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

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

## August 4, 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=e0ee34e2dc482536db53bd372982b1db5

## To access the meeting by phone:

Call in Number: 1-650-479-3208 Access Code: 2539 172 3512

Attendee: #

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

## Agenda

Time	#	Item						
8:00	I	CALL TO ORDER						
8:02	II	APPROVAL OF AGENDA						
8:05	Ш	APPROVAL OF BOARD MINUTES  • Draft of June 2, 2022 Regular Session Minutes						
8:10	IV	<ul> <li>REPORTS</li> <li>Applications approved pursuant to Licensure Policy 13-01</li> <li>Monthly report from Probation</li> <li>Board Delegated Review pursuant to Licensure Policy 14-02</li> <li>PSUD Report-Policy 17-03</li> <li>Research Drug Study report pursuant to Staff Action Policy 18-02</li> </ul>						

8:20	V	<ul> <li>FLEX</li> <li>Pharmacy issues related to COVID-19</li> <li>APhA Institute on Substance Use Disorders Overview</li> <li>NABP Executive Committee District Nominations</li> </ul>	K. Thornell
8:30	VI	<ul> <li>APPLICATIONS</li> <li>Walgreens Central Fill– Request for temporary pharmacy</li> <li>Walmart- Petition for waiver</li> <li>Rite Aid- Petition for waiver</li> <li>Cornerstone Health Solutions (DS90083)- Petition for central fill and pilot project request</li> <li>Steward Employee Pharmacy- New Community Pharmacy</li> <li>New Health Charlestown Pharmacy – New Community Pharmacy</li> <li>UMass Specialty Pharmacy (DS89822)- Renovation-Expansion</li> <li>Upham's Community Care - Pharmacy - New Community Pharmacy</li> </ul>	
10:00	VII	<ul> <li>POLICY         <ul> <li>Policy 2022-06: COVID-19 Therapeutics</li> </ul> </li> <li>Policy 2022-05: COVID-19 Vaccine and EVUSHELD™ Administration by Qualified Pharmacy Personnel</li> <li>Policy 2022-04: Use of Pharmacy Technician Trainees to Stock Automated Dispensing Devices</li> <li>Policy 2020-15: Licensee Scope of Practice</li> <li>Joint Policy 2019-02: Automated Dispensing Device Use</li> <li>Policy 22-xx: Expedited Processing of Reciprocal License Applications in response to disease outbreak or other critical public health concern</li> </ul>	

		FILE 1	REVIEW		
		1	CAS-2021-0685	PHA-2022-0016	Option Care, DS90107
		2	CAS-2021-1271	PHA-2021-0119	Big Y #65, DS3276
		3	CAS-2022-0009	PHA-2022-0004	Walgreens #6072, DS3004
		4	CAS-2021-0975	PHA-2022-0119	Innocent Akani, PH25261
		5	CAS-2021-1140	SA-INV-19031	Edge Pharma, NO00015
		6	CAS-2022-0112	PHA-2022-0013	Wal-Mart #10-2629, DS3508
		7	CAS-2022-0025	PHA-2022-0006	Walgreens #12869, DS89777
		8	CAS-2022-0252	PHA-2022-0038	Walgreens #1855, DS1418
		9	CAS-2022-0253	PHA-2022-0046	Walgreens #13135, DS89732
		10	CAS-2022-0254	PHA-2022-0041	Packard Pharmacy, DS373
		11	CAS-2022-0276	PHA-2022-0050	Eterna Pharmacy, DS90272
		12	CAS-2022-0275	PHA-2022-0052	Leslie's Pharmacy, DS3302
		13	CAS-2022-0335	PHA-2022-0066	Walgreens #10639, DS3570
		14	CAS-2022-0287	PHA-2022-0060	Walgreens #17214, DS90117
10:30	VIII	15	CAS-2022-0443	PHA-2022-0093	Walgreens #7329, DS3362
		16	CAS-2022-0336	SA-INV-19610	Walgreens #17605, DS90237
		17	CAS-2022-0336	PHA-2022-0071	William Collins, PH16711
		18	CAS-2022-0250	PHA-2022-0039	Rite Aid #10074, DS2895
		19	CAS-2022-0415	SA-INV-19753	Cardinal Health 110, WD352
		20	CAS-2022-0301	PHA-2022-0062	CVS #26, DS2912
		21	CAS-2022-0519	PHA-2022-0108	CVS #26, DS2912
		22	CAS-2022-0387	PHA-2022-0078	CVS #672, DS89987
		23	CAS-2022-0240	PHA-2022-0044	CVS #2592, DS3011
		24	CAS-2022-0523	PHA-2022-0113	CVS #2592, DS3011
		25	CAS-2022-0023	PHA-2022-0007	CVS #1855, DS2901
		26	CAS-2022-0195	SA-INV-19398	CVS #382, DS89637
		27	CAS-2022-0238	PHA-2022-0043	CVS #2138, DS2815
		28	CAS-2022-0341	SA-INV-19681	Walgreens #2330, DS1736
		29	CAS-2022-0307	PHA-2022-0061	CVS #705, DS3428
		30	CAS-2022-0280	PHA-2022-0054	CVS #117, DS3207
12:00		LUNCH BREAK			

General Session Agenda August 4, 2022

12:30	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.	
1:00	X	M.G.L. c. 112, § 65C SESSION	
3:30	XI	ADJOURNMENT	

# COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

# MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting August 4, 2022

#### **Board Members Present**

Sebastian Hamilton, Pharm D, MBA, RPh President
Caryn Belisle, RPh, MBA, President-Elect (arrives 8:30 AM)
Carly Jean-Francois, RN, NP Secretary
Julie Lanza, CPhT
Susan Cornacchio, JD, RN (leaves meeting at 3:20 PM)
Jennifer Chin, RPh
John Rocchio, RPh, PharmD (leaves meeting at 3:20 PM)
Sami Ahmed, Pharm.D., RPh, BCPS, BCSCP
Delilah Barnes, RPh
Rita Morelli, PharmD, BCACP, RPh
Katie Thornell, RPh, MBA
Dawn Perry, JD (leaves meeting at 3:10 PM)

#### **Board Members Not Present**

Dr. Richard Lopez, MD

#### **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
Ed Taglieri, MSM, NHA, RPh PSUD Supervisor
Joanna Chow, Office Support Specialist
Taylor Lee, Office Support Specialist
Joanne Trifone, RPh, Director of Investigations
Christina Mogni, RPh, Investigator
Gregory Melton, RPh, Investigator
Julienne Tran, PharmD, Investigator

## **TOPIC I**. Attendance by roll call:

#### **CALL TO ORDER 8:07 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; S. Ahmed, yes; R. Morelli, yes; K. Thornell, yes: D. Perry, yes. (C. Jean-Francois joins meeting 8:30 AM)

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Topic II.

**Approval of Agenda** 

**TIME 8:09 AM** 

Agenda 8/4/22

**DISCUSSION:** 

None.

#### **ACTION:**

Motion by J. Lanza, seconded by J. Chin and voted unanimously by those present to approve the agenda with deferral of New Health Charlestown Pharmacy.

Topic III Approval of Board Minutes

**TIME: 8:10 AM** 

Minutes

1. Draft 6/2/22

Change: Note application #1 change from Walmart to Walgreen

Action:

Motion by S. Ahmed seconded J. Lanza and voted unanimously to approve the regular session minutes of 6/2/22 with noted changes by roll call vote.

TOIC IV Reports
Applications approved pursuant to Licensure Policy 13-01

TIME: 8:11 AM

PRESENTED BY: M. BOTTO

<u>DISCUSSION:</u> 68 Change of Manager applications, two closures, and one relocation were approved via Staff Action pursuant to licensure policy 13-01 since the last Board meeting.

So noted.

Topic IV. REPORTS

**Monthly Report from Probation** 

**TIME: 8:11 AM** 

PRESENTED BY: M. BOTTO

<u>DISCUSSION:</u> M. BOTTO reported 1 successful completion of probation monitoring since the last Board meeting. To date, 10 facilities have successfully completed probation monitoring for the year with 18 active cases.

So noted.

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Topic IV. REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

PRESENTED BY: M. BOTTO

<u>DISCUSSION:</u> M. BOTTO reported 1 CE deficiency that was closed via Staff Action with no disciplinary action warranted. A Cornerstone waiver renewal request has been approved since the last Board meeting.

**TIME: 8:11 AM** 

**TIME: 8:12 AM** 

**TIME: 8:12 AM** 

So noted.

Topic IV. REPORTS

PSUD report by Staff Action 17-03

PRESENTED BY: E. TAGLIERI

<u>DISCUSSION:</u> E. TAGLIERI reported 1 admission to the PSUD program since the last Board meeting.

Currently, there are 13 active participants enrolled in the program.

So noted.

Topic IV. REPORTS

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

PRESENTED BY: M. CHAN, W. FRISCH

<u>DISCUSSION:</u> M. CHAN reported 5 new retail pharmacies participating in studies. To date, there are 19 active studies, 3 of which involve investigational drug substances. A total of 3 new studies have been approved since the last report.

So noted.

TOPIC V Flex

1. Pharmacy Issues Related to Covid-19 and State of Emergency Time: 8:12 AM

Presented by: D. SENCABAUGH

**Discussion:** The exemption to the open meeting law was extended to March 15, 2023, allowing the virtual Board meeting format to continue until then.

So noted.

