COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

NOTICE OF THE REGULARLY SCHEDULED MEETING OF THE BOARD OF REGISTRATION IN PHARMACY April 4, 2024

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

Join link:

https://eohhs.webex.com/eohhs/j.php?MTID=m75d3bfb413d069f531e23fb3e1e7ae75

Webinar number: 2537 378 1431

Webinar password:

BOP123 (267124 from phones and video systems)

Join by phone:

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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	Ш	 APPROVAL OF BOARD MINUTES Draft of March 7, 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 Research Drug Study report pursuant to Staff Action Policy 18-02 		
8:15	V	 FLEX Board Policy 2022-01: Loss or Theft of Controlled Substance ○ Reporting will be via ELX platform Letter on Implantable Infusion Pumps 		
8:20	VI	REGULATION •247 CMR 2.00: Definitions and Severability		M. Chan

8:30	VII		LICATIONS Meraki Pharmacy- New	Community Pharmacy	
		FILE REVIEW			
		1	CASE-2023-0742	PHA-2023-0259	Rite Aid #10209, DS2899
		2	CAS-2023-0113	PHA-2023-0221	Shifa Ali, PH239619
		3	CASE-2023-0658	PHA-2023-0239	Optum Infusion Services, DS90100
		4	CASE-2023-0740	PHA-2023-0262	Soleo Health, DS89958
		5	CASE-2023-0740	PHA-2023-0263	Kimmi Cheung, PH238352
		6	CASE-2024-0128	PHA-2024-0023	Walgreens #2564, DS1925
		7	CASE-2023-0826	PHA-2023-0274	West Concord Pharmacy, DS3607
		8	CASE-2023-0783	PHA-2023-0269	Stop & Shop #784, DS2132
		9	CASE-2023-0508	PHA-2023-0231	Blue Hill Pharmacy, DS89942
		10	CASE-2023-0508	PHA-2024-0026	Victoria Okeke, PH25059
00	VIII	11	CASE-2023-0763	PHA-2023-0266	Walgreens #10209, DS3529
		12	CASE-2023-0738	PHA-2023-0260	CVS #505, DS89977
		13	CAS-2023-1132	PHA-2024-0016	Laura DeSimone, PT5232
		14	CASE-2023-0540	PHA-2024-0010	Gregory Rodrigues, PH23347
		15	CASE-2023-0620	PHA-2023-0219	CVS #2339, DS2877
		16	CASE-2023-0594	PHA-2023-0256	CVS #166, DS3449
		17	CASE-2023-0677	PHA-2023-0251	CVS #1007, DS90074
		18	CAS-2023-0898	PHA-2023-0271	Gabriel Rusanescu, PH239940
		19	CASE-2023-0675	PHA-2023-0250	CVS #635, DS2871
		20	CAS-2021-0591	PHA-2023-0272	Xia Li, PH233540
		21	CASE-2023-0618	PHA-2023-0217	CVS #719, DS1906
		22	CASE-2023-0616	INV8553	CVS #119, DS89835
		23	CASE-2023-0686	PHA-2023-0246	Coram CVS/ Specialty Infusion Services, DS3601

10:30	IX	RECONSIDERATION • Compare Quality Pharmacy, DS89874, PHA-2019-0043	J. Petrillo
10:45	X	REVIEW OF A PREVIOUS DECISION • CVS #2878, DS3092, PHA-2023-0144 / CAS-2023-0843 – heard February 1, 2024, for loss of controlled substances.	
11:00	XI	EXECUTIVE SESSION The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition, or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, evaluate the Good Moral Character as required for registration for a pending applicant.	
11:30		LUNCH BREAK	
12:00	XII	M.G.L. c. 112, § 65C SESSION	
4:00	XIII	ADJOURNMENT	

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting April 4, 2024

Board Members Present

Board Members Not 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
Dawn Perry, JD
Mark Sciaraffa, CPhT Leaves at
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
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
Keith Johnstone, Compliance Officer

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: 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; D. Perry, yes; K. Thornell, yes; J. Dorgan, yes; S. Dinno, yes.

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Topic II. Approval of Agenda TIME 8:02 AM

Agenda: 4/4/24

DISCUSSION: No changes.

ACTION:

Motion by S. Hamilton seconded by R. Lopez and voted unanimously by those present to approve the agenda by roll call vote.

Topic III Approval of Board Minutes TIME: 8:03 AM

Minutes

1. Draft 3/7/24

Change: Correct last name; Saad Dinno

Action:

Motion by D. Barnes seconded S. Hamilton and voted unanimously to approve the regular session minutes of 3/7/2024 with the noted change by roll call vote. J. Rocchio, R. Morelli and D. Perry recused.

Topic IV. REPORTS

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: M. BOTTO

<u>DISCUSSION</u>: M. Botto reported a total of 31 Change in MOR applications and 1 facility closure that have been approved via Staff Action since the February 1st Board meeting.

TIME: 8:03 AM

TIME: 8:04 AM

So noted.

Topic IV. REPORTS

Monthly Report from Probation TIME: 8:03 AM

PRESENTED BY: M. BOTTO

<u>DISCUSSION:</u> M. Botto reported 1 licensee that was given the opportunity to cure, and 2 licensees that were issued final notice by Board counsel since the last Board meeting. Currently, there are a total of 25 active probation monitoring cases.

So noted.

Topic IV. REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

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PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto indicated a total of 8 CE deficiencies during BDCR, all closed with discipline not

warranted.

So noted.

Topic IV. REPORTS

PSUD report by Staff Action 17-03

PRESENTED BY: M. BOTTO

<u>DISCUSSION:</u> M. Botto indicated no new changes to the PSUD program since the last Board meeting.

TIME: 8:04 AM

Currently, there are a total of 8 active participants enrolled in the program.

So noted.

Topic IV. REPORTS

Research Drug Study report pursuant to Staff Action Policy 18-02 TIME: 8:04 AM

PRESENTED BY: M. CHAN

<u>DISCUSSION:</u> M. Chan reported on a total of 3 retail pharmacies participating in research studies. Currently, there are 16 active studies, 5 of which involve investigational drug substances. 2 new studies have been approved since the last report.

So noted.

