

RECUSAL: NONE

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

- During an inspection on 10/20/23, it was determined that Current MOR Appelt's last day worked was 9/18/23 and BORP licensing staff had received no notification of a change of MOR (A repeat deficiency). According to the POC, Interim MOR Medin assumed the role on 11/6/23. She alleged Current MOR Appelt who was on a LOA bounced his check to the BORP without notifying leadership.
- On 11/20/23, BORP licensing received notification of Interim MOR Medin with her start date listed as 10/15/23 and Current MOR Appelt's expected to return date as 12/15/23. Interim MOR Medin stated she served as Interim from 2/16/23-5/7/23 then assumed the role again on 11/6/23.
- According to WAG.SOP-RX-071 Pharmacist-in-Charge Change Notifications, it is the responsibility of the DM to ensure the State BOP is notified of MOR changes and to ensure CS inventories are completed by the incoming and outgoing MOR.
- DM Sawyer stated Current MOR Appelt was expected back on 1/1/24. Current MOR Appelt confirmed his last day worked was 9/18/23 and he would be returning on 1/1/24 (more than 100 days). Interim MOR Medin, DM Sawyer and AHCS Saleem were notified that a change of MOR application must be submitted.
- DM Sawyer stated she will email the BORP within 5 days of a MOR change and ensure the BORP website gets updated. Interim MOR Marin and Former Interim MOR Gill attested to review of WAG.SOP-RX-071 Pharmacist-in-Charge Change Notifications.

ACTION: Motion by D. BARNES, seconded by S. DINNO, and voted unanimously by those present, to CONSOLIDATE the matter (PHA-2023-0237) with PHA-2022-0206, and refer 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 #22/CASE-2023-0688
PHA-2023-0248 New England Life Care, DS90241 Time: 11:26 AM

RECUSAL: NONE

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

• Inspectional deficiencies of observed visual evidence of insanitary conditions which did not meet or comply with USP 797 standards in the anteroom, ISO 7 room, and all four ISO 5 hoods on 10/25/23. Deficiencies included, but were not limited to, observed rust, scratches, cracked fixtures, chipped paint, gauged flooring, gaps in frames, and ISO 5 splash contamination. The composition of materials of the pass throughs, racks, and carts were also cited. The Pharmacy agreed to voluntarily suspend compounding and implement a continuity of care plan.
• Implementation of the POC will occur in three phases to allow reopening as soon as possible. After remediating, EM and recertification will occur with 4-day BUDs assigned until EM results are received. Due to significant lead times, replacement of the pass throughs, racks, and carts will occur in Phase 3. MOR Loriaux reviewed readmission data for the previous 2 months, with no significant change in trends for line infections found. As of 10/25/23, care of patients was transferred to NELC in Woburn.
• In response to actionable EM in August 2018, the Pharmacy increased triple cleans from monthly to biweekly. In 2021, Peridox was added as the primary sporicidal agent. MOR Loriaux believed that over the years the caustic nature of Peridox impacted the integrity of the compounding suite. He contended, "The level of facilities upkeep has not kept pace with the linear progression of degradation caused by the increased cleaning frequency". Detailed actions for each observation noted on the inspection report were submitted.
• The frequency of facilities observations was increased to weekly and a running log of items requiring attention will be kept. Monthly surface sampling will be performed subsequent to a satisfactory sterile compounding inspection. All excursions will be reported to the BORP within 24 hours.

ACTION: Motion by R. LOPEZ, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0248), 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.

