COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

October 13, 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=e4ffebb4154a0813700d0a36ddcb05313

To access the meeting by phone:

Call in Number: 1-650-479-3208 Access Code: 2531 116 2472

Attendee: #

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

Agenda

Time	#	Item	Page	
8:00	I	CALL TO ORDER		
8:02	II	 APPROVAL OF AGENDA Introduction of new Board Member: Johanna Lopez Re-appointment of Board Member: Dawn Perry Farewell to Susan Cornacchio 		
8:05	Ш	 APPROVAL OF BOARD MINUTES Draft of September 1, 2022 Regular Session Minutes 		
8:10	IV	 Applications approved pursuant to Licensure Policy 13-01 Monthly report from Probation Board Delegated Review pursuant to Licensure Policy 14-02 PSUD Report-Policy 17-03 Research Drug Study report pursuant to Staff Action Policy 18-02 		

Summary of NABP District 1&2 Meeting Promethazine with Codeine Products Notice of the election of Board officers POLICIES W. The Code of the code o	1 1
Promethazine with Codeine Products	cabaugh
Notice of the election of Board officers	Thornell
POLICIES Policy 2022-02: Extended Absence of a Manager of Record M.	
Policy 2022-02: Extended Absence of a Manager of Record	
Policy 2020-14: COVID-19 Testing	Frisch
APPLICATIONS Walmart N/A Petition for waiver Rite Aid N/A Petition for waiver Rite Aid N/A Petition for waiver Genoa Healthcare N/A New Pharmacy & Waivers New Health Charlestown N/A Waiver Whittier Health Pharmacy DS89795 Relocation Cornerstone Health DS90083 Renovation Solutions MedWiz of Mass, LLC Renovation REGULATIONS • 247 CMR 13.00: Registration requirements and minimal professional standards for nuclear pharmacies FILE REVIEW 1 CAS-2022-2026 PHA-2022-0034 The Baker Pharmacy, DS12518 2 CAS-2022-2026 PHA-2022-0035 Zachary Barrieau, PH238037 3 CAS-2022-0278 PHA-2022-0051 Walgreens #19695, DS90174 4 CAS-2022-0277 PHA-2022-0047 Walgreens #3016, DS2277 5 CAS-2022-0416 PHA-2022-0085 Walgreens #12399, DS89688	Chan
Walmart	
Rite Aid	
9:00 VII Genoa Healthcare N/A New Pharmacy & Waivers	
New Health Charlestown N/A Waiver	
Whittier Health Pharmacy DS89795 Relocation	
Cornerstone Health DS90083 Renovation	
Solutions MedWiz of Mass, LLC Renovation 9:45	
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5 CAS-2022-0416 PHA-2022-0085 Walgreens #12399, DS89688	
6 CAS-2022-0549 PHA-2022-0111 Walgreens #2330, DS1736	
7 CAS-2022-0701 PHA-2022-0133 Cardinal Health, WD352	
8 CAS-2021-1166 PHA-2022-0021 Big Y #63, DS3179	

9	CAS-2022-0333	PHA-2022-0067	Market 32 Pharmacy, DS2526
10	CAS-2022-0242	PHA-2022-0045	Option Care, DS90107
11	CAS-2022-0237	PHA-2022-0042	CVS #686, DS89903
12	CAS-2022-0239	PHA-2022-0033	CVS #2254, DS2866
13	CAS-2022-0189	PHA-2022-0029	CVS #10502, DS90067
14	CAS-2022-0249	PHA-2022-0040	CVS #2322, DS2895
15	CAS-2022-0281	PHA-2022-0055	CVS #2070, DS2711
16	CAS-2022-0285	PHA-2022-0058	CVS #2533, DS2933
17	CAS-2022-0392	PHA-2022-0083	CVS #2171, DS2865
18	CAS-2022-0548	PHA-2022-0114	CVS #2171, DS2865
19	CAS-2022-0638	PHA-2022-0125	CVS #272, DS90325
20	CAS-2022-0666	PHA-2022-0127	CVS #1248, DS2875
21	CAS-2022-0751	PHA-2022-0136	CVS #1248, DS2875
22	CAS-2022-0705	PHA-2022-0129	CVS #8437, DS3549

12:00		LUNCH BREAK	
12:30	X	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.	
1:15	XI	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)	
2:00	XII	M.G.L. c. 112, § 65C SESSION	
3:30	XIII	ADJOURNMENT	

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting October 13, 2022

Board Members Present

Board Members Not Present

Sebastian Hamilton, Pharm D, MBA, RPh President (leaves meeting 2:20 PM)

Caryn Belisle, RPh, MBA, President-Elect Carly Jean-Francois, RN, NP Secretary

Johanna Lopez

Julie Lanza, CPhT

Jennifer Chin, RPh (Leaves meeting 2:35 PM) Dawn Perry, JD

John Rocchio, RPh, PharmD (leaves 2:39 PM)

Dr. Richard Lopez, MD

Sami Ahmed, Pharm.D., RPh, BCPS, BCSCP (arrives meeting at 9:30 AM)

Delilah Barnes, RPh

Rita Morelli, PharmD, BCACP, RPh

Katie Thornell, RPh, MBA

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 Jacqueline Petrillo, PharmD, RPh, JD, Board Counsel Michelle Chan, RPh, Quality Assurance Pharmacist Richard Harris, Program Analyst Ed Taglieri, MSM, NHA, RPh PSUD Supervisor Joanna Chow, Office Support Specialist Taylor Lee, Office Support Specialist Joanne Trifone, RPh, Director of Investigations Nancy Aleid, Compliance Officer Christina Mogni, RPh, Investigator Gregory Melton, RPh, Investigator Julienne Tran, PharmD, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:04 AM

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

Roll call attendance: S. Hamilton, yes; C. Belisle, yes; D. Barnes; J. Rocchio, yes; J. Chin, yes; J. Lopez, yes; R. Lopez, yes; R. Morelli, yes; K. Thornell, yes. S. Ahmed joins meeting at 9:30 AM.