Topic V. FLEX TIME: 8:05 AM

Board Policy 2022-01: Loss or Theft of Controlled Substance - Reporting will be via ELX platform

PRESENTED BY: Joanne Trifone

<u>DISCUSSION</u>: JOANNE TRIFONE notified BORP, BOPR licensees, and the public that the process for reporting the loss or theft of controlled substances will change from the current fillable PDF submitted to BORP by email to an electronic platform on the Massachusetts Health Professions Licensing System. The change is anticipated to go in effect on May 1, 2024. TRIFONE emphasized that BORP Policy 2022-01: Loss or Theft of Controlled Substances will not change only the process for submitting the documents required by the policy. TRIFONE added that a notification will be sent through BORP's email distribution list when the change occurs. TRIFONE then encouraged BORP licensees to add their email address to the distribution list.

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ACTION: None

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Topic V. FLEX

Letter on Implantable Infusion Pumps

PRESENTED BY: William Frisch

<u>DISCUSSION:</u> WILLIAM FRISCH notified BORP about a letter submitted by Pentec Health regarding implantable infusion pumps. FRISCH then provided a brief overview of the history of the approval of Pentec Health's license on Jan 7, 2014. FRISCH described that the approval was contingent upon receipt of an affidavit stating that they will not compound any "unapproved" drugs or unapproved drug combinations as sterile preparations unless they obtain scientific evidence demonstrating that the preparation will remain sterile and stable for the entire time it remains in the infusion pump.

TIME: 8:06 AM

FRISCH then explained that Pentec Health uses Medtronic infusion pumps that are implanted in the body and slowly infuse CSPs from the reservoir (which is at body temperature) for up to 90 days. These CSPs may be single drugs or a combination of drugs with some that have been compounded from non-sterile ingredients. Pentec Health's formulary is currently restricted to 13 drug combinations based on either scientific literature or direct validation testing.

Frisch next explained that administration is not in the scope of the chapter according to USP <797>. However, BORP Staff requested an opinion from USP regarding at what point administration occurs. He provided an example as follows: Is administration defined as infusion into the patient's bloodstream or instilling into an internal reservoir? He stressed that the issue was not simple and clarification by USP was integral to determine if it is the pharmacy's responsibility to ensure that the assigned beyond use date encompasses the time in the pump. However, USP had not responded to the inquiry, yet.

FRISCH then described that Pentec requested to be released from the requirement to obtain scientific evidence for each compounded sterile preparation. FRISCH then recommended on behalf of BORP Staff that BORP refer the matter to the Pharmacy Advisory Committee (PAC) to study the topic and render their opinion to report back to BORP.

SEBASTIAN HAMILTON inquired whether the current standard of practice differed from when BORP approved Pentec Health's license in 2014. FRISCH responded that the issue has not been researched yet to obtain the current standard of practice. CARYN BELISLE requested clarification on whether the issue was the sterility and stability of the drug prior to or after placement of drug in the pump's reservoir in the body. FRISCH clarified that the issue was whether the pharmacy was responsible for the sterility and stability of the drug over the 90-day infusion period after placement of the drug in the reservoir in the body.

HAMILTON inquired as to length of time for PAC to study the topic and render an opinion to report back to BORP. FRISCH estimated that PAC would require few months. FRISCH then recommended again that BORP refer the matter to PAC to study the topic and render their opinion to report back to BORP.

<u>ACTION:</u> SEBSTATIAN HAMLITON motioned to refer the issue to PAC for consideration; CARYN BELISLE seconded the motion then BOARD MEMBERS present voted unanimously by roll call to approve motion.

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TOPIC VI REGULATION

247 CMR 2.00: 247 CMR 2.00: Definitions and Severability TIME: 8:15 AM

Presented by: M. CHAN and W. FRISCH

Discussion: The Board had already approved this for administrative review and public comment, but the definitions for "Authorized Pharmacist" and "Transfer of Ownership" have since been struck. The Authorized Pharmacist definition refers to CDTM pharmacists which is already defined in 247 CMR 16.00 and a Transfer of Ownership definition is not needed since these are handled as the closing of one pharmacy and the opening of a new one.

Action: Motion by J. ROCCHIO, seconded by J. LOPEZ, and voted unanimously by roll call of those present, to approve the edits and forward the document for administrative review and approval to hold a public hearing.

VII: APPLICATIONS

Meraki Pharmacy New Community Pharmacy TIME: 8:16 AM

Represented by: Alexander Majounes

Recusal: N/A

Discussion:

I am here to request approval for a closed door pharmacy. All prescriptions will be done via delivery through the pharmacy and we will be assisting nursings homes, skilled nursing facilities, and other similar facilities.

Meraki Pharmacy is requesting 10 waivers, which are fairly typical for a closed door pharmacy and they are as follows:

- 247 CMR 9.01 (15)
 - o which is regarding limiting services to a particular population
- 247 CMR 9.01 (16)
 - o which is regarding not refusing to compound
- 247 CMR 6.01 (5) (d) (1)
 - o which is consult area with a sign
- 247 CMR 9.07 (3) (c)
 - which is the Dear patients sign
- 247 CMR 6.01 (5) (a) (4)
 - o which is the requirement balance
- 247 CMR 6.02(4)
 - o which is the requirement for sufficient variety of chemicals necessary to compound
- 247 CMR 6.01(5)(a)(5)
 - o which is the equipment for necessary to conduct the practice of pharmacy

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- 247 CMR 6.02(5)
 - which is the presence of pharmacy sign
- 247 CMR 6.02(7)
 - o which is the pharmacy sign with MOR name
- 247 CMR 6.02 (8) (a)
 - which is the posting of hours

Action: A motion by S. Hamilton to approve the application as submitted pending a successful inspection with waivers; Seconded by R. Lopez then board members present voted unanimously by roll call to approve the motion.

TOPIC XIII FILE REVIEW

Case #1/CASE-2023-0742

PHA-2023-0259 Rite Aid #10209, DS2899 Time: 08:21 AM

RECUSAL: NONE

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

- During a retail compliance inspection (ISP30259-RCCOM) conducted on 11/08/2023, a vaccine refrigerator was observed stored in unlicensed space.
- MOR Weisburgh indicated that the refrigerator was inventory from another pharmacy and that he was not aware that the consultation room was not licensed space.
- The MOR indicated that he moved the fridge into the pharmacy along with the medication.
- The staff has been made aware that medications cannot be stored in the immunization room.

