COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

May 5, 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=e166d0f50f597f3bb7a140ab835e7abf0

To access the meeting by phone:

Call in Number: 1-650-479-3208

Access Code: 2532 900 2445

Attendee: #

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator **Sofie Daley**, *sofie.daley@mass.gov* 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	
8:00	Ι	CALL TO ORDER	
8:02	II	APPROVAL OF AGENDA	
8:05	Ш	APPROVAL OF BOARD MINUTES • Draft of April 7, 2022 Regular Session Minutes	
8:10	IV	REPORTS Applications approved pursuant to Licensure Policy 13-01• Monthly report from Probation• Board Delegated Review pursuant to Licensure Policy 14-02• PSUD Report-Policy 17-03	

		FLEX
8:15		Pharmacy issues related to Covid-19 and the state of emergency
	V	Plan of Correction Data Report
		Summer Meeting Schedule
		APPLICATIONS
		Walmart Pharmacies-Waiver Requirement
	VI	Cape Cod Healthcare Pharmacy at Falmouth Hospital - DS90082:
		petition for waiver
		Cape Cod Healthcare Pharmacy at Cape Cod Hospital -
		DS90036: petition for waiver
8:20		• NIMVAX- DS90369 – pilot update / request to end pilot
		Tufts Medicine Home Infusion Services-change in scope
		Pelmeds Fitchburg, LLC – New Community Pharmacy
		 BNHC Pharmacy – New Community Pharmacy
		• Lynn Community Health Pharmacy – New Community
		Pharmacy
0.20	VII	POLICIES
9:30	VII	Policy 2019-04: Transfer of Unfilled Prescriptions
9:45	VIII	ADVISORY • Information for Managers of Record

		FILE REVIEW		
		1CAS-2021-1071SA-INV-18792Tiffany Battles LeBlanc, PH233605		
	IX	2 CAS-2021-0790 PHA-2021-0077 Rite Aid #10084, DS2780		
		3 CAS-2021-0848 SA-INV-18429 Walgreens #17728, DS90161		
		4 CAS-2021-0894 PHA-2021-0083 Walgreens #13135, DS89732		
10:00		5 CAS-2021-1037 PHA-2021-0105 Walgreens #3469, DS2593		
10:00		6 CAS-2021-1280 PHA-2022-0001 Walgreens #19525, DS90219		
		7 CAS-2021-1140 SA-INV-19031 Edge Pharma, NO00015		
		8 CAS-2021-1049 PHA-2021-0102 CVS #2172, DS2817		
		9 CAS-2021-1267 PHA-2021-0121 CVS #207, DS2864		
		10 CAS-2022-0182 PHA-2022-0032 CVS #207, DS2864		
11:00	X	EXECUTIVE SESSION Image: Constraint of the purpose of discussing the reputation, character, physical condition, or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, to evaluate the Good Moral Character as required for registration for a pending applicant.		
12:00		LUNCH BREAK		
12:30	XI	M.G.L. c. 112, § 65C SESSION		
1:15	XII	ADJOURNMENT		

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting May 5, 2022

Board Members Present

Sebastian Hamilton, Pharm D, MBA, RPh President Caryn Belisle, RPh, MBA, President-Elect Carly Jean-Francois, RN, NP Secretary Julie Lanza, CPhT (leaves meeting 9:29 AM to 9:40 AM) Susan Cornacchio, JD, RN (Leaves meeting 12:46 PM) Jennifer Chin, RPh John Rocchio, RPh, PharmD (Leaves meeting 12:46 PM) Dr. Richard Lopez, MD Sami Ahmed, Pharm.D., RPh, BCPS, BCSCP Delilah Barnes, RPh Rita Morelli, PharmD, BCACP, RPh (arrives 9:08 AM)

Board Staff Present

David Sencabaugh, RPh, Executive Director Monica Botto, CPhT, Assistant Executive Director Heather Engman, 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 Julienne Tran, PharmD, Investigator Board Members Not Present Dawn Perry, JD Katie Thornell, RPh, MBA

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:06 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: S. Hamilton, yes; J. Lanza, yes; C. Belisle, yes; D. Barnes; J. Rocchio, yes; J. Chin, yes; S. Cornacchio, yes; R. Lopez, yes; S. Ahmed, yes; C. Jean-Francois, yes. (R. Morelli joins meeting 9:08 AM)

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Draft Minutes General Session: 5/5/22 BOP Approved: 6/2/22 Topic II.

Approval of Agenda

TIME 8:05 AM

Agenda 5/5/22

DISCUSSION:

Changes: defer SA-INV-19031 Edge Pharma NO00015

ACTION:

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

Topic III

Approval of Board Minutes

TIME: 8:08 AM

Time: 8:09 AM

Time: 8:09 AM

Minutes

1. Draft 4/7/22

Change: no changes

Action:

Motion by C. Belisle seconded J. Lanza and voted unanimously to approve the regular session minutes of 4/7/22 with no noted changes by roll call vote. J. Chin abstains.