2. APhA Institute on Substance Use Disorders Overview Time: 8:13 AM

Presented by: K. THORNELL

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**Discussion:** This Utah meeting provided an extensive overview of substance use disorders with attendees from many different health care professionals including pharmacy students.

So noted.

#### 3. NABP Executive Committee District Nominations

Time: 8:16 AM

Presented by: D. SENCABAUGH

**Discussion:** The upcoming NABP District 1 and 2 meeting is coming up and the Board is encouraged to develop resolutions as well as choose a Board-delegate and alternate to vote on the Board's behalf. These will be voted upon at the September Board meeting.

The Executive Committee of NABP has an opening and is seeking applications. Applications are due 9/15/22.

So noted.

#### **TOPIC VI**

#### **Applications**

#### 1. Walgreens Central Fill

**Request for Temporary Pharmacy** 

**TIME: 8:22 AM** 

<u>REPRESENTED BY</u>: Kevin McMurray- Site Director, Matthew Cook- Divisional Vice President, Mike Godek RECUSAL: NONE

<u>DISCUSSION:</u> Walgreens Central Fill addressed concerns that arose during an on-site visit in June. meeting Board approved Central fill Mansfield location in June of 2022. Walgreens Central Fill representatives answered questions Board members had concerning risk the location of the temporary pharmacy.

<u>ACTION:</u> Motion by S. HAMILTON, seconded by S. CORNACCHIO, voted unanimously by those present to approve the phased approach of the temporary pharmacy space with a 6:1 staffing ratio that is subject to change pending monitoring of the space by Board investigators.

#### 2. Walmart Petition to Waive TIME: 9:01 AM

REPRESENTED BY: Jacob Creel- Director, Practice Compliance

**RECUSAL: NONE** 

<u>DISCUSSION:</u> Jacob appeared before the Board expressing concern over stocking Promethazine-codeine in-store and the safety of Walmart's associates. Walmart petitioned restriction of the medication and to recommend alternative products to prescribers. Jacob answered questions Board members had concerning stocking of the medication.

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<u>ACTION:</u> Motion by S. HAMILTON, seconded by S. CORNACCHIO, voted unanimously by those present to defer action on the petition to a later date.

3. Rite Aid Petition to Waive TIME: 9:25 AM

REPRESENTED BY: None present

**RECUSAL: NONE** 

<u>DISCUSSION</u>: A petition for waiver was received to restrict Promethazine-codeine in their facilities, similar to the petition for waivers that was presented by Walmart. No Rite Aid representatives were available at the time of the Board meeting.

<u>ACTION:</u> Motion by S. HAMILTON, seconded by J. CHIN, voted unanimously by those present to defer action on the petition to a later date.

4. Cornerstone Health Solutions (DS90083) Pilot Project Central Fill TIME: 9:35 AM

<u>REPRESENTED BY</u>: Estefania Lewis- MOR, Paul Magno- Director of Outpatient Pharmacy Services, Robert Miranda- Director of Pharmacy Operations

**RECUSAL:** S. HAMILTON

<u>DISCUSSION:</u> Cornerstone representatives proposed a model for a central fill location. The applicant requested two partial waivers:

- 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.
- To waive the requirement to serve Board-licensed retail pharmacies as required by Section IV(A)
  of Policy 2021-02: Shared Pharmacy Service Models Including Central Fill, Remote Processing,
  and Telepharmacy.

Cornerstone representatives also outlined detailed procedures to ensure patient safety and quality.

<u>ACTION:</u> Motion by C. JEAN-FRANCOIS, seconded by R. MORELLI, voted unanimously by those present to approve petition for Central Fill location.

A second motion was made by J. LANZA, seconded by R. MORELLI, voted unanimously by those present to approve the pilot project for 1 year with quality metrics submitted monthly pending approval from HCQ.

A third motion was made by J. LANZA, seconded by C. JEAN-FRANCOIS, voted unanimously by those present to approve submitted partial waivers.

5. Steward Employee Pharmacy New Community Pharmacy TIME: 10:20 AM

REPRESENTED BY: Mark Ferreira- Proposed MOR, Michael Roberts

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**RECUSAL: K. THORNELL** 

<u>DISCUSSION:</u> Steward Employee Pharmacy will be a closed-door pharmacy that will move into an

existing space. They will be utilizing UPS for delivery and tracking of all prescriptions, though employees

are not restricted to mail-in order. Representatives petitioned the following waivers:

1. 247 CMR 9.01 (15): may not limit services

2. 247 CMR 9.01 (16): may not refuse to compound

3. 247 CMR 6.01 (5) (d) (1): consult area w/sign

4. 247 CMR 9.07 (3) (c): Dear patients sign

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

6. 247 CMR 6.02(4): sufficient variety of chemicals necessary to compound

7. 247 CMR 6.02(5): presence of Rx sign

8. 247 CMR 6.02(8)(a), (b), & (c): posting hours

ACTION: Motion by S. HAMILTON, seconded by C. BELISLE, voted unanimously by those present to

approve application as submitted pending a successful inspection. A second motion was made by D.

BARNES, seconded by R. MORELLI, voted unanimously by those present to approve submitted waivers

upon a satisfactory inspection.

6. UMass Specialty Pharmacy (DS89822) Renovation/Expansion

on/Expansion TIME: 10:33 AM

REPRESENTED BY: Harshvina Patel- MOR, Chris Conboy- Director

**RECUSAL:** C. BELISLE

**DISCUSSION:** UMass Specialty Pharmacy presented a request for renovation in order to provide storage

for verified packages that courier service can pick up. The facility is currently located on the 1st floor of

an ambulatory center. Harshvina described the proposed space to the Board's satisfaction.

ACTION: Motion by D. BARNES, seconded by R. MORELLI, voted unanimously by those present to

approve application as submitted pending successful inspection and HCQ approval.

7. Upham Community Care Pharmacy New Community Pharmacy TIME: 10:40 AM

REPRESENTED BY: Marina Rabinovich- Pharmacy Director, Kerry Mitza- Director of Compliance

**RECUSAL: NONE** 

**DISCUSSION:** Representatives of Upham Community Care Pharmacy proposed to expand their scope to

retail in order to expand their services to Dorchester and the surrounding area. Scope of practice

includes a 1:3 staffing ratio that is subject to change in pharmacist staff based on store traffic.

Representatives answered questions Board members had to satisfaction.

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<u>ACTION:</u> Motion by S. HAMILTON, seconded by R. D. BARNES, voted unanimously by those present to approve application as submitted pending successful inspection. The applicant has withdrawn their compounding attestation.

TOPIC VII Policies

1. TOPIC V Policy 2022-06: COVID-19 Therapeutics Time: 10:47 AM

Presented by: M. CHAN

**Discussion:** This policy lists the requirements to prescribe and either dispense or administer medications to treat COVID-19. It also gives specific information on the prescribing of Paxlovid™ as pharmacists are now able to prescribe it in accordance with the updated Emergency Use Authorization (EUA).

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

# 2. Policy is 2022-05: COVID-19 Vaccine and EVUSHELD™ Administration by Qualified Pharmacy Personnel Time: 10:49 AM

Presented by: M. CHAN

**Discussion:** This policy provides an update to the COVID-19 vaccine policy as well as adds instruction for training to administer Evusheld™ for the prevention of COVID.

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

# 3. Policy 2022-04: Use of Pharmacy Technician Trainees to Stock Automated Dispensing Devices Time: 10:50 AM

Presented by: M. CHAN

**Discussion:** In conjunction with the Drug Control Program and the Bureau of Health Care Safety and Quality, this policy was developed to allow pharmacy technician trainees to transport, load, and check expiration dates of Schedule III - VI medications without direct pharmacist supervision in the hospital setting.

**Action:** Motion by C. BELISLE, seconded by S. AHMED, and voted unanimously by roll call by all present to approve the policy.

#### 4. Policy 2020-15: Licensee Scope of Practice Time: 10:58 AM

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Presented by: M. CHAN

**Discussion:** Along with other minor updates, edits were made to be in line with the new pharmacy

technician trainee and therapeutics policies.

**Action:** Motion by J. LANZA, seconded by R. MORELLI, and voted unanimously by roll call by all present to approve updates to the policy.

5. Joint Policy 2019-02: Automated Dispensing Device Use Time: 11:00 AM

Presented by: M. CHAN

Discussion: A minor change was made clarifying that pharmacy technicians may load ADDs with

Schedule III through VI medications.

Action: Motion by J. LANZA, seconded by C. BELISLE, and voted unanimously by roll call by all present to

approve updates to the policy.

6. Policy 22-01: Expedited Processing of Reciprocal License Applications in response to disease outbreak or other critical public health concern

Time: 11:01 AM

Presented by: H. ENGMAN

**Discussion:** This policy will allow Board staff to expedite the processing of reciprocal license applications for pharmacists at the direction of the Commissioner of the Department of Public Health ("Commissioner"), provided the Commissioner determines there are or will be an insufficient number of pharmacists in Massachusetts to properly respond to disease outbreak or other critical public health concern.

**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-2021-0685

PHA-2022-0016 Option Care, DS90107 Time: 11:15 AM

**RECUSAL**: NONE

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

- At the 2/3/2022, the Board voted to elevate SA-INV-18350 to a complaint PHA-2022-0016 specific for allegations of violating staffing ratios.
- On 2/25/2022 a request for additional information including documents to substantiate compliance was made.