J. Dorgan leaves the meeting at 11:30 AM

Case #23/CASE-2023-0621
PHA-2023-0218 ProCare LTC, DS90042 Time: 11:44 AM

RECUSAL: NONE

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

• Inspectional deficiencies on 10/12/23 of conditions which did not meet or comply with USP 797 standards including, but not limited to, rust on carts; dents and scratches on PECs; dents on walls; caulking on ceiling and floors needing attention; and missing documentation for daily cleaning for multiple days and a monthly clean. Additionally, the Pharmacy failed to properly remediate an AAL reported on 8/16/23 for 1 CFU of aspergillus in an ISO 7 air sample when only repeat air sampling occurred. The POC addressed each deficiency with the corresponding remediation.
• MOR Gorka provided the chronology of events for the reported AAL. On 8/9/23, EM was performed and 1 CFU was discovered on an air plate in the buffer room on 8/11/23. On 8/16/23 the report was received which identified the 1 CFU as aspergillus and the BORP was notified and a triple clean was performed. Repeat EM was conducted on 8/18/23 with no growth shown. MOR Gorka related the staff were reeducated to change their scrubs if they leave the Pharmacy and the consultant purchased

another tester. She stated, “Unfortunately, despite going back to the remediation policy and procedure for ISO Class 7 Low Risk, we missed the text referring to resampling all samples done in the ISO class, as we were focused on the BUD”.
• MOR Gorka stated new carts and PECs were purchased. Minor repairs were performed to remediate facility deficiencies. Pharmacy staff were reeducated to report any observed rust on equipment to the Supervisor and to document the daily cleaning on all appropriate logs. Pharmacy staff were also “…reeducated in resampling all sample areas located in the ISO Class of which the growth was discovered”.

ACTION: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0218), 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 #24/CASE-2023-0485
PHA-2023-0225 CAPS, DS3312 Time: 12:05 PM

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

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

• A CAPS employee complaint was received on 9/7/23 detailing compliance violations for cleaning procedures and a bubble/pump failure. During a 09/11/23 site visit (ISP30010-SV), a 9/19/23 site visit (ISP30020-SV), and a 11/20/23 797 inspection (ISP30023-SCCOM), Investigators observed extensive visual evidence of contamination and insanitary conditions which did not meet or comply with USP 797. On 9/11/23, CAPS voluntarily ceased compounding and implemented a continuity of care plan.
• In addition to an AAL reported on 12/13/23, CAPS reported 18 AALs from 8/20/21-11/13/23, many for repeat organisms, displaying a lack of a state of control. During the site visits, it was determined CAPs needed extensive remediation to fix cleanroom issues for a 20-year-old facility. There was a high turnover of staff with limited sterile compounding experience who failed to adhere to cleaning protocols, hand hygiene and garbing procedures, and material transfer processes.
• During the 797 inspection, it was observed new PECs, flooring, lights, and wall bumpers were installed, new stainless steel carts were purchased, and vent screws were replaced. Additionally, a new sink with knee pedals was installed in the gowning room. Aseptic qualifications were completed by the compounding staff in the new PECs. On 11/21/23, CAPS resumed compounding.
• MOR Gomatos stated safeguards have been put in place to prevent future occurrences including, increased internal inspections, staff retraining on cleaning and product introduction, and enhanced SOPS. The Facilities Maintenance Checklist was updated to include all pump equipment and scales; undersides of tables, carts, and PECs; metal parts i.e. hinges, screws and plates; plexiglass; and air exhaust panels. The CAPS Corporate Facilities Team will take a 3-week course on reliability and asset management by Life Cycle Institute to evaluate CAPS current maintenance program and preparation to implement a more robust program with specific requirements for managing all CAPS assets.

ACTION: Motion by J. LOPEZ, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0225), 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 #25/CASE-2023-0689
PHA-2023-0247 Partners of MA, DS3419 Time: 11:49 AM

