

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

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

December 7, 2023

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

Join link:

<https://eohhs.webex.com/eohhs/j.php?MTID=m0d4725f5ce48ea61b1d61680357fdd03>

Webinar number:
2534 620 5538

Webinar password:
Bop123 (267124 from phones and video systems)

Join by phone
+1-617-315-0704 United States Toll (Boston)
+1-650-479-3208 United States Toll

Access code: 253 462 05538

*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 November 2, 2023, Regular Session Minutes		
8:10	IV	REPORTS <ul style="list-style-type: none">• Applications approved pursuant to Licensure Policy 13-01• Monthly report from Probation• Board Delegated Review pursuant to Licensure Policy 14-02• PSUD Report-Policy 17-03		

8:15	V	<p>FLEX</p> <ul style="list-style-type: none"> • Election of Board Officers <u>President Elect Nominees:</u> <ul style="list-style-type: none"> ○ Sami Ahmed ○ Delilah Barnes ○ Johanna Lopez <u>Secretary Nominees:</u> <ul style="list-style-type: none"> ○ Rita Morelli ○ Johanna Lopez • Board members update <ul style="list-style-type: none"> ○ Julie Dorgan – Nurse seat ○ Mark Sciaraffa – Pharmacy Technician seat • Testosterone discussion 		
9:00	VI	<p>APPLICATIONS</p> <ul style="list-style-type: none"> • CVS/Specialty; DS3416 – Renovation • MedWiz of Mass, LLC- DS90404 – Renovation • Baystate Specialty Pharmacy; DS90099 – Renovation • Tufts Medicine Home Infusion DS90378 - Waiver Requests • Greater Lawrence Family Health Care; DS89675 – Relocation • BILH Pharmacy Direct; DS90336 - Request to Change Business Model 		
9:20	VII	<p>POLICIES</p> <ul style="list-style-type: none"> • Policy 14-02: Board Delegated Review (BDR) • Policy 2020-15: Scope of Practice • Policy 2023-07: Non-Sterile Compounding • Policy 2023-09: Action Level Environmental Monitoring Results 		M. Chan
9:30	VIII	<p>ADVISORY</p> <ul style="list-style-type: none"> • Compounded Ketamine 		
9:45	IX	<p>REPEAT DEFICIENCIES/REVIEW OF COMPLIANCE</p> <ul style="list-style-type: none"> • CVS #321, DS2989, PHA-2021-0049 		

9:45	X	FILE REVIEW					
		1	CAS-2023-0596	PHA-2023-0173	Stop & Shop #45, DS1754		
		2	CAS-2023-0418	PHA-2023-0176	Stop & Shop #64, DS90161		
		3	CAS-2023-1060	PHA-2023-0171	Price Chopper Pharmacy 240, DS89863		
		4	CAS-2023-0397	PHA-2023-0174	Bianca Mota, PTT16619		
		5	CAS-2023-0817	PHA-2023-0147	Oscos #2583, DS3194		
		6	CAS-2023-0971	PHA-2023-0159	Walgreens #12558, DS89902		
		7	CAS-2023-0807	PHA-2023-0151	CVS #1238, DS2058		
		8	CAS-2023-0966	PHA-2023-0160	CVS #1198, DS2831		
		9	CAS-2023-1061	PHA-2023-0172	CVS #6466, DS89773		
		10	CAS-2023-0898	PHA-2023-0156	Azeb Sequar, PTT14180		
		11	CAS-2023-0898	SA-INV-22537	CVS #10891, DS90281		
		12	CAS-2023-1007	PHA-2023-0168	CVS #433, DS89786		
		13	CASE-2023-0431	PHA-2023-0205	CVS #505, DS89977		
		14	CAS-2023-1101	PHA-2023-0183	CVS #1204, DS2239		
11:30	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.					
12:00	LUNCH BREAK						
12:30	XII	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)					
12:45	XIII	M.G.L. c. 112, § 65C SESSION					
4:00	XIV	ADJOURNMENT					

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

December 7, 2023

Board Members Present

Caryn Belisle, RPh, MBA, President
Katie Thornell, RPh, MBA President Elect
Dr. Richard Lopez, MD
Sebastian Hamilton, Pharm D, MBA, RPh 8:05a
John Rocchio, RPh, PharmD
Sami Ahmed, PharmD., RPh, BCPS, BCSCP
Rita Morelli, PharmD, BCACP, RPh
Delilah Barnes, RPh
Dawn Perry, JD 8a-12p
Mark Sciaraffa

Board Members Not Present

Johanna Lopez, MS
Julie Dorgan

Board Staff Present

David Sencabaugh, RPh, Executive Director
Jacqueline Petrillo, PharmD, RPh, JD, Board Counsel
Michael Egan, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh, Quality Assurance Pharmacist
Richard Harris, Program Analyst
Joanna Chow, Program Analyst
Taylor Lee, Office Support Specialist
Joanne Trifone, RPh, Director of Investigations
Gregory Melton, JD, PharmD, BCPS, Investigator
Julienne Tran, RPh PharmD, Investigator
Christina Mogni, RPh, Investigator
Keith Johnston, Compliance Officer

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:03 AM

A quorum of the Board was present, established by roll call. President Caryn Belisle chaired the meeting and explained that the Board of Pharmacy was recording the meeting.

