COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

March 2, 2023

Webex Information

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

For video access click on the following link:

https://eohhs.webex.com/eohhs/onstage/g.php?MTID=eae6ff2ccf3cfe8f807c153c9a704c841

To access the meeting by phone:

Call in Number: 1-650-479-3208

Access Code: 2533 481 7050

Attendee: #

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Erin Bartlett, <u>erin.bartlett2@mass.gov</u> 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.

Time	#	Item	Page	
8:00	Ι	CALL TO ORDER		C. Belisle
8:02	II	APPROVAL OF AGENDA		
8:05	III	 APPROVAL OF BOARD MINUTES Draft of February 2, 2023 Regular Session Minutes Introduction of Vedi Patel the newest Pharmacy intern from Massachusetts College of Pharmacy and Health Sciences 		
8:10	IV	 REPORTS Applications approved pursuant to Licensure Policy 13-01 Monthly report from Probation Board Delegated Review pursuant to Licensure Policy 14-02 PSUD Report-Policy 17-03 		

Agenda

		FLEX				
8:15		Pharmacy issues	related to COVID-1	9	D.	
	V	• Election of deleg	gate and alternate to t	he NABP annual meeting	Sencabaugh	
		-	tions from NABP			
	Clarification of Controlled Substance Loss Protocol					
		APPLICATION				
		• Westminster Pharma				
8:45	VI	•SymbriaRx – New C				
		• EternaPharmacy –]	•	5		
		•Health Care Pharma	•			
		•Genoa-Framingham POLICIES	; Follow up on licens	e approval		
			Extended Absence of	r Departure of a Manager of		
9:45	VII	Record				
		Policy 14-02: Bo	oard Delegated Revie	ww (BDR)		
		REGULATIONS				
10:00	• 247 CMR 3.00 Licensure and Continuing Education Requirements		0 1			
	for Individual Pharmacy Professionals					
		FILE REVIEW				
		1 CAS-2022-0665	SA-INV-20260	CAPS Pharmacy, DS3312		
		2 CAS-2022-0868	SA-INV-20914	CAPS Pharmacy, DS3312		
		3 CAS-2022-0767	PHA-2022-0143	Walgreens #9405, DS3475		
		4 CAS-2022-1200	PHA-2022-0186	Walgreens #2699, DS2129		
		5 CAS-2022-1111	SA-INV-20640	Walgreens #10319, DS3517		
		6 CAS-2022-1111	SA-INV-20641	Christopher Cushing, PH25844		
10:30	IX	7 CAS-2022-0415	PHA-2022-0200	Cardinal Health 110, WD352		
		8 CAS-2022-1024	SA-INV-20508	Westminster Pharmacy, DS1710		
		9 CAS-2022-1260	PHA-2022-0197	Sullivan's Healthcare Inc, DS3335		
		10 CAS-2022-1289	PHA-2022-0204	CVS #127, DS3420		
		11 CAS-2022-1293	PHA-2022-0205	CVS #7232, DS3461		
		12 CAS-2022-1544	PHA-2022-0223	CVS #7232, DS3461		
		13 CAS-2022-1500	PHA-2022-0217	CVS #844, DS1402		
		14 CAS-2022-1131	PHA-2022-0182	CVS #669, DS2846		
				1		

12:00		LUNCH BREAK	
12:30	х	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 request to discharge successfully form PSUD and license returned to status of current, review of a change of manager application and to evaluate the Good Moral Character as required for registration for a pending applicant.	
2:00	XI	M.G.L. c. 112, § 65C SESSION	
4:00	XII	ADJOURNMENT	

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting March 2, 2023

Board Members Present Caryn Belisle, RPh, MBA, President Katie Thornell, RPh, MBA President Elect Board Members Not Present Carly Jean-Francois, RN, NP Jennifer Chin, RPh Secretary Johanna Lopez, MS

Sebastian Hamilton, Pharm D, MBA, RPh (leaves meeting 2 to 3:30 PM) John Rocchio, RPh, PharmD (leaves meeting 4:20 PM) Dr. Richard Lopez, MD Sami Ahmed, PharmD., RPh, BCPS, BCSCP Rita Morelli, PharmD, BCACP, RPh Delilah Barnes, RPh Julie Lanza, CPhT Dawn Perry, JD (Leaves meeting 3:46 PM)

Board Staff Present

David Sencabaugh, RPh, Executive Director Monica Botto, Associate Executive Director Jacqueline Petrillo, PharmD, RPh, JD, Board Counsel Michael Egan, JD, Board Counsel William Frisch, RPh Director of Pharmacy Compliance Michelle Chan, RPh, Quality Assurance Pharmacist Ed Taglieri, MSM, NHA, RPh PSUD Supervisor Richard Harris, Program Analyst Joanna Chow, Office Support Specialist Taylor Lee, Office Support Specialist Joanne Trifone, RPh, Director of Investigations Gregory Melton, JD, PharmD, BCPS, Investigator Julienne Tran, RPH PharmD, Investigator Nancy Aleid, Compliance Officer

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:00 AM

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

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

Topic II.