RECUSAL: NONE

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

• 797 IDs on 10/19/23 including, but not limited to, no documented lean training; rust on carts, castors, stools, screws, tables, and edge of PECs; residue and contamination on PECs; damaged walls; loose/missing caulking on ceiling, vents, and floors; and green oxidation on sink pipes. Additionally, the Pharmacy failed to report 1 CFU of a gram negative rod in an anteroom air sample and 1 fungal CFU in an anteroom surface sample on 5/25/23.
• July 2023, the Pharmacy suspended compounding after losing staff then resumed on 10/16/23. Pre-mixed bags, unplugged mini-bag systems, or immediate use kits with instructions to mix were sent to facilities. The Pharmacy were attaching mini-bag plus vials to bags in the buffer room with 14-day BUDs for approximately 12 patients/day. The Pharmacy voluntarily ceased compounding. The POC addressed each deficiency with the corresponding remediation and the AAL was reported.
• A change of management had occurred including the hiring of MOR Grattan on 3/6/23 and DOP Gancarz on 12/26/22. Issues with rust from using bleach had already been identified and were being addressed prior to the inspection. After resuming limited compounding, the Pharmacy focused on staffing. Compounding would resume only after the proper staff had been onboarded and trained.
• MOR Grattan contended that the Azzur Labs report showed that both plates were designated as a "pass" result for the 5/25/23 EM causing the failure to recognize the growths as AALs that required reporting. EM was repeated on 6/6/23 with zero CFUs.
• DOP Gancarz and MOR Grattan are responsible for ensuring all EM and ISO area control oversight compliance. P&Ps for monthly checks and mandatory cleanings were implemented along with checks and balances for AAL EM with a clear CAPA procedure including RCA, necessary reporting, and CAs. An ID specialist at Azzur Labs will be consulted directly to comply with the updated BORP policy 2023-09.

ACTION: Motion by J. LOPEZ, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0247), 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 #26/CASE-2023-0587
PHA-2023-0201 Amherst Pharmacy, DS89775 Time: 11:54 AM

RECUSAL: NONE

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

• 1 year probation effective 12/14/23
• Repeat controlled substance recordkeeping deficiencies on 10/5/23 and failure to remediate deficiencies from 11/15/21 and 1/6/22 in a POC. Perpetual inventories were inaccurate, a prescription

recorded for oxycodone 5mg was for Tobradex, an oxycodone 5mg prescription was missing, and dispensing errors were observed. An incomplete POC was submitted.
• MOR Nikitas contended the POC addressed the observed deficiencies which were corrected a few days after the inspection. He stated the PMP is checked if needed and the CSs are double counted by hand and recorded by the pharmacist.
• A review of the perpetual inventories, prescriptions, DEA 222s, and the PMP was performed. Reconciliation errors were carried over and not immediately corrected, all prescriptions were not reported to the PMP, prescriptions were inaccurately reported to the PMP for quantities and/or strength, unresolved dispensing errors occurred, and #100 oxycodone 20mg tablets were received on 9/21/23 but not added to the perpetual inventory.
• SOP Controlled Substance Handling and Perpetual Inventory states a real-time perpetual inventory must be maintained and confirmed with an actual count of BOH. CS prescriptions must be double-counted and back-counted. Perpetual inventories are conducted prior to opening to avoid interruptions and prevent errors. MOR Nikitas and PTT Nikitas confirmed review of the SOP.

ACTION: Motion by D. BARNES, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2023-0201), 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 #27/CASE-2023-0518
PHA-2023-0233 CVS #1531, DS89663 Time: 11:58 AM

RECUSAL: NONE

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

• Inspectional deficiencies cited on 09/22/2023 for storage of epinephrine auto-injectors and needles/syringes in non-licensed pharmacy space, an immunization/consultation room. During the inspection, the pharmacist on duty removed all the items from the room. The PIC indicated the pharmacist will ensure Sharps and epinephrine are stored in the Pharmacy when not in use.
• MOR Accime, Pharmacist Li, PI Bobby, and PT Demosthese stated the deficiency "…occurred due to the consultation room being used as the vaccination room and the EpiPens, needles/syringes were there to be used for vaccine preparation".
• CVS policy Pharmacist Administered Immunization Program states following administration of an immunization, all immunization supplies, including the emergency kit and Sharps container, are to be returned to the pharmacy.
• MOR Accime, Pharmacist Li, PI Bobby, and PT Demosthese stated, "Going forward, all EpiPens, needles and syringes will be stored inside in the pharmacy in shelves near the consultation room. Vaccines will be prepared inside the pharmacy before entering the consultation room". MOR Accime, Pharmacist Li, PI Bobby, and PT Demosthene attested that all policies and procedures for immunization have been reviewed.

