COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

June 1, 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=m2d8f29b1a44bc6b87767ecc3a304d58d

To access the meeting by phone:

Call in Number: 1-650-479-3208 Access Code: 2534 632 6833

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 May 4, 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	FLEX • NABP Annual Meeting Summary	K.Thornell
9:00	VI	 APPLICATION HealthCare Technology; WD507 – Relocation ProCare LTC; DS90042 – Petition for a waiver Geiger Gibson Community Health Pharmacy; DS89760- 	Waiver
9:45	VII	 POLICIES Policy 2020-15: Scope of Practice (Revisions) Policy 2023-08: Pharmacy Technician Stocking of A Dispensing Devices (ADD) 	utomated
10:00	VIII	 Policy 2022-04: Use of Pharmacy Technician Traine Automated Dispensing Devices Advisory: Use of Technology to Check Inventory Marketivities Performed by Certified Pharmacy Technic 	anagement
10:10	IX	VIOLATION OF STAYED PROBATION • CVS#321, DS2989 - PHA-2021-0049	
10:30	X	FILE REVIEW 1 CAS-2022-1629 PHA-2023-0011 Victoria Okel PH25059 2 CAS-2022-1111 PHA-2023-0065 Christopher OpH25844 3 CAS-2022-1111 SA-INV-21764 Walgreens #1 DS90207 4 CAS-2023-0081 PHA-2023-0026 Prince Ogbor PH22660 5 CAS-2023-0306 SA-INV-21789 Joslyn Pesta,	Oushing 9240 Ina,
		6 CAS-2023-0300 PHA-2023-0086 Letourneaus DS2777 7 CAS-2023-0229 PHA-2023-0051 Ash Pharmac DS90321	Pharmacy,
		8 CAS-2023-0233 PHA-2023-0052 CVS #444, D 9 CAS-2022-1573 PHA-2023-0007 CVS #23, DS	
		10 CAS-2022-1383 PHA-2022-0212 CVS #1862,	DS2712

12:00		LUNCH BREAK		
12:30	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, to review a violation of stayed probation and to evaluate the Good Moral Character as required for registration for a pending applicant.		
1:30	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 June 1, 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
Carly Jean-Francois, RN, NP (leaves 2 PM)

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, Associate Executive Director
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, Program Analyst
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

Board Members Not Present

Dawn Perry, JD Delilah Barnes, RPh

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; J. Rocchio, yes; J. Chin, yes; R. Lopez, yes; S. Ahmed, yes; R. Morelli, yes; K. Thornell, yes. J. Lopez, yes. C. Belisle, yes; C. Jean-Francois joins meeting 8:05 AM

Topic II. Approval of Agenda TIME 8:00 AM

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Draft Minutes General Session: 6/1/23

Agenda 6/1/23

DISCUSSION:

Defer: ProCare LTC; DS90042 Petition for Waiver in Applications.

ACTION:

Motion by J. LANZA, seconded by K. THORNELL and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:03 AM

TIME: 8:04 AM

TIME: 8:04 AM

TIME: 8:04 AM

Minutes

1. Draft 5/4/23

Change: no changes

Action:

Motion by K. THORNELL seconded J. LANZA and voted unanimously to approve the regular session minutes of 5/4/23 with no noted changes by roll call vote.

TOIC IV REPORTS

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: M. BOTTO

<u>DISCUSSION</u>: M. Botto reported the applications listed in the Board packet have been approved by staff action Policy 13-01 since the last Board meeting.

So noted.

Topic IV. REPORTS

Monthly Report from Probation

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto indicated 19 active probation cases, 1 of which has successfully completed

probation monitoring 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 eight CE deficiencies, all of which were closed with no discipline warranted, remediation complete. Four inspectional deficiencies were reported and issued a reprimand. So noted.

Topic IV. REPORTS

PSUD report by Staff Action 17-03

TIME: 8:05 AM

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PRESENTED BY: E. TAGLIERI

<u>DISCUSSION:</u> E. Taglieri reported a total of 7 active members in the PSUD program. There have been two discharges in June and two pending admissions. The next quarterly meeting is in July.

So noted.

TOPIC V FLEX

NABP Annual Meeting Summary

Presented by: K. THORNELL

Discussion: The NABP annual meeting that was held in Nashville included topics such as Just Culture, DSCSA, and USP <797> and <795>. Six resolutions were approved including Point of Care test and treat, DSCSA, opioid use disorder medication access, and pharmacy technician scope of practice.