Approval of Agenda

TIME: 8:04 AM

Agenda 3/2/23

DISCUSSION:

Defer: Flex: Clarification of Controlled Substance Loss Protocol

ACTION:

Motion by J. Lanza, seconded by D. Perry and voted unanimously by those present to approve the agenda with noted change by roll call vote.

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

Minutes

1. Draft 2/2/23

Change: Remove secretary from D. Barnes name on attendance

Action:

Motion by S. Ahmed seconded K. Thornell and voted unanimously to approve the regular session minutes of 2/2/23 with noted changes by roll call vote. D. Perry abstains.

TOIC IV Reports Applications approved pursuant to Licensure Policy 13-01 **TIME: 8:04 AM** PRESENTED BY: M. BOTTO DISCUSSION: M. Botto reported 28 Change of Manager applications and 5 facility closures that have been approved via Staff Action since the February 2nd Board meeting. So noted. **Topic IV.** REPORTS Monthly Report from Probation **TIME: 8:04 AM** PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto indicated no Board Delegated Review to report since the last Board meeting. So noted.

Topic IV.

REPORTS

Monthly Report from BDCR pursuant to Policy 14-02 PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported 5 cases that were heard during the Board Delegated Review, 3 involving CE deficiencies, all of which were closed with no discipline warranted. 1 controlled substance loss case was reported and issued a non-disciplinary stayed probation for one year with CS protocol. One inspectional deficiency case was deferred for more information. So noted.

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Topic IV. REPORTS PSUD report by Staff Action 17-03 **TIME: 8:05 AM** PRESENTED BY: E. TAGLIERI DISCUSSION: E. Taglieri reported a total of 9 active members in the PSUD program with anticipation of 4 successful discharges within the next 3-4 months. E. Taglieri confirmed that the Bureau of Substance Addiction Services (BSAS) and the Bureau of Health Professions Licensure (BHPL) have secured funding of up to \$2000/participant to cover the costs of baseline testing required for admission into the program. So noted.

то	PIC V	Flex	
1.	Pharmacy issues related to COVID-19		Time: 8:07 AM
	Presented by: D. SENCABAUGH		
	Nothing to report.		
2.	Election of delegate and alternate to the	NABP annual meeting	Time: 8:07 AM
	Presented by: D. SENCABAUGH		
	Action: The Board voted for K. THORN the NABP annual meeting.	IELL to be the delegate ar	nd J. LANZA to be the alternate a

3. Proposed resolutions for NABP

Presented by: D. SENCABAUGH

Discussion: A vote is needed to either allow the delegates to vote on the Board's behalf at the annual meeting, or to take a vote on each proposed resolution for the delegates to carry forward to the meeting.

Action: Motion by J. ROCCHIO, seconded by D. PERRY, and voted unanimously by roll call of those present, to allow K. THORNELL and/or J. LANZA to vote on resolutions on the Board's behalf at the NABP annual meeting.

4. Clarification of Controlled Substance Loss Protocol

Deferred.

Time: 8:12 AM

Time: 8:12 AM

TOPIC VI

Applications

1.Westminster Pharmacy DS1710 Renovation

TIME: 8:14 AM

Represented by: Mudar Chalati-MOR

Recusal: Discussion:

Westminster pharmacy is coming before the board to request a renovation to include a non-sterile compounding room. M. Chalati indicates that there is a need for a non-sterile compounding pharmacy in the area as they service group homes who get their medications through a tube. They stated that they considered compounding the medications to make things easier for the patients. C. Belsile inquired if the MOR performed non-sterile compounding to which M. Chalati responds that he has performed non-sterile compounding and USP 800 and indicates that he was a manager of record in New Hampshire for a chain pharmacy. C. Belisle inquired what the pharmacy's plans were with regards to compounding training and if they planned on compounding hazardous medications. M. Chalati responds that they do not plan on compounding hazardous medications and that he brought in with him another fully trained technician who has worked with compounding for many years, along with another compounding pharmacist. C. Belisle asked the MOR if he knew about that revisions to the USP 795 chapters and he responds that he is familiar with the chapters and that they are ready to implement all any changes to be in compliance with all compounding regulations and noted that M. Chalati planned on completing those renovations.

Motion to approve the attestation to engage in complex non-sterile compounding made by C. Belisle; Seconded by R. Morelli, then Board Members present voted unanimously by rollcall to approve motion.