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- On 3/22/2022 The Pharmacy reaffirmed that they calculate ratio by including all licensed Pharmacists and Technicians in the building, both licensed and unlicensed space, and that they could provide documents to show compliance, but no documents were provided.
- On 3/29/2022 documents were collected from the Pharmacy during a Retail Compliance (ISP-18111) and 797 Compliance (ISP-18112) inspection including Technician payroll punches and RPh payroll documents.
- Review of technician punches and the staffing schedule provided in the 11/4/2021 response identified multiple technicians arriving earlier than their scheduled times, and/or not identified on schedule.
   RPh payroll information did not show arrival time. On 5/6/2022, the Pharmacy provided response to investigator requests stating that their security system purges data after 120 days therefore not allowing ability to truly determine compliance. If the Pharmacy had provided this data with the original request in their 11/4/2021 response, it is very likely that a true determination of compliance/non-compliance would have been made.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0016), 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 #2/CAS-2021-1271

PHA-2021-0119 Big Y #65, DS3276 Time: 11:18 AM

**RECUSAL: NONE** 

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

- During a retail compliance inspection (ISP-17563) on 12/17/2021, it was observed that PTT Mortali was working with an expired license and immunizing patients and Pharmacist McCarrick was unable to provide proof of immunization training.
- MOR Martucci noted that PTT Mortali accumulated 500 hours as a PTT on 2/5/2021, took and passed the board approved exam on their internal computer-based training system on March 5, 2021. At that point, PTT Mortali was eligible to submit a pharmacy technician application but failed to do so because they were working during the pandemic.
- As a result, PTT Mortali immediately gathered and completed a PT application and submitted it on December 19, 2021. Her duties were limited to the pharmacy cashier until the license was issued. On January 17, 2022, PTT Mortali received her pharmacy technician license.
- Senior Manager Pharmacy Services and Regulatory Affairs, George Pappas noted that there was a staffing shortage. Additionally, he indicated that the internal audits conducted by the Asset Protection was paused because of the pandemic. As a result, the license checks did not occur and the last audit conducted at the Walpole location was completed on March 10, 2020, with no licensing issues noted. A dispensing report for vaccinations administered by PTT Mortali showed she administered a total of 51 vaccinations during the time frame of 09/03/2021 to 12/13/2021, including 25 COVID-19, 15 influenza, and 1 shingles vaccine.
- Pharmacist McCarrick provided documentation from NUE titled "Adult Immunization Training Program" with a completion date of September 18, 2011, stating that 2.0 CEUs (20 CE credits) were posted to NABP's CPE monitor. However, the NEU documentation does not have Pharmacy McCarrick's name on it

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- Corrective Actions: include complete audit of all vaccinating technicians, company subscribes to a service that tracks license status as well as exclusions from federal programs, and a routine reporting for 30-, 60- and 90-day notice of an upcoming license expirations.
- MOR Martucci attested that he read Board Policy 2020-12: Vaccine Administration by Qualified Pharmacy Technicians.

<u>ACTION</u>: Motion by J. CHIN, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2021-0119), 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-2022-0009

PHA-2022-0004 Walgreens #6072, DS3004 Time: 11:22 AM

**RECUSAL: NONE** 

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

- On January 3, 2022, OPP Investigator Geaney conducted a retail compliance inspection (ISP-17632) and observed )that former MOR Tranter was still listed as the MOR even though he is no longer working for Walgreens and the failure to conduct weekly perpetual inventory since November 2021.
- Additionally, MOR Mahmoud started February 1, 2022, as a MOR but there was no change in the MOR application filed with the Board.
- MOR Mahmoud indicated that she became the MOR of this Pharmacy effective February 1, 2022, and signed and attested to having completed a full controlled substance inventory upon acceptance of the position.
- Healthcare Supervisor McMurray indicated that Former MOR Tranter was moved to a different location, and he has been unable to fill the MOR role at the Pharmacy until 2/1/2022.
- As of this report, an application for a Change in Manager for the Pharmacy for MOR Mahmoud has not been submitted to the Board.
- MOR Mahmoud indicated that if she were to transition to another location, she would be committed
  to completing an exit inventory along with working with the current District Manager on an MOR
  replacement strategy.

<u>ACTION</u>: Motion by D. BARNES, seconded by K. THORNELL, and voted unanimously by those present, to REFER the matter (PHA-2022-0004), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #4/CAS-2021-0975

PHA-2022-0119 Innocent Akani, PH25261 Time: 11:25 AM

**RECUSAL: NONE** 

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

- BORP was notified by the National Association of Boards of Pharmacy (NABP) Clearinghouse that Pharmacist Akani was disciplined by the Texas Board of Pharmacy (TXBOP) in 2018.
- Pharmacist Akani entered into an Agreed Board Order with the TXBOP effective August 7, 2018, based on allegations that while acting as a pharmacist-in-charge and sole managing officer of a pharmacy in

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- Houston, TX, he dispensed approximately 2,700 invalid prescriptions for controlled substances and approximately 1,900 invalid prescriptions for dangerous drugs and over-the-counter available products that were not issued for a legitimate medical purpose by a practitioner.
- TXBOP imposed a sixty-day suspension followed by a five-year probation and prohibited Pharmacist Akani from serving as a pharmacist-in-charge or holding an ownership interest in any pharmacy for the duration of the order.
- On April 22, 2021, Pharmacist Akani petitioned the TXBOP to modify the terms of the original Agreed Board Order to terminate the restriction that he shall not serve as a pharmacist-in-charge of any pharmacy during the duration of the Order. The restriction was terminated effective August 3, 2021, and the Probation is currently in effect.
- In his statement, Pharmacist Akani indicated that a DEA agent visited him in 2017 regarding prescriptions written by a prescriber. According to the DEA agent, the prescriber's credentials were used, under a false pretense by the clinic owners, to obtain prescription pads without her consent. He also, noted that the revised Order with the TXBOP allows him to work and support his family.
- On June 8, 2022, Pharmacist Akani provided a response to the complaint indicating he does not have any additional information to provide.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2022-0119), 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 to align with the Texas Board of Pharmacy probation due to end 08/17/2023.

Time: 11:28 AM

Case #5/CAS-2021-1140

SA-INV-19031 Edge Pharma,NO00015

**RECUSAL: NONE** 

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

- Self-report from Edge Pharma of a CA Settlement Order for probation from 10/26/2021 through 10/26/2025 for 21 CFR violations of cGMPs for outsourcing facilities observed during an inspection conducted 8/3/21-8/5/21 by CA Inspectors with repeat issues cited. From 7/31/20-8/30/21, the CA BOP had conducted 9 investigations of Edge Pharma for non-compliance. Additionally, the FDA issued a 483 from an inspection conducted 3/4/20-3/30/20. A C&D Order was issued on 8/6/21 which stated, "Edge Pharma LLC has failed to remedy these areas of non-compliance despite having adequate opportunities to do so". Violations included inappropriate BUDs, inadequate shipping validations, USP 788/789 testing not performed for all applicable products, continuous non-viable monitoring not fully implemented, inadequate pest control, out of specification pressure differentials, stability indicating test methods not fully validated for many APIs, inadequate cleaning validation, and refrigeration units and dishwasher not adequately maintained and fully validated.
- On 12/7/21, a recall was posted on the FDA stating, "Edge Pharma, LLC is voluntarily recalling all lots of all drugs compounded by Edge Pharma, LLC to the consumer level. All products are being recalled due to process issues that could lead to lack of sterility assurance for products intended to be sterile and could impact the safety and quality of non-sterile products".
- The response submitted by Edge Pharma included the Inspection Report with Written Notice with the detailed violations. According to documentation submitted, over 93,000 units of sterile and non-sterile compounds were shipped into MA in 2020 and 2021. President Chatoff addressed each of the

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- violations. SOPs and documents showing compliance with the terms of the CA probation were provided.
- Edge Pharma has ceased shipping allergen extracts to CA. Quality control testing and specification
  review will be added to the Annual Product Review to ensure USP monograph testing updates are
  applied in a timely manner. SOP "HPLC Method Validation" was updated. A "New FID Checklist" form
  was created which generated a process by which the QA Department can ensure compliance with all
  relative SOPs and check that all new FIDs have valid potency methods developed. President Chatoff
  completed 14.25 CEs for remediation and the Edge Allergy Department Manager Morina completed
  15 CEs for remediation.
- On 6/3/22, the BORP received notification of the closure of Edge Pharma effective 5/27/2022.

<u>ACTION</u>: Motion by K. THORNELL, seconded by R. MORELLI, and voted unanimously by those present, to CLOSE the matter (SA-INV-19031), No Discipline Warranted.

