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

## NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE BOARD OF REGISTRATION IN PHARMACY June 6, 2024

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

Join link:

https://eohhs.webex.com/eohhs/j.php?MTID=mcbfed414c7a58893a2477b7100c7bc66

Webinar number: 2532 908 4778 Webinar password: BOP123 (267124 from phones and video systems) Join by phone: +1-617-315-0704 United States Toll (Boston) +1-650-479-3208 United States Toll

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Stacy Hart, <u>Stacy.Hart@mass.gov</u> or 857-274-1120 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.

Agritua				
		Item	Page	
8:00	Ι	CALL TO ORDER		K. Thornell
8:05	Π	APPROVAL OF AGENDA Board Updates		
8:10	III	<ul> <li>APPROVAL OF BOARD MINUTES</li> <li>Draft of May 2, 2024, Regular Session Minutes</li> </ul>		
8:15	IV	<ul> <li>REPORTS</li> <li>Applications approved pursuant to Licensure Policy 13-01</li> <li>Monthly report from Probation</li> <li>Board Delegated Review pursuant to Licensure Policy 14-02</li> <li>PSUD Report-Policy 17-03</li> </ul>		
8:20	v	<ul> <li>FLEX</li> <li>NABP Annual Meeting update</li> <li>Pharmacy Advisory Committee meeting reminder – June 12, 2024</li> </ul>		J. Rocchio

# Agenda

			LICATIONS Health Care Pharmacy	1 New Community	Pharmacy	
8:45	VI	•				
	FILE REVIEW					
		1	CASE-2024-0127	PHA-2024-0035	Vital Care of Hopkinton, DS90415	
		2	CASE-2024-0998	PHA-2024-0051	Compare Quality Pharmacy, DS89874	
		3	CASE-2024-0998	PHA-2024-0052	Sreenivas Athuluri, PH26974	
		4	CASE-2024-1166	PHA-2024-0056	Birds Hill Pharmacy, DS90094	
		5	CASE-2024-0129	PHA-2024-0037	Walmart 10-2904, DS2977	
	CASE-2023-0870 PHA-2024-0001 Sulliva		Paul R Casale, PT23845			
			Sullivans Healthcare, DS3335			
		8 CASE-2023-0873 PHA-2024-0005 Rite Aid #10205,		Rite Aid #10205, DS2573		
9:30	VII	9	CASE-2023-0791	PHA-2023-0270	Rite Aid #10209, DS2899	
		10	CASE-2024-1218	PHA-2024-0061	Chicopee Pharmacy, DS90423	
		11	CASE-2023-0782	INV8911	Stop & Shop #782, DS2299	
		12	CASE-2023-0420	PHA-2024-0034	Pharmscript of MA, LLC, DS90251	
		13	CASE-2023-0871	PHA-2024-0008	SCA Pharmaceutical, NO00045	
		14	CASE-2024-1010	PHA-2024-0049	CVS #10596, DS90262	
		15	CASE-2024-1010	PHA-2024-0050	Evis Bruzho, PH238501	

		<b>16</b> CASE-2024-0944 P			
<b>17</b> CASE-2024-0944 PHA-2024-006			HA-2024-0065	Jeffrey Dumond, PH239205	
	18         CASE-2024-0944         PHA-2024-0066         Myle Nguyen, PH241380           19         CASE-2024-0944         PHA-2024-0067         Theresa Pham, PTT100904			Myle Nguyen, PH241380	
				Theresa Pham, PTT100904	
		<b>20</b> CASE-2024-0990 P	HA-2024-0045	CVS #8437, DS3549	
		<b>21</b> CASE-2024-1241 IN	JV10124	CVS #17529, DS89992	
		<b>22</b> CASE-2023-0829 P	HA-2024-0002	CVS #507, DS89841	
		<b>23</b> CASE-2023-0616 P	HA-2024-0078	Nancy Edwards, PH238675	
		<b>24</b> CASE-2024-0009 P	HA-2024-0020	CVS #2476, DS2904	
		<b>25</b> CASE-2024-1221 PHA-2024-0060 CVS #2592, DS3011			
11:00	VIII	EXECUTIVE SESSIONThe Board will meet in Executive Session as authorized pursuant to M.G.L. c.30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition, or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, evaluate the Good Moral Character as required for registration for a pending applicant.			
12:00		LUNCH BREAK			
12:30	IX	M.G.L. c. 112, § 65C SESSION			
3:00	X	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)			
4:00	XI	ADJOURNMENT			

#### COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting June 6, 2024

#### **Board Members Present**

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

#### **Board Staff Present**

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

TOPIC I. Attendance by roll call:

#### CALL TO ORDER 8:00 AM

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

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

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Draft Minutes General Session: 6/6/24 BOP Approved: 8/1/24 **Board Members Not Present** 

Dawn Perry, JD

Topic II. Agenda: 6/6/24

**DISCUSSION: None** 

**ACTION:** Motion by S. Hamilton, seconded by D. Barnes and voted unanimously by those present to approve the agenda with no noted change by roll call vote.

Action: Motion by S. Ahmed seconded D. Barnes and voted unanimously to approve the regular session minutes of 5/2/2024 with no noted changes by roll call vote.

REPORTS

**Approval of Board Minutes** 

TOIC IV

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: M. BOTTO

<u>DISCUSSION</u>: M. Botto reported a total of 29 Change of MOR applications and 2 facility closures that have been approved via Staff Action since the May 5th Board meeting.

So noted.

Topic IV.

Monthly Report from Probation

PRESENTED BY: M. BOTTO

<u>DISCUSSION</u>: M. Botto reported 1 facility that was given the opportunity to cure and 1 facility that has successfully completed probation monitoring since the May 5th Board meeting. Currently, there are a total of 41 active probation monitoring cases.

So noted.

**TIME 8:08 AM** 

TIME: 8:09 AM

TIME: 8:09 AM

TIME: 8:08 AM

REPORTS

Topic III

1. Draft 5/2/24

Change: No changes

Minutes

# Draft Minutes General Session: 6/6/24 BOP Approved: 8/1/24

DISCUSSION: M. Botto indicated no new admissions or changes to the PSUD program since the last Board meeting. Currently, there are a total of 8 active participants enrolled in the program.

So noted.

Topic V.

NABP Annual Meeting update PRESENTED BY: John Rocchio

PRESENTED BY: M. BOTTO

DISCUSSION:

a. The 120th annual meeting of NABP was held from May 14-17, 2024 in Fort Worth, T exas.

FLEX

b. Resolutions were passed as follows:

> i. Drug Shortages. Resolved that NABP collaborate with other organizations, including industry, federal agencies, pharmacy associations, and pharmacy benefit managers to develop additional strategies and technological tools to address drug shortages.

Development of a National Forum for Pharmacy Professional Recovery ii. Programs.

iii. Task Force to Assess Expanding Access to NABP Competency Assessment Examinations.

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# REPORTS Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto indicated 6 cases of CE deficiencies, all of which have been closed with no discipline warranted. 2 instances of unlicensed practice were reported, each of which has been issued a reprimand. One count of controlled substance loss was reported, resulting in the issuance of a reprimand. One petition for waiver renewal for DS100132 Genoa Healthcare LLC has been approved since the last Board meeting.

REPORTS

So noted.

Topic IV.

PSUD report by Staff Action 17-03

**TIME: 8:10 AM** 

**TIME: 8:10 AM** 

**TIME: 8:09 AM** 

- c. Next year the annual meeting will be held in Fort Lauderdale.
- d. The District 1 & 2 meeting will be held on October 7-9, 2024 in Everett, Massachusetts.