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Topic II.

Approval of Agenda

TIME 8:07 AM

Agenda 10/13/22

DISCUSSION:

Defer: Applications for Waiver Walmart and Rite Aid; Cornerstone Health Solutions Renovation Dave and Board Members thanks Susan Cornacchio for her service and wish her well.

Dave introduces new Board Member Johanna Lopez

Michelle introduces MCP Worcester APPE student Quinta Teneng

ACTION:

Motion by K. Thornell, seconded by C. Belisle and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:14 AM

TIME: 8:15 AM

TIME: 8:15 AM

Minutes

1. Draft 9/1/22

Change: no changes

Action:

Motion by K. Thornell seconded J. Chin and voted unanimously to approve the regular session minutes of 9/1/22 with no noted changes by roll call vote. D. Barnes and J. Lopez abstain.

TOIC IV Reports

Applications approved pursuant to Licensure Policy 13-01

PRESENTED BY: R. HARRIS

<u>DISCUSSION:</u> R. Harris reported 60 Change of Manager applications that have been approved via Staff

Action since the September 1st Board meeting.

So noted.

Topic IV. REPORTS

Monthly Report from Probation

<u>PRESENTED BY</u>: R. HARRIS DISCUSSION: R. Harris indicated no new reports since the last Board meeting.

So noted.

Topic IV. REPORTS

Monthly Report from BDCR pursuant to Policy 14-02 TIME: 8:15 AM

PRESENTED BY: D. SENCABAUGH

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<u>DISCUSSION</u>: D. Sencabaugh reported 4 cases of unknown controlled substance losses that were each issued non-disciplinary stayed probation for one year with controlled substance loss protocol. So noted.

Topic IV. REPORTS

PSUD report by Staff Action 17-03

PRESENTED BY: E. TAGLIERI

<u>DISCUSSION:</u> E Taglieri reported one successful discharge from the program. Currently, there are 12 active participants in the PSUD program. A new admission assessment tool for practitioners will be utilized by Substance Addiction Recovery Program (SARP) and PSUD. The tool was presented and reviewed with Board members. SARP and PSUD are working together with BSAS to ensure consistency within Bureau programs.

TIME: 8:16 AM

TIME: 8:18 AM

Time: 8:19 AM

So noted.

Topic IV. REPORTS

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

PRESENTED BY: W. FRISCH, M. CHAN

<u>DISCUSSION</u>: M. Chan reported that five retail pharmacies are participating in research drug studies for a total of 20 active studies, 4 of which involve investigational drug substances. M. Chan indicates that one new study has been approved since the last report.

So noted.

TOPIC V Flex

1. Pharmacy Issues related to Covid-19 and state of emergency. Time: 8:18 AM

Presented by: D. SENCABAUGH

Nothing to report.

2. 2023 Board meeting calendar

Presented by: D. SENCABAUGH

Discussion: The extension of the public meeting law allows virtual Board meetings to continue through March 2023. Whether the meetings will continue virtually or be in-person after that date will be communicated when it becomes available. Board meeting dates for 2023 are:

January 12 February 2 March 2

April 6

May 4

June 1

July 6

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August 3

September 7

October 5

November 2

December 7

Action: Motion by C. BELISLE, seconded by K. THORNELL, and voted unanimously by roll call of those present, to approve the 2023 Board meeting schedule.

Time: 8:21 AM

Time: 8:26 AM

3. Summary of NABP District 1&2 meeting

Presented by: K. THORNELL

Discussion: Topics of the NABP District 1&2 meeting included expanding the role of the pharmacist in opioid overdoses, leadership style in times of uncertainty, purchasing medications online, and pharmacy licensee well-being.

Both resolutions presented by Massachusetts were approved to go forward. They were the point of care test and treat resolution and the Standards of Patient Care Initiative resolution.

So noted.

4. Promethazine with Codeine products

Presented by: M. CHAN

Discussion: Promethazine with codeine products have become highly sought-after products for illicit use resulting in fraudulent prescriptions and pharmacy robberies across the country.

In the interest of safety and to stop carrying these products, some pharmacies have asked for waivers from 247 CMR 6.02(4) which requires pharmacies to maintain a sufficient variety of medications to meet the needs of the community.

Rather than issuing waivers, a memo has been drafted stating that 247 CMR 6.02(4) would not be enforced for promethazine with codeine products only. The memo would be in effect for one year when the situation will be reevaluated.

However, if a valid prescription is received, the pharmacist must contact the prescriber to find an alternative product or arrange for the medication to be provided by another means.

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Action: Motion by J. ROCCHIO, seconded by K. THORNELL, and voted unanimously by roll call of those present, to approve the memo titled Promethazine with Codeine Products.

Time: 8:29 AM

Time: 8:33 AM

5. Notice of the election of Board officers

Presented by: D. SENCABAUGH

Discussion: Board members were asked to bring nominations for next year's officers to the November Board meeting. Elections will take place in December.

So noted.