2.Symbria RX New Community Pharmacy

TIME: 8:28 AM

Represented by: Patrick Hussey & Derek Brown

Recusal: Discussion:

D. Brown indicates that they are a regional chain pharmacy that serve long term care facilities and provide rehab services. Their goal is to bring a pharmacy to Massachusetts to supplement their existing service offerings. P. Hussey also includes that the pharmacy is an employee-owned company, and they have an existing footprint. D. Barnes inquired about the pharmacy's contingency plan for missed deliveries and medications that are not able to make it to the facility, refused medications, and drug storage in between the time that the delivery driver receives the medications to when the pharmacy will open. D. Brown indicates that the pharmacy is in the process of developing an ante room that the drivers will have access to so that they can leave the medications/ put the medications that need to be refrigerated. He notes that the drivers will only have access to the ante room and not

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the pharmacy. Their plan is to obtain licensure so they can begin working on PBM contacts and build the ante room. D. Brown indicates that they will resubmit appropriate paperwork with the ante room to the board once it has been finalized. P. Hussey indicates that they are planning to move towards a more in-house model and include their own drivers. E. Taglieri inquires if the pharmacy representatives know the difference between the orders in a nursing home vs. the orders in an assisted living facility. D. Brown indicates that they use an operating system called framework LTC which is able to designate between both operating systems along with other backend reporting systems. B. Frisch inquired about the proposed MOR and D. Brown indicates that the MOR responsibilities will eventually transition to P. Hussey who described his pharmacy experience. M. Chan read the waivers requested by Symbria RX.

Motion to approve the application for a new community pharmacy with the 5 waiver requests pending successful inspection made by C. Belisle; Seconded by J. Lanza, then Board Members present voted unanimously by rollcall to approve motion.

3. EternaPharmacy New Community Pharmacy

TIME: 8:43 AM

Represented by: Felix Baez, Ron Lanton

Recusal: Discussion:

F. Baez proposed MOR summarized the reason why he is coming before the board to apply for a new community pharmacy. S. Ahmed inquired about the pharmacy hours and the person delegated to respond to a voicemail when the pharmacy is closed. F. Baez responds that there is an on-call pharmacist who gets a notification on their cell-phone when someone leaves a voicemail. S. Ahmed inquires as to how the pharmacy will respond to emergency scripts when the pharmacy is closed and F. Baez states that the script can be transferred to the 24-hour store and a pharmacist lives 10 minutes from the facility and may also be able to fill the script. D. Barnes inquiries about the contingency plan if a drug is returned by a driver. F. Baez responds that the pharmacist doesn't leave the store until the driver returns back to the store and the drivers use company cars, so the cars come back to the pharmacy along with the scripts. C. Belisle inquires if they plan on doing non-sterile compounding and F. Baez responds that they don't plan on doing so and none of their pharmacists have been in the field. The most compounding they've done is magic mouthwash. If they receive a script that needs compounding, they transfer it to another participating pharmacy that specializes in compounding. C. Belisle inquiries about the name of the pharmacy and F. Baez indicates that this pharmacy has a different LLC but has the same name.

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

4. Health Care Pharmacy DS1585 Petition for Waiver Represented by: David Moniz

TIME 8:55 AM

Recusal:

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Discussion:

D. Moniz indicates that he is coming before the board to apply a waiver for the balance requirement. He states that he has been at the company for over 10 years, and they do not perform any compounding services. He notes that the only time the scale gets taken off the shelf is once a year to get tested and sealed. C. Belisle inquires if Health Care Pharmacy has a mechanism to refer their patient to another pharmacy if they were to need a compounded product and D. Moniz responds that there is a compounding pharmacy that they refer their patients to which is about 20 minutes away.

Motion to approve the waiver made by R. Lopez; Seconded by S. Hamilton, then Board Members present voted unanimously by rollcall to approve motion.

5. Genoa Pharmacy Framingham Use Space Review TIME: 8:57 AM Represented by: Alyssa Allard, Megan Garrity, Kent Farmer

Recusal: D. Sencabaugh Discussion:

M. Garrity briefly described why they were appearing before the board and indicated that they did obtain licensure however they are not currently administering LAIs given the board's concerns. M. Garrity indicated that they will create a window within the facility that will be used primarily as a consultation area near the point of sale and would like to use the closed off room for LAI administration. These plans were outlined in the board packets for review. B. Frisch indicated that this pharmacy is different because this room is the only means of egress for employees to go back and forth but his understanding is that those doors would lock and M. Garrity confirmed that the doors do lock.

Motion to approve LAI administration pending proposed renovation of consultation window addition and successful inspection made by C. Belisle; Seconded by D. Barnes, then Board Members present voted unanimously by rollcall to approve motion.

TOPIC VII

Policies

1. Policy 2022-02: Extended Absence or Departure of a Manager of Record

Time: 9:06 AM

Presented by: M. CHAN

Discussion: Procedural requirements for when a Manager of Record (MOR) permanently leaves their MOR position were added to this policy including the naming of an Interim Manager and submission of a change in MOR application.

