

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

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

June 2, 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=e0718a9f522445ca4c9744b121cb8a3df>

To access the meeting by phone:

Call in Number: 1-650-479-3208

Access Code: 2535 798 9170

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	I	CALL TO ORDER		
8:02	II	APPROVAL OF AGENDA		
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of May 5, 2022 Regular Session Minutes		
8:10	IV	REPORTS <ul style="list-style-type: none">• Applications approved pursuant to Licensure Policy 13-01• Monthly report from Probation• Board Delegated Review pursuant to Licensure Policy 14-02• PSUD Report-Policy 17-03		

8:15	V	FLEX <ul style="list-style-type: none"> • Pharmacy issues related to COVID-19 • PSUD Rehabilitation Evaluation Committee- MD appointment, Jasra Ali Bhat, MD • NABP Annual Meeting Summary 					
8:30	VI	APPLICATIONS <ul style="list-style-type: none"> • Walgreens - Central Fill Request 					
8:45	VII	POLICY <ul style="list-style-type: none"> • Policy 2022-03: Unfilled Prescriptions 					
8:50	VIII	FILE REVIEW					
		1	CAS-2022-0105	SA-INV-19318			MyLyfe Specialty Pharmacy, DS90324
		2	CAS-2021-0827	SA-INV-18403			Long Term Pharmacy Solutions, DS90330
		3	CAS-2021-1140	SA-INV-19031			Edge Pharma, NO00015
		4	CAS-2022-0982	PHA-2021-0094			Walgreens #2977, DS2250
		5	CAS-2021-0976	SA-INV-18622			Stuart Tolman, PH238753
		6	CAS-2022-1099	PHA-2021-0106			Big Y #22, DS89811
		7	CAS-2021-0862	PHA-2022-0012			Amy Joseph, PH24935
		8	CAS-2021-1200	PHA-2021-0115			CVS #224, DS20589
		9	CAS-2021-1100	PHA-2021-0107			CVS #16613, DS90022
		10	CAS-2022-0187	PHA-2022-0027			CVS #1844, DS89666
		11	CAS-2022-0186	PHA-2022-0026			CVS #1006, DS2715
		12	CAS-2022-0166	PHA-2022-0053			CVS #23, DS90049
		13	CAS-2022-0179	PHA-2022-0022			CVS #23, DS90049
		14	CAS-2022-0181	PHA-2022-0023			CVS #127, DS3420
		15	CAS-2022-0184	PHA-2022-0025			CVS #291, DS3271
		16	CAS-2021-1281	PHA-2021-0120			CVS #1248, DS2875
		17	CAS-2022-0051	PHA-2022-0008			CVS #444, DS2704
18	CAS-2022-0389	PHA-2022-0080	CVS #1252, DS3612				

9:50	IX	EXECUTIVE SESSION The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition, or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, to evaluate the Good Moral Character as required for registration for a pending applicant.		
11:30	X	M.G.L. c. 112, § 65C SESSION		
12:30	XI	ADJOURNMENT		

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

June 2, 2022

Board Members Present

Sebastian Hamilton, Pharm D, MBA, RPh President
Caryn Belisle, RPh, MBA, President-Elect
Julie Lanza, CPhT
Susan Cornacchio, JD, RN (Leaves at 1:36 pm)
Jennifer Chin, RPh
John Rocchio, RPh, PharmD (Leaves at 1:36 PM)
Dr. Richard Lopez, MD
Sami Ahmed, Pharm.D., RPh, BCPS, BCSCP
Delilah Barnes, RPh
Rita Morelli, PharmD, BCACP, RPh
Katie Thornell, RPh, MBA (leaves at 10:00 AM)

Board Members Not Present

Dawn Perry, JD
Carly Jean-Francois, RN, NP Secretary

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

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:01 AM

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

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

Topic II.

Approval of Agenda

TIME 8:01 AM

Agenda 6/2/22

DISCUSSION:

No changes

ACTION:

Motion by J. Lanza, seconded by S. Ahmed and voted unanimously by those present to approve the agenda with no noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:05 AM

Minutes

1. Draft 5/5/22

Change: no changes

Action:

Motion by J. Lanza seconded J. Lanza and seconded by J. Chin and voted unanimously to approve the regular session minutes of 5/5/22 with no noted changes by roll call vote. K. Thornell and J. Chin abstain.

TOIC IV

Reports

Applications approved pursuant to Licensure Policy 13-01

Time: 8:06 AM

Presented by: R. HARRIS

Discussion: R. HARRIS reported a total of 19 Change of Manager applications that were approved by Staff Action since the last Board meeting.

So noted.

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:07 AM

Presented by: R. HARRIS

Discussion: R. HARRIS noted that there were three successful completions of probation for three corresponding pharmacies that took place during the month of May. There are currently 11 active probation cases.

So noted.

TOPIC IV**REPORTS****Monthly Report from BDCR pursuant to Policy 14-02****Time: 8:07 AM**

Presented by: D. SENCABAUGH

Discussion: D. SENCABAUGH reported that Board Delegated review took place on May 5, 2022, during which 8 self-reported cases of CE deficiencies were heard. All cases have been remediated and closed with no discipline warranted.