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

Topic II.

Approval of Agenda

TIME 8:05 AM

Agenda 12/7/23

DISCUSSION: The discussion on Testosterone is being moved to Advisory. Cases for Stop & Shop #45; PHA-2023-0173 and Stop & Shop #64; PHA-2023-0176 are deferred.

ACTION:

Motion by Dr. Lopez, seconded by R. Morelli and voted unanimously by those present to approve the agenda with the noted changes by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:06 AM

Minutes

1. Draft 11/2/2023

Change: no changes

Action:

Motion by S. Hamilton seconded S. Ahmed and voted unanimously to approve the regular session minutes of 11/2/23 with no noted changes by roll call vote. M. Sciaraffa and D. Perry abstained.

TOIC IV

Reports

Applications approved pursuant to Licensure Policy 13-01

TIME: 8:07 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris reported a total of 41 Change of Manager applications and 7 facility closures that have been approved via Staff Action since the November 2nd Board meeting.

So noted.

Topic IV.

REPORTS

Monthly Report from Probation

TIME: 8:08 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris indicated 1 issuance of final notice by Board Counsel and 3 successful cases of probation monitoring since the last Board meeting. Currently, there are 18 active cases of probation monitoring.

So noted.

Topic IV.

REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

TIME: 8:08 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris indicated that 1 CE deficiency case was closed with no discipline warranted, remediation complete. 6 inspectional deficiencies were reported, each issued a reprimand. One CS loss was reported that requires controlled substance protocol.

So noted.

Topic IV.

REPORTS

PSUD report by Staff Action 17-03

TIME: 8:09 AM

PRESENTED BY: E. TAGLIERI

DISCUSSION: E. Taglieri reported 7 active PSUD participants with no pending discharges or admissions. Updates continue to be made to the URAMP program as it becomes finalized.

So noted.

TOPIC V

Flex

1. Election of Board Officers

Time: 8:22 am

President Elect Nominees:

- Sami Ahmed
- Delilah Barnes
- Johanna Lopez

Secretary Nominees:

- Rita Morelli
- Johanna Lopez

Presented by: David Sencabaugh

Recusal: none

Discussion:

- **Rita is running unopposed as Secretary as Johanna Lopez will not be seeking re-appointment to the Board, so she is removing herself from the election.**

Board Members present voted unanimously by roll call to elect Rita Morelli as the Secretary for 2024

Discussion:

- **Sami and Delilah spoke briefly concerning their nominations for President Elect**

Board Members present voted by the majority via roll call vote to elect Sami Ahmed as the President Elect for 2024

Caryn voted for Sami, Katie voted for Sami, Rita voted for Sami, Sebastian voted for Deliliah, Sami voted for Sami, Dr. Lopez voted for Sami, John voted for Sami, Delilah voted for Sami, Dawn voted for Sami, Mark voted for Sami

2. Board members update

TIME: 8:09am

- a. Julie Dorgan – Nurse seat
- b. Mark Sciaraffa – Pharmacy Technician seat

Presented by: David Sencabaugh

Recusal: None

Discussion:

- **New Board member Mark Sciaraffa from MGH was introduced who is the Pharmacy Technician Board member replacing Julie Lanza**
 - **Julie Durgin from Mass Eye and Ear is replacing Carly-Jean Francois as the Nursing Board member.**
 - **Caryn Belisle, John Rocchio, Rita Morelli, and Katie Thornell have been reappointed as Board members.**
 - **Johnna Lopez is not seeking re-appointment to the Board.**
-

TOPIC VI

Applications

1. CVS/Specialty; DS3416

Renovation

TIME: 8:06

Deferred

2. MedWiz of Mass, LLC- DS90404

Renovation

TIME: 8:30

am

Represented by: MOR Hina Patel and Ernest Gates

Recusal: none

Discussion:

- Pages 36 to 44 of General Session packet
- Re-submission of the application due to renovations outside and inside the constructed 797 non-HD cleanroom suite; HVAC system has not been completed.
- Compounding staff will be trained via Critical Point
- No pharmacy activities will occur adjacent to the cleanroom suite.
- BORP staff has reviewed the plans and has no objections to approving the application.

Action: A motion was made by S. Hamilton to approve CVS /Specialty Pharmacy’s application for a renovation pending a successful inspection; Seconded by S. Ahmed then Board Members present voted unanimously by roll call to approve motion.

M: Caryn, Katie, Dr. Lopez, Sebastian, John, Sami, Rita, Delilah, Mark, Dawn

S: Caryn, Katie, Dr. Lopez, Sebastian, John, Sami, Rita, Delilah, Mark, Dawn

V: Caryn aye, Katie aye, Rita aye, Sebastian aye, Sami aye, Dr. Lopez aye, John aye, Delilah aye, Dawn aye, Mark aye

3. Baystate Specialty Pharmacy; DS90099

Renovation

TIME 8:43am

Represented by: Danae Dupras, Kevin T. Miller, Chris Conboy, Kristofer Kennedy, Kyle Deskus, and Edward Jacques

Recusal: None

Discussion:

- Pages 45-57 of General Session packet
- Renovation to create a larger area for receiving and shipping by expanding into existing administrative area to enhance workflow for the pharmacy.

