

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

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

September 7, 2023

WebEx Information

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

For video access click on the following link:

<https://eohhs.webex.com/eohhs/j.php?MTID=m6a0ee4cae65de9877b83baf68af4b6be>

To access the meeting by phone:

Call in Number: 1-650-479-3208

Access Code: 2535 151 3067

*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		C. Belisle
8:02	II	APPROVAL OF AGENDA		
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of August 3, 2023 Regular Session Minutes		
8:10	IV	REPORTS <ul style="list-style-type: none">• Applications approved pursuant to Licensure Policy 13-01• Monthly report from Probation• Board Delegated Review pursuant to Licensure Policy 14-02• PSUD Report-Policy 17-03		

8:15	V	FLEX <ul style="list-style-type: none"> • Selection of a delegate for the NABP District I & II meeting • NABP Resolution: Stimulant Drug Shortages • Pharmacist prescribing and dispensing of hormonal contraceptive patches and self-administered oral hormonal contraceptives 		
8:45	VI	APPLICATIONS <ul style="list-style-type: none"> • Freedom FP Fertility; DS89716 – Relocation • Freedom Fertility; DS89717 – Relocation • Price Chopper; DS89863 – Petition for Waiver • Springfield Pharmacy; DS90286-Petition for Waiver 		
9:30	VII	POLICIES <ul style="list-style-type: none"> • Policy 14-02: Board Delegated Review (BDR) • Policy 13-01: Licensure Applications and Notices • Policy 2023-10: Unfilled Prescriptions • Policy 2023-02: Vaccine Administration • Policy 2020-15: Scope of Practice • Policy 2023-11: Pharmacy Technician Training and Examinations 		

10:00	VIII	FILE REVIEW					
		1	CAS-2023-0106	PHA-2023-0556			Walgreens #3151, DS2470
		2	CAS-2023-0311	PHA-2023-0064			SOFIE, NU00021
		3	CAS-2023-0309	PHA-2023-0063			Amerita, DS90296
		4	CAS-2023-0169	PHA-2023-0028			NIMVAX, Inc, DS90369
		5	CAS-2023-0396	PHA-2023-0078			Bouvier Pharmacy, DS90037
		6	CAS-2023-0126	PHA-2023-0027			Worcester Pharmacy, DS90368
		7	CAS-2023-0536	PHA-2023-0089			NELC, DS3513
		8	CAS-2023-0691	PHA-2023-0128			Advanced Compounding Solutions, WD521
		9	CAS-2023-0760	PHA-2023-0132			Advanced Compounding Solutions, RO00001
		10	CAS-2023-0240	PHA-2023-0058			CVS #84, DS89733
		11	CAS-2023-0026	PHA-2023-0018			CVS #2533, DS2933
		12	CAS-2023-0533	PHA-2023-0097			CVS #2128, DS2720
		13	CAS-2023-0554	PHA-2023-0105			CVS #2500, DS3606
11:00	IX	EXECUTIVE SESSION The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition, or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, to evaluate the Good Moral Character as required for registration for a pending applicant.					
12:00		LUNCH BREAK					
12:30	X	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)					
1:00	XI	M.G.L. c. 112, § 65C SESSION					
4:00	XII	ADJOURNMENT					

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

**MINUTES OF THE GENERAL SESSION
Via Remote WebEx Meeting
September 7, 2023**

Board Members Present

Caryn Belisle, RPh, MBA, President
Jennifer Chin, RPh, Secretary
Katie Thornell, RPh, MBA President Elect
Dr. Richard Lopez, MD
Sebastian Hamilton, Pharm D, MBA, RPh
John Rocchio, RPh, PharmD
Sami Ahmed, PharmD., RPh, BCPS, BCSCP
Rita Morelli, PharmD, BCACP, RPh
Johanna Lopez, MS
Julie Lanza, CPhT
Delilah Barnes, RPh
Dawn Perry, JD

Board Members Not Present

Carly Jean-Francois, RN, NP

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, Associate Executive Director
Jacqueline Petrillo, PharmD, RPh, JD, Board Counsel
Michael Egan, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh, Quality Assurance Pharmacist
Richard Harris, Program Analyst
Joanna Chow, Program Analyst
Taylor Lee, Office Support Specialist
Joanne Trifone, RPh, Director of Investigations
Gregory Melton, JD, PharmD, BCPS, Investigator
Julienne Tran, RPh PharmD, Investigator
Christina Mogni, RPh, Investigator
Keith Johnston, 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 Caryn Belisle chaired the meeting and he explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: J. Lanza, yes; S. Hamilton, yes; C. Belisle, yes; D. Barnes; J. Rocchio, yes; J. Chin, yes; R. Lopez, yes; S. Ahmed, yes; R. Morelli, yes; K. Thornell, yes; D. Perry, yes; J. Lopez, yes.