<u>ACTION</u>: Motion by C.BELISLE, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0259), 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-2023-0113

PHA-2023-0221 Shifa Ali, PH239619 Time: 08:23 AM

RECUSAL: NONE

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

• During January 2023, BORP learned that Pharmacist Ali was fined \$250.00 by the Kentucky Board of Pharmacy because she failed to complete annual CE during 2020 and 2021. Upon further investigation, Pharmacist Ali was determined to be deficient a total of 25.5 contact hours of annual CE during 2020, 2021, and 2022 including 12 contact hours in live format and 6 contact hours in any format in pharmacy law.

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- Initially, BORP opened a staff-assignment investigation concerning Pharmacist Ali and requested that she remediate her CE deficiencies on a 1:1 basis. Ultimately, Pharmacist Ali failed to remediate her CE deficiencies as requested despite being granted multiple extensions to the due date for completion.
- BORP then opened a complaint against Pharmacist Ali during November 2023 and again requested that Pharmacist Ali remediate her CE deficiencies on a 1:1 basis. In turn, Pharmacist Ali was notified by certified mail and email about the investigation and request for remediation. The due date for completion of remediation was on or before December 31, 2023.
- Upon review, Pharmacist Ali completed a total of 40 contact hours of CE during 2023 including 4 contact hours in live format and 3 contact hours in pharmacy law and 0 contact hours of CE during 2024 as of January 31, 2024. Therefore, Pharmacist Ali failed to remediate 8 contact hours of CE in live format and 3 contact hours in any format in pharmacy law on a 1:1 basis as requested by BORP as of January 31, 2024.

<u>ACTION</u>: Motion by S. AHMED, seconded by S. DINNO, and voted unanimously by those present, to refer the matter (PHA-2023-0221), 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-2023-0658

PHA-2023-0239 Optum Infusion Services, DS90100 Time: 08:26 AM

RECUSAL: NONE

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

- On October 18, 2023, Investigator Allen conducted a sterile compounding inspection at Optum. During the inspection, Investigator Van Allen discovered multiple instances of insanitary condition of which the most significant involved Optum's failure to properly remediate a recurring water leak for over five months and, thus, permitted insanitary conditions to continue during that period. In addition, remedial microbiological sampling was also continually delayed due to unavailability of equipment and trained personnel during the period of the water leaks.
- Furthermore, Optum failed to report AAL results of a highly pathogenic microorganism which occurred during the period of the leaks until Investigator Van Allen apprised them of the AAL result as being reportable per Board Policy.
- POC/CA: Optum agreed to cease compounding pending completion of a renovation of the compounding facility and initiate its continuity of care plan for remaining patients requiring CSPs. Of significance, BORP's renovation process includes a requirement of a satisfactory inspection prior to recommencement of compounding. Of note, Optum's renovation application (DSRN10009) was incomplete as of April 2, 2024.

<u>ACTION</u>: Motion by J. LOPEZ, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0239), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #4

/CASE-2023-0740

PHA-2023-0262 Soleo Health, DS89958 Time: 08:30 AM

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RECUSAL: NONE

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

- On November 14, 2023, Investigators Brosnan and Seed conducted a post-renovation sterile compounding inspection at Soleo. During the inspection, Investigators Brosnan and Seed discovered multiple instances of insanitary conditions at the compounding facility involving primary and secondary engineering controls.
- Accordingly, Investigators Brosnan and Seed issued a POC for insanitary conditions. In addition, BORP requested that Soleo continue their continuity of care plan including no compounding until (1) complete remediation of all observations cited in the November 14, 2023 inspection, (2) postremediation EM within action level limits, (3) a satisfactory reinspection.
- BORP also contended that Soleo and MOR Cheung failed to properly remediate above action level results from microbiological air sampling on August 25, 2023. However, Soleo and MOR Cheung remediated as directed by BORP QA RPh Chan including continuing restricted BUD and cessation of use of affected PEC until completion of renovation as requested despite EM within action level limits.
- Soleo voluntarily agreed to continue its continuity of care plan for patients until complete remediation of all observations cited in the November 14, 2023 inspection, (2) post-remediation EM within action level limits, (3) a satisfactory reinspection.

ACTION: Motion by D. BARNES, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0262), 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-2023-0740

PHA-2023-0263 Time: 08:32 AM Kimmi Cheung, PH238352

RECUSAL: NONE

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

- On November 14, 2023, Investigators Brosnan and Seed conducted a post-renovation sterile compounding inspection at Soleo. During the inspection, Investigators Brosnan and Seed discovered multiple instances of insanitary conditions at the compounding facility involving primary and secondary engineering controls.
- Accordingly, Investigators Brosnan and Seed issued a POC for insanitary conditions. In addition, BORP requested that Soleo continue their continuity of care plan including no compounding until (1) complete remediation of all observations cited in the November 14, 2023 inspection, (2) postremediation EM within action level limits, (3) a satisfactory reinspection.
- BORP also contended that Soleo and MOR Cheung failed to properly remediate above action level results from microbiological air sampling on August 25, 2023. However, Soleo and MOR Cheung remediated as directed by BORP QA RPh Chan including continuing restricted BUD and cessation of use of affected PEC until completion of renovation as requested despite EM within action level limits.

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• Soleo voluntarily agreed to continue its continuity of care plan for patients until complete remediation of all observations cited in the November 14, 2023 inspection, (2) post-remediation EM within action level limits, (3) a satisfactory reinspection.

<u>ACTION</u>: Motion by C. BELISLE, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0263), Discipline Not Warranted, Remediation Complete.

Case #6/CASE-2024-0128

PHA-2024-0023 Walgreens #2564, DS1925 Time: 08:34 AM

RECUSAL: NONE

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

- WAG 2564 submitted an initial notification of a loss of controlled substances on December 18, 2023. No further information was provided in the initial notice of loss and a final report of loss was not submitted.
- WAG 2564 indicated that the initial notice of loss reported on December 18, 2023 involved 15 amphetamine mixed salts 20mg tablets. An internal investigation revealed that the loss was caused by an overfill of a prescription issued for a quantity of 75 tablets but dispensed with the wrong quantity of 90 tablets. The loss was confirmed with the patient who returned the 15 tablets dispensed in error. The returned tablets were immediately quarantined for destruction.
- CII handled by pharmacists only. CII would require "double or triple count the quantity to dispense first and then back-count" going forward. Error would be reviewed with staff. All possible RLCS would be properly investigated prior to submitting a report of loss. Lastly, Former MOR Dang provided copies of 247 CMR 15.00: Continuous Quality Improvement Program and BORP Policy 2022-01.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2024-0023), 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-2023-0826

PHA-2023-0274 West Concord Pharmacy, DS3607 Time: 08:36 AM

RECUSAL: S. DINNO 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.