Action: A motion was made by S. Hamilton to approve Baystate Specialty Pharmacy’s application for a renovation pending a successful inspection; Seconded by D. Barnes then Board Members present voted unanimously by roll call to approve motion

4. Tufts Medicine Home Infusion DS90378

Waiver Requests

TIME 8:55am

Represented by: Joelle Hall

Recusal: None

Discussion:

- Pages 58-82 of General Session packet
- Tufts Medicine Home Infusion is a limited services retail drug store pharmacy specializing in compounding sterile preparations.
- Waivers requested for:
 - 247 CMR 6.01 (5) (d) (1)
 - 247 CMR 6.01 (5) (a) (4)
 - 247 CMR 6.01 (5) (a) (5)
 - 247 CMR 6.02 (4)
 - 247 CMR 9.01 (15)
 - 247 CMR 9.01 (16)

Action: A motion was made by D. Barnes to approve Tufts Medicine Home Infusion waiver requests; Seconded by K. Thornell then Board Members present voted unanimously by roll call to approve motion.

5. Greater Lawrence Family Health Care; DS89675 Relocation TIME 9.02am
Represented by: Alicia daCunha, Tina Starner, and Thomas Bruzzese

Recusal: None

Discussion:

- Pages 83-91 of General Session packet
- Greater Lawrence Family Health Care requested to temporarily relocate to 73D Winthrop Ave, Lawrence, MA while the pharmacy underwent a renovation. Greater Lawrence Family Health Care added that the Winthrop Ave relocation site was the site of a former retail drug store. Greater Lawrence Family Health Care temporary relocation request also included a request for temporary waivers for one year for the relocation site as follows.
- Temporary Waivers requested for:
 - 247 CMR 6.01 (5) (d) (1)
 - 247 CMR 6.02 (5)
 - 247 CMR 6.02 (7)
 - 247 CMR 6.02 (8) (a)
 - 247 CMR 9.07 (3) (c)

Action: A motion was made by D. Barnes to approve Greater Lawrence Family Health Care temporary relocation and temporary waiver requests pending successful inspection and approval by BHCSQ and DMH if applicable; Seconded by R. Morelli then Board Members present voted unanimously by roll call to approve motion.

5. BILH Pharmacy Direct; DS90336 Request to Change Business Model TIME 9:11am

Represented by: Matthew Daniel Pungitore and Neil Gilchrist

Recusal: None

Discussion:

- Pages 92-101 of General Session packet
- BILH Pharmacy Direct requested to expand a waiver previously granted partial waiver Request of 247 CMR 6.02(6)(d) and 247 CMR 6.02(6)(e) to include approval to dispense Schedule II controlled substances used to treat attention-deficit/hyperactivity disorder (ADHD).

Action: A motion was made by S. Hamilton to approve request to expand partial waiver to include approval to dispense Schedule II controlled substances used to treat attention-deficit/hyperactivity disorder (ADHD); Seconded by D. Barnes then Board Members present voted unanimously by roll call to approve motion.

TOPIC VII

Policies

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

Time: 9:21 AM

Presented by: M. CHAN

Discussion: Last month, a list of waivers for "closed door" pharmacies was added to this policy allowing the BDR group the ability to approve them. The request was made to add one additional regulation: 247 CMR 6.01 (5) (a) (5): which is the equipment necessary to conduct the practice of pharmacy according to the standards set forth by most current edition of the United States Pharmacopoeia.

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

2. Policy 2020-15: Scope of Practice

Time: 9:23 AM

Presented by: M. CHAN

Discussion: A statement clarifying that the pharmacist is responsible for the accuracy of the final dispensed prescription was added.

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

3. Policy 2023-07: Non-Sterile Compounding

Time: 9:24 AM

Presented by: M. CHAN

Discussion: Based on feedback from several stakeholders regarding the addition of flavoring agents and USP's position that it is considered compounding, several modifications were made to the policy.

These include that flavoring may be added upon patient request even if the prescriber has not indicated it on the script, stability studies may be used whether the results have been published or not, the flavoring "station" may be in a separate area from the "designated" compounding area, and a log sheet with all the required fields may serve as both the master formulation record and compounding record.

A statement was also added that except for complex non-sterile compounding, all pharmacies licensed by the Board are expected to engage in non-sterile compounding in accordance with Board regulations.

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

4. Policy 2023-09: Action Level Environmental Monitoring Results Time: 9:26 AM

Presented by: M. CHAN

Discussion: Changes to this policy clarify that instead of the old USP language stating that highly pathogenic microorganisms include gram negative rods, coagulase positive staphylococcus, and fungi, growth must now be evaluated by a qualified microbiology professional to determine whether the organisms are highly pathogenic.

Action: Motion by D. BARNES, seconded by R. MORELLI, and voted unanimously by roll call of those present, to approve the edits to this policy.