Topic II.**Approval of Agenda****TIME 8:01 AM****Agenda: 9/7/23****DISCUSSION:**

Defer: Springfield Pharmacy; DS90286 Petition for Waiver and Policy 2023-11 – Pharmacy Technician Training and Examinations.

ACTION:

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

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

Minutes

1. Draft 8/3/23

Change: no changes

Action:

Motion by J. Chin seconded J. Lanza and voted unanimously to approve the regular session minutes of 8/3/23 with no noted changes by roll call vote.

Topic IV.**REPORTS****Applications approved pursuant to Licensure Policy 13-01****TIME: 8:03 AM**PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported 32 Change of Manager applications that have been approved via Staff Action since the August 3rd Board meeting.

So noted.

Topic IV.**REPORTS****Monthly Report from Probation****TIME: 8:03 AM**PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto indicated a total of 18 active probation cases. 1 licensee has successfully completed probation monitoring since the August 3rd Board meeting.

So noted.

Topic IV.

REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

TIME: 8:03 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported 1 Controlled Substance loss, which warranted stayed probation for 1 year. A total of 3 CE deficiencies were reported, all of which have been closed with no discipline warranted. Two renewal waivers have been received since the last Board meeting.

So noted.

Topic IV.

REPORTS

PSUD report by Staff Action 17-03

TIME: 8:04 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported no new changes to the PSUD program since the last board meeting. Currently, there are 8 active participants enrolled in the program.

So noted.

TOPIC V.

FLEX

1. Selection of a delegate for the NABP District I & II meeting

Time: 8:04 AM

Presented by: D. SENCABAUGH

Discussion: Delegates are needed to vote on the behalf the Board at the NABP District I & II meeting.

Action: Motion by J. LANZA, seconded by S. HAMILTON, and voted unanimously by roll call of those present, to approve K. THORNELL as the delegate and J. ROCCHIO as the alternate.

1. NABP Resolution: Stimulant Drug Shortages

Time: 8:09 AM

Presented by: W. FRISCH

Discussion: As discussed at the August meeting, the Board reviewed language requesting that NABP explore potential solutions at the pharmacy and patient level regarding the shortage of stimulant medications for the treatment of ADD/ADHD.

Action: Motion by D. BARNES, seconded by S. HAMILTON, and voted unanimously by roll call of those present, to formally approve the language.

2. Pharmacist prescribing and dispensing of hormonal contraceptive patches and self-administered oral hormonal contraceptives **Time: 8:11 AM**

Presented by: M. CHAN

Discussion: The Department of Public Health is in the process of developing guidance for pharmacists to prescribe and dispense oral and transdermal contraception pursuant to the new statute at M.G.L. c. 94C, § 19F.

So noted.

TOPIC VI.

Applications

1. Freedom FP Fertility; DS89716

Relocation

TIME 8:12 AM

Represented by: Hilary Veinot and Philip D’Amato

Recusal: none

Discussion:

- Pages 25-58 of General Session packet
- Relocation from Byfield to Newburyport in March/April 2024 for the pharmacy for self-pay patients
- Waivers requested for:
 - 247 CMR 6.01 (5) (a) (4): requirement for a balance
 - 247 CMR 6.02(4): requirement to have a sufficient variety of chemicals to meet the usual needs of the community
 - 247 CMR 9.01 (16): may not refuse to compound customary preparations
 - 247 CMR 9.02 (3)(c)(2)(e): capture name, address, DEA number, and prescription number from transferring pharmacy - limited waiver requested from having to capture a DEA number when a transferring pharmacy does not have one

Action: A motion was made by S. Hamilton to approve Freedom FP Fertility’s application for a relocation with the requested waivers pending a successful inspection; Seconded by S. Ahmed then Board Members present voted unanimously by roll call to approve motion.