TIME: 8:05 AM

So noted.

TOPIC VI Applications

1. HealthCare Technology Relocation TIME: 8:09 AM

Represented by: Jenny Morey

Recusal: None Discussion:

- Pages 25-33 in General Session packet
- Relocation from 200 Butterfield Drive in Ashland to 56 Lowland Street in Holliston for additional space and expansion
- For CVIs only; no federally controlled substances
- Licensee has already moved to the new location including all inventory but J. Morey did not believe there was any CVIs in stock

Action: A motion was made by J. LANZA to approve HealthCare Technology's application for a relocation pending a successful inspection; Seconded by S. HAMILTON then Board Members present voted unanimously by roll call to approve motion.

2. ProCare LTC; DS90042

Petition for Waiver

Removed from the agenda

1. Geiger Gibson Community Health Pharmacy; DS89760 Petition for Waiver TIME: 8:16 AM

Represented by: Pharmacist Maria Escobar

Recusal: None Discussion:

- Pages 34-37 in General Session packet
- Request to waive the requirement for a balance

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Pharmacy has not used the balance since opening

Action: A motion was made by S. HAMILTON to approve Geiger Gibson Community Health Pharmacy's waiver for a balance; Seconded by J. LOPEZ then Board Members present voted unanimously by roll call to approve motion.

TOPIC VII POLICIES

2. Policy 2023-08: Pharmacy Technician Stocking of Automated Dispensing Devices (ADD)

Time: 8:20 AM

Time: 8:23 AM

Presented by: M. CHAN

Discussion: This new policy consolidates Policy 2022-04: *Use of Pharmacy Technician Trainees to Stock Automated Dispensing Devices* and the Advisory titled *Use of Technology to Check Inventory Management Activities Performed by Certified Pharmacy Technicians*.

It also incorporates a new allowance for Pharmacy Technicians working in hospitals to transport and load pharmacist-verified Schedule II through VI stock medications into Automated Dispensing Devices located in patient care areas. This change is notable since non-certified Pharmacy Technicians are generally not permitted to handle Schedule II medications.

Board members J. CHIN and J. ROCCHIO had previously commented on the applicability of this allowance in the retail and LTC settings, but since the policy involves two other agencies, the request was to move it forward as written and bring edits forward at a future meeting.

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

3. Policy 2020-15: Scope of Practice

Presented by: M. CHAN

Discussion: Edits to this policy include changes resulting from the new policy 2023-08 that was just approved as well as some previously approved policies and circular letters pertaining to immunizations and injections. There were also some clarifications made in the "Testing" section and various technical edits to improve clarity.

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

TOPIC VIII RECISSIONS

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Time: 8:24 AM

Time: 9:02 AM

Presented by: M. CHAN

Discussion: With the new policies that have been recently approved, a request was made to rescind the following two documents:

- Policy 2022-04: Use of Pharmacy Technician Trainees to Stock Automated Dispensing Devices
- Advisory: Use of Technology to Check Inventory Management Activities Performed by Certified Pharmacy Technicians

Action: Motion by J. LANZA, seconded by J. CHIN, and voted unanimously by roll call of those present, to rescind these documents.

TOPIC IX

Violation of Stayed Probation

1. CVS #321 DS2989; PHA-2021-0049

Presented by: Karen Fishman

Recusal: John Rocchio

Discussion:

- Pages 48-53 in General Session packet
- Non-Disciplinary Stayed Probation for 1-year effective May 27, 2022 for unknown loss of CIV controlled substances
- CVS #321 was inspected on 4/27/2023 with a Plan of Correction issued for storage of
 prescription products outside of the pharmacy which would merit a complaint with disciplinary
 action violating the terms of the stayed probation agreement

Action: A motion was made by C. BELISLE to modify the current agreement to lift the stayed probation and extend the probation for 1 year with the same terms and conditions; Seconded by S. HAMILTON then Board Members present voted unanimously by roll call to approve motion.

