

COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

May 4, 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=m13e30e4035b800ed5f3ea69e6d3518a9>

To access the meeting by phone:

Call in Number: 1-650-479-3208

Access Code: 253 759 64420

*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 April 6, 2023 Regular Session Minutes		
8:10	IV	REPORTS <ul style="list-style-type: none">Applications approved pursuant to Licensure Policy 13-01Monthly report from ProbationBoard Delegated Review pursuant to Licensure Policy 14-02PSUD Report-Policy 17-03		

8:15	V	FLEX <ul style="list-style-type: none"> • Pharmacy issues related to COVID-19 • PSUD Program Update • Cornerstone Health Solutions Central Fill Pilot Project Report <ul style="list-style-type: none"> ○ Request for additional location • Guidance Implementing Executive Order 609 Regarding Reproductive Health Medications • Pharmacy Advisory Committee Meeting Update • Pharmacy Advisory Committee summary and discussion on Compounded Ketamine Nasal Spray 	D. Sencabaugh J. Petrillo S. Ahmed E. Taglieri
9:00	VI	APPLICATION <ul style="list-style-type: none"> • HMC Pharmacy; DS90414 – Waivers • Vital Care; DS90415-Waivers 	
9:30	VII	POLICIES <ul style="list-style-type: none"> • Staff Action Policy 14-01: Individual Licensure Applications Requiring Good Moral Character Evaluation • Policy 2023-07: Non-Sterile Compounding • Policy 2023-06: Schedules II and III Quantity Limits • Policy 2023-03: COVID-19 Control Measures • Policy 2023-02: Vaccine Administration • Pharmacy Practice Updates 	W. Frisch M. Chan
10:00	VIII	POLICY RECISSIONS <ul style="list-style-type: none"> • Policy 2020-11: Vaccine Administration • Policy 2020-12: Vaccine Administration by Qualified Pharmacy Technicians • Policy 2020-14: COVID-19 Testing • Policy 2022-05: COVID-19 Vaccine Administration by Qualified Pharmacy Personnel • Policy 2022-06: COVID-19 Therapeutics 	W. Frisch M. Chan
10:15	IX	RECONSIDERATION <ul style="list-style-type: none"> • CVS 7140; DS89729: PHA-2020-0070 	M. Egan

10:20	X	FILE REVIEW					
		1	CAS-2022-1380	PHA-2022-0209	Rite Aid #10209, DS2899		
		2	CAS-2023-0018	SA-INV-21359	Holly Mattoes, PH232472		
		3	CAS-2023-0042	PHA-2023-0022	West Concord Pharmacy, DS3607		
		4	CAS-2022-1294	PHA-2023-0013	G Medical LLC dba Pharmaceutics, WD488		
		5	CAS-2022-1022	PHA-2022-0174	Walgreens #9538, DS3474		
		6	CAS-2022-1568	PHA-2023-0001	Walgreens #4072, DS2788		
		7	CAS-2023-0173	PHA-2023 -0036	CVS #672, DS89987		
		8	CAS-2023-0123	PHA-2023-0035	CVS #155, DS2471		
		9	CAS-2023-0129	PHA-2023-0031	CVS #1868, DS3518		
		10	CAS-2022-1382	PHA-2022-0211	CVS #1859, DS2945		
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 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

May 4, 2023

Board Members Present

Caryn Belisle, RPh, MBA, President
Jennifer Chin, RPh Secretary
Katie Thornell, RPh, MBA President Elect (leaves meeting 11:00 AM returns 11:13 AM)
Dr. Richard Lopez, MD
Sebastian Hamilton, Pharm D, MBA, RPh
John Rocchio, RPh, PharmD (leaves meeting at 2 PM)
Sami Ahmed, PharmD., RPh, BCPS, BCSCP
Rita Morelli, PharmD, BCACP, RPh
Delilah Barnes, RPh
Johanna Lopez, MS (arrives 11:45 AM)
Julie Lanza, CPhT
Carly Jean-Francois, RN, NP (leaves 2 PM)
Dawn Perry, JD (leaves 12:30 PM)

Board Members Not Present

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
Ed Taglieri, MSM, NHA, RPh PSUD Supervisor
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
Nancy Aleid, 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; C. Jean-Francois, yes; K. Thornell, yes. D. Perry joins meeting 8:02 AM, J. Lopez joins meeting 11:45 AM.