TOIC IV Reports
Applications approved pursuant to Licensure Policy 13-01
Presented by: R. HARRIS

Discussion: R. HARRIS reported a total of 27 Change of Manager applications and 2 facility closures that were approved by Staff Action since the last Board meeting.

REPORTS

So noted. **TOPIC IV Monthly Report from Probation** Presented by: R. HARRIS

Discussion: R. HARRIS indicated that there was no monthly probation to report for the month of April at the time of the meeting.

So noted.

ΤΟΡΙϹ ΙV	REPORTS
Monthly Report from BDCR	pursuant to Policy 14-02

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Presented by: D. SENCABAUGH

Discussion: D. SENCABAUGH reported that there were 10 cases of Board Delegated Review on April 7th, 2022, eight of which were self-reported CE deficiencies that were remediated and closed. One waiver renewal request was approved, and the final report regarded an unknown loss of controlled substances, which was deferred to the Office of Prosecution for an Order to Show Cause with authorization to be resolved with a Consent Agreement with Stayed Probation for a one-year period.

Soı	noted.		
PSL	PIC IV JD Report by Staff Action 17-03 sented by: E. TAGLIERI	REPORTS	Time: 8:10 AM
	cussion: E. TAGLIERI reported that there and the states of		ipants currently enrolled in the
Soi	noted.		
то	PIC V	Flex	
1.	Pharmacy issues related to Covid-19 a	nd state of emergency.	Time: 8:10 AM
	Presented by: D. SENCABAUGH		
	Nothing to report.		
2.	Plan of Correction Data Report		Time: 8:10 AM
	Presented by: N. ALEID		
	Discussion: Retail inspections and	subsequently plans of corr	ection have increased over the

Discussion: Retail inspections, and subsequently, plans of correction have increased over the past year due to the relaxation of COVID restrictions.

So noted.

3. Summer Meeting Schedule

Presented by: D. SENCABAUGH

Discussion: The proposal was made to cancel the July Board meeting since it is scheduled so near to the July 4th holiday.

Time: 8:13 AM

Action: Motion by J. LANZA, seconded by J. CHIN, and voted unanimously by roll call of those present, to cancel the July 2022 Board meeting.

TOPIC VI

Applications

Waiver Requirement

TIME: 8:11 AM

1. Walmart Pharmacies Represented by: N/A

Recusal: None Discussion:

Executive director D. Sencabaugh states that during a routine inspection one of the board's investigators observed a sign at a Walmart pharmacy indicating that they did not stock Promethazine with Codeine products. The board has been in communication with Walmart regarding this issue as it relates to section 9 of 247 CMR which outlines the pharmacy's requirement to have a sufficient supply of medication to service the needs of the community. In the past, such issues would require a waiver and Walmart states that this decision was a nationwide decision made to ensure the safety of their staff. According to Walmart, there has not been any negative impacts and pharmacy staff has been very happy with this decision. This matter is coming before the board to determine if this decision violates section 9. Board counsel H. Engman states that the board is looking for some direction as to whether refusing to stock this medication is a violation of the regulation that requires the pharmacy to provide the medications that service the needs of the patient. D. Sencabaugh states that Walmart has offered to find a location that does stock the medication and send the patient there or work with the prescriber to find an alternate medication. S. Cornacchio inquired as to what this would do to our ability to enforce the regulations if we don't inquire them to seek a waiver. She states that this is a compelling case that makes sense however the board wouldn't want to tie their hands if they need to enforce the waiver later down the line. H. Engman responds that with Walmart having very concrete signage and policy that they don't stock this medication and it would be appropriate to have them fill out a waiver so that the board doesn't run into any inconsistencies with other pharmacies. H. Engman states that there is a compelling public interest which would justify a waiver however, this might not apply in all circumstances. D. Barnes states that refusing to stock a medication goes beyond the duty to provide services to the patient. She understands the safety concerns but explains that this might set a negative precedent if the pharmacy were to decide they didn't want to stock other medications in the future. S. Cornacchio states that based on what D. Barnes stated she would be in favor of having Walmart request a waiver and they would have to make a compelling argument as to why they are making a request.

Motion to have the chain come before the board and petition a waiver made by S. Cornacchio; seconded by C. Francois; then Board members present voted unanimously by rollcall to approve the motion.