TOPIC X File Review

Case #1/CAS-2022-1629

PHA-2023-0011 Victoria Okeke, PH25059 Time: **8:27 AM**

RECUSAL: NONE

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

• On 12/21/22 Board of Pharmacy (BOP) investigator arrived on site to conduct an inspection and the pharmacy was closed contrary to the signage posted on the door indicating that the pharmacy would be open 12:00 PM-5:00 PM Monday-Friday. When the investigator contacted the owner/manager of record PH Okeke, he was told that she would not be back at the pharmacy for another 1-2 hours.

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- MOR responded with a copy of the most recent Plan of Correction and policies and procedures for hours of operation and prescription delivery
- On 5/9/2023 Investigator Geaney arrived at the pharmacy for a retail compliance inspection at 12:20pm and the pharmacy was closed with a sign in place stating 'keep calm. On delivery. I'll be back.(With a phone number)

<u>ACTION</u>: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to schedule an Investigative Conference and have the licensee appear before the Board.

Case #2/CAS-2022-1111

PHA-2023-0065 Christopher Cushing, PH25844 Time: 08:29 AM

RECUSAL: NONE

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

- During its March 2023 Meeting, BORP reviewed the staff-assignment investigations concerning WAG
 10319 and Pharmacist Cushing after BORP learned that Pharmacist Cushing engaged in the
 administration of vaccines on 14 occasions at two different Walgreens Pharmacies and oversaw the
 administration of vaccines on 119 occasions at three different Walgreens Pharmacies prior to
 completing the requisite 20 contact hour ACPE accredited training course.
- BORP voted to close the investigation concerning WAG 10319 as discipline not warranted remediation complete. BORP then voted to open a complaint against Pharmacist Cushing for not
 completing the requisite vaccine training and CE deficiencies incidentally discovered during the
 investigation. In addition, BORP voted to open a staff-assignment concerning WAG 19240 for failing to
 properly vet Pharmacist Cushing's credentials as his home pharmacy.
- Pharmacist Cushing was notified about the complaint against his license. He wrote in his response, "...Attached is a copy of our correspondence regarding my prior vaccinating history. I will emphasize that the Massachusetts Department of Public Health gave me the credentials to vaccinate people. As I understand that a pharmacist's role is different, I was already quite familiar with the technique. I now have all of the necessary certification and will re certify my CPR. [I]f there are any CEUs that I need to make up, please let me know and I will be glad to take my time to do them."
- WAG 19240 was notified about the staff-assignment investigation concerning the pharmacy's license.
 HCS DeLeo responded that the "Healthcare Supervisor and/or District Manager" for the area initially vet a job candidate's immunization credentials during the hiring process. Then, the MOR of the pharmacy assigned as the candidate's "home location... maintains the documentation and ensures that it does not expire, and all other relevant training is completed."
- HCS DeLeo further explained that no policy and procedure existed at Walgreens pertaining to a "home' or "home' pharmacy location despite her earlier reference to a home location and specific requirements for the home MOR to monitor credentials for those assigned to that MOR's pharmacy. HCS DeLeo next asserted that credentials for pharmacists, pharmacy intern, pharmacy technician were kept in the Walgreens On-Line Licensing System (WOLF) and WOLF was "accessible to all store locations to review active and inactive team members."
- Significantly, HCS DeLeo also specifically addressed the decision-making which led to incident involving Pharmacist Cushing's credentials. HCS DeLeo wrote, "In this instance, [Pharmacist Cushing] was

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interviewed by the district manager and offered employment. We were waiting for him to produce the necessary documents for Immunization certification. The document he produced did not look like the normal APHA certificate, so the district manager sent an image to [HCS DeLeo] for review. When [HCS DeLeo] viewed the document, it did appear different from the normal APHA certificate but thought that his training as an EMT was sufficient to support the certificate, and his previous experience as immunizing for the state during the pandemic."

• CA: HCS DeLeo wrote, "Since this incident occurred and moving forward when reviewing Immunization credentials for pharmacists where they are not APHA Certification documents, the Healthcare Supervisor will send them to our Support Office for review by our legal team to ensure appropriateness and meeting all regulatory and legal standards for that state."

<u>ACTION</u>: Motion by J. CHIN, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2023-0065), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a 6 MONTH PROBATION, with special terms to include remediation of CE deficiency.