So noted.

TOPIC IV**REPORTS****PSUD Report by Staff Action 17-03****Time: 8:07 AM**

Presented by: E. TAGLIERI

Discussion: E. TAGLIERI reported that there are currently 13 active participants enrolled in the PSUD program. There has been one successful admission to the program since the last Board meeting.

So noted.

TOPIC V**Flex****1. Pharmacy Issues Related to Covid-19 and State of Emergency****Time: 8:07 AM****Presented by:** D. SENCABAUGH

Discussion: No meeting will be held in July. The next Board meeting will be August 4th.

So noted.

2. PSUD REC MD appointment, Jasra Ali Bhat, MD**Time: 8:08 AM****Recusal:** C. BELISLE**Presented by:** E. TAGLIERI

Discussion: Jasra Ali Bhat, MD, a psychiatrist with a specialty in addiction, has applied for the medical doctor seat on the Rehabilitation Evaluation Committee (REC) and has passed all required background checks.

Action: Motion by J. LANZA, seconded by K. THORNELL, and voted unanimously by roll call by all those present to appoint Jasra Ali Bhat, MD, for a 4-year term as the medical doctor on the REC.

3. NABP Annual Meeting**Time: 8:10 AM****Presented by:** K. THORNELL

Discussion: An overview of the 118th NABP annual meeting agenda, which occurred in Phoenix, AZ from 05/19/22 to 05/21/22 was presented. Six resolutions were adopted including defining pharmacists as health care providers and exploring e-prescribing concerns.

So noted.

TOPIC VI

Applications

1. Walgreen Pharmacies

Walgreen Central Fill

TIME: 8:21 AM

Represented by: Jeenu Philip, Steve Pashko, Matthew Cook, & Mike Senco

Recusal: none

Discussion:

Members from Walgreens Corporate are coming before the Massachusetts Board of Pharmacy for consideration of a pharmacy license registration for a Centralized Prescription Dispensing facility. Jeenu Philip presented a slide show which provided an overview of the Centralized Prescription Dispensing Model and its benefits, the journey of the prescription from when it's received until when its dispensed, and the various waivers being requested which are not applicable or impractical to this model. J. Philip indicates that they have a pending application for a Centralized Prescription Dispensing facility located in Mansfield, and they intend on expanding the model to four additional states in Rhode Island, Maine, New Hampshire, and Vermont. J. Philip indicates that there are 9 waivers of Massachusetts pharmacy rules and regulations which are not applicable to the Central Fill model. At the conclusion of the presentation, board member D. Barnes inquired as to whether pharmacists can verify the final product once the prescription has been filled. J. Philip responds that the system labels and caps the product and there is no PV2 check. R. Morrelli inquired as to whether they have data to compare the rates of regular fill vs central fill as Massachusetts would be the 7th facility to adopt this type of model. M. Cook responds that there is no available data yet but there are processes involved in the filling of the canisters as the machine does not make an error. R. Morrelli also asked how long central fill has been occurring in other states. S. Cook responds that Arizona was opened in April of last year and Texas was opened in May of last year and over 10 million prescriptions have been filled since then. The floor was open for other board members to ask questions and some members inquired about the turnaround times for when the prescriptions are filled, feedback that pharmacists have provided on the processes, feedback from patients, and how information is being logged in the central fill facilities including auditing, quality assurance steps, and etc. S. Hamilton inquired as to what the staffing arrangement would be, and J. Philip responds that there were tasks in the facility that do not require licensure i.e. recycling empty stock bottles and other responsibilities requiring a license. Walgreens corporate indicates that they are petitioning the board to waive 247 CMR 6.01 (15), 247 CMR 6.01 (16), 247 CMR 6.02 (5), 247 CMR 6.02 (8)(a), 247 CMR 6.01 (5)(a), 247 CMR 6.01 (1)(d), 247 CMR 9.07 (c), 247 CMR 8.06 (3), and 247 CMR 14.01 as they are not applicable to their Central Fill Model. In particular, Walgreens is requesting to operate with up to 10 technicians per pharmacist irrespective of certification, as opposed to 247 CMR 8.06 (3) which outlines the current 4:1 pharmacist supervisory ratio. Walgreens staff states that 10:1 would meet the needs of the facility as they are not operating like a traditional retail pharmacy.

Motion to approve the application for a DS pharmacy pending successful inspection made by S. Hamilton; Seconded by J. Lanza, then Board Members present voted unanimously by rollcall to approve motion.

Motion to approve the petition for central fill made by D. Barnes; Seconded by J. Lanza, then board Members present voted unanimously by rollcall to approve motion.

Motion to waive the requirement to have the words "central fill" on Schedule VI prescriptions that are centrally filled as required by Section IV(B)(iii) of Policy 2021-02: Shared Pharmacy Service Models Including Central Fill, Remote Processing, and Telepharmacy made by J. Chen; Seconded by D. Barnes, then board Members present voted unanimously by rollcall to approve motion.

Motion to approve the following 7 waivers made by C. Belisle, Seconded by S. Ahmed, then board Members present voted unanimously by rollcall to approve motion.