2. Freedom Fertility; DS89717

Relocation

TIME 8:12 AM

Represented by: Hilary Veinot and Philip D’Amato

Recusal: none

Discussion:

- Pages 59-109 of General Session packet

- Relocation from Byfield to Newburyport for the patients with insurance and compounding pharmacy
- Waiver requested for 247 CMR 9.02 (3)(c)(2)(e): capture name, address, DEA number, and prescription number from transferring pharmacy - limited to having to capture a DEA number when a transferring pharmacy does not have one
- If the draft regulations pass, the Pharmacy will need to request a waiver to allow for placement of the in unclassified space as the proposed plan has the sink in unclassified space

Action: A motion was made by J. Chin to approve Freedom Fertility’s application for a relocation pending a successful inspection; Seconded by D. Barnes then Board Members present voted unanimously by roll call to approve motion.

3. Price Chopper 240; DS89863

Petition to Waiver

TIME 8:40 AM

Represented by: Heather King, Compliance Officer

Recusal: None

Discussion:

- Pages 109-119 of General Session packet
- Limited waiver requested for 247 CMR 6.02(6)(b) requirement to store all CVIs within the prescription area- allowance to only store vaccines in the consultation/immunization room that is only accessible to the public when accompanied by a pharmacist.
- Immunization/consultation room is unlicensed space which previously contained 2 refrigerators and 1 freezer. One of the refrigerators was able to be moved into the Pharmacy but there is currently 1 refrigerator and 1 freezer in the space
- Ms. King stated if the waiver is granted, locks would be added to the refrigerator and freezer. Board members expressed concerns of adding locks.
- Ms. King stated they are exploring other options including replacing small refrigerator(s) in the Pharmacy with full-size ones and renovation of pharmacy space which she estimated may take 6-12 months to implement.
- Director of Compliance William Frisch, Board Counsel, and Board members expressed concerns with granting a precedent setting waiver for storage of prescription products outside of licensed pharmacy space.
- Ms. King withdrew the waiver request.

4. Springfield Pharmacy; DS90286

Petition for Waiver

TIME _____

Discussion: Deferred

TOPIC VII.

Policies

1. Policy 14-02: Board Delegated Review (BDR)

Time: 9:18 AM

Presented by: M. CHAN

Discussion: Edits to the policy allow certain closed-door waivers to be approved by Board Delegated Review (BDR) which includes one Board member.

Action: Motion by S. HAMILTON, seconded by J. LANZA, and voted unanimously by roll call of those present, to approve the edits to this policy.

2. Policy 13-01: Licensure Applications and Notices

Time: 9:20 AM

Presented by: M. CHAN

Discussion: Edits to this policy allow staff approval of licensure applications with certain waivers after the waivers have been approved by BDR.

Action: Motion by S. HAMILTON, seconded by D. PERRY, and voted unanimously by roll call of those present, to approve the edits to this policy.

3. Policy 2023-10: Unfilled Prescriptions

Time: 9:21 AM

Presented by: M. CHAN

Discussion: The DEA has established rules regarding the transfer of unfilled federally controlled substance prescriptions. Unfilled electronic scripts may only be transferred electronically. Policy changes were made accordingly.

Action: Motion by J. CHIN, seconded by S. HAMILTON, and voted unanimously by roll call of those present, to approve the edits to this policy.

4. Policy 2023-02: Vaccine Administration

Time: 9:23 AM

Presented by: M. CHAN

Discussion: Edits to this policy allow qualified pharmacy personnel to administer routine vaccines that have been approved by the ACIP/CDC but are not yet on the Immunization Schedule. The impetus for this change is the recent approval of RSV vaccine. Changes now also allow CDTM pharmacists to administer travel vaccines and other non-routine vaccines in accordance with their CDTM agreement.

Action: Motion by S. HAMILTON, seconded by J. LOPEZ, and voted unanimously by roll call of those present, to approve the edits to this policy.

5. Policy 2020-15: Scope of Practice

Time: 9:24 AM

Presented by: M. CHAN

Discussion: Changes were made to be consistent with the vaccine administration policy changes.

Action: Motion by J. LANZA, seconded by J. CHIN, and voted unanimously by roll call of those present, to approve the edits to this policy.

6. Policy 2023-11: Pharmacy Technician Training and Examinations

Deferred

TOPIC VIII.