- Investigator Lathum observed during an RCI that a PTT was working with an expired license on 12/05/2023. Investigator Lathum noted that the PTT license expired on 11/01/2023.
- This is a repeat ISP-D. The first ISP was on 01-06-2023 during which a RI licensed pharmacy intern was observed working without a MA intern license. The ISP-D resulted in the opening of a complaint (PHA-2023-0022) and BORP voted to offer a CA for reprimand during the 05/04/2023 Board Meeting to resolve the complaint.

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- West Concord Pharmacy's MOR indicated that "[the pharmacy] implemented additional internal process to ensure continued license verification process within our pharmacy" by "add[ing] another procedure to ensure continued process involving MOR, HR manager, and owner with license verification of all licensed staff." West Concord Pharmacy's owner described that the expired status of the PTT's license "'slipped through the cracks' "despite an existing policy for verification of staff licensure status.
- In addition, the owner indicated that "...to rectify this, my Human Resources Manager... has implemented another internal process check involving an Excel spreadsheet. We have attached this as well. Essentially [the HR manager], our MOR... and myself will get together routinely by comparing reports of whose license is expiring to ensure compliance with both our internal policy and with Massachusetts licensing regulations..."
- Of note, the PTT was granted an extension of the expiration of her PTT license on 12/06/2023 then obtained licensure as a pharmacy technician on 12/29/2023.

<u>ACTION</u>: Motion by J. ROCCHIO, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2023-0274), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND. A second motion was made by S. AHMED, seconded by C. BELISLE, to open a complaint against MOR MASEREJIAN (PH24058).

Case #8/CASE-2023-0783

PHA-2023-0269 Stop & Shop #784, DS2132 Time: 08:42 AM

RECUSAL: K. THORNELL 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.

- Deficiency on 11/28/23 for incorrect BUDs on labels affixed to the compounding log. This issue was discussed and noted on 2 previously inspections in 2023.
- MOR Burdick cited recent staffing challenges as a contributing factor. Pharmacist Soto Gonzalez had performed data entry, verification, and compounding on 7/25/23 of Rx1 for a suspension assigned BUD of 8/24/24 instead of a 14-day BUD.
- PTT Stack performed data entry of Rx2. MOR Burdick verified and compounded a flavoring added to a reconstituted antibiotic assigned a BUD of 7/26/24 instead of a 10-day BUD. Since the prescription label stated to use the medication for 10 days, she believed that superseded the BUD assigned. The patient was counseled to discard remaining medication after 10 days. Effective 10/12/23, S&S has discontinued adding flavorings to prescriptions.
- Floater Pharmacist Patel performed data entry, verification, and compounding on 9/26/23 of Rx3 for a suspension assigned BUD of 10/26/24 instead of a 14-day BUD. In his urgency to compound the medication for the waiting patient, an inaccurate BUD was assigned.
- Upon hire, annually, and prior to engaging in any compounding activity each S&S pharmacist shall self-evaluate and attest to their knowledge in core compounding competencies including reading S&S's Compounding of Nonsterile Preparations P&P containing BUD guidelines. MOR Burdick stated the compound log was modified to contain a STOP page in large print with a reminder to update the BUD and a copy of S&S policy which includes USP 795 BUD requirements. It was reinforced with current pharmacists to make sure to update all components of any compounded medication. Pharmacy staff

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and Floater Pharmacist Patel attested to review of S&S CNSP Policy, USP 795 Establishing BUDs, and BORP Policy 2023-07 Non-Sterile Compounding.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by D. PERRY, and voted unanimously by those present, to refer the matter (PHA-2023-0269), 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 #9/CASE-2023-0508

PHA-2023-0231 Blue Hill Pharmacy, DS89942 Time: 08:47 AM

RECUSAL: NONE

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

- The matter of PHA-2022-0122 for the Pharmacy was heard at the 12/01/2022 BORP meeting which resulted in a Probation for the Pharmacy effective 11/13/23. On 12/21/22 and 5/9/23, inspections could not be completed as the Pharmacy was closed during posted hours of operation. On 9/20/23, the Pharmacy was closed again, and an inspection could not be completed. The Pharmacy failed to implement the POC for the 5/9/23 site visit which stated. "The pharmacy will be open during normal operation hours as long as there are no events/deliveries needed urgently".
- The matter of PHA-2023-0011 for MOR Okeke was heard at the 6/1/23 BORP meeting which resulted in an investigation conference on 8/3/23 with MOR Okeke for these same issues. She was issued a Reprimand.
- The response stated MOR Okeke was at the Pharmacy during posted hours of operation on 9/20/23. She alleged the Boston Building Inspector with her at 11:30am to inspect the building and confirm the Pharmacy's alarm was working. Investigator Geaney provided photographic evidence showing the security grate was down and the lights were off at the time he attempted to inspect on 09/20/23.
- MOR Okeke is the only employee of the Pharmacy and delivers the prescriptions. Prescriptions are processed at the Pharmacy. On average, the prescription volume was 20/day on weekdays and 25/day on weekends from 8/2023-9/20/23 but the Pharmacy is closed on weekends. Three different reports were submitted as delivery logs, but one report didn't confirm the delivery dates.
- POC dated 10/20/2023 included the following as corrective action: "The pharmacy will remove any misleading signs on the door and windows showing the pharmacy is closed during posted hours and if [sic] pharmacy is undergoing any unexpected situation or inspections that will require temporary closure the MOR will notify the pharmacy board. The pharmacy hours of operation will be 12 noon to 4pm and deliveries will be done after 4pm until closing".
- Companion complaint PHA-2024-0026 was opened for MOR Okeke for a failure to be open for inspection during posted hours of operation on 01/17/24 and a failure to implement remediation in the previous POCs. MOR Okeke responded she will be open 12-4pm and expressed possible plans for expansion including establishing a health center.