### ACTION: None

TOPIC VI

Topic V.		FLEX	
Pharmacy Advi	Pharmacy Advisory Committee (PAC) meeting reminder		
PRESENTED BY	: David	Sencebaugh	
DISCUSSION:			
	a.	The next meeting is on June 12, 2024, beginning at 9 AM.	
	b.	The agenda is posted online.	
	c.	William Frisch, RPh, Director of Compliance added that Board m Ahmed, RPh, PharmD, BCPS, BCSCP will present recommendation Implantable Infusion Pumps.	
ACTION : None			

# 1. Health Care Pharmacy New Community Pharmacy TIME: 8:18 AM

APPLICATIONS

Represented by: Romin Patel and Jessica Strom Recusal:

**Discussion:** We are looking to open a retail/340B pharmacy at the Community Health Center of Franklin County. There is no pharmacy at this location so we are looking to open a new one. There are no waivers.

Questions from Board members:

- Who is going to be the Manager of Record (MOR) for the pharmacy?
  - I, Romin Patel, will be the MOR.
- What type of compounding is expected to be done at this facility? Sterile or Non-Sterile?
   We will be doing Non-sterile, simple compounding
- Do you have any experience in that role?
  - Yes I have been a pharmacist for approximately 10 years
- Do you have experience with non sterile compounding?
  - Yes I do, prior to the USP 795 guidelines being updated we did a lot of non-sterile compounding in my role. Now less so because of this change, but still a significant amount of compounding.
- Is this a 340B pharmacy?
  - Yes it would be a 340B and retail pharmacy

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- Will you be offering delivery? Or is this a pick up only pharmacy?
  - Right now this is only pick up only, but we are looking into delivery options.
- You're closed on Sundays, what is your plan to help people who may need assistance or have questions after hours?
  - There will be a central line for people to call if they need assistance but we need to be closed on the day that the healthcare facility is closed.
- Your application states that you all will be doing simple and moderate compounding can you clarify this?
  - We will only be doing simple, non-sterile, compounding.
- Do you have hoods?
  - $\circ$  No we will not be using hoods.
- Will the proposed pharmacy be in the same building as the facility or separate?
  - It will be in the same building, but it is a separate suite in a multi-tenant building. This pharmacy will be a separate store in this same building. The space which will be used by this pharmacy is currently not licensed by Massachusetts DPH.
- Are you only planning to be open during the same hours as the clinic is open?
   Yes
- Are you restricting your patient population to clinic patients only?
  - o No

**Action:** A motion by C. Belisle was made to approve the application for the new community health care pharmacy upon successful inspection; seconded by S. Hamilton and voted unanimously by roll call to approve the motion.

## 2. Nimvax; DS90369

Renovation

TIME: 8:27 AM

Represented by: Nimit Deocampo Recusal: Sami Ahmed

## Discussion:

## Introduction:

Dr. Deocampo explained that he may be joined by his Lawyer later due to his Lawyer's prior obligation. He also expressed his thanks to the Board of Registration in Pharmacy staff for their assistance and guidance through the for their assistance in the renovation application process.

# Board staff then provided an introduction of this matter, which is as follows:

Nimvax has submitted a renovation application which expresses their desire to transition to a fullservice retail pharmacy. Nimvax was originally licensed in September 2021 with a business model to only provide vaccine administration. Based on that business model they were issued a controlled substance registration for Schedule VI medications only. They were also granted three waivers for (insert on 2<sup>nd</sup> time through).

This renovation and business model change request, Nimvax is requesting a change in their controlled substance registration to include scheduled II-VI. It should be noted that on or around January 25<sup>th</sup>, 2023, the Board and DEA investigators conducted an onsite inspection. It was discovered at that time

that Nimvax had obtained a DEA registration that included federally scheduled drugs without first obtaining authorization from The Board. As a result, the DEA investigator revoked their DEA registration for cause. The Board opened a complaint (PHA-2023-0028) to address the matter and it is currently with the prosecutor's office.

Licensing files indicate the following timeline. They were licensed September 1<sup>st</sup>, 2021, on January 11<sup>th</sup>, 2023 we received an email request to update the controlled substance registration to Schedules II-VI. That email included the DEA registration which included schedules II-VI. In January 25<sup>th</sup>, 2023, the previously mentioned inspection occurred. On February 15<sup>th</sup>, 2023, licensee withdrew their request to amend their CS application. In December of 2023 they renewed their DS and CS application. In March 2024, the licensee submitted a controlled substance amendment application, and withdrew that application in May 2024. On May 21<sup>st</sup>, 2024, the licensee submitted a renovation application which included a change to the controlled substance registration to include Schedules II-VI.

## Discussion:

- Dr. Deocampo attempted to explain that the DEA registration was surrendered by the licensee to the DEA. Board counsel and investigator confirmed that the information received from the DEA is that the license was "revoked with cause."
  - Board Counselor, with the assistance of a Board investigator, further explained that this registration issue has occurred two times. Specifically, that Nimvax's initial application for controlled substance registration was for Schedule V & VI, but The Board a that time only approved the controlled substance registration for Schedule VI.
  - The DEA issued a schedule V and VI license based on representation from Nimvax that The Board issued a registration for schedule V & VI.
  - At a later time, when the DEA registration needed renewal, an application for Schedules II-V registration from the DEA was submitted, with an attestation from Dr. Deocampo that they had received registration from the Board of Pharmacy for schedules II-VI. However only a Schedule VI had been issued from The Board.
- Dr. Deocampo explained that he has a signed statement of surrender to the DEA regarding the Schedule V registration and they would be willing to provide that to The Board.
- Dr. Deocampo further explained that they applied for the DEA licensure approximately three years ago at the suggestion of a consultant, "as part of normal standard practice." However, Dr. Deocampo did not realize the discrepancy with the registration until the DEA and Board of Registration in Pharmacy inspection from January 2023.
- Dr. Deocampo stated that Nimvax has only dispense vaccines and have not dispense any other medications
- Dr. Deocampo also stated that they did not receive approval for a DEA registration for Schedules II-V, just the DEA Schedule V.

## Questions:

- Did the DEA issue a registration for Schedule II-V?
  - Per Dr. Deocampo: No, they did not, We only received approval for Schedule V in September of 2021. We used The Board letter that we were approved, but The Board's letter we had on file did not specify schedule VI only.
  - Per Board Investigator: The DEA issued a registration for Schedule II-V. "Dr. Deocampo provided a snippet of an application which he said is a DEA registration and is misrepresenting this to the board." When you apply for a DEA license the expectation

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is that you have already been approved by your local registering body (i.e. Mass BORP, lowa BOP, etc...). You cannot contemporaneously apply. On two occasions Dr. Deocampo applied and attested on the DEA applications that he was authorized for a Schedule II - V

