COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

January 12, 2023

Webex Information

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

For video access click on the following link:

https://eohhs.webex.com/eohhs/onstage/g.php?MTID=ee614447137083f760b7ee02921f1b46a

To access the meeting by phone:

Call in Number: 1-650-479-3208 Access Code: 2534 338 3264

Attendee: #

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

Agenda

Time	#	Item		
8:00	I	CALL TO ORDER		C. Belisle
8:02	II	APPROVAL OF AGENDA • Introduction of Interns: ○ Nicholas Vo – MCPHS University ○ Lauren Sieracki- Western New England University		
8:05	Ш	 APPROVAL OF BOARD MINUTES Draft of December 1, 2022 Regular Session Minutes 		

8:10 8:15	IV V	 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 Research Drug Study report pursuant to Staff Action Policy 18-02 FLEX Pharmacy issues related to COVID-19 Implementation of new and revised USP chapters Pharmacy Advisory Committee Meeting – January 25, 2023 10am Recommendation document 23-01 for Advisory 		D. Sencabaugh	
9:00	VI	APPLICATIONS • Walgreens #21400: DS90395 Request for Increase Ratio and Storage Space - • Southcoast Pharmacy; DS89859 – Petition to waiver • Southcoast Pharmacy; DS89872 – Petition to waiver • Option Care: DS90107 – Central Fill arrangement request • Genoa Pharmacy (Greenfield)- New Community Pharmacy • Genoa Pharmacy (West Springfield) – New Community Pharmacy • Tufts Medicine Home Infusion; DS90378– Petition to waiver • Boston Home Infusion; DS90029 – Petitions to waiver			
11:00	VII	• Apothecare Pharmacy LLC – Transfer of Ownership REGULATIONS • 247 CMR 17.00: Sterile Compounding			
12:00	VIII	POLICIES • Policy 2022-07: Automated Pharmacy Systems • Licensure Policy 13-01: Licensure Applications and Notices • Licensure Policy 14-02: Board Delegated Review (BDR)			
12:30		LUNCH BREAK			

		FILE	E REVIEW			
		1	CAS-2022-1506	SA-INV-21137	William Collins, PH16711	
		2	CAS-2022-0813	PHA-2022-0145	Walgreens #6349, DS3062	
		3	CAS-2022-0813	SA-INV-20828	Veronica Lewis, PH240503	
		4	CAS-2021-1265	PHA-2021-0116	Pelham Community Pharmacy, DS89647	
		5	CAS-2021-1265	SA-INV-19688	Brenda Fortin, PH21323	
		6	CAS-2022-0786	PHA-2022-0137	Richmond Pharmacy, DS1650	
		7	CAS-2022-0961	PHA-2022-0161	Stop & Shop Pharmacy #499, DS2996	
		8	CAS-2022-0681	PHA-2022-0134	Rite Aid #10092, DS2886	
		9	CAS-2022-0964	PHA-2022-0159	Rite Aid #10199, DS1996	
1:00	IX	10	CAS-2022-1075	PHA-2022-0178	Eaton Apothecary #3035, DS89891	
		11	CAS-2022-1296	PHA-2022-0203	Osco #3577, DS3163	
		12	CAS-2022-1055	PHA-2022-0176	CVS #582, DS3525	
		13	CAS-2022-0959	PHA-2022-0160	CVS #2500, DS5606	
		14	CAS-2022-0522	PHA-2022-0112	CVS #818, DS1403	
		15	CAS-2022-0414	PHA-2022-0090	CVS #1130, DS1690	
		16	CAS-2022-0417	PHA-2022-0088	CVS #498, DS3349	
		17	CAS-2022-0442	PHA-2022-0094	CVS #1250, DS89756	
		18	CAS-2022-0514	PHA-2022-0110	CVS #524, DS2532	
		19	CAS-2022-0475	PHA-2022-0099	CVS #365, DS2452	
		20	CAS-2022-1019	PHA-2022-0172	CVS #1850, DS2089	
		21	CAS-2022-0958	PHA-2022-0157	CVS #1121, DS2042	
		22	CAS-2021-1137	PHA-2022-0201	Sabahat Saadat Ahmed, PH26241	
2:00	X	The land c. 30 phys an in charge	A, § 21(a)(1) for the ical condition, or mendividual, or to discusses brought against, a	xecutive Session as a purpose of discussin ntal health, rather that is the discipline or di a public officer, empl	authorized pursuant to M.G.L. g the reputation, character, an professional competence, of smissal of, or complaints or loyee, staff member or	
			tration for a pending		Moral Character as required for	

2:45	XI	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)	
3:00	XII	M.G.L. c. 112, § 65C SESSION	
4:00	XIII	ADJOURNMENT	

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting January 12, 2023

Board Members Present

Board Members Not Present
Sebastian Hamilton, Pharm D, MBA, RPh

Caryn Belisle, RPh, MBA, President (leaves meeting 4 PM)
Katie Thornell, RPh, MBA President Elect
Jennifer Chin, RPh, Secretary
Delilah Barnes, RPh (leaves meeting 2 PM)
Carly Jean-Francois, RN, NP (leaves meeting at 4 PM)
John Rocchio, RPh, PharmD
Dr. Richard Lopez, MD
Sami Ahmed, PharmD., RPh, BCPS, BCSCP
Rita Morelli, PharmD, BCACP, RPh
Johanna Lopez (Leaves meeting 11-12 and 1-2)
Julie Lanza, CPhT
Dawn Perry, JD (leaves meeting 1:45 PM)

Board Staff Present

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

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:01 AM

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

Roll call attendance: C. Belisle, yes; J. Lanza, yes; D. Barnes; J. Rocchio, yes; J. Chin, yes; K. Thornell, yes; R. Morelli, yes; C. Jean-Francois, yes; S. Ahmed, yes; J. Lopez, yes; Dr. Lopez, yes; D. Perry, yes.

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Topic II. Approval of Agenda TIME 8:04 AM

Agenda 1/12/23

DISCUSSION:

None

ACTION:

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

Introductions: Dave welcomes new officers of the Board, Ed introduces APPE Student N. Vo and Michelle introduces APPE Student L. Sieracki.

Topic III Approval of Board Minutes TIME: 8:06 AM

Minutes

1. Draft 12/1/22

Change:

Remove W. Frisch from present Update spelling on J. Lopex to Lopez

Action:

Motion by J. Lanza seconded K. Thornell and voted unanimously to approve the regular session minutes of 12/1/22 with noted changes by roll call vote; C. Jean-Francois abstains.

TIME: 8:07 AM

TIME: 8:08 AM

TOIC IV Reports

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: M. BOTTO

<u>DISCUSSION</u>: M. Botto reported 73 Change of Manager applications and 5 facility closures that have been approved via Staff Action since the December 1st Board meeting.

So noted.

Topic IV. REPORTS

Monthly Report from Probation

PRESENTED BY: M. BOTTO

<u>DISCUSSION:</u> M. Botto indicated 12 successful completions of probation monitoring since the last Board

meeting with a total of 25 active cases.

So noted.

Topic IV. REPORTS

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Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: M. BOTTO

<u>DISCUSSION:</u> M. Botto reported 2 cases of CE deficiencies and 1 controlled substance loss since the last

TIME: 8:08 AM

TIME: 8:08 AM

TIME: 8:09 AM

Time: 8:09 AM

Time: 8:09 AM

Board meeting, all of which were closed with no discipline warranted.