Case #6/CAS-2022-0112

PHA-2022-0013 Wal-Mart #10-2629, DS3508 Time: 11:29 AM

**RECUSAL: NONE** 

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

- Inspectional deficiency cited on 1/27/22 for 2 epinephrine auto-injectors stored in a caddy in an unsecured temporary immunization area outside of the pharmacy. Additionally, a Sharps container was observed on a table in the same area. Investigator Seed noted this noted on the previous inspection conducted on 7/19/21.
- In the POC, MOR Lopriore stated all team members were retrained on the policy of bringing the caddy with supplies back to the Pharmacy with each immunization. The pharmacist on duty will be monitoring and enforcing the policy and all immunizing staff are responsible for following the policy.
- MOR Lopriore responded that on the day of the inspection, a patient stated that he would be coming
  in immediately for his vaccine and the immunizer did not bring the caddy back to the Pharmacy after
  the immunization. MOR Lopriore stated this was against policy. MOR Lopriore clarified the observed
  immunization area is not temporary area but is the permanent on-site vaccination area with portable
  privacy panels.
- CPhT Eckles was the immunizer and provided a response. CPhT Eckles didn't intentionally leave the caddy unattended, and she had a view of it from the drop-off window the entire time. In the future, it will be brought whenever an immunizer isn't in the immunization area. Pharmacist Shyllberg was the pharmacist on duty during the inspection and acknowledged it was her responsibility to ensure all protocols were followed.
- Per the POC, MOR Lopriore indicated the staff was retrained. A statement signed and dated by the
  immunizing Pharmacy staff was submitted which stated they reviewed the security and immunizing
  policies POM 902 and POM 1014 (copy provided) describing Wal-Mart's required process for
  administering an immunization and where prescription products are stored.

<u>ACTION</u>: Motion by J. CHIN, seconded by S.AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0013), 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-2022-0025

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PHA-2022-0006 Walgreens #12869, DS89777

**RECUSAL: NONE** 

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

Inspectional deficiencies for inspection (ISP-17675) on 1/6/22 for missing signage; Former MOR Shea's (MOR on file) last day on 11/5/21; 400-600 RTS vials; 100of 160 CIIs not reconciled in last 10 days (many not since 11/21/21; cleanliness; unlabeled vials on shelve; overstocked refrigerator; and incomplete compounding records. Additional observations noted included an intern processing 2 boxes of VARs.

Time: 11:33 AM

- POC stated signage was ordered 2/9/22; change of MOR paperwork was completed 11/16/2021 but
  not received by BORP so a new application was completed on 01/25/2022; Current MOR Raposo
  working to ensure adequate staffing for improved operations; cleaning schedules created; unlabeled
  medications were quarantined and properly discarded; refrigerator re-organized; and missing
  compounding records located. Supporting documentation and photos were included.
- Challenges due to COVID and staffing contributed to the deficiencies. CII counts were performed with
  discrepancies resolved. No significant losses to report. SOPs were not followed due to prioritizing
  direct patient care. The overstocked refrigerator was due to inventory counts using the incorrect units
  or products were marked as out of stock leading to auto-generated orders based on incorrect
  information.
- Change of MOR paperwork and tracking will be kept on file in the Pharmacy; MOR signage was posted; SOPs and processes for cited deficiencies were reviewed with the staff. Signed and dated copies of requested policies and procedures were submitted confirming review. Repeat deficiencies were cited on 3/11/22 for inspection (ISP-17969) for lock box signage and the overstocked refrigerator.

<u>ACTION</u>: Motion by C. JEAN-FRANCOIS, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0006), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #8/CAS-2022-0252

PHA-2022-0038 Walgreens #1855, DS1418 Time: 11:36 AM

**RECUSAL: NONE** 

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

- Inspectional deficiencies for no MOR and CPhT Tauson working with an expired PTT license ( 5/17/2020). MOR Abdulky was MOR 12/17/2021 to 1/8/2022. DM Cantella assumed Pharmacist LaFreniere became the Interim MOR, but Pharmacist LaFreniere maintained he was not named nor accepted the role as Interim MOR which DM Cantella acknowledged.
- Pharmacist LaFreniere stated he is a staff pharmacist who worked with floaters during MOR Abdulky's absence from 1/8/2022-3/24/2022. He maintained the daily operations with the support of the technicians and Store Manager, CPhT Tauson. DM Cantella stated he rehired MOR Abdulky on 3/24/2022 with a start date as MOR of 3/28/2022. A change of MOR application was received 4/4/2022.

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- CPhT Tauson requested and received extensions of his PTT license through May 2020 then misunderstood the emergency extensions of licenses posted on the mass.gov website. He believed his license would be active until 6/30/2022. He also thought he had submitted an application for his PT license in October 2021 but never followed up. Up until becoming the Store Manager in August 2019, he had worked daily in the Pharmacy then he began working 10-12 hours per week. His duties as a PTT included requesting and accepting new/refill prescriptions, data entry, retrieving stock bottles for a prescription and affixing labels to the prescription containers. DM Cantella stated it is the responsibility of each person to ensure their license is active. Additionally, the MOR and Store Manager are to verify active licensure monthly which is reviewed by the DM.
- DM Cantella will ensure compliance when there is a change of MOR in his area. Licenses will be reviewed during the first 3 days each month and at the DM touchpoint meetings. CPhT Tauson submitted a PT license which was issued 3/17/2022.

<u>ACTION</u>: Motion by S, AHMED, seconded by K.THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0038), 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-2022-0253

PHA-2022-0046 Walgreens #13135, DS89732 Time: 11:41 AM

**RECUSAL**: NONE

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

- RLCS for 60 various CIII-CVs on 12/17/21 when Clean Earth removed all expired/damaged drugs
  including CSs along with the hazardous waste. Floater Pharmacist Ochigbo was newly hired working
  his first or second day after training. PT Pocius and PT Meehan had instructed Clean Earth to only take
  the hazardous gray bins but disposed of the contents of all totes and bins. Contributing factors to the
  losses were the expired CIII-CVs were not immediately processed for reverse distribution after being
  pulled and staff were unaware of the proper protocols for hazardous disposal and supervision of
  unauthorized personnel.
- APM Borosavage was notified of the losses on 1/21/22 and video was reviewed confirming the actions of the staff and the Clean Earth employees. MOR Rezendes reviewed on-hand inventories, invoices, cycle counts, biennial inventory, staffing schedules and inventory reports from the last CIII-CV inventory on 06/10/2021. On 01/12/2022, a CIII-CV inventory was conducted after hours, and an audit of CIII-CVs was performed to determine the losses. All other policies and procedures pertaining to controlled substance ordering, receiving, accountability and management were followed.
   Statements were provided by Floater Pharmacist, PT Pocius, and PT Meehan which related the actions viewed on video.
- Floater Pharmacist Ochigbo and Pharmacy staff were retrained on the procedures for proper hazardous waste disposal, proper reverse distribution, and the supervision of all unauthorized personnel. Pharmacy staff were instructed to ensure any expired medications are returned immediately to the wholesaler according to Walgreen's policies. CII-CVs must be quarantined in a locked safe/cabinet, expired/damaged medications are to be pulled monthly and processed for return.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0046), No Discipline Warranted, Remediation Complete.

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Case #10/CAS-2022-0254 PHA-2022-0041

Packard Pharmacy, DS373

**RECUSAL: NONE** 

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

Time: 11:44 AM

- Inspectional deficiencies 3/2/22 for failure to reconcile the perpetual inventory, refrigerator temperature excursions and re-packaging 8 OTCs for re-sale. On 3/9/22, MOR Desmet agreed to immediately cease re-packaging OTCs.
- Attorney Lanton contended that the Pharmacy submitted a POC and was unable to show a good faith
  effort to comply with Investigator Murray's cited deficiencies through a re-inspection to verify
  compliance. He stated the Pharmacy was unaware that re-packaging OTCs for sale is a function of a
  wholesaler only.
- MOR Desmet stated that understaffing and the overwhelming demands from COVID contributed to the failure to reconcile the perpetual from 11/10/2021-2/5/22. She contended that although she continued to record temperatures 32°F or below from 10/1/21-1129/21, product was not frozen, the refrigerator was never out of range and the digital data-logger was inaccurate as confirmed on 10/1/21.
- MOR Desmet contended the Pharmacy had re-packaged OTCs since 1983, the Pharmacy was open concerning the practice, and it was observed during past inspections with assurances that it was fine. MOR Desmet stated, "These prepacks that we did were in full view during every single inspection and were commented on frequently by the inspectors. At no time did the inspectors find any problem with what we were doing up until the inspection on 3/2/22". When directed to cease the practice, MOR Desmet pulled all items off the shelves and ceased selling them.
- The reconciliation of the perpetual inventory was added into the weekly schedule on Saturdays which MOR Desmet confirms as completed on Mondays. A new insulin refrigerator with ddl were purchased. Pharmacy staff provided signed and dated statements confirming review of all P&Ps related to controlled substances, the proper storage of refrigerated products and handling temperature excursions.

<u>ACTION</u>: Motion by J. CHIN, seconded by K. THORNELL, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0041), No Discipline Warranted, Remediation Complete.

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Case #11/CAS-2022-0276

PHA-2022-0050 Eterna Pharmacy, DS90272 Time: 11:47 AM

**RECUSAL: NONE** 

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

• Inspectional deficiencies on 3/9/2022 for CPhT Melo working without a MA PT license and PTT (Santos) Costa working with an expired license (7/3/2021). In the POC, MOR Chung stated both individuals were immediately removed from PT duties.

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- MOR Chung stated CPhT Melo submitted a PT application when she was began working in March 2021, but it was not followed up on. MOR Chung indicated both he and the former MOR should have checked all Pharmacy staff had active licenses.
- CPhT Melo stated her initial application was lost but since obtained her PT license (3/23/2022). PTT
   (Santos) Costa failed to request a PTT license extension. She stated she had acquired the number of
   hours and one-year experience to obtain her PT but felt there were aspects of her duties that needed
   improvement to acquire proficiency. PTT (Santos) Costa also didn't recall getting an email reminder or
   letter for an upcoming expired license. From 6/24/2020 to 4/8/2022, PTT (Santos) Costa worked
   3,507.54 hours.
- To prevent future license lapses, the Pharmacy has subscribed to PRS Compliance and Credentialing services to maintain and alert of upcoming expiring licenses. License checks are included with the perpetual inventory tasks. CPhT Melo stated, "I have made sure the Board of Pharmacy has my correct email address for correspondence and have set a reminder notification for myself for one month prior to my Pharmacy Technician License expiration on 07/16/2024". PTT (Santos) Costa indicated she updated her email address with the BORP and received an extension for her PTT license to 6/30/2022.