Topic II. Approval of Agenda TIME 8:05 AM

Agenda 5/4/23

DISCUSSION:

None

ACTION:

Motion by S. Ahmed, seconded by J. Lanza 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 4/6/23

Change: no changes

Action:

Motion by S. Hamilton seconded S. Ahmed and voted unanimously to approve the regular session minutes of 4/6/23 with no noted changes by roll call vote. J. Chin and Dr. Lopez recuse.

TOIC IV Reports TIME: 8:03 AM
Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported 50 Change of Manager applications and 6 facility closures that have been approved via Staff Action since the April 6th Board meeting.

So noted.

Topic IV. REPORTS TIME: 8:03 AM
Monthly Report from Probation

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto indicated 20 active probation cases, 1 of which has successfully completed probation monitoring since the April 6th Board meeting.

So noted.

Topic IV. REPORTS TIME: 8:03 AM
Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported 7 CE deficiencies, all of which were closed with no discipline warranted. 7 inspectional deficiencies were reported and issued a reprimand. 2 petitions for waiver renewals have been approved since the last Board meeting.
So noted.

Topic IV.

REPORTS

PSUD report by Staff Action 17-03

TIME: 8:04 AM

PRESENTED BY: E. TAGLIERI

DISCUSSION: E. Taglieri reported a total of 7 active members in the PSUD program. There has been one successful completion of the program since the April 6th Board meeting. Currently, there are two pending admissions for the coming months.
So noted.

TOPIC V

Flex

1. Pharmacy issues related to COVID-19

Time: 8:05 AM

Presented by: D. SENCABAUGH

Discussion: Nothing to report.

2. PSUD Program Update

Time: 8:06 AM

Presented by: E. TAGLIERI

Discussion: Pursuant to Chapter 177 of the Acts of 2022 Section 36, the Bureau of Health Professions Licensure will be implementing a combined substance use disorder program to be available for all the Boards under the Bureau. The process will take 6-12 months to complete, and the pharmacy substance use disorder program will become part of it.

Although Ed will be retiring as of June 9, 2023, he will be staying on a few days per week to assist with the transition.

So noted.

3. Cornerstone Health Solutions Central Fill Pilot Project Report

- **Request for additional location**

Time: 8:16 AM

Presented by: Paul Magno, Robert Miranda, Sam Lee

Recusals: S. HAMILTON, R. MORELLI, D. PERRY

Discussion: A report of recent delivery delays, error rates, and other quality related events was presented. The request was made to add their newly licensed Crosstown Pharmacy to the pilot

program. As with the other pharmacies in the pilot, no compounds and only Schedule VI medications will be centrally filled.

Action: Motion by D. BARNES, seconded by R. LOPEZ, and voted unanimously by roll call of those present, to approve the addition of Crosstown Pharmacy to the central fill pilot.

4. Guidance Implementing Executive Order 609 Regarding Reproductive Health Medications

Time: 8:30 AM

Presented by: J. PETRILLO

Discussion: The governor has signed an executive order regarding continued access to medication abortion and emergency contraception. See the Board's policy that was approved last month for further details.

So noted.

5. Pharmacy Advisory Committee Meeting Update

Time: 8:34 AM

Presented by: S. AHMED

Discussion: The Board has sought the Pharmacy Advisory Committee's input and opinion on the safety and necessity of the compounding of ketamine nasal spray since the FDA has issued an alert regarding potential risks associated with it. The alert references Spravato[®], which is an FDA approved, commercially available nasal spray for treatment-resistant depression that is only available through a restricted distribution system and is subject to a Risk Evaluation and Mitigation Strategy (REMS) program.

Unlike Spravato[®], which contains only the S isomer of ketamine, the compounded nasal formulation is made from racemic ketamine and therefore contains both the R and S isomers. These compounded formulations are not FDA approved, nor are they compliant with any REMS program or related safety requirements.

Spravato[®] is prohibited from being dispensed directly to patients and must be administered in the prescriber's office so the patient can be monitored for sedation and dissociation for at least 2 hours after use. Compounded nasal ketamine, however, is generally dispensed directly to patients for home use.

The FDA states that a commercially available product cannot be compounded merely because it is cheaper or more convenient for the patient. In this situation, however, the FDA has stated that compounded ketamine nasal products are not the same as Spravato[®].