ACTION: Motion by S. AHMED, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0233), 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 #28/CASE-2023-0685

PHA-2023-0255 CVS #11131, DS99287 Time: 12:01 PM

RECUSAL: NONE

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

- Inspectional deficiency on 11/3/23 for storage of Pfizer COVID-19 preservative-free vaccine for immediate administration in pre-drawn syringes. The POC stated, the pre-drawn vaccines were used within 1 hour of preparation and Pfizer BioNTech vaccine could be store in syringes for 6 hours refrigerated.
- On 11/3/23, 14 vaccines were administered prior to the inspection. VARs submitted showed 20 Pfizer COMIRNATY for 12 years of age+ were administered by MOR Munson.
- MOR Munson was the only immunizer on duty on 11/3/23. Vaccines administered prior to the inspection were administered immediately following preparation. At 1pm, MOR Munson decided to pre-draw 20 COVID vaccines for upcoming afternoon appointments. She quarantined the pre-drawn syringes after Investigator Horn informed her the vaccine was intended for immediate administration because there was no preservative.
- MOR Munson called Pfizer's medical testing team at ~2:15pm and inquired if the pre-drawn vaccine in syringes were stabile after the puncture and if they had to be damaged or could still be used, since they contained no preservative. The Pfizer representative told her they were stable and could be used for up to 12 hours. She determined the vaccines were safe to administer and administered them to 20 patients from 2:48pm to 5:22pm.
- Board Policy 2023-02: Vaccine Administration states, "Drawing up vaccines for future use (i.e., greater than 1 hour) is considered sterile compounding and must be performed under sterile conditions in accordance with USP <797>.
- Senior Analyst Furtado related, "Outreach attempts were made to all 20 customers who received the pre-drawn vaccines on 11/3/23. No adverse effects were reported".
- The POC stated vaccines will not be drawn in advance and all vaccines will be administered immediately after preparation. MOR Munson stated, "…going forward I will not pre-draw any syringes". MOR Munson and Pharmacist Wegge reviewed CVS ROPP-0051 Pharmacist Administered Immunization Program and BORP Policy 2023-02: Vaccine Administration.

ACTION: Motion by R. LOPEZ, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2023-0255), 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.

J. Dorgan enters the meeting at 12:05 PM

Case #29/CASE-2023-0561
PHA-2023-0257 CVS #4200, DS89646 Time: 12:11 PM

RECUSAL: NONE

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

- RLCS unknown loss of 625mL lacosamide 10mg/mL identified on 8/11/23 via corporate controlled substance monitoring. Controlled substance recordkeeping was reviewed along with staffing schedules and video but the reason for the loss was undetermined.
- Sr. Analyst Furtado stated amber bottles were used to measure the drug during production and no brand-name Vimpat was dispensed 4/30/23-8/29/23.
- MOR Gilman stated daily cycle counts were initiated after being notified of the discrepancy. She worked with LPM Mahoney to investigate the loss. MOR Gilman stated, "We found a return that had been done and a cycle count that had been adjusted around the same time. We presume that some of the product was close to expiring and was segregated from the other product to be returned. After this was done the product was cycle counted before the return was processed. This is where the problem would have originated…The product should have been accounted for until the return was processed".
- Pharmacy staff are now aware not to change any cycle count of a CS still in the Pharmacy. The Pharmacy-specific policy was changed to only dispense lacosamide 10mg/mL as full bottles to prevent any future problems. MOR Gilman, Pharmacist Jaquez PT Gouldthorpe, PT Davenport-Singh and PTT Gentile attested to review of all policies and procedures for the proper storage and handling of controlled substances.

ACTION: Motion by S. AHMED, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0257), 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 a STAYED PROBATION for a period of 1 year, with special terms to include the CS Loss Protocol for all lacosamide products.

