

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

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

September 1, 2022

Webex Information

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

For video access click on the following link:

<https://eohhs.webex.com/eohhs/onstage/g.php?MTID=e7210e85ce0645ddfb9a526fd1a96cd44>

To access the meeting by phone:

Call in Number: 1-650-479-3208

Access Code: 2531 388 0446

Attendee: #

*If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator **Erin Bartlett**, erin.bartlett2@mass.gov or 857-262-7431 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.*

Agenda

Time	#	Item	Page	
8:00	I	CALL TO ORDER		
8:02	II	APPROVAL OF AGENDA <ul style="list-style-type: none">• Introduction of Board Counsel	1	
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of August 4, 2022 Regular Session Minutes	4	
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	35 38 39	

8:15	V	FLEX		40 43	D. Sencabaugh	
		<ul style="list-style-type: none"> • Pharmacy issues related to COVID-19 • Standing Order for Dispensing Emergency Contraception Pills • Pharmacy Advisory Committee Meeting: September 28, 2022 • Recommendation Document 22-02: Pharmacy Advisory Committee • Presentation on Standards of Patient Care • Resolutions for the District 1&2 NABP meeting • Election of a delegate and alternate for the District 1&2 NABP meeting • Review of upcoming Board meetings 				
8:45	VI	APPLICATIONS			44 48 51 68 109 131 149 158	
		Central Admixture Pharmacy Services	DS3312	Petition for waiver		
		Central Admixture Pharmacy Services	DS3312	Board review of sterile compounding sink placement and gowning sequence		
		New Health Charlestown Pharmacy	N/A	New Community Pharmacy		
		MedMinder Pharmacy	DS90072	Relocation		
		BHCHP Pharmacy	N/A	New Community Pharmacy		
		BAMSI Pharmacy	N/A	New Community Pharmacy		
		Walmart	N/A	Petition for waiver		
Rite Aid	N/A	Petition for waiver				
10:15	VII	REGULATIONS			163	
		<ul style="list-style-type: none"> • 247 CMR 13.00: Nuclear Pharmacy Licensure Requirements and Professional Practice Standards 				
10:45	VIII	POLICIES			182	
		<ul style="list-style-type: none"> • Policy 2022-08: Compliance Packaging • Policy 2022-07: Automated Pharmacy Systems • Joint Policy 2020-09: Emergency Contraception Standing Order – Rescind 			185	
					187	

11:00	IX	FILE REVIEW				
		1	CAS-2022-0415	SA-INV-19753	Cardinal Health 110, WD352	189
		2	CAS-2022-0321	SA-INV-19559	Dustin Teich, PH239857	196
		3	CAS-2022-0489	PHA-2022-0098	Walgreens #3564, DS2760	221
		4	CAS-2021-1303	PHA-2021-0117	Walgreens #18122, DS90224	242
		5	CAS-2022-0248	PHA-2022-0074	Walgreens #2781, DS3468	244
		6	CAS-2022-0441	PHA-2022-0091	Walgreens #6850, DS3169	247
		7	CAS-2022-0479	PHA-2022-0097	Walgreens #19460, DS90146	249
		8	CAS-2022-0521	PHA-2022-0109	Dominic Regalbuto, PH238864	252
		9	CAS-2022-0303	PHA-2022-0063	CVS #2054, DS2588	255
		10	CAS-2022-0456	PHA-2022-0095	CVS #1221, DS2988	258
		11	CAS-2022-0386	PHA-2022-0077	CVS #109, DS3586	261
		12	CAS-2022-0362	PHA-2022-0075	CVS #1230, DS2023	277
		13	CAS-2022-0185	PHA-2022-0020	CVS #302, DS2599	301
12:00		LUNCH BREAK				
12:30	X	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 licensee's request for early termination of an agreement and to evaluate the Good Moral Character as required for registration for a pending applicant.			304	
1:15	XI	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)			387	
2:00	XII	M.G.L. c. 112, § 65C SESSION			408	
3:30	XIII	ADJOURNMENT				

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

September 1, 2022

Board Members Present

Sebastian Hamilton, Pharm D, MBA, RPh President
Caryn Belisle, RPh, MBA, President-Elect
Carly Jean-Francois, RN, NP Secretary (arrives 8:05 AM)
Julie Lanza, CPhT
Jennifer Chin, RPh
John Rocchio, RPh, PharmD
Dr. Richard Lopez, MD
Sami Ahmed, Pharm.D., RPh, BCPS, BCSCP (Arrives 8:21 AM)
Rita Morelli, PharmD, BCACP, RPh
Katie Thornell, RPh, MBA

Board Members Not Present

Dawn Perry, JD
Delilah Barnes, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Heather Engman, JD, General Counsel
Jaqueline 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
Ed Taglieri, MSM, NHA, RPh PSUD Supervisor
Joanna Chow, Office Support Specialist
Taylor Lee, Office Support Specialist
Joanne Trifone, RPh, Director of Investigations
Nancy Aleid, Compliance Officer
Christina Mogni, RPh, Investigator
Gregory Melton, RPh, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 AM

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

Roll call attendance: J. Lanza, yes; S. Hamilton, yes; C. Belisle, yes; J. Rocchio, yes; J. Chin, yes;
R. Lopez, yes; R. Morelli, yes; K. Thornell, yes. (S. Ahmed and C. Jean-Francois join meeting after vote).

Topic II.

Approval of Agenda

TIME 8:03 AM

Agenda 03/03/03

DISCUSSION:

Defer: New Health Charlestown Pharmacy Application

Dave and Heather introduce new Board Counsel Jaqueline Petrillo and welcome her.

Dave updates Board on Susan Cornacchio's position has been completed and thanks her for her contributions.

Dave updates everyone on 10/22 meeting being moved to 10/13/22 due to conflict with NABP District I meeting.

ACTION:

Motion by R. Morelli, seconded by C. Jean-Francois and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:09 AM

Minutes

1. Draft 8/4/22

Change: no changes

Action:

Motion by R. Morelli seconded C. Jean-Francois and voted unanimously to approve the regular session minutes of 8/4/22 with no noted changes by roll call vote. Dr. Lopez abstains.

TOIC IV

Reports

PSUD report by Staff Action 17-03

TIME: 8:10 AM

PRESENTED BY: E. TAGLIERI

DISCUSSION: E. Taglieri reported 13 active participants currently enrolled in the PSUD program. A successful quarterly meeting was completed in July and the next meeting is expected to take place in October. One PSUD participant is expected to graduate from the program later in September.
So noted.

Topic IV.

REPORTS

Applications approved pursuant to Licensure Policy 13-01

TIME: 8:11 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris reported 61 Change of Manager applications and Facility Renovation applications that have been approved via Staff Action since the August 4th Board meeting.