So noted.

Topic IV. REPORTS

PSUD report by Staff Action 17-03

PRESENTED BY: E. TAGLIERI

<u>DISCUSSION</u>: E. Taglieri reported 9 total participants in the program, 7 of which are currently practicing in pharmacy. 2 discharges have been reported since the last Board meeting, including 1 successful completion and 1 withdrawal from the program without completion.

So noted.

Topic IV. REPORTS

Research Drug Study report pursuant to Staff Action Policy 18-02

PRESENTED BY: M. CHAN

<u>DISCUSSION</u>: M. Chan reported 5 retail facilities currently involved in research drug studies. There are currently 20 active studies, 4 of which involve investigational drug studies. No new studies have been approved since the last report.

So noted.

TOPIC V Flex

1. Pharmacy issues related to COVID-19

Presented by: D. SENCABAUGH

Nothing to report.

2. Implementation of new and revised USP chapters

Presented by: M. CHAN

Discussion: The revised USP <795>, <797>, <800>, and <825> chapters will become compendially applicable on November 1, 2023, and there have been several inquiries on the Board's stance in regard to enforcement.

Enforcement of USP <795>, <797>, and <825> will be done through coaching during non-punitive inspections to ensure compliance as of November 1, 2023, and no discipline will be issued until that time.

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However, USP <800> became official on December 1, 2019, and prior to that on October 3, 2019, the Board voted to inspect pharmacies on USP <800> with the intention of directing pharmacies to develop an action plan to work towards compliance. It was suggested to move forward with a more formal approach to compliance at this time.

Action: Motion by J. LANZA, seconded by S. AHMED, and voted unanimously by roll call of those present, to provide education and coaching for USP <795>, <797>, and <825> to ensure compliance by November 1, 2023; but to issue plans of correction for pharmacies that are not yet in compliance with USP <800>.

3. Pharmacy Advisory Committee Meeting: January 25, 2023
Recommendation Document 23-01: Pharmacy Advisory Committee Time: 8:12 AM

Presented by: W. FRISCH

Discussion: The Pharmacy Advisory Committee is requested to review and provide input to the Draft Regulations, 247 CMR 18.00 *Non-Sterile Compounding* at their January 25, 2023, meeting. Designation of a Board Member to present the recommendation document to the Pharmacy Advisory Committee and provide a summary of the meeting to the Board was also requested.

Action: Motion by J. LANZA, seconded by J. LOPEZ, and voted unanimously by roll call of those present, to approve D. BARNES, C. BELISLE and / or S. AHMED to present the Pharmacy Advisory Recommendation request (23-01) to the Pharmacy Advisory Committee on January 25, 2023, and then provide an update to the Board at the February 2, 2023, meeting.

TOPIC VI Applications

1. Walgreens #21400: DS90395 Request for Increase Ratio and Storage Space TIME: 8:19 AM Represented by: Robert Puishys, Isabel Perez, Jeenu Philip, Kevin McMurray Recusal:

Discussion:

J. Philip indicated that Walgreens is interested in moving forward with the facility expansion that was previously approved by the board and requesting that they increase the ratio that was also previously approved by board staff. J. Philip indicates they are coming before the board to increase their ratios from 6:1 to 10:1. J. Philip presented a slide show to the board which provided the board with security measures, timelines, blueprints, and other relevant information pertinent to their request. Board staff had the opportunity to ask questions regarding the logistics of the proposed renovations for increased ratios and storage space. B. Frisch inquired about the certificate of occupancy and if they were to get a permanent certificate of occupancy and not just a temporary one to which K. McMurray responded that they would.

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A motion was made by J. Lanza to approve the 10:1 ratio contingent upon the renovation work being executed as presented to the board of pharmacy on 1.12.23; Seconded by K. Thornell; then board members voted unanimously by roll call to approve motion.

2.Southcoast Pharmacy; DS89859 - Petition to waiver

Represented by:

Recusal:

Discussion:

R. Harris indicated that Southcoast appeared before the board to request a waiver of 247 CMR 6.01 (5)(a)(4) which is to keep and maintain a balance. This pharmacy does not compound as they use commercially available kits and therefore do not have any necessity for the balance. The waivers being presented are for the same petition to remove the balance requirement but for their Fairhaven and Fall River branches.

TIME: 8:46 AM

TIME: 8:48 AM

TIME: 8:50 AM

A motion was made by J. Lanza to approve the waiver of 247 CMR 6.01(5)(a)(4); Seconded by J. Rocchio; then board members voted unanimously by roll call to approve motion.

3.Southcoast Pharmacy; DS89872 – Petition to waiver

Represented by:

Recusal:

Discussion:

R. Harris indicated that Southcoast appeared before the board to request a waiver of 247 CMR 6.01 (5)(a)(4) which is to keep and maintain a balance. This pharmacy does not compound as they use commercially available kits and therefore do not have any necessity for the balance. The waivers being presented are for the same petition to remove the balance requirement but for their Fairhaven and Fall River branches.

A motion was made by J. Lanza to approve the waiver of 247 CMR 6.01(5)(a)(4); Seconded by R. Morelli; then board members voted unanimously by roll call to approve motion

4. Genoa Pharmacy (Greenfield)- New Community Pharmacy

Represented by: Megan Garrity, Aaron Blanchette

Recusal:

Discussion:

M. Garrity indicated that both locations coming before the board has a very similar business model to other Genoa locations. C. Belisle inquired about the 6 waivers that were presented and M. Garrity confirmed that these were the standard waivers that all other Genoa branches have requested. B. Frisch read the waivers being requested for the record which included the following- 247 CMR 6.02(5): signage, 247 CMR 9.01(15): limited services, 247 CMR 6.01(5)(8)(a): logbook for OTC drug, 247 CMR 9.01(16): compounding, 247 CMR 6.01(5)(a)(4): balance, and 247 CMR 6.02(4): sufficient supply of chemicals and medicinals.

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A motion was made by J. Lanza to approve the application for a new community pharmacy with the 6 waivers pending successful inspection; Seconded by C. Francois; then board members voted unanimously by roll call to approve motion.

5. Genoa Pharmacy (West Springfield) – New Community Pharmacy TIME: 8:50 AM

Represented by: Megan Garrity, Thomas Spring

Recusal: Discussion:

M. Garrity indicated that both locations coming before the board has a very similar business model to other Genoa locations. C. Belisle inquired about the 6 waivers that were presented and M. Garrity confirm that these were the standard waivers that all other Genoa branches have requested. B. Frisch indicated that they were still waiting on receipt of updated blueprint for this location so approval would be contingent upon the documents being sent in. B. Frisch read the waivers being requested for the record which included the following- 247 CMR 6.02(5): signage, 247 CMR 9.01(15): limited services, 247 CMR 6.01(5)(8)(a): logbook for OTC drug, 247 CMR 9.01(16): compounding, 247 CMR 6.01(5)(a)(4): balance, and 247 CMR 6.02(4): sufficient supply of chemicals and medicinals.

A motion was made by J. Lanza to approve the application for a new community pharmacy with the 6 waivers pending successful inspection and updated blueprint; D. Perry; then board members voted unanimously by roll call to approve motion.