TOPIC VI Policies

1. Policy 2022-02: Extended Absence of a Manager of Record Time: 8:32 AM

Presented by: M. CHAN

Discussion: Minor changes to this policy require the Interim Manager and Manager of Record (MOR) to complete a controlled substance inventory and notify the Board upon the MOR's return.

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

2. Policy 2020-14: COVID-19 Testing

Presented by: M. CHAN

Discussion: After discussions with the Bureau of Infectious Disease, this policy was clarified in that a CLIA waiver is required for COVID-19 testing and that no part of testing may occur in the licensed prescription area. The counseling/immunization room may be used for testing since this area is accessible to the public and is therefore not licensed pharmacy space.

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

TOPIC VII Application

1. Walmart Petition to Waive Deferred

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2. Rite Aid Deferred

Petition to Waiver

3. Genoa Healthcare

New Community Pharmacy/Waivers

TIME: 8:30 AM

Represented by: Samuel Trask & Megan Garrity

Recusal: none Discussion:

Board staff member B. Frisch indicates that Genoa is coming before the board with 6 waivers that typically pertain to a closed-door pharmacy. He adds that there are a few things missing from the application including an architectural seal and a few additional minor details and asks the board that

Motion to approve the new pharmacy application and the 6 waivers, pending an updated blueprint and satisfactory inspection made by K. Thornell; Seconded by , then Board Members presented voted unanimously by rollcall to approve motion.

4. New Health Charlestown

Waiver

TIME: 8:36 AM

Represented by:

Recusal: Belisle Discussion:

Board member S. Hamilton indicates that the application for the pharmacy permit has been approved through staff action however, they are coming before the board with a waiver for removal of the balance per 247 CMR 6.01(5)(a)(4).

Motion to approve the waivers for 247 CMR 6.01(5)(a)(4) for the balance made by J. Chen; Seconded

5. Whittier Health Pharmacy DS89795 Relocation

TIME 8:38 AM

Represented by: Lauretta Okoye

Recusal: none Discussion:

L. Okoye indicates that the reason for the relocation is that the lease where she is currently staying has been canceled so she has no option left but to relocate her pharmacy. S. Hamilton inquires if she has the new space secured with security measures, continuity of care with patients, security, and etc.

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L. Okoye indicates that she has made a previous move before and her process is to count the narcotics, secure them, and she uses movers to do that. The location is two blocks down the street, and she will count the narcotics again once she's in the new facility. She has secured doors, windows, and the alarm system will be in place once she's ready to move. S. Hamilton inquires if the move is done during off hours. L. Okoye responds that the pharmacy is not open on Sunday, so she plans on moving on Saturday at 5 PM when the pharmacy closes. S. Hamilton inquired about signage indicating that the pharmacy was going to move. L. Okoye responds that she has signage, text messaging, flyers, and will contact every patient to inform them about the move and transfer any medications if the patients have that request. B. Frisch inquiries about the vaccination room and whether there was a door that would close for the vaccination room. L. Okoye responds that there is a door that closes into the pharmacy and another door for the patient to come through. L. Okoye indicates that the vaccination room has two doors and B. Frish asks L. Okoye to work with her architect to make the door situation clearer in the blueprint. B. Frish indicates that he didn't see a provision in the blueprint for a controlled substance safe and refrigerator and asks for that to be added to the blueprint.

Motion to approve the relocation application pending satisfactory inspection and updated blueprint

6. Cornerstone Health Solutions DS90083 Renovation

Deferred

7. MedWiz of Mass, LLC Renovation TIME: 8:45 AM
Represented by: Kendalyn Armington, Larry Kososki, Robert Falkum, Ernie Gates, Pamela Benson

Recusal: Discussion:

K Armington indicates that the application for renovation is to add a clean room to the current site. They currently don't have any drugs in the room so there is no concern of drug security. S. Hamilton inquires if they are adding a clean room so that they can conduct some level of compounding in the facility and K. Armington confirms that this is their intent with the renovation. S. Hamilton inquires how the facility is providing compounding services to their patients right now if their hood is not ready. K Armington responds that they are not fully operational yet, and their sister location is in New York who will be completing a long run to service the locations that require the IVs. S. Hamilton inquires if they are able to meet the 24-48-hour turnaround time and K. Armington responds that the facility is able to meet those needs in that timeframe. C. Belisle inquired about the type of compounding they plan on conducting. L. Kososki responds that they are compounding patient specific scripts primarily low to medium and primarily antibiotics and hydration for patients residing in skilled nursing facilities. C. Belisle inquired if they have someone on their staff who is familiar with operating cleanrooms, and the quality assurance, environmental monitoring, and etc. L. Kososki responds that they have a lead technician with 17 years of IV service and that he worked in a hospital setting responsible for multiple cleanrooms and worked for home infusion companies as director of operations and is very familiar with the 797 standards. C. Belisle inquires as to who will clean and disinfect the cleanroom. L. Kosoki responds that the lead technician will be responsible for cleaning, disinfecting, and will manage the standard testing for employees and certification in house. They will

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also use an outsourced certification company for the hood and rooms. C. Belisle inquired about the viable samples. L. Kosoki responds that he will do it per their policy and will be tested by a member of their team will take the samples, incubate them, and documenting them. C. Belisle inquired if they have an incubator yet and L. Kososki responds that they do have an incubator it has not been set up yet because they still have some work to do on the room and get an inspection. C. Belsile inquired about the training tools to train staff. L. Kososki responds that they have several corporate wide training programs as they operate 3 other pharmacies across the country with clean room program. P. Benson responds that they are using an outsourced training program called Critical Point. B. Frisch indicates that the BOP staff do not have any objections to the proposed plans based on their discussions. B. Frisch also noted that the applicants should familiarize themselves with board policies particularly the reporting requirements around action level results. C. Belisle inquired if additional licensure is required such a compounding registration and if it would be under CMR 17. B. Frisch responds that it is not applicable yet until the new licensing requirements are promulgated and that the license would be under the drug store, and they would require a separate compounding license later on. D. Barnes inquired if any of the facilities required TPNs and if it would be outsourced through a different company or through their New York facility. K. Armington responds that they will outsource the TPNs and use CAPS/ work directly with them.