<u>ACTION</u>: Motion by D.BARNES, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0050), 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.

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Case #12/CAS-2022-0275

PHA-2022-0052 Leslie's Pharmacy, DS3302 Time: 11:51 AM

**RECUSAL: NONE** 

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

- DEA notified BORP on March 9, 2022, that the Leslie's Pharmacy entered into a MOA to resolve violations of federal regulations involving the failure to maintain complete and accurate recordkeeping and the failure properly secure federally scheduled controlled substances cited during an inspection. Specifically, DEA audited the pharmacy's Schedule II-V controlled substance records for the period from May 31, 2021, to November 16, 2021.
- During the audit, DEA determined that "inaccurate recordkeeping revealed significant discrepancies with Amphetamine 20 mg with an overage at 0.50%, Amphetamine 30 mg with an overage at 1.92%, Hydrocodone 10/325 mg with an overage of 1.66%, Clonazepam 1 mg with a shortage at -0.48%, Alprazolam I mg with a shortage at -11% and Diazepam 10 mg with an overage at 0.48%."
   Significantly, DEA attributed the discrepancies to "Leslie Pharmacy's Rx Que computerized system not coinciding with Parata Max, the pill dispensing machine."
- In addition, DEA discovered that "expired [federally scheduled controlled substances] awaiting destruction were stored on a shelf inside an office rather in the controlled substance cabinet."
- The violations described above were also violations of BORP regulations requiring pharmacies to follow federal regulations and maintain security of prescription drugs in the pharmacy. In addition, Leslie's Pharmacy failed to notify BORP about entering into the MOA with DEA as required by BORP regulations.

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- As part of the MOA, Leslie's Pharmacy admitted that the facts described above were true and correct and agreed to the following terms and conditions for a period of three years effective January 28, 2022:
- Maintain accurate and complete records even when its computerized system is down. Data in the main computer system must correspond to the dispensing machine and have controlled drugs taken out to alleviate counting issues. This inventory must be sent to DEA every six months. Expired drugs must be locked in the controlled substance cabinet segregated from the other controls. Allow DEA personnel to enter the registered location at any time and for unannounced random inspections during regular business hours without a warrant or other means of entry. Maintain all copies of all controlled substance records for a period of three years, from the effective date of the MOA, which will be available to DEA for inspection. Abide by all federal, state, and local statutes and regulations relating to controlled substances.
- CA: Controlled substances were removed from the Parata automated dispensing machine to eliminate any inaccuracies caused by the machine in recordkeeping. An inventory will be kept on a 6-month basis of all schedules 3-6 medications, as well as schedule 2 perpetual inventory. Control substances awaiting reverse distribution would be stored in the locked controlled substance cabinet, labeled as expired and segregate. Additional security cameras were installed "in strategic spots to cover the pharmacy area for added security" upon review and approval by DEA. Applicable pharmacy staff were notified that any nonroutine notices, correspondence, and disciplinary actions must be reported to BORP within seven business days of receipt.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by K, THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0052), 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 to align with the DEA MOA scheduled to end 01/28/2025.

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Case #13/CAS-2022-0335

PHA-2022-0066 Walgreens #10639, DS3570 Time: 11:57 AM

**RECUSAL: NONE** 

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

- On March 22, 2022, Investigator Seed conducted a retail compliance inspection (ISP-18054) at WAG 10639. During the inspection, Investigator Seed discovered that the pharmacy failed to appoint a new MOR or Interim MOR after the former MOR left on February 18, 2022. In addition, the outgoing MOR failed to complete a reconciliation of Schedule II-V controlled substances as required under 247 CMR 6.03(1)(a).
- Walgreens Area 36 Healthcare Supervisor Susan A. DeLeo responded on behalf of the pharmacy.
   Supervisor DeLeo acknowledged that WAG 10639 failed to submit a change in MOR application within
   30 days of a change in MOR and failed to complete a Schedule II-V reconciliation at the time the
   outgoing MOR left. She explained that WAG 10639 planned to appoint former MOR Vishesh Patel as
   Interim MOR until a new MOR was identified. However, former MOR Patel was unable to continue
   working for WAG 10639 due to conflict of interest with his new employer. This left WAG 10639
   without a MOR or Interim MOR. Supervisor DeLeo next explained that the district manager for WAG

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10639 "was unaware that we no longer had the 30-day time frame to replace the MOR and that is why it did not happen immediately."

 CA: Supervisor DeLeo indicated that the district manager was "made aware of all of the changes and will now follow the correct timeline regarding the replacement of a MOR, either interim or permanent."

<u>ACTION</u>: Motion by S. HAMILTON, seconded by D. PERRY, and voted unanimously by those present, to refer the matter (PHA-2022-0066), 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.

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Case #14/CAS-2022-0287

PHA-2022-0060 Walgreens #17214, DS90117 Time: 12:00 PM

**RECUSAL: NONE** 

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

- On or about March 14, 2022, BORP was notified by PTT Marlene Moniz that she performed technician duties prior to licensure as a PTT on February 14, 2022, since she was hired by WAG 17214 in March 2021. PTT Moniz explained that she was allowed to practice as a PTT without a license while her license application was held up by administrative issues.
- BHPL Investigator Stephen Horn then contacted WAG District Manager (DM) McGrath on or about March 22, 2022, who indicated that PTT Moniz had been working parttime at WAG 17214 for approximately one year. DM then indicated that PTT Moniz worked mostly as a cashier but acknowledged that she performed pharmacy technician duties during the year prior to PTT licensure.
- Investigator Horn contacted Former MOR Kohut on or about March 22, 2022, who explained that she rreferealized PTT Moniz was not licensed as a PTT shortly before relocating to a WAG in Ohio, so she had PTT Moniz apply for licensure. Former MOR Kohut also indicated that PTT Moniz worked mostly as a cashier but acknowledged that she performed pharmacy technician duties during the year prior to PTT licensure.
- Current MOR Cabral explained that PTT Moniz was licensed when she assumed MOR duties on March
  1, 2022. Current MOR Cabral reported that PTT Moniz was hired in March 2021 and PTT Moniz's lack
  of licensure was discovered during a "BOP audit." According to Current MOR Cabral, Former MOR
  Kohut believed that PTT Moniz was authorized to work for one year before she was required to obtain
  licensure as a PTT.
- CA: Current MOR Cabral indicated that all new hires for pharmacy technicians will receive an
  application for PTT licensure with instructions about the licensure process. Importantly, new hires will
  not start until issuance of a PTT license. Current MOR Cabral also explained that she uses Walgreens
  corporate license maintenance system to validate licensure status on a weekly basis. MOR further
  wrote, "I also have all employee licenses' expiration dates documented on a calendar located in the
  pharmacy as a backup."

<u>ACTION</u>: Motion by D. BARNES, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0060), 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.

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Case #15/CAS-2022-0443 PHA-2022-0093

Walgreens #7329, DS3362

**RECUSAL: NONE** 

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

During a retail compliance inspection on April 15, 2022, PTT Jesse Stodder, IV was observed
performing PTT duties with a license that expired on 09/15/2021. At that time of the inspection, WAG
7329 was notified that PTT Stodder cannot perform any PTT duties due to his expired license. A plan
of correction (POC) was issued.

Time: 12:04 PM

- In a POC submitted by MOR Sargent she indicated that PTT Stodder would apply for licensure as a pharmacy technician and would not perform technician duties until properly licensed. MOR Sargent also indicated that she would "monitor registrations and expiration date[s] to ensure compliance."
- In response to this complaint, MOR Sargent described that PTT Stodder was responding to a call for help from the pharmacy because "more than 3 people were in line at the pharmacy to be rung up and needed assistance." PTT Stodder was attending to cashier duties when he observed that a patient's prescription needed to be filled.
- MOR Sargent described that PTT Stodder believed his license was in good standing due to the DPH's deferral on expiration of BHPL licenses ordered as part of the COVID-19 State of Emergency. Thus, he proceeded to fill the prescription then handed the prescription off to the pharmacist on duty for verification. He observed that the pharmacist on duty was preoccupied with the Investigator's inspection "so with good intent he was being helpful and proceeded to fill printed prescriptions." MOR Sargent indicated that PTT Stodder immediately ceased performing technician duties as soon as the Investigator notified WAG 7329 about PTT Stodder's expired license during the inspection.
- The following additional corrective action was implemented in response to this complaint: Going forward, MOR Sargent that she would include front store employees who may respond to calls for help from the pharmacy in the monthly license audits she currently conducts. She will then ensure that that staff without proper licensure would "only perform the duties of a pharmacy cashier." MOR Sargent added that PTT Stodder planned to enroll in Walgreens' national certification course for pharmacy technicians in the future and apply for licensure as a pharmacy technician after completion of the course.