The Advisory Committee also discussed FDA's concerns about misuse and abuse associated with compounded ketamine nasal spray, but ultimately recommended that the Board allow the compounding and dispensing of nasal ketamine to continue with guardrails and have offered to meet again if the Board so desires.

So noted.

6. Pharmacy Advisory Committee (PAC) summary and discussion on Compounded Ketamine Nasal Spray **Time: 8:36 AM**

Presented by: E. TAGLIERI

Discussion: The PAC discussed the compounding of Ketamine Nasal Spray and voted to recommend the continuation of the practice with safety guidelines to balance patient access to needed therapy while ensuring patient safety. The PAC did not have specific guideline recommendations.

Board staff discussed the recommendations and input from the PAC in conjunction with the FDA Advisory and recommends use of an advisory to provide best practice, evidence-based recommendations. This will allow continued access to patients, as well safety guidelines for the compounding and dispensing of Ketamine Nasal Spray.

Action: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by roll call of those present, to approve the advisory titled Compounded Ketamine Nasal Spray.

TOPIC VI

Applications

1. HMC Pharmacy; DS90414 – Waivers

TIME: 8:41

Represented by: Felipe Goncalves and Drew Holleman

Recusal: none

Discussion:

- Pages 42 to 61 of the General Session packet
- Request for 5 waivers including 247 CMR 6.01(5)(a)(4) for a balance; 247 CMR 6.02(4) for a sufficient variety of chemicals to compound; 247 CMR 9.01(16) for no refusal to compound; 247 CMR 9.01(15) for no limiting of services; 247 CMR 6.01(5)(a)(8) for a book for the recording of OTC controlled substances.

Action: A motion was made by S. Hamilton to approve HMC Pharmacy's requested waivers; Seconded by J. Lanza then Board Members present voted unanimously by roll call to approve the motion.

2. Vital Care Pharmacy DS90415 - Waivers

TIME: 8:45

Represented by: Hadee Alkhandak and Summer Bosarge

Recusal: none

Discussion:

- Pages 62 to 76 of the General Session packet

- Request for 5 waivers including 247 CMR 6.01(5)(d)(1) for a patient consultation area; 247 CMR 6.01(5)(a)(4) for a balance; 247 CMR 6.02(4) for a sufficient variety of chemicals to compound; 247 CMR 9.01(16) for no refusal to compound; 247 CMR 9.01(15) for no limiting of services.

Action: A motion was made by S. Hamilton to approve HMC Pharmacy's requested waivers; Seconded by J. Lanza then Board Members present voted unanimously by roll call to approve the motion.

TOPIC VII

Policies

1. Staff Action Policy 14-01: Individual Licensure Applications Requiring Good Moral Character Evaluation Time: 8:49 AM

Presented by: M. CHAN

Discussion: The proposed edits would allow Board staff to issue a license if the applicant has had administrative fines or minor sanctions issued by another Board of Pharmacy, but only if they have been resolved and are older than 3 years. The more serious sanctions of suspension, revocation or probation would still be brought before the Board for evaluation prior to issuance of a license.

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

2. Policy 2023-07: Non-Sterile Compounding Time: 8:51 AM

Presented by: M. CHAN

Discussion: This policy provides an overview of non-sterile compounding requirements including documentation for adding flavoring agents to conventionally manufactured products in accordance with USP's stance that this constitutes compounding. The policy would allow the USP requirements of the master formulation record and compounding record to be on the same document. This policy replaces the Board's current advisory.

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

3. Policy 2023-06: Schedules II and III Quantity Limits Time: 8:53 AM

Presented by: M. CHAN

Discussion: This new policy clarifies M.G.L. 94C § 23(d) that restricts dispensing of Schedule II and III medications to a 30 days' supply except for certain drugs in the case of minimal brain

dysfunction and narcolepsy. The policy describes what would constitute "minimal brain dysfunction" (i.e., ADD/ADHD) and which drugs would be eligible for dispensing a 60-day supply.

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

4. Policy 2023-03: COVID-19 Control Measures

Time: 8:56 AM

Presented by: M. CHAN

Discussion: This new document was approved by EOHHS in response to M.G.L. c. 94C, §19E. It covers dispensing and administering of COVID-19 tests and medications. The PREP Act may still contain other allowances that would continue to supersede state policies and regulations.