- Were you present during the board meeting when the board initially issued the Sch-VI licensure?
  - o Yes
- Additionally, of the images you provided, one was the Board of pharmacy issued registration that you signed and said Sch-6 only. You signed that, correct?
  - Yes I signed that back in September of 2021, and we never used it and put it away and did not notice that discrepancy until the DEA inspected.
- Can you give us an idea of why you have made the decision to expand to a whole service pharmacy?
  - We would remain a vaccination clinic, however more patients cannot afford to pay for vaccines out of pocket. If we continue to only dispense vaccines we are not able to join a PBM so patients can have their vaccines paid by insurance. The solution for this is to become a full service pharmacy.
- What is the renovation?
  - The renovation will be adding a wall to ceiling barrier that will separate the facility to a pharmacy and nonpharmacy area, because we have a bit of a unique set up we are adding this to help stay in compliance.
- What experience do you or your staff have with non-sterile compounding?
  - We will comply with USP-795
  - Previously, before I started Nimvax, I used to work in a 503b as a pharmacist and I used to compound non-sterile. So I have extensive experience in non-sterile compounding.
- I heard you say that you were looking to change your model to a full-service pharmacy so you could get reimbursed for vaccine administration, is that correct?
  - Dr. Deocampo: No that is not correct
  - Board Counsel: "But you just said that. You literally just said that. If you are applying to be a full service pharmacy you need to act as a full service pharmacy. The Board and the DEA are not able to issue "shelf" licensure. That is licensure that you do not intend to actually utilize to service patients but instead for other purposes. And what I heard is that you are intending to use this licensure to join a PBM to get reimbursement and that is different than what was represented to myself and other board staff."
  - Dr. Deocampo: That is part of the reason we are seeking this Board approval. Not being able to have access to a PBM, limits access to our patients. We've either lost or had to turn away thousands of patients as a result of this because we cannot service our patients. We are finding that we cannot service our patients if we stay as a vaccine clinic because of these PBMs that are apart of popular health plans.
- What services are you trying to provide your patients?
  - Dr. Deocampo: Vaccines
- C. Belisle: How about filling their prescriptions because that is what is being applied for today. Are you here to have a full-service pharmacy to fill prescriptions for the public and community?

- Yes, we are intending to become a full-service pharmacy. Not only are we providing vaccinations, but we are looking to provide prescriptions as well.
- What are your planned hours of operation?
  - Monday Friday 9:00am 5:30pm
  - Saturday 9:00am -1:00pm
  - Sunday closed because the building which has this pharmacy in it is closed on Sundays.
- What is your plan to help people who may have issues or an emergency?
  - Patients can use the on-call service for the pharmacy, or they may submit inquiries on the website.
- In the past year, you have been closed for a month, and then a few weeks. Do you plan to close for extended periods of time if you are issued a full retail license?
  - No, we do not plan on having closures unless we are in an emergency situation. If that were to happen, we have a contingency plan.
- What is that plan?
  - Dr. Deocampo: I can supply that to you via email.
  - Board Counsel: That was part of the request prior to this meeting. Are you able to answer the question of what is your contingency plan if you are unable to service patients due to a closure?
  - Dr. Deocampo: Yes, we will notify the board of the closure, and also notify our patients. In the event of any alarm or emergency, either myself or the staff pharmacist will be notified. If our emergency supply is in jeopardy, we can move our inventory to a local repository.
- What is your contingency plan for if you have a closure, for your patients to be able to continue to access their medications?
  - $\circ \quad \text{We do not intend to close.}$
- When your pharmacy needs to close; what is your plan, or do you have a plan, for providing patients with continuity of care?
  - We have a backup pharmacy that, once we have approval, we will contract with a local pharmacy to provide that continuity of care.

Note: at approximately 9:10am, Attorney Rozzi for Dr. Deocampo joined the meeting discussion

- What is your staffing plan if you are going to open a full-service retail store?
  - We have one part time pharmacist, 2 technicians and an intern, in addition to myself as a full time pharmacist. We should be able to meet our obligations as a full service pharmacy.

Attorney Rozzi provided a summary of Dr. Deocampo's desires for this licensure, expressing that this will be a full-service pharmacy with the long-term goal of expansion. There will be plans to have delivery as well including uber delivery, and other services including non-third-party delivery options as well. Attorney Rozzi stated that Dr. Deocampo's goals are to be a pharmacist for the community and that Dr. Deocampo is working to right his past mistakes and misdoings.

[a 10-minute break was taken so Attorney Rozzi could speak with Dr. Deocampo]

Attorney Rozzi and Dr. Deocampo requested to withdraw their application.

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### S. Hamilton leaves the meeting at 8:35 AM

ΤΟΡΙϹ VII	FILE REVIEW	
Case #1/CASE-2024-0127		
PHA-2024-0035	Vital Care of Hopkinton, DS90415	Time: 09:36 AM

### RECUSAL: NONE

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

- On 1/10/24, Investigators Brosnan and Seed attempted to conduct a retail compliance inspection and a 797 site visit, but the Pharmacy was closed during posted hours of operation, 8am-6pm Monday-Thursday. They called the phone number on the door. MOR Alkhandak was at a nearby physician's office promoting his services and arrived back in 10 minutes. He stated when the Pharmacy's slow, he visits local prescribers. He was informed the BORP must be notified if the Pharmacy is not open during posted hours.
- MOR Alkhandak stated that he is currently the only employee of the Pharmacy. He confirmed he was at a local physician's office when the Investigators arrived about 9:45am on 1/10/24. He stated, "I acknowledge the importance of prior notification and clear communication with the board. The inspector rightly recommended informing the board via email in advance and leaving a note on the door in the future. I take this advice seriously and assure you that moving forward, I will adhere to these recommended actions to ensure better coordination". MOR Alkhandak took responsibility for what he deemed as a rare occurrence.
- No prescriptions were dispensed from when the license was issued in February 2023 through September 2023. From 10/05/23 to 2/7/24, 38 prescriptions were dispensed over 13 days total.
- MOR Alkhandak stated that in case of an urgent matter requiring closure of the Pharmacy, he will email the BORP and will leave a notification on the Pharmacy's door. MOR Alkhandak related he was actively in the process of hiring additional staff including Pharmacists for coverage as the business grows which would eliminate the need to close the Pharmacy for any reason.

<u>ACTION</u>: Motion by C. BELISLE, seconded by J. LOPEZ, and voted unanimously by those present, with the exception of S. AHMED who abstained, to refer the matter (PHA-2024-0035), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #2/CASE-2024-0998		
PHA-2024-0051	Compare Quality Pharmacy, DS89874	Time: 09:40 AM

RECUSAL: NONE

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

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Draft Minutes General Session: 6/6/24 BOP Approved: 8/1/24

- Inspectional deficiencies on 1/9/24 for Pharmacist Collins not named on the Standing Order as an immunizer and MOR Athuluri administering vaccines with an expired CPR card. The Standing Order named specific pharmacists authorized. The POC indicated Pharmacist Collins was employed at the Pharmacy from 11/21/23-1/19/24 and had administered 3 vaccines.
- MOR Athuluri was unaware the Standing Order was restricted to him and 2 other pharmacists until he reviewed it. He believed any pharmacist certified to immunize was authorized. Current Pharmacist Aboumirah was not named on the Standing Order and administered a vaccine on 10/20/23.
- An updated Standing Order effective 2/20/24 was obtained that only authorized MOR Athuluri to immunize patients 18 years or older.
- MOR Athuluri completed the online portion for CPR recertification in a timely manner but had difficulty scheduling the in-person training. On 1/28/24, he completed the in-person training. MOR Athuluri administered 9 vaccines from 11/29/23-1/23/24. Despite being cited on 1/9/24 for his expired CPR card, MOR Athuluri proceeded with administering a vaccine on 1/23/24.
- MOR Athuluri added an alert to renew his CPR certification in his electronic calendar and complete inperson training 30 days prior to expiration. He confirmed review of BORP Policy 2023-02 Vaccine Administration.