<u>ACTION</u>: Motion by S. AHMED, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2022-0093), 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-2022-0336

SA-INV-19610 Walgreens #17605, DS90237 Time: 12:08 PM

**RECUSAL: NONE** 

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

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- During a RCI on March 23, 2022, it was observed that MOR Collins left a needle in the septum of a multidose COVID-19 vaccine vial to facilitate withdrawal of multiple doses of vaccine for administration. The practice was stopped after the Investigator intervened.
- Seven vials of expired Moderna COVID-19 vaccine (exp. 2/8/22) were observed stored in the refrigerator . A household refrigerator to store refrigerated prescriptions drugs and vaccines was also observed. As a result, a POC was issued.
- MOR Collins submitted a POC which indicated that pharmacy staff attested to have read and
  understood Walgreens corporate policy and CDC's preparation and administration summary for the
  Moderna COVID 19 vaccine. MOR Collin indicated that he would follow corporate and CDC policy on
  COVID 19 vaccines going forward.
- MOR Collins confirmed that no patients were administered the expired COVID-19 vaccine. He
  explained that expirations dates for medications were checked monthly and expired medications were
  disposed of according to Walgreens corporate policy. MOR Collins then indicated that staff pull any
  expired medications on a nightly basis going forward. MOR Collins confirmed that a new refrigerator
  was ordered.
- In response to the complaint MOR Collins acknowledged that the practice of leaving a needle in the septum of a vaccine vial to draw multiple doses was not SOP at the pharmacy and the practice stopped at WAG 17605.
- MOR Collins next indicated that expired Covid-19 vials were not stored with active inventory after
  February 8, 2022. He provided a list of patients who received Moderna Covid-19 vaccine from
  February 8, 2022, through March 30, 2022, which confirmed that no patients were administered the
  expired COVID-19 vaccine. MOR Collins then indicated that a new commercial refrigerator was
  purchased and installed on or about April 6, 2022. He added that no temperature excursions occurred
  while the household refrigerator observed during the inspection on March 23, 2022, was in service.
- CA: MOR Collins added that a sign would be posted in the pharmacy as a visual cue prohibiting the
  practice of leaving a needle in the septum of a vial. All staff were retrained on proper disposal of
  expired medications.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to CLOSE the matter (SA-INV-19610), No Discipline Warranted, Remediation Complete.

Case #17/CAS-2022-0336

PHA-2022-0071 William Collins, PH16711 Time: 12:12 PM

**RECUSAL: NONE** 

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

- During a RCI on March 23, 2022, it was observed that MOR Collins left a needle in the septum of a multidose COVID-19 vaccine vial to facilitate withdrawal of multiple doses of vaccine for administration. The practice was stopped after the Investigator intervened.
- Seven vials of expired Moderna COVID-19 vaccine (exp. 2/8/22) were observed stored in the refrigerator . A household refrigerator to store refrigerated prescriptions drugs and vaccines was also observed. As a result, a POC was issued.
- MOR Collins submitted a POC which indicated that pharmacy staff attested to have read and understood Walgreens corporate policy and CDC's preparation and administration summary for the

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- Moderna COVID 19 vaccine. MOR Collin indicated that he would follow corporate and CDC policy on COVID 19 vaccines going forward.
- MOR Collins confirmed that no patients were administered the expired COVID-19 vaccine. He
  explained that expirations dates for medications were checked monthly and expired medications were
  disposed of according to Walgreens corporate policy. MOR Collins then indicated that staff pull any
  expired medications on a nightly basis going forward. MOR Collins confirmed that a new refrigerator
  was ordered.
- In response to the complaint MOR Collins acknowledged that the practice of leaving a needle in the septum of a vaccine vial to draw multiple doses was not SOP at the pharmacy and the practice stopped at WAG 17605.
- MOR Collins next indicated that expired Covid-19 vials were not stored with active inventory after
  February 8, 2022. He provided a list of patients who received Moderna Covid-19 vaccine from
  February 8, 2022, through March 30, 2022, which confirmed that no patients were administered the
  expired COVID-19 vaccine. MOR Collins then indicated that a new commercial refrigerator was
  purchased and installed on or about April 6, 2022. He added that no temperature excursions occurred
  while the household refrigerator observed during the inspection on March 23, 2022, was in service.
- CA: MOR Collins added that a sign would be posted in the pharmacy as a visual cue prohibiting the
  practice of leaving a needle in the septum of a vial. All staff were retrained on proper disposal of
  expired medications.

<u>ACTION</u>: Motion by K. THORNELL, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2022-0071), 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-2022-0250

PHA-2022-0039 Rite Aid #10074, DS2895 Time: 12:13 PM

**RECUSAL: NONE** 

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

- On December March 1, 2022, Investigator Michael Brosnan conducted a retail compliance inspection at Rite Aid 10074. During the inspection, Investigator Brosnan observed an unlicensed staff member, "Nicole Pera[t]ta," performing duties in the pharmacy which required licensure as a pharmacy technician or pharmacy. At that time, Investigator Brosnan advised MOR Pierre Kocjan that "Ms. Pera[t]ta cannot perform any technician duty until at least a Pharmacy Technician Trainee license has been obtained (i.e. ring register only)" and issued a plan of correction (POC). MOR Kocjan submitted a plan of POC as requested.
- MOR Kocjan acknowledged in his complaint that Ms. Peratta was performing pharmacy technician
  duties without a license during the retail inspection on March 1, 2022. He explained that Ms. Perrata
  was enrolled in Rite Aid's Pharmacy Technician University, and he mistakenly believed that staff
  members were authorized to perform technician duties upon enrollment in the program. He also
  acknowledged now understanding that staff members must be licensed by BORP as a technician or
  technician trainee in accordance with 247 CMR 8.00 prior to performing any technician duties.
- In addition, MOR Kocjan divulged after further inquiry that PTT Christie Earley also performed PTT duties without a license prior to the March 1, 2022, inspection. MOR Kocjan explained that PTT Earley was also enrolled in Rite Aid's Pharmacy Technician University prior to the inspection on March 1,

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- 2022. He reiterated that he mistakenly believed that staff members were authorized to perform technician duties upon enrollment in the program as he did with Ms. Peratta. MOR Kocjan provided a current roster of staff members in the pharmacy and no further issues with unlicensed practice were identified.
- CA: MOR Kocjan indicated in his POC and response to this complaint that he implemented that following corrective action mitigate recurrence of a similar violation. He described that that he immediately ceased the practice of allowing staff including Ms. Peratta to perform technician duties without licensure as a technician or technician trainee after Investigator Brosnan's advisement during the inspection on March 1, 2022. MOR Kocjan reiterated that Ms. Peratta obtained a technician trainee license shortly after the inspection. MOR Kocjan then explained that he would check licensure status of staff members on a monthly basis and ensure that newly hired technicians were properly licensed before allowing new hires to perform technician duties.

<u>ACTION</u>: Motion by J. CHIN, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2022-0039), 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 #19/CAS-2022-0415

SA-INV-19753 Cardinal Health 110, WD352 Time: 12:16 PM

**RECUSAL: NONE** 

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

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

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<u>ACTION</u>: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (SA-INV-19753), 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-2022-0301

PHA-2022-0062 CVS #26, DS2912 Time: 12:20 PM

<u>RECUSAL</u>: S. CORNACCHIO and J. ROCCHIO 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.

- On March 25, 2022, CVS 26 submitted a final BORP Report of Loss of Controlled Substances (RLCS),
  DEA Form 106 Report of Theft or Loss of Controlled Substances (DEA 106), and supplemental
  information required by BORP Policy 2018-05 for an unknown loss. According to CVS 26, an unknown
  loss of 844 lorazepam 0.5mg tablets was discovered by CVS Health's corporate controlled substance
  monitoring program on December 9, 2021. A reason for the loss was unable to be determined after
  completion of an internal investigation including review of surveillance video.
- CVS 26 indicated that the following corrective action was implemented to mitigate recurrence of a similar incident, "All Loss Prevention policy and procedures will be reviewed with the Pharmacy Team to prevent future losses. This includes diligent inventory management and dispensing standards." CVS 26 had no further information to provide in response to the complaint.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by R. MORELLI, and voted unanimously by those present, to consolidate the matter (PHA-2022-0062), with PHA-2022-0108 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 to include all Benzodiazepines.

Case #21/CAS-2022-0519

PHA-2022-0108

CVS #26, DS2912

Time: 12:21 PM

<u>RECUSAL</u>: S. CORNACCHIO and J. ROCCHIO 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.

- On April 28, 2022, Investigator Geaney conducted a retail compliance inspection and observed that PTT Janeiro was performing PTT duties with an expired PTT license. As a result, Investigator Geaney issued a POC
- CVS 26 confirmed in the POC that PTT Janeiro was later granted an extension of her PTT license expiration date to May 2, 2023. CVS 26 then explained that "notice has gone to entire staff to ensure licensing standards are being upheld and are current. All pharmacy staff have been notified to monitor their license and ensure the necessary steps are taken prior to expiration."
- Current MOR Dumond explained in the pharmacy's response to the complaint that PTT Janeiro was "a
  front store clerk, who mainly stays on the registers to ring out patients." Current MOR Dumond
  indicated that PTT Janeiro passed a technician exam and was now a "full pharmacist technician." Of

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- note, CVS 26 was notified that PTT Janeiro's application for a pharmacy technician license was pending as of June 21, 2022, and she needed to contact BORP staff because the application was incomplete.
- CA: Current MOR Dumond indicated that "[he] informed [PTT Janeiro] to be attentive to licensing situations as well as renewal dates and showed her the link to the MA Board of Pharmacy website to look up and see what the status of her license is." Current MOR Dumond then reiterated that he notified all pharmacy staff to monitor the expiration dates and status of their respective licenses.
- Current MOR Dumond also provided a copy of CVS Health's internal policy for managing licensing. CVS
  Health's policy required a MOR to obtain a copy of all required licensure, certification or similar
  documentation at hire and before the date of expiration for all staff members supervised by the MOR.
  Current MOR Dumond's was notified that he was not compliant with CVS Health's policy.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by R.MORELLI, and voted unanimously by those present, to consolidate the matter (PHA-2022-0108) with PHA-2022-0062, 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 to include all Benzodiazepines.