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

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

Time: 9:07 AM

Presented by: M. CHAN

Discussion: This policy would allow the BDR work group to issue a reprimand to pharmacies if it has been greater than 30 days since the MOR has been absent from or has permanently departed and neither has an Interim Manager been named nor a change in MOR application been submitted.

Also, if it has been greater than 100 days since the MOR has been absent from the position, the BDR Work Group would be permitted to issue a reprimand to pharmacies that have not submitted an application to change their MOR.

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

TOPIC VIII

Regulations

247 CMR 3.00: Licensure and Continuing Education Requirements for Individual Pharmacy Professionals Time: 9:09 AM

Presented by: W. FRISCH and M. CHAN

Discussion: Pharmacy regulations at 247 CMR 3.00, 4.00, and 8.00 outline the licensing requirements for pharmacists, pharmacy technicians, and interns, as well as pharmacist continuing education and technician duties. Due to changes in practice and to further streamline the regulations, Board staff is proposing a consolidation of these three sections into a single section (247 CMR 3.00).

The goal would be to rescind sections 4.00 and 8.00 at the same time revisions to section 3.00 are promulgated. The proposed changed section at 247 CMR 3.00 would be titled *Licensure and Continuing Education Requirements for Individual Pharmacy Professionals*.

105 CMR 700.000 *Implementation of M.G.L. C. 94C* has been updated to now allow pharmacy technicians to administer vaccines. The current regulations at 247 CMR 8.00 *Pharmacy Interns and Technicians* specifically prohibit pharmacy technicians from administering vaccines and was one of the primary drivers for updating these regulations.

Other proposed changes include changing the vaccination CE requirement to 1 contact hour each year and moving the ratio requirement to policy until it can be incorporated into 247 CMR 9.00 *Professional Practice Standards.*

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

ΤΟΡΙϹ ΙΧ	File Review	,
Case #1/CAS-2022-0665 SA-INV-20260	CAPS, DS3312	Time:
DEF	ERRED	
Case #2/CAS-2022-0868		
SA-INV-20914	CAPS, DS3312	Time:
DEF	ERRED	
Case #3/CAS-2022-0767		
PHA-2022-0143	Walgreens #9405, DS3475	Time: 09:25 AM
RECUSAL: NONE		

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

- WAG 9405 reported unknown losses of multiple Schedule II & IV controlled substances discovered in separate incidents on June 20, 2022, and August 10, 2022, including 300 hydrocodone-acetaminophen 5-325mg tablets and 704 tramadol 50mg tablets. WAG 9405 later retracted the loss of hydrocodoneacetaminophen after determining the count taken during a corporate audit was wrong. Of note, WAG 9405 failed to submit BORP RLCS Form and supplemental information required by BORP Policy 2022-01.
- After learning of the losses, DEA also opened an investigation during Summer 2022 and issued a letter
 of admonishment because WAG 9405 pharmacy failed to maintain complete and accurate records for
 federally scheduled controlled substances, failed to provide information requested by DEA in a timely
 manner, and failed to maintain a current CMEA self-certification in violation of Federal laws and
 regulations.
- CA: MOR Ososanwo indicated that the "store has committed to maintaining accuracy in control counting and inventory. Weekly perpetual inventories will continue, and any discrepancies will be addressed promptly." In addition, MOR Ososanwo indicated that the pharmacy will "double counting all controlled substances. Making sure that all C2 prescription meds are locked up in the safe when not in use. Circle and initial all controlled substances prescription dispensed." Lastly, tramadol 50mg tablets was moved to CII safe.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2022-0143), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a PROBATION for a period of 1 year, with special terms to include the CS Loss Protocol for all tramadol containing products.

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Case #4/CAS-2022-1200 PHA-2022-0186

Walgreens #2699, DS2129

Time: 09:29 AM

RECUSAL: NONE

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

- On October 3, 2022, Investigator Brosnan observed Epipens stored in an unlocked vaccine room, separate from the pharmacy space, while conducting a retail compliance inspection. A Plan of Correction (POC) was issued. In the POC response, WAG 2699 stressed that the Epipens were taken outside of vaccine room and placed in the pharmacy in an accessible area in case of emergency. Also, a ticket was put in and door was fixed and now locks.
- In response to the complaint, MOR Sucharski indicated that the broken lock was first discovered by a floater pharmacist on October 1, 2022, and a work order was placed. MOR Sucharski then described that staff rigged the door handle with tape to "prevent the lock from going too deep into the strike plate and causing the door to jam." She indicated that the temporary fix allowed staff access to the vaccine room "when the code on the keypad was entered instead of having to enter the code and turning the handle numerous times until the door unlocked."
- MOR Sucharski next asserted that she only aware of the broken lock on the same day as the inspection on October 3, 2022. She acknowledged that she chose not to remove the Epipens from the room because "it was still necessary to enter a code in order to enter the vaccine room."
- CA: According to MOR Sucharski, the Epipens were removed from the vaccine room and stored in the pharmacy in "the emergency bag that contains the Epipens is brought to and from the room upon administration of a vaccine." In addition, MOR Sucharski indicated that the lock on the door for the vaccine room was fixed.