<u>ACTION</u>: Motion by S. HAMILTON, seconded J. ROCCHIO, and voted unanimously by those present, to refer the matter (PHA-2024-0051), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case#3/CASE-2024-0998 PHA-2024-0052

Sreenivas Athuluri, PH26974

Time: 09:44 AM

## RECUSAL: NONE

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

- Inspectional deficiencies on 1/9/24 for Pharmacist Collins not named on the Standing Order as an immunizer and MOR Athuluri administering vaccines with an expired CPR card. The Standing Order named specific pharmacists authorized. The POC indicated Pharmacist Collins was employed at the Pharmacy from 11/21/23-1/19/24 and had administered 3 vaccines.
- MOR Athuluri was unaware the Standing Order was restricted to him and 2 other pharmacists until he reviewed it. He believed any pharmacist certified to immunize was authorized. Current Pharmacist Aboumirah was not named on the Standing Order and administered a vaccine on 10/20/23.
- An updated Standing Order effective 2/20/24 was obtained that only authorized MOR Athuluri to immunize patients 18 years or older.
- MOR Athuluri completed the online portion for CPR recertification in a timely manner but had difficulty scheduling the in-person training. On 1/28/24, he completed the in-person training. MOR Athuluri administered 9 vaccines from 11/29/23-1/23/24. Despite being cited on 1/9/24 for his expired CPR card, MOR Athuluri proceeded with administering a vaccine on 1/23/24.
- MOR Athuluri added an alert to renew his CPR certification in his electronic calendar and complete inperson training 30 days prior to expiration. He confirmed review of BORP Policy 2023-02 Vaccine Administration.

<u>ACTION</u>: Motion by J. ROCCHIO, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2024-0052), 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-2024-1166 PHA-2024-0056 Birds Hill Pharmacy, DS90094 Time: 09:45 AM

### RECUSAL: NONE

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

- During an inspection on 2/16/24, it was discovered the Pharmacy was compounding in a renovated/expanded HD room prior to obtaining a successful BORP inspection. The application and blueprints were submitted and approved in 4/2023. A wall was moved and a sink, dishwasher, and additional hood were added to the HD room.
- When Current MOR Tranter became MOR on 1/5/24, he was unaware a request for inspection of the expansion had not occurred prior to using the expanded space. Former MOR Stein accepted responsibility for the oversight. Upon returning from the New Year, the demands of the day were high, including the visit by the certification company and onboarding a new employee. Due to increasing demands on his attention, he appointed Current MOR Tranter as the MOR of the Pharmacy to assume the day-to-day responsibilities but overlooked notifying the BORP of the completion of the renovation. Despite this, the Pharmacy ensured compliance with USP standards.
- Contributing factors included difficulty obtaining a start date for construction and receiving needed supplies and equipment. Construction began on 11/11/23 and was completed 11/12/23. The hoods and HD room were certified 11/13/23 and compounding in the renovated suite commenced. On 12/31/23, an additional hood was installed in the HD room. On 1/2/24, the hoods and HD room were certified again.
- Former MOR Stein stated, "I regret this unintended failure to notify the board". To prevent future occurrences and avoid non-compliance issues, Current MOR Trantor assumed the day-to-day responsibilities and CQI meetings were increased to weekly. Current MOR Tranter stated the importance of documentation was reviewed and it will be his duty to prevent future reporting issues and assume all management of the Pharmacy.

<u>ACTION</u>: Motion by S. AHMED, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2024-0056), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #5/CASE-2024-0129 PHA-2024-0037

Walmart 10-2904, DS2977

Time: 09:49 AM

Case #4

RECUSAL: NONE

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

- During a retail compliance inspection conducted on 01/12/2024, the Investigator observed that the Pharmacy was not engaging in simple and moderate compounding since 11/01/2023.
- Director of Corporate Compliance Creel indicated that after considering the new requirements, and the potential need for new testing, training, and documentation that some states intended to require, a decision was made to discontinue offering compounding on a nation-wide basis.
- MOR Salwierz indicated that current policy is if a customer presented with a prescription for a compounded product, that an offer would be made to transfer the prescription to the patient's pharmacy of choice. The MOR did state that he was aware of the decision to reconsider the action taken.
- Director Creel indicated that after discussing the matter with Board representatives, Walmart has reconsidered its decision. Based on Board guidance, a program is being developed and will be fully implemented by April 1, 2024.
- On 6/3/24, Investigator Horn conducted a site-visit and the Pharmacy is resuming simple and moderate compounding.

ACTION: Motion by C. BELISLE, seconded by R. MORELLI, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0037), No Discipline Warranted, Remediation Complete.

Case #6/CASE-2023-0398		
PHA-2024-0063	Paul R Casale, PT23845	Time: 09:51 AM

**RECUSAL: NONE** 

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

- During the 03/07/2024 Board meeting, it was unanimously voted to elevate INV8069 on PT Casale's license to this complaint for practicing with an expired license.
- On 08/08/2023, it was observed during an inspection that PT Casale was practicing with an expired license at Union Pharmacy. PT Casale was provided instructions on how to renew his license.
- PT Casale responded to the staff assignment 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 continued to work without confirming his renewal application had been approved.
- Per eLX, PT Casale's License Renewal application was then submitted again on 11/15/2023 and subsequently approved by Board staff on 12/06/2023.
- In response to this complaint, PT Casale had no additional information to provide except that he no longer works at Union Pharmacy.

ACTION: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2024-0063), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #7/CASE-2023-0870 PHA-2024-0001

Sullivans Healthcare, DS3335

Time: 09:53AM

<u>RECUSAL</u>: D.BARNES recused and was not present for the vote or discussion in this matter.

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

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- During a USP <797> compliance inspection conducted on 11/03/2023, Investigators observed that the licensee had extensive contamination and insanitary issues.
- The following deficiencies were observed and addressed in a POC response submitted on 11/27/2023: a. Spider with web observed in buffer room;

b. Edgegard HEPA-filtered primary engineering control (PEC) with broken light cover in ISO 5 space and rust observed in multiple spots on exterior of this PEC;

c. Wall behind PEC damaged, not smooth;

d. Routine EM results performed in the last few months are not readily retrievable during the inspection;

e. Rust transferred to floor from Buffer Room table legs;

f. Chair in PEC - observed underside of adjustable chair with contamination transfer to wipe, chipped paint and rust underneath; and,

g. Dust transferred to wipe from Germfree compounding aseptic containment isolator (CACI) castor.

- On 11/03/2023, Pharmacist Peirce indicated that the Pharmacy would voluntarily suspend all sterile compounding and provided a copy of their adverse event surveillance policy.
- The continuity of care plan included sending patients in need of sterile compounding products to Johnson Compounding and Wellness.
- MOR Barnes responded to the complaint indicating that she became MOR approximately one month prior to the inspection and focused her attention on administrative issues noting that although she had not personally visited the sterile lab, that she had reviewed past BORP inspections which revealed no negative results.
- The Pharmacy resumed compounding on 01/15/2024 after addressing additional deficiencies observed during subsequent follow up site visits conducted on 12/13/2023 and 01/12/2024.

<u>ACTION</u>: Motion by S. AHMED, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2024-0001), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #8/CASE-2023-0873		
PHA-2024-0005	Rite Aid #10205, DS2573	Time: 09:57 AM

RECUSAL: NONE

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

- RLCS- #150 Oxycodone 10mg tablets attributed to an unknown loss discovered on 11/11/2023.
- Regional Pharmacy Leader (RPL) Chelsea Guyette responded that MOR Butler (Gray) is no longer with the company and that the Pharmacy permanently closed on 01/24/2024. During the closure, they located the missing medication and withdrew the initial DEA 106 form on 01/24/2024.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by S. DINNO, and voted unanimously by those present, with the exception of D. BARNES who abstained, to DISMISS the matter (PHA-2024-0005), No Violation.