Motion to approve the renovation to include a compounding area as submitted pending satisfactory inspection made by S. Hamilton; Seconded by C. Belisle, then Board Members presented voted unanimously by rollcall to approve motion.

TOPIC VIII Regulations

247 CMR 13.00: Nuclear Pharmacy Licensure Requirements and Professional Practice Standards
Time: 9:01 AM

Presented by: W. FRISCH

Discussion: Since the September 1, 2022, meeting of the Board when the draft of 247 CMR 13.00 was approved, there have been some technical edits and other minor revisions.

Action: Motion by C. BELISLE, seconded by R. MORELLI, and voted unanimously by roll call of those present, to forward the edited document for administrative review and approval to hold a public hearing.

TOPIC IX File Review

Case #1/CAS-2022-2026

PHA-2022-0034 The Baker Pharmacy, DS12518 Time: 09:12 AM

RECUSAL: NONE

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

- BORP opened complaints against The Baker Pharmacy and MOR Barrieau after Investigators Brosnan and Seed discovered that The Baker Pharmacy dispensed prescriptions for office use on January 27, 2022, for 100 Sulfamethoxazole-trimethoprim 800-160mg tablets, on February 10, 2022, for 9 albuterol inhalers, and on February 19, 2022, for 100 Sulfamethoxazole-trimethoprim 800-160mg tablets.
- MOR Barrieau admitted that the prescriptions described above were dispensed for office use at The Baker Pharmacy and indicated that he was not aware that MGL prohibited retail pharmacies from dispensing drugs for office use.
- CA: MOR Barrieau agreed to immediately cease the practice at The Baker Pharmacy of dispensing prescriptions issued by prescribers for office use. He also obtained a copy MGL prohibiting dispensing drugs for office use for reference at The Baker Pharmacy.
- BORP then amended the complaint against The Baker Pharmacy after learning that the pharmacy
 misbranding prescriptions in certain circumstances by dispensing prescriptions with false or misleading
 labels. Specifically, prescription labels at The Baker Pharmacy listed the manufacturer and the
 corresponding national drug code (NDC) of the drug purported to be contained in the prescription
 bottle. However, the manufacturer and NDC listed on the label may not, in fact, be the actual
 manufacturer and NDC of the drug dispensed to the patient in violation of recognized standards of
 pharmacy practice.
- MOR Barrieau admitted that The Baker Pharmacy misbranded prescriptions by dispensing prescriptions with false or misleading labels in certain circumstances as describe above. He then asserted, "Those circumstances [when misbranded prescriptions were dispensed] seem to be within my understanding of what is common and permissible in a retail setting." He then described that misbranded prescriptions were dispensed when distributors assigned new NDC to repackaged drugs which insurers would not reimburse. Misbranded prescriptions were also dispensed when the NDC package code for a bulk package did not match the individually dispensed drug such as a bulk package of individual packets of oral contraceptives because "many insurance companies recognize only the NDC of the box or the NDC of the individual pack, but rarely both." In addition, Misbranded prescriptions were also dispensed when the NDC package code did not match "due to variations in package size."
- MOR Barrieau also indicated that issues with The Baker Pharmacy's "computerized inventory system" contributed to the issue because variations in manufacturers and corresponding NDC of a particular drug required a pharmacist to update the information during the verification process and sometimes this did not happen due to human error. In addition, MOR Barrieau explained that The Baker Pharmacy's wholesale distributor also contributed to the issue because the wholesale distributor automatically substituted their preferred manufacturer when orders were submitted causing changes in manufacturers and corresponding NDC which require a pharmacist to update the information during the verification process and sometimes this did not happen due to human error.
- CA: MOR Barrieau indicated that he was "conducting a thorough review of flagged NDCs and ordered NDCs to remove the possibility of an NDC other than the NDC billed being dispensed." MOR Barrieau described that "the process will include comparing the price of the submitted NDC to the auto-substituted NDC that McKesson provides, finding an ideal NDC for the pharmacy to use going forward, and changing the drug profile for that particular NDC to include 'Do Not Substitute' for purposes of the auto-order. This will make sure that the Baker Pharmacy exclusively is provided a single NDC from

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McKesson, so that it is otherwise impossible for an NDC other than the billed NDC to be dispensed." MOR Barrieau insisted that the "possibility of human error" would be eliminated after completion of his review.