TOPIC VIII

Advisory

1. Testosterone Discussion

Time: 9:28 AM

Presented by: M. CHAN

Discussion: Based on recent questions regarding the quantity of injectable testosterone vials and how to interpret the proper days' supply, Advisory: Sterile Injectable Dispensing (Including Testosterone) was developed explaining the difference between single dose and multiple dose sterile injectable vials and how they should be dispensed to patients.

Action: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by roll call of those present, to approve this new advisory.

2. Compounded Ketamine

Time: 9:29 AM

Presented by: M. CHAN

Discussion: Last May, the Board approved an advisory regarding compounded nasal ketamine based on an FDA alert. The FDA has since released another document providing more cautions regarding the use of all compounded ketamine products, not just the nasal spray and the advisory has been updated accordingly.

Action: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by roll call of those present, to approve the edits to this advisory.

TOPIC IX

Repeat Deficiencies/Review of Compliance

CVS #321, DS2989, PHA-2021-0049

Time: 9:43 AM

Presented by: Karen Fishman

Recusal: Rocchio and Dawn

Discussion: Drug Store Entered into a Non-Disciplinary State Probation of 1 year, for an unknown drug loss (effective 5/27/2022). Earliest release day is TBD based on what is happening here now, and the board also voted to extend the probation for 1 year in June of 2023. This matter has been brought before the board because the licensee entered into this agreement, and the licensee has not had any issues that I was aware of with regard to the unknown loss protocol, but they appear to have violated paragraph 4a of the agreement. On October 18th 2023, [licensee] was cited for a repeat deficiency storing epinephrine autoinjectors, needles, and syringes outside the licensed space in the immunization/consultation room. Prior board action was brought on June 1st for the exact same issue. The MOR was the same MOR who was cited for the previous citation that occurred on April 27th, 2023. At that time, the Board vote was to modify the vote and lift the stay, resulting in a disciplinary probation for 1 year.

At triage at 10/25/2023, the triage committee referred this to the probation department for violations.

Other than this issue, the licensee has complied with everything. Licensee has submitted their documentation of staff retraining pretty much on time. I would like to ask if there was a decision to bring in the MOR on this matter? [Board Counsel noted that this had not yet been discussed.]

I don't believe that notices went out to the licensee for the previous violation. [Board Counsel confirmed that this did not get sent to the licensee because when the notice was being drafted, the new violation was found].

The option for the board to consider based on paragraph 7 of the agreement states that if the pharmacy doesn't materially comply with each requirement of the agreement, or the board opens a subsequent complaint during the stayed probation period, the registrant agrees that the probation matter may be extended, modified, or suspended. Considering the pharmacy has been subject to the agreement since May of 2022 and they did not remediate the issue of improper storage of needles and syringes of the earlier violation in April of this year. The Board may want to consider an additional extension beyond 5/27/2024 and to have a requirement that the pharmacy review the proper procedure for storing needles, etc., inside the license space and submit attestations to that affect. I think it would make sense to extend their probation more.

Board Counsel: The original consent agreement was for unknown loss of controlled substances. The stayed probation included the controlled substance loss protocol for benzodiazepines. As Karen already stated, the board already voted to lift the stay, making it a disciplinary probation, and extending it another year. I want the board members to keep in mind that any extension of that would also be an extension of the controlled substances loss protocol that is included within the probation agreement.

Caryn Belisle: Can I just ask one question? Going back to Karen, what you mentioned about the repeat deficiency which is unsecured unattended epinephrine outside the pharmacy space. You said that the staff were to review CMR and provide attestation. Was that part of the- No?

Karen: No there was, they had to provide originally with the Loss protocol requirements. They had to provide an attestation that they were all trained based on the unknown loss protocol.

Caryn: So nothing to do with unsecured meds?

Karen: No and the recommended action is to consider having them do an attestation that they have reviewed the proper procedure to store needles, etc. So that would be part of the suggestion. And that comes from corroboration with board staff in terms of recommendation.

Board Counsel: There's a couple of options the board can take, and it is up to all of you. Karne made it out very nicely. You can extend the probation period; the stay was already lifted. That notice was not already sent because this recent issue came up before the notice could be sent. So the decision was made to hold that notice of violation until this went to board and see what the ultimate decision was so that there would be only one notice sent. The stay has already been lifted by the board prior vote and the probation has already been extended by one year from your prior vote. So the board can, at this time, extend the probation by 1 additional year, you can add having an attestation that all pharmacy staff has review proper storage of syringes and needles. It is up to the board what they are comfortable doing.

Sebastian: And we can do both, right?

Board Counsel: You absolutely can do both. You can do something different if anybody on the board has any suggestions as to what that is, that is certainly up for discussion and debate amongst all of you.

Action: Motion by S. HAMILTON, seconded by S. Belisle, and voted unanimously by roll call of those present to extend the probation for an additional year, in addition to the one year already in place, and attestation that all team members have reviewed the proper storage of needles and associated medical devices.

TOPIC X

File Review

Open Session

TIME 10:28 AM

Case #1/CAS-2023-0596

PHA-2023-0173

Stop & Shop #45, DS1754

DEFERRED

Case #2/CAS-2023-0418

PHA-2023-0176

Stop & Shop #64, DS0161

DEFERRED

Case #3/CAS-2023-1060

Page **10** of **20**

Minutes General Session: 12/7/23

BOP Approved: 1/11/2023.