247 CMR 6.01 (5)(a)(4) balance

247 CMR 6.01 (5)(d) Patient Consultation Area

247 CMR 6.02 (5) pharmacy exterior signage

247 CMR 6.02 (8)(a) posted hours of operation

247 CMR 9.01 (15) not limit services to a particular segment or segments of the public.

247 CMR 9.01 (16) not refuse to compound customary pharmaceutical preparations

247 CMR 9.07 (3)(c) counseling sign (Dear patients...)

Motion to approve a 5-year limited waiver for 247 CMR 8.06 (3)(a) (3) Supervisory Ratios to allow a maximum of 10 support personnel (regardless of national certification) to 1 pharmacist for the central filling of Schedule VI medications only. Quality / safety data and employee / patient feedback to be submitted to the Board 6 months after opening. Any scope of practice changes for the technicians or if the scope is to be extended to federally controlled substances must be re-evaluated by the Board made by R. Lopez; Seconded by S. Cornacchio, then board Members present voted unanimously by rollcall to approve motion.

K. Thornell leaves meeting at 10:00 AM

TOPIC VII

Policies

Time: 10:02 AM

1. Policy 2022-03: Unfilled Prescriptions

Presented by: M. CHAN

Discussion: This policy allows pharmacies to send unfilled electronic prescriptions for federally controlled substances, including Schedule II, to another pharmacy for initial fill. This can be done either by verbal transfer or electronic transmission, but both methods must be pharmacist-to-pharmacist and follow the transfer requirements of 21 CFR §1306.25.

Action: Motion by S. HAMILTON, seconded by J. LANZA, and voted unanimously by roll call by all present to approve the policy.

TOPIC VIII**File Review**

Case #1/CAS-2022-0105
SA-INV-19318

MyLyfe Specialty Pharmacy, DS90324

Time: 10:05 AM

RECUSAL: NONE

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

- Mylyfe Specialty Pharmacy has requested to reduce its operating hours from 30 hours per week to be open by appointment only. This request also indicated that pharmacists would be available 24 hours per day 365 days per year via a toll-free phone number. MOR Lagasse explained that Mylyfe Specialty Pharmacy has no foot traffic into the pharmacy, is very specialized and mainly deals with the bleeding disorders of the community. Because of the focus on such rare diseases, a small patient population and the fact that their patient population does not reside in the immediate area they have created a model that requires them to deliver the medications. Their closest patient is 50 minutes away and the farthest is over 5 hours away [at this time]. Also, due to COVID-19 the Pharmacy leadership is trying to eliminate staff exposure to others when they can offer the same exceptional services remotely. He also noted that prescriptions and accompanying supplies will be filled and dispensed from the Pharmacy and not remotely. The only task that they may perform remotely would be to enter their wholesale order.
- Pharmacists will still go on site for approximately 10 hours per week to perform all of the functions needed to fill their patients' prescriptions, compile supplies and get those orders ready for delivery. MOR Lagasse feels that posting reduced hours of "by appointment only", or even 8 am - 12 pm on Fridays does not in any way affect the care or services that they provide to their patient population and that a pharmacist's free time after fulfilling all patient needs is better spent trying to build their network with other medical professionals rather than being attached to a physical pharmacy during hours where a patient does not need a pharmacist to be there.

ACTION: Motion by D. BARNES, seconded by C. BELISLE, and voted unanimously by those present, to CLOSE the matter (SA-INV-19318), No Discipline Warranted.

Case #2/CAS-2021-0827
SA-INV-18403

Long Term Pharmacy Solutions, DS90330

Time: 10:11 AM

RECUSAL: NONE

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

- Inspectional deficiencies for 797 inspection (ISP-16568) on 8/9/21 for compounding high-risk CSPs instead of using commercially available injectable forms of hydromorphone and methadone, using ScanRDI for sterility testing, and failure to perform bubble point filter integrity tests as recommended.

On 8/13/2021, the BORP requested the Pharmacy to test to the bubble point and the Pharmacy complied.