Case #9/CASE-2023-0791 PHA-2023-0270 Rite Aid #10209, DS2899

Time: 09:59 AM

RECUSAL: NONE

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

- The licensee provided an initial report of a Reported Loss of Controlled Substances to BORP on 11/6/2023 but failed to provide the finalized loss documents to the BORP within 21 calendar days of the initial submission.
- The Pharmacy submitted an untimely final RLCS report for an unknown loss of #72 lorazepam 0.5mg tablets on or about 11/04/2023.
- On the morning of 11/04/2023, Pharmacy Intern Jacob Dasilva notified the MOR that it appeared the inventory was short 60 tablets of the lorazepam 0.5mg tablets. So, he checked the on-hand counts versus the computer system's count and that it was short 60 tablets.
- MOR noted that there were discrete counts completed, dispensing history drug reports completed, and additional counts completed.
- MOR Weisburgh indicated that moving forward, all cases will be completed from start to finish in 21 days.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0270) 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-2024-1218 PHA-2024-0061

Chicopee Pharmacy, DS90423

Time: 10:01 AM

### RECUSAL: NONE

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

- On 03/01/2024, Chicopee Pharmacy was cited for inspectional deficiencies related to refrigeration.
- Manual temperature logs documented that most daily temperatures were outside of range from 01/01/2024-03/01/2024. Electronic temperature readings were not retrievable after 01/18/2024. A copy of the electronic log showed that refrigeration temperatures were out of range on multiple days, with the lowest temperature recorded as 31.1 degrees Fahrenheit and average temperature as 34.6 degrees Fahrenheit.
- MOR Shenouda returned all refrigerated medications to McKesson and Inmar. He also set his digital logger to the appropriate range of 36- and 46-degrees Fahrenheit. He signed a 3-year contract with Primex, Inc for monitoring of refrigerator and freezer temperatures 24/7.
- MOR Shenouda attested to reviewing all policies and procedures for appropriate refrigerated medication and vaccine storage.
- On 04/22/2024, MOR Shenouda emailed that he intended to sell the Pharmacy.

<u>ACTION</u>: Motion by B. BARNES, seconded by C. BELISLE, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0061), No Discipline Warranted, Remediation Complete.

Case #11/CASE-2023-0782 INV8911

Stop & Shop #782, DS2299

Time: 10:04 AM

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<u>RECUSAL</u>: K. THORNELL recused and was not present during the vote or discussion in this matter.

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

- On November 16, 2023, S&S 782 submitted a final report of a loss of 126 eszopiclone 2mg tablets. According to the final report, a possible loss of 126 eszopiclone 2mg on was discovered on November 2, 2023. An internal investigation revealed that "two stock bottles containing a total of #126 tablets were inadvertently discarded during a dispensing that occurred on 10/3/2023." Of note, the stock bottles inadvertently discarded were distributed by the manufacturer as 100 tablets stock bottles. Of note, the loss was attributed to clutter in the product dispensing workplace which did not comply with S&S 782 policies to maintain "a clean and orderly workspace."
- Surveillance video was provided which staff at S&S 782 used to confirm the inadvertent discard of two bottles of drug into a recycle bin on October 3, 2023. Staff then monitored over the next two days to ensure the discard was not a ruse. Ultimately, the recycle bin was removed from the pharmacy and disposed of per usual course of business on October 5, 2023. Thus, staff determined that no diversion occurred.
- CA: The following were emphasized: "The importance of an organized workspace, maintaining accurate controlled substance inventories, proper handling/storage of controlled substances. reporting any controlled substance discrepancies in a timely manner as well as full compliance with Stop and Shop controlled substance polices and state laws and rules."

<u>ACTION</u>: Motion by C. BELISLE, seconded by S. HAMILTON, and voted unanimously by those present, to ELEVATE the matter (INV8911), to a complaint.

Case #12/CASE-2023-0420 PHA-2024-0034 Pharmscript of MA, LLC, DS90251 Time: 10:07 AM

RECUSAL: NONE

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

- On 08-22-2023, Pharmscript reported AAL results after three colony forming units of bacteria grown from surface sampling performed on August 4, 2024 from a cart in the ISO 8 anteroom were found to contain staphylococcus and gram-negative rods which were deemed highly pathogenic under USP <797> (ver. 2008).
- Significantly, MOR Adjei attested in the report that "all ISO classified spaces shall have repeat environmental sampling results within action levels prior to resuming the facility's standard sterile compounding activities" as required by policy in effect at the time.
- However, Investigators Seed and Allen discovered that the pharmacy only performed repeat surface sampling of the affected cart during a sterile compounding inception on October 3, 2023. Accordingly, a POC was issued based in part on the failure to properly remediate AAL results.
- POC: MOR Adjei indicated that air and surface sampling was scheduled to be completed by a thirdparty vendor on October 31, 2023. MOR Adjei added that repeat air and surface sampling would be performed in response to above action level results going forward.

• CA: MOR Adjei indicated that that repeat environmental monitoring of all air and surface sample sites in the affected ISO classified space was performed on 10-31-2023 with no AAL results. In addition, all IV personnel were retrained on proper response to and remediation of AAL results including repeat EM of all sample sites in the affected ISO classified space. MOR and Corporate would perform a review of all state regulations for sterile compounding and SOPs would be updated as needed. Of note, Pharmscript was provided a copy of current policy for AAL results: BORP Policy 2023-09 Action Level Environmental Monitoring Results (rev. 12-07-2023).

<u>ACTION</u>: Motion by R. MORELLI, seconded by S. DINNO, and voted unanimously by those present, to refer the matter (PHA-2024-0034), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

		Case
#13/CASE-2023-0871		
PHA-2024-0008	SCA Pharmaceutical, NO00045	Time: 10:11 AM

<u>RECUSAL</u>: C. BELISLE recused and was not present for the vote or discussion in this matter.

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

- On 11-30-2023, NABP notified BORP that SCA underwent an FDA inspection which resulted in the issuance of an FDA-483. In addition, NABP reported that SCA filed a complaint in the USDC requesting emergency injunctive relief in response to a recall request by FDA of all sterile products within expiry. Of note, the matter in USDC remained open as of 04-22-2024.
- Upon review, FDA issued SCA an FDA-483 listing 10 observations of objectionable conditions after an inspection between 09-18-2023 to 10-20-2023. SCA responded with a plan of correction in accordance with SOP after issuance of an FDA-483. However, FDA had not closed-out the inspection as of 04-22-2024.
- SCA responded to BORP's complaint with a request for dismissal because the FDA-483 was being challenged in USDC.
- SCA indicated that procedures were being updated to include notification to BORP of any FDA inspections and issuances of an FDA-483 as corrective action to mitigate recurrence of a similar incident.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2024-0008), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #14/CASE-2024-1010 PHA-2024-0049 CVS #10596, DS90262

Time: 10:14 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter.