RECUSAL: NONE

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

- Inspectional deficiencies on 7/31/23 for storage of medications outside the licensed pharmacy area including epinephrine auto-injectors, needles/syringes, vaccines, injectable biologics, insulin, gabapentin solution, and lorazepam solution.
- The 8/4/23 POC indicated all refrigerated prescription products, epinephrine auto-injectors and the immunization kit were moved from the immunization/consultation room and into the Pharmacy on 7/31/23 and the freezer was being moved by the week's end. The Pharmacy submitted a limited waiver request to allow storage of vaccines only in the immunization/consultation room which was heard at the 9/7/23 Board meeting. After discussion, the waiver request was ultimately withdrawn. On 9/13/23, a second POC was submitted stating the Moderna COVID vaccine was moved from the freezer into a refrigerator and plans were underway to redesign the Pharmacy to accommodate full size refrigerators.
- Compliance Manager King stated in 2020 during the pandemic, the refrigerators and freezer were installed in the immunization/consultation room due to the increase in immunizations and lack of space in the Pharmacy. She contended the room was always part of the licensed Pharmacy and it was secured as such. She indicated that having the vaccines and epi-pens immediately available there was important for safety. She claimed the only prescription products in the room were Moderna COVID vaccine, Shingrix, Vaxneuvance, Boostrix and epinephrine pens.
- The freezer was emptied and the Moderna COVID vaccine was allegedly discarded; one refrigerator was emptied; the other was moved into the Pharmacy; the Pharmacy will be renovated to accommodate the full-size refrigerators on order; and epinephrine auto-injectors will be carried back and forth from the Pharmacy for each immunization. Patients will be directed to nearby pharmacies for immunizations that can no longer be stocked or stored given space constraints. MOR Valenti and Pharmacist Pulawski signed acknowledgements indicating they reviewed the outlined corrective action and the provided policies.

ACTION: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2023-0171), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #4/CASE-2023-0397

PHA-2023-0174

Bianca Mota, PTT16619

Time: 10:06 AM

RECUSAL: NONE

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

- During an inspection on 8/1/23 at Rite Aid #10198 in Fall River, PTT Mota was observed performing PT duties with a license that expired on 7/13/23. The POC stated that her application had been lost in the mail and was resubmitted on 8/7/23. Of note, the Pharmacy closed on 9/7/23.

- On 8/16/23, the BORP received the PT application dated 8/7/23 which indicated PTT Mota had passed her PT exam on 1/18/23 and had worked 1,000 hours.
- PTT Mota stated she contacted PCS several times in July prior to leaving for vacation but they could not find her in their system. She alleged she double checked with the MOR who told her it was okay, and it was all set. She returned from vacation on 7/31/23. During the inspection, PTT Mota related she asked Investigator Horn if he would check the status of her PT license since she had sent her application in February. She stated that after the inspection she only worked at the register until the Pharmacy's closure. She indicated she was rehired at another Rite Aid Pharmacy on 10/5/23 after being issued pharmacy technician license PT95984 on 9/27/23.

ACTION: Motion by D. BARNES, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2023-0174), 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 REPRIMAND.

Case #5 /CAS-2023-0817

PHA-2023-0147

Osco #2583, DS3194

Time: 10:09 AM

RECUSAL: NONE

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

- RLCS- Osco Pharmacy #2583 (Pharmacy) for an unknown loss of #67 methylphenidate 20mg tablets on or about 05/12/2023.
- In his report, Pharmacy Supervisor Valenza indicated that he was performing the perpetual Schedule II inventory count and noticed that the count for methylphenidate 20mg tablets was short 67 tablets.
- The inventory and transaction history as followed for methylphenidate 20mg tablets stated:
 - a. 04/28/2023 – 447 tablets
 - b. 05/01/2023- prescription filled by Pharmacist Valenza for 180 tablets
 - c. 05/06/2023- correctly counted as 267 tablets as inventoried by MOR Chaprazian
 - d. 05/12/2023- inventoried by Pharmacist Valenza for a count of 200 tablets with 67 tablets missing.
- MOR Chaprazian indicated the corrective action taken since this incident is the removal of the recycle bin to avoid any accidental disposal and each schedule II open stock bottles sealed with blue colored tape with the back count. All scheduled II products are restricted to pharmacist counting, back counting and dispensing.

ACTION: Motion by S. AHMED, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2023-0147), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #6/CAS-2023-0971

PHA-2023-0159

Walgreens #12558, DS89902

Time: 10:12 AM

RECUSAL: NONE

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

- During a retail compliance inspection conducted on 07/06/2023, two epinephrine auto-injectors, one recently expired, were observed stored in unlicensed space.
- MOR Andrews indicated that the root cause of this issue was that there were a series of floating pharmacists covering the Pharmacy and not all of them were aware of the procedures.
- The Emergency Kit Supplies document submitted with the response states, “Do not store the emergency kit outside of the pharmacy.”
- MOR Andrews indicated that to prevent this from recurring, a tote has been put together, which will be kept inside the pharmacy at all times, except when giving a vaccination. The immunizer will pick up the tote, which includes all needed supplies for administering vaccines, and carry it to the room. He or she will then return the tote upon completion of each immunization.