<u>ACTION</u>: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2022-0186), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

Case #5/CAS-2022-1111		
SA-INV-20640	Walgreens #10319, DS3517	Time 09:32 AM

<u>RECUSAL</u>: R. MORELLI and Intern V. PATEL recused and were not present for the vote or discussion in this matter.

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

• On September 13, 2022, Investigator Paul Seed conducted a retail compliance inspection at WAG 10319. During the inspection, Investigator Seed noted that Pharmacist Cushing was unable to provide proof of completion of initial training required to engage in or oversee administration of vaccines. At that time, Investigator Seed required Pharmacist Cushing to cease engaging in or overseeing vaccine administration until he completed requisite training, the pharmacy's DM was notified, and a POC was issued.

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- In the POC, WAG 10319 and Area HCS DeLeo indicated that all documentation required for respective staff to engage in or oversee administration of vaccines would be kept in "File #17 of the Pharmacy Records and Retention system." WAG 10319 underscored that "the documentation will be collected on the first day of a new team member's employment" going forward and "be reviewed periodically for accuracy and expiration."
- In addition, Area HCS DeLeo indicated that Pharmacist Cushing engaged in or oversaw administration of vaccines at WAG 10319, WAG 11120, and WAG 18335. He administered 14 vaccines and oversaw the administration of 119 vaccines by 8 different licensees. She also indicated that Pharmacist Cushing immediately ceased engaging in or overseeing administration of vaccines on September 13, 2022. Then, HCS DeLeo indicated that Pharmacist Cushing would not engage in or oversee administration of vaccines until he completed requisite training.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by those present to CLOSE the matter (SA-INV-20640), No Discipline Warranted, Remediation Complete. A second motion was made by D. BARNES, seconded by D. PERRY, to open a staff assignment investigation on Walgreens #19240 in Dudley (DS90207).

Case #6/CAS-2022-1111		
SA-INV-20641	Christopher Cushing, PH25844	Time: 09:40 AM

<u>RECUSAL</u>: R. MORELLI and Intern V. PATEL recused and were not present for the vote or discussion in this matter.

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

- On September 13, 2022, Investigator Paul Seed conducted a retail compliance inspection at WAG 10319. During the inspection, Investigator Seed noted that Pharmacist Cushing was unable to provide proof of completion of initial training required to engage in or oversee administration of vaccines. At that time, Investigator Seed required Pharmacist Cushing to cease engaging in or overseeing vaccine administration until he completed requisite training, the pharmacy's DM was notified, and a POC was issued.
- In the POC, WAG 10319 and Area HCS Susan Deleo indicated that all documentation required for respective staff to engage in or oversee administration of vaccines would be kept in "File #17 of the Pharmacy Records and Retention system." WAG 10319 underscored that "the documentation will be collected on the first day of a new team member's employment" going forward and "be reviewed periodically for accuracy and expiration."
- In addition, Area HCS Susan DeLeo indicated that Pharmacist Cushing engaged in or oversaw administration of vaccines at WAG 10319, WAG 11120, and WAG 18335. He administered 14 vaccines and oversaw the administration of 119 vaccines by 8 different licensees. She also indicated that Pharmacist Cushing immediately ceased engaging in or overseeing administration of vaccines on September 13, 2022. Then, HCS DeLeo indicated that Pharmacist Cushing would not engage in or oversee administration of vaccines until he completed requisite training.

<u>ACTION</u>: Motion by J. ROCCHIO, seconded by D. BARNES, and voted unanimously by those present, to ELEVATE the matter (SA-INV-20641) to a complaint.

Case #7/CAS-2022-0415	i	
PHA-2022-0200	Cardinal Health 110, WD352	Time: 09:42 AM
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Draft Minutes General	1 Session: 3/2/23	

BOP Approved: 4/6/23

RECUSAL: NONE

<u>DISCUSSION</u>: 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.
- 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 Connecticut 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.
- Cardinal's general counsel argued that Cardinal did not admit to any wrongdoing in the settlement agreement and the agreement was a non-disciplinary action. Thus, BORP should not take disciplinary action against Cardinal for discipline in another jurisdiction because disciplinary action did not occur.
- CA: "To ensure the address mismatch does not occur in the future, Cardinal Health has changed how it 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."

<u>ACTION</u>: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present EXCEPT D. PERRY, to refer the matter (PHA-2022-0200), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

Case #8/CAS-2022-1024		
SA-INV-20508	Westminster Pharmacy, DS1710	Time: 09:47 AM

RECUSAL: NONE

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

 On August 22, 2022, Investigator Seed conducted a retail compliance inspection at Westminster. During the inspection, Investigator Seed first observed a broken lock on a cabinet used to secure CIII-CV. Investigator Seed also observed a compounding record and corresponding MFR for omeprazole 2mg/mL oral suspension with instructions to check and adjust pH with no corresponding documentation of a pH check or adjustment. In addition, an extended BUD of 60 days was used without a USP monograph or supporting stability and sterility studies.