File Review

Case #1/CAS-2023-0106

PHA-2023-0556

Walgreens #3151, DS2470

Time: 09:37 AM

RECUSAL: NONE

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

- RLCS of #100 Adderall XR 5mg discovered on 2/20/23 during the reconciliation of the perpetual inventory. MOR Montville reviewed on-hand inventories, controlled substance recordkeeping, and staffing schedules. The trash and DPI bins were checked. Video was reviewed but was inconclusive. The reason for the loss was not determined but the bottle may have been discarded with empty bottles.
- Overnight Pharmacist Smreczak discovered the discrepancy. She reviewed dispensing records, verified the BOH in the perpetual inventory vs. the electronic record and completed a bin reconciliation. She reported the loss to MOR Montville on 2/20/23.
- MOR Montville contacted the 3 patients who had been dispensed Adderall XR 5mg since the previous reconciliation on 2/12/23 and none reporting receiving an extra bottle which he confirmed through video review.
- MOR Montville stated, "Each time a C2 is being filled it is to be removed from the safe, filled by RPh, CPhT or intern, and returned immediately to the pharmacist. The C2 will be counted twice by the initial filling team member, then a third time by another RPh, CPhT or Intern. The pharmacist will take the bottles and place them back in the safe before verifying another prescription." Additionally, "When the RPh is auditing the C2 tote, it is to be done under the camera by the C2 safe and immediately stored in the safe". These procedures for handling CII were outlined in a document entitled "Controlled Substance Handling" which was signed and dated by the Pharmacy staff confirming review.

ACTION: Motion by J. ROCCHIO, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2023-0106), 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-2023-0311

PHA-2023-0064

SOFIE, NU00021

Time: 09:41 AM

RECUSAL: NONE

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

- Failure to timely submit mandated sterile compounding reports by February 15, 2023 to BORP.
- MOR Gerges-Maalouf indicated that since December 2022, there were two pharmacists that were appointed to the MOR position but resigned within one month of each other. The MOR noted that she was transferred from the Albany facility to the Haverhill facility and appointed MOR.
- The MOR noted that she was working the night shift and longer than normal hours to minimize patient impact. Consequently, the sterile reporting requirement was missed.
- The MOR noted that she will refresh herself on Board of Pharmacy notification requirements, add the due date of the next report to the site metrology sheet that tracks various due dates for the facility and updated the reporting requirements to the Pharmacy Manual site attachment for SOFIE Haverhill.

ACTION: Motion by S .HAMILTON, seconded by R. MORELLI, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0064), No Discipline Warranted, Remediation Complete.

Case #3/CAS-2023-0309

PHA-2023-0063

Amerita, DS90296

Time: 09:43 AM

RECUSAL: NONE

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

- Failure to timely submit their sterile compounding reports by February 15, 2023.
- MOR Patel noted that from 8/15/2022-11/18/2022, there were a change of 3 MORs. He noted that he was named MOR on 11/18/2022.
- As new MOR, MOR Patel was not aware of the sterile compounding reporting requirement and had not compiled or submitted this report for the Pharmacy prior to this time. He noted that it was only scheduled in the calendar of the previous MOR and therefore not reported timely in February. He has subsequently submitted the required documentation to the Board.
- MOR Patel indicated that since this notice of non-compliance, the mandated reporting requirement has been added to the branch compliance management system, as well as on all the Pharmacist' Outlook calendars as a reminder. The documentation of scheduled mandatory reporting is now visible to the pharmacy staff, and the corporate clinical services/compliance department.

ACTION: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0063), No Discipline Warranted, Remediation Complete.

Case #4/CAS-2023-0169

PHA-2023-0028

NIMVAX, DS90369

Time: 09:45 AM

RECUSAL: NONE

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

- On 01-25-2023, Investigator Geaney conducted a site visit with DEA after MOR Deocampo applied for and was issued a DEA Registration to dispense CII-V. Upon arrival, Investigator Geaney and DEA knocked on the door to the business to gain entry and were greeted by a technician. The technician indicated that MOR Deocampo was in a meeting.
- Investigator Geaney inquired whether the technician was alone in the pharmacy and the technician confirmed that she was alone. Investigator Geaney described that “the door to the drug storage area was open when we arrived. [Technician Motta] closed it and then I witnessed her enter a code and re-open the door. No pharmacist was present until [MOR Deocampo] arrived approximately 25 minutes later.”
- Next, DEA cancelled NIMVAX’s DEA Registration because NIMVAX failed to obtain licensure from BORP to dispense CII-V.
- CA/POC-MOR Deocampo indicated that he applied for DEA Registration because he applied for a CV-VI registration from BORP and was not aware that NIMVAX’s licensee was for Schedule VI only. He explained that NIMVAX’s DEA Registration was surrendered for cause. He stressed that NIMVAX “never dispensed, acquired, or distributed any other schedule than C-VI” and will only handle CVI until proper registrations were acquired.
- In addition, he indicated that “a registered pharmacist shall be on duty and on the pharmacy premises at all times when pharmacy is open for business and shall be present at all times when non-pharmacist personnel have unrestricted access to the pharmacy. The alarm to drug storage will be set; if the door is open, it will sound and generate a report. Only pharmacist and MOR will have the alarm code. Temporary Absence of a Pharmacist policy has been updated accordingly.” MOR Deocampo added that a “Pharmacist or MOR shall review the alarm report monthly” to ensure ongoing compliance with the POC”