ACTION: Motion by R. LOPEZ, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0159), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #7/CAS-2023-0807

PHA-2023-0151

CVS #1238, DS2058

Time: 10:16 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 #517 clonazepam 0.5mg tablets discovered on or about 05/11/2023 via corporate controlled substance monitoring.
- MOR Giambanco confirmed reviewing the cycle counts, biennial inventories, staffing schedules and inventory reports for the applicable time period [dated 05/31/2023] and were unable to identify the reason for the loss.
- The MOR stated that all Loss Prevention policy and procedures will be reviewed with the Pharmacy Team.

ACTION: Motion by D. BARNES, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2023-0151), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION, for a period of 1 year, with special terms to include the CS Loss Protocol for all Benzodiazepines.

Case #8/CAS-2023-0966

PHA-2023-0160

CVS #1198, DS2831

Time: 10:18 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.

- During a retail compliance inspection (ISP-21661) conducted on 07/06/2023, Investigator Seed observed 2 emergency kits containing 4 epinephrine auto injectors stored in the unlicensed, unsecured immunization room.

- Of note, during Investigator Seed’s previous inspection on 01/03/2023, during which the Pharmacy was undergoing a renovation to add the consultation/immunization room, he proactively discussed with MOR Beauvais that drug could not be stored in this space as it was unlicensed space.
- MOR Beauvais stated in the POC response that all staff are aligned and will ensure no immunization supplies are left behind post each immunization administration. In the complaint response she reiterated that only non-prescription supplies would be stored in the immunization room.

ACTION: Motion by S. HAMILTON, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0160), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #9/CAS-2023-1061
-2023-0172

CVS #6466, DS89773

Time: 10:20 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.

- Complaint alleging the on 07/31/2023 Pharmacy refused to fill a veterinary prescription for a Schedule VI medication without the DEA number of the prescribing veterinarian.
- It was noted that the Pharmacy would not fill the prescription without a DEA number even after they were informed that it was not required. When staff attempted to pick up the prescription at the Pharmacy for their hospitalized patient, they said they were told it would have to be ordered.
- MOR Estrela indicated that she did not refuse to fill the prescription for Xarelto 2.5mg on 07/31/2023. The MOR said that the issue was that the provider gave a preferred first name not the name the license is under which made it difficult to locate the prescriber in the system.
- MOR noted that the prescription was filled that same day as she was familiar with the prescriber's correct first name as this issue occurred in the past. MOR Estrela further noted that the prescription sat in the waiting bin for 14 days before it was returned to stock.
- PT Mello indicated that she took the verbal prescription that day and could not find the prescriber in the system because she was searching under the prescriber’s preferred first name. She asked for the prescriber’s DEA number to locate the prescriber, but it was not given, and the office staff indicated that they would call back but never did.
- MOR Estrela submitted a signed attestation of the pharmacy staff having reviewed “105 CMR 721.00” section related to the veterinary prescriptions issued for CVI prescriptions in Massachusetts that do not require DEA number.
- MOR Estrela indicated that the policy and procedure was reviewed with the team and reminded them to always include the pharmacist with any issues that cannot be resolved.

ACTION: Motion by R. LOPEZ, seconded by K. THORNELL, and voted unanimously by those present, to DISMISS the matter (PHA-2023-0172), No Discipline Warranted, Remediation Complete.

Case #10/CAS-2023-0898
PHA-2023-0156

Azeb Sequar, PTT14180

Time: 10:23 AM

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

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

- On July 26, 2023, Investigator Geaney observed during an RCI (ISP-21607) that PTT Sequar was working as a PTT with an expired PTT license. Accordingly, Investigator Geaney issued a POC based partly on PTT Sequar working with an expired license.
- Former MOR Muehlbauer indicated in the pharmacy's POC that PTT Sequar was promptly removed from the pharmacy roster until she was able to reactivate her registration. MOR Muehlbauer avowed that she would monitor the status of "all technician licenses going forward." In addition, MOR Muehlbauer indicated that a "discussion on accountability" with PTT Sequar was carried out to mitigate recurrence of a similar event.
- BORP opened a complaint against PTT Sequar and she acknowledged that she worked with an expired license. She explained that she did so only because Pharmacist Gabriel Rusanescu directed her to return drugs to stock and signed her in the computer system under his credentials. She assumed that Pharmacist Rusanescu was aware of her license status but did not inform him.
- CA: PTT Sequar first explained that she understood she must keep track of her licensure and not rely on work or others to determine her license status. She also indicated that she must notify the pharmacist on duty about her issues with her license status such as an expired status. She acknowledged that she was wrong to assume that Pharmacist Rusanescu was aware that her license was expired. Lastly, PTT Sequar confirmed that she understood she must use her credentials only in the pharmacy even when a pharmacist permits her to do so. Of note, PTT Sequar was granted an expiration date extension to January 18, 2024.
- In addition, BORP opened a staff-assignment investigation and Former MOR Muehlbauer acknowledged that PTT Sequar was working with an expired license on June. MOR Muehlbauer explained that PTT Sequar submitted an application for extension of the expiration of her PTT license in May 2023 and she was supposed to only work as a cashier until her extension was confirmed. However, "[Pharmacist Rusanescu] was not familiar with [PTT Sequar]'s situation and [PTT Sequar] ended up returning medications to the shelf under the [Pharmacist Rusanescu]'s credentials."
- CA: Former MOR Muelberger indicated that PTT Sequar was removed from the pharmacy until her license was granted an expiration date extension. She then summarized, "To close, issue has been remedied as Azeb is now licensed and going forward I will continue license monitorization to ensure continued compliance."

