COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

February 2, 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/onstage/g.php?MTID=ed9237bce2807d1f83610bf0d8c26b361

To access the meeting by phone:

Call in Number: 1-650-479-3208 Access Code: 2533 559 1449

Attendee: #

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 Draft of January 12, 2023 Regular Session Minutes 		
8:10	IV	 REPORTS Applications approved pursuant to Licensure Policy 13-01 Monthly report from Probation Board Delegated Review pursuant to Licensure Policy 14-02 PSUD Report-Policy 17-03 		

8:15	V	 Pharmacy issues related to COVID-19 NABP Annual Meeting – May 10-12, 2023, Nashville, TN Summary of Pharmacy Advisory Committee Meeting held on January 25, 2023 Pharmacy Advisory Committee Meeting Recommendation document 23-02 for upcoming Advisory Committee meeting Clarification of Controlled Substance Loss Protocol Discussion of Open Meeting Law 	D. Sencabaugh S. Ahmed	
9:00	VI	 APPLICATIONS HMC Pharmacy – New Community Pharmacy Westminster Pharmacy; DS1710 – Renovation Nimvax; DS90369 – Petition to Change the Controlled Substance permit Option Care – Petition for Waiver Mina Hanna; PH164658 – Petition for Waiver 		
10:00	VII	REGULATIONS • 247 CMR 18.00: Non-Sterile Compounding		
10:20	VIII	FILE REVIEW 1 CAS-2022-0245 PHA-2022-0049 Walgreens #17169, DS90196 2 CAS-2022-0714 PHA-2022-0128 Walgreens #17169, DS90196 3 CAS-2022-1057 PHA-2022-0175 Walgreens #7734, DS3411 4 CAS-2022-1198 PHA-2022-0189 Fenway Pharmacy, DS3583 5 CAS-2022-1192 PHA-2022-0185 CVS #505, DS89977 6 CAS-2022-1074 SA-INV-20825 CVS #17727, DS90243 7 CAS-2022-1013 PHA-2022-0170 CVS #6, DS18582 8 CAS-2022-1101 PHA-2022-0179 CVS #1854, DS2085		
12:00		LUNCH BREAK		

12:30	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.	
1:30	X	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)	
2:00	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 February 2, 2023

Board Members Present

Caryn Belisle, RPh, MBA, President
Katie Thornell, RPh, MBA President Elect (leave 2:56 PM)
Jennifer Chin, RPh, Secretary
Sebastian Hamilton, Pharm D, MBA, RPh
Carly Jean-Francois, RN, NP
John Rocchio, RPh, PharmD (leaves 2:21 PM)
Dr. Richard Lopez, MD
Sami Ahmed, PharmD., RPh, BCPS, BCSCP (leaves 1:36 PM)
Rita Morelli, PharmD, BCACP, RPh
Johanna Lopez, MS

<u>Board Members Not Present</u> Delilah Barnes, RPh

Dawn Perry, JD

Board Staff Present

Julie Lanza, CPhT

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
Ed Taglieri, MSM, NHA, RPh PSUD Supervisor
Richard Harris, Program Analyst
Joanna Chow, Office Support Specialist
Taylor Lee, Office Support Specialist
Joanne Trifone, RPh, Director of Investigations
Christina Mogni, RPh, Investigator
Gregory Melton, JD, PharmD, BCPS, Investigator
Nancy Aleid, Compliance Officer

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:01 AM

A quorum of the Board was present, established by roll call. President C. 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; J. Rocchio, yes; J. Chin, yes; J. Lopez; R. Lopez, yes; S. Ahmed, yes; R. Morelli, yes; C. Jean-Francois, yes; K. Thornell.

Draft Minutes General Session: 2/2/23

Topic II. Approval of Agenda TIME 8:02 AM

Agenda: 2/2/23

DISCUSSION:

Defer Application: Westminster Pharmacy

Defer Application: Nimvax

Edit license number for Application M. Hanna

ACTION:

Motion by J. Lanza, seconded by J. Chin and voted unanimously by those present to approve the agenda with no noted change by roll call vote.