Case #3/CAS-2022-1111

SA-INV-21764

Walgreens #19240, DS90207

vvaigreens 11 192 10, 1935 0207

Time: 08:36 AM

RECUSAL: NONE

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

- During its March 2023 Meeting, BORP reviewed the staff-assignment investigations concerning WAG
 10319 and Pharmacist Cushing after BORP learned that Pharmacist Cushing engaged in the
 administration of vaccines on 14 occasions at two different Walgreens Pharmacies and oversaw the
 administration of vaccines on 119 occasions at three different Walgreens Pharmacies prior to
 completing the requisite 20 contact hour ACPE accredited training course.
- BORP voted to close the investigation concerning WAG 10319 as discipline not warranted remediation complete. BORP then voted to open a complaint against Pharmacist Cushing for not
 completing the requisite vaccine training and CE deficiencies incidentally discovered during the
 investigation. In addition, BORP voted to open a staff-assignment concerning WAG 19240 for failing to
 properly vet Pharmacist Cushing's credentials as his home pharmacy.
- Pharmacist Cushing was notified about the complaint against his license. He wrote in his response, "...Attached is a copy of our correspondence regarding my prior vaccinating history. I will emphasize that the Massachusetts Department of Public Health gave me the credentials to vaccinate people. As I understand that a pharmacist's role is different, I was already quite familiar with the technique. I now have all of the necessary certification and will re certify my CPR. [I]f there are any CEUs that I need to make up, please let me know and I will be glad to take my time to do them."
- WAG 19240 was notified about the staff-assignment investigation concerning the pharmacy's license. HCS DeLeo responded that the "Healthcare Supervisor and/or District Manager" for the area initially vet a job candidate's immunization credentials during the hiring process. Then, the MOR of the pharmacy assigned as the candidate's "home location... maintains the documentation and ensures that it does not expire, and all other relevant training is completed."
- HCS DeLeo further explained that no policy and procedure existed at Walgreens pertaining to a " 'home'" or "'non-home'" pharmacy location despite her earlier reference to a home location and

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- specific requirements for the home MOR to monitor credentials for those assigned to that MOR's pharmacy. HCS DeLeo next asserted that credentials for pharmacists, pharmacy intern, pharmacy technician were kept in the Walgreens On-Line Licensing System (WOLF) and WOLF was "accessible to all store locations to review active and inactive team members."
- Significantly, HCS DeLeo also specifically addressed the decision-making which led to incident involving Pharmacist Cushing's credentials. HCS DeLeo wrote, "In this instance, [Pharmacist Cushing] was interviewed by the district manager and offered employment. We were waiting for him to produce the necessary documents for Immunization certification. The document he produced did not look like the normal APHA certificate, so the district manager sent an image to [HCS DeLeo] for review. When [HCS DeLeo] viewed the document, it did appear different from the normal APHA certificate but thought that his training as an EMT was sufficient to support the certificate, and his previous experience as immunizing for the state during the pandemic."
- CA: HCS DeLeo wrote, "Since this incident occurred and moving forward when reviewing Immunization credentials for pharmacists where they are not APHA Certification documents, the Healthcare Supervisor will send them to our Support Office for review by our legal team to ensure appropriateness and meeting all regulatory and legal standards for that state."

ACTION: Motion by S. HAMILTON, seconded by J. CHIN, and voted unanimously by those present, to ELEVATE the matter (SA-INV-21764), to a COMPLAINT.

Case #4/CAS-2023-0081

PHA-2023-0026 Prince Ogbonna, PH22660 Time: 08:37 AM

RECUSAL: NONE

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

- During January 2023, BORP was notified that Pharmacist Ogbonna's ME pharmacist license was disciplined by ME BOP after he made material misrepresentations. Specifically, Pharmacist Ogbonna owned Machias Friendly Pharmacy in ME. During 2017, Machias Friendly Pharmacy suffered from financial difficulties.
- ME BOP inquired about the pharmacy's operational status on August 8, 2017. Pharmacist Ogbonna responded on August 9, 2017 that Machias continued to operate as a pharmacy, it was not closing, and its legal entity was being sold when, in fact, the pharmacy ceased operations on or about August 2, 2017.
- ME BOP ordered discipline on March 1, 2018 against Pharmacist Ogbonna for the material misrepresentations as follows: 30-day suspension, 3-year probation with restriction from serving as MOR or preceptor, & \$1,500 fine. Pharmacist Ogbonna appealed the order, and his appeal was denied.
- In response to this complaint, Pharmacist Ogbonna submitted a notice of complaint and dismissal from TX BOP regarding the discipline ordered by ME BOP described above. Significantly, TX BOP dismissed the complaint in a later dated March 24, 2020 after an investigative conference held on March 4, 2020.
- Pharmacist Ogbonna also included a rebuttal that he submitted to TX BOP. In the rebuttal, he provided an overview of his professional history which included owning, operating, and managing