ACTION: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2023-0156), 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 REPRIMAND.

Case #11/CAS-2023-0898

SA-INV-22537

CVS #10891, DS90281

Time: 10:27 AM

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

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

- On July 26, 2023, Investigator Geaney observed during an RCI (ISP-21607) that PTT Sequar was working as a PTT with an expired PTT license. Accordingly, Investigator Geaney issued a POC based partly on PTT Sequar working with an expired license.
- Former MOR Muehlbauer indicated in the pharmacy's POC that PTT Sequar was promptly removed from the pharmacy roster until she was able to reactivate her registration. MOR Muehlbauer avowed that she would monitor the status of "all technician licenses going forward." In addition, MOR Muehlbauer indicated that a "discussion on accountability" with PTT Sequar was carried out to mitigate recurrence of a similar event.
- BOP opened a complaint against PTT Sequar, and she acknowledged that she worked with an expired license. She explained that she did so only because Pharmacist Gabriel Rusanescu directed her to return drugs to stock and signed her in the computer system under his credentials. She assumed that Pharmacist Rusanescu was aware of her license status but did not inform him.
- CA: PTT Sequar first explained that she understood she must keep track of her licensure and not rely on work or others to determine her license status. She also indicated that she must notify the pharmacist on duty about her issues with her license status such as an expired status. She acknowledged that she was wrong to assume that Pharmacist Rusanescu was aware that her license was expired. Lastly, PTT Sequar confirmed that she understood she must use her credentials only in the pharmacy even when a pharmacist permits her to do so. Of note, PTT Sequar was granted an expiration date extension to January 18, 2024.
- In addition, BOP opened a staff-assignment investigation and Former MOR Muehlbauer acknowledged that PTT Sequar was working with an expired license on June. MOR Muehlbauer explained that PTT Sequar submitted an application for extension of the expiration of her PTT license in May 2023 and she was supposed to only work as a cashier until her extension was confirmed. However, "[Pharmacist Rusanescu] was not familiar with [PTT Sequar]'s situation and [PTT Sequar] ended up returning medications to the shelf under the [Pharmacist Rusanescu]'s credentials."
- CA: Former MOR Muelberger indicated that PTT Sequar was removed from the pharmacy until her license was granted an expiration date extension. She then summarized, "To close, issue has been remedied as Azeb is now licensed and going forward I will continue license monitorization to ensure continued compliance."

ACTION: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to CLOSE the matter (SA-INV-22537), No Discipline Warranted, Remediation Complete. Second motion by S. HAMILTON, seconded by R. LOPEZ, and vote unanimously by those present, to open a complaint on Pharmacist Rusanescu (PH239940)

Case #12/CAS-2023-1007

PHA-2023-0168

CVS #433, DS89786

Time: 10:29 AM

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

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

- On July 13, 2023, Investigator Brosnan observed during an inspection that an unlicensed staff member, Kaleigh Krzysztof, was performing duties which required a PTT license including "...reversing the claims through the computer, pulling medication bottles for other technicians and pharmacists to fill prescriptions with and putting the order away."
- MOR Sulkey and Ms. Krzysztof were advised that Ms. Krzysztof "can only operate registers, drive through included, and pull RTS prescriptions from the waiting bin but cannot reverse them through the computer." In addition, a plan of correction (POC) was issued for permitting an unlicensed staff member to perform duties which required a PTT license.
- POC/CA: MOR Sulkey indicated that he would have Ms. Krzysztof "contact MA BOP to resubmit her application/find out where the problem was after she submitted in June 2022." Of note, Ms. Krzysztof's application was filed but was incomplete according to BORP records. Thus, she still was not licensed by BORP as of October 19, 2023. CVS 433 was also advised on the same day that MS. Krzysztof remained unlicensed.
- In addition, MOR Sulkey also assured BORP that "all employees without a valid state technician license will be advised and enforced that they can only operate registers and can pull RTS without reversing the claims." MOR Sulkey further assured BORP that he would ensure pharmacy staff "have valid licenses and if a valid technician license is not present, only operate registers."

ACTION: Motion by S. AHMED, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2023-0168), 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 REPRIMAND.

Case #13/CASE-2023-0431

PHA-2023-0205

CVS #505, DS89977

Time: 10:31 AM

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

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

- On August 31, 2023, CVS 505 reported an unknown loss of 334 acetaminophen-codeine 300-30mg tablets (CIII, 500 tablet stock bottle) discovered on August 10, 2023 "via the corporate controlled substance monitoring.
- CA: MOR O'Hearn wrote, "All Loss Prevention policy and procedures have been reviewed with the Pharmacy Team. This includes diligent inventory management."