Action: Motion by D. BARNES, seconded by K. THORNELL, and voted unanimously by roll call of those present, to approve this policy.

5. Policy 2023-02: Vaccine Administration

Time: 8:58 AM

Presented by: M. CHAN

Discussion: This new document has been approved by EOHHS in accordance with updates to 105 CMR 700.004(B)(6). It includes all vaccine requirements including training, specific vaccines that pharmacists, interns, and technicians are permitted to administer (including COVID-19), as well as the revised youngest age (5 years old) they can administer to. The PREP Act may still contain other allowances that would continue to supersede state policies and regulations.

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

6. Pharmacy Practice Updates

Time: 9:00 AM

Presented by: M. CHAN

Discussion: This document provides an overview of new and continued allowances for after May 11 when the PREP Act ends. It includes allowances for higher supervisory ratios, less frequent perpetual inventories, as well as discusses the vaccine administration changes and COVID-19 control measures. It would replace the current document on the homepage.

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

TOPIC VIII**Policy Recissions****Time: 9:01 AM****Presented by:** M. CHAN

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

Policy 2020-11: Vaccine Administration

Policy 2020-12: Vaccine Administration by Qualified Pharmacy Technicians

Policy 2020-14: COVID-19 Testing

Policy 2022-05: COVID-19 Vaccine Administration by Qualified Pharmacy Personnel

Policy 2022-06: COVID-19 Therapeutics

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

TOPIC IX**Reconsideration****1. CVS 7140; DS89729; PHA-2020-0070****Time: 9:03****Presented by:** M. Egan**Recusal:** D. Perry/J. Rocchio**Discussion:**

- In April 2021 CVS #7140 entered into a one-year probation but there were issues with receiving and processing the agreement
- In April 2022, the Board members voted to extend the probation but there had been no additional compliance issues since then
- Board Counsel Egan requested that the Board members reconsider to rescind the extension of the probation and end the probationary period

Action: A motion was made by C. Belisle to rescind the extension of the probation and end the probationary period for CVS #7140; Seconded by S. Hamilton then Board Members present voted unanimously by roll call to approve the motion.

TOPIC X**File Review**

Case #1 /CAS-2022-1380

PHA-2022-0209

Rite Aid #10209, DS2899

Time: 09:17 AM**RECUSAL:** NONE

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

- RLCS-#389mL phenobarbital 20mg/5mL on or about 10/06/2022 during transit.
- On 9/14/22, Rite Aid Pharmacy #10206 located in New Bedford, MA closed the business, and all the medication inventory was transferred to Rite Aid #10209.
- A Controlled Substance inventory was conducted upon receipt of inventory from Rite Aid #10206 but failed to include the #389mL phenobarbital 20mg/5mL at that time.
- Approximately 3 weeks later on 10/06/2022, when the phenobarbital liquid was later discovered in a non-controlled substance tote, it was inventoried and determined that at some point the phenobarbital liquid had spilled in the tote.

ACTION: Motion by D. BARNES, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2022-0209), 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-2023-0018

SA-INV-21359

Holly Mattoes, PH232472

Time: 09:19 AM

RECUSAL: NONE

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

- Repeat CE deficiency- On 12/31/2022, Pharmacist Mattoes reported that she is missing 4.0 CEs in live from 2022 because she confused the MA requirements with CT requirements.
- PH Mattoes indicated that CT waived live requirements in 2022 due to COVID, as a result she was deficient in MA.
- PH Mattoes remediate her deficiency in 2023.

ACTION: Motion by S. HAMILTON, seconded by R. MORELLI, and voted unanimously by those present, to CLOSE the matter (SA-INV-21359), No Discipline Warranted, Remediation Complete.

Case #3/CAS-2023-0042

PHA-2023-0022

West Concord Pharmacy, DS3607

Time: 09:20 AM

RECUSAL: NONE

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

- On 01-06-2023, Investigator Lathum observed Jessica R. Tosi performing production during a retail compliance inspection at West Concord Pharmacy. Ms. Tosi was licensed as a pharmacy intern in Rhode Island but was not licensed in Massachusetts.
- West Concord explained that Ms. Tosi was a student in the pharmacy program at URI and licensed in Rhode Island as a pharmacy intern. Ms. Tosi's Massachusetts credentials were not verified when she was hired.
- West Concord described that "We should have checked to make sure [Ms. Tosi] had a license in good standing with the Massachusetts BOP as we do with any new hire, and we did not in this case..." Ms. Tosi later obtained a Massachusetts pharmacy technician trainee (PTT) license so she could work in the pharmacy because she left the pharmacy program at URI. Thus, she was no longer eligible for a Massachusetts intern license.