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

Minutes

1. Draft: 1/12/23

Change: no changes

Action:

Motion by K. Thornell, seconded by S. Ahmed and voted unanimously by those present to approve the agenda with no noted change by roll call vote. S. Hamilton abstains.

TOIC IV Reports
Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: M. BOTTO

<u>DISCUSSION:</u> M. Botto reported 30 Change of Manager applications, 1 transfer of ownership, and 2 facility closures that have been approved via Staff Action since the January 12th Board meeting. So noted.

TIME: 8:05 AM

TIME: 8:05 AM

TIME: 8:05 AM

Topic IV. REPORTS

Monthly Report from Probation

PRESENTED BY: M. BOTTO

<u>DISCUSSION:</u> M. Botto indicated no Board Delegated Review to report since the last Board meeting.

So noted.

Topic IV. REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: M. BOTTO

<u>DISCUSSION:</u> M. Botto reported 5 CE discrepancies that were closed with no discipline warranted and remediation complete. 1 CE loss complaint was reported, which warranted non-disciplinary stayed probation for 1 year.

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So noted.

Topic IV. REPORTS

PSUD report by Staff Action 17-03

PRESENTED BY: E. TAGLIERI

<u>DISCUSSION:</u> E. Taglieri reported a total of 9 active members in the PSUD program with no new

admissions pending.

So noted.

TOPIC V Flex

1. Pharmacy issues related to COVID-19

i. Presented by: D. SENCABAUGH

Discussion: The federal emergency declarations will terminate on May 11, 2023. Updates will be provided as they become available.

TIME: 8:06 AM

Time: 8:06 AM

Time: 8:10 AM

ii. Presented by: M. CHAN

Discussion: Last week, the FDA sent a notification that Evusheld is no longer FDA authorized for emergency use. However, the Board has an existing joint policy with Drug Control Program and the Immunization Program regarding its administration.

The Evusheld information was removed from *Policy 2022-05: COVID-19 Vaccine and Evusheld Administration by Qualified Pharmacy Personnel* leaving only the COVID-19 vaccine information in place.

The policy has been renamed *Policy 2022-05: COVID-19 Vaccine Administration by Qualified Pharmacy Personnel.*

Action: Motion by J. LANZA, seconded by C. JEAN-FRANCOIS, and voted unanimously by roll call of those present, to approve the edits to the policy.

2. NABP Annual Meeting – May 10-12, 2023, Nashville, TN

Presented by: D. SENCABAUGH

Discussion: The NABP annual meeting will be held in May and next month, a vote will be held for a delegate and an alternate to represent the Board. NABP offers one grant up to \$1500 for one person to attend.

So noted.

3. Summary of Pharmacy Advisory Committee Meeting held on January 25, 2023, Time: 8:12 AM Presented by: S. AHMED

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Draft Minutes General Session: 2/2/23

Discussion: An overview of the January 25, 2023, Advisory Committee meeting was presented. The topic was 247 CMR 18.00 Non-Sterile Compounding where the Advisory Committee members offered input for the Board to discuss further.

So noted.

4. Recommendation document 23-02 for upcoming Pharmacy Advisory Committee meeting Time: 8:15 AM

Presented by: W. FRISCH

Discussion: The Pharmacy Advisory Committee is requested to review and provide input to the Draft Regulations, 247 CMR 2.00 *Definitions and Severability* at their March 22, 2023, meeting. Designation of a Board Member to present the recommendation document to the Pharmacy Advisory Committee and provide a summary of the meeting to the Board was also requested.

Action: Motion by S. HAMILTON, seconded by R. MORELLI, and voted unanimously by roll call of those present, to appoint S. AHMED with J. LANZA as an alternate to present the Pharmacy Advisory Recommendation request (23-02) to the Pharmacy Advisory Committee on March 22, 2023, and then provide an update to the Board at the April 6, 2023, meeting.