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- Accordingly, Investigator Seed issued a POC. In turn, MOR Mudar Chalati submitted a POC on behalf of the pharmacy as required. MOR Mudar Chalati attested that the broken lock was replaced, and an extra lock was now kept at the pharmacy in case the lock broke again.
- MOR Chalati next indicated that the PH level check in the MFR for the omeprazole oral suspension was removed because the check was not required when the omeprazole was suspended in reconstituted SyrSpend SF Alka. He then provided referces supporting the removal of the PH level check and the extended BUD of 60 days.
- CA: Westminster was notified of this complaint and MOR Chalati responded on behalf of the pharmacy. He indicated that corrective action was implemented as described in the POC. In addition, MOR Chalati provided a copy of Westminster's policy and procedures pertaining to compounded non-sterile preparations. The policy and procedures were extensive at approximately 386 pages. The manual included a chapter on Quality Assurance with a specific section called, "Quality Assurance of Oral and Topical Liquids."

<u>ACTION</u>: Motion by S. AHMED, seconded by K. THORNELL, and voted unanimously by those present EXCEPT D. PERRY, to CLOSE the matter (SA-INV-20508), No Discipline Warranted, Remediation Complete.

Case #9/CAS-2022-1260		
PHA-2022-0197	Sullivans Healthcare Inc., DS3335	Time: 09:51 AM

<u>RECUSAL</u>: D. BARNES 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.

- Inspectional deficiency for allowing PTT Bedard to perform pharmacy technician duties with a license that expired on 5/19/22. In the POC, MOR Fensky indicated a PTT extension request was faxed to the BORP on 10/19/22, the day of the inspection. Her PTT license was extended to 01/19/23. PTT Bedard has recently passed the exam for her PT license. On 10/21/22 her PT application was submitted to PCS. According to documentation provided in the POC, PTT Bedard had worked 908 hours as of 10/21/22.
- MOR Fensky indicated PTT Bedard was licensed in May 2021 and was not expected to return to work in the Pharmacy after graduating college in May 2022. When she could not find work in her field of study, she returned to work at the Pharmacy. Both the Technician Manager and MOR Fensky failed to check that her license wasn't expired. The Technician Manager had been on a LOA and the check was missed.
- PTT Bedard indicated that she was unaware her PTT license was expired since she wasn't working when it expired in May until August. When she returned to the Pharmacy in August 2022, she was not told it was expired or prompted to request an extension. PTT Bedard worked 474.78 hours with an expired license. PTT Bedard was issued PT license PT29487 on 11/04/2022.
- A spreadsheet was developed to track license expiration dates and number of days until license expiration. For PTTs, the number of hours completed, the last date PTT hours were validated, and hours until eligible for PT examination are also tracked. Going forward, the spreadsheet shall be referenced and updated upon hiring of employees, checked on a monthly basis, and after each payroll run by the Technician Manager and MOR Fensky.

<u>ACTION</u>: Motion by R. MORELLI, seconded by J. ROCCHIO, and voted unanimously by those present, to refer the matter (PHA-2022-0197), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

 Case #10/CAS-2022-1289

 PHA-2022-0204
 CVS #127, DS3420
 Time: 10:08AM

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

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

- Inspectional deficiencies for numerous packages of needles/syringes and vials of 0.9% sodium chloride for injection stored unsecured outside of the Pharmacy in an immunization booth. A POC was issued but the initial POC did not address these deficiencies.
- MOR Lamptey stated they kept receiving more immunization supplies than needed resulting in an overstock originally stored in a secured space in the backroom. Pharmacist Cordor related that prior to the 2022 annual inventory, Front Store Manager PT Frederick instructed a front store employee to use immunization booth #2 to store the excess immunization supplies, including needles/syringes and 0.9% sodium chloride for injection, without the Pharmacy staff's input. The immunization booth continued to be used as storage after the inventory.
- As corrective action, additional shelves were mounted in the Pharmacy for the storage of the immunization supplies removed from the immunization booth. MOR Lamptey reached out to the vaccination team to put a hold on the shipment of vaccination supplies until needed. Going forward, all immunization supplies will be delivered directly to the Pharmacy for storage. The pharmacist on duty will perform daily physical inspections of the immunization booths to ensure that there is no storage of immunization supplies in them. Access to the immunization booths will be restricted to immunizers only. The Pharmacist on duty will be responsible for the security of the immunization booths that will be locked at all times. MOR Lamptey and Pharmacist Cordor signed and dated a copy of CVS ROPP-052388 "Routine Temperature Monitoring and Drug Product Storage" confirming review.