- In the POC, Former MOR Rice indicated that except for the compounding of hydromorphone 20mg/mL cassettes, the Pharmacy transitioned to the use of commercially available hydromorphone as the primary source of API for compounded hydromorphone preparations. Validation reports for “Rapid Scan RDI - Method Suitability Test” for hydromorphone 20mg/mL (dated 06/23/2017), for morphine 20mg/mL (dated 07/27/2017) and for methadone 20mg/mL (dated 08/03/2017) (Exhibit 2) were submitted supporting the use of ScanRDI® so the Pharmacy continued to use ScanRDI® for sterility testing. A method suitability validation must be completed on each specific formulation to determine the appropriate test method. The formulation must stay the same for the method to be valid for the sterility test on future lots.
- Since 1/1/2021, the Pharmacy compounded high risk CSPs for 1mg/mL, 2mg/mL, 5mg/mL (2 formulations), 10mg/mL (2 formulations), 20mg/mL and methadone 5mg/mL and 10mg/mL. COAs for testing from 11/14/2012 to 2/18/2015 for high-risk CSPs of hydromorphone, methadone, and morphine were submitted as direct validation supporting use extended BUDs but the documentation did not show BUD information or specific storage conditions. MFRs were submitted for only 6 of 9 formulations showing assignment of 90 days to expire with no specific storage conditions. Former MOR Rice claimed “... the compendial method does not provide a rapid enough turnaround needed by our hospice patient population and LTPS would have to eliminate sterility validation and resort to shortened Beyond-Use-Dating”.
- Former MOR Rice stated, “From a practicality standpoint, LTPS does not feel there is any significant data shown that bringing the filter to the bubble point vs. demonstrating that a pressure in excess of the failure point is maintained for an extended period. Although we believe our previous filter integrity testing is a way to receive more realistic application of the filters’ failure point, we will continue to comply with testing to the bubble point...” In 2017 and 2018 after FDA shortages for commercially available injectable products began intermittently, the Pharmacy validated high-risk compounding for hydromorphone, methadone, and morphine in 2017. Former MOR Rice indicated the unpredictable availability caused concern with compounding these preparations sterile-to-sterile one month then non-sterile-to-sterile the next month, so the Pharmacy continued high-risk compounding as the focus was directed at maintaining these CSPs and less on signs of a potential sufficient and continuous market supply of the injectable forms.
- Documentation provided as validation of ScanRDI® equivalence to the compendial standard USP 71 included a Type V DMF, which Former MOR Rice inaccurately purported was FDA approval of the technology, and the referenced articles for Eagle’s detailed analysis of ScanRDI.
- SOP 107 - Filter Integrity Test was updated on 08/13/2021 with the addition of filter failure point documentation and added to the MFR. The Pharmacy has continued to move further along in the testing phases utilizing commercially available injectable forms. Eagle Analytical had completed method suitability, product sterility, potency, and endotoxin testing and were testing for use of 60-day BUDs.
- A <797> Compliance Inspection (ISP-18188) was conducted on 04/05/2022. A POC was issued regarding the use of the ScanRDI sterility test as the sole method for sterility testing. In an email dated 04/26/2022, Current MOR Pich-Sak stated “As recommended by the Board, Long Term Pharmacy Solutions will no longer look to ScanRDI to verify the sterility of our product. Going forward, LTPS will revert to standard USP beyond-use-dating for all of its product. Should our direction change, we will reach out to the Board or its resources for guidance”.

ACTION: Motion by S. AHMED, seconded by J. ROCCHIO, and voted unanimously by those present, to CLOSE the matter (SA-INV-18403), No Discipline Warranted, Remediation Complete.

Case #3 /CAS-2021-1140

SA-INV-19031

Edge Pharma, NO00015

Time: 10:19 AM

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

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

- On February 18, 2022, CVS 1844 reported an unknown loss of a completed prescription for 60 Adderall XR 30mg extended-release capsules discovered missing from the waiting bin on January 5, 2022. CVS 1844 suspected that a PTT who quit almost immediately after learning of the investigation of the loss of the amphetamine diverted the prescription from the waiting bin. However, CVS 1844 acknowledged that no evidence existed to support those suspicions including surveillance video reviewed at the pharmacy.
- CVS 1844 reported the incident to Lunenburg Police. Lunenburg Police contacted the PTT. The PTT denied diverting the amphetamine prescription and indicated she quit working at CVS 1844 because she did not like her hours. Lunenburg Police indicated PTT Smith would not be charged at that time because CVS 1844 did not have sufficient evidence.
- In addition, attempts were made to obtain a statement from PTT Smith regarding this complaint. However, PTT Smith failed to respond to messages left on her voicemail and email at the time of this report.

ACTION: Motion by S. CORNACCHIO, seconded by D. BARNES, and voted unanimously by those present, to ELEVATE the matter (SA-INV-19031), to a complaint.

Case #4 /CAS-2022-0982

PHA-2021-0094

Walgreens #2977, DS2250

Time: 10:31 AM

RECUSAL: NONE

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

- RLCS-#100 oxycodone 5mg tablets on or about September 24, 2021.
- MOR McPartlin noted that on September 21, 2021, during the perpetual inventory, it was discovered that they were short #100 oxycodone 5mg tablets.
- The entire pharmacy was searched for the medication and patients who received the medication during this time between the last reconciliation and the loss were contacted to determine if they received more than intended. Although not all the patients called back of those who did, none reported an over dispense.
- MOR McPartlin said that going forward, to prevent any future loss, the pharmacist staff will now conduct back counts on all schedule II medications with the bottles reflecting the quantity remaining, the dispensing Pharmacist will need to know the number of bottles in the safe so that upon entering the quantity dispensed in the Integrity system an accurate count will be known at all times. Also, a note has been placed on the safe as a reminder to staff and any floaters.