<u>ACTION</u>: Motion by C. BELISLE, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0231), 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-2023-0508

PHA-2024-0026 Victoria Okeke, PH25059 Time: 08:52 AM

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RECUSAL: NONE

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

- The matter of PHA-2022-0122 for the Pharmacy was heard at the 12/01/2022 BORP meeting which resulted in a Probation for the Pharmacy effective 11/13/23. On 12/21/22 and 5/9/23, inspections could not be completed as the Pharmacy was closed during posted hours of operation. On 9/20/23, the Pharmacy was closed again, and an inspection could not be completed. The Pharmacy failed to implement the POC for the 5/9/23 site visit which stated. "The pharmacy will be open during normal operation hours as long as there are no events/deliveries needed urgently".
- The matter of PHA-2023-0011 for MOR Okeke was heard at the 6/1/23 BORP meeting which resulted in an investigation conference on 8/3/23 with MOR Okeke for these same issues. She was issued a Reprimand.
- The response stated MOR Okeke was at the Pharmacy during posted hours of operation on 9/20/23. She alleged the Boston Building Inspector with her at 11:30am to inspect the building and confirm the Pharmacy's alarm was working. Investigator Geaney provided photographic evidence showing the security grate was down and the lights were off at the time he attempted to inspect on 09/20/23.
- MOR Okeke is the only employee of the Pharmacy and delivers the prescriptions. Prescriptions are processed at the Pharmacy. On average, the prescription volume was 20/day on weekdays and 25/day on weekends from 8/2023-9/20/23 but the Pharmacy is closed on weekends. Three different reports were submitted as delivery logs, but one report didn't confirm the delivery dates.
- POC dated 10/20/2023 included the following as corrective action: "The pharmacy will remove any misleading signs on the door and windows showing the pharmacy is closed during posted hours and if [sic] pharmacy is undergoing any unexpected situation or inspections that will require temporary closure the MOR will notify the pharmacy board. The pharmacy hours of operation will be 12 noon to 4pm and deliveries will be done after 4pm until closing".
- Companion complaint PHA-2024-0026 was opened for MOR Okeke for a failure to be open for inspection during posted hours of operation on 01/17/24 and a failure to implement remediation in the previous POCs. MOR Okeke responded she will be open 12-4pm and expressed possible plans for expansion including establishing a health center.

ACTION: Motion by C. BELISLE, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2024-0026), 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: 1. Licensee may not act as preceptor for any pharmacy interns for purposes of earning hours towards NABPLEX eligibility; 2. The Licensee must ensure that Blue Hill Pharmacy be open and staffed with a licensed pharmacist at all times during posted hours of operation; and 3. The Licensee must attest to having read and understood 247 CMR in its entirety within 30 days.

Case #11/CASE-2023-0763

PHA-2023-0266 Walgreens #10209, DS3529 Time: 08:57 AM

RECUSAL: NONE

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

- Failure to comply with the requirements for a change in MOR cited as a deficiency during a Site Visit on 11/17/23. Former MOR Vann and Former MOR Bertoli conducted a CS inventory on 10/6/23 but the BORP had not been notified of the Change in MOR. The POC stated a change of MOR application was submitted on 11/20/23. The change of MOR application was incomplete as there was no Outgoing MOR listed and no dates documented.
- DM Cantella contended when Former MOR Vann left, there was a miscommunication for notifying the BORP that Former MOR Bertoli was the interim MOR. Once the miscommunication was realized, a change of MOR application was submitted. Current MOR Behl had been named as the permanent MOR of the Pharmacy as of 1/4/24.
- BORP confirmed that an application was received on 01/09/2024 for Incoming MOR Behl as of 1/4/24 and Outgoing MOR Bertoli as of 1/3/24.
- DM Cantella stated, "Moving forward in similar circumstances when there is a change in MOR in any of my locations, I will ensure to comply with BOP guidelines by identifying an incoming or interim MOR within the designated timeframe and following up to ensure the BOP is aware of said changes".

<u>ACTION</u>: Motion by R. LOPEZ, seconded by D. PERRY, and voted unanimously by those present, to refer the matter (PHA-2023-0266), 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-2023-0738

PHA-2023-0260

CVS #505, DS89977

Time: 09:01 AM

<u>RECUSAL</u>: J. ROCCHIO and D. PERRY recused and were 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.

- Inspectional deficiency on 11/8/23 for storage of 2 emergency bags containing epinephrine autoinjectors in an unlocked, open immunization booth in the store.
- MOR O'Hearn stated the inspection took place during a high immunization time and felt the bags were unintentionally left in the immunization booth.
- Immunizing staff provided statements acknowledging awareness that the emergency bags cannot be left in the immunization room.
- MOR O'Hearn stated, "I have spoken to all staff members including pharmacist, intern and technicians who work at our location about the importance of not leaving behind the Emergency Kit in the immunization room and for everyone to be aware of the location of the kits in the pharmacy in case of an emergency". MOR O'Hearn, Pharmacist Mapes, Pharmacist Yovino, CPhT Barto, PT Laboy, PT Hernandez, and PT Roman reviewed CVS ROPP-0051 Pharmacist Administered Immunization Program and CVS ROPP-046268 Cold Chain Product Storage.

<u>ACTION</u>: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0260), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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#13/CAS-2023-1132

PHA-2024-0016 Laura DeSimone, PT5232 Time: 09: 04 AM

<u>RECUSAL</u>: J. ROCCHIO and D. PERRY recused and were 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.