ACTION: Motion by S. HAMILTON, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0028), 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 /CAS-2023-0396

PHA-2023-0078

Bouvier Pharmacy, DS90037

Time: 09:49 AM

RECUSAL: NONE

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

- On 03-20-2023, Investigator Rick Geaney discovered during a retail compliance inspection at Bouvier that an unlicensed staff member was working in the pharmacy. In addition, he observed that the pharmacy was “out of ratio 2:7 with only 1 nationally certified technician.”
- CA/POC-MOR Gavin indicated that the unlicensed staff member would “resubmit [a] PTT application along with [Pharmacy Technician] application.” MOR Gavin also indicated that she would “keep copy

of any applications in employee file & follow up after applications are sent” going forward. Of note, the unlicensed staff member was issued a pharmacy technician license (PT30374) on April 26, 2023.

- Next, MOR Gavin indicated that she adjusted the pharmacy schedule to 2:5 including one nationally certified pharmacy technician. MOR Gavin indicated that technicians would be required to obtain national certifications “as necessary” and the schedule with the 2:5 supervisory ratio would be maintained going forward.

ACTION: Motion by D.BARNES, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2023-0078), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #6/CAS-2023-0126

PHA-2023-0027

Worcester Pharmacy, DS90368

Time: 09:51 AM

RECUSAL: NONE

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

- On January 19, 2023, Investigator Seed arrived at WP to conduct a RCI at approximately 9:50am and discovered that the front entrance was locked. He then observed that “there were lights on and 2 people were observed in the pharmacy department area. There is no gate securing the pharmacy department from the front store.”
- Investigator Seed was ultimately let in the front entrance by two pharmacy technicians. Investigator Seed learned that one of the technicians accessed the pharmacy with a key and alarm code. Investigator Seed also discovered that no pharmacist was present. The technicians indicated that they were “only cleaning” the pharmacy and were not filling prescriptions. They then explained that MOR El-Jarouch was delayed by traffic, and he was expected to arrive in about 2.5 hours.
- WP explained that MOR El-Jarouch was delayed by a traffic jam caused by a multi-car accident. The technician had the key to the pharmacy but not the alarm code because she was given the key to provide to a relief pharmacist. MOR EL-Jarouch decided to give her the code so the technicians could come into the pharmacy out of the cold.
- CA: WP indicated that “if the sole Pharmacist on Duty is ever required to leave the pharmacy premises for any reason, all pharmacy personnel would be required to depart, the pharmacy would be alarmed and locked, and signage would be posted to inform the public of the temporary closure of the pharmacy.” In addition, MOR El-Jarouch attested that non-pharmacist personnel no longer possessed front entrance keys or alarm codes. Furthermore, a new lock and key was installed in the front entrance. Lastly, WP was provided BOP Policy 2022-02 to facilitate compliance during any future absences of MOR.”

ACTION: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0027), 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/CAS-2023-0536