- Owner Dinno stressed that he hired Ms. Tosi and he failed to properly vet her credentials. MOR Maserejian was not involved in the process.
- POC/CA: West Concord described that the pharmacy “instituted a layered policy with multiple checks for licensure upon hiring (included in the POC paperwork) which would hold the Manager of Human Resources, the MOR of the individual store, and one (or both) of the owners responsible for verifying MA BOP licensure of any qualifying employee” and provided a copy of the policy.
- West Concord added that HR, MOR, and owners were also reeducated on license verification websites and requirements for an out-of-state pharmacy intern to obtain a Massachusetts specific intern license.

ACTION: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0022), 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-2022-1294

PHA-2023-0013

G Medical LLC dba Pharmaceuticals, WD488

Time: 09:23 AM

RECUSAL: NONE

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

- During an inspection at G Medical it was noted that the WD was investigated by DEA for “controlled substance record keeping deficiencies.” Effective December 21, 2022, G Medical and DEA entered a MOU for a three-year period. G Medical admitted that CIII’s were distributed to several hospitals and clinics not authorized by their DEA Registration to handle CIII’s on multiple occasions from 2012 to 2019 then in 2020 and again in 2021. G Medical admitted in the MOU to the violations.
- G Medical agreed to a number of terms and conditions in the MOU to resolve the violations cited by DEA including requirements to provide additional on training on “proper handling, recordkeeping, security, and storage procedures” for federally controlled substances to all staff.
- In addition G Medical was required to review licensing details for all current customers to ensure those customers hold proper registration with DEA and respective state agencies required to handle controlled substances being distributed to those customers, establish and maintain a policy for verifying the status of a new customers’ registration with DEA and respective state agencies, and retain the services of a regulatory compliance consultant for an additional period of one-year after the effective date of the MOU. Lastly, G Medical agreed to allow DEA entry at any time during regular business hours without prior notice to verify compliance with the MOU. On 4-18-23, Chief Penta indicated that DEA confirmed G Medical had complied with the MOU , thus far.
- In response to this complaint, G Medical explained that the violations were caused by the complexity of the regulations for distribution of buprenorphine. G Medical stressed that all the customers were authorized to handle CIII’s when the buprenorphine was distributed but did not possess the “X-Waiver” specifically required to order buprenorphine for the treatment of opioid-use disorder.

ACTION: Motion by J. CHIN, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0013), 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 PROBATION for a period of 3 years to align with the DEA MOU timeline.

RECUSAL: NONE

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

- On August 15, 2022, WAG 9538 notified BORP about a possible loss of 52 oxycodone 5mg tablets (CII, 100 tablet stock bottle). Of note, WAG 9538 failed to submit an initial BORP RLCS.
- On August 21, 2022, WAG 9538 submitted a DEA 106 and a final BORP RLCS. According to the reports, WAG 9538 discovered an unknown loss of 52 oxycodone 5mg tablets on August 8, 2022. Of note, WAG 9538 failed to submit supplemental information required by board policy.
- MOR Christopher Gallo later submitted the supplemental information in his response to this complaint. He described that the loss was discovered while performing a back count. He indicated that an extensive investigation was initiated including “counts were redone, perpetual inventory checked, the entire pharmacy was searched for a missing bottle, floors were checked, and camera system was reviewed.” However, MOR Gallo was unable to account for the loss. MOR Gallo also described possible reasons for the loss including “medication misplaced in pharmacy, bottle of medication rolled or fell behind a pharmacy counter or pharmacy fixture, medication thrown out in the garbage, [or] employee theft.”
- MOR Gallo indicated that WAG 9538 continued to monitor for any additional losses of oxycodone. In addition, MOR Gallo wrote, “Ensure only one bottle of stock medication open at a time. Security cameras overlooking C-II safe will be installed.”

ACTION: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by those present, refer the matter (PHA-2022-0174), 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.