ACTION: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2021-0094), 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-2021-0976

SA-INV-18622

Stuart Tolman, PH238753

Time: 10:33 AM

RECUSAL: NONE

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

- BOP was notified through NABP's Clearinghouse in September 2021 that the ORBOP issued Pharmacist Tolman a reprimand on April 19, 2016. Specifically, while Pharmacist Tolman was pharmacist-in-charge of a pharmacy in Boca Raton, FL, prescriptions were dispensed and sent into Oregon for patients, that were issued without a valid patient-prescriber relationship. The prescriptions were written for patients in Oregon after telephone conversation(s) with patients by a nurse practitioner (NP) in New Jersey who failed to meet the minimum standards of practice in order to prescribe a prescription to a patient.
- Reciprocal discipline followed; TXBOP reprimanded Pharmacist's Tolman pharmacist license effective May 2, 2017, and ALBOP imposed a \$3000 administrative fine on October 19, 2017, both as a result of the Oregon state order.
- In his statement, Pharmacist Tolman noted that he entered into a consent agreement for a reprimand in Oregon for filling a prescription for an "Oregon" NP who had written a prescription for an Oregon patient for a non-controlled substance. He stated that it was not disclosed that the prescription(s) were generated based on a telemedicine visit. Pharmacist Tolman noted that he agreed to the reprimand in Oregon to avoid the expense of challenging the proposed action.

ACTION: Motion by R. LOPEZ, seconded by R. MORELLI, and voted unanimously by those present, to CLOSE the matter (SA-INV-18622), No Discipline Warranted, Remediation Complete.

Case #6/CAS-2022-1099

PHA-2021-0106

Big Y #22, DS89811

Time: 10:43 AM

RECUSAL: NONE

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

- RLCS- #43 Vyvanse 50mg capsules on or about October 14, 2021, as a result of a partial bottle thrown in the trash.
- MOR Somers indicated that on October 14, 2021, the loss of #43 Vyvanse 50mg capsules was discovered during the filling of a prescription.
- There were no other Vyvanse 50mg prescriptions filled between October 9, 2021, when the count of 116 capsules was verified and October 14, 2021, when the loss was discovered.
- In the evening of October 14, 2021, Pharmacist Hathaway counted all strengths of Vyvanse and went through the entire safe looking for an extra bottle of Vyvanse 50mg capsules but did not find any bottles.
- On October 15, 2021, MOR Somers reported the shortage to her supervisor and began an investigation.

- On October 27, 2021, after reviewing all the evidence, the most probable explanation is that Pharmacist Hathaway discarded a partial bottle.
- MOR Somers indicated that she implemented a system where a back count is completed on partial bottles and the count checked against the perpetual log during the product dispensing step for all Schedule II prescriptions to identify a problem before any empty bottles are discarded.

ACTION: Motion by S. AHMED, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2021-0106), 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-2021-0862

PHA-2022-0012

Amy Joseph, PH24935

Time: 10:46 AM

RECUSAL: NONE

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

- National Association of Boards of Pharmacy (NABP) notified BOP that Pharmacist Joseph was reprimanded on 04/25/2019 by the Rhode Island Board of Pharmacy as a result of a continuing education (CE) deficiency for the 2017-2018 renewal period.
- Pharmacist Joseph was ordered to complete an additional 10 live and 20 non-live CE hours as remediation. It was also discovered that she did not complete CEs as required for Massachusetts. Her CPE monitor shows no CEs reported for 2017 or 2018, 42.5 CEs reported for 2019 and none for 2020 or 2021.
- Pharmacist Joseph did not respond to the SA investigation.
- At the February 3, 2022, Board meeting, the Board members voted unanimously by those present, to elevate the matter (SA-INV-18496) to a complaint and notify PH Joseph that a response is required.
- On March 7, 2022, Pharmacist Joseph was notified of this complaint via email and USPS. Additionally, on March 24, 2022, Pharmacist Joseph was further notified via USPS at 3 different mailing addresses. On April 21, 2022, a 5th notification was sent via USPS which was confirmed via USPS tracking as delivered on April 23, 2022. At the time of this report, Pharmacist Joseph has not responded to the multiple requests for a response regarding this complaint.
- Pharmacist Joseph's pharmacist license status in MA and RI is currently expired.

ACTION: Motion by S. HAMILTON, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2022-0012), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #8/CAS-2021-1200

PHA-2021-0115

CVS #224, DS20589

Time: 10:57 AM

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

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

- On November 29, 2021, OPP Investigator Cheryl Latham conducted a retail compliance inspection (ISP-17446) at CVS #224 and observed that former MOR Fell was still listed as the MOR even though she has not worked in this capacity since mid-July 2021.

- MOR Rembis indicated that became the MOR of this Pharmacy effective July 1, 2021, and completed the PIC change inventory on July 14, 2021. She was informed that the application had been sent to CVS's licensure department on July 26, 2021. By October 2021, she reached out to her district leader letting her know that she did not receive the new Drug Store license with her name on it.
- In October 2021, DL Ricciuto reached out to CVS' licensure department and was informed that the Application for Change in Manager was not received. She then started the process of resubmitting the application but due to an unexpected leave of absence, she was not able to do so until December 6, 2021, and followed up to ensure it was processed and submitted to the Board.
- On December 14, 2021, OPP received an Application for Change in Manager which indicated that the date the change of manager took place was July 24, 2021.