PHA-2023-0089

NELC, DS3513

Time: 09:55 AM

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

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

- On 4-11-2023, Investigator Van Allen issued a POC during an RCI to NELC after he discovered that the pharmacy failed to report a loss of 1 fentanyl 50mcg/mL-50mL vial. In turn, MOR Russo responded in a POC that “DEA Form 106 was completed. Form was sent to the DEA and BOP. Loss of Controlled Substance Form was completed and also submitted to the BOP” and “the DEA Form 106 will be completed for any loss and the Board will be notified of the loss within 7 days” going forward. Significantly, MOR Russo did not submit the supplemental items required by BORP Policy 2022-01.
- MOR Russo described in her response to this complaint that Pharmacist Jennifer Leung was interrupted by a staff member asking a question while removing 15 fentanyl 50mcg/mL-50mL vials from “cardboard box containers.” MOR Russo next described that “upon return to the task, [Pharmacist Leung] disposed of all fifteen boxes (fourteen empty & one full) with the assumption all boxes were empty.
- MOR Russo indicated that she reviewed surveillance video and confirmed that the vial was accidentally discarded in the trash. She explained that surveillance video was only stored for 30 days so was no longer available. MOR Russo then described that “upon determining the vial had been discarded, I completed DEA Form 41 [dated March 3, 2023] believing it was considered a destruction of a controlled substance, as we knew the root cause of the missing vial...”
- CA: MOR Russo described that a “Pharmacy Interruption Free Zone” was created where “all narcotic packages are to be opened and prepared to enter the clean room in front of the security camera...” MOR Russo added that any loss of narcotics would be promptly reported to BORP and DEA going forward.

ACTION: Motion by J .LOPEZ, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0089), 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/CAS-2023-0691

PHA-2023-0128

Advanced Compounding Solutions, WD521

Time: 10:00 AM

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

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

- On May 16, 2023, Investigator Lathum discovered during a WDI that ACS WD was not engaged in the wholesale distribution of prescription drugs and devices. Instead, ACS WD was using the licensed space to store overflow and expired products from a different business, ACS 503B RO. Investigator Lathum then discovered that ACS WD obtained a DEA Registration as a distributor for Schedule 3N & 4 controlled substances while only being licensed by BORP to distribute Schedule VI controlled substances.
- Accordingly, Investigator Lathum issued a POC based partly on the above-mentioned violations. In turn, ACS WD VP John Fantasia responded on behalf of the WD. Initially, VP Fantasia indicated that ACS WD would maintain its current use of the facility and may engage in wholesale distribution in the

future. Later, VP Fantasia agreed to relinquish ACS WD's BORP issued wholesale distributor licensure. In addition, ACS WD's surrendered its DEA Registration for cause.

- VP Fantasia explained that he relied on guidance from BORP Director of Pharmacy Compliance William Frisch when ACS WD obtained WD licensure from BORP. He provided emails in which ACS WD detailed that the space would be used to store supplies and Schedule VI drugs for ACS 503B RO and Director Frisch's guidance to apply for WD Licensure.

ACTION: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0128), No Discipline Warranted, Remediation Complete.

Case #9/CAS-2023-00760

PHA-2023-0132

Advanced Compounding Solutions, RO00001 Time: 10:03 AM

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

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

- BORP learned that ACS was issued a Warning Letter (WL) on 05-16-2023 by FDA and failed to notify BORP. According to the WL, FDA investigators inspected ACS from March 21, 2022 to April 28, 2022 of which ACS also failed to notify BORP.
- During the inspection, FDA investigators "noted that drug products you produced failed to meet the conditions of section 503B of the FDCA necessary for drugs produced by an outsourcing facility to qualify for exemptions from certain provisions of the FDCA. In addition, the investigators noted serious deficiencies in your practices for producing drug products intended or expected to be sterile, which put patients at risk." An FDA-483 was issued on April 28, 2022 based on the observed "serious deficiencies" which posed a risk to patients. ACS failed to notify BORP about the FDA-483.
- ACS worked to remediate the deficiencies over the next year. However, FDA ultimately deemed remediation inadequate and issued the WL. Of significance, FDA did not prohibit ACS from continuing to operate as a 503B facility and distribute drug product commercially.
- VP Fantasia admitted that ACS failed to notify BORP about the inspection, FDA-483, and WL. He indicated that failure was due to a lack of written policy on required notifications.
- CA: VP Fantasia indicated that senior leadership reviewed BORP regulations for outsourcing facilities "and worked with an outside quality and regulatory consultant and outside legal counsel regarding the response to this matter."
- Next, VP Fantasia described that ACS was in the process of finalizing "a standard operating procedure for addressing required notifications to the various federal and state regulatory bodies that regulate its operations." Once finalized, initial training will be rolled out followed by annual training. In addition, ACS's Board of Directors was notified about the complaint and the implementation of the new standard operating procedure.

ACTION: Motion by J. CHIN, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2023-0132), 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/CAS-2023-0240

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.