- Companion to PHA-2023-0180 for CVS #708 heard and dismissed on 1/11/24 for ID on 8/3/23 when CPhT DeSimone was heard counseling a patient at POS. Pharmacist Keeman was notified by Investigator Seed. She changed her credential code and spoke to CPhT Desimone. The POC stated the MOR will ensure Pharmacy staff are aware of their scope of practice and that Pharmacist's credentials are not shared.
- CPhT Desimone stated when reading the DUR to inform Pharmacist Keeman, the customer stated the doctor went over it with her already. She stated, "I did not counsel the patient and I did not intend to at any time". Since Pharmacist Keeman had previously counseled at POS, CPhT Desimone was aware of her credentials and entered them for this DUR.
- Pharmacist Keeman stated she was unaware of the incident as she was at the drop-off station. She stated, "I did not give her my credentials, but she may have known what they were because we have to go over each time and enter them into the computer for DUR's". Once notified during the inspection, she changed them immediately.
- MOR Dester believed that CPhT Desimone obtained Pharmacist Keeman's credentials from Pharmacist Keeman going to POS multiple times throughout the morning to complete DURs.
- MOR Dester and Pharmacist Keeman reiterated to CPhT Desimone a pharmacist is still required to counsel despite a patient communicating knowledge of the intended counseling. Under no circumstances are the pharmacist's credentials shared when completing DURs and will be immediately changed if exposed. They have been more intentional about protecting their credentials. Pharmacy staff reviewed CVS MA Technician Duties, policy Filling/Dispensing Prescriptions Stores with Two Step Verification Workflow, policy Professional Standards for Patient Counseling.
- In response to PHA-2024-0016, CPhT DeSimone provided essentially the same statement as provided for the complaint against CVS #708.

<u>ACTION</u>: Motion by J. LOPEZ, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2024-0016), 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-2023-0540

PHA-2024-0010 Gregory Rodrigues, PH23347 Time: 09:08 AM

<u>RECUSAL</u>: J. ROCCHIO and D. PERRY recused and were 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.

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- CE deficiencies indicated on an application for a change of MOR received on 8/10/23 for CVS #16926. Pharmacist Rodrigues was contacted and he stated the box was erroneously checked no and he had completed his 2021 and 2022 CEs through the Pharmacist's Letter. A review of his 2021 CPE Monitor showed no CEs completed and his 2022 CPE Monitor showed no live CEs were completed. This was a repeat deficiency.
- Pharmacist Rodrigues claimed he mailed his CE certificates of completion for 2021 to BORP staff. On 10/19/23, he was notified of INV8375 and was asked to remediate by 1/1/24. On 1/2/24, his CPE Monitor only showed completion of 20 CEs total including 3 live CEs, 3 law CEs, and 1 CE in immunizations with no remediation of his 2021 and 2022 deficiencies. On 01/03/2024, INV8375 was elevated to PHA-2024-0010 by BORP staff action.
- On 1/4/24, the Pharmacist's Letter was contacted to confirm if Pharmacist Rodrigues was issued credits for any CEs completed in 2021. It was confirmed he received credit for 15 CEs including 1 live CE which were applied for 2021. On 2/22/24, his 2023 CPE Monitor showed 28.5 CEs were completed including 10.5 live CEs, 5 law CEs, and 1 CE in immunizations and his 2024 CPE Monitor showed 6 live CEs were completed.
- Pharmacist Rodrigues was reminded that CEs completed for remediation would not count for his 2024 requirements. He attested CEs completed for remediation would not count for his 2024 requirements.

<u>ACTION</u>: Motion by R. MORELLI, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter (PHA-2024-0010), No Discipline Warranted, Remediation Complete.

Case #15/CASE-2023-0620

PHA-2023-0219 CVS #2339, DS2877 Time: 09:12 AM

<u>RECUSAL</u>: J. ROCCHIO and D. PERRY recused and were 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 October 16, 2023, Investigator Brosnan observed during an RCI that "totes containing the
 pharmacy order were staged just outside of the pharmacy in the front store area" and a PTT
 immunizing patients when BORP does not authorize PTTs to immunize. In turn, he issued a POC
 to the pharmacy.
- Upon further investigation, the PTT administered approximately 286 vaccines to patients from 5 years-old to 96 years-old including COVID-19, influenza, pneumococcal, shingles, RSV, TDAP, MMR, and HPV vaccines.
- Of note, the PTT did not complete immunization training required prior to administering
 vaccines even if she had been an authorized technician. She did have a valid CPR card. In
 addition, the started a pharmacy technician application on 10/15/2023 and provided an
 immunizing training certificate completed on the same day. The PT application was pending as
 of 02/23/2024.
- POC/CA: In the POC, CVS 2339 indicated that the totes containing the pharmacy order were immediately moved to the licensed prescription area when Investigator Brosnan pointed out the violation during the inspection and the order would be brought into the licensed prescription area immediately upon receipt going forward.

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- In addition, the PTT stopped immunizing immediately and the PTT "completed training, will become licensed as a technician, and complete the requirements found in Policy 2023-02 before immunizing again."
- Later, CVS 2339 added in response to the complaint that "going forward, we will ensure all technicians are certified before allowing them to vaccinate." Of note, the PTT Please add info indicating that application not started until 10/16/23 and that immunization certificate of completion was also dated 10/16/23.

<u>ACTION</u>: Motion by S. AHMED, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2023-0219), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND. A second motion was made by S. AHMED, seconded by R. LOPEZ, and voted unanimously by those present, to open a complaint on MOR ANDRADE (PH232623) and a third motion made by D. BARNES, seconded by J. LOPEZ to open a complaint on PTT BEACH (PTT20458).

Case #16/CASE-2023-0594

PHA-2023-0256 CVS #166, DS3449 Time: 09:19 AM

<u>RECUSAL</u>: J. ROCCHIO and D. PERRY recused and were 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 October 12, 2023, CVS 166 submitted a final report for an unknown loss of 400 clonazepam 0.5mg tablets discovered on September 21, 2023. According to the final report, the loss of clonazepam was first discovered on September 21, 2023 during via "corporate controlled substance monitoring." An internal investigation was initiated at that time but, ultimately, the cause of the loss was unable to be determined.
- CVS 166 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 dispensing standards" as corrective action to militate recurrence of a similar incident.

<u>ACTION</u>: Motion by D. BARNES, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2023-0256), 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 1 year, with special terms to include the CS Loss Protocol for all Benzodiazepines.

Case #17/CASE-2023-0677

PHA-2023-0251 CVS #1007, DS90074 Time: 09:20 AM

<u>RECUSAL</u>: J. ROCCHIO and D. PERRY recused and were 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.