So noted.

Topic IV.

REPORTS

Page 2 of 23

Draft Minutes General Session: 9/1/22

BOP Approved: 10/13/22

Monthly Report from Probation

TIME: 8:11 AM

PRESENTED BY: R. HARRIS

DISCUSSION: R. Harris indicated no new reports since the last Board meeting.
So noted.

Topic IV.

REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

TIME: 8:11 AM

PRESENTED BY: D. SENCABAUGH

DISCUSSION: D. Sencabaugh reported 5 CE deficiencies that have been remediated and closed with no discipline warranted since the last Board meeting. 3 waiver renewal requests had been approved during the Board Delegated review. 3 reports of controlled substance losses were reported and issued non-disciplinary stayed probation with controlled substance protocol.
So noted.

TOPIC V

Flex

1. Pharmacy Issues related to Covid-19 and state of emergency.

Time: 8:12 AM

Presented by: D. SENCABAUGH

Discussion: The FDA has authorized Pfizer and Moderna's updated Covid-19 boosters.

So noted.

2. Standing Order for Dispensing Emergency Contraception Pills

Time: 8:13 AM

Presented by: M. CHAN

Discussion: DPH has issued a standing order for emergency contraception. A link will be posted on the Board's website.

So noted.

**3. Pharmacy Advisory Committee Meeting: September 28, 2022
Recommendation Document 22-02: Pharmacy Advisory Committee**

Time: 8:13 AM

Presented by: W. FRISCH

Discussion: The topic of discussion will be the Board's Draft Regulations at 247 CMR 17, *Sterile Compounding*. A revised draft of USP <797> was released on September 1, 2021, reflecting changes from appeals and public comment. At that time, the Board approved Board staff to submit public comments to USP on their behalf.

Major changes to the revised draft of USP <797> centered around the addition of a new "Category 3" for compounded sterile preparations (CSPs). The proposed Category 3 CSPs are

allowed to have extended beyond-use dates (up to 180 days) provided that additional risk mitigation requirements (e.g., enhanced personnel and environmental monitoring, etc.) are met.

Board staff has updated the draft of 247 CMR 17 to reflect these changes as well as other minor improvements.

Action: Motion by J. LANZA, seconded by S. HAMILTON, and voted unanimously by roll call of those present, to approve for C. BELISLE and / or S. AHMED to present the Pharmacy Advisory Recommendation request (22-02) to the Pharmacy Advisory Committee on September 28, 2022, and then provide an update to the Board at the October 13, 2022, meeting.

4. Presentation on Standards of Patient Care Initiative

Time: 8:19 AM

Presented by: D. SENCABAUGH

Discussion: Board staff have been conducting meetings with several community pharmacy corporate leadership teams and has plans to meet with the Massachusetts Independent Pharmacists' Association (MIPA) to improve communications and address any concerns. The meetings have been very productive and educational for both parties. Having a corporate point person has helped address pressing patient concerns and on-going issues; and the Board has been able to respond to corporate requests regarding practice allowances during staffing shortages as well as assist with urgent licensing requests.

So noted.

5. Resolutions for the District 1&2 NABP Meeting

Time: 8:26 AM

Presented by: W. FRISCH

Discussion: Board staff presented two resolution topics for the NABP District 1 & 2 meeting. The first is for a taskforce to investigate and develop a blueprint for a Standards of Patient Care Initiative to improve communications between pharmacies and state Boards of Pharmacy. The second is to survey state data and develop a blueprint for pharmacists to perform point of care testing and initiate treatment based on the results.

Action: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by roll call of those present, to forward the Standards of Patient Care Initiative resolution to the district meeting.

Action: Motion by J. ROCCHIO, seconded by K. THORNELL, and voted unanimously by roll call of those present, to forward the point of care test and treat resolution to the district meeting.

6. Election of a delegate and alternate for the District 1&2 NABP meeting

Time: 8:35 AM

Presented by: D. SENCABAUGH

Discussion: The delegate would present the Board's resolutions at the meeting as well as vote on other resolutions on the Board's behalf. The alternate would complete these tasks if the delegate were not available to do so.

Action: Motion by K. THORNELL, seconded by S. HAMILTON, and voted unanimously by roll call of those present, for K. THORNELL to be the Board's delegate at the district meeting.

Action: Motion by J. ROCCHIO, seconded by R. MORELLI, and voted unanimously by roll call of those present, for J. ROCCHIO to be the Board's alternate at the district meeting.

7. Review of upcoming Board meetings

Time: 8:41 AM

Presented by: D. SENCABAUGH

Discussion: The October meeting has been delayed due to a conflict with the NABP District 1&2 meeting. There has also been an extension of the public meeting law allowing virtual Board meetings to continue through March 2023. Board meeting dates through March 2023 are:

October 13, 2022

November 3, 2022

December 1, 2022

January 12, 2023

February 2, 2023

March 2, 2023

Action: Motion by J. LANZA, seconded by K. THORNELL, and voted unanimously by roll call of those present, to approve the Board meeting schedule.

TOPIC VI

Applications

1. Central Admixture Pharmacy Services DS3312 Petition to Waive

TIME: 8:44 AM

Represented by: George Gomas & Younes

Recusal:

Discussion:

BOP W. Frisch provided a brief synopsis about why Central Admixture Pharmacy Services (CAPS) were coming before the board. He indicated that CAPS located in Woburn, MA is one of the board's licenses which engages in sterile compounding operations. W. Frisch indicated that one of the documents in the board packet is a petition to waive the requirement to a pharmacy balance which the board has no objections to. The next petition pertains to the placement of the handwashing sink in the sterile compounding area, as well as a variation from the USP 797 of the gowning sequence. W. Frisch notes that compliance with all chapters of USP 797 is included in board regulations. A memo was also

included explaining the history of a previously submitted waiver for the gowning sequence and sink placement in 2016. Upon reviewing the matter it has been determined that a waiver was not required however, board staff requested that CAPS provide a formal petition for the placement of the handwashing sink outside of the Anti-room along with the request for the gowning sequence. CAPS provided their rationale for these requests and included steps to mitigate contamination concerns. W. Frisch indicates that the board has no objections to these requests and respectfully asks for a board vote to approve the balance waiver and vote that no waiver is required for the placement of handwashing sink outside of the anti-room and no enforcement action would be taken for the variation in the gowning sequence outlined by USP 797. Board member S. Ahmed inquired about the weekly fingertip testing and whether it was being completed on all employees. G. Gomatos responds that all compounding employees are being tested.

Motion to approve the balance waiver by J. Lanza; Seconded by J. Chin, then Board Members presented voted unanimously by rollcall to approve motion.