5. Clarification of Controlled Substance Loss Protocol

Presented by: J. PETRILLO

Discussion: Clarification was requested regarding the controlled substance Unknown Loss Protocol that requires that the area pharmacy supervisor or loss prevention manager to review and validate, at least every 30 days, the pharmacy's compliance with medication counts as well as to maintain documentation of such.

Time: 8:19 AM

Time: 8:08 AM

This review and validation may take place remotely and a written attestation that the review has been completed must be submitted to the Board's probation officer with a copy readily available in the pharmacy.

6. Discussion of Open Meeting Law

Presented by: D. SENCABAUGH

Discussion: The exception to the open meeting law allowing virtual Board meetings is scheduled to end on March 31, 2023. Unless the allowance is extended or changed, Board meetings will be inperson starting with the April meeting.

So noted.

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TOPIC VI Applications

1.HMC Pharmacy - New Community Pharmacy

Represented by: Philipe Goncalvez & Eric Teer

Recusal: none Discussion:

E. Teer indicates that they are opening a retail pharmacy as patients are being discharged from the hospital that way, they can get their medications quicker. They have several of these pharmacies across the country and plan on opening the pharmacy to the public as well. C. Belisle inquires if the pharmacy will be located within the hospital and whether they have gotten approval from Health Care Quality. E. Teer indicates that they have received approval from Health Care Quality and have a letter from them stating that they did not need to go through the formal inspection process because it had no impact on hospital operations. D. Sencabaugh indicates that the pharmacy should have a mechanism in place allowing patients to choose any pharmacy of their choice which is a requirement in Massachusetts. E. Teer indicates that they have staff who present the pharmacy program and give them the option to switch over or keep their current pharmacy. C. Belisle inquired if they would provide meds to beds for a certain number of days before transferring the script over and if that was an option the pharmacy was going to provide. E. Teer responds that they do provide that service, offer free mail orders, and have an automated system to send out reminders regarding refills. S. Hamilton inquires what system the pharmacy would use. E. Teer responds that they use whatever system the hospital uses, and the designation of the pharmacy happens in Epic. E. Taglieri states that he wants to ensure that the pharmacy is working off a script and not just a hospital order. E. Teer indicates that they do e-prescribe. J. Chen inquires what happens if the pharmacy is discharged on the weekend and E. Teer responds that the script will go to their regular pharmacy, and they don't receive notifications. J. Rocchio inquires when the cut off for taking scripts will be. E. Teer responds that the cut off is Friday at 5 PM. Other board members had the opportunity to ask questions and inquire about the business model of HMC pharmacy and HMC representatives responded. J. Lopez inquired if the pharmacy were to put medication instructions in other languages and E. Teer responded that they did. B. Frisch asked the pharmacy to withdraw their attestations to engage in complex level non-sterile compounding and sterile compounding if they are not engaging in these practices. E. Teer responded that they did mark the area for the non-sterile compounding and included that in the drawing. E. Teer responds that they will not be performing complex non-sterile and sterile compounding.

TIME: 8:41 AM

Motion to approve the application for a new community pharmacy pending successful inspection and withdrawal of complex non-sterile and sterile compounding attestations made by S. Hamilton; Seconded by R. Lopez, then Board Members presented voted unanimously by rollcall to approve motion.

2. Westminster Pharmacy DS1710- Renovation

Deferred

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3. Nimvax- Change of CS registration

Deferred

4. Option Care- Petition for Waiver

Represented by: Kathrine McDowell, Brier Olsen

Recusal: none Discussion:

K. McDowell indicates that she is before the board to request a waiver to longer carry CII pain medication therapy. She indicates that Option Care specializes in IV, antibiotics, TPN, and specialty medications and CII pain medications are not an area of their clinical specialization as a company. If they receive a prescription for a CII pain medication, they refer both the prescriber and the patient to an alternative provider who specializes in that as they do not service hospice patients. C. Belisle inquired if they were requesting a waiver of 247 CMR 6.02 (4) requiring a pharmacy to maintain a sufficient supply of medical preparations and chemicals. K. McDowell indicated that this information was correct and that they carry a few CIII-CV medications.