6. Tufts Medicine Home Infusion; DS90378– Petition to waiver TIME: 8:58 AM

Represented by: Joelle Hall Recusal: D. Sencabaugh

Discussion:

J. Hall indicated that Tufts Home Infusion is coming before the board to request a waiver of 247 CMR 6.02(5) the requirement for external signage on the building. She indicates that they are a closed-door pharmacy, and all of their prescriptions are delivered through home delivery and their pharmacy is still in compliance with all internal signage. R. Harris indicated that if the waiver were to be approved, they would have to fill out the appropriate waiver form to which J. Hall responded that she did send the form but would be happy to resend it.

TIME: 9:01 AM

A motion was made by R. Lopez to approve the waiver pending receipt of the waiver form; Seconded by J. Lanza; then board members voted unanimously by roll call to approve motion.

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7. Boston Home Infusion; DS90029 – Petitions to waiver

Represented by: David Trinks, Rachel Gallagher

Recusal: Discussion:

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D. Trinks indicates that the waivers he has are 6.02(4) and 9.01(15). R. Harris indicates that he believed that the waivers were addressed at the last board meeting when discussing the decommissioning of the clean room, but no formal vote was made on the waivers in the minutes. The waivers are being brought back to the 01.12.23 board meeting to make a vote on those waivers.

A motion was made by to approve the waivers submitted made by J. Chen; Seconded by J. Lanza; then board members voted unanimously by roll call to approve motion.

TIME: 9:08 AM

8. Apothecare Pharmacy LLC – Transfer of Ownership

Represented by: Steven Brien, Brian Franks, Thomas Mckenney

Recusal:

Discussion:

S. Brien indicates that on December 15th, there was a close of transaction on the sale of Apothecare and since this change, there have been no changes in the operational standards or staffing of the pharmacy. B. Franks adds that there have also been no changes made to the facilities or licensed space and everything in the pharmacy operations is running the same prior to the change in ownership. J. Petrillo states that her understanding of the change in ownership is that this change was made at the parent level from Apothecare Pharmacy to Telly Corp LLC based off the organizational charts. J. Petrillo indicates that Telly Corp LLC is seen as another parent corporation which is why they are coming before the board for a change in ownership.

A motion was made by to approve the transfer of ownership made by D. Barnes; Seconded by R. Morelli; then board members voted unanimously by roll call to approve motion.

TOPIC VII REGULATIONS

247 CMR 17.00: Sterile Compounding Time: 9:31 AM

Presented by: W. FRISCH and M. CHAN

Discussion: On April 30, 2021, the Board reviewed and approved a revised draft of the Sterile Compounding regulations, 247 CMR 17.00. The revisions were due in large part to significant changes that resulted from public comment and to be consistent with the 2019 draft of USP <797>.

This draft, with revisions resulting from changes in the 2021 draft of USP <797>, was brought before the Pharmacy Advisory Committee on September 28, 2022, where additional revisions were made.

Subsequent to this meeting, a final version of USP <797> was released on November 1, 2022, reflecting changes from appeals and public comment to the prior drafts. Major changes to new version of USP <797> center around the addition of a new "Category 3" for compounded sterile preparations which allow for extended beyond-use dates (up to 180 days) provided that additional risk mitigation requirements (e.g., enhanced personnel and environmental monitoring, etc.) are met.

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Board staff has updated the draft of 247 CMR 17.00 to account for some of these changes as well as make other improvements such as eliminating duplicative standards. Board members C. BELISLE, J. LANZA, and S. AHMED, have previously reviewed the document as subject matter experts on the topic.

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

TOPIC VIII POLICIES

1. Policy 2022-07: Automated Pharmacy Systems Time: 10:03 AM

Presented by: M. CHAN

Discussion: The change to this policy is a statement that an Automated Pharmacy System (APS) that meets all the requirements of the policy, and having been approved by the Board, is considered an extension of the pharmacy's licensed area whether its location is contiguous or non-contiguous to the pharmacy.

As a reminder, one of the requirements of the policy is that the APS must be located at the same physical address as the pharmacy.

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

2. Licensure Policy 13-01: Licensure Applications and Notices Time: 10:05 AM

Presented by: M. CHAN

Discussion: In addition to some minor changes, language was added to allow Board staff to approve APS machines if the pharmacy is in good standing, and the machine and its location are in compliance with the Board's policy.

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

3. Licensure Policy 14-02: Board Delegated Review (BDR) Time: 10:07 AM

Presented by: M. CHAN

Discussion: Edits to this policy allow the BDR group to issue a reprimand to a pharmacy if they've allowed an individual to practice without a license for any amount of time.

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Also, the changes would allow BDR to issue a reprimand to pharmacies that have not submitted an application to change their Manager of Record or Designated Pharmacist-in-Charge within 100 days of departure.

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

TOPIC IX File Review

Case #1/CAS-2022-1505

SA-INV-21137 William Collins, PH16711 Time: 10:10 AM

RECUSAL: NONE

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

- CE deficiency for Pharmacist Collins was discovered during a relocation inspection on 11/29/2022 at Walgreens in Winchendon. The proposed MOR only had 2 CE documented for 2021.
- Pharmacist Collins cannot produce CEs he claims to have completed from The Pharmacist Letter (TRC) in 2021. Collins claims TRC told him he had multiple accounts, but TRC has no record of 2021 CEs.
 Collins claims when he logged into NABP CPE Monitor, he received an error message "problem with account please contact us". Collins is deficient a total of 18 CE (5 Live, 2 Law) for 2021.
- In review of CPE Monitor Transcripts for 2018, 2019, 2020, Pharmacist Collins has met the CE requirements for each year.
- The Licensee understands any CEs completed for remediation must be above and beyond his 2022 CE requirements.
- Pharmacist Collins completed remediation for 2021 after 11/29/2022 with 22.25 Total CE, 8 Live, 4 Law, 2 Immunization. In addition, he has also met his 2022 CE requirements.

<u>ACTION</u>: Motion by C. JEAN-FRANCOIS, seconded by R. MORELLI, and voted unanimously by those present, to CLOSE the matter (SA-INV-21137), No Discipline Warranted, Remediation Complete.

Case #2/CAS-2022-0813

PHA-2022-0145 Walgreens #6349, DS3062 Time: 10:12 AM

RECUSAL: NONE

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

• On July 5, 2022, Investigator Geaney learned during a retail compliance inspection that Former MOR Jessica Munson who was listed as the MOR in BHPL records at that time was no longer MOR. Instead, Former MOR Boniface Ochigbo was, in fact, the MOR.

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- Upon further investigation, BORP received an incomplete change in MOR application which appointed Former MOR Ochigbo as MOR from WAG 6349 on or about January 13, 2022. Specifically, the application was missing an attestation from the outgoing MOR, or staff pharmacist in cases where the outgoing MOR was unavailable, that an inventory of Schedule II-V controlled substances was completed.
- In addition, the application was missing information regarding whether Former MOR Ochigbo completed continuing education during 2020 and 2021. BORP staff accepted payment for the change in MOR from WAG 6349 then requested that WAG 6349 submit a completed application on January 14, 2022. WAG 6349 did not provide a completed application.
- Current MOR Lewis indicated that the following corrective action was implemented to mitigate
 recurrence of a similar incident. She wrote, "Appropriate count and application was completed per
 CMR guidelines where application were signed appropriately on the handoff from Ochigbo to
 Veronica. Going forward District Manager, Nicholas Carreira, will follow up on all MOR changes to
 ensure execution per CMR guidelines."