ACTION: Motion by J. CHIN, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2021-0115), 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-2021-1100

PHA-2021-0107

CVS #16613, DS90022

Time: 10:59 AM

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

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

- On November 10, 2021, OPP Senior Investigator Cheryl Lathum conducted a retail compliance inspection at CVS 16613. During the inspection, Investigator Lathum discovered that a change in MOR occurred in September 2021 but not reported to BORP. Investigator Lathum learned that an incoming Schedule II-V inventory was conducted on August 1, 2021, by an Interim MOR. Next, the Interim MOR and current MOR completed outgoing and incoming inventories on September 3, 2021, respectively. Last of all, the current MOR was named MOR on September 5, 2021.
- A POC was issued for CVS 16613's failure to report the change in MOR. CVS 16613 responded that the application was completed on the local level in a timely fashion and sent to CVS Health's corporate licensing team. However, the licensing team failed to submit the application.
- BORP opened this complaint for the failure to report the change in MOR. CVS 16613's District Leader explained that she recalled submitting an interim change in manager notice and a change in manager application in a timely fashion to CVS Health's licensing department. CVS 16613's DL indicated that the licensing department, however, denied receiving the application and CVS 16613's DL no longer had tracking information for the documents to further investigate.
- CVS 16613 indicated in the POC that the district manager for the area would work with the corporate licensing team to ensure the proper submission of change in manager applications. Subsequently, a change in manager application from CVS 16613 "officially" appointing the current MOR as pharmacy manager was received December 22, 2021, according to BORP records. Of note, CVS 16613 reported an additional change of manager on February 13, 2022.

ACTION: Motion by D. BARNES, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2021-0107), 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 #10/CAS-2022-0187

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

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

- On February 18, 2022, CVS 1844 reported an unknown loss of a completed prescription for 60 Adderall XR 30mg extended-release capsules discovered missing from the waiting bin on January 5, 2022. CVS 1844 suspected that a PTT who quit almost immediately after learning of the investigation of the loss of the amphetamine diverted the prescription from the waiting bin. However, CVS 1844 acknowledged that no evidence existed to support those suspicions including surveillance video reviewed at the pharmacy.
- CVS 1844 reported the incident to Lunenburg Police. Lunenburg Police contacted the PTT. The PTT denied diverting the amphetamine prescription and indicated she quit working at CVS 1844 because she did not like her hours. Lunenburg Police indicated PTT Smith would not be charged at that time because CVS 1844 did not have sufficient evidence.
- In addition, attempts were made to obtain a statement from PTT Smith regarding this complaint. However, PTT Smith failed to respond to messages left on her voicemail and email at the time of this report.

ACTION: Motion by C. BELISLE, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0027), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #11/CAS-2022-0186

PHA-2022-0026

CVS #1006, DS2715

Time: 11:07 AM

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

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

- On March 30, 2022, CVS 1006 reported an unknown loss of 545 alprazolam (CIV, 1000 tablet stock bottle) 1mg tablets discovered by CVS Health's corporate controlled substance monitoring program on January 5, 2022. A reason for the loss was unable to be determined.
- CVS 1006 indicated that "all Loss Prevention policy and procedures will be reviewed with the Pharmacy Team to prevent future losses. This includes diligent inventory management."

ACTION: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2022-0026), 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 #12/CAS-2022-0166

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

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

- On February 16, 2022, CVS 23 reported an unknown loss of 100 oxycodone-acetaminophen (CII, 100 tablet stock bottle) 10-325mg tablets was discovered during a routine perpetual inventory count on December 17, 2021. A reason for the loss was unable to be determined.
- CVS 23 wrote, "All C-II dispensing policy and procedures have been reviewed with the Pharmacists. This includes diligent inventory management. We have reviewed back counting of all narcotics at the time of dispensing to ensure accuracy."

ACTION: Motion by S. HAMILTON, seconded by J. LANZA, and voted unanimously by those present, to consolidate the matter (PHA-2022-0053) with PHA-2022-0022, and refer to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 1 year, with special terms to include the CS loss protocol for all phenobarbital containing products.

Case #13/CAS-2022-0179

PHA-2022-0022

CVS #23, DS90049

Time: 11:11 AM

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

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

- On April 21, 2022, CVS 23 submitted an untimely final RLCS for an unknown loss of 365 phenobarbital 16.2mg tablets (CIV, 1000 tablet stock bottle) discovered on January 5, 2022, by CVS Health's corporate controlled substance monitoring program. A reason for the loss was unable to be determined.
- MOR Linda Roope described corrective action implemented to mitigate recurrence of a similar incident. She wrote, "All Loss Prevention policy and procedures will be reviewed with the Pharmacy Team to prevent future losses. This includes diligent inventory management."

ACTION: Motion by S. HAMILTON, seconded by J. LANZA, and voted unanimously by those present, to consolidate the matter (PHA-2022-0022) with PHA-2022-0053, and refer to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 1 year, with special terms to include the CS loss protocol for all phenobarbital containing products.

Case #14/CAS-2022-0181

PHA-2022-0023

CVS #127, DS3420

Time: 11:14 AM

RECUSAL: 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.