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

- 02/8/2024, Investigator Seed observed during an RCI that an unlicensed staff member, Leena Patel, was "placing prescription stock bottles onto the pharmacy shelves." He notified MOR Bruzho and Ms. Patel that "since [Ms. Patel] is not licensed, she can only perform cashier duties. She must not be asked to put the order away or perform any other PT/PTT functions."
- Later, Investigator Seed discovered that PTT Joana Velez's license expired on 12/22/2023 when she entered the pharmacy for her shift. PTT Velez admitted that she continued to perform PTT duties as needed at CVS 10596 after her license expired.
- Significantly, Investigator Seed notified MOR Bruzho and PTT Velez that PTT Velez was permitted to "only perform cashier duties until she receives an extension on her PTT or her PT is issued." However, MOR Bruzho then proceeded to instruct PTT Velez "to put the order on the shelves, which she started to do" after Investigator Seed's notification.
- Investigator Seed intervened and PTT Velez ceased the activity. Investigator Seed then provided instructions to PTT Velez to request an extension of expiration from BORP for her PTT license. In turn, PTT Velez was granted an extension during the inspection to 05/08/2024.
- Ms. Patel ceased performing duties requiring BORP licensure. PTT Velez requested an extension of expiration for her PTT license and was granted an extension to 05/08/2024. She later applied for and was granted licensure as a pharmacy technician. MOR Bruzho pledged that "MOR to monitor and keep track of license renewals and consistently inform technicians of their duties if there is any license expiration in order to maintain compliance" going forward. Lastly, Senior Analyst Furtado pledged that "All licenses going forward will be monitored to ensure they are current/valid."

<u>ACTION</u>: Motion by D. BARNES, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2024-0049), 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-2024-1010		
PHA-2024-0050	Evis Bruzho, PH238501	Time: 10:18 AM

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

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

- 02/8/2024, Investigator Seed observed during an RCI that an unlicensed staff member, Leena Patel, was "placing prescription stock bottles onto the pharmacy shelves." He notified MOR Bruzho and Ms. Patel that "since [Ms. Patel] is not licensed, she can only perform cashier duties. She must not be asked to put the order away or perform any other PT/PTT functions."
- Later, Investigator Seed discovered that PTT Joana Velez's license expired on 12/22/2023 when she entered the pharmacy for her shift. PTT Velez admitted that she continued to perform PTT duties as needed at CVS 10596 after her license expired.
- Significantly, Investigator Seed notified MOR Bruzho and PTT Velez that PTT Velez was permitted to "only perform cashier duties until she receives an extension on her PTT, or her PT is issued." However, MOR Bruzho then proceeded to instruct PTT Velez "to put the order on the shelves, which she started to do" after Investigator Seed's notification.
- Investigator Seed intervened, and PTT Velez ceased the activity. Investigator Seed then provided instructions to PTT Velez to request an extension of expiration from BORP for her PTT license. In turn, PTT Velez was granted an extension during the inspection to 05/08/2024.

• Ms. Patel ceased performing duties requiring BORP licensure. PTT Velez requested an extension of expiration for her PTT license and was granted an extension to 05/08/2024. She later applied for and was granted licensure as a pharmacy technician. MOR Bruzho pledged that "MOR to monitor and keep track of license renewals and consistently inform technicians of their duties if there is any license expiration in order to maintain compliance" going forward. Lastly, Senior Analyst Furtado pledged that "All licenses going forward will be monitored to ensure they are current/valid."

<u>ACTION</u>: Motion by S. AHMED, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2024-0050), 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 #16/CASE-2024-0944 PHA-2024-0042 CVS #2500, DS3606

Time: 10:19 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter.

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

- ID on 1/18/24 for storage of needles/syringes in an unsecured immunization room with companion complaints for allowing PT Pham to administer vaccines as a PTT.
- MOR Dumond acknowledged the cited deficiency. Pharmacist Nguyen thought needles/syringes could be stored in the immunization room as long as it was locked. PT Pham was identified as an immunizer and was unaware of the storage requirements. PT Pham was issued a PTT license on 1/24/23 (expired 1/31/24) and a PT license on 2/1/24. Her immunization certification was completed on 9/12/23.
- CVS ROPP-0051 Retail Pharmacy Administered Immunizations Program states "…Once vaccine administration is complete, the immunizer should return to the pharmacy with all administration and emergency safety supplies, including the Sharps container, unless more patients are awaiting a vaccine". It also states, "Pharmacy Interns and Pharmacy Technicians are encouraged to participate by assisting with and providing immunization services (where allowed by state regulations)".
- MOR Dumond related PT Pham was hired in March 2023 with the plan for her to be an immunizer. Although she completed the requirements for a PT license, it was not issued before she completed the immunization training. Pharmacist Nguyen's and PT Pham's responses corresponded to MOR Dumond's. After submitting the application, they failed to ensure the PT license was issued. PT Pham administered 562 vaccines from 8/16/23-12/28/23 including 4 vaccines prior to issuance of her immunization certification on 9/12/23.
- All needles/syringes were removed from the immunization room and placed in a dedicated vaccine preparation area and all immunizing staff are aware. MOR Dumond and Pharmacist Nguyen will ensure that PT licensure is obtained prior to immunization certification. MOR Dumond, Pharmacist Nguyen, and PT Pham reviewed BORP/DCP Joint Policy 2023-02 Vaccine Administration, BORP Policy 2020-15: Scope of Practice PT section, and CVS ROPP-051 Retail Pharmacy Administered Immunizations in its entirety.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by R. MORELLI and voted unanimously by those present, to refer the matter (PHA-2024-0042), 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-2024-0944 PHA-2024-0065 Jeffrey Dun

Jeffrey Dumond, PH239205

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

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

- ID on 1/18/24 for storage of needles/syringes in an unsecured immunization room with companion complaints for allowing PT Pham to administer vaccines as a PTT.
- MOR Dumond acknowledged the cited deficiency. Pharmacist Nguyen thought needles/syringes could be stored in the immunization room as long as it was locked. PT Pham was identified as an immunizer and was unaware of the storage requirements. PT Pham was issued a PTT license on 1/24/23 (expired 1/31/24) and a PT license on 2/1/24. Her immunization certification was completed on 9/12/23.
- CVS ROPP-0051 Retail Pharmacy Administered Immunizations Program states "…Once vaccine administration is complete, the immunizer should return to the pharmacy with all administration and emergency safety supplies, including the Sharps container, unless more patients are awaiting a vaccine". It also states, "Pharmacy Interns and Pharmacy Technicians are encouraged to participate by assisting with and providing immunization services (where allowed by state regulations)".
- MOR Dumond related PT Pham was hired in March 2023 with the plan for her to be an immunizer. Although she completed the requirements for a PT license, it was not issued before she completed the immunization training. Pharmacist Nguyen's and PT Pham's responses corresponded to MOR Dumond's. After submitting the application, they failed to ensure the PT license was issued. PT Pham administered 562 vaccines from 8/16/23-12/28/23 including 4 vaccines prior to issuance of her immunization certification on 9/12/23.
- All needles/syringes were removed from the immunization room and placed in a dedicated vaccine preparation area and all immunizing staff are aware. MOR Dumond and Pharmacist Nguyen will ensure that PT licensure is obtained prior to immunization certification. MOR Dumond, Pharmacist Nguyen, and PT Pham reviewed BORP/DCP Joint Policy 2023-02 Vaccine Administration, BORP Policy 2020-15: Scope of Practice PT section, and CVS ROPP-051 Retail Pharmacy Administered Immunizations in its entirety.

<u>ACTION</u>: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2024-0065), 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 #18/CASE-2024-0944		
PHA-2024-0066	Myle Nguyen, PH241380	Time: 10:25 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter.