Case #30/CASE-2023-0491
PHA-2023-0208 CVS #17589, DS90006 Time: 12:14 PM

RECUSAL: NONE

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

- On 09/18/2023, Investigator Horn arrived on site to conduct an inspection to find the Pharmacy closed. No signs or additional information was provided for patients coming to the Pharmacy.
- MOR McCrorie indicated that cases of sick calls, CVS will work with the Target team to request a sign be hung at the pharmacy stating the pharmacy is temporarily closed and when they are expected to re-open as well as nearby pharmacies for any emergencies.
- The pharmacy's normal operating hours should have been 10:00am-6:00pm but instead they were open 1:00pm-6:00pm on 09/18/2023.
- DPRA Lariviere indicated that the day of the incident, the store did execute all appropriate actions to alert the BOP. However, due to an administrative error in the established process used by CVS, the notification was inadvertently not sent.
- DPRA Lariviere noted that they are reviewing internally this process.

ACTION: Motion by R. LOPEZ, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2023-0208), 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 #31/CASE-2023-0516
PHA-2023-0210 CVS #1238, DS2058 Time: 12:17 PM

RECUSAL: NONE

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

- During a retail compliance inspection conducted on 07/26/2023, it was observed that Rx Cooler 1 had experienced a temperature excursion without any documentation of actions.
- Investigator Murray indicated that Rx Cooler 1, used to store medications had a temperature excursion on 06/27/2023 with a high temperature of 53 degrees Fahrenheit.
- MOR Giambanco indicated that the intern was reorganizing Rx Cooler 1 on 06/27/2023, the day of the cited excursion and indicated that "a true temperature excursion did not occur". The MOR did not address the fact that there was no documented action taken for the noted excursion.
- The MOR indicated that he would ensure the fridge and freezer temperatures are continuously monitored and any temperature variations are addressed immediately.

ACTION: Motion by S. AHMED, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2023-0210), 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 #32/CASE-2023-0543
PHA-2023-0258 CVS #1002, DS3060 Time: 12:19 PM

RECUSAL: NONE

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

- RLCS-#60 Zenzedi 20mg tablets attributed to an unknown loss on or about 09/18/2023.
- DL Rock indicated that loss of Zenzedi was discovered on 09/18/2023 when a prescription could not be located in the waiting bin. He noted that the prescription may not have been filed properly or scanned out appropriately. Video was reviewed.
- MOR Singh confirmed that cycle counts, biennial inventories, staffing schedules and inventory reports for the applicable time period were reviewed and they could not identify the reason for the loss.
- DL Rock reviewed that all loss prevention policy and procedures will be reviewed with the Pharmacy Team. This includes diligent CII inventory management and dispensing standards. He also reviewed back counting of narcotics at the time of dispensing to ensure accuracy.

ACTION: Motion by D. BARNES, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0258), 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 #33/CASE-2023-0483
PHA-2023-0226 CVS #1852, DS3462 Time: 12:21 PM

RECUSAL: NONE

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

- During the 09/07/2023 Board of Registration in Pharmacy meeting, it was discovered that Pharmacy Technician Trainee (PTT) applicant Christina Fitzgerald had been performing pharmacy technician duties without a license.
- Director, Pharmacy Regulatory Affairs (DPRA), Leo Lariviere stated that PTT Fitzgerald was not "serving as a pharmacy technician" nor performing any functions which fall under the definition of a pharmacy technician… The colleague in question was acting as a salesclerk, which doesn't count in ratio and is distinguished by regulation from a technician".
- PTT Fitzgerald's hire date was 09/29/2021 and the PTT started on the registers around July 2023 before getting her pharmacy license in September 2023.

ACTION: Motion by S. AHMED, seconded by J .LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0226), 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 #34/CAS-2023-0819
PHA-2023-0145 Wegman Food Market, Inc, DS89914 Time: 12:23 PM