2. Cape Cod Healthcare Pharmacy at Falmouth Hosp DS90082 Petition to Waiver TIME: 8:17 AM Represented by: PH Angela Medeiros

Recusal: None Discussion:

S. Hamilton states that the information pertaining to the waiver request is in the board packet and is straightforward. If board members have no questions or objections S. Hamilton will move straight to making a motion to approve the waiver for 247 CMR 6.01 (5)(a)(4) for the balance scale. Board staff M. Chan inquires as to which DS is being voted on and S. Hamilton responds that the DS is in Falmouth.

Motion to approve the waiver made by S. Hamilton; seconded by J. Lanza; then Board members present voted unanimously by rollcall to approve the motion.

3. Cape Cod Healthcare Pharmacy at Cape Cod Hospital DS90036 Petition to Waiver TIME: 8:20 AM

Represented by: PH Courtney Kelly

Recusal: None Discussion:

S. Hamilton states that the information pertaining to the waiver request is in the board packet and is straightforward. If board members have no questions or objections S. Hamilton will move straight to making a motion to approve the waiver for the balance scale as submitted. PH Kelly inquired as to whether she will receive any documentation about the waiver's approval and R. Harris responded she will receive a packet with a waiver that is valid for 5 years at which point she would have to come back before the board to request another waiver.

Motion to approve the waiver made by S. Hamilton; seconded by J. Rocchio; then Board members present voted unanimously by rollcall to approve the motion.

4. NIMVAX DS90369 Request to End Pilot Represented by: PH Nimit Deocampo

Recusal: S. Ahmed Discussion:

PH Deocampo states that he is the founder and owner of NIMVAX and is coming before the board to provide a detailed update about the progress of the pilot project and how they have achieved the project objectives. PH Deocampo presents the slides to the board which are also included in the board packets. C. Belisle inquires as to how long the duration of the pilot was and PH Deocampo states that it was an 18-month pilot. C. Belisle then asks if the total number of vaccinations occurred during those 18 months. S. Hamilton stated that they began vaccinating around September and the pilot was 6 months. PH Deocampo states that their number of vaccinations occurred throughout a total of 5

TIME: 8:24 AM

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months. C. Belisle discusses the waiver which requires pharmacies to store the typical pharmacy inventory as NIMVAX is for vaccinations only and wants to ensure that this is the appropriate channel for this vaccine clinic as opposed to a pharmacy and wants to make that determination from the board's perspective. D. Sencabaugh responds that if they were approved to come off the pilot the board would need to create a policy that can be used by other entities however, the circumstances would need to be the same or very similar. Given the world that we are in today and that NIMVAX is not limiting or making the vaccines but are performing a very valuable service for the foreseeable future. D. Sencabaugh inquires as to what this would mean for other entities. H. Engman responds that her recommendation is for the board to put together a policy or advisory and for NIMVAX to request a waiver. B. Frisch responds that NIMVAX did submit the waivers one for the balance, one for not compounding, and the waiver that deals with requiring the pharmacy to stock sufficient chemicals and medicinal which 247 CMR 6.02(4) and mentions that specialty pharmacy and closed-door pharmacies submit waivers for limited stocks and inventories. S. Hamilton discusses a previous case that was seen before the board regarding a pharmacy that just wanted to stock bowel prep medications and inquired as to how NIMVAX would be different. D. Sencabaugh responded that the other pharmacy was using their own products and that was the major difference between the two cases. S. Hamilton inquired as to how this would affect other pharmacies if the pilot were to be extended for another year and how it would hinder the progression of this particular pharmacy. D. Sencabaugh responded that if a policy or advisory were to be created, it would allow other pharmacies to go through a similar business model would not have to come before the board in a pilot. H. Engman adds that one of the key features is the compelling public interest in access to vaccines whereas there might not be that interest with other pharmacies.

Motion to end the pilot pending another successful inspection made by C. Belisle; seconded by S. Cornacchio; then Board members present voted unanimously by rollcall to approve the motion.

Motion to approve the waivers made by D. Barnes; seconded by C. Belisle; then Board members present voted unanimously by rollcall to approve the motion.

5. Tufts medicine Home Infusion Services Change Business Model TIME: 8:45 AM Represented by: PH Nicholas Capote

Recusal: D. Sencabaugh Discussion:

PH Capote indicates that in November the initial program was discuss and the organization has changed their intent to invest in the facility that they were going to be co-located in. The facility will no longer be conducive to home infusion facilities and as a result they have changed their pathway as well in terms of where their final footprint will be. They wanted to change the scope of the project in a way that makes sense while simultaneously be responsible for the resources of the organizations. That being said, this does not change the intent or purpose of the pharmacy and any patient that needs a prescription filled will be serviced by the organization's networks. They are hoping with the change of scope that they wanted to relay that their clean room is in a different area, and they will not have a hazardous buffer room as they will not have hazardous drugs stored. The one request they are making is to avoid making changes to the numbers that they have for the drug store and controlled substance

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numbers as a result of contracting issues. B. Frisch is fine with the amendments but wanted to bring the matter before the board as a formality to weigh in on the change in scope, but he does not have any concerns. B. Frisch also states that he believes the numbers can remain the same to be able to do third party contracting and serves to ratify the change in scope.