<u>ACTION</u>: Motion by D. BARNES, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0145), 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 #3/CAS-2022-0813

SA-INV-20828 Veronica Lewis, PH240503 Time: 10:17 AM

RECUSAL: NONE

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

- Pharmacist Lewis was appointed manager of record (MOR) at Walgreens Pharmacy #6349 during the
 investigation of a complaint for failing to notify BORP about a change in MOR (PHA-2022-0145).
 Pharmacist Lewis's CE records were evaluated as part of a review of requirements in her application
 for change in MOR. The evaluation revealed that Pharmacist Lewis failed to complete two contact
 hours of pharmacy law during 2021 in violation of annual requirements for CE.
- Pharmacist Lewis completed two contact hours of CE in pharmacy law to remediate and acknowledged that the remedial CE cannot be used to satisfy any other CE. In addition, Pharmacist Lewis submitted a statement to BORP. Pharmacist Lewis explained that she misinterpreted BORP Policy 2021-04. She described that 247 CMR 4.03(4)(a) stated "all registrants must complete at least two contact hours per calendar year in the area of pharmacy law." On the other hand, BORP Policy 2021-04 only stated "at least 2 contact hours must be in the area of pharmacy law..."
- MOR Lewis explained that she did not understand BORP Policy 2021-04 supplemented 247 CMR 4.03(4)(a) and was "not in lieu of." She then indicated that she promptly completed two contact hours of CE in pharmacy law when she was made aware of her misunderstanding.
- CA: Pharmacist Lewis completed two contact hours of CE in pharmacy law to remediate for the 2021 deficiency and acknowledged that the remedial CE cannot be used to satisfy any other CE.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by R. MORELLI, and voted unanimously by those present, to CLOSE the matter (SA-INV-20828), No Discipline Warranted, Remediation Complete.

Case #4/CAS-2021-1265

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Pelham Community Pharmacy, DS89647

Time: 10:20 AM

RECUSAL: NONE

PHA-2021-0116

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

- On or about December 10, 2021, Wilmington Board of Health reported that Pelham was contracted to provide COVID-19 vaccines for a booster clinic on December 9, 2021. A pharmacist from Pelham arrived with pre-drawn syringes which were not "filled to the correct dose and [the pharmacist] wasn't sure if they were Moderna or Pfizer" because the syringes were not labeled.
- BORP dispatched Investigator Van Allen to conduct a site visit at Pelham after learning about Wilmington Board of Health's complaint. Investigator Van Allen reported that he reviewed Wilmington Board of Health's complaint with MOR Aimee Drew. MOR Drew acknowledged that she was aware of the complaint. She indicated an internal investigation revealed that Pharmacist Brenda Fortin took the unlabeled pre-drawn syringes from the pharmacy prior to completion of preparation in violation of procedures at Pelham.
- MOR Drew later acknowledged that written procedures for preparation of pre-drawn syringes and corresponding training did not exist. Pharmacist Fortin indicated that Pelham had no written procedures for preparing pre-drawn syringes or training.
- MOR Drew described that Pelham's standard procedure for COVID-19 vaccine preparation was to prepare pre-drawn syringes with the correct volume. Then, the syringes were packed in a Ziploc bag. A label was attached to the Ziploc bag with relevant vaccine information. Significantly, MOR Drew indicated that compounding records were not kept for the preparation of pre-drawn syringes. MOR Drew and Pharmacist-Owner Bhuren Patel later asserted that pre-drawn syringes were only prepared on one occasion on December 9, 2021, when the Wilmington Board of Health's clinic occurred.
- Pharmacist Fortin denied that she deviated from usual SOP. She emphasized and Pelham admitted that no written P&P for preparation, storage, shipping, or administration of immunizations existed.
- CA: MOR Drew indicated that Pelham no longer prepared pre-drawn syringes. Instead, Pelham would prepare syringes in real time at vaccine clinics going forward. MOR Drew noted that the rejected predrawn syringes were replaced, and consent forms were provided at the booster clinic, so patients were able to receive their booster at the Wilmington Board of Health Clinic.
- CA: Pharmacist Fortin facilitated the replacement of vaccine and provided additional consent forms on behalf Pelham as described by MOR Drew.

ACTION: Motion by D. BARNES, seconded by K. THORNELL, and voted unanimously by those present, to call an Investigative Conference, to include MOR Drew, PH/Owner Patel and PH Fortin.

Case #5/CAS-2021-1265

SA-INV-19688 Brenda Fortin, PH21323 Time: 10:20 AM

RECUSAL: NONE

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

• On or about December 10, 2021, Wilmington Board of Health reported that Pelham was contracted to provide COVID-19 vaccines for a booster clinic on December 9, 2021. A pharmacist from Pelham

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- arrived with pre-drawn syringes which were not "filled to the correct dose and [the pharmacist] wasn't sure if they were Moderna or Pfizer" because the syringes were not labeled.
- BORP dispatched Investigator Van Allen to conduct a site visit at Pelham after learning about
 Wilmington Board of Health's complaint. Investigator Van Allen reported that he reviewed
 Wilmington Board of Health's complaint with MOR Aimee Drew. MOR Drew acknowledged that she
 was aware of the complaint. She indicated an internal investigation revealed that Pharmacist Brenda
 Fortin took the unlabeled pre-drawn syringes from the pharmacy prior to completion of preparation in
 violation of procedures at Pelham.
- MOR Drew later acknowledged that written procedures for preparation of pre-drawn syringes and corresponding training did not exist. Pharmacist Fortin indicated that Pelham had no written procedures for preparing pre-drawn syringes or training.
- MOR Drew described that Pelham's standard procedure for COVID-19 vaccine preparation was to prepare pre-drawn syringes with the correct volume. Then, the syringes were packed in a Ziploc bag. A label was attached to the Ziploc bag with relevant vaccine information. Significantly, MOR Drew indicated that compounding records were not kept for the preparation of pre-drawn syringes. MOR Drew and Pharmacist-Owner Bhuren Patel later asserted that pre-drawn syringes were only prepared on one occasion on December 9, 2021, when the Wilmington Board of Health's clinic occurred.
- Pharmacist Fortin denied that she deviated from usual SOP. She emphasized and Pelham admitted that no written P&P for preparation, storage, shipping, or administration of immunizations existed.
- CA: MOR Drew indicated that Pelham no longer prepared pre-drawn syringes. Instead, Pelham would prepare syringes in real time at vaccine clinics going forward. MOR Drew noted that the rejected pre-drawn syringes were replaced, and consent forms were provided at the booster clinic, so patients were able to receive their booster at the Wilmington Board of Health Clinic.
- CA: Pharmacist Fortin facilitated the replacement of vaccine and provided additional consent forms on behalf Pelham as described by MOR Drew.

<u>ACTION</u>: Motion by D. BARNES, seconded by K. THORNELL, and voted unanimously by those present, to call an Investigative Conference, to include MOR Drew, PH/Owner Patel and PH Fortin.