RECUSAL: NONE

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

- BORP initially opened a complaint against Wegmans after the pharmacy was issued a POC during an RCI on 06-08-2023 for permitting two staff to work as PTTs without a license. The complaint was then amended to include an additional violation of after a different PTT was observed working with an expired license during subsequent RCI on 09-12-2023. In addition, BORP opened a staff-assignment investigation concerning Former MOR Ward for the repeat violations during both inspections.
- POC/CA: Current MOR Levesque described that steps were added "to create an account and apply for a Technician Training License on day 1." Current MOR Levesque then emphasized that the MOR and the division trainer would ensure proper licensure was obtained before a staff member performed any duties requiring licensure. In addition, the MOR and the division trainer would ensure that PTTs would apply for pharmacy technician licensure upon completion of training in a timely manner.
- Current MOR Levesque also emphasized that Wegmans would ensure that "MOR's completely understand the responsibilities and duties of their role." He explained that the division trainer would "send follow up communications to MOR and employee utilizing new employee checklist and training guides. This will ensure all licensing is up to date and applications are submitted on time."
- MOR Ward blamed the violations on issues with the PTT and PT application process. In addition, he blamed Wegmans for not providing sufficient support. He noted that when he worked at CVS that licensing was done automatically, and he received emails when a license was going to expire but he had to create a spreadsheet at Wegmans.

ACTION: Motion by S. HAMILTON, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0145), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #35/CAS-2023-0819
INV8500 Matthew Ward, PH234090 Time: 12:26 PM

RECUSAL: NONE

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

- BORP initially opened a complaint against Wegmans after the pharmacy was issued a POC during an RCI on 06-08-2023 for permitting two staff to work as PTTs without a license. The complaint was then amended to include an additional violation of after a different PTT was observed working with an expired license during subsequent RCI on 09-12-2023. In addition, BORP opened a staff-assignment investigation concerning Former MOR Ward for the repeat violations during both inspections.
- POC/CA: Current MOR Levesque described that steps were added "to create an account and apply for a Technician Training License on day 1." Current MOR Levesque then emphasized that the MOR and the division trainer would ensure proper licensure was obtained before a staff member performed any duties requiring licensure. In addition, the MOR and the division trainer would ensure that PTTs would apply for pharmacy technician licensure upon completion of training in a timely manner.
- Current MOR Levesque also emphasized that Wegmans would ensure that "MOR's completely understand the responsibilities and duties of their role." He explained that the division trainer would "send follow up communications to MOR and employee utilizing new employee checklist and training guides. This will ensure all licensing is up to date and applications are submitted on time."
- MOR Ward blamed the violations on issues with the PTT and PT application process. In addition, he blamed Wegmans for not providing sufficient support. He noted that when he worked at CVS that licensing was done automatically and he received emails when a license was going to expire but he had to create a spreadsheet at Wegmans.

ACTION: Motion by C. BELISLE, seconded by S. HAMILTON, and voted unanimously by all present, to ELEVATE the matter (INV8500), to a complaint.

Case #36/CASE-2023-0567
PHA-2023-0200 CVS #2201, DS2770 Time: 12:28 PM

RECUSAL: NONE

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

- On October 6, 2023, Investigator Murray issued a POC during an RCI based in part that needles and syringes were stored outside of the licensed prescription area in the CVS 2201's immunization room.
- On October 12, 2023, Investigator Murray issued a POC during a follow-up SV based in part that needles and syringes were again observed stored outside of the licensed prescription area in the pharmacy's immunization room.
- CVS 2201's MOR explained that "on October 6, 2023 and October 12, 2023, the pharmacy staff consisted of employees unfamiliar with the pharmacy space. They were under the impression that since the vaccination room locked that it was part of the pharmacy."
- POC/CA: CVS 2201's MOR described that "all needles and syringes have been removed from this unlicensed pharmacy space. All staff have been retrained not to store anything in the vaccination room,

and I will continue to educate new staff when they are working in the building." In addition, needles and syringes would be stored in licensed prescription area going forward.

ACTION: Motion by S. AHMED, seconded by S. DINNO, and voted unanimously by those present, to refer the matter (PHA-2023-0200), 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: **Executive Session Call to Order:** **Time: 12:31 PM**

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

Action: A motion was made by S. Hamilton to enter Executive Session; Seconded by J. Lopez then Board Members present voted unanimously by roll call to approve motion.

Roll call attendance: Katie aye, Caryn aye, Johanna aye, Dr. Lopez aye, Sebastian aye, Sami aye, Delilah aye, Mark aye, Julie aye, Saad aye.