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- multiple pharmacies. Pharmacist Ogbonna described that he was the victim of a scam after he bought a pharmacy in Texas which negatively affected all of his businesses including Machias Friendly Pharmacy.
- Pharmacist Ogbonna then asserted that he was "trapped" by ME BOP which caused his statements to be mischaracterized as material misrepresentations. Pharmacist Ogbonna emphasized that the attorney he chose to represent him in Maine did not provide good representation and "dropped the ball" during" the appeal of ME BOP discipline.

<u>ACTION</u>: Motion by J. CHIN, seconded by J. LOPEZ, and voted unanimously by those present, DISMISS the matter (PHA-2023-0026), No Discipline Warranted, Remediation Complete.

Time: 08:41 AM

Case #5/CAS-2023-0306 SA-INV-21789

Joslyn Pesta, PH27574

RECUSAL: S. AHMED 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.

- Self-report of discipline by the NYBOP of a \$500 fine for failure to correct a technician's sterile
 compounding technique when first air was blocked. The mandatory reporting form stated NYBOP
 laws were recently change that a pharmacist must directly supervise a PT compounding and cannot
 perform any other duties during compounding. The NYBOP visited every pharmacy in the state this
 past year, citing misconduct on this matter. Pharmacist Pesta indicated only pharmacists now perform
 sterile compounding at her workplace.
- During a NYBOP inspection on 3/1/22, the investigator observed a bag of D5W hung so that first air
 was blocked when the technician reconstituted Delvance vials due to port curling of the bag.
 Pharmacist Pesta was the supervising pharmacist. The observation was discussed with the pharmacy
 director and retraining was conducted on port placement if bags were curling. Additionally, the
 pharmacy's current processes were being evaluated to determine facility SOPs for a high-volume
 facility.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by J. ROCCHIO, and voted unanimously by those present, to CLOSE the matter (SA-INV-21789), No Discipline Warranted, Remediation Complete.

Case #6/CAS-2023-0046

PHA-2023-0086 Letourneaus Pharmacy, DS2777 Time: 08:44 AM

RECUSAL: NONE

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

• SA-INV-21386 was heard at 4/6/23 BORP meeting and elevated to a complaint. MOR Picard contacted the BORP on 12/23/22 for further guidance for compounding acetaminophen on prescription due to the shortage. MOR Picard was notified oral acetaminophen products were not on the FDA shortage

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- list and may not be compounded. MOR Picard agreed to cease compounding acetaminophen on 12/23/22 and the remaining compounded acetaminophen was discarded with the Pharmacy's hazardous waste company.
- The week of 12/19/22, the Pharmacy had received calls from prescribers and patients for liquid acetaminophen that was on back-order. MOR Picard compounded 5 prescriptions for acetaminophen 160mg/5mL suspension from 12/21/22-12/23/22. All parents were aware it was compounded, and no adverse reactions were reported as of 1/23/23.
- MOR Picard compounded 2 batches (1,000mL each) of "Acetaminophen Spectrum Formula 160mg/5mL" based off a formula for acetaminophen 65mg/mL found on spectrumrx.com. She documented on the first batch it contained 32mg/mL and did not properly calculate the conversation to 160mg using this formula (160mg/2.46mL). The formula did not identify the dosage form, complete instructions, physical description of the final preparation, all labeling requirements, and all QC procedures. A 90-day BUD was assigned for room temperature and refrigerated storage. A copy of a Medisca formula was obtained by this investigator with a 14 BUD, refrigerated. MOR Picard didn't test and adjust the pH of the compound.
- FDA posted FAQs (current as of 3/10/23) indicating compounded acetaminophen oral suspension could be compounded as long as it was not compounded regularly or in inordinate amounts and complied with the conditions of section 503A.
- In response to the complaint MOR Picard stated the Pharmacy doesn't compound commercially available products. She acknowledged she should have done her due diligence per her normal practice prior to compounding acetaminophen suspension. There was no intent behind compounding it other than providing care to the patients. Provided SOPs encompass the elements of USP 1163 QA in Pharmaceutical Compounding. MOR Picard failed to follow the Pharmacy's SOPs.
- Going forward, MOR Picard will always check the FDA shortage list prior to compounding a
 commercially available product. MOR Picard discussed the Pharmacy's related policy for "Procedure:
 Determining the Availability of a Commercial Drug" with the Pharmacy staff with a signed and dated
 copy submitted confirming review.