Case #6/CAS-2022-0786

PHA-2022-0137 Richmond Pharmacy, DS1650 Time: 10:27 AM

RECUSAL: NONE

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

- On May 24, 2022, Richmond notified BORP about a possible loss of "a bottle of generic Percocet." Richmond then submitted a note and a DEA 106 to BORP received on June 7, 2022, which reported that 140 oxycodone-acetaminophen 5-325mg tablets were lost in transit on May 23, 2022. Richmond's final report did not include a BORP RLCS, or supplemental information required by BORP Policy 2022-01.
- MOR Frassica later described to Investigator Richard Geaney and in a response to this complaint that a completed prescription of 140 oxycodone-acetaminophen 5-325mg tablets for a home-delivery patient was lost on May 20, 2022. MOR Frassica explained that the prescription was placed in the delivery area and verified by a pharmacist. However, the delivery driver did not recall taking the prescription. The patient then called on May 23, 2022, to report the prescription was not delivered.

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- MOR Frassica promptly initiated an internal investigation. All patients who were delivered prescriptions on May 20, 2022, were contacted to confirm they received the correct prescriptions. The delivery driver's vehicle was searched in case the prescription was lost in the vehicle. The delivery route was searched by retracing the route in case the prescription fell out of the vehicle. MOR Frassica searched his entire pharmacy stock to ensure the prescription was not misplaced in the stock. He indicated that five days of trash in the building and the building's dumpster were searched in case the prescription was inadvertently thrown away. Ultimately, MOR Frassica indicated that he was unable to find the missing prescription.
- CA: MOR Frassica wrote, "All delivery CII Rxs logged by pharmacist and given directly to driver. The driver then signs and dates and time of receipt of drug."

<u>ACTION</u>: Motion by J. LOPEZ, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2022-0137), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #7/CAS-2022-0961

PHA-2022-0161

Stop & Shop #499, DS2996

Time: 10:31 AM

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

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

- On June 30, 2022, S&S 499 submitted a RLCS which notified BORP about a possible unknown loss of 180 clonazepam 1mg tablets discovered on June 24, 2022. Of note, S&S 499 failed to submit a DEA. S&S 499 then failed to submit a final report of loss in accordance with BORP Policy 2022-01: Loss or Theft of Controlled Substances.
- MOR Jonathan Hersey was notified of the complaint, submitted the final RLCS, and explained that a
 negative variance of 180 clonazepam 1mg tablets was discovered on June 24, 2022, while dispensing a
 routine prescription between the actual quantity on hand at the pharmacy and the quantity according
 to the pharmacy's "dispensing system."
- MOR Hersey wrote, "Since then, the suspected loss has been investigated and the 180 Clonazepam
 1mg were recovered and are accounted for. The investigation determined that no loss actually
 occurred." He indicated that an e-prescription was transmitted to the pharmacy, filled, and placed in
 the will-call bin for the patient to pick up. The prescriber later cancelled the prescription before the
 prescription was dispensed. However, the prescription was not removed from the will-call bin at that
 time which caused the appearance of a discrepancy.
- CA: MOR Hersey described that he would remind staff about the importance of promptly removing prescription from the will-call bin when a prescriber cancels a prescription. In addition, MOR Hersey indicated that he would establish a "a protocol to periodically review all bags in will-call bin to ensure that all electronically cancelled prescription have been removed from the will-call bins."

<u>ACTION</u>: Motion by J. CHIN, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0161), No Discipline Warranted.

Case #8/CAS-2022-0681

PHA-2022-0134 Rite Aid #10092, DS2886 Time: 10:34 AM

RECUSAL: NONE

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

- On May 4, 2022, Rite Aid 10092 notified BORP about a possible loss of controlled substances discovered on May 1, 2022, but failed to submit an official BORP RLCS Form until May 13, 2022, in violation of requirements to submit the RLCS Form within 7 days of the discovery a loss.
- Rite Aid 10092 then failed to submit a final RLCS and DEA 106 within 21 days of the initial notification of the loss on May 4, 2022. Rite Aid 10092 additionally failed to submit supplemental information until June 16, 2022, which also was required within 21 days of the initial notification of the losses on May 4, 2022.
- According to final reports and supplemental information, the pharmacy discovered various losses Schedule III, IV, & V controlled substances on May 1, 2022. Rite Aid 10092 attributed the losses to dispensing errors. However, Rite Aid 10092 failed to provide any evidence to support dispensing errors caused the losses. Thus, the losses were, in fact, unknown losses.
- CA: Former Rite Aid Regional Pharmacy Leader (RPL) Sabine Chibueze described that "procedures for the accurate handling, dispensing and accountability of controlled drugs" were reviewed with pharmacy staff. Former RPL Chibueze also indicated that the pharmacy would "continue to follow policy and procedures" for management of controlled substance "to ensure the highest level of accuracy of controlled substance inventory in accordance with MA regulations."
- Former RPL Chibueze then wrote, "All controlled prescriptions will be counted twice by tech and/or pharmacist. Only the pharmacist will double count CIIs; initial on the prescription label; and back count. The pharmacist will take a monthly count of CII and highlighted control substances to ensure there are no further losses. Reviewed proper reporting procedures to ensure Region Pharmacy Leader and Asset Protection Leader are both notified of the loss within 24 hours."

<u>ACTION</u>: Motion by D. BARNES, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2022-0134), to the office 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 Controlled Substance Loss Protocol for all testosterone containing products.

Case #9/CAS-2022-0964

PHA-2022-0159 Rite Aid #10199, DS1996 Time: 10:39 AM

RECUSAL: NONE

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

- ID cited on 8/11/22 for allowing PTT Cabral to work with a license that expired on 6/15/22. The POC stated she was issued her PT license on 8/29/22 and had worked 979 hours while licensed and 179 hours with an expired license.
- MOR Tompkins stated her PT application was likely sent out around 6/10/22 but no copy or record was kept. In retrospect, he indicated an PTT extension should have been obtained until the PT license was issued. He claimed PTT Cabral contacted either PCS or the BORP for an extension, but nothing was provided in writing and the wrong agency may have been contacted. A copy of her PT application

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- showed MOR Tompkins signed it on 6/16/22 and it was notarized on 6/17/22. PTT hours were tracked by requesting the information from HR or manually totaling the hours in Kronos.
- PT Cabral provided a statement that included her duties performed as a PTT including working at POS, data entry, production, performing RTS from the will call bin, and pulling expired medications and preparing them for return.
- The BORP will be contacted 30 days prior to a PTT license expiration regardless of whether a PT application has been submitted or not. MOR Tompkins will have PTTs complete the training program 45 days before the PTT license expires to allow PCS reasonable time to process a PT application. For pending licenses without an extension granted, MOR Tompkins will ensure the PTT does not perform pharmacy functions. MOR Tompkins reviewed the Rite Aid Pharmacy Technician Training Manual Program Guide.

<u>ACTION</u>: Motion by S. AHMED, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2022-0159), to the office 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-2022-1075

PHA-2022-0178 Eaton Apothecary #3035, DS89891

Time: 10:43 AM Stopped @ 10:44 AM Resumed @ 10:54 AM

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

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

- During a retail inspection on 8/3/22, it was observed that a controlled substance inventory for a change of MOR was completed on 1/6/22 but Former MOR Zafiri was still listed as the MOR with the BORP. A copy of the initial application was obtained while on site.
- Sr. Analyst Pacia stated the paperwork with payment was submitted by the POA Manager team, but it was sent to the wrong BORP address and was returned to sender. UPS notifications were provided which showed 3 delivery attempts were made on 1/17/22, 1/19/22, and 1/31/22.
- The application was notarized a second time on 8/11/22 and it was resubmitted with a check dated 8/5/22. On 8/23/22, the paperwork was delivered, and payment was posted on 8/26/22.