2. Central Admixture Pharmacy Services DS3312 BOP Review Sink/Gowning Sequence

TIME: 8:44 AM

Represented by: George Gomatos & Younes

Recusal: C. Belisle

Discussion:

BOP W. Frisch provided a brief synopsis about why Central Admixture Pharmacy Services (CAPS) were coming before the board. He indicated that CAPS located in Woburn, MA is one of the board's licenses which engages in sterile compounding operations. W. Frisch indicated that one of the documents in the board packet is a petition to waive the requirement to a pharmacy balance which the board has no objections to. The next petition pertains to the placement of the handwashing sink in the sterile compounding area, as well as a variation from the USP 797 of the gowning sequence. W. Frisch notes that compliance with all chapters of USP 797 is included in board regulations. A memo was also included explaining the history of a previously submitted waiver for the gowning sequence and sink placement in 2016. Upon reviewing the matter it has been determined that a waiver was not required board staff requested that CAPS provide a formal petition for the placement of the handwashing sink outside of the Anti-room along with the request for the gowning sequence. CAPS provided their rationale for these requests and included steps to mitigate contamination concerns. W. Frisch indicates that the board has no objections to these requests and respectfully ask for a board vote to approve the balance waiver and vote that no waiver is required for the placement of handwashing sink outside of the anti-room and no enforcement action would be taken for the variation in the gowning sequence outlined by USP 797. Board member S. Ahmed inquired about the weekly fingertip testing and whether it was being completed on all employees. G. Gomatos responds that all compounding employees are being tested.

Motion made to approve no longer having to request a waiver for the sink and not taking any action for the variation in gowning sequence by J. Lanza; Seconded by S. Ahmed, then Board Members presented voted unanimously by rollcall to approve motion.

3. New Health Charlestown Pharmacy New Community Pharmacy

Deferred

4. MedMinder Pharmacy DS90072 Relocation TIME: 9:51 AM
Represented by: Elizabeth Travis, David Brass, & Allison Hill

Recusal:
Discussion:

E. Travis explains that MedMinder is a growing the facility that has currently outgrown their existing facility which is why they are petitioning the board for a relocation. B. Frisch indicates that MedMinder is coming before the board with 4 waivers which would be new to the facility. E. Travis indicates that MedMinder is a synchronized pharmacy compliance packaging and deliver to all patients in conjunction with a proprietary device which is programed according to the specific medication times of the individual. She states that they are a multi-dose compliance packaging that is dispensed. S. Hamilton inquires if this is 100% this type of model which E. Travis responds that some patients prefer vials and some patients that prefer dispill packaging without the device. B Frisch identifies that waivers being requested by MedMinder which include the following- 247 CMR 6.02(4) which pertains to sufficient supplies of medicinal and chemicals, 247 CMR 6.02 (5) signage, 247 CMR 9.01 (15) shall not restrict services, and 247 CMR 9.01 (16) compounding. These waivers are more typical of a closed-door operation which the board has no objections to the board approving those waivers or the relocation application as it is transferable over to their new facility.

Motion made to approve the waivers and relocation application by S. Hamilton; Seconded by C. Jean-Francois, then Board Members presented voted unanimously by rollcall to approve motion.

5. BHCHP New Community Pharmacy TIME: 9:03 AM
Represented by: James Pearse , Barry Bock, and Agnes Long

Recusal: J. Rocchio
Discussion:

J. Pearse indicates that he is coming before the board to open a pharmacy to serve the underserved homeless population. They would like to start their own pharmacy to have more control of pharmacy operations. They plan on taking the same space as they were previously in inside of a facility previously run by CVS. B. Frisch indicates that the board has no comments, objections, or concerns. S. Ahmed inquiries about hazardous compounding or if they are doing solid dosage forms. J. Pearse responds that they indicate which medications are hazardous are segregated and are kept in yellow bags. They use software to indicate which medications are hazardous. S. Hamilton indicates that they have to get approval from HCQ. C. Jean-Francois inquires if they have current staff. J. Pearse responds that because of their contracts they can't begin hiring staff, but they plan on hiring additional staff in

the future. J. Pearse indicates that they also have a clinic license and are closing on Friday and plan on opening on Monday contingent upon an inspection from the Board. J. Perase is inquiring if they can fill the medications in the clinic on the 4th floor and store them in a bin downstairs. S. Hamilton responds that there may be a way to obtain a license number before the doors open to begin the process. D. Sencabaugh responds that this may not be as simple, and we can schedule an inspector to go on site that Monday morning. D. Sencabaugh indicates that he doesn't know if we can address the clinic section as HCQ or DCP would be able to address. B. Frisch indicates that DCP and other involved entities could meet in the upcoming week offline to discuss this inquiry further.

Motion made to approve the application for a new community pharmacy as submitted pending successful inspection by S. Hamilton; Seconded by S. Ahmed, then Board Members presented voted unanimously by rollcall to approve motion.

**6. BAMS Pharmacy
Represented by: Matt Moen**

New Community Pharmacy

TIME: 9:16 AM

**Recusal:
Discussion:**

M. Moen indicates that BAMS is a non-profit human service organization located in Brockton that serves patients who primarily reside in the south shore area from Worcester and extending out to the cape area. The pharmacy is designed to service individuals residing in group homes. They have a large number of residential programs that service individuals with developmental disabilities or mental health issues. They are not a compounding pharmacy however they plan on having the capacity to accommodate for simple and moderate non-sterile compounding as required by board regulations. The staffing ratios will initially begin with two technicians in a 1:2 ratio and plan on building pharmacracy staff as needed. S. Hamilton inquired about immunizations, compliance packaging, and delivery services. M. Moen responds that they don't plan on administering any immunizations however if that were to change, they would follow the appropriate guidelines to comply with board requirements. They do intend on delivering through a courier service or through employed drivers they are still trying to make that determination. In terms of compliance packaging the patients that fall into the MAP program and will be single-dose and not multi-dose packaging products as stipulated by MAP requirements. C. Belisle inquired if hazardous medications will be compounded at the facility. M. Moen indicated no hazardous medications will be compounded only simple and moderate.

Motion made to approve the application as submitted pending successful inspection by C. Belisle; Seconded by J. Chen, then Board Members presented voted unanimously by rollcall to approve motion.