- On 01/30/2023, the Pharmacy submitted a timely RLCS, confirming an unknown loss of 100 hydrocodone 10 mg/ acetaminophen 325 mg tablets discovered during a cycle count on 01/10/2023. It is believed a bottle of 100 was accidentally discarded in the trash while the order was being checked in.
- MOR Scheer stated that she will review loss prevention policy and procedures with the staff in addition to reminding staff to back count all narcotics at the time of dispensing.
- All staff attested to reviewing the Policy and Procedure titled Pharmacy Colleague Asset Analytics and Insights/Drug Diversion.
- A Retail Compliance Inspection (ISP-21759) conducted on 07/20/2023 was deemed satisfactory.

ACTION: Motion by S. AHMED, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0058), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #11/CAS-2023-0026

PHA-2023-0018

CVS #2533, DS2933

Time: 10:10 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.

- A Retail Compliance Inspection conducted on 12/30/2022 indicated repeat deficiencies related to supervisory ratios and insanitary conditions, previously cited during an inspection on 07/01/2022.
- The 01/27/2023 POC response addressed the ratios and insanitary conditions, indicating that an ongoing review of schedules would occur to ensure compliance with BORP ratios, and the Pharmacy was working to get technicians certified. Additionally, a maintenance schedule was implemented to keep the Pharmacy organized and sanitary, as well as monthly monitoring of outdates.
- The response to the complaint indicated that the Pharmacy was out of ratio day on day of inspection because extra staff were brought in for couple of hours to help with workflow and clean up the Pharmacy. Former MOR Khalid indicated that the short staffing, as well as not having the ability to have a lead tech at the time contributed to this incident.
- Former MOR Khalid indicated that the overdue returns were addressed by scheduling additional staff at the Pharmacy. She also noted that the “short staffing is still the bigger and more important factor here to help avoid such incidents from occurring in the future”.
- A follow up inspection conducted on 03/31/2023 indicated that the Pharmacy was still cluttered and unorganized but did show improvement from the previous inspection. The POC response stated that expectations around cleanliness and organization in the Pharmacy were set with Current MOR Nguyen (effective 04/20/2023).

ACTION: Motion by D. BARNES, seconded by R. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0018), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND, with increased inspections.

Case #12

CAS-2023-0533

PHA-2023-0097

CVS #2128, DS2720

Time: 10:13 AM

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

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

- Inspectional deficiencies cited on 04/13/2023 for storage of epinephrine auto-injectors and needles/syringes in non-licensed pharmacy space, an immunization room. The POC stated the staff were trained to store these immunization supplies in the Pharmacy.
- The immunizing staff were unaware of the requirement so the immunization supplies were stored in the immunization room to be readily accessible. MOR Khalid indicated the room was newly constructed. The immunization supplies were moved into the Pharmacy next to the pharmacist station.
- CVS policy Pharmacist Administered Immunization Program states following administration of an immunization, all immunization supplies, including the emergency kit and Sharps container, are to be returned to the pharmacy.
- MOR Khalid stated the staff pharmacist, floater pharmacist, and immunizing technicians reviewed the policies regarding the location of the immunization kits in the Pharmacy. MOR Khalid, Pharmacist Brisbois, CPhT Nesterova, and PT Petrucci provide signed statements attesting CVS ROPP-0051 Pharmacist Administered Immunization Program had been reviewed.
- During a follow up inspection conducted on 07/17/2023, Investigator observed repeat deficiencies in the areas of drug storage, CS recordkeeping, refrigeration and 795 compounding.

ACTION: Motion by J. CHIN, seconded by R. MORELLI, and voted unanimously by those present, to CONSOLIDATE the matter (PHA-2023-0076), with PHA-2022-0082 and PHA-2022-0138, and refer to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 1 year, with special terms to include the CS Loss Protocol for all Benzodiazepines.