- RLCS for an untimely, unknown loss of 903 phenobarbital 16.2mg tablets identified on 10/29/21 during a cycle count. Four letters of continuation were submitted. A review of cycle counts, BOH inventories, and inventory reports was conducted. Security footage was reviewed with no evidence of diversion. The investigation determined there was no active loss and it may have been due to a delivery discrepancy. MOR Lamptey contended staffing issues contributed to the delay in reporting.
- The reconciliation spreadsheet submitted showed an audit end date of 10/25/21 with a variance of 903 tablets with the only delivery of stock occurring on 6/15/21 for 1x1,000 tablets. Cycle counts were submitted but did not reflect a discrepancy corresponding to the 10/25/21 audit end date.
- In the response, MOR Lamptey stated, "I will continue to follow all Loss Prevention policy and procedures, including diligent inventory management, and this will also be reviewed with the Pharmacy Team".

ACTION: Motion by C. BELISLE, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2022-0023), 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 phenobarbital containing products. .

Case #15/CAS-2022-0184

PHA-2022-0025

CVS #291, DS3271

Time: 11:16 AM

RECUSAL: 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.

- RLCS for untimely, unknown loss of #1,831 phenobarbital 16.2mg tablets identified on 11/24/21 via corporate controlled substance monitoring. Three letters of continuation were submitted. The reconciliation going back to 5/1/21 showed only one prescription was dispensed with no returns to vendor.
- DAPL Peterson stated the diversion team monitored for an active loss for about 5 weeks then he reviewed security footage on 12/16/21 going back to 10/30/21. When video was reviewed the bottles were no longer on the shelf. MOR Graffam recalled returning the drug but couldn't recall the strength. Interviews of the Pharmacy staff were conducted with no new information obtained. No active loss was determined, and the case was closed.
- MOR Graffam stated the untimely reporting was due to the investigation involved multiple weeks of counts, interviews, and thorough review of applicable records to ensure all possible causes were identified and reviewed. MOR Graffam contended, "While the loss is unknown, it is believed that the product in question was returned as an expired product but was not accurately accounted for in the key rec process". Documentation provided only showed one cycle count on 11/3/21.

- MOR Graffam stated the expectations and procedures for expired product returns have been reviewed with the applicable Pharmacy staff. A signed, dated statement was provided indicating all policies and procedure for proper storage and handling of controlled substances were reviewed by the Pharmacy staff.

ACTION: Motion by J. CHIN, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2022-0025), 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 phenobarbital containing products.

Case #16/CAS-2021-1281

PHA-2021-0120

CVS #1248, DS2875

Time: 11:19 AM

RECUSAL: 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 a retail compliance inspection conducted on 12/17/21 it was noted that the Pharmacy failed to submit a change in MOR application since July 2021. A POC received 1/24/22 indicated an application was submitted 1/10/22 but as of 2/4/22, Former MOR Bozoian was still the MOR on file with the BORP. Ms. Pacia confirmed delivery of the application on 2/1/22.
- DL Racette stated she decided to change the MOR at the Pharmacy on 7/15/21 when the district was realigned. Current MOR El Khoury was given the necessary paperwork to submit to CVS corporate. Former MOR Bozoian reviewed the controlled substance inventory and change of MOR packet with Current MOR El Khoury. Former MOR Bozoian assumed the packet had been sent in and received. MOR El Khoury claimed she conducted a controlled substance inventory with Former MOR Bozoian on 7/23/21 but the copies provided were only signed by Current MOR El Khoury. She stated she completed the paperwork, had it notarized, and submitted it to corporate prior to her vacation on 8/1/21. She assumed the long wait time was due to COVID. When she learned it was not received, she immediately sent in a new application.
- Former MOR Bozoian stated, "Going forward, if I participate in a change of MOR, I will be sure to ask for a copy of the tracking number and keep (sic) for my records". DL Racette reviewed the timelines for change of MOR submissions with Current MOR El Khoury. Going forward, DL Racette will confirm receipt of applications with CVS corporate.

ACTION: Motion by S. AHMED, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2021-0120), 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 #17/CAS-2022-0051

PHA-2022-0008

CVS #444, DS2704

Time: 11:22 AM

RECUSAL: 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.

- Inspectional deficiencies observed on 1/11/22 including unlabeled, pre-drawn syringes of Pfizer COVID vaccine, sodium chloride for injection vials, epinephrine auto-injectors, and needles/syringes in unstaffed, unsecured “immunization booths” set up in the front store. Additionally, boxes of needles/syringes were stored on the floor. According to the dilution log, MOR Daher added the diluent to Pfizer COVID vaccine at 7:45am. The POC stated a new lock were ordered and installed. Going forward, the immunization booths will be locked when an immunizer is not present, and needles/syringes will not be stored on the floor.
- MOR Daher stated the log for the pre-filled syringes contained all necessary information. He alleged the Pharmacy had received no information regarding storage of epinephrine auto-injectors and needles/syringes in immunization booths. On 1/11/22, 9 vials of vaccine were reconstituted, and 66 doses of vaccine were administered starting at 8:06am until 8:07pm. The package inserts for BioNTech vaccine states once the vaccine is withdrawn from the vial to, “Administer immediately”. Vaccine must be used within 6 hours of dilution. The CVS logbook labeled as “PEDIATRIC COVID-19 vaccine dilutions” states, “After dilution...Discard after 12 hours”.
- Communications distributed to CVS pharmacies regarding the storage of epinephrine autoinjectors and/or needles/syringes outside of the pharmacy area was requested. The response stated, “This is an internal document and cannot be provided externally”. According to the response, CVS has no policies and procedures specific to the continued use of COVID-19 “immunization booths” including their security, COVID-19 immunizer programs, and COVID-19 vaccine storage and handling including, but not limited to, pre-filling syringes at pharmacy locations with required documentation. The CVS “Pharmacist Administered Immunization Program” policy did state pre-filling of syringes of vaccine is not permitted.
- MOR Daher contended that the Pharmacy immediately stopped pre-drawing syringes. New locks for the immunization booth were installed on 01/12/2022. The immunization booths will always be locked when an immunizer is not present. MOR Daher stated, “We will also make sure to keep and store EpiPen and syringes in the pharmacy at the end of the day”. MOR Daher will ensure all immunizers will follow the expectations of the corrective action plan. Pharmacy staff signed a statement confirming understanding of the corrective action plan.