• MOR Barrieau added that he planned to develop a formal written "policy and standard operating procedure on billing and dispensing NDCs" to maintain ongoing compliance with regulatory requirement regulations when dispensing prescriptions after completion of his NDC review.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2022-0034), 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-2022-0206

PHA-2022-0035 Zachery Barrieau, PH238037 Time: 09:20 AM

RECUSAL: NONE

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

- BORP opened complaints against The Baker Pharmacy and MOR Barrieau after Investigators Brosnan and Seed discovered that The Baker Pharmacy dispensed prescriptions for office use on January 27, 2022, for 100 Sulfamethoxazole-trimethoprim 800-160mg tablets, on February 10, 2022, for 9 albuterol inhalers, and on February 19, 2022, for 100 Sulfamethoxazole-trimethoprim 800-160mg tablets.
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 misleading labels. Specifically, prescription labels at The Baker Pharmacy listed the manufacturer and
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 manufacturer and NDC of the drug dispensed to the patient in violation of recognized standards of
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- prescriptions were also dispensed when the NDC package code did not match "due to variations in package size."
- MOR Barrieau also indicated that issues with The Baker Pharmacy's "computerized inventory system" contributed to the issue because variations in manufacturers and corresponding NDC of a particular drug required a pharmacist to update the information during the verification process and sometimes this did not happen due to human error. In addition, MOR Barrieau explained that The Baker Pharmacy's wholesale distributor also contributed to the issue because the wholesale distributor automatically substituted their preferred manufacturer when orders were submitted causing changes in manufacturers and corresponding NDC which require a pharmacist to update the information during the verification process and sometimes this did not happen due to human error.
- CA: MOR Barrieau indicated that he was "conducting a thorough review of flagged NDCs and ordered NDCs to remove the possibility of an NDC other than the NDC billed being dispensed." MOR Barrieau described that "the process will include comparing the price of the submitted NDC to the autosubstituted NDC that McKesson provides, finding an ideal NDC for the pharmacy to use going forward, and changing the drug profile for that particular NDC to include 'Do Not Substitute' for purposes of the auto-order. This will make sure that the Baker Pharmacy exclusively is provided a single NDC from McKesson, so that it is otherwise impossible for an NDC other than the billed NDC to be dispensed." MOR Barrieau insisted that the "possibility of human error" would be eliminated after completion of his review.
- MOR Barrieau added that he planned to develop a formal written "policy and standard operating
 procedure on billing and dispensing NDCs" to maintain ongoing compliance with regulatory
 requirement regulations when dispensing prescriptions after completion of his NDC review.

<u>ACTION</u>: Motion by K. THORNELL, seconded by R. MORELLI, and voted unanimously by those present, to have PH Barrieau come before the Board for an Investigative Conference.

S. Ahmed arrives at 9:30 AM

Case #3 /CAS-2022-0278 PHA-2022-0051

Walgreens #19695, DS90174 Time: 09:30 AM

RECUSAL: NONE

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

- On March 10, 2022, Investigator Horn discovered during a retail compliance inspection that WAG
 19695 had lacked a manager of record (MOR) or interim MOR since former MOR McDonald's last shift
 on January 21, 2022. In addition, Investigator Horn discovered that a Schedule II-V controlled
 substance inventory was not completed by former MOR McDonald when he left. Investigator Horn
 notified the pharmacist on duty, Clifford MacDermid, and the district manager for the area about the
 violations. A plan of correction (POC) was issued.
- The POC response indicated that Pharmacist MacDermid was appointed Interim MOR and completed an incoming Schedule II-V controlled substance inventory on March 17, 2022, then appointed MOR on April 6, 2022, and an additional change in manager inventory was completed at that time. WAG 19695

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- then pledged that, going forward, the district manager for the area and the current MOR "will ensure if/when there are changes in MOR status/placements, that CMR guidelines are followed."
- Current MOR Yi was appointed MOR on May 27, 2022 and completed a Schedule II-V inventory with Former Interim MOR/MOR MacDermid on that date (copies of change in MOR application and inventory provided).
- Current MOR Yi also provided copies of former Interim MOR/MOR Clifford MacDermid's application for a change in MOR on April 6, 2022, when he transitioned from Interim MOR to MOR and his incoming inventory. In addition, copies of former Interim MOR/MOR MacDermid's change in MOR inventory on March 17, 2022, when he was appointed, Interim MOR were also submitted. Of note, MOR MacDermid completed incoming and outgoing counts for the inventories completed on March 17, 2022, and April 6, 2022, instead of with another pharmacist if the outgoing MOR was not available.
- CA: Current MOR Yi wrote, "As a Manager of Record, I understand that should I no longer service in this capacity at Walgreens #19695, I must complete a change in Manager of Record controlled substance inventory as well as work with the incoming Manager of Record to fully complete and submit an Application for Change in Manager of Record".

<u>ACTION</u>: Motion by D. BARNES, seconded by J. CHIN, and voted unanimously by those present, to REFER the matter (PHA-2022-0051), 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-2022-0277

PHA-2022-0047 Walgreens #3016. DS2277 Time: 09:41 AM

RECUSAL: NONE

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

- On March 7, 2022, Investigator Murray discovered during a site visit that Former MOR Mae Myers
 who was listed in BORP records as the current MOR at the time of the inspection ceased serving as
 MOR for at least two months prior to the inspection according to pharmacy staff At that time,
 Investigator Murray issued a plan of correction (POC) based on the violations of BORP regulations and
 policies for changes in MOR.
- WAG 3016 submitted a POC as required. WAG 3016 admitted that Former MOR Myers left as MOR on November 16, 2020. Next Former MOR Jack Vinciguerra was MOR from November 30, 2020, until February 16, 2021. WAG 3016 did not have an MOR for from February 16, 2021, until November 13, 2021. Then, Former MOR Nguyen served as MOR from November 13, 2022, until March 25, 2022. Lastly, Current MOR, Youmna H. Mahmood, was appointed on March 25, 2022.
- During the investigation of the complaint, Investigator Melton determined that Former MOR Jack Vinciguerra's change in manager application was not submitted to BORP. In addition, Former MOR Nguyen application for change in MOR was submitted but was incomplete. Lastly, WAG 3016 was advised on requirements for changes in manager and submitted a change in manager application during the investigation of this complaint to officially appoint Current MOR Mahmood as MOR.