Motion to approve the change in scope with the floor plans as submitted by C. Belisle; seconded by J. Lanza; then Board members present voted unanimously by rollcall to approve the motion.

6. Pelmeds Fitchburg, LLC New Community Pharmacy TIME: 8:51 AM Represented by: Vera Parker & Bhuren Patel

Recusal: None Discussion:

PH Parker indicates that they have a new building in Fitchburg, and they have a robotics machine that packages blister medications. They will be doing prescriptions for group homes, assisted living facilities, and residential schools and programs. The move to Fitchburg would allow them to reach patients further west and would assist their drivers logistically to deliver the medications in a timely manner. V. Parker indicates that the move allows them to streamline their process and maximize the number of staff they have. In regard to security, there will be a separate locked controlled room with a pull-down barrier to secure the medications along with steel doors to secure the pharmacy. They plan on having a small retail front store to stock non-prescription pharmacy essentials such as gloves and hand sanitizer. There is a small patient consultation area and deliveries using a different entry and exit way. S. Hamilton inquires as to whether they will provide certified architectural plans. V. Parker responds that these plans were emailed to the board. V. Parker indicates that she will be the starting pharmacist and at some point, in the future will be onboarding along with a few other technicians. B. Patel indicates that they are in the process of identifying the homes that they will serve. Some of the technicians in the Worcester area will transfer to the Fitchburg area and are looking to hire additional pharmacists. B. Patel indicates that Pelmeds is a closed-door pharmacy that primarily services adults and children with intellectual and developmental disabilities. S. Hamilton inquiries about the central fill process. V. Parker responds that they currently complete a cycle fill and attempt to fill all the patient's medications for that month and deliver it to the facility. Fitchburg allows them to have more space and want to do the automated central fills in Fitchburg. If the patient was from Waltham the data entry and verification would occur in Waltham and it would be filled and processed in Fitchburg, then sent back to the patient in Waltham. They are attempting to streamline some of the processes. J. Chen inquires how the completed product will be moved from Fitchburg to Waltham for delivery. V. Parker responds that they will have some of their drivers have the products packaged in totes or bags and have some drivers but will hire additional ones to deliver the medications. V. Parker indicates that Pelmeds employees only will be handling the medications throughout the entire process. B. Patel states that when the deliveries leave from Fitchburg, they are labeled with a delivery manifest so that they are fully accounted for. B. Frisch inquired as to whether they will be accommodating walk-in prescriptions. B. Patel responds that they will be accommodating walk-ins and built a consultation for local walk-in patients. V. Parker indicates that they will also be administering vaccines in the consult room. S. Hamilton inquires if they intend on servicing everyone or if their scope of service is restricted to a specific patient population. B. Patel responds that anyone can walk into the pharmacy, but their

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specialty is mental health. B. Patel indicates that the pharmacy is fully alarmed and has a key code access to get into the pharmacy and this access is limited only to pharmacy employees. There is also a steel door and 12 cameras on the outside and inside of the building. B. Frisch indicates that the board members would need 2 votes one for the petition for central fill and the other to operate a new community pharmacy.

Motion to approve the application for a new community pharmacy pending successful inspection made by J. Rocchio; seconded by S. Ahmed; then Board members present voted unanimously by rollcall to approve the motion.

Motion to approve the central fill operation as submitted made by J. Rocchio; seconded by J. Chen; then Board members present voted unanimously by rollcall to approve the motion.

7. BNHC Pharmacy	New Community Pharmacy	Time: 9:05 AM
Represented by: Michael Berube		

Recusal: J. Rocchio, S. Cornacchio Discussion:

M. Berube indicates that they are planning on opening a pharmacy within BNHC that will be 340 B and a retail pharmacy to serve the whole community. They are looking to be on the same platform as the health center. They are also looking to add some things to the pharmacy such as immunization and deliveries with a local currier. M. Berube states that they will have some robotics and a bagging system to keep things organized. They will have cameras, motion detectors, a locking door, and a separate door for pharmacy personnel. S. Hamilton inquires if the pharmacy will be located within a licensed DPH facility. M. Berube responds that it will be. S. Hamilton states that Health Care Quality should also agree to the operation and M. Berube responds that they do. S. Hamilton states that they are an open-door pharmacy even though they are on campus and take any patient but will most likely be seeing patients from the facility. M. Berube agrees with this statement and states that he doesn't want to limit the pharmacy to certain patients because the patients that don't come to the center have a need for deliveries. S. Hamilton inquires as to how the pharmacy plans on ensuring the integrity of the medications until they are delivered to the patient. M. Berube responds that the bag will get closed out and documented and are looking to use a web-based system requiring signatures to track the packages. S. Hamilton inquires as to whether there is any compounding and M. Berube responds that they will not compound. S. Hamilton indicates that he doesn't see any waivers and will have every drug, a scale, etc. B. Frisch states that if there is no compounding the pharmacy may have to submit some waivers in the future, but if they were to do compounding, they wouldn't need any. B. Frisch also states that the approval of Health Care quality and a satisfactory board inspection should be contingent on the vote. B. Frisch states that the board can issue the applicant an inactive license number for the purpose of contracting. J. Lanza inquiries about their staffing plans. M. Berube responds that that he would have to discuss this with his boss but anticipates approximately 6 pharmacists technicians and students and will adhere to the ratio requirements.