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

- ID on 1/18/24 for storage of needles/syringes in an unsecured immunization room with companion complaints for allowing PT Pham to administer vaccines as a PTT.
- MOR Dumond acknowledged the cited deficiency. Pharmacist Nguyen thought needles/syringes could be stored in the immunization room as long as it was locked. PT Pham was identified as an immunizer

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and was unaware of the storage requirements. PT Pham was issued a PTT license on 1/24/23 (expired 1/31/24) and a PT license on 2/1/24. Her immunization certification was completed on 9/12/23.

- CVS ROPP-0051 Retail Pharmacy Administered Immunizations Program states "...Once vaccine administration is complete, the immunizer should return to the pharmacy with all administration and emergency safety supplies, including the Sharps container, unless more patients are awaiting a vaccine". It also states, "Pharmacy Interns and Pharmacy Technicians are encouraged to participate by assisting with and providing immunization services (where allowed by state regulations)".
- MOR Dumond related PT Pham was hired in March 2023 with the plan for her to be an immunizer. Although she completed the requirements for a PT license, it was not issued before she completed the immunization training. Pharmacist Nguyen's and PT Pham's responses corresponded to MOR Dumond's. After submitting the application, they failed to ensure the PT license was issued. PT Pham administered 562 vaccines from 8/16/23-12/28/23 including 4 vaccines prior to issuance of her immunization certification on 9/12/23.
- All needles/syringes were removed from the immunization room and placed in a dedicated vaccine preparation area and all immunizing staff are aware. MOR Dumond and Pharmacist Nguyen will ensure that PT licensure is obtained prior to immunization certification. MOR Dumond, Pharmacist Nguyen, and PT Pham reviewed BORP/DCP Joint Policy 2023-02 Vaccine Administration, BORP Policy 2020-15: Scope of Practice PT section, and CVS ROPP-051 Retail Pharmacy Administered Immunizations in its entirety.

<u>ACTION</u>: Motion by R. MORELLI, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2024-0066), 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-2024-0944
 Theresa Pham, PTT100904
 Time: 10:26 AM

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

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

- ID on 1/18/24 for storage of needles/syringes in an unsecured immunization room with companion complaints for allowing PT Pham to administer vaccines as a PTT.
- MOR Dumond acknowledged the cited deficiency. Pharmacist Nguyen thought needles/syringes could be stored in the immunization room as long as it was locked. PT Pham was identified as an immunizer and was unaware of the storage requirements. PT Pham was issued a PTT license on 1/24/23 (expired 1/31/24) and a PT license on 2/1/24. Her immunization certification was completed on 9/12/23.
- CVS ROPP-0051 Retail Pharmacy Administered Immunizations Program states "...Once vaccine administration is complete, the immunizer should return to the pharmacy with all administration and emergency safety supplies, including the Sharps container, unless more patients are awaiting a vaccine". It also states, "Pharmacy Interns and Pharmacy Technicians are encouraged to participate by assisting with and providing immunization services (where allowed by state regulations)".
- MOR Dumond related PT Pham was hired in March 2023 with the plan for her to be an immunizer. Although she completed the requirements for a PT license, it was not issued before she completed the immunization training. Pharmacist Nguyen's and PT Pham's responses corresponded to MOR Dumond's. After submitting the application, they failed to ensure the PT license was issued. PT Pham

administered 562 vaccines from 8/16/23-12/28/23 including 4 vaccines prior to issuance of her immunization certification on 9/12/23.

 All needles/syringes were removed from the immunization room and placed in a dedicated vaccine preparation area and all immunizing staff are aware. MOR Dumond and Pharmacist Nguyen will ensure that PT licensure is obtained prior to immunization certification. MOR Dumond, Pharmacist Nguyen, and PT Pham reviewed BORP/DCP Joint Policy 2023-02 Vaccine Administration, BORP Policy 2020-15: Scope of Practice PT section, and CVS ROPP-051 Retail Pharmacy Administered Immunizations in its entirety.

<u>ACTION</u>: Motion by C. BELISLE, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2024-0067), 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 #20/CASE-2024-0990		
PHA-2024-0045	CVS #8437, DS3549	Time: 10:27 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter.

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

- Repeat deficiency on 1/24/24 for expired medications in the ScriptPro (5 expired in 2022 and 7 expired in 2023). The POC indicated all expired medications were removed and processed for return.
- Sr. Analyst Furtado related that none of the expired medications were dispensed. MOR Samson was not MOR when the previous inspection was conducted. MOR Samson stated, "At the time our process for removing expired medications consisted of removing medications only when receiving notifications that a prescription could not be filled because the specific NDC was expired. Since the majority of the NDCs listed where [sic] non-preferred medications and not assigned as ScriptPro drugs in RxConnect, we did not receive these error messages". As soon as he was notified during the inspection, the expired medications were removed.
- Pharmacist O'Donnell and Pharmacist Do followed the procedure of removing expired medications when receiving notification that a prescription could not be filled because the specific NDC was expired. At the time, the expired medications were not addressed because they weren't used to fill prescriptions.
- MOR Samson implemented a process to review the medications in the ScriptPro monthly and remove any medication expiring in the next 3 months to prevent future issues. Pharmacist O'Donnell and Pharmacist Do indicate they will be following this new process. MOR Samson, Pharmacist O'Donnell, and Pharmacist Do confirmed review of all policies and procedures for the removal of expired CII-CVI medications from active inventory.

<u>ACTION</u>: Motion by J. LOPEZ, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2024-0045), 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 #21/CASE-2024-1241		
INV10124	CVS #17529, DS89992	Tir

Time: 10:30 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter.

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

- Refusal to fill a veterinary prescription for Freestyle Libre without the prescriber's DEA number. CPhT Melendez alleged stated it was against CVS policy and state/federal laws to fill it without the DEA number. The prescription was subsequently called into CVS #1056 where it was filled.
- CPhT Melendez accepted the prescription from the veterinary assistant and asked for Dr. Llorens' DEA or NPI number but the assistant refused to provide it. Pharmacist Tailor clarified that only the MCSR number was needed but she wouldn't provide that either. CPhT Melendez claimed she answered a second call from the office with both the assistant and Dr. Llorens on the line shouting in angry tones. Dr. Llorens asked her to look her up in the system. CPhT Melendez related, "I stated that I am unable to search for her in our system...", apologized and told her she was unable to fill the prescription because she couldn't validate it.
- Pharmacist Tailor also stated, "I apologized to the agent that I would not be able to fill the order without all the elements and I have not been able to validate the prescription".
- MOR Sunak was informed of the incident the following day. She explained to CPhT it is not required to obtain a DEA number to fill a prescription for a non-controlled medication.
- DL Betancourt reviewed the requirements for veterinary prescriptions with all staff in her district. MOR Sunak discussed the incident in depth with CPhT Melendez as a learning experience for her.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by S. DINNO, and voted unanimously by those present, to CLOSE the matter (INV10124), Insufficient Evidence.

Case #22/CASE-2023-0829		
PHA-2024-0002	CVS #507, DS89841	Time: 10:34 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter.