Represented by: Jacob Creel

Recusal:

Discussion:

D. Sencabaugh indicated that Walmart and Rite Aid petitioned the board not to stock promethazine with codeine. This posed a very complex matter given board regulations to stock medications that are necessary to serve the needs of the community. Last month the board voted to hold the vote and bring it back this month to vote on the waiver request. J. Creel indicated that Walmart's commitment is to the patient and there are other therapeutic alternatives that can be stocked that don't have the same potential dangers as promethazine with codeine. C. Belisle inquires if Walmart is requesting not to stock promethazine with codeine if a patient came in with a prescription with alternatives that don't work for the patient, would the pharmacist be able to order the product for a patient as deemed medically necessary by the provider. J. Creel responds that the pharmacy would not be able to order promethazine with codeine for the patient given they have signage indicating that promethazine with codeine will not be stocked in the pharmacy to deter counter jumpers. J. Creel also indicates that this plan has been proposed throughout the states and they have not seen any instance where this has occurred. R. Lopez inquires if any other state has declined this request for the waiver and if Walmart has considered putting promethazine with codeine in a secure location to deter counter jumpers. J. Creel responds that no other regulators have been opposed to this decision not to carry this product given the availability of other alternatives and the safety concerns. He also indicates that they have other liquid forms of medications that kept in a safe are not as targeted as this medication based on the data that has come from throughout the country as it is a target of gang activity. S. Hamilton inquires if this is a global corporate position and if so, no other entity has commented on this decision. J. Creel confirms that this is a corporate decision and that no other entity has commented on this decision. J. Creel indicates that they have not had formal conversations regarding this decision however they have had on-off conversations with board executives and other regulators regarding their decision not to stock promethazine with codeine. S. Hamilton inquired as to what the stance of other states were, and J. Creel responded that he would have to check to confirm but to his knowledge there was no approvals or prohibitions on it. S. Ahmed inquires if there has been any discussion surrounding the establishment of a central distribution center to protect staff and avoid counter jumpers. J. Creel indicates that if this situation were to arise Walmart would be flexible. R. Morelli inquired if there was an increase in counter jumpers amongst other chains in states that no longer stock promethazine with codeine on their shelves. J. Creel responds that he has no data to show if there was an increase or decrease in counter jumping but he has not heard from any other partners in the industry who are experiencing this and are considering making this change. C. Jean-Francois inquires if the other pharmacies are locking the medication in a different way. J. Creel does not know how other partners are handling this situation. C. Jean-Francois inquired if a patient comes to Walmart, and they don't carry the drug if they would be willing to transfer the patient to another pharmacy that does carry it.

Motion made to defer the waiver vote made by S. Hamilton; Seconded by R. Morelli, then Board Members presented voted unanimously by rollcall to approve motion.

8. Rite Aid

Petition to Waiver

TIME: 9:40 AM

Represented by: Jermaine Smith & Janet Hart

Recusal:

Discussion:

J. Smith indicates that his colleagues at Walmart covered the same points and that they don't operate in all 50 states, but they operate in 17 states. Massachusetts was the only state that required Rite Aid to come before the board and they did not get a thumbs up or a thumbs down on their decision not to stock promethazine with codeine. Patient safety and associate safety is a priority given the increase in violence for obtaining this drug. J. Hart spoke to the fraudulent activity and states that there have been over 800 fraudulent prescriptions for this drug. J. Hart indicates that Rite Aid has been proactive in providing alternatives for individuals who need this drug. S. Hamilton inquired about the safety of other pharmacies if this chain were to decide to stop stocking this drug. J. Hart responds that this could be a possibility. R. Morelli inquires if there has been any discussion on putting the drug in the safe with any other regulators. J. Hart responds that she would welcome this change if the drug would get rescheduled and effectuating this change would take a very long time. J. Hart also adds that they would not want to encounter a hostage situation with patients or pharmacy staff if the drug were to be in a safe. R. Lopez inquired if they voted on this waiver if it would bind the board to a precedent not to stock other drugs of concern. H. Engman responds that this could create a precedent and there is a concern that other pharmacies may decide not to stock a drug due to a low profit margin. D. Sencabaugh indicates that this matter is being brought to board given the unique requirement to stock all necessary drugs. D. Sencabaugh indicates that waivers are usually valid for 5 years and it may be beneficial to shorten the length of the waiver in these cases to a year so that there can be an assessment of how effective or lack thereof this proposed solution was. D. Sencabaugh also indicates that perhaps we can create a policy as it pertains to this drug so that the board is not inundated with waiver requests for promethazine with codeine.

Motion made to defer the waiver vote made by S. Hamilton; Seconded by K. Thornell, then Board Members presented voted unanimously by rollcall to approve motion.

TOPIC VII

Regulations

247 CMR 13.00: Nuclear Pharmacy Licensure Requirements and Professional Practice Standards

Time: 10:17 AM

Presented by: M. CHAN

Discussion: Although existing regulations at 247 CMR 13.00 *Nuclear Pharmacy Licensure Requirements and Professional Practice Standards* have already undergone a public hearing, revisions have been made regarding non-resident nuclear pharmacy licensure as well as for USP <825>, *Radiopharmaceuticals*, a new stand-alone section developed exclusively for nuclear pharmacy practice that incorporates elements of sterile and non-sterile compounding.

During the revision, Board staff utilized the NABP model act and has received input from the Radiation Control Program as well as nuclear pharmacy stakeholders.

Action: Motion by C. BELISLE, seconded by S. HAMILTON, and voted unanimously by roll call of those present, to forward the document for administrative review and approval to hold a public hearing.

TOPIC VIII

Policies

1. Policy 2022-08: Compliance Packaging

Time: 10:24 AM

Presented by: M. CHAN

Discussion: Upon request of a stakeholder, this policy replaces Policy 98-011 *Customized Patient Packaging* using the language from the pending regulations at 247 CMR 9.00. This allows a pharmacy to accept a patient's multi-drug single dose package, make necessary changes, and re-dispense to the same patient. The policy would remain in effect until 247 CMR 9.00 is promulgated.

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

2. Policy 2022-07: Automated Pharmacy Systems

Time: 10:26 AM

Presented by: M. CHAN

Discussion: Upon request of a stakeholder, this policy replaces Policy 2010-02: *Use of Automated Pharmacy Systems for the Storage and Dispensing of Schedule VI Controlled Substance Prescriptions in Pharmacies* using language from pending regulations at 247 CMR 9.00. This allows dispensing of new and refilled Schedule IV through VI controlled substances provided the machine is located within the same building as a pharmacy. The policy would remain in effect until 247 CMR 9.00 is promulgated.

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

3. Rescission of Joint Policy 2020-09: Emergency Contraception Standing Order

Time: 10:28 AM

Presented by: M. CHAN

Discussion: Now that Chapter 127 of the Acts of 2022, *An Act Expanding Protections for Reproductive and Gender-Affirming Care* has been signed into law, an emergency contraception standing order has been developed by DPH. Pharmacist training is no longer required, and pharmacies no longer have to obtain their own orders from a physician. A link to the standing order and reporting instructions will be maintained on the Board’s website.