TIME: 9:05 AM

TIM: 9:09 AM

Motion to approve the waiver as submitted made by S. Hamilton; Seconded by S. Ahmed, then Board Members presented voted unanimously by rollcall to approve motion.

5. Mina Hanna PH164658- Reactivation Waiver

Represented by: Mina Hanna

Recusal: J. Rocchio

Discussion:

M. Hanna indicated that he is coming before the board of request a waiver of the requirement to retake the MPJE due to a lapse in his license expiration. He provided board members with context as to why there was a lapse in his licensure given some health issues he experienced. M. Botto indicated that Mr. Hanna would still have to go through the entire licensure reactivation process but was only looking to waive the MPJE component of it.

Motion to approve the waiver to retake the MPJE and receipt of all requested documents made by R. Lopez; Seconded by C. Francois, then Board Members presented voted unanimously by rollcall to approve motion.

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TOPIC VII Regulations

247 CMR 18.00: Non-Sterile Compounding Time: 9:20 AM

Presented by: W. FRISCH and M. CHAN

Discussion: This section has undergone some changes since the Board last approved a draft on April 2, 2021, primarily due to the publication of the revised USP <795> that was released on November 1, 2022.

Many suggestions from the Pharmacy Advisory Committee were incorporated, but a few proposed standards were flagged for Board discussion. Many duplicative standards that are also in the revised USP <795> were removed making for a substantially streamlined document.

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

TOPIC VIII File Review

Case #1 CAS-2022-0245 PHA-2022-0049 Walgreens #17169, DS90196 Time: 09:42 AM

RECUSAL: NONE

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

- On December 21, 2021, WAG 17169 notified BORP about a possible loss of federally scheduled controlled substances. However, WAG 17169 failed to submit an initial BORP RLCS form at that time. Then, failed to submit a final RLCS within 21 days of the pharmacy's initial report of loss. After prompting by BORP, WAG 17169 ultimately submitted a final report on March 9, 2022.
- According to the reports, unknown losses of multiple Schedule II controlled substances including 793
 amphetamine mixed salts tablets of various strengths, 73 methylphenidate 20mg tablets, and 130
 oxycodone 5mg tablets were discovered on December 21, 2021. Ultimately, WAG 17169 was unable
 to resolve the discrepancies or determine a cause for the losses. However, WAG 17169 indicated that
 no evidence of diversion was uncovered, and no further discrepancies occurred since the losses
 discovered on December 21, 2021.
- DEA and BORP inspected the pharmacy after learning of the above-mentioned losses. DEA indicated
 that the vast majority of discrepancies occurred when Former MOR Shakeri was MOR. DEA indicated
 that WAG 17169 would have been issued an LOA and would have requested Former MOR Shakeri be
 terminated from employment had he still been MOR due to very poor recordkeeping. DEA did not
 suspect diversion just terrible recordkeeping by Former MOR Shakeri. Of note, DEA was unable also
 unable to reconcile WAG 17169's inventory.
- DEA chose not to issue a LOA because Current MOR Patel had done an outstanding job reconciling the
 past controlled substance inventory while maintaining good order for current recordkeeping during
 his tenure as MOR. DEA requested and Walgreens corporate agreed to allot Current MOR Patel time

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- designated for controlled substance recordkeeping so he could maintain good order in the pharmacy going forward in lieu of a LOA.
- CA: MOR Patel indicated that "verbal counseling with the pharmacists working at this location to properly receive and log control medications. Going forward, when there is a discrepancy, it should be brought to the attention and solved."