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

- A loss of #681 alprazolam 2mg, #340 alprazolam 1mg, #260 alprazolam 2mg, #432 alprazolam 1mg, #294 alprazolam 1mg, and #30 alprazolam 1mg tablets attributed to an unknown loss. The date investigation concluded was documented as 11/28/2023.
- Former MOR Hsu indicated that the losses of alprazolam 1mg and alprazolam 2mg tablets were discovered via corporate controlled substance monitoring on 11/02/2023.
- In the response, MOR Amin indicated that when he first started as MOR, the Pharmacy was severely under-staffed and he had no additional time to complete secondary tasks like cycle counts, return to stocks, and other tasks.
- MOR Amin completed daily loss prevention initiated (LPI) counts.
- According to the Loss Prevention (LP) group, a review of video footage did not show any suspicious activity. The LP group later reported not finding any additional quantity losses. Between 09/10/2023 and 11/24/2023, there were no active losses and the decision was made to close the case.
- MOR Hsu indicated that all Loss Prevention policy and procedures have been reviewed with the Pharmacy Team to prevent future losses. This includes diligent inventory management, and bag/smock checks.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2024-0002), to the Office of Prosecution for the issuance of an order to show

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Draft Minutes General Session: 6/6/24 BOP Approved: 8/1/24 cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 1 year, with special terms to include the Controlled Substance Loss Protocol for all Benzodiazepines.

Case #23/CASE-2023-0616 PHA-2024-0078

Nancy Edwards, PH238675

Time: 10:40 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was not present for the vote or discussion in this matter.

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

- At the 04/04/2024 board meeting, this case was voted to be elevated to a complaint.
- On or about 10/12/2023, the doctor prescribed prednisolone 5mg for the feline but was dispensed prednisone 5mg tablets instead.
- MOR Hom indicated that Pharmacist Edwards took a verbal order for prednisolone and indicated that it was not available in stock. She allegedly got the approval to change the script from prednisolone to prednisone after explaining to the caller that prednisone converts to prednisolone in the body. The next day, the vet called back indicating that the prescription was incorrect and that cats cannot metabolize prednisone like humans.
- Pharmacist Edwards failed to document the error or inform the MOR.
- The pharmacy did order the medication and corrected the prescription but due to price, the complainant decided to order the medication through an online vendor.
- Pharmacist Edwards submitted a signed attestation that she reviewed 247 CMR 15: Continuous Quality Improvement (CQI) Program and completed 2 CEs in patient safety.
- At the 04/04/2024 Board Meeting, it was voted to open a complaint against Pharmacist Edwards.
- Pharmacist Edwards responded that the veterinarian notified her of the mistake. She immediately acknowledged her responsibility for the error and explained that she thought changing the verbal order from prednisolone to prednisone to be okay. The veterinarian explained that cats cannot metabolize prednisone effectively, hence the need for prednisolone.
- She noted that the root cause of this error lies in her assumption that prednisone and prednisolone were equivalent. She noted that she should have exercised greater caution and sought clarification when the verbal order specified prednisolone instead of prednisone.
- Going forward, she noted that when receiving verbal orders, she will ask clarifying questions whenever there is any uncertainty, particularly when dealing with veterinary medications. She will thoroughly review and document all verbal orders to ensure accuracy and prevent misunderstandings and remain vigilant in ensuring the correct dispensing of medications to maintain patient safety and prevent future errors.

<u>ACTION</u>: Motion by J. LOPEZ, seconded by R. MORELLI, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0078), No Discipline Warranted, Remediation Complete.

Case #24/CASE-2024-0009 PHA-2024-0020 CVS #2476, DS2904 Time:10:44 AM

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

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

• Loss of #413 lorazepam 0.5mg tablets on or about 11/29/2023 due to an unknown loss

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Draft Minutes General Session: 6/6/24 BOP Approved: 8/1/24  In response to the loss, the Drug Loss Associate Manager indicated that the DEA 106 form submitted on 12/19/2024 has been withdrawn. After further investigation, the medication was found in the Pharmacy resulting in no loss.

ACTION: Motion by R. LOPEZ, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0020), No Violation.

Case #25/CASE-2024-1221		
PHA-2024-0060	CVS #2592, DS3011	Time: 10:45 AM

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

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

- On 02/20/2024, the Pharmacy submitted the final report of an unknown loss of #310 lorazepam 0.5 mg.
- MOR stated that the reason for the loss may possibly include inaccurate counts by the Kirby Lester, double counts not being performed, and lorazepam bottles falling into the trash.
- Corrective action included double counting by hand only, reviewing of all policies and procedures with staff, and moving lorazepam closer to the pharmacist station.

ACTION: Motion by R. LOPEZ, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2024-0060), 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 Controlled Substance Loss Protocol for all Benzodiazepines.

**Topic VIII:** 

**Executive Session Call to Order:** 

Time: 10:48 AM

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

Action: Motion by J. LOPEZ, seconded by M. SCIARAFFA, voted unanimously by roll call to enter executive session #1. Roll call attendance:

**Topic IX:** 65C Sessions MGL c. 112 section 65C Time: 11:23 AM

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

Action: At 9:45 A.M. J Lopez, seconded by D. Barnes and voted unanimously by all those present to enter 65C by roll call vote.

**Topic X:** 

Adjudicatory Session (M.G.L. ch. 30A, §18) Time: 4:13 PM

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By: President K. Thornell request a motion to enter Adjudicatory session.

Action: At 4:13 PM, J Lopez, seconded by D. Barnes and voted unanimously by all those present to enter Adjudicatory by roll call vote.

#### **Topic XI:**

#### ADJOURMENT OF MEETING

TIME: 4:31 PM

Action: Motion by C. Belisle seconded by J. Lopez and voted unanimously by all those present to adjourn the meeting by roll call vote.

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

- 1. Draft Agenda of the 6/6/2024 General Session
- 2. Draft Minutes of the 5/2/2024 Meeting
- 3. Report on Applications approved pursuant to Licensure Policy 13-01
- 4. Report on Board Delegated Complaint Review to licensure policy 14-02
- 5. Report on PSUD 17-03
- 6. Health Care Pharmacy- New Pharmacy Application
- 7. Nimvax-Renovation Application
- 8. PHA-2024-0035 Vital Care of Hopkinton, DS90415
- 9. PHA-2024-0051 Compare Quality Pharmacy, DS89874
- 10. PHA-2024-0052 Sreenivas Athuluri, PH26974
- 11. PHA-2024-0056 Birds Hill Pharmacy, DS90094
- 12. PHA-2024-0037 Walmart 10-2904, DS2977
- 13. PHA-2024-0063 Paul R Casale, PT23845
- 14. PHA-2024-0001 Sullivans Healthcare, DS3335
- 15. PHA-2024-0005 Rite Aid #10205, DS2573
- 16. PHA-2023-0270 Rite Aid #10209, DS2899
- 17. PHA-2024-0061 Chicopee Pharmacy, DS90423
- 18. INV8911
   Stop & Shop #782, DS2299
- 19. PHA-2024-0034 Pharmscript of MA, LLC, DS90251
- 20. PHA-2024-0008 SCA Pharmaceutical, NO00045
- 21. PHA-2024-0049 CVS #10596, DS90262
- 22. PHA-2024-0050 Evis Bruzho, PH238501
- 23. PHA-2024-0042 CVS #2500, DS3606
- 24. PHA-2024-0065 Jeffrey Dumond, PH239205
- 25. PHA-2024-0066 Myle Nguyen, PH241380
- 26. PHA-2024-0067 Theresa Pham, PTT100904
- 27. PHA-2024-0045 CVS #8437, DS3549
- 28. INV10124 CVS #17529, DS89992
- 29. PHA-2024-0002 CVS #507, DS89841
- 30. PHA-2024-0078 Nancy Edwards, PH238675
- 31. PHA-2024-0020 CVS #2476, DS2904
- 32. PHA-2024-0060 CVS #2592, DS3011

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