Action: Motion by S. HAMILTON, seconded by R. MORELLI, and voted unanimously by roll call of those present, to rescind the policy.

TOPIC IX

File Review

Case #1/CAS-2022-0415
SA-INV-19753

Cardinal Health 110, WD352

Time: 10:29 AM

RECUSAL: NONE

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

- BORP was learned through the National Association of Boards of Pharmacy (NABP)'s clearinghouse during April 2022 that the Connecticut Commission of Pharmacy fined Cardinal \$3K for selling controlled substances to a practitioner that did not have an active Connecticut Controlled Substances Certificate of Registration.
- A copy of the agreement (Case No. 2021-349) to settle the matter described above between the Connecticut Department of Consumer Protection and Cardinal was obtained from the Connecticut Commission of Pharmacy. According to the agreement, Cardinal sold controlled substances to a practitioner that did not have an active Connecticut Controlled Substances Certificate of Registration between October 2019 and January 2021. Cardinal agreed to settle the matter by a payment of \$3K to the Department of Consumer Protection without admitting wrongdoing.
- Cardinal acknowledged that it improperly shipped controlled substances ordered by a physician using the physician’s personal Connecticut controlled substance registration to one of multiple facilities where the physician practiced. Specifically, the physician’s principal place of business or practice was not the facility where the controlled substances were shipped, and the particular facility did not have a controlled substance registration. Cardinal explained that address for the facility was mismatched in its computer system.
- CA: “To ensure the address mismatch does not occur in the future, Cardinal Health has changed how to loads and reviews accounts for purchasers in Connecticut to ensure the address on the [controlled substance registration] matches the ship-to address for the purchaser.”

ACTION: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to ELEVATE the matter (SA-INV-19753), to a complaint.

Case #2/CAS-2022-0321
SA-INV-19559

Dustin Teich, PH239857

Time: 10:32 AM

RECUSAL: NONE

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

- On March 14, 2022, Pharmacist Teich self-disclosed to BORP that he failed to satisfy his 2021 annual CE requirements. Specifically, Pharmacist Teich completed only one contact hour of CE during 2021. Of note, Pharmacist Teich was a 2020 pharmacy graduate according to BORP records. Thus, he was not required to complete annual CE in 2020.
- Pharmacist Teich remediated on a one-to-one basis in accordance with standard operating procedure for licensees who self-disclose CE deficiencies on a first- and one-time basis. He also acknowledged that CE completed in 2022 to remediate his 2021 CE deficiency cannot be used to satisfy any other CE requirements.
- BORP later amended this investigation to include violations of regulations against perjury in 247 CMR 6.03(1) after learning that Pharmacist Teich wrongly certified meeting requirements for annual CE in 2021 in a change in manager of record application notarized on January 3, 2022, prior to his self-disclosed CE deficiency described above.
- Pharmacist Teich explained, "I incorrectly submitted that I had completed all CE requirements in the past 2 years on my MOR application because I mistakenly believed that due to my recent graduation and licensure, I didn't need to complete CEs just yet, so I marked yes on the application..."
- CA: Pharmacist Teich indicated that he "completed all required CEs."

ACTION: Motion by K. THORNELL, seconded by J. LANZA, and voted unanimously by those present, to CLOSE the matter (SA-INV-19559), Discipline Not Warranted, Remediation Complete.

Case #3 /CAS-2022-0489

PHA-2022-0098

Walgreens #3564, DS2760

Time: 10:35 AM

RECUSAL: NONE

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

- On April 22, 2022, during a retail compliance inspection it was observed that staff member, Naomi Gabriel, was performing duties which required licensure as a pharmacy technician trainee (PTT). Investigator Van Allen described that Ms. Gabriel submitted a PTT application but the application was not processed. WAG 3564 immediately agreed during the inspection to reassign Ms. Gabriel to duties which did not require a PTT license until she was duly licensed. A plan of correction (POC) was issued.
- MOR Choi indicated in the POC response that BORP was contacted and the issues which delayed Ms. Gabriel's PTT application were resolved. MOR Choi further indicated that, going forward, she would verify licensure of staff members at the time of hire and on a monthly basis, thereafter.
- In response to this complaint, MOR Choi stated that Ms. Gabriel submitted her PTT application during February 2022 after being offered employment at WAG 3564 and began employment on April 4, 2022. MOR Gabriel asserted that Ms. Gabriel completed eLearning modules as part of WAG 3564's training program and did not actually start working in the pharmacy until April 19, 2022. MOR Choi acknowledged that Ms. Gabriel performed PTT technician duties without a license.

- CA: MOR Choi indicated that Ms. Gabriel immediately ceased performing PTT duties upon notification of unlicensed practice. Ms. Gabriel was issued a PTT license on April 22, 2022. MOR Choi next wrote, "Going forward, I will review license information for each new hire or transfer prior to the start of pharmacy technician job functions and will review the Walgreens Online Licensing Function (WOLF) weekly to ensure team member licensure is in compliance."

ACTION: Motion by S. AHMED, seconded by J. ROCCHIO, and voted unanimously by those present, to REFER the matter (PHA-2022-0098), 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 /CAS-2021-1303

PHA-2021-0117

Walgreens #18122. DS90224

Time: 10:39 AM

RECUSAL: NONE

DISCUSSION: N. ALEID presented and summarized the investigative report that pertained to this matter.

- Investigator Brosnan conducted a site visit (ISP-17580) and observed that former MOR Burdick was still listed as the MOR even though she has not worked in this capacity since November 2021. Additionally, MOR O'Brien started mid-February 2022 as an interim MOR.
- Healthcare Supervisor (HS) Deleo noted that this location has open positions for both MOR and staff pharmacist at the store. The pharmacy had interim MOR Burdick who took over when the previous MOR left the company. MOR Burdick filled out the necessary paperwork and also completed a controlled substance inventory. She took over on October 13, 2021, as an interim MOR until she decided to leave on November 5, 2021.
- The pharmacy has an experienced Pharmacy Manager that has been going up to this location once a week to make sure that things are getting done and patient care is a priority. HS Deleo noted that she has been sending pharmacists up to this location for a week at a time to ensure consistency and to mitigate closure situations.
- A retail compliance inspection (ISP-17783) conducted on 02/08/2022 was deemed satisfactory.