<u>ACTION</u>: Motion by J. CHIN, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2022-0178), 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-2022-1296

PHA-2022-0203 Osco #3577, DS3163 Time: 10:44 AM

RECUSAL: NONE

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

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- RLCS for #112 hydromorphone 4mg tablets identified on 9/29/22 by Floater Pharmacist Blocksidge when a filled prescription could not be located in the waiting bin. Pharmacist Blocksidge searched all bags in the will call bin. On 9/30/2022, MOR Henen searched the shelves, the narcotics safes, the floor, and every vial in the will call bin. She conducted a CII audit and reviewed the drug detail movement report and all invoices for hydromorphone. The discrepancy was reported to Osco DM Parker and Loss Prevention. An internal investigation was initiated including review of security camera footage.
- On 11/17/22, MOR Henen reported the missing vial of hydromorphone was found while she was verifying a prescription for ondansetron. It had been mislabeled as an ondansetron returned to stock on 9/28/22. MOR Henen stated the hydromorphone bottle had mistakenly been pulled from the will call bin and labeled with the return to stock label. Both prescriptions were for the same patient. MOR Henen counted the tablets in the vial and all missing hydromorphone was accounted for. The vial was correctly relabeled and placed in the safe. She notified compliance and withdrew the DEA 106.

<u>ACTION</u>: Motion by C. BELISLE, seconded by K. THORNELL, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0203), No Discipline Warranted, Remediation Complete.

Case #12/CAS-2022-1055

PHA-2022-0176 CVS #582, DS2525 Time: 10:56 AM

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

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

- Inspectional deficiencies on 8/31/22 for a non-functioning sink with hot and cold running water, a plumbing leak, water damage to the sink cabinet and surrounding carpet, water-damaged ceiling tiles and bugs in the light covers. Additionally, the counter where immunizations, compounds and reconstitutions were prepared needed cleaning. The Pharmacy was asked to cease immunizing, compounding, and utilizing the Fill Master which they agreed to. On 9/7/22, the BORP learned the Pharmacy's sink was removed and there was no hot/cold running water. Reconstitutions were done using distilled water and a graduated cylinder. Hand sanitizer was used at each station.
- The POC stated on 9/14/22, a new sink and cabinet were installed. The ceiling tiles and carpet were replaced, and the counter was cleaned. No immunizations were administered.
- MOR (Hakim) Porcaro stated the sink began leaking on 8/2/22 with a work order immediately submitted. She indicated the deficiencies were remediated as indicated in the POC. She stated the surrounding CVS pharmacies supported patients' needs for immunization, compounding and reconstitutions during the Pharmacy's pause. An Excel spreadsheet of the work orders for the issues was provided showing the dates submitted, the issues reported and the resolution. Drug Usage reports showed that from when the sink began leaking on 8/2/22 until the inspection on 8/31/22, 198 immunizations were administered, 2 compounds were prepared, and 46 medications were reconstituted. Another 25 medications were reconstituted from 9/1/22-9/15/22. No immunizing or compounding occurred after 8/31/22.
- According to the POC, the Pharmacy team will continue to monitor the sink area for any leaks and "...will ensure a fix will be in place immediately". In addition, the counter will be cleaned on daily basis.

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• On 09/19/2022 a site visit was conducted at the Pharmacy and deemed satisfactory.

<u>ACTION</u>: Motion by K. THORNELL, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2022-0176), 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.

J. Lopez Leaves Meeting 11:00 am to 12:00 PM

Case #13/CAS-2022-0959

PHA-2022-0160 CVS #2500, DS3606 Time: 11:02 AM

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

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

- RLCS for #60 Vyvanse 60mg capsules discovered on 6/30/22 when a prescription was not found in the waiting bin. Video was not reviewed.
- On 6/17/22, Pharmacist El-Khoury performed data entry, production, and verification of the prescription which had no copay. On that day, the Pharmacy's registers were offline and prescriptions with no copay were dispensed to patients after manually verifying their information. Once the system came back online, the transactions were processed. As the patient had picked up other prescriptions after 6/17/22, it was presumed she had received it on 6/17/22 when the registers weren't functioning properly.
- On 6/30/22, Pharmacist Calamonici documented in the perpetual inventory "medication cannot be found in the bin, the system was down the day the prescription was filled but patient reports she did not pick it up". A search was conducted in the waiting bin, return to stock bin, and bins of recently verified prescriptions to be filed. Additionally, the safe was double checked and the quantity on hand matched the perpetual inventory. The response stated, "After consulting with Field Leadership, it was decided that we would take care of the patient...and the prescription was reissued, resulting in the loss". Pharmacist Calamonici reprinted a label and recorded an inventory adjustment of -60 in the perpetual inventory.
- DL Gagnon stated all policies and procedures for the proper storage and handling of controlled substances have been reviewed with the Pharmacy Team. The Pharmacy staff provided a signed statement attesting review of CVS DOC-040606 Pharmacy Colleague Asset Analytics and Insights/Drug Diversion.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0160), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #14/CAS-2022-0522

PHA-2022-0112 CVS #818, DS1403 Time: 11:05 AM

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

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

- On 5/11/22, an untimely RLCS form and DEA 106 for a loss of #430 phenobarbital 15mg tablets was submitted. On 5/23/22, the BORP received notification that the missing drug was located with medications prepared for a return to Inmar and the DEA 106 was amended to no loss.
- MOR Couture stated on 5/13/22, Pharmacist Smith discovered the missing phenobarbital 15mg tablets in a tote in the Pharmacy with medications waiting to be processed as outdates. Although he and Pharmacist Smith had previously looked through the totes, they both overlooked it upon first check. A copy of the key rec was provided.

<u>ACTION</u>: Motion by R. MORELLI, seconded by J. CHIN, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0112), No Violation.

Case #15/CAS-2022-0414

PHA-2022-0090 CVS #1130, DS1690 Time: 11:06 AM

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

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

- RLCS for an untimely unknown loss of #100 oxycodone/APAP 10/325mg tablets discovered on 2/12/22 during the perpetual inventory reconciliation. MOR Maserati reported it was due to a suspected dispensing error that could not be confirmed.
- The loss was identified by Pharmacist Adongo who discovered an overage of #100 oxycodone/APAP 7.5/325 mg and a shortage of #100 oxycodone/APAP 10/325mg. Patients who received those medications from 2/5/22-2/12/22 were contacted over 3 days with none reporting receipt of the wrong medication. It was recommended patients return to the Pharmacy with their vials for a pharmacist to confirm the contents. All patients declined.
- MOR Maserati reviewed CII invoices and video to confirm all CII orders from 2/5/22-2/12/22 were checked in correctly. A drug usage report for all prescriptions filled for both strengths of oxycodone/APAP from 2/5/22-2/12/22 was compared to the perpetual inventory with no further discrepancies identified. Video of each prescription filled was also reviewed. MOR Maserati discovered on 2/7/22, prescriptions for both strengths of oxycodone/APAP were verified minutes apart. The prescription for oxycodone/APAP 7.5/325mg was for over 100 tablets. He indicated this was possibly the prescription affected. Although multiple bottles were scanned to confirm the NDC number used, a bottle could have been removed from the safe after this was completed. The patient was contacted again, and he stated he received the correct medication and didn't need the Pharmacy to review the contents of his vial.
- The final reports stated, "All Loss Prevention policy and procedures will be reviewed with the Pharmacy Team to prevent future losses. This includes diligent inventory management and dispensing

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standards". MOR Maserati stated, "The verifying and all staff pharmacists were re-trained in best practices on filling C2 prescriptions, the importance of filling only 1 prescription at a time and checking the perpetual inventory after filling each C2 prescription to ensure the correct back count".