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<u>ACTION</u>: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2022-0047), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #5/CAS-2022-0416

PHA-2022-0085 Walgreens #12399, DS89688 Time: 09:44 AM

RECUSAL: NONE

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

- On March 22, 2022, Investigator Horn discovered that an unlicensed staff member, Arriel Holligan
 was performing duties in the pharmacy requiring licensure as a pharmacy technician trainee (PTT).
 Investigator Horn notified WAG 12399 about Ms. Holligan's unlicensed practice and required WAG
 12399 to reassign Ms. Holligan to non-technician duties only until she was duly licensed. Investigator
 Horn then issued a plan of correction (POC) to the pharmacy for the unlicensed practice.
- POC: MOR Melissa Barbara Pau indicated that a Ms. Holligan's PTT application was submitted on March 31, 2022 and required licensure documentation would be completed prior to a staff member working in the pharmacy. MOR Pau explained that WAG 12399's Pharmacy Operations Manager, currently Technician Dawn Cambra, would prepare licensure documentation to confirm licensure status for new hires prior to new hires working in the pharmacy. MOR Pau would then review the documentation before the new hire would be permitted to work in the pharmacy. In addition, MOR Pau indicated that she would check licensure status monthly for all staff members using Walgreens database used to maintain and track licensing for pharmacy staff called Walgreens Online Licensing Function (WOLF).
- Of note, Ms. Holligan was issued a PTT license (PTT15711) on April 5, 2022.
- MOR Pau acknowledged in her response to the complaint that Ms. Holligan performed duties in the
 pharmacy requiring PTT licensure without a PTT license. She explained that Ms. Holligan was hired
 during January 2022 when the pharmacy was administering 65 to 90 COVID-19 booster vaccines on a
 daily basis. MOR Pau indicated that hiring at that time was completed entirely by WAG 12399
 Pharmacy Operations Manager Cambra and Front Store Manager Francis Madden because the high
 daily rate of vaccine administration required her full attention.
- Front Store Manager Madden notified MOR Pau that Ms. Holligan's application for licensure as a technician trainee was "mailed out with three other employee's paperwork" when Ms. Holligan was hired. MOR Pau explained, "Due to the lag processing that we experienced due to the pandemic I did not question the length of time it was taking for the license to be mailed to [Ms. Holligan]. When [Investigator Horn] informed us [Ms. Holligan] still did not have anything on record with the state, we had her redo the paperwork."
- Of note, MOR Pau also accounted for the three employees whose applications were mailed with Ms. Holligan's application. MOR Pau indicated that three employees left WAG 12399 before completion of the licensure process.
- CA: MOR Pau reiterated the corrective action implemented as she described in her plan of correction mentioned above. She added that Ms. Holligan's PTT license was added to WOLF for monitoring.

<u>ACTION</u>: Motion by C. BELISLE, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-20228500), 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 #6/CAS-2022-0549 PHA-2022-0111

Walgreens #2330, DS1736

RECUSAL: NONE

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

Time: 09:48 AM

- Inspectional deficiencies for failure to submit a change of MOR application since 11/7/21 when Former MOR Shah left, and PTT Laparra was working with an expired license. PTT Wolf was also identified as having an expired license. The POC indicated an application for Current MOR Nguyen was submitted on 4/14/22.
- Former MOR Daniels stated she was MOR from 12/6/21 to 4/14/22. DM Carreira alleged applications for a change of MOR were submitted for both Former MOR Daniels and Current MOR Nguyen. He provided an email dated 4/14/22 notifying the BORP of the MOR changes. A copy of the controlled substance inventory completed on 4/15/22 by Current MOR Nguyen only as the incoming MOR and the application notarized on 4/26/22 were submitted. DM Carreira stated Former MOR Daniels did not complete a controlled substance inventory as incoming MOR.
- PTT Laparra had submitted a PT application but was notified by PCS on 4/21/22 that it was incomplete. Due to the changing of MORs at the Pharmacy, PTT Laparra was unaware her license had expired, and she had worked over 1500 hours. The missing information was provided, and she was issued a PT license on 5/11/22.
- PTT Wolf stated she received her PTT license while working as a PTT at another location. She stated she has only worked as a customer service associate since transferring to Walgreens #2330 and has never performed any technician tasks in the Pharmacy. She indicated that she no longer wants to work in the Pharmacy. Her PTT license remains in expired status.
- DM Carreira will ensure that a controlled substance inventory is completed, and an application is submitted to the BORP for a MOR change. Current MOR Nguyen will track PTT hours and ensure licensure within an appropriate timeframe. Licenses are proactively checked monthly and quarterly by the store manager and MOR to ensure they are current.

<u>ACTION</u>: Motion by S. AHMED, seconded by D.BARNES, and voted unanimously by those present, to refer the matter (PHA-2022-0111), 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-2022-0701

PHA-2022-0133 Cardinal Health, WD352 Time: 09:51 AM

RECUSAL: NONE

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

• RLCS for a loss of #100 oxymorphone 10mg discovered on 4/29/22 during a routine inventory. An internal investigation was immediately initiated to determine the cause. Manager Trammell indicated that if the variance was resolved, the report would be withdrawn.