Motion to approve the application for a community pharmacy pending successful inspection and healthcare quality approval made by J. Chen; seconded by J. Lanza; then Board members present voted unanimously by rollcall to approve the motion.

8. Lynn Community Health Pharmacy New Community Pharmacy Represented by: Yena Kim, Kimberly Eng

TIME: 9:20 AM

Recusal: None Discussion:

Y. Kim indicates that they currently don't have a retail pharmacy on site and would like to open one in the health center to provide integrated care. They will be providing regular retail dispensing, administer vaccines, currier delivery services, and blister packaging. Pharmacy personnel and currier services will have a separate entrance in the back, badge access, and security cameras. They plan on having an area for non-sterile simple compounding, narcotic cabinets, separate counseling rooms, and separate vaccine rooms. The pharmacy will start with 3 full time pharmacists and 8 technicians and as their business grows, they will probably expand more. Y. Kim states that the only time she believes there will be 1 pharmacist staffed is 30 minutes before closing otherwise there will always be 2 pharmacists on staff and a 1:4 ratio with 2 certified technicians. C. Belisle asks if they plan on doing hazardous compounding and Y. Kim responds that they will not. R. Morelli inquires as to where the pharmacy is located in respect to the rest of the facility and what their security will look like. K. Eng states that there are 2 adjoining buildings, and the pharmacy will be on the first floor off the main lobby. As far as the security goes, there is typical alarms, motion sensors, and badge access.

Motion to approve the application for a community pharmacy pending successful inspection and healthcare quality approval made by D. Barnes; seconded by S. Ahmed; then Board members present voted unanimously by rollcall to approve the motion.

TOPIC VII

Policies

1. Policy 2019-04: Transfer of Unfilled Prescriptions

Time: 9:44 AM

Presented by: M. CHAN

Discussion: The existing document references the transfer of unfilled electronic Schedule II - V prescriptions based on a 2017 letter issued by the DEA. However, the letter did not specifically address how an unfilled Schedule II prescription could be transferred or forwarded to another pharmacy since it is currently not allowed.

Since the DEA has now proposed regulations regarding unfilled electronic prescriptions, the document was changed to reflect the one-time transfer for Schedule III - V until those regulations are finalized.

Action: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by roll call of those present, to approve the policy changes.

TOPIC VIII

Advisory

1. Information for Managers of Record

Time: 9:46 AM

Presented by: M. CHAN

Discussion: The existing advisory was completely overhauled to address current concerns for MORs to be aware of including dispensing veterinary prescriptions without a DEA number and ID for dispensing federally controlled drugs and gabapentin.

Action: Motion by S. AHMED, seconded by D. BARNES, and voted unanimously by roll call of those present, to approve the advisory.

ΤΟΡΙϹ ΙΧ	File Review	
Case #1/CAS-2021-1071		
SA-INV-18792	Tiffany Battles LeBlanc, PH233605	Time: 09:48 AM

RECUSAL: NONE

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

- NHBOP reprimanded Pharmacist Battles LeBlanc's license in 2018 as a result of failure to comply with continuing education requirements in 2017. She was deficient in 3 live CEs in 2017.
- On May 31, 2018, she signed a Settlement Agreement with the NHBOP (effective 06/05/2018) to pay a \$1,500 administrative fine and complete the 3 missing live CEs by 07/31/2018.
- During the course of the investigation, it was discovered that after she remediated her 2017 deficiency in 2018, she was still deficient 4 CEs in 2018; 1 CE 2019; 7 CEs in 2020 based on her MA requirements.

<u>ACTION</u>: Motion by C. BELISLE, seconded by J. ROCCHIO, and voted unanimously by those present, to CLOSE the matter (SA-INV-18792), No Discipline Warranted, Remediation Complete.