<u>ACTION</u>: Motion by J. CHIN, seconded by R. MORELLI, and voted unanimously by those present, refer the matter (PHA-2023-0086), 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. A second motion was made by J. CHIN, seconded by S. AHMED, and voted unanimously by those present, to open a COMPLAINT on Pharmacist Alicia Picard, PH234605.

Case #7/CAS-2023-0229

PHA-2023-0051 Ash Pharmacy, DS90321 Time: 08:50 AM

RECUSAL: NONE

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

- During a retail compliance inspection conducted on 02/08/2023, it was observed that there were multiple expired items on the pharmacy shelves, including an epinephrine auto injector in the immunization room, and Schedule II drugs in the safe.
- The POC submitted indicated that the expired medications were returned to INMAR. The expired and used epinephrine auto-injector will be placed in the hazardous bin for proper disposal.

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MOR Tona indicated that the corrective action plan for the expired medications would be checked on
a monthly basis to look for expired medications. Yellow tags would be placed on all medications that
will expire within 6 months. All expired medications will be quarantined immediately. The expiration
date of the epinephrine and other durable medical equipment in the immunization room will be listed
and placed on file to serve as a reminder.

<u>ACTION</u>: Motion by J. LOPEZ, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0051), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

Case #8/CAS-2023-0233

PHA-2023-0052

CVS #444, DS2704

Time: 08:53 AM

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

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

- During a retail compliance inspection (ISP-20661) conducted on 02/09/2023, unsecured epinephrine auto injectors were observed stored in the vaccination room, which is unlicensed space.
- This is a repeat deficiency previously observed during an inspection on 01/11/2022.
- Current MOR Megna acknowledged that "storing these items within the vaccine room is not permitted".
- The CVS response indicated that there is no specific policy and procedure on storage but noted that the Pharmacy Manager and the Pharmacist on duty must ensure all pharmacy product is stored accordingly.
- As corrective action Current MOR Megna indicated that she discussed with all the pharmacists and floaters that the emergency kits cannot be left in the vaccination room.
- CVS #444 has a reprimand pending from the 01/11/2022 inspectional deficiencies.

<u>ACTION</u>: Motion by J. CHIN, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2023-0052), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a a 1 year PROBATION.

Case #9/CAS-2022-1573

PHA-2023-0007

CVS #23, DS90049

Time: 08:56 AM

RECUSAL: J. ROCCHIO recused and was 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.

• On 12/12/2022, the Pharmacy submitted a timely Report of Loss of Controlled Substances and DEA Form 106. According to the final reports, an investigation confirmed the unknown loss of #60 morphine sulfate ER 10 mg capsules on 11/21/2022. The reason for the loss is documented as a "suspected dispensing error".

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- The Pharmacy later concluded there was no theft or loss. The #60 morphine sulfate 10mg capsules were "found in the pharmacy with medications set aside for a return". The DEA Form 106 was withdrawn by CVS in a letter to the DEA Boston Division Office dated 02/13/2023.
- In a follow-up response, CVS clarified that the missing morphine capsules were not "found in the pharmacy with medications set aside for a return" as stated in the DEA 106 withdrawal letter. The morphine capsules were not set aside for a return via a Reverse Distributor, the morphine capsules were found in the will call bins when return to stocks were being pulled. CVS indicated that even though several staff members had already checked, the #60 morphine sulfate 10mg capsules were found in the pharmacy waiting bin on 12/26/2022, when staff were cleaning out the bins "by date".
- As corrective action, the pharmacy team will complete a thorough waiting bin clean up every week by
 visually inspecting prescriptions in the waiting bin by date, not just using the Day 14 report.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by R. MORELLI, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0007), No Discipline Warranted, Remediation Complete.

Case #10/CAS-2022-1383

PHA-2022-0212 CVS #1862, DS2712 Time: 08:58 AM

<u>RECUSAL</u>: J. ROCCHIO recused and was 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.