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• In response to the complaint, Manager Trammell apologized for not sending a notice rescinding the 106. He included an email thread sent to the DEA. On 6/3/22, Manager Trammell informed the DEA he rescinded the DEA 106 as the item was found in the most recent monthly inventory.

<u>ACTION</u>: Motion by C. BELISLE, seconded by J. ROCCHIO, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0133), No Violation.

Case #8/CAS-2021-1166

PHA-2022-0021 Big Y #63, DS3179 Time: 09:53 AM

RECUSAL: NONE

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

- Unknown loss of #187 amphetamine/dextroamphetamine 15mg tablets.
- On Friday, 10/26/2021, MOR Kimball dispensed a prescription for #60 amphetamine/dextroamphetamine 15mg tablets. He counted out #60 tablets, with 1 empty stock bottle in a recycling basket on the counter and he then accidentally put the remaining 2 stock bottles into the recycling basket on the counter and threw out the bottles.
- On November 4, 2021, the staff Pharmacist Martineau discovered the missing medication while she was dispensing another prescription. Both MOR and the staff pharmacist looked in the safe and the pharmacy for the missing tablets.
- The MOR indicated that the root cause for the incident is completing the perpetual logbook entry in the middle of the process of counting instead of at the end. As a result, he got distracted and threw out the bottles by mistake.
- As a corrective measure, he noted that he will empty the countertop recycling basket one bottle at a time rather than dumping all at once into our main recycling as a way to double check that each bottle is empty. The workflow is also changed so that the perpetual logbook is now documented last.

<u>ACTION</u>: Motion by J. CHIN, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0021), 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-2022-0333

PHA-2022-0067 Market 32 Pharmacy, DS2526 Time: 09:55 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-18050) conducted on 03/22/2022 OPP Investigator observed pharmacy technician trainee (PTT) Yarelis Fred performing PTT duties with an expired license.

MOR Showalter stated that PTT Fred was working at another pharmacy and PTT Fred's license was about to expire. As a result, he noted that a new application was completed for her and sent to the Board.

• MOR Showalter stated that he was on vacation in 01/2022 and he not aware that PTT Fred had received a call from the Board asking if she needed an extension for her PTT registration.

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- He was informed by the Pharmacy that PTT Fred was "good to go on the schedule and start her training".
- He noted that from about 2/09/2022-3/20/2022, PTT Fred worked 108 hours while without a valid license. PTT Fred was issued an extension on her PTT license on 03/22/2022 for 1 year.
- MOR Showalter stated that it is the company's policy that all prospective technicians are registered with the state as PTT before starting their training and once they reach 500 hours, the company administers the Pharmacy Technician exam and registers them as a Pharmacy Technician with the state.
- Going forward MOR Showalter will check the status of each employee and post their expiration date.

<u>ACTION</u>: Motion by D. BARNES, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0067), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #10/CAS-2022-0242

PHA-2022-0045 Option Care, DS90107 Time: 09:58 AM

RECUSAL: NONE

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

- OPP received notification that the Pharmacy had an unknown loss of hydromorphone injection 10mg/ml on or about 12/30/2021; and during a 797 inspection, it was observed that Senior director of operations, Chris Czech, has access to controlled substance storage box. Employee is unlicensed in the state of Massachusetts.
- On 12/30/2021, a Pharmacy staff member discovered a single 50ml vial of hydromorphone 10mg/ml
 was short approximately 6ml when drawn up into a syringe. The internal investigation included a drug
 screening of all staff who have access to or handle controlled substances; review of alarm
 arming/disarming and badge swipe logs; and review of patient records and prescriptions.
- Security footage was reviewed with no evidence of diversion.
- The Attorney stated that after a thorough investigation, the Pharmacy determined the loss was not significant and did not qualify as a reportable loss according to Board Policy 2022-01.
- Former MOR Rogers stated that although there was no evidence of diversion, the Pharmacy took this incident as an opportunity to review and improve controlled substance security.
- Former MOR Rogers indicated Sr. DOO Czech's role does not include practicing pharmacy. He stated that Mr. Czech's involvement was limited to cycle counts for financial purposes, where he would use a scanner to verity the contents in the cabinet...Mr. Czech would occasionally assist in the inventory check when licensed pharmacists were occupied with their daily duties. Mr. Czech's role in the inventory checks was supervisory. Former MOR Rogers indicated that after the reported loss of hydromorphone, only he and Sr. DOO Czech had access to the controlled substance storage box out of an abundance of caution.
- A Retail Compliance Inspection (ISP-18111) was conducted on 03/29/2022 with deficiencies cited for scale not sealed, and naloxone supply was not sufficient.

<u>ACTION</u>: Motion by K. THORNELL, seconded by D. BARNES, and voted unanimously by those present, to DEFER the matter (PHA-2022-0045), for further investigation.

Case #11/CAS-2022-0237

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PHA-2022-0042 CVS #686, DS89903 Time: 10:11 AM

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

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

- RLCS- unknown loss of #542 lorazepam 0.5mg tablets on or about 11/18/2021.
- The loss was discovered via corporate controlled substance monitoring.
- District Leader Victoria Dunford attested that cycle counts, biennial inventories, staffing schedules and inventory reports for the applicable time period and were unable to identify the reason for the loss.
- DL Dunford indicated that all loss prevention policy and procedures will be reviewed with the Pharmacy Team to prevent future losses.
- A retail compliance inspection (ISP-18830) conducted on June 16, 2022, was deemed satisfactory.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to REFER the matter (PHA-2022-0042), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION for a period of 1 year, with special terms to include the CS loss protocol for all benzodiazepines.