RECUSAL: NONE

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

- On 12/14/22, Jomarielis Rosario was observed to be working as a technician without a license. POC Issued (ISP-20255).
- Jomarielis Rosario was hired on July 2, 2020 and transitioned to the pharmacy department on October 10, 2022. She worked 216.30 hours during that period.
- Jomarielis Rosario stated she was not aware a license was required. She was issued PTT18813 on 1/6/23.
- MOR Mariana Pires Guandalin stated that she will ensure all employees are appropriately licensed.

ACTION: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, refer the matter (PHA-2023-0001), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

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.

- Allegation the Pharmacy refused to fill a vet prescription without the veterinarian's DEA number. The Complainant, a Clinical Supervisor at PetMedic Urgent Care, called in the prescription and provided the prescriber's MCSR and name multiple times. She alleged Pharmacist Diep implied she would not fill the prescription and was going to end the call. The Complainant eventually provided the DEA number since the pet needed the medication.
- MOR Thach related they understood a DEA number is not required for a CVI prescription, but a prescription cannot be processed without the prescriber information. Pharmacist Diep accepted the verbal prescription for mometasone 0.1% ointment from the Complainant and requested the DEA number. Pharmacist Diep stated, " I could not locate the provider's information without the DEA or NPI number in our computer database. The Complainant refused to provide the DEA number and I told her 'If we cannot find the doctor, then we cannot fill the prescription.'"
- MOR Thach stated, "Following the incident, we were provided with instructions on how to locate and add a veterinarian without needing an NPI or DEA number. We also discovered that we could contact the CVS helpdesk for assistance in adding a doctor without a DEA number. This the practice we will pursue in the future". A copy was provided of the MVMA FAQ regarding DEA numbers for C-VI medications was signed and dated by the Pharmacy staff confirming review.

ACTION: Motion by R. MORELLI, seconded by K. THORNELL, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0036), No Discipline Warranted, Remediation Complete.

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 unknown loss of #90 amphetamine salts 10mg reported as discovered on 12/28/22 when the prescription could not be found in the waiting bin. MOR O'Brien related Pharmacist Ughreja discovered the loss on 12/26/22 and the loss was confirmed, the paperwork was filed on 12/28/22. MOR O'Brien contended the loss was likely due to a procedural error such as not scanning it out properly. The investigation included a search of the CII waiting bin, the shelves, and the safe and a review of controlled substance recordkeeping. Video was reviewed by Pharmacist Ughreja and DAPL Spiedel. Although MOR O'Brien stated patients were contacted who were dispensed the drug since the last reconciliation, the only prescription filled was for the Patient on 12/19/22.

- When the Patient’s father came in to pick up the prescription on 12/26/22, Pharmacist Ughreja could not find it, so he duplicated the fill to dispense it. He confirmed with the Patient that she had not been dispensed the medication on 12/19/22.
- MOR O’Brien stated, “All Loss Prevention policy and procedures have been reviewed with the Pharmacy Team to prevent future losses. This includes diligent waiting bin management, as well as back counting of all narcotics at the time of dispensing to ensure accuracy”. Specifically, waiting bin procedures and the Pharmacy Loss Prevention Drug Diversion policy were reviewed with the Pharmacy staff. A statement that was signed and dated by the Pharmacy staff was submitted attesting all policies and procedures for the proper storage and handling of controlled substances had been reviewed.

ACTION: Motion by D. BARNES, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2023-0035), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

Case #9/CAS-2023-0129

PHA-2023-0031

CVS #1868, DS3518

Time: 09:42 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.

- Unknown loss of #486 clonazepam 1mg tablets (NDC#00093-3212-05), and #726 clonazepam 1mg tablets (NDC#16729-0137-16) on or about 12/08/2022. An updated RLCS submitted, edited the loss of both NDC#s to “no loss.”
- MOR Brosco reported the loss was identified on 12/08/2022 via a corporate controlled substance monitoring but upon investigation of the clonazepam 1mg bottle, it was discovered not to be a true loss due to a delivery issue.
- On 10/31/2022, Floater Pharmacist Lisa Cohen checked in 4 bottles of clonazepam 1mg, of which was noted on the invoices but did not check each item. The next day, Cardinal called Pharmacist Poitras stating that they shipped an extra bottle in error and would send an invoice. On 11/04/2022, Cardinal sent an invoice without a physical bottle of clonazepam 1mg, which triggered a loss when the team did cycle counts on the drug.
- The MOR noted that he worked with the field management to review all invoices over the last 4-5 months and the video footage of the delivery from 10/31/2022 to determine that there was no loss.