Lunch 12:35 PM to 1:05 PM

J. Lopez leaves the meeting at 2:28 PM

Topic XI: **Adjudicatory** **Time: 2:53 PM**

DISCUSSION: None
ACTION: President K. Thornell request a motion to enter Adjudicatory.

At 2:53 PM J Lopez, seconded by D. Barnes and voted unanimously by all those present to enter Adjudicatory by roll call vote.

Topic XII: **65C Sessions MGL c. 112 section 65C** **Time: 2:54 PM**

DISCUSSION: None
ACTION: President K. Thornell request a motion to enter 65C.

At 2:54 PM S. Hamilton, seconded by S. Ahmed and voted unanimously by all those present to enter 65C by roll call vote.

S. Dinno leaves the meeting at 3:05 PM

Topic XIII: **ADJOURMENT OF MEETING** **TIME: 3:10 PM**

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

XHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 3/7/24 General Session
2. Draft Minutes of the 2/1/24 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Monthly report from Probation
5. Reconsideration Memo CVS Pharmacy #26; DS2912; PHA-2023-0104
6. Reconsideration Memo CVS Pharmacy #23; DS90049; PHA-2022-0108
7. Review of Compliance: Blue Hill Pharmacy; DS89942; PHA-2022-0122
8. Blue Hill Pharmacy; Change of Pharmacy Hours of Operation
9. CVS/Specialty; – Renovation application
10. BMC Pharmacy South Boston – New community pharmacy application
11. BILH Pharmacy 41 Mall Road, Burlington – New community pharmacy application
12. Bravo Pharmacy – Relocation application
13. Nerphron Sterile Compounding Center – Non-Resident Outsourcing
14. PHA-2022-0207 Nephron SC, Inc, NO00036
15. PHA-2023-0170 SOFIE, NU00021
16. PHA-2024-0013 SOFIE, NU00021
17. PHA-2024-0014 SOFIE, NU00021
18. INV8186 BWH Nuclear Pharmacy, NU16
19. INV8849 BWH Nuclear Pharmacy, NU16
20. PHA-2023-0265 Walgreens #5445, DS2964
21. PHA-2023-0234 Imad Haidardiab, PH24533
22. PHA-2023-0236 Walgreens #17531, DS90420
23. PHA-2023-0216 Walgreens #15390, DS89867
24. PHA-2023-0249 Tufts Medicine Infusions Services, DS90378
25. PHA-2023-0177 Fresenius Kabi Compounding, RO00002
26. PHA-2023-0195 Michael Martin, PH19637
27. PHA-2023-0232 Walgreens 4966, DS2924
28. INV8069 Paul R Casale, PT23845
29. PHA-2023-0198 Market 32, DS2526
30. INV8698 Paul Rohde, PH15575
31. PHA-2023-0238 McNabb Pharmacy, DS90087
32. PHA-2023-0243 Walgreens #7063, DS3238
33. PHA-2023-0244 Walgreens #17545, DS90127
34. PHA-2023-0237 Walgreens #5756, DS3252

35. PHA-2023-0248 New England Life Care, DS90241
36. PHA-2023-0218 ProCare LTC, DS90042
37. PHA-2023-0225 CAPS, DS3312
38. PHA-2023-0247 Partners of MA, DS3419
39. PHA-2023-0201 Amherst Pharmacy, DS89775
40. PHA-2023-0233 CVS #1531, DS89663
41. PHA-2023-0255 CVS #11131, DS99287
42. PHA-2023-0257 CVS #4200, DS89646
43. PHA-2023-0208 CVS #17589, DS90006
44. PHA-2023-0210 CVS #1238, DS2058
45. PHA-2023-0258 CVS #1002, DS3060
46. PHA-2023-0226 CVS #1852, DS3462
47. PHA-2023-0145 Wegman Food Market, Inc, DS89914
48. INV8500 Matthew Ward, PH234090
49. PHA-2023-0200 CVS #2201, DS2770

Respectfully Submitted,
Rita Morelli, Secretary