<u>ACTION</u>: Motion by J. CHIN, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0090), 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 #16/CAS-2022-0417

PHA-2022-0088 CVS #498, DS3349 Time: 11:10 AM

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

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

- Inspectional deficiency on 4/8/22 for unlicensed practice by CPhT (Grzelcki) Archambault working with a PT license that expired on 1/30/22. According to the POC, she renewed her PT license that same day.
- MOR Swalec stated the contributing factor was CPhT (Grzelcki) Archambault's prior last name was
 misspelled on the BORP website as "Grezelcki". Normally, the MOR receives an automatic notification
 from the CVS licensure monitoring team of an upcoming license expiration date and the employee
 would not be able to work if a license had not been renewed. Due to the misspelling this did not
 occur.
- The POC indicated MOR Swalec would meet with all PTs for re-education on Massachusetts regulations regarding PT license renewal procedures. In the response, MOR Swalec stated, "Due to this deficiency, the MOR will be manually checking all license expiration dates at the beginning of each month instead of relying solely on notifications from CVS Corporate".

<u>ACTION</u>: Motion by S. AHMED, seconded by K. Thornell, to refer the matter (PHA-2022-0088), 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-2022-0442

PHA-2022-0094 CVS #1250, DS89756 Time: 11:13 AM

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

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

• During an inspection on 4/15/22, it was observed that Former MOR Antenor who went out on a LOA was still listed as the MOR on file and no change of MOR paperwork was available. Additionally, PTT Francois was working with a license that expired on 1/30/22. Investigator Horn was informed that

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- Former MOR Belmore had completed a CS inventory on 4/12/22. The POC indicated that the change of MOR was in process on the day of the inspection and did not address PTT François' expired license.
- Covering DL Knight stated Former MOR Antenor went out on an unplanned LOA and Former MOR Belmore assumed the role when DL Knight became aware of the LOA.
- Former MOR Belmore stated he was submitting the change of MOR paperwork to CVS Corporate on the day of the inspection and the completed paperwork was added to the regulatory box. Copies of unsigned CS inventories without coversheets were submitted showing they were completed on 4/12/22.
- Former MOR Belmore contended a PT application for PTT Francois was submitted to PCS in December 2021, but it appeared it had not been processed. PTT Francois was still able to receive credentials from CVS to work in the Pharmacy and the issue was not known until past the date of expiration when Former MOR Antenor investigated and began the process of fixing the issue. He claimed he was unaware the license was expired prior to the inspection. An application was immediately submitted to PCS. On 10/25/21, the BORP received a request for a PTT extension indicating he had worked 1278 hours as of 9/16/21. From 1/30/22-5/19/22, he worked 468 hours.
- All other technician licenses were monitored by Former MOR Belmore who ensured PTTs become licensed PTs when the criteria have been met. On 06/01/2022, PTT Francois was issued PT license PT28672.

<u>ACTION</u>: Motion by R. LOPEZ, seconded by K. THORNELL, to refer the matter (PHA-2022-0094), 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 #18/CAS-2022-0514

PHA-2022-0110 CVS #524, DS2532 Time: 11:17 AM

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

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

- Inspectional deficiencies on 4/29/22 for failure to submit a change of MOR application and storage of medication outside of licensed space. The completed paperwork and CS inventory from January 2022 when the change in MOR took place were in the regulatory box, but Former MOR Edwards was still listed as MOR on the public website. A locked cabinet containing filled prescriptions was observed outside the locked/alarmed Pharmacy space. Only the pharmacists had the key. The POC indicated as of 5/5/22, the MOR on the public website was updated as Current MOR Preziosi and the large will call bags were moved into the Pharmacy.
- DL Naguib stated the change of MOR application was received by the BORP on 02/09/22 with 01/31/22 as the effective date for the MOR change. DL Naguib indicated that at no time was the Pharmacy without a MOR. Pharmacist Shi stated Former MOR Edwards began a LOA on 02/01/22 on which date Current MOR Preziosi became MOR. The fee for a change of MOR was received and posted on 2/16/22 in MLO.
- Current MOR Preziosi was under the impression that the new license may take a few months to arrive in the mail which was why an updated license had not been received to post in the Pharmacy and file

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- in the regulatory box. Large bags containing filled prescriptions had been stored in the locked cabinet outside of the Pharmacy gate and out of reach of the public due to lack of space in the Pharmacy.
- The Pharmacy will ensure MOR information remains current and correct. New shelves were ordered where large prescription bags are now stored in the Pharmacy.
- An inspection was conducted on 11/28/22 with no POC issued.

<u>ACTION</u>: Motion by J. CHIN, seconded by S. AHMED, to refer the matter (PHA-2022-0110), 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 REPRIMAND.

Case #19/CAS-2022-0475

PHA-2022-0099 CVS #365, DS2452 Time: 11:20 AM

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

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

- RLCS for unknown loss of #60 amphetamine salts ER 25mg capsules discovered on 3/10/22 when a
 prescription could not be found in the waiting bin. All controlled substance recordkeeping was
 reviewed along with security footage according to the final reports.
- MOR McCarthy stated he searched the entire waiting bin after hours on 3/10/22 without success. The area containing the large bags, refrigerator, compounding area, and reconstitution station were also searched. MOR McCarthy surmised, "The prescription is presumed to have been accidentally dispensed to a different customer without being rung out through the register. One other prescription was filled during this time [RX #Redacted]. That patient was contacted and confirmed they received the correct quantity and label on their prescription". The Pharmacy staff member who filed the prescription could not be determined. CII prescriptions are not segregated from the regular bin. MOR McCarthy performed daily inventory counts for a few weeks with no additional losses identified. Diversion was not suspected.
- The CVS District Leader met with the Pharmacy staff to review the waiting bin process. MOR
 McCarthy conducted a formal training with Pharmacy staff to ensure proper behaviors are used while
 selling medications at POS. Loss Prevention policy and procedures and POS procedures were reviewed
 with the Pharmacy Team to prevent future losses.

<u>ACTION</u>: Motion by R. MORELLI, seconded by K. THORNELL, to refer the matter (PHA-2022-0099), 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 #20/CAS-2022-1019

PHA-2022-0172 CVS #1850, DS2089 Time: 11:23 AM

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

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

- During an inspection on 8/23/22, it was observed that a controlled substance inventory for a change of MOR was completed on 4/30/22 but Former MOR Rowland was still listed as the MOR.
- Current MOR Noel-Fils stated she assumed the MOR role on 4/25/22 when Former MOR Rowland left the company. Copies of the CS inventories that were only signed by Current MOR Noel-Fils were provided. She indicated an application was completed on the week of 04/25/22 and was given to DL Ricciuto to submit.
- DL Ricciuto stated there was misunderstanding between her and Current MOR Noel-Fils of who was submitting the application to the CVS licensure team. She did not follow up to verify the application was received. DL Ricciuto indicated she sent the application to the CVS licensure team in June and resubmitted it on 8/24/22 but it was not received so she resubmitted it a third time.
- On 10/7/22, the BORP received the Application for Change in Manager. The attestation of the CS inventory section was signed by Current MOR Noel-Fils and DL Ricciuto with a notation the outgoing PIC started a new position and was unable to sign. On 11/18/22, the Pharmacy was contacted, and a CS inventory completed by Former MOR Rowland could not be located.