<u>ACTION</u>: Motion by S. AHMED, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0204), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

Case #11/CAS-2022-1293		
PHA-2022-0205	CVS #7232, DS3461	Time: 10:11 AM

<u>RECUSAL</u>: 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.

• Inspectional deficiencies on 10/28/22 including PTT Tunis who was observed pulling drugs from the shelves with a license that expired on 7/31/22. MOR Hunt and PTT Tunis where informed PTT Tunis could only perform non-technician duties. The POC stated PTT Tunis applied to renew her license.

- MOR Hunt indicated when she began working in the Pharmacy in July 2022, she had PTT Tunis apply for an extension which was denied as she had previously been given an extension. MOR Hunt stated PTT Tunis applied for a PT license and she would not be handling any medications until licensed. Going forward, MOR Hunt would ensure licensure of all staff.
- PTT Tunis stated she had occasionally put away medication deliveries in addition to working as a cashier and at the drive-thru when her license was expired. She indicated she did not perform any credentialing activity. From 8/2/22 to 12/2/22, she had worked 134.26 hours with an expired license.
- MOR Hunt reviewed all P&Ps for the scope of responsibility in the duties delegated to CPhTs and PTTs and CVS technician training guidelines.

<u>ACTION</u>: Motion by D. BARNES, seconded by R. MORELLI, and voted unanimously by those present, to consolidate the matter (PHA-2022-0205) with PHA-2022-0223, and 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 a REPRIMAND.

 Case #12/CAS-2022-1544

 PHA-2022-0223
 CVS #7232, DS3461
 Time: 10:13 AM

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

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

- Repeat inspectional deficiency of PTT Tunis performing PT functions with a license that expired on 07/31/2022 observed during a site visit on 12/9/22. The Pharmacy failed to implement the POC for the inspection on 10/28/22 and the CA for PHA-2022-0205.
- MOR Hunt stated in the fall of 2022, PTT Tunis took the PT exam and submitted the application. MOR Hunt gave the application to management for payment and had assumed it was submitted. Once alerted, she ensured it was submitted.
- PTT Tunis indicated she was unaware her license was expired. She related she took the PT exam and obtained PT licensure. She acknowledged she had occasionally put away the deliveries in addition to working at the register and drive-thru while unlicensed. PTT Tunis was issued PT29773 on 1/4/23.
- CVS policy "Professional Licensure" states, "After hire, Management must verify that colleagues are maintaining the proper Credentials by conducting a primary source verification at each renewal, prior to expiration, and at least annually thereafter".
- DL Gilman reviewed CVS policy "Professional Licensure" with all the CVS pharmacies that he supervises. He related all MORs were instructed on how to search Mass.gov to determine licensure status. He stated he would be alerted of any pharmacist, PT, and PTT that has an upcoming license expiration date. MOR Hunt stated, to ensure compliance, she verified all PTT licenses, will track all PTT hours, and will administer the PT exam as soon as eligible. She will follow up with all staff licensure in a timely manner, noting and reminding each employee of their expiration dates. MOR Hunt provided a signed statement confirming review of the CVS pharmacy technician training guidelines and "Professional Licensure" policy. PT Tunis' license information was posted within the Pharmacy and a copy filed in the Pharmacy's regulatory box.

<u>ACTION</u>: Motion by C. BELISLE, seconded by D. BARNES, and voted unanimously by those present, to consolidate the matter (PHA-2022-0223) with PHA-2022-0205, and then refer to the Office of

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Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

Case #13/CAS-2022-1500 PHA-2022-0217 CVS #844, DS1402 Time: 10:18 AM

<u>RECUSAL</u>: 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.

- Inspectional deficiencies on 10/27/22 for refrigeration temperature excursions on 9/1/22, 9/9/22 and 9/29/22 affecting 20 completed prescriptions for medications stored in 2 refrigerators with temperatures below freezing.
- Pharmacists McGoodwin worked on each day of excursions but couldn't recall what specifically occurred. She related what her normal practice is when a TempAlert is received. She stated she didn't remember getting multiple notifications from TempAlert. Action to the excursions occurred after Investigator Murray brought the excursions to her attention during the inspection.
- Pharmacist Le worked overnight on 9/1/22 and 9/9/22 and recalled that on one of those days he received a TempAlert voicemail and realized there was also an audible alert. He claimed one of the refrigerator doors was open, he closed it, and the temperature corrected itself. Pharmacist Rodrigues worked overnight on 9/29/22 but alleged the alert happened before she arrived.
- Senior Analyst Furtado provided the response but didn't provide specific documentation requested including the actual documented temperatures from TempAlert, any text message/email alerts, and documented actions in response to alerts. The refrigerators involved contained filled prescriptions for pickup. Manufacturer guidelines were reviewed to determine if the medications were safe for dispensing. CVS discard and keep lists were provided. No vaccines were stored in the refrigerators. Patient outreach for affected medications occurred as part of the POC in November 2022.
- MOR Sabokrooh discussed the incidents with Pharmacists McGoodwin, Pharmacist Le, and Pharmacist Rodrigues and the TempAlert policy was reviewed. Each pharmacist confirmed receiving reeducation for action to excursions. MOR Sabokrooh, Pharmacist McGoodwin, Pharmacist Le, and Pharmacist Rodrigues signed copies of policies CVS ROPP-052388 "Routine Temperature Monitoring and Drug Product Storage" and CVS ROPP-048822 "Temperature Excursions Impacting Store Products and Colleagues" confirming review.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0217), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