ACTION: Motion by J. CHIN, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0049), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a 1-year PROBATION with special terms to include a CII perpetual inventory to be conducted every 10 days with a monthly attestation sent to the Board's Probation Monitor. A second motion was made by J. CHIN, seconded by J. LOPEZ, and voted unanimously by those present, to open a complaint on Former MOR Mohammad Shakeri (PH19962).

Case #2/CAS-2022-0714

PHA-2022-0128 Time: 09:48 AM Walgreens #17169, DS90196

RECUSAL: NONE

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

- Initially, BORP opened a complaint (PHA-2022-0049) against WAG 17169 after the pharmacy reported unknown losses of multiple Schedule II controlled. On June 8, 2022, BORP Investigator Nathan Van Allen and diversion investigators from the United States Drug Enforcement Administration (DEA) conducted a joint inspection (ISP-18755) at WAG 17169 as part of the investigation of the abovementioned unknown losses.
- During the inspection, Investigator Van Allen learned that Current MOR Mitul Patel was appointed MOR on September 13, 2021. However, WAG 17169 failed to notify BORP about the change in MOR. Consequently, Investigator Van Allen issued a plan of correction (POC) to the pharmacy. This complaint was then opened against WAG 17169 for failing to report the change in MOR discovered during ISP-18755.
- On July 1, 2022, WAG 17169 was sent notice of this. At the same time, WAG 17169 was notified that the pharmacy must properly notify BORP on or before July 25, 2022, about the change in MOR appointing Current MOR Patel.
- WAG 17169 failed to submit the change in MOR application as required. On September 7, 2022, Investigator Van Allen conducted a retail compliance inspection (ISP-19574) at WAG 17169. Investigator Van Allen followed up with Current MOR Patel about the status of the pharmacy's change in MOR application.
- Current MOR Patel explained that the application was sent to Walgreens' corporate office in early August 2022, but Walgreens' corporate office had not acted any further on the application. Investigator Van Allen, again, issued a POC to WAG 17169 based in part on the continued failure to properly notify BORP about the change in MOR appointing Current MOR Patel.
- Ultimately, BORP received WAG 17169's application on October 11, 2022, erroneously indicating the change in MOR took place on 09/04/2022.

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<u>ACTION</u>: Motion by J. CHIN, seconded by K. THORNELL, and voted unanimously by those present, to consolidate the matter (PHA-2022-0145) with PHA-2022-0049, 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 a 1-year PROBATION.

Case #3/CAS-2022-1057

PHA-2022-0175 Walgreens #7734, DS3411 Time: 09:52 AM

RECUSAL: NONE

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

- On August 31, 2022, Investigator Nathan Van Allen discovered that Melissa Scrima, who was listed as
 the MOR in BORPBHPL records at that time, was on extended leave. At that time, WAG 7734 was
 unable to confirm whether an Interim MOR or permanent MOR was appointed. WAG 7734 was also
 unable to confirm whether requirements to notify BORP about the change in MOR and complete a
 change in MOR CS inventory were accomplished.
- Accordingly, Investigator Van Allen issued a plan of correction in part for the violations described above and WAG 7734 submitted a POC as required. The pharmacy indicated that BORP was notified on September 1, 2022, that Current MOR Deborah Hallett "would serve as MOR until Former MOR Scrima's return."
- According to DM Feeney, Former MOR Scrima "unexpectedly left active employment for [LOA]" on August 22, 2022. BORP was notified on September 1, 2022, that Current MOR Hallett would be serving as Interim MOR until Melissa Scrima's return. Then, Current MOR Hallett completed a change in MOR application appointing her permanent MOR on September 14, 2022, and a corresponding controlled substance inventory on September 19, 2022. BORP Staff confirmed that an email appointing Current MOR Hallett as Interim MOR and a change in MOR application appointing her permanent MOR were received.
- Of note, WAG 7734 was only able to provide a copy of an incoming controlled substance inventory completed in September 2022 for the permanent change in MOR.
- CA: DM Feeney notified BORP about the changes in MOR appointing Current MOR Hallett as Interim followed by permanent MOR. DM Feeney underscored that "Walgreens is committed to a timely permanent replacement for [Former MOR Scrima] should she not return to work within the 100-day timeframe and will notify the Board of Pharmacy as appropriate."