Time: 12:25 PM

Case #22/CAS-2022-0387

PHA-2022-0078

CVS #672, DS89987

<u>RECUSAL</u>: S. CORNACCHIO and J. ROCCHIO 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.

- On March 8, 2022, CVS 672 submitted an untimely initial notification of an unknown loss of 515 Lorazepam 0.5 mg tablets (CIV, 500 tablet stock bottle) discovered on February 25, 2022. CVS 672 later submitted a retraction of the unknown loss as insignificant without further explanation on April 6, 2022.
- MOR Trach explained that she uncovered the possible loss of 515 lorazepam tablets while performing a weekly reconciliation on February 19, 2022. MOR Thach indicated that she searched the pharmacy without success for the missing lorazepam and contacted loss prevention. Loss prevention instructed MOR Thach to conduct reconciliations every day for a week. MOR Thach continued the daily reconciliations for a few weeks until loss prevention travelled to the pharmacy to conduct an internal investigation. Loss prevention opined the lorazepam was misplaced. Ultimately, the lorazepam was located, and loss prevention concluded the initial count was inaccurate. Thus, the loss was retracted.
- Of note, CVS 672 later reaffirmed that the loss was retracted because the missing lorazepam was located.
- CA: MOR Thach indicated that she implemented the following corrective action to mitigate recurrence
  of a similar incident. MOR Thach wrote, "Moving forward, only pharmacists can perform cycle counts.
  We also coached our new hire not to put drugs [back] if they are not sure of the location... The
  pharmacist is responsible to complete cycle counts for all controls. Interns and technicians cannot
  perform control cycle counts."

<u>ACTION</u>: Motion by J. CHIN, seconded by C. BELISLE, and voted unanimously by those present, to refer the DISMISS (PHA-2022-0078), No Violation.

Case #23/CAS-2022-0240

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PHA-2022-0044 CVS #2592, DS3011 Time: 12:28 PM

<u>RECUSAL</u>: S. CORNACCHIO and J. ROCCHIO 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.

- On March 22, 2022, CVS 2592 reported an unknown loss of 168 oxycodone-acetaminophen 5-325mg tablets (CII, 100 tablet stock bottle) that was discovered on December 16, 2021, while completing return to stock inventory.
- CVS 2592 suspected that a staff member unintentionally discarded a bottle containing the 168
   oxycodone-acetaminophen 5-325mg tablets in the trash while performing return to stock. However,
   CVS 2592 was unable to provide evidence to support an inadvertent discard occurred including
   surveillance video.
- CA: CVS 2592 indicated "we will remind all Pharmacists to make sure that stock bottles and return to stock bottles are empty before discarding in the trash."

<u>ACTION</u>: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by those present, to consolidate the matter (PHA-2022-0044) with PHA-2022-0113, 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 to include all Tramadol containing products.

Case #24/CAS-2022-0523

PHA-2022-0113 CVS #2592, DS3011 Time: 12:29 PM

<u>RECUSAL</u>: S. CORNACCHIO and J. ROCCHIO 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.

- On May 6, 2022, CVS 2592 submitted an untimely final report of loss and DEA 106 for an unknown loss of 385 tramadol 50mg tablets. The loss was discovered on March 31, 2022, by CVS Health's corporate controlled substance monitoring program and a reason for the loss was unable to be determined.
- CA: CVS 2592 wrote, "All Loss Prevention policy and procedures have been reviewed with the Pharmacy Team to prevent future losses. This includes diligent inventory management."

<u>ACTION</u>: Motion by S. HAMILTON, seconded by S. AHMED, and voted unanimously by those present, to consolidate the matter (PHA-2022-0113) with PHA-2022-0044, 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 to include all Tramadol Containing Products.

Case #25/CAS-2022-0023

PHA-2022-0007 CVS #1855, DS2901 Time: 12:31 PM

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

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

- During a retail compliance inspection (ISP-17598) conducted on 12/27/2021, an unlicensed pharmacy staff member was working as a Pharmacy Technician Trainee (PTT) without a license. Additionally, the Pharmacy did not adhere to the supervisory ratios, having a 1:3 ratio of one pharmacist to 1 technician, 1 technician trainee, and 1 unlicensed staff member acting as a technician trainee.
- A PTT application for PTT Kiboro was submitted on 12/27/2021 and her PTT license was issued on 01/05/2022.
- During the period when PTT Kiboro was unlicensed from 10/18/2021-12/27/2021, she worked 253.62 hours.
- MOR Njoroge stated, "Going forward, I will ensure all technician hires are licensed before working in the pharmacy." MOR Njoroge also indicated that support personnel will be scheduled in a manner that does not exceed ratio and technicians scheduled for vaccine clinics will be instructed to not perform technician duties.

<u>ACTION</u>: Motion by J. CHIN, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0007), 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 #26/CAS-2022-0195

SA-INV-19398 CVS #382, DS89637 Time: 12:33 PM

<u>RECUSAL</u>: S. CORNACCHIO and J. ROCCHIO 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.

- Failure to submit an acceptable POC with adequate documentation supporting refrigerated and frozen products subject to temperature excursions on 10/27/2021 and 10/28/2021 due to a power outage were safe and effective for dispensing.
- CVS Regulatory Affairs Senior Analyst, Lauren Pacia responded, "The CVS Clinical Review team advised what medications to quarantine or not. The clinical team personnel rely on materials/documents which are highly dependent on the specific drug in question. Specific materials that may have been reviewed may be based on extended stability data received from manufacturers, telephonic or other such outreach to the manufacturer(s), as well as clinical judgement. The process by which any recommendation is made is proprietary in nature". Ms. Pacia stated new medications were ordered for those patients needing refrigerated products ahead of the Pharmacy's receipt of instructions for affected inventory.
- MOR Keough stated when the power was restored, all medications were quarantined until the Retail
  TempEval team provided a Keep/Discard list to determine which medications could be dispensed or
  damaged for return. All records for the occurrence have been retained including temperature logs,
  Keep/Discard lists, and return documents. Documentation was submitted for temperature recordings
  of the excursions that occurred for 3 refrigerators and 1 freezer.

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• CVS policy ROPP-048822 "Temperature Excursions Impacting Store Product and Colleagues" was provided that was signed and dated by the Pharmacy staff confirming review. A signed and dated statement by Pharmacy staff was also provided confirming review of Board Policy 2020-05: Proper Storage of Refrigerated and Frozen Medications.

<u>ACTION</u>: Motion by K. THORNELL, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to CLOSE the matter (SA-INV-19398), No Discipline Warranted, Remediation Complete.

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Case #27/CAS-2022-0238

PHA-2022-0043 CVS #2138, DS2815 Time: 12:36 PM

<u>RECUSAL</u>: S. CORNACCHIO and J. ROCCHIO 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 untimely, unknown loss of #120 amphetamine salts 30mg tablets discovered on 12/8/21 when a prescription was missing from the waiting bin. MOR Capozzi contended she submitted an initial notification on 12/12/21 and had understood CVS corporate would file the DEA 106. She suspected multiple changes in the DL and DAPL contributed to the delayed reporting even though she reported it immediately to her DL and DAPL.
- The prescription was filled on 12/4/21 during the overnight shift by Pharmacist Shafai who was not the person who filed the bag in the assigned waiting bin. When the patient presented on 12/8/21, Pharmacist Teixeira and the pharmacy technician searched the bins but couldn't locate the missing prescription. MOR Capozzi was notified. The waiting bins, trash, pharmacist station, drop off window, and drive thru were searched again on 12/9/21. Video was reviewed on 12/8/21 and 12/9/21 by front store management and on 12/10/21 by MOR Capozzi, then the investigation was turned over to corporate. The prescription was put on hold then reprocessed on 12/12/21.
- MOR Capozzi stated, "In the event of another drug loss, I will be sure to follow up with CVS Regulatory and AP that the 106 is filed within the 7-day window". MOR Capozzi stated that she implemented a process in which CII meds that are filled be stored near the pharmacist checking station and not filed in the regular waiting bin. A statement that was signed and dated by the Pharmacy staff was provided attesting all policies and procedures for the proper storage and handling of controlled substances have been reviewed.

<u>ACTION</u>: Motion by S. AHMED, seconded by D. BARNES, and voted unanimously by those present, to consolidate the matter (PHA-2022-0043), 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 REPRIMAND.

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Case #28/CAS-2022-0341

SA-INV-19681 Walgreens #2330, DS1736 Time: 12:39 PM

<u>RECUSAL</u>: S. CORNACCHIO and J. ROCCHIO 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.