Case #2/CAS-2021-0790 PHA-2021-0077 Rite Aid #10084, DS2780

Time: 9:50 AM

RECUSAL: NONE

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

- RLCS- #4 clobazam 10mg, #58 diazepam 5mg, #34 alprazolam 0.5mg, #4 buprenorphine/naloxone 2-0.5mg tablets, and #29 alprazolam 1mg tablets.
- MOR Fullem noted that on May 1, 2021, the annual controlled drug inventory was performed, and the drugs mentioned in the loss were less than the expected on-hand inventory.
- The MOR noted that diazepam and alprazolam are from 500 count stock bottles and these medications were not regularly back-counted and compared to the on-hand. She noted that it is not part of their daily practice to compare the on-hand amount to the amounts listed in the computer during the verification process.
- MOR Fullem noted that during the investigation, she began triple-counting the Schedule II-V medications. During the investigation, she noted staying after each of her shifts to hand count the listed drugs and reported the counts to the loss prevention manager. She had asked her staff to double-count medications and the staff pharmacist was not following her policy.
- Pharmacist Georgiadis has been issued a written warning regarding adherence to the controlled substance counting procedures.
- MOR Fullem indicated that she instituted a stock bottle back counting policy at the Pharmacy, to help mitigate future losses. The technicians are to double count the medication, and back count the remainder in the stock bottle and the pharmacist is to triple count the medication and compare the back count to the on-hand quantity in the computer on each verification. She also noted that the company has moved away from purchasing 500 count bottles to help make it easier to back count.

<u>ACTION</u>: Motion by D. BARNES, seconded by S. AHMED, and voted unanimously by those present, to DISMISS the matter (PHA-2021-0790), No Discipline Warranted, Remediation Complete.

Case #3 /CAS-2021-0848 SA-INV-18429 Walgreens #17728, DS90161 Time: 09:53 AM

RECUSAL: NONE

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

- OPP received an anonymous complaint that alleged an immunizer was not wearing a mask while administering immunizations.
- On September 3, 2021, Investigator Geaney reached out to MOR Johnson to make her aware of the complaint and requested the company policy on mask wearing for immunizers.
- MOR Johnson noted that the complaint was also made to the store manager via phone.
- MOR Johnson noted that she shared the immunization policy with all the immunizing technicians and pharmacists and provided printed copies of the standard operating procedure for everyone to review. She noted that face masks should be worn by employees at all times during their shift, and face shields are donned over the face mask in the immunization room during vaccination.

<u>ACTION</u>: Motion by C. BELSILE, seconded by R. MORELLI, and voted unanimously by those present, to CLOSE the matter (SA-INV-18429), No Discipline Warranted, Remediation Complete.

Case #4/CAS-2021-0894 PHA-2021-0083

Walgreens #13135, DS89732

Time: 09:55 AM

RECUSAL: NONE

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

- During a retail compliance inspection (ISP-16898) conducted on September 8, 2021, it was discovered that the Pharmacy was operating without a Manager of Record since May 2021.
- Former MOR Henrion responded that he was no longer MOR of this Pharmacy since June 2021.
- Current MOR Rezendes indicated that the former MOR Henrion left his MOR position with the company early June 2021.
- MOR Rezendes noted that there was approximately a five-month gap that the Pharmacy was without a MOR. She explained it was due to lack of pharmacist interest/availability and staffing issues as a result of the pandemic. Staff Pharmacist Rachel Borges reported that although she declined the position, she fulfilled the managerial duties of the MOR during the absence.
- MOR Rezendes noted that she is the new MOR effective November 1, 2021.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2021-0083), 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-2021-1037		
PHA-2021-0105	Walgreens #3469, DS2593	Time: 09:57 AM

RECUSAL: NONE

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

- RLCS initially reported as an unknown loss of #32 amphetamine salts 30mg tablets but final reports were submitted for an unknown loss of #185 on the DEA 106 and #186 on the RLCS form for amphetamine salts 30mg tablets discovered on 10/10/21. According to the final RLCS, an audit completed from 6/10/20 to 10/26/21 identified a loss of 186 tablets attributed to miscounts over that period. The DEA 106 indicated there was no significant loss based on the Pharmacy's volume with the loss attributed to assumed employee theft.
- Although the MOR realized the discrepancy of -32 on 10/17/21 during the reconciliation of the perpetual inventory online, it had been noted on 10/3/21 on the CII inventory worksheet but she was not notified. Her investigation included a review of footage of production of the prescriptions and outreach to patients to confirm the correct quantity was dispensed. Conflicting reasons for the loss were provided including a mathematical error of 32 tablets, operational error, miscounts, and possible theft. An Excel spreadsheet provided with the response did not show a discrepancy of 185 tablets but did show the entry noted on 10/17/2021 for -32 tablets. According to the MOR the Rx integrity team reported a shortage on the basis of a discrepancy between the system on-hand quantity vs the perpetual inventories. The Rx integrity team told the MOR that discrepancies between the two systems can occur when an out-of-stock medication is taken out before the order is posted or if smart counts are not done before the order is posted.
- MOR Santiago-Rodriguez stressed the importance of following policy and procedure with staff, informing her of all suspected discrepancies right away, and accurately posting the daily order and how to handle smart counts. All standard operating procedures regarding controlled substances were reviewed with the staff pharmacists. A copy of SOP Controlled Substances Inventory signed by the staff pharmacist was provided confirming review. MOR spoke with the front store manager to ensure

the security cameras are always working properly, and she has instructed all floater and staff pharmacists to note any discrepancy being investigated in the electronic perpetual inventory.