ACTION: Motion by J. CHIN, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2021-0117), 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-2022-0248

PHA-2022-0074

Walgreens #2781, DS3468

Time: 10:42 AM

RECUSAL: NONE

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

- RLCS for a loss of #51 methylphenidate 10mg tablets when a stock bottle was inadvertently disposed of after filling a prescription. The loss was identified by Pharmacist Marino during the weekly CII count on 2/18/22. Only one prescription had been filled since the previous reconciliation on 2/11/22. On 2/12/22, two different prescriptions of methylphenidate were filled for one patient. A review of video

showed Pharmacist Marino bring 3 bottles to production for 2 prescriptions. He is seen discarding 2 bottles after production. Based on the starting quantities in each bottle, there should have been only one empty bottle to discard. The ending BOH for methylphenidate 10mg should have been 351.

- Pharmacist Marino stated contributing factors included distractions, being interrupted during production, and filling two prescriptions at the same time.
- MOR Jamieson stated the incident was discussed with Pharmacist Marino. The use of a separate receptacle on the counter was implemented to discard empty CII bottles. It is checked at the end of the day to verify the bottles are empty prior to discarding into the regular trash. Only one CII is filled at a time now then the bottle is returned to the safe immediately after filling. Pharmacist Marino stated, “We will also fill each CII separately and use separate totes for each one even if there are multiple CII for the same patient. We will perform one task at a time to avoid distractions”. A signed and dated statement was provided by the Pharmacy staff confirming review of all policies and procedures for the proper storage and handling of controlled substances.

ACTION: Motion by C. JEAN-FRANCOIS, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0074), 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-2022-0441

PHA-2022-0091

Walgreens #6850, DS3468

Time: 10:45 AM

RECUSAL: NONE

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

- Inspectional deficiencies on 4/12/22 for PTT Pinto performing technician duties with a license that expired 2/19/22. The POC stated PTT Pinto renewed the license and submitted a PT application on 4/19/22 which is still pending.
- MOR Pacheco stated PTT Pinto was hired on 12/23/2021. She was hired with the knowledge that she had been hired in 2/2021 at Rite-Aid and had applied for a PTT license but she never worked for them due to a family situation. Once her expired license was discovered during the inspection, her tasks were limited to cashier duties and filing bags. MOR Pacheco acknowledged he failed to catch the expired license during his monthly checks because it was not posted. MOR Pacheco is responsible for tracking PTT hours and PTT Pinto has worked 701 hours as of 5/12/22.
- PTT Pinto confirmed her date of hire and indicated the duties she had performed as a PTT. She submitted a PTT extension request which was received on 4/19/22.
- MOR Pacheco will perform a monthly audit review on all staff licenses and will address with all employees the need to maintain an active license. Anyone with an expired license will not be allowed to work in the Pharmacy. License renewals will be required to occur 2 months prior to expiration. MOR Pacheco stated, “Going forward I will now take the technicians names off the schedule and will manually do a license check on the Board of Pharmacy website. I will still display everyone's active license in the pharmacy and will still add new employees as they receive their documentation of licensure”. MOR Pacheco stated PTT Pinto’s license is active until 10/19/2022.

ACTION: Motion by J. CHIN, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2022-0091), 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-2022-0479

PHA-2022-0097

Walgreens #19460, DS90146

Time: 10:48 AM

RECUSAL: NONE

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

- Deficiency cited on 4/21/22 for failure to submit a change of MOR application with Former MOR Megha Patel still listed as MOR. The inspection noted change of MOR inventories were performed on 6/20/21 by Former MOR Megha Patel, on 7/8/21 and 11/4/21 by Former MOR Kush Patel; and on 12/11/21 by Current MOR Dong.
- DM Paquette indicated Former MOR Kush Patel was the MOR when the Pharmacy was reassigned to her. She discussed the process of submitting a change of MOR application and performing a controlled substance inventory with Current MOR Dong. DM Paquette claimed she discovered Current MOR Dong was not reflected as MOR of the Pharmacy on the BORP website sometime in March while reviewing all pharmacy locations in her district. She believed the original application was submitted without the fee but there was no notification from the BORP.
- Former MOR Kush Patel sent an application to Walgreens headquarters, never received any notification of an issue, and did not keep a copy. He was made aware of the issue during an inspection on 08/17/2021 and was informed it may take time to process the application. There was no follow up and he claimed sending a notification to the BORP 10 days before leaving his position that he was no longer MOR.
- Current MOR Dong was unaware she needed to complete the application. Once it was brought to her attention, she completed it on 4/27/22 which was submitted and received.
- Controlled substance inventories for outgoing/incoming MOR were submitted that documented completion by one pharmacist only. Walgreens SOP Pharmacist-In-Charge Change Notifications stated the DM is responsible for notifying the state BOP.
- DM Paquette implemented a biweekly calendar reminder to check all new MOR changes in her district to ensure accuracy. Former MOR Kush Patel and Current MOR Dong reviewed Board Policy 2022 "Extended Absence of a Manager of Record" and Walgreens SOP "Pharmacist-In-Charge Change Notifications". Current MOR Dong also reviewed 247 CMR 6.03.

ACTION: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2022-0097), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #8/CAS-2022-0521

PHA-2022-0109

Dominic Regalbuto, PH238864

Time: 10:52 AM

RECUSAL: NONE

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

- Self-report of discipline by NY of using pharmacy technicians to measure ingredients and compound and failing to ensure Finasteride Plus 1.25mg capsules were compounded properly while employed at MasterPharm on or about 2/27/2020. On 5/6/2020, MasterPharm issued a voluntarily recall of the compounded lot to the consumer level after 33 reports of increased heart rate, water retention, dizziness and low blood pressure were received. Pharmacist Regalbuto's NY license was suspended for two-years with the last 23 months stayed and placed on a two-year probation. He was also fined \$2500. MasterPharm's NY license was discontinued 12/23/2020.
- Attorney Tarlow stated Pharmacist Regalbuto had been one of three pharmacists employed at MasterPharm and was hired August 2017 and became Assistant Director in February 2019. Attorney Tarlow contended the Director of the Pharmacy, not Pharmacist Regalbuto, was responsible for performing QC checks of technician's work, reviewing prescriptions, evaluating the suitability of compound ingredients, and assessing the identity, strength, and purity of medications. Attorney Tarlow alleged MasterPharm had no records which pharmacist was responsible for the technician's work on the date of the error but acknowledged documentation showed Pharmacist Regalbuto did perform a homogeneous check and uniformity test. Pharmacist Regalbuto entered into the NY Consent Agreement as he did not have the means to retain counsel and contest the charges.
- Pharmacist Regalbuto notified all other states in which he is licensed. AZ, FL, and VA had open investigations and there was a mandatory suspension in VA per their regulations which he self-reported to the BORP. Pharmacist Regalbuto paid the fine and is adhering to the terms of the probation. He is not currently employed as a pharmacist. Attorney Tarlow indicated Pharmacist Regalbuto is willing to voluntarily surrender his MA license for 3 years then re-apply.