Case #13/CAS-2023-0554

PHA-2023-0105

CVS #2500, DS3606

Time: 10:17 AM

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

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

- RLCS for an amended unknown loss of #469 lorazepam 0.5mg discovered via corporate controlled substance monitoring on 3/16/23. Cycle counts, controlled substance recordkeeping, schedules, and video were reviewed.
- MOR Dumond stated he was instructed to perform cycle counts. He indicated that upon further investigation he alleged the loss was due to PT Bui performing incorrect cycle counts. He related that lorazepam tablets are double counted by hand. The labels for the prescription are initialed by the team member who counted the medication at production indicating it was double counted.
- Cycle counts for 12/31/22 to 4/1/23 were provided for all NDCs stocked by the Pharmacy from 12/31/22 to 4/1/23. Cycle counts for the reported NDC loss were performed by MOR Dumond, PT Bui, PTT Milonopoulos, and PI Salazar and showed an overall variance of only -78 based on the BOH in the Pharmacy. The initial reconciliation report provided for -408 tablets was performed for the date range of 12/2/22 to 3/26/23. The amended reconciliation report provided for -469 tablets was performed for the date range of 5/1/22 to 4/9/23.
- MOR Dumond spoke with PT Bui and under direct supervision reviewed his method of performing cycle counts. MOR Dumond stated, "After observation, I gave him detailed instructions as to how the cycle counts must be done. I reviewed his cycle counts for 2 weeks to see if they were properly executed, which they were". MOR Dumond attested that all policies and procedures for the proper storage and handling of controlled substances have been reviewed.

ACTION: Motion by R. LOPEZ, seconded by K. THORNELL , and voted unanimously by those present, to refer the matter (PHA-2023-0105), 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 STAYED PROBATION, for a period of 1 year, with special terms to include the CS Loss Protocol for all Benzodiazepines.

Topic IX: Executive Session Call to Order: Time: 10:22 AM

By: C. Belisle reads the executive session language and requests a motion to enter executive session.

Action: A motion was made by to D. Barnes enter Executive Session; Seconded by R. Lopez and Board Members present voted unanimously by roll call to approve motion. Roll call attendance: J. Lanza, yes; S. Hamilton, yes; C. Belisle, yes; D. Barnes; J. Rocchio, yes; J. Chin, yes; R. Lopez, yes; S. Ahmed, yes; R. Morelli, yes; K. Thornell, yes; D. Perry, yes; J. Lopez, yes.

Topic X: Adjudicatory Session (M.G.L. ch. 30A, §18) Time: 11:07 AM

DISCUSSION: None

ACTION: President C. Belisle request a motion to enter 65C.

At 10:33 AM J. Lanza, seconded by C. Jean-Francois and voted unanimously by all those present to enter 65C by roll call vote.

Topic XI:

65C Sessions MGL c. 112 section 65C

Time: 10:33 AM

DISCUSSION: None

ACTION: President C. Belisle request a motion to enter 65C.

At 10:33 AM J. Lanza, seconded by C. Jean-Francois and voted unanimously by all those present to enter 65C by roll call vote.

Lunch 11:59 AM to 12:30 pm

Topic XI

ADJOURNMENT OF MEETING

TIME: 1:27 PM

ACTION: Motion by S. Hamilton seconded by D. Barnes and voted unanimously by those present, to adjourn from General Session by roll call vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 9/7/22 General Session
2. Draft Minutes of the 8/3/23 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on probation
5. Report on Board Delegated Complaint Review to licensure policy 14-02
6. Report on PSUD 17-03
7. Application: Freedom FP Fertility; DS89716 – Relocation
8. Application: Freedom Fertility; DS89717 – Relocation
9. Application: Price Chopper; DS89863 – Petition for Waiver
10. Policy 14-02: Board Delegated Review (BDR)
11. Policy 13-01: Licensure Applications and Notices
12. Policy 2023-10: Unfilled Prescriptions
13. Policy 2023-02: Vaccine Administration
14. Policy 2020-15: Scope of Practice
15. CAS-2023-0106 PHA-2023-0556 Walgreens #3151, DS2470
16. CAS-2023-0311 PHA-2023-0064 SOFIE, NU00021
17. CAS-2023-0309 PHA-2023-0063 Amerita, DS90296
18. CAS-2023-0169 PHA-2023-0028 NIMVAX, Inc, DS90369
19. CAS-2023-0396 PHA-2023-0078 Bouvier Pharmacy, DS90037
20. CAS-2023-0126 PHA-2023-0027 Worcester Pharmacy, DS90368
21. CAS-2023-0536 PHA-2023-0089 NELC, DS3513
22. CAS-2023-0691 PHA-2023-0128 Advanced Compounding Solutions, WD521

- 23. CAS-2023-0760 PHA-2023-0132 Advanced Compounding Solutions, RO00001
- 24. CAS-2023-0240 PHA-2023-0058 CVS #84, DS89733
- 25. CAS-2023-0026 PHA-2023-0018 CVS #2533, DS2933
- 26. CAS-2023-0533 PHA-2023-0097 CVS #2128, DS2720
- 27. CAS-2023-0554 PHA-2023-0105 CVS #2500, DS3606

Respectfully Submitted,
Jennifer Chin, RPh, Secretary