ACTION: Motion by S. AHMED, seconded by R.MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0031), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a STAYED PROBATION for a period one 1 year, with special terms to include the Controlled Substance Loss Protocol for all benzodiazepines.

Case #10/CAS-2022-1382

PHA-2022-0211

CVS #1859, DS2945

Time: 09:45 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.

- RLCS-unknown loss of #502 clonazepam 2mg tablets on or about 10/22/2022. MOR Cooper reported the loss was identified on 10/14/2022 via a corporate controlled substance monitoring.
- The employees directly involved in the handling of the specific medication over the past 3 months, the exact cause of the loss is unknown, but it is presumed that a full bottle may have been mistakenly discarded in the garbage bin.
- Contributing factors include new staff starting over the summer and pharmacy technicians that were training.
- Video footage did not provide additional insights.
- MOR Cooper reviewed the Loss Prevention policy and procedures to prevent future losses. This includes bag checks, as well as no personal items allowed in the pharmacy.
- Additionally, the MOR, the staff RPh, and the lead technician are taking over all ownership of inventory of controlled medication indefinitely.

ACTION: Motion by D. BARNES, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0211), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a STAYED PROBATION for a period one 1 year, with special terms to include the Controlled Substance Loss Protocol for all benzodiazepines.

Topic XI: **Executive Session Call to Order:** **Time: 9:49 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 S. Ahmed 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; C. Jean-Francois, yes; D. Perry, yes; K. Thornell, yes. J. Lopez joins meeting at 11:45 AM

Topic XII: **65C Sessions MGL c. 112 section 65C** **Time: 9:56 AM**

DISCUSSION: None

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

At 9:56 AM J. Chin, seconded by S. Ahmed and voted unanimously by all those present to enter 65C by roll call vote.

Lunch 12:00 PM to 12:30 pm

K. Thornell leaves meeting 11:00 AM; returns 11:13 AM

D. Perry leaves meeting 12:30 PM

J. Rocchio leaves meeting 2:00 PM

C. Jean-Francois leaves meeting 2:00 PM

Topic XIII

ADJOURNMENT OF MEETING

TIME: 2:18 PM

ACTION: Motion by S. Hamilton seconded by Dr. Lopez 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 5/4/23 General Session
2. Draft Minutes of the 4/6/23 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. Chapter 177 of the acts of 2022; section 36
8. Advisory: Compounded Ketamine Nasal Spray
9. Applications: HMC Pharmacy; DS90414; Waivers
10. Vital Care; DS90415; Waivers
11. Staff Action Policy 14-01: Individual Licensure Applications Requiring Good Moral Character Evaluation
12. Policy 2023-07: Non-Sterile Compounding
13. Policy 2023-06: Schedules II and III Quantity Limits
14. Policy 2023-03: COVID-19 Control Measures
15. Policy 2023-02: Vaccine Administration
16. Pharmacy Practice Updates
17. Policy 2020-11: Vaccine Administration
18. Policy 2020-12: Vaccine Administration by Qualified Pharmacy Technicians
19. Policy 2020-14: COVID-19 Testing
20. Policy 2022-05: COVID-19 Vaccine Administration by Qualified Pharmacy Personnel
21. Policy 2022-06: COVID-19 Therapeutics
22. CVS 7140; DS89729: PHA-2020-0070
23. CAS-2022-1380 PHA-2022-0209 Rite Aid #10209, DS2899
24. CAS-2023-0018 SA-INV-21359 Holly Mattoes, PH232472
25. CAS-2023-0042 PHA-2023-0022 West Concord Pharmacy, DS3607
26. CAS-2022-1294 PHA-2023-0013 G Medical LLC dba Pharmaceutics, WD488
27. CAS-2022-1022 PHA-2022-0174 Walgreens #9538, DS3474

- 28. CAS-2022-1568 PHA-2023-0001 Walgreens #4072, DS2788
- 29. CAS-2023-0173 PHA-2023 -0036 CVS #672, DS89987
- 30. CAS-2023-0123 PHA-2023-0035 CVS #155, DS2471
- 31. CAS-2023-0129 PHA-2023-0031 CVS #1868, DS3518
- 32. CAS-2022-1382 PHA-2022-0211 CVS #1859, DS2945

Respectfully Submitted,
Jennifer Chin, RPh Secretary