ACTION: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2022-0109), 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 2-year SUSPENSION (23 months STAYED) followed by a 2-year PROBATION.

Case #9/CAS-2022-0303

PHA-2022-0063

CVS #2054, DS2588

Time: 10:57 AM

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

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

- RLCS for an unknown loss of 1,081 lorazepam 0.5mg tablets identified via corporate controlled substance monitoring on 1/13/22 presumed to be due to errors in cycle counts and inventory adjustments. Security footage was reviewed, interviews were conducted, and MOR Murray searched the Pharmacy shelves.
- MOR Murray stated lorazepam 0.5mg tablets are stored in the ScriptPro. In December 2021, there were 2 instances of issues with receipt of 500 count lorazepam 0.5mg deliveries. DAPL Ogwuru determined several instances when PT Kaur and Pharmacist Vo failed to manually count the stock in the ScriptPro when completing cycle count causing large variances. No active losses were identified and DAPL Ogwuru closed the case file.
- MOR Murray coached the Pharmacy staff regarding the proper procedure for CIII-CVs acquired from the warehouse or the outside vendor. He also coached them regarding cycle count adjustments for any variance must be double counted by a pharmacist. All cycle counts for CIII-CVs in the ScriptPro must be counted by hand by a pharmacist. A statement signed and dated by the Pharmacy staff was

provided attesting that all policies and procedures for the proper storage and handling of controlled substance have been reviewed.

ACTION: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2022-0063), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a 1 year STAYED PROBATION, with special terms to include the Unknown Loss Protocol for all benzodiazepines.

Case #10/CAS-2022-0456

PHA-2022-0095

CVS #1221, DS2988

Time: 11:00 AM

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

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

- Inspectional deficiency for nine epinephrine auto-injectors, needles/syringes and a Sharps container without a lid observed in an unsecured “immunization booth” outside of the Pharmacy. The POC stated these immunization supplies were removed on 4/19/22, the day of the inspection, and will be kept in the Pharmacy.
- MOR Patel indicated MORs had been instructed to assemble Emergency/Anaphylactic Kits for the immunization rooms. MOR Patel stated, “Emergency/Anaphylaxis Kits, Sharps containers, and syringes/needles were kept in the vaccine rooms to better service our patients and ensure their safety in the event of an anaphylactic reaction during vaccine administration. At the end of each day, Emergency/Anaphylaxis Kits and the sharps container were brought back into the pharmacy and the vaccine room was locked for the night”.
- CVS policy Pharmacist Administered Immunization Program states following administration of an immunization, all immunization supplies, including the emergency kit and Sharps container, are to be returned to the pharmacy.
- Corrective actions were immediately implemented including using a designated basket containing the Emergency/Anaphylaxis Kit and the Sharps container that is stored in the Pharmacy in view of the pharmacist on duty. MOR Patel stated, “The immunizer will bring the basket in and out of the vaccine room in between each patient. The room is locked after each vaccination. Once the room has been locked, all immunizers are required to sign off on a log after each use”. MOR Patel retrained the staff on these protocols which was reflected in the statements provided by the immunizing staff. A statement signed and dated by Pharmacy staff immunizers was provided confirming CVS ROPP-0051 “Pharmacist Administered Immunization Program” had been reviewed.
- On 8/3/22, an inspection was conducted, and the corrective action was observed as implemented. No POC was issued.

ACTION: Motion by R. MORELLI, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0095), 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-2022-0386

PHA-2022-0077

CVS #109, DS3586

Time: 11:04 AM

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

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

- RLCS of 304 buprenorphine-naloxone 8-2mg (CIII, 30 films/carton) sublingual films discovered on February 17, 2022. CVS 109 then retracted the loss in a letter dated April 14, 2022, because “an investigation of this matter has concluded there was no theft or significant loss” without further description.
- MOR Morales explained that a cycle count completed for buprenorphine-naloxone 8-2mg sublingual films on February 4, 2022, failed to include drug stored in the overstock area below the active stock area reserved for buprenorphine-naloxone resulting in the negative variance of 304. MOR Morales next described that the cycle count variance triggered an internal investigation led by CVS Health’s district asset protection leader with assistance from MOR Morales.
- MOR Morales indicated that an “offsetting” cycle count was completed again on March 11, 2022, which resulted in a net change of 319 films. MOR Morales wrote, “Upon further review, we reconciled all other cycles of this NDC from 05/01/21-02/19/2022 and there was a variance of -3 films. The case was closed by the [district asset protection leader] after discovering there was no active drug loss outside of the 3 films.”
- CVS 109 also provided dispensing reports and inventory records for all manufacturers of buprenorphine-naloxone 8-2mg sublingual films covering February 2021 to February 2022. In addition, Dispensary Activity Report was obtained from the Massachusetts Prescription Awareness Tool (MassPAT) covering the same period. However, completion of an accurate independent reconciliation to confirm CVS 109’s retraction was not possible because buprenorphine-naloxone (CIII) was not kept on perpetual inventory. Furthermore, problematic prescriptions including duplicate fills and fills not transmitted to MassPAT were identified during the review which added to difficulties for a reconciliation.

ACTION: Motion by K. THORNELL, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0077), Discipline Not Warranted, Remediation Complete.

Case #12/CAS-2022-0362

PHA-2022-0075

CVS #1230, DS2023

Time: 11:07 AM

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

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

- On March 30, 2022, BHPL Investigator Paul Seed conducted a retail compliance inspection and observed unsecured epinephrine auto injectors, needles, and syringes in a temporary immunization area (unlicensed space) adjacent to the pharmacy. Investigator Seed then issued a plan of correction (POC) to CVS 1230 based in part on the violations described above.
- CVS 1230 confirmed in the POC that the unsecured epinephrine auto injectors, needles, and syringes observed by Investigator Seed in the temporary immunization area were moved into the pharmacy (licensed space). CVS 1230 affirmed that, going forward, “all immunization supplies are kept secure and in the pharmacy at all times when not actively providing immunizations.” CVS 1230 described that a portable “emergency kit” containing epinephrine auto injectors, immunization supplies, and a

sharps container was created to use during administration of vaccines. CVS 1230 indicated that kit was stored in the pharmacy and brought “back and forth after each [vaccine] administration.”