ACTION: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0205), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION, for a period of 1 year, with special terms to include the CS Loss Protocol for all APAP/codeine solid dosage forms.

Case #14/CAS-2023-1101

PHA-2023-0183

CVS #1204, DS2239

Time: 10:33 AM

RECUSAL: J. ROCCHIO and D. PERRY recused and was 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 #60 Adderall XR 60mg allegedly discovered on 7/11/23 when a prescription could not be found in the waiting bin. Controlled substance recordkeeping was reviewed, and the waiting bins were searched.
- Contrary to the RLCS report, MOR DeSimone stated the loss was first discovered on 7/2/23 when the customer came in to pick up the medication and it was not found. The pharmacist left MOR DeSimone a note. MOR DeSimone also searched the waiting bins. MOR DeSimone stated, "I reviewed the footage of myself filling the prescription and placing it into the correct bin. I watched this same view to try to see when it was removed from the bin, but it was too difficult to tell". MOR DeSimone contended, "I believe what most likely happened is someone did not ring out the prescription properly at pick up, so it did not register as sold". Employee diversion was ruled out, "...as this is the first time a controlled substance has gone missing, and we've been unable to locate it".
- Pharmacist Ly stated she did not recall the details of the incident.
- The E-Rx was issued on 6/26/23, then filled and verified by MOR DeSimone on 6/27/23. MOR DeSimone reprinted a label for the prescription on 7/5/23 then it was dispensed to the patient. MOR DeSimone adjusted the perpetual inventory on 7/11/23 for the unknown loss noting, "Script went missing from waiting bin. Have on camera RPh filling and placing into correct bin. Likely was given to customer without properly being rung out; further investigation required".
- MOR DeSimone provided a signed statement which stated, "I hereby attest that all policies and procedure for the proper storage and handling of controlled substances have been reviewed".

ACTION: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to COMBINE the matter (PHA-2023-0183) with PHA-2022-0123, then 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 REPRIMAND.

Topic XI:

Executive Session Call to Order:

Time: 10:39 AM

By: Caryn 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 K. Thornell and Board Members present voted unanimously by roll call to approve motion.

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

Topic XII: ADJUDICATORY SESSION (M.G.L. ch. 30A, §18) Time: 11:16 AM

DISCUSSION: None

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

At 11:16 AM S. Hamilton, seconded by S. Ahmed and voted unanimously by all those present to enter 65C by roll call vote.

Topic XIII: 65C Sessions MGL c. 112 section 65C Time: 11:22 AM

DISCUSSION: None

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

At 11:16 AM S. Hamilton, seconded by S. Ahmed and voted unanimously by all those present to enter 65C by roll call vote.

D. Perry leaves meeting at 12:00 PM

Topic XIV: ADJOURNMENT OF MEETING TIME: 12:16 PM

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

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 12/7/23 General Session
2. Draft Minutes of the 11/2/23 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on Board Delegated Complaint Review to licensure policy 14-02
5. Report on PSUD 17-03
6. CVS/Specialty: DS3416 – Renovation
7. MedWiz of Mass, LLC -DS90404– Renovation
8. Baystate Specialty Pharmacy; DS90099-Renovation
9. Tufts Medicine Home Infusion; DS90378-Waiver Requests
10. Greater Lawrence Family Health Care: DS89675-Relocation
11. BILH Pharmacy Direct; DS90336 – Request to change business model
12. Policy 14-02: Board Delegate Review (BDR)

13. Policy 2020-15: Scope of Practice
14. Policy 2023-07: Non-Sterile Compounding
15. Policy 2023-09: Action Level Environmental Monitoring Results
16. Advisory: Compounded Ketamine
17. CVS #321; DS2928, PHA-2021-0049 – Repeat Deficiencies/ Review of Compliance
18. CAS-2023-0596 PHA-2023-0173 Stop & Shop #45, DS1754
19. CAS-2023-0418 PHA-2023-0176 Stop & Shop #64, DS90161
20. CAS-2023-1060 PHA-2023-0171 Price Chopper Pharmacy 240, DS89863
21. CAS-2023-0397 PHA-2023-0174 Bianca Mota, PTT16619
22. CAS-2023-0817 PHA-2023-0147 Osco #2583, DS3194
23. CAS-2023-0971 PHA-2023-0159 Walgreens #12558, DS89902
24. CAS-2023-0807 PHA-2023-0151 CVS #1238, DS2058
25. CAS-2023-0966 PHA-2023-0160 CVS #1198, DS2831
26. CAS-2023-1061 PHA-2023-0172 CVS #6466, DS89773
27. CAS-2023-0898 PHA-2023-0156 Azeb Sequar, PTT14180
28. CAS-2023-0898 SA-INV-22537 CVS #10891, DS90281
29. CAS-2023-1007 PHA-2023-0168 CVS #433, DS89786
30. CASE-2023-0431 PHA-2023-0205 CVS #505, DS89977
31. CAS-2023-1101 PHA-2023-0183 CVS #1204, DS2239

DRAFT