Case #14/CAS-2022-1131 PHA-2022-0182 CVS #669, DS2846

Time: 10:21 AM

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

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

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- On September 19, 2022, Investigator Van Allen conducted a retail compliance inspection (ISP-19566) at CVS 669. During the inspection, he discovered that Former MOR Nogarotto, who was listed as the MOR in BORP records at that time, left as MOR approximately two months prior to the inspection and Current MOR Duong was appointed. In addition, CVS 669 was unable to confirm whether requirements to notify BORP about the change in MOR and complete a change in MOR inventory were accomplished in violation of 247 CMR 6.03.
- Accordingly, Investigator Van Allen issued a plan of correction in part for the violations described above and CVS 669 submitted a POC as required. The pharmacy indicated that Current MOR Duong's application for a change in MOR and change in MOR CS inventory were completed on October 6, 2022. CVS 669 then emphasized that "Going forward, any change in MOR will be relayed to the BOP in the required time frame."
- CA: Current MOR Duong notified BORP about the change in MOR appointing her permanent MOR and completed a change in MOR inventory. Current MOR Duong added that "I will assist and guide the next MOR with departing paperwork to mitigate recurrence of a similar incident."

<u>ACTION</u>: Motion by R. MORELLI, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0182), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a REPRIMAND.

Topic X:Executive Session Call to Order:Time: 10:25 AMBy: C. Belisle reads the executive session language and requests a motion to enter executive session.

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

Topic XI:

65C Sessions MGL c. 112 section 65C

Time: 10:29 AM

DISCUSSION: None

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

At 10:29 AM J. Lanza, seconded by D. Barnes and voted unanimously by all those present to enter 65C by roll call vote.

Lunch 12:00 PM to 12:30 pm

S. Hamilton Leaves Meeting 2 PM to 3:30 PM

- D. Perry leaves meeting 3:46 PM
- J. Rocchio leaves meeting 4:20 PM

ACTION: Motion by J. Lanza seconded by S. Hamilton 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 3/2/23 General Session
- 2. Draft Minutes of the 2/2/23 Meeting
- 3. Report on Applications approved pursuant to Licensure Policy 13-01
- 4. Report on probation
- 5. Report on Board Delegated Complaint Review to licensure policy 14-02
- 6. Report on PSUD 17-03
- 7. Application: Westminster Pharmacy: DS1710 Renovation
- 8. Application: SymbriaRx; New Community Pharmacy
- 9. Application: EternaPharmacy; New Community Pharmacy
- 10. Application: Health Care Pharmacy; DS1585 Petition for Waiver
- 11. Application: Genoa-Framingham; Follow up on incense approval
- 12. Policy 2022-02: Extended Absence or Departure of a Manger of Record Policy 14-02: Board

Delegated Review (BDR)

- 13. Regulation: 247 CMR 3.00 Licensure and Continuing Education Requirements For Individual Pharmacy Professionals
 - 14. CAS-2022-0665 SA-INV-20260 CAPS Pharmacy, DS3312
 - 15. CAS-2022-0868 SA-INV-20914 CAPS Pharmacy, DS3312
 - 16. CAS-2022-0767 PHA-2022-0143 Walgreens #9405, DS3475
 - 17. CAS-2022-1200 PHA-2022-0186 Walgreens #2699, DS2129
 - 18. CAS-2022-1111 SA-INV-20640 Walgreens #10319, DS3517
 - 19. CAS-2022-1111 SA-INV-20641 Christopher Cushing, PH25844
 - 20. CAS-2022-0415 PHA-2022-0200 Cardinal Health 110, WD352
 - 21. CAS-2022-1024 SA-INV-20508 Westminster Pharmacy, DS1710
 - 22. CAS-2022-1260 PHA-2022-0197 Sullivan's Healthcare Inc, DS3335
 - 23. CAS-2022-1289 PHA-2022-0204 CVS #127, DS3420
 - 24. CAS-2022-1293 PHA-2022-0205 CVS #7232, DS3461
 - 25. CAS-2022-1544 PHA-2022-0223 CVS #7232, DS3461
 - 26. CAS-2022-1500 PHA-2022-0217 CVS #844, DS1402
 - 27. CAS-2022-1131 PHA-2022-0182 CVS #669, DS2846

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Respectfully Submitted, Jennifer Chin, RPh Secretary

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