<u>ACTION</u>: Motion by S. AHMED, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2022-0175), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a. REPRIMAND

Case #4/CAS-2022-1198

PHA-2022-0189 Fenway Pharmacy, DS3583 Time: 09:56 AM

RECUSAL: NONE

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

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- RLCS for unknown loss of #38 oxycodone 10mg tablets. On the RLCS form MOR Balram indicated he
 concluded that the missing bottle of 38 tablets may have mistakenly fallen in the trash which is next to
 the CII cabinet. The DEA 106 stated the loss may have occurred as miscounting of an order or
 discarded. A copy of the perpetual inventory for the NDC in question was submitted which showed
 no movement since 04/13/2022.
- Pharmacist Lee discovered the discrepancy during the reconciliation of the perpetual inventory. He
 searched all the shelves. All NDCs were recounted, and the tablets were inspected to ensure two
 NDCs had not been combined when the last prescription was filled. MOR Balram was notified, and he
 contacted the patient who had received the last fill. The patient confirmed receiving only one NDC of
 tablets and no extra tablets.
- MOR Balram stated it was presumed Pharmacist MacCurtain inadvertently discarded the tablets when she filled the last prescription on 7/7/22. The filling bench had multiple bottles of medications which may have contributed to the loss.
- MOR Balram advised Pharmacist MacCurtain to back count future CII fills, fill CII prescriptions away
 from trash containers, perform CII inventories away from trash containers, and keep the work area
 organized including reducing multiple stock bottles in her workspace. The staff pharmacists provided
 a signed and dated statement which indicated, "All pharmacists know how to handle, log, and secure
 all controlled substances and to report any discrepancies to the pharmacy manager as soon as
 possible".

<u>ACTION</u>: Motion by S. HAMILTON, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2022-0189), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

Case #5/CAS-2022-1192

PHA-2022-0185

CVS #505, DS89977

Time 09:59 AM

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

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

- During an inspection on 10/3/22, it was observed that a controlled substance inventory for a MOR change was completed on 9/18/22 but Former MOR Hanslia was still listed as MOR.
- Current MOR O'Hearn stated she assumed the MOR role on 9/18/22 when a CS inventory was completed. A copy of the CIII-CV inventory only was provided that was signed by Current MOR O'Hearn and Former MOR Hanslia. The application was completed, signed, and notarized on 10/4/22 and was mailed on 10/6/22. UPS tracking showed it was delivered on 10/7/22. MOR O'Hearn and DL Frageau both stated the application was completed within a 30-day window.
- According to the POC, the MOR will ensure that all process steps for future MOR changes are
 completed and submitted to the BORP as expected. A copy of CVS "Pharmacists in Charge and Powers
 of Attorney at CVS Health" was provided that was signed by the staff pharmacists confirming it had
 been reviewed.

<u>ACTION</u>: Motion by J. CHIN, seconded by S. AHMED, and voted unanimously by those present, refer the matter (PHA-2022-0185), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