<u>ACTION</u>: Motion by C. BELISLE, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2021-0105), 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-2021-1280		
PHA-2022-0001	Walgreens #19525, DS90219	Time: 10:02 AM

RECUSAL: NONE

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

- Deficiency cited on 12/21/21 for failure to submit a change of MOR application after Former MOR Moin's last day on 10/13/21. It was noted that a controlled substance inventory had been performed by Former MOR Moin and Current MOR Teich on 10/13/21.
- In an email dated 01/09/22, a copy of the change of MOR application notarized on 1/3/22 was provided. Current MOR Teich stated this paperwork was mailed to Walgreen's corporate on 1/4/22. The application was received by BORP staff on 1/19/22.
- DM Gregoire indicated there was miscommunication between multiple parties. He stated he emailed the paperwork to the Pharmacy and the store manager to be mailed to corporate after it was notarized. He was unaware it was never completed. Per Walgreens policy (copy provided), DM Gregoire is responsible for ensuring the BORP is notified of a change of MOR.
- Current MOR Teich stated he thought he was only the interim MOR and that an application would be submitted when a new MOR was found. He did not realize he needed to complete the change of MOR application. Former MOR Moin responded she was MOR of the Pharmacy from 5/25/20 to 10/13/21. A copy of the controlled substance inventory completed on 10/13/21 was submitted.
- DM Gregoire stated, "Going forward, I will ensure that there is a follow up process in future dealings with MOR changes".

<u>ACTION</u>: Motion by J. CHIN, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0001), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #7/CAS-2021-1140 SA-INV-19031	Edge Pharma, NO00015	Time: XX:XX AM
	DEFERRED	
Case #8/CAS-2021-1049		
PHA-2021-0102	CVS #2172, DS2817	Time: 10:07 AM

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

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

- During an inspection on 10/26/21, Investigator Seed observed PTT Henry, the front store manager, practicing in the Pharmacy with a license that expired 6/6/19. She was putting the order and RTSs on the shelves.
- MOR Brown stated PTT Henry has never been scheduled or worked in the Pharmacy as a PTT. PTT Henry became licensed while working at another location in an initiative to cross-train front store managers. On 10/26/21, PTT Henry was in the Pharmacy helping with a long pickup line. According to MOR Brown, once the lines slowed down, in hopes of being helpful, PTT Henry began putting some medications away. MOR Brown indicated, "When addressed, Patricia immediately stopped putting the medications away and was re-educated that her duties were to remain strictly cashier".
- PTT Henry related she went into the Pharmacy to assist them clean up and organize. PTT Henry indicated that she was unaware she could not touch medications, even if it was just to organize them. She was also unaware that her license had expired. PTT Henry stated she does not work shifts in the Pharmacy and is not involved in the prescription process.
- MOR Brown instructed PTT Henry to obtain an extension of her PTT license or her pharmacy technician license before performing Pharmacy tasks. Future unlicensed employees will receive the same counseling and training prior to working in the Pharmacy. PTT Henry stated she was working on an extension for her PTT license. A statement signed and dated by the Pharmacy staff was provided confirming review of all policies and procedures for the scope of responsibilities and duties delegated to certified pharmacy technicians, pharmacy technicians, and pharmacy technician trainees.

<u>ACTION</u>: Motion by D. BARNES, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2021-0102), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #9/CAS-2021-1267 PHA-2021-1267 CVS #207, DS2864 Time: 10:10 AM

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

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

- An initial RLCS only was received for a loss of #306 lorazepam 1mg tablets identified on 9/23/2021. Six letters of continuation dated 10/14/2021, 11/04/2021, 11/23/2021, 12/14/2021, 01/04/2022, and 01/25/2022 were submitted stating the investigation was ongoing.
- Final reports with additional information were requested on 1/5/22 with untimely final reports received on 2/04/22 indicating the investigation concluded on 2/3/22 for an amended loss of #320 lorazepam 1mg. The variance was identified via controlled substance monitoring. DL Savory stated the reason for the loss was unknown and the investigation was still active. Cycle counts, biennial inventories, staffing schedules and inventory reports were reviewed along with security footage. MOR Stanton indicated the variance was believed to be due to an employee incorrectly cycle counted the drug, and it was not properly corrected triggering a variance detection. CVS Asset Protection has not identified any internal or external cause for the loss and diversion is not suspected. MOR Stanton stated, "We are still actively investigating to show there was no true loss by reviewing balance on hand modifications and all pertinent inventory documents in partnership with loss prevention partners".