Case #12/CAS-2022-0239

PHA-2022-0033 CVS #2254, DS2866 Time: 10:13 AM

RECUSAL: J. ROCCHIO recused and was 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-17846) conducted on 02/28/2022, the Pharmacy was cited for deficiencies, including but not limited to, epinephrine auto-injectors, sodium chloride, needles and syringes stored unsecured in a temporary immunization area outside of the pharmacy.
- MOR Lin indicated in the POC that all epinephrine auto-injectors, needles/syringes, sodium chloride
 vials and Sharps containers have been moved into the secured pharmacy department under
 supervision of pharmacist on duty. Going forward, MOR and staff pharmacists will monitor temporary
 immunization area daily to ensure proper storage of items.
- MOR Lin indicated that in November 2021, store teams were asked to create emergency kits that could be assessed in the event of a post-vaccination emergency.
- A copy of CVS' SOP titled "Pharmacist Administered Immunization Program" was provided. According to the SOP, the immunizer shall be responsible for returning to the pharmacy with all immunization supplies, including the emergency kit and Sharps container.
- MOR Lin provided a signed attestation from the pharmacy staff that they have reviewed all policies regarding immunization.

<u>ACTION</u>: Motion by D. BARNES, seconded by C. BELISLE, and voted unanimously by those present, to refer the matter (PHA-2022-0033), 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 #13/CAS-2022-0189

PHA-2022-0029 CVS #10502, DS90067 Time: 10:16 AM

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RECUSAL: J. ROCCHIO recused and was 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.

- RLCS- unknown loss of #60 Vyvanse 60mg capsules discovered on or about 10/27/2021 during a back count of a prescription.
- MOR Hiett indicated that the previous prescription was immediately recounted, and it was verified that the correct quantity was in the bottle. The waiting bin was searched for any missing prescription and all prescriptions for Vyvanse in the waiting bin were double counted to confirm the quantity.
- The MOR also indicated that there were no record keeping issues discovered. No break-down in procedures were identified. The team was consistently back counting and double counting prescriptions. The safe was reportedly not left open.
- Security camera footage reviewed was inconclusive and did not confirm an overfill.
- The MOR indicated that 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. MOR Hiett indicated that a review of back counting procedures of all narcotics at the time of dispensing to ensure accuracy would also occur.

<u>ACTION</u>: Motion by S. AHMED, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0029), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #14/CAS-2022-0249

PHA-2022-0040 CVS #2322, DS2895 Time: 10:18 AM

RECUSAL: J. ROCCHIO recused and was 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.

- OPP Investigator Horn conducted a site-visit (ISP-17871) and observed that former MOR was still listed as former MOR Burke even though she has not worked in this capacity on or about since 12/28/2021.
- MOR Allen indicated that she became the MOR of this Pharmacy effective 01/31/2022. She indicated that during this time, she was overwhelmed by the transition to a higher volume pharmacy.
- District Leader (DL), Keith Day noted that former MOR Burke put in her notice due to her relocation to Florida but agreed to stay on as MOR until 12/31/2021. He noted that he had a new candidate to start 1/1/2022 but that person backed out of the position 2 days prior to their start date.
- DL Day noted that MOR Allen accepted the position as MOR, and she was scheduled to start as of 1/30/2022. However, he noted that MOR Allen did not complete the change in manager paperwork upon taking over as the MOR. She submitted an application to the board on 3/17/2022.
- MOR Allen stated that she currently has no plans on changing pharmacy locations in the near future, if she were to become MOR of another pharmacy, she would be proactive in submitting the application for change in MOR.

<u>ACTION</u>: Motion by J. CHIN, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2022-0040), 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-2022-0281

PHA-2022-0055 CVS #2070, DS2711 Time: 10:20 AM

RECUSAL: J. ROCCHIO recused and was 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.

- RLCS-unknown loss of #532 clonazepam 0.5mg tablets.
- MOR Ramachandran indicated the loss was discovered on 01/27/2022 via corporate controlled substance monitoring. The reason for the loss remains unknown.
- Video footage was not reviewed.
- MOR Ramachandran noted that the loss was suspected to be a result of posting more bottles than received then negatively adjusting the balance on hand to correct. The drug was counted for 2 months after the loss was discovered with no additional losses.
- MOR Ramachandran indicated that she retrained the Pharmacy team on performing cycle counts and will continue to monitor the drug. All Loss Prevention policy and procedures, including diligent inventory management, will be reviewed with the Pharmacy team to prevent future losses.
- A Retail Compliance Inspection (ISP-17831) conducted on 02/24/2022 was deemed satisfactory.

<u>ACTION</u>: Motion by C. BELISLE, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0055), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION for a period of 1 year, with special terms to include the CS loss protocol for all benzodiazepines.

Case #16/CAS-2022-0285

PHA-2022-0058 CVS #2533, DS2933 Time: 10:23 AM

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

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

- A suspected loss of #510 lorazepam 1mg tablets on or about 01/13/2022.
- MOR Kurjanowicz indicated in the statement that on 01/13/2022, the loss was discovered via corporate controlled substance monitoring and counts were conducted in response to the loss.
- No video footage was reviewed. An investigation of the matter concluded that there was