- On 11/04/2022, the Pharmacy submitted a timely final Board Report of Loss of Controlled Substances (RLCS) and DEA Form 106 Report of Theft or Loss of Controlled Substances (DEA 106) to the OPP. In the final reports, the date the investigation concluded was not documented on the RLCS and the quantity of the unknown loss was documented as #398 alprazolam 0.5mg tablets. The DEA 106 and the reconciliation spreadsheet submitted documented the variance as #397 alprazolam 0.5mg tablets.
- MOR Nguyen reported the loss was identified by CVS Corporate controlled substance monitoring as a variance on 10/14/2022. Security camera footage was not reviewed.
- MOR Nguyen who stated, "Drug loss was notified by CVS corporate on 10/14/22. The Pharmacy
 Manager was directed to complete an LP initiated drug loss count daily for Alprazolam 0.5mg tablets
 for one month. The manner of which the loss occurred is still unknown. If it did occur, it may be due to
 Alprazolam 0.5mg being a fast mover and located near the confidential trash bin. Our guess is that it
 may have been knocked over and into the bin."
- MOR Nguyen indicated that going forward, the pharmacy team will strictly be implementing the following processes regarding controlled substances:
 - ② All CIII-CV medications will be checked in from Cardinal totes as soon as delivered and colleague checking in the order will then put bottles away on the shelves immediately
 - Trash bins will be moved to a different location as to not accidentally knock prescriptions into the bin
 - Cycle counts must be done before 5pm DAILY
 - ② ALL colleagues are to put drugs away immediately in the correct location after counting at production.

<u>ACTION</u>: Motion by J. CHIN, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0212), to the Office of Prosecution for the issuance of an order to show

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cause and to authorize resolution of the matter by a consent agreement for a STAYED PROBATION for a period one 1 year, with special terms to include the Controlled Substance Loss Protocol for all benzodiazepines.

Topic XI: Executive Session Call to Order: Time: 9:14 AM

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

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

Topic XII: 65C Sessions MGL c. 112 section 65C Time: 9:21 AM

DISCUSSION: None

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

Thornell, yes. J. Lopez, yes. C. Belisle, yes; C. Jean-Francois, Yes.

At 9:21 AM S. Hamilton, seconded by J. Lopez and voted unanimously by all those present to enter 65C by roll call vote.

Lunch 11:29 AM to 12:00 pm

Topic XIII: ADJOURMENT OF MEETING TIME: 2:22 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 6/1/23 General Session
- 2. Draft Minutes of the 5/4/23 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. NABP Annual Meeting Summary
- 8. HealthCare Technology; WD507 Relocation
- 9. ProCare LTC; DS90042 Petition for a waiver
- 10. Geiger Gibson Community Health Pharmacy; DS89760-Waiver

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- 11. Policy 2020-15: Scope of Practice (Revisions)
- 12. Policy 2023-08: Pharmacy Technician Stocking of Automated Dispensing Devices (ADD)
- 13. Recission: Policy 2022-04: Use of Pharmacy Technician Trainees to Stock Automated Dispensing Devices
- 14. Recission: Advisory: Use of Technology to Check Inventory Management Activities Performed by Certified Pharmacy Technicians
- 15. Violation of Stayed Probation: CVS#321, DS2989 PHA-2021-0049 16. CAS-2022-1629 PHA-2023-0011 Victoria Okeke, PH25059 17. CAS-2022-1111 PHA-2023-0065 Christopher Cushing PH25844 18. CAS-2022-1111 SA-INV-21764 Walgreens #19240 DS90207 19. CAS-2023-0081 PHA-2023-0026 Prince Ogbonna, PH22660 20. CAS-2023-0306 SA-INV-21789 Joslyn Pesta, PH27574 PHA-2023-0086 Letourneaus Pharmacy, DS2777 21. CAS-2023-0046 22. CAS-2023-0229 PHA-2023-0051 Ash Pharmacy, DS90321 23. CAS-2023-0233 PHA-2023-0052 CVS #444, DS2704 24. CAS-2022-1573 PHA-2023-0007 CVS #23, DS90049 25. CAS-2022-1383 PHA-2022-0212 CVS #1862, DS2712

Respectfully Submitted, Jennifer Chin, RPh, Secretary

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