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- On 10/25/2023, Investigator Horn conducted a site visit at CVS 1007. During the visit, he discovered that a permanent change in MOR occurred on 09/08/2023 which was not reported to BORP after the former MOR left. In addition, a change in MOR CII-V CS inventory was not completed.
- Investigator Horn contacted CVS 1007 DL CVS Health District Leader and the DL explained that a new MOR was hired. The DL assured Investigator Horn that the change in MOR CS inventory would be completed during the coming weekend and a change in MOR application would be submitted.
- POC: CVS Health RA explained on behalf of CVS 1007 that "the previous DL told the new MOR that she submitted a temp pic letter in September when the prior MOR left. Incoming MOR completed the count and submitted paperwork. Current MOR in place. For any future MOR changes DL will help support transition and ensure appropriate documentation is submitted timely." Of note, Current MOR Silva's change in MOR application was not submitted until 12/13/2023.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2023-0251), 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/CAS-2023-0898

Time: 09:23 AM

PHA-2023-0271

Gabriel Rusanescu, PH239940

<u>RECUSAL</u>: J. ROCCHIO and D. PERRY recused and were 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.

- BORP opened a complaint against Pharmacist Rusanescu during the 12-07-2023 Board Meeting after he permitted PTT Sequar to work with an expired license using his credentials in CVS Pharmacy #10891's prescription software system,
- Pharmacist Rusanescu explained that he worked as a part-time Floater Pharmacist for CVS Health and for the first time after several months at CVS 10891 on the date of Investigator Geaney's inspection. He described that he was not familiar with staff at CVS 10891, Land he was not aware that PTT Sequar's license was expired.
- Pharmacist Rusanescu then admitted that he permitted PTT Sequar to work under his credentials in the prescription software system. He asserted that "[PTT Sequar] asked [him] to log her into the pharmacy system." He assumed that PTT Sequar was unable to use her credentials due to technical issues. Pharmacist Rusanescu explained that "[he] had never encountered such a situation before, and [he] did not realize that it may have been due to an expired license. Since she was scheduled to work on that day, [he] thought she had the appropriate credentials to do so..."
- Pharmacist Rusanescu indicated that he implemented the following corrective action to mitigate recurrence of a similar incident. He confirmed that PTT Sequar's license was valid when he worked with her on his subsequent shift. In addition, Pharmacist Rusanescu indicated that [he] will make sure in the future to check pharmacy staff licenses when such system access issues arise."

<u>ACTION</u>: Motion by J. LOPEZ, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2023-0271), 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-2023-0675

PHA-2023-0250 CVS #635, DS2871 Time: 09:26 AM

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

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

- During a retail site-visit (ISP30046-SV) on 10/25/2023, the Investigator observed that there was no named interim Manager and a new MOR application was not submitted to the Board.
 - The POC stated that former Mashburn gave her notice and her last day was 10/21/2023. MOR Frannie Hsu was named as MOR as of 10/26/2023.
 - The Application for Change in Manager submitted indicated that the date the Change in Manager occurred was 10/29/2023.
 - A Schedule II through V inventory was completed on 11/11/2023.

<u>ACTION</u>: Motion by J. LOPEZ, seconded by D. BARNES, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0250), No Discipline Warranted, Remediation Complete.

Case #20/CAS-2021-0591

PHA-2023-0272 Xia Li, PH233540 Time: 09:28 AM

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

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

- CVS Pharmacy #321 reported losses of benzodiazepines due to a suspected employee pilferage and was on a consent agreement for stayed probation with monthly counts. At the 08/03/2023 Board meeting the stay was lifted and the Pharmacy was put on probation.
- On 10/18/2023 a Retail Compliance Inspection was conducted at the Pharmacy and a repeat deficiency was observed. At the 12/07/2023 Board Meeting this deficiency was considered a violation of the current probation of the Pharmacy and Board members voted to open this complaint against MOR Li as she was the MOR during the initial and repeat inspections in which immunization supplies were observed in the unlicensed space at CVS #321.
- MOR Li was listed as MOR at CVS #21 until 10/28/2023 even though she was transferred to CVS #2125 (Natick, MA) on 10/15/2023 to be the MOR there. She noted that she continued to ensure that no immunization supplies were in the unlicensed space at this new location. She related that when she became a pharmacy manager at CVS#321, it was her first time as a pharmacy manager. She said that being MOR offers her the opportunity to understand more regulatory procedures and career growth and understands that there are lots of regulatory procedures that she still needs to learn, and she would challenge herself to explore more to have better service for her patients and community.

<u>ACTION</u>: Motion by D. BARNES, seconded by R. LOPEZ, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0272), No Discipline Warranted, Remediation Complete.

Case#21/CASE-2023-0618

PHA-2023-0217 CVS #719, DS1906 Time: 09:30 AM

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

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

- During a retail compliance inspection conducted on 10/12/2023, the Investigator observed that there was no controlled substance inventory conducted and a Change in MOR application was not submitted to the Board.
- Former MOR St. Marie's last day as MOR was 09/29/2023 and Current MOR Baum's first day as MOR was 10/03/2023.
- Current MOR Baum noted that the outgoing MOR did not show up to complete the inventory on 10/15/2023 so another pharmacist came in the next day to assist her. She noted that she picked up extra shifts and did not mail the paperwork until 10/30/23 with overnight shipping.
- Per eLX, the MOR application was submitted and approved on 11/20/2023. In the MOR application, the proposed MOR is listed as Current MOR Baum with a start date of 10/16/2023 and the outgoing MOR with an end date of 10/05/2023.
- MOR Baum indicated that she would ensure any changes will be made timely for future pharmacy manager changes.

ACTION: Motion by C. BELISLE, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0217), 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-2023-0616 INV8553 CVS #119, DS89835 Time: 09:33 AM

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

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

- The Pharmacy failed to fill a prescription properly.
 - 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.
 - MOR Hom indicated that he will also ensure that technicians are handing off difficult situations to the pharmacists on duty if necessary. He has discussed these with his entire team and ensured they are implemented in their daily workflow practices.

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• MOR Hom submitted a signed attestation that the staff reviewed 247 CMR 15: Continuous Quality Improvement (CQI) Program by PT Emmons, PT Bernard and Pharmacist Edwards. Also, Pharmacist Edwards completed 2 CEs in patient safety.

<u>ACTION</u>: Motion by D. BARNES, seconded by S. DINNO, and voted unanimously by those present, to CLOSE the matter (INV8553), No Discipline Warranted, Remediation Complete. A second motion was made by S. HAMILTON, seconded by S. AHMED to open a complaint on Pharmacist EDWARDS (PH238675).