Case #6/CAS-2022-1074

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Time: 10:02 AM

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

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

- Allegation by PT Gilman that the Pharmacy did not have a MOR for 5 months and a floater pharmacist, identified as Former MOR Rigas, brought her unlicensed daughter, PTT Rigas, into work at the Pharmacy on multiple occasions. PTT Rigas' license expired on 6/26/20.
- During a site visit on 9/8/22, it was noted Former MOR Rigas became MOR on 07/1/22. The Pharmacy was cluttered, needed organization, and expired CIIs were not reconciled. Investigator Van Allen discussed the allegations with DL Ekbatani who "acknowledged the unlicensed individual in the pharmacy and noted that corrective action had been conducted". On 10/7/22, Sr. Analyst Furtado stated Former MOR Rigas was no longer employed by CVS and a potential new MOR was hired. The POC stated HR was investigating the specific instance of PTT Rigas working in the Pharmacy.
- Former MOR Rigas responded her last day was on 10/6/22. Until April 2022, she had worked as a floater then was assigned to the Pharmacy. After Former MOR Rasla gave her notice, she agreed under duress to temporarily become the MOR temporarily until August. She completed CS inventories on 7/17/22, worked 7/19/22 then was off until 8/9/22. She alleged she had minimal to no help in the Pharmacy, so she asked PTT Rigas to come in as a last resort. She claimed PTT Rigas worked one day in May as a cashier only (when Former MOR Rigas was a staff pharmacist). CVS HR had no record of PTT Rigas working after 9/2/21 but worked unlicensed for 137 hours total at 2 other locations from 7/16/20-9/2/21.
- A response could not be obtained by CVS from PT Gilman. DL Ekbatani confirmed Former MOR Rigas
 agreed to become MOR temporarily and the potential MOR hired for August didn't occur. Current
 MOR Amin assumed the role on 10/18/22. After the fact, PTT Rigas was found working without
 punching in against CVS policies.
- According to the POC, having non-CVS and unlicensed employees in the pharmacy is strictly against
 policy and is addressed during training which DL Ekbatani reviewed with her pharmacy team. DL
 Ekbatani and Current MOR Amin will ensure compliance is met. DL Ekbatani will double check all MOR
 change paperwork for accuracy prior to submitting to avoid future delays. Current MOR Amin and
 Staff pharmacist signed copies of BORP Policy 2022-02: Extended Absence of a Manager of Record and
 CVS policies Pharmacists in Charge and Powers of Attorney at CVS Health Professional Standards
 confirming review.

<u>ACTION</u>: Motion by C. BELISLE, seconded by K. THORNELL, and voted unanimously by those present, to DEFER the matter (SA-INV-20825). A second motion was made by C. BELISLE, seconded by S. AHMED, to open a complaint on Pharmacist Irene Rigas, (PH23188). A third motion was made by C. BELISLE, seconded by C. JEAN-FRANCOIS, to open a complaint on Pharmacy Technician Trainee Angelique Rigas (PTT05467).

Case #7/CAS-2022-1013

PHA-2022-0170 CVS #6, DS18582 Time: 10:30 AM

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

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

- On August 23, 2022, Investigator Nathan Van Allen discovered during a retail compliance inspection (ISP-19352) at WAG 6349CVS #6 that Ahmed Seid who was listed as the MOR in BORP records at that time, was no longer MOR. Instead, Seid was transferred in July 2022 and Former MOR Jessica Kwak was appointed MOR. Accordingly, Investigator Van Allen issued a plan of correction (POC) to CVS 6.
- CVS 6 submitted a POC as required. The pharmacy indicated that Former MOR Kwak completed a change in MOR inventory on 08/29/2022 and submitted change in MOR application on 08/25/2022 to correct the deficiencies cited during ISP-19352.
- In addition, CVS 6 indicated that Current MOR Jhanvi Shah had also completed a change in MOR inventory and submitted a change in MOR application on 09/06/2022 as required in anticipation of her appointment as MOR in September 2022.
- BORP opened this complaint against CVS 6 for the above-mentioned violations. District #3 Leader (DL)
 Kizzie Carter responded on behalf of the pharmacy on 010/24/2022. DL Carter indicated that she
 recently was appointed DL and she was responsible for CVS 6.
- According to DL Carter, the former DL for the area did not complete Former Interim MOR Kwak's
 change in MOR application "which would have caused a delay in follow up with the District Admin or
 DPC [District Performance Coordinator] who normally files the paperwork."
- CA: DL Carter underscored that she would "ensure the DPC immediately is informed and completes the MOR paperwork follow up as soon as we become aware there will be a change." In addition, copies of 247 CMR 6 and BORP 2022-02 were sent to CVS Health Regulatory Affairs with an emphasis on requirements for the outgoing and incoming MOR or Interim MOR to complete Schedule II-V inventories.