- Allegation from CVS #46 MOR Dall on 03/21/2022 that the Pharmacy was understaffed and negligent
  in failing to answer the telephone for transfers of prescriptions on numerous occasions in the last 6
  months. During a site visit at Walgreens # 2330, Former MOR Daniel indicated Walgreens #1871 in
  West Newton had closed [BORP records document date of closure as 11/08/2021] and business was
  transferred to the Pharmacy with an increase of about 100 prescriptions/week. Additional staff had
  been sent to the Pharmacy for the first few weeks after the closure.
- Current MOR Nguyen related the closure of Walgreens #1871 and the impact of COVID on staffing caused increased telephone hold times. The issues were managed by hiring and training new staff. There were no planned or unexpected closures of the Pharmacy. From 11/18/2021 to 11/30/2021, additional staff had been scheduled in the Pharmacy including immunizers (6 days, 55 hours total), pharmacists (6 days, 65 hours total), pharmacy technicians (3 days, 21 hours total), and store managers (6 days, 41 hours total). The weekly averages of prescriptions and immunizations were provided for 10/2021 to 3/2022 which showed approximately 411 immunizations/week were given in October then dropped significantly thereafter.
- Current MOR Nguyen stated, "Our plan of action includes approaches to not only staffing improvements but also training which leads to more associates having time to answer the phone. Likewise, we are now following proper workflow with trained team members". The volume on the telephone was increased to create better awareness for promptly answering the telephone. The Pharmacy actively focused on leveraging efficiency tools such as Save a Trip to help align patient medications, 90-day refill, and digital refill, etc. to ensure patients get the right experience.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by R. MORELLI, and voted unanimously by those present, to CLOSE the matter (SA-INV-19681), No Discipline Warranted, Remediation Complete.

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Case #29/CAS-2022-0307

PHA-2022-0061 CVS#705, DS3428 Time: 12:39 PM

<u>RECUSAL</u>: S. CORNACCHIO and J. ROCCHIO 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 including six unsecured epinephrine auto-injectors, a box of needles and a
  Sharps container with the lid off observed in the immunization area outside of the Pharmacy. The
  POC stated all epinephrine auto-injectors, needles and the Sharps container were immediately
  removed from vaccination area. All immunizers will be retrained in keeping controlled substances out
  of the vaccination area while a vaccination is not being given.
- MOR Colombie stated there was a new Floater Pharmacist who was immunizing was on duty with the Staff Pharmacist on the day of the inspection. The Floater was a new hire. MOR Colombie indicated they should have ensured she was aware of all company policies regarding storage of the emergency kit, needles, and Sharps container prior to her entering the vaccination area. The deficiency was not the normal practice of the Pharmacy.

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- CVS policy Pharmacist Administered Immunization Program states following administration of an immunization, all immunization supplies, including the emergency kit and Sharps container, are to be returned to the pharmacy.
- Immunizing staff attested to review of policies and procedures, including CVS policy Pharmacist Administered Immunization Program, for storage of all prescription medications in the pharmacy area. Pharmacy staff immunizers will ensure that all immunizing staff entering the Pharmacy are aware of all policies and procedures to maintain compliance with all rules and regulations. They will continue to ensure that all prescriptions, emergency kits, needles, and Sharps containers are stored only in the secured Pharmacy area. The Pharmacy was reinspected on 06/24/22 with no POC issued.

<u>ACTION</u>: Motion by D. BARNES, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0061), 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 #30/CAS-2022-0280

PHA-2022-0054 CVS #117, DS3207 Time: 12:45 PM

<u>RECUSAL</u>: S. CORNACCHIO and J. ROCCHIO 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 #510 zolpidem 5mg identified via controlled substance monitoring identified on 1/13/22. Three letters of continuation were submitted, and the investigation concluded 3/29/22.
   The loss was assumed to be due to the bottle (500 count) falling in the trash located below the usual place of storage.
- MOR Myers contended the thorough investigation performed to locate the missing stock bottle contributed to the delay in reporting including cycle counts, an extensive review of video, review of controlled substance recordkeeping and BOH changes, and a thorough search of the entire Pharmacy. All other possible reasons for the loss, including diversion, were ruled out.
- MOR Myers stated the trash cans were moved away from the storage shelf to prevent drugs from
  potentially falling into the trash. Production employees will put away drugs on a regular basis to
  ensure that the production bench doesn't become cluttered which may cause errors or drugs to be
  thrown away. Loss Prevention policy and procedures will be reviewed with the Pharmacy Team to
  prevent future losses. This includes diligent inventory management and dispensing standards. MOR
  Myers provided a signed statement attesting that all policies and procedures for the proper storage
  and handling of controlled substances was reviewed.

<u>ACTION</u>: Motion by J. CHIN, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2022-0054), 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 zolpidem products.

Topic IX: Executive Session Call to Order: Time: 12:49 PM

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

**Action:** A motion was made by to J. Lanza enter Executive Session; Seconded by D. Barnes 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; S. Ahmed, yes; R. Morelli, yes; K. Thornell, yes: D. Perry, yes; C. Jean-Francois, yes.

Lunch: 12:50 PM to 1:30 PM

Topic X: 65C Sessions MGL c. 112 section 65C Time: 1:47 PM

**DISCUSSION: None** 

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

At 1:47 PM J. Lanza, seconded by C. Jean-Francois and voted unanimously by all those present to enter 65C by roll call vote.

- D. Perry leaves meeting 3:10 PM
- S. Cornacchio leaves meeting 3:20 PM
- J. Rocchio leaves meeting 3:20 PM

Topic XI ADJOURMENT OF MEETING TIME: 3:52 PM

ACTION: Motion by J. Lanza seconded by S. Ahmed 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 8/4/22 General Session
- 2. Draft Minutes of the 6/2/22 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. Research Drug Study report pursuant to Staff Action Policy 18-02
- 8. Walgreens Central Fill-Request for temporary pharmacy
- 9. Walmart- Petition for waiver
- 10. Rite Aid Petition for waiver

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- 11. Cornerstone Health Solutions DS90083: Petition for central fill and pilot project request
- 12. Steward Employee Pharmacy- New Community Pharmacy
- 13. New Health Charlestown Pharmacy- New Community Pharmacy
- 14. UMass Specialty Pharmacy DS89822 Renovation Expansion
- 15. Upham's Community Care Pharmacy New Community Pharmacy
- 16. Policy 2022-05: COVID-19 Vaccine and EVUSHELD™ Administration by Qualified Pharmacy Personnel
- 17. Policy 2022-06: COVID-19 Therapeutics
- 18. Policy 2022-04: Use of Pharmacy Technician Trainees to Stock Automated Dispensing Devices
- 19. Policy 2020-15: Licensee Scope of Practice
- 20. Joint Policy 2019-02: Automated Dispensing Device Use
- 21. Policy 22-xx: Expedited Processing of Reciprocal License Applications in response to disease outbreak or other critical public health concern
- 22. CAS-2021-0685 PHA-2022-0016 Option Care, DS90107
- 23. CAS-2021-1271 PHA-2021-0119 Big Y #65, DS3276
- 24. CAS-2022-0009 PHA-2022-0004 Walgreens #6072, DS3004
- 25. CAS-2021-0975 PHA-2022-0119 Innocent Akani, PH25261
- 26. CAS-2021-1140 SA-INV-19031 Edge Pharma, NO00015
- 27. CAS-2022-0112 PHA-2022-0013 Wal-Mart #10-2629, DS3508
- 28. CAS-2022-0025 PHA-2022-0006 Walgreens #12869, DS89777
- 29. CAS-2022-0252 PHA-2022-0038 Walgreens #1855, DS1418
- 30. CAS-2022-0253 PHA-2022-0046 Walgreens #13135, DS89732
- 31. CAS-2022-0254 PHA-2022-0041 Packard Pharmacy, DS373
- 32. CAS-2022-0276 PHA-2022-0050 Eterna Pharmacy, DS90272
- 33. CAS-2022-0275 PHA-2022-0052 Leslie's Pharmacy, DS3302
- 34. CAS-2022-0335 PHA-2022-0066 Walgreens #10639, DS3570
- 35. CAS-2022-0287 PHA-2022-0060 Walgreens #17214, DS90117
- 36. CAS-2022-0443 PHA-2022-0093 Walgreens #7329, DS3362
- 37. CAS-2022-0336 SA-INV-19610 Walgreens #17605, DS90237
- 38. CAS-2022-0336 PHA-2022-0071 William Collins, PH16711
- 39. CAS-2022-0250 PHA-2022-0039 Rite Aid #10074, DS2895
- 40. CAS-2022-0415 SA-INV-19753 Cardinal Health 110, WD352
- 41. CAS-2022-0301 PHA-2022-0062 CVS #26, DS2912
- 42. CAS-2022-0519 PHA-2022-0108 CVS #26, DS2912
- 43. CAS-2022-0387 PHA-2022-0078 CVS #672, DS89987
- 44. CAS-2022-0240 PHA-2022-0044 CVS #2592, DS3011
- 45. CAS-2022-0523 PHA-2022-0113 CVS #2592, DS3011
- 46. CAS-2022-0023 PHA-2022-0007 CVS #1855, DS2901
- 47. CAS-2022-0195 SA-INV-19398 CVS #382, DS89637
- 48. CAS-2022-0238 PHA-2022-0043 CVS #2138, DS2815
- 49. CAS-2022-0341 SA-INV-19681 Walgreens #2330, DS1736
- 50. CAS-2022-0307 PHA-2022-0061 CVS #705, DS3428
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