Case #23/CASE-2023-0686

PHA-2023-0246 Coram CVS/ Specialty Infusion Services, DS3601 Time: 09:39 AM

<u>RECUSAL</u>: J. ROCCHIO, D. PERRY and J. TRIFONE recused and were not present for the vote or discussion in this matter.

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

- During a USP <797> compliance inspection (ISP-30013) on 10/24/2023, the Investigators observed that the licensee had extensive contamination and insanitary issues, which is not compliant with USP guidelines.
- On 10/24/2023, the Pharmacy voluntarily suspended compounding and informed the staff not to ship any finished products made on this day.
- On 10/27/2023, Investigator Brosnan conducted a site-visit to ensure that the cleanrooms were shut down with no active compounding on site.
- MOR Mikhail that in response to the 10/24/2023 inspection, they made considerable corrections for cleanroom A.
- On 11/21/2023, Investigators Nathan Van Allen and Michael Brosnan conducted a site-visit (ISP-30071) at the Pharmacy to assess Cleanroom A, reviewed the interior cleanroom and the current state of operation. Recertification of cleanroom A was conducted and passed. EM reports were within normal limits.
- The Pharmacy resumed compounding in Cleanroom A on 11/22/2023.

ACTION: None

IX. RECONSIDERATION

Compare Quality Pharmacy, DS89874, PHA-2019-0043

Presented by: J. Petrillo

Recusal: none

Discussion:

- Page 209 to 210 of the Board packet
- On 6/25/2021, the Board members voted to authorize a Consent Agreement for a two year
 Probation for the matter of PHA-2019-0043. J. Petrillo summarized the violations cited in PHA-

TIME: 9:53am

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2019-0043 and noted the Board members also voted for an increase in inspections which did occur.

- There are two outstanding matters pending for Compare Quality Pharmacy.
- The matter was lost to follow up following the Board vote. Presuming the agreement went into
 effect in June 2021, the probation would have expired in June 2023. PHA-2019-0043 is being
 brought back for reconsideration with a recommendation to authorize a Consent Agreement for
 Reprimand.

Action: A motion was made by D. Barnes to refer the matter of PHA-2019-0043 to the Office of Prosecution for the Issuance of an Order to Show Cause and authorize the resolution with a Consent Agreement for a Reprimand; Seconded by S. Hamilton then Board Members present voted unanimously by roll call to approve the motion.

Topic X: Executive Session Call to Order: Time: 9:59 AM

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

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

Roll call attendance: C. Belisle, yes; S. Hamilton, yes; D. Barnes; J. Rocchio, yes; R. Lopez, yes; S. Ahmed, yes; R. Morelli, yes; J. Lopez, yes; D. Perry, yes; K. Thornell, yes; J. Dorgan, yes; S. Dinno, yes. M. Sciaraffa was not present for the vote.

Topic XI: 65C Sessions MGL c. 112 section 65C Time: 10:39 AM

DISCUSSION: None

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

At 10:39 A.M. S. Hamilton, seconded by S. Ahmed and voted unanimously by all those present to enter 65C by roll call vote.

Topic XII: ADJOURMENT OF MEETING TIME: 2:12 PM

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

Draft Minutes General Session: 4/2/24

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. Draft Agenda of the 4/4/24 General Session
- 2. Draft Minutes of the 3/7/24 Meeting
- 3. Report on Applications approved pursuant to Licensure Policy 13-01
- 4. Monthly report from Probation
- 5. Report on Board Delegated Complaint Review to licensure policy 14-02
- 6. Report on PSUD 17-03
- 7. Research Drug Study report pursuant to Staff Action Policy 18-02
- 8. Board Policy 2022-01: Loss or Theft of Controlled Substance Reporting will be via ELX platform
- 9. Letter on Implantable Infusion Pumps
- 10. 247 CMR 2.00: Definitions and Severability
- 11. Meraki Pharmacy- New Community Pharmacy
- 12. CASE-2023-0742 PHA-2023-0259 Rite Aid #10209, DS2899
- 13. CAS-2023-0113 PHA-2023-0221 Shifa Ali, PH239619
- 14. CASE-2023-0658 PHA-2023-0239 Optum Infusion Services, DS90100
- 15. CASE-2023-0740 PHA-2023-0262 Soleo Health, DS89958
- 16. CASE-2023-0740 PHA-2023-0263 Kimmi Cheung, PH238352
- 17. CASE-2024-0128 PHA-2024-0023 Walgreens #2564, DS1925
- 18. CASE-2023-0826 PHA-2023-0274 West Concord Pharmacy, DS3607
- 19. CASE-2023-0783 PHA-2023-0269 Stop & Shop #784, DS2132
- 20. CASE-2023-0508 PHA-2023-0231 Blue Hill Pharmacy, DS89942
- 21. CASE-2023-0508 PHA-2024-0026 Victoria Okeke, PH25059
- 22. CASE-2023-0763 PHA-2023-0266 Walgreens #10209, DS3529
- 23. CASE-2023-0738 PHA-2023-0260 CVS #505, DS89977
- 24. CAS-2023-1132 PHA-2024-0016 Laura DeSimone, PT5232
- 25. CASE-2023-0540 PHA-2024-0010 Gregory Rodrigues, PH23347
- 26. CASE-2023-0620 PHA-2023-0219 CVS #2339, DS2877
- 27. CASE-2023-0594 PHA-2023-0256 CVS #166, DS3449
- 28. CASE-2023-0677 PHA-2023-0251 CVS #1007, DS90074
- 29. CAS-2023-0898 PHA-2023-0271 Gabriel Rusanescu, PH239940
- 30. CASE-2023-0675 PHA-2023-0250 CVS #635, DS2871
- 31. CAS-2021-0591 PHA-2023-0272 Xia Li, PH233540
- 32. CASE-2023-0618 PHA-2023-0217 CVS #719, DS1906
- 33. CASE-2023-0616 INV8553 CVS #119, DS89835
- 34. CASE-2023-0686 PHA-2023-0246 Coram CVS/ Specialty Infusion Services, DS3601

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Respectfully Submitted, Rita Morelli, Secretary