• MOR Stanton will continue to monitor lorazepam. MOR Stanton reviewed all policies and procedures for the proper storage and handling of controlled substances including diligent inventory management with the Pharmacy staff.

<u>ACTION</u>: Motion by C. BELISLE, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2021-0121), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for Stayed Probation for a period of 1 year, with special terms to include the CS loss protocol for all benzodiazepines.

Case #10/CAS-2022-0182		
PHA-2022-0032	CVS #207, DS2864	Time: 10:13 AM

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

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

- An initial RLCS only was received for losses of 755mL methylphenidate 5 mg/5mL; #170 hydrocodone/acetaminophen 7.5/300 mg tablets; #88 hydrocodone/acetaminophen 10/300 mg tablets; #40 hydrocodone/acetaminophen 10/300 mg tablets; #70 codeine sulfate 30 mg tablets; #3 oxycodone/acetaminophen 5/325 mg tablets; #2 oxycodone/acetaminophen 10/325 mg tablets; #2 amphetamine salts 30 mg tablets; and #1 methylphenidate ER 10 mg tablets on 9/27/21.
- In response to the request for all final reports, MOR Stanton stated the RLCS was submitted for expired and damaged medications thought to be lost in transit to Inmar for return. The Inmar website verified the return was received on 10/13/2021. Documentation was provided showing the BORP was notified via email on 10/14/21 that the loss was retracted with supporting reverse distribution proof.

<u>ACTION</u>: Motion by J. CHIN, seconded by S. AHMED, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0032), No Violation.

Topic X:Executive Session Call to Order:Time: 10:18 AMBy: S. Hamilton reads the executive session language and requests a motion to enter executive session.

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

TOPIC XI

Adjudicatory

Time: 10:21 AM

<u>DISCUSSION</u>: None <u>ACTION</u>: President S. Hamilton request a motion to enter 65C.

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At 10:21 AM S. Ahmed, seconded by R. Morelli and voted unanimously by all those present to enter 65C by roll call vote.

Topic XII:

65C Sessions MGL c. 112 section 65C

Time: 1:10 PM

DISCUSSION: None

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

At 1:10 PM S. Hamilton, seconded by J. Lanza and voted unanimously by all those present to enter 65C by roll call vote.

J. Rocchio leaves meeting at 12:46 PM

S. Cornacchio leaves meeting at 12:46 PM

Topic XIII

ADJOURMENT OF MEETING

TIME: 1:13 PM

ACTION: Motion by J. Lanza seconded by C. Jean-Francois and voted unanimously by those present, to adjourn from General Session by roll call vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. Draft Agenda of the 5/5/22 General Session
- 2. Draft Minutes of the 4/7/22 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. Walmart Pharmacies-Waiver Requirement
- 8. Cape Cod Healthcare Pharmacy at Falmouth Hospital DS90082: petition for waiver
- 9. Cape Cod Healthcare Pharmacy at Cape Cod Hospital DS90036: petition for waiver
- 10. NIMVAX- DS90369 pilot update / request to end pilot
- 11. Tufts Medicine Home Infusion Services-change in scope
- 12. Pelmeds Fitchburg, LLC New Community Pharmacy
- 13. BNHC Pharmacy New Community Pharmacy
- 14. Lynn Community Health Pharmacy New Community Pharmacy
- 15. Policy 2019-04: Transfer of Unfilled Prescriptions
- 16. Advisory: Information for Managers of Record
- 17. CAS-2021-1071 SA-INV-18792 Tiffany Battles LeBlanc, PH233605
- 18. CAS-2021-0790 PHA-2021-0077 Rite Aid #10084, DS2780
- 19. CAS-2021-0848 SA-INV-18429 Walgreens #17728, DS90161
- 20. CAS-2021-0894 PHA-2021-0083 Walgreens #13135, DS89732

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21. CAS-2021-1037	PHA-2021-0105 Walgreens #3469, DS2593
22. CAS-2021-1280	PHA-2022-0001 Walgreens #19525, DS90219
23. CAS-2021-1140	SA-INV-19031 Edge Pharma, NO00015
24. CAS-2021-1049	PHA-2021-0102 CVS #2172, DS2817
25. CAS-2021-1267	PHA-2021-0121 CVS #207, DS2864
26. CAS-2022-0182	PHA-2022-0032 CVS #207, DS2864

Respectfully Submitted, Carly Jean-Francois, NP, Secretary