ACTION: Motion by C. BELISLE, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0008), 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 #18/CAS-2022-0389

PHA-2022-0080

CVS #1252, DS3612

Time: 11:27 AM

RECUSAL: 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.

- RLCS for unknown loss of #446 lorazepam 0.5mg tablets identified on 2/10/22 via corporate controlled substance monitoring. On 3/10/22, the BORP was notified the Pharmacy was closing at EOB on 4/1/22 with all records and inventory transferred to CVS #3307.
- A response was requested from CVS Corporate. DL Nagiub stated once he was notified of the variance, an investigation was initiated with DAPL Amazeen which included review of video; daily counts of the NDC by the pharmacist; interviews with the Pharmacy team; a search of the waiting bins and shelves; and a review of dispensing reports. The loss was suspected to be due to a bottle either being inadvertently discarded or it fell into the trash. Based on interviews of the Pharmacy staff, theft was ruled out.
- DAPL Amazeen went to the Pharmacy on 2/15/22 and determined the loss occurred between 7/27/21 and 2/3/22 . She also discovered an exception BOH for this NDC was escalated on 7/27/21 after a significant cycle count was created on 7/21/21. Former MOR Wallenberg who was MOR at that time has since left CVS. During interviews of the Pharmacy staff, there was no admission of theft but there was an admission bag checks were not being completed when leaving the store. A final reconciliation identified a true loss.
- According to the final reports, MOR Lee indicated, "All Loss Prevention policy and procedures will be reviewed with the Pharmacy Team to prevent future losses. This includes diligent inventory management.

ACTION: Motion by J. CHIN, seconded by D. BARNES, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0080), No Discipline Warranted.

Topic IX: Executive Session Call to Order: Time: 9:33 AM
 By: S. Hamilton reads the executive session language and requests a motion to enter executive session.

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

Lunch 12:21 pm to 12:50 PM

Topic X: 65C Sessions MGL c. 112 section 65C Time: 12:20 PM

DISCUSSION: None

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

At 12:20 PM J. Chin, seconded by S. Ahmed and voted unanimously by all those present to enter 65C by roll call vote.

J. Rocchio leaves meeting at 1:36 PM
S. Cornacchio leaves meeting at 1:36 PM

Topic XI

ADJOURNMENT OF MEETING

TIME: 1:40 PM

ACTION: Motion by R. Lopez seconded by J. Lanza and voted unanimously by those present, to adjourn from General Session by roll call vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 3/3/22 General Session
2. Draft Minutes of the 2/3/33 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. Applications: Walgreens Central Fill Request, new community pharmacy
8. Policy: 2022-03 Unfilled Prescriptions
9. CAS-2022-0105 SA-INV-19318 MyLyfe Specialty Pharmacy, DS90324
10. CAS-2021-0827 SA-INV-18403 Long Term Pharmacy Solutions, DS90330
11. CAS-2021-1140 SA-INV-19031 Edge Pharma, NO00015
12. CAS-2022-0982 PHA-2021-0094 Walgreens #2977, DS2250
13. CAS-2021-0976 SA-INV-18622 Stuart Tolman, PH238753
14. CAS-2022-1099 PHA-2021-0106 Big Y #22, DS89811
15. CAS-2021-0862 PHA-2022-0012 Amy Joseph, PH24935
16. CAS-2021-1200 PHA-2021-0115 CVS #224, DS20589
17. CAS-2021-1100 PHA-2021-0107 CVS #16613, DS90022
18. CAS-2022-0187 PHA-2022-0027 CVS #1844, DS89666
19. CAS-2022-0186 PHA-2022-0026 CVS #1006, DS2715
20. CAS-2022-0166 PHA-2022-0053 CVS #23, DS90049
21. CAS-2022-0179 PHA-2022-0022 CVS #23, DS90049
22. CAS-2022-0181 PHA-2022-0023 CVS #127, DS3420
23. CAS-2022-0184 PHA-2022-0025 CVS #291, DS3271
24. CAS-2021-1281 PHA-2021-0120 CVS #1248, DS2875
25. CAS-2022-0051 PHA-2022-0008 CVS #444, DS2704
26. CAS-2022-0389 PHA-2022-0080 CVS #1252, DS3612

Respectfully Submitted,
Carly Jean-Francois, NP, Secretary