<u>ACTION</u>: Motion by S. AHMED, seconded by D. BARNES, to refer the matter (PHA-2022-0172, 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 #21/CAS-2022-0958

PHA-2022-0157 CVS #1121, DS2042 Time: 11:26 AM

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

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

- During a retail compliance inspection (ISP-19206) conducted on 08/05/22, it was observed that Pharmacy Technician Trainee (PTT) Aaron Mamoon was allowed to practice with an expired license.
- PTT Aaron Mamoon was observed performing pharmacy technician duties with a PTT license that expired on 06/22/2022 and an extension was provided on site until 11/22/2022.
- During the time that PTT Mamoon had an expired license from 6/22/2022-08/05/2022, he worked a total of 105.82 hours.
- MOR Arsiwala did not provide any corrective action taken by her to prevent this violation from recurring."

<u>ACTION</u>: Motion by C. JEAN-FRANCOIS, seconded by J. CHIN, to refer the matter (PHA-2022-0157), 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 #22/CAS-2021-1137

PHA-2022-0201 Sabahat Saadat Ahmed, PH26241 Time: 11:28 AM

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

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

- Pharmacist Ahmed indicated that she reviewed 247 CMR 15.00 and completed 1.5 hours of CE in patient safety in addition to annual requirements for 2021 as part of corrective action after a vaccine administration error investigated during SA-INV-18869. However, Pharmacist Ahmed did not, in fact, complete annual CE requirements for 2021. She was deficient 12 hours.
- Pharmacist Ahmed acknowledged that she did not complete 2021 CE requirements. She indicated that she renewed her license for 2019-2020 cycle on June 29, 2021, in accordance with COVID-19 expiration deferrals and asserted "it was unclear whether all 20 contact hours of continuing education had to be completed in the six months that remained in [2021] or if more time would be given..."
- Pharmacist Ahmed next indicated that her position as a part-time immunizer expanded to full-time "as the fight against COVID-19 continued and a need for immunizers persisted..." She then explained that her expanded role as an immunizer was in addition to "a high burden of personal responsibilities, which were also sustained." The combination caused her to fall behind on completing her 2021 CE requirements. She asserted that she had intended to complete the outstanding 2021 CE during 2022. Pharmacist Ahmed added that "[she did] not anticipate this to happen again."
- CA: Pharmacist Ahmed subsequently completed 12 hours of CE to remediate for her 2021 deficiency.

<u>ACTION</u>: Motion by D. BARNES, seconded by K. THORNELL, to refer the matter (PHA-2022-0201), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for a STAYED PROBATION for a period of 60 days, with special terms to include the 2:1 remediation of PH Ahmed's 2021 CE deficiency.

Topic X: Executive Session Call to Order: Time: 11:35 AM

By: C. Belisle 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 Dr. Lopez and Board Members present voted unanimously by roll call to approve motion.

Roll call attendance: C. Belisle, yes; J. Lanza, yes; D. Barnes; J. Rocchio, yes; J. Chin, yes; K. Thornell, yes; R. Morelli, yes; C. Jean-Francois, yes; S. Ahmed, yes; Dr. Lopez, yes; D. Perry, yes.

Topic XI: 65C Sessions MGL c. 112 section 65C Time: 11:45 AM

DISCUSSION: None

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

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At 11:45 AM R. Morelli, seconded by S. Ahmed and voted unanimously by all those present to enter 65C by roll call vote.

Topic XII: Adjudicatory Session

Deferred

Lunch 12:20 pm to 1:00 PM

- D. Perry Leaves meeting at 1:45 PM
- D. Barnes leaves meeting at 2:00 PM
- C. Jean-Francois leaves meeting 4:00 PM
- C. Belisle leaves meeting 4:00 PM

Topic XIII ADJOURMENT OF MEETING TIME: 4:40 PM

ACTION: Motion by J. Chin 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 1/12/23 General Session
- 2. Draft Minutes of the 12/1/22 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. Report Research Drug Study Report pursuant to staff action policy 18-02
- 8. Application: Walgreens #21400: DS90395 Request for Increase Ratio and Storage Space -
- 9. Application: Southcoast Pharmacy; DS89859 Petition to waiver
- 10. Application: Southcoast Pharmacy; DS89872 Petition to waiver
- 11. Application: Genoa Pharmacy (Greenfield)- New Community Pharmacy
- 12. Application: Genoa Pharmacy (West Springfield) New Community Pharmacy
- 13. Application: Tufts Medicine Home Infusion; DS90378- Petition to waiver
- 14. Application: Boston Home Infusion; DS90029 Petitions to waiver
- 15. Application: Apothecare Pharmacy LLC Transfer of Ownership
- 16. 247 CMR 17.00: Sterile Compounding
- 17. Policy 2022-07: Automated Pharmacy Systems
- 18. Licensure Policy 13-01: Licensure Applications and Notices
- 19. Licensure Policy 14-02: Board Delegated Review (BDR)
- 20. CAS-2022-1506 SA-INV-21137 William Collins, PH16711

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21. CAS-2022-0813	PHA-2022-0145 Walgreens #6349, DS3062
22. CAS-2022-0813	SA-INV-20828 Veronica Lewis, PH240503
23. CAS-2021-1265	PHA-2021-0116 Pelham Community Pharmacy, DS89647
24. CAS-2021-1265	SA-INV-19688 Brenda Fortin, PH21323
25. CAS-2022-0786	PHA-2022-0137 Richmond Pharmacy, DS1650
26. CAS-2022-0961	PHA-2022-0161 Stop & Shop Pharmacy #499, DS2996
27. CAS-2022-0681	PHA-2022-0134 Rite Aid #10092, DS2886
28. CAS-2022-0964	PHA-2022-0159 Rite Aid #10199, DS1996
29. CAS-2022-1075	PHA-2022-0178 Eaton Apothecary #3035, DS89891
30. CAS-2022-1296	PHA-2022-0203 Osco #3577, DS3163
31. CAS-2022-1055	PHA-2022-0176 CVS #582, DS3525
32. CAS-2022-0959	PHA-2022-0160 CVS #2500, DS5606
33. CAS-2022-0522	PHA-2022-0112 CVS #818, DS1403
34. CAS-2022-0414	PHA-2022-0090 CVS #1130, DS1690
35. CAS-2022-0417	PHA-2022-0088 CVS #498, DS3349
36. CAS-2022-0442	PHA-2022-0094 CVS #1250, DS89756
37. CAS-2022-0514	PHA-2022-0110 CVS #524, DS2532
38. CAS-2022-0475	PHA-2022-0099 CVS #365, DS2452
39. CAS-2022-1019	PHA-2022-0172 CVS #1850, DS2089
40. CAS-2022-0958	PHA-2022-0157 CVS #1121, DS2042
41. CAS-2021-1137	PHA-2022-0201 Sabahat Saadat Ahmed, PH26241

Respectfully Submitted, Jennifer Chin, RPh Secretary