- MOR DiTommaso assured BORP that the violations observed by Investigator Seed on March 20, 2022, involving the unsecured epinephrine auto-injectors, needles, and syringes in the temporary immunization area were “a one-off deficiency and is NOT standard operating procedure of this pharmacy.”
- CA: MOR DiTommaso described that he implemented the following corrective action to mitigate recurrence of a similar incident. MOR DiTommaso reiterated supplies for vaccine administration including the “emergency response kit” were kept secure in the pharmacy when not actively administering vaccines and returned to the pharmacy after completion of administration. MOR DiTommaso also explained that ISP-18132 was conducted when he was on a leave of absence (approximately a week into his LOA) and “several floating pharmacists” provided coverage for this period. MOR DiTommaso indicated that “all pharmacists have been notified of the violation and a corrective action plan has been set in place to ensure that this violation is not repeated.”

ACTION: Motion by C. BELISLE, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2022-0075), 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/CAS-2022-0185

PHA-2022-0020

CVS #302, DS2599

Time: 11:10 AM

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

DISCUSSION: N. ALEID presented and summarized the investigative report that pertained to this matter.

- On 02/14/2022, Investigator Seed conducted a retail compliance inspection (ISP-17793) at the Pharmacy. He noted epinephrine auto injectors along with the sharp’s containers unsecured in the immunization area outside of the pharmacy department. A Plan of Correction (POC) was issued.
- MOR Lehner indicated that during the time of the inspection, Pharmacist Abdelmalak was on duty. MOR Lehner noted that the Sharps container should be kept in the pharmacy during non-immunizing times and brought back and forth with the immunizer to the immunization area.
- The MOR noted that during the clinic hours, the epi-pens were kept in the immunization area in case of an emergency, while the area was staffed for the entire shift. She noted that the last immunizer only returned the Sharps container and left the Epi-pens out in the immunization area, failing to see then in the 3-drawer unit that contains the extra immunization supplies.
- MOR Lehner reminded staff that the Sharps container or the Epi-pens are not allowed to be left unattended in the immunization area and must be returned to the pharmacy after each immunization. To help with the transport of bringing these items back and forth from the immunization area, emergency kits have been set up. The Epi-pens are kept inside a sealed tote with all other emergency items. The emergency kits are moved as a whole to help decrease the potential risk of the items being left unattended, in the immunization area. Each day, the immunization area will be inspected to make sure no items are left out.

ACTION: Motion by R. MORELLI, seconded by S. Ahmed, and voted unanimously by those present, to refer the matter (PHA-2022-0020), 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 X:

Executive Session Call to Order:

Session #1

Time: 11:13 AM

By: S. Hamilton reads the executive session language and requests a motion to enter executive session.

Action: A motion was made by to K. Thornell enter Executive Session; Seconded by J. Lanza and Board Members present voted unanimously by roll call to approve motion. Roll call attendance:

J. Lanza, yes; S. Hamilton, yes; C. Belisle, yes; J. Rocchio, yes; J. Chin, yes; R. Lopez, yes; S. Ahmed, yes; R. Morelli, yes; C. Jean-Francois, yes; K. Thornell, yes.

Session #2:

Time 12:25 PM

Action: A motion was made by to J. Lanza 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; J. Rocchio, yes; J. Chin, yes; R. Lopez, yes; S. Ahmed, yes; R. Morelli, yes; C. Jean-Francois, yes; K. Thornell, yes.

Session #3:

Time: 12:31 PM

Action: A motion was made by to K. Thornell enter Executive Session; Seconded by J. Lanza and Board Members present voted unanimously by roll call to approve motion. Roll call attendance:

J. Lanza, yes; S. Hamilton, yes; C. Belisle, yes; J. Rocchio, yes; J. Chin, yes; R. Lopez, yes; S. Ahmed, yes; R. Morelli, yes; C. Jean-Francois, yes; K. Thornell, yes.

Topic XI:

Adjudicatory Session

Time: 12:15 PM

DISCUSSION: None

ACTION: President S. Hamilton request a motion to enter Adjudicatory Session.

At 12:15 PM K. Thornell, seconded by J. Lanza and voted unanimously by all those present to enter Adjudicatory Session by roll call vote.

Topic XII: 65C Sessions MGL c. 112 section 65C

DISCUSSION: None

ACTION: President S. Hamilton request a motion to enter 65C.

Session #1

Time: 12:27 PM

At 12:27 PM J. Lanza, seconded by S. Hamilton and voted unanimously by all those present to enter 65C by roll call vote.

Session #2

Time: 12:46 PM

At 12:46 PM S. Hamilton, seconded by R. Morelli and voted unanimously by all those present to enter 65C by roll call vote.

Lunch 12:50 pm to 1:15 PM

Topic XIII

ADJOURNMENT OF MEETING

TIME: 3:36 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 9/1/22 General Session
2. Draft Minutes of the 8/4/22 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. Central Admixture Pharmacy Services DS3312 Petition for waiver
8. Central Admixture Pharmacy Services DS3312 Board review of sterile compounding sink placement and gowning sequence
9. New Health Charlestown Pharmacy N/A New Community Pharmacy
10. MedMinder Pharmacy DS90072 Relocation
11. BHCHP Pharmacy N/A New Community Pharmacy
12. BAMS Pharmacy N/A New Community Pharmacy
13. Walmart N/A Petition for waiver
14. Rite Aid N/A Petition for waiver
15. 247 CMR 13.00: Nuclear Pharmacy Licensure Requirements and Professional Practice Standards
CAS-2021-0989 PHA-2021-0095 Walgreens #9233, DS3407

16. Policy 2022-08: Compliance Packaging
17. Policy 2022-07: Automated Pharmacy Systems
18. Joint Policy 2020-09: Emergency Contraception Standing Order – Rescind
19. CAS-2022-0415 SA-INV-19753 Cardinal Health 110, WD352
20. CAS-2022-0321 SA-INV-19559 Dustin Teich, PH239857
21. CAS-2022-0489 PHA-2022-0098 Walgreens #3564, DS2760
22. CAS-2021-1303 PHA-2021-0117 Walgreens #18122, DS90224
23. CAS-2022-0248 PHA-2022-0074 Walgreens #2781, DS3468
24. CAS-2022-0441 PHA-2022-0091 Walgreens #6850, DS3169
25. CAS-2022-0479 PHA-2022-0097 Walgreens #19460, DS90146
26. CAS-2022-0521 PHA-2022-0109 Dominic Regalbuto, PH238864
27. CAS-2022-0303 PHA-2022-0063 CVS #2054, DS2588
28. CAS-2022-0456 PHA-2022-0095 CVS #1221, DS2988
29. CAS-2022-0586 PHA-2022-0117 CVS #299, DS3596
30. CAS-2022-0386 PHA-2022-0077 CVS #109, DS3586
31. CAS-2022-0362 PHA-2022-0075 CVS #1230, DS2023
32. CAS-2022-0185 PHA-2022-0020 CVS #302, DS2599

Respectfully Submitted,
Carly Jean-Francois, NP, Secretary