<u>ACTION</u>: Motion by J. LOPEZ, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2022-1013), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

Time: 10:33 AM

Case #8/CAS-2022-1101

PHA-2022-0179

CVS #1854, DS2085

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

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

- On September 12, 2022, Investigator Van Allen conducted a retail compliance inspection (ISP-19515) at CVS 1854. During the inspection, he discovered that Devin Bachmann, who was listed as the MOR in BORP records at that time, was no longer MOR. Instead, Current MOR Christopher Dean was MOR. Investigator Van Allen noted that a change in MOR inventory was completed on January 28, 2022, but the corresponding application for the change in MOR was not on record as received by BORP.
- Accordingly, Investigator Van Allen issued a plan of correction in part for the violations described above and CVS 1854 submitted a POC as required. CVS 1854 asserted that the application for a change in MOR appointing Current MOR Dean as MOR was submitted to BORP and the check to pay for the change was cashed by BORP.

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 BORP opened this complaint against CVS 1854 for the above-mentioned violations cited by Investigator Van Allen during ISP-19515 before CVS 1854 submitted proof of submission of the application and payment in the POC. BORP Staff confirmed that the CVS 1854 did submit the application and payment as asserted in the pharmacy's POC. Thus, the pharmacy did notify BORP about the change in MOR.

ACTION: Motion by S. HAMILTON, seconded by J. CHIN, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0179), No Violation.

Topic IX: Executive Session Call to Order: Time: 10:36 AM

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

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

Sami Ahmed, PharmD., RPh, BCPS, BCSCP (leaves 1:36 PM)

Topic X: Adjudicatory Session MGL chapter 30A; section 18 Time: 2:03 PM

DISCUSSION: None

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

At 2:03 PM S. Hamilton, seconded by J. Chin and voted unanimously by all those present to enter 65C by roll call vote.

John Rocchio, RPh, PharmD (leaves 2:21 PM) Katie Thornell, RPh, MBA President Elect (leave 2:56 PM)

Topic XI: 65C Sessions MGL c. 112 section 65C Time: 10:42 AM

DISCUSSION: None

ACTION: President C. Belisle request a motion to enter M.G.L 65 c Session.

At 10:42 AM J. Lanza seconded by J. Lopez and voted unanimously by all those present to enter M.G.L. chapter 65 c Session by roll call vote.

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TIME: 3:46 PM

ACTION: Motion by S. Hamilton seconded by J. Lanza 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 2/2/23 General Session
- 2. Draft Minutes of the 1/12/23 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. HMC Pharmacy New Community Pharmacy
- 8. Westminster Pharmacy; DS1710 Renovation
- 9. Nimvax; DS90369- Petition to Change the Controlled Substance permit
- 10. Option Care Petition for Waiver
- 11. Mina Hanna; PH164658 Petition for Waiver
- 12. 247 CMR 18.00: Non-Sterile Compounding

13. CAS-2022-0245	PHA-2022-0049 Walgreens #17169, DS90196
14. CAS-2022-0714	PHA-2022-0128 Walgreens #17169, DS90196
15. CAS-2022-1057	PHA-2022-0175 Walgreens #7734, DS3411
16. CAS-2022-1198	PHA-2022-0189 Fenway Pharmacy, DS3583
17. CAS-2022-1192	PHA-2022-0185 CVS #505, DS89977
18. CAS-2022-1074	SA-INV-20825 CVS #17727, DS90243
19. CAS-2022-1013	PHA-2022-0170 CVS #6, DS18582
20. CAS-2022-1101	PHA-2022-0179 CVS #1854, DS2085

Respectfully Submitted, Jennifer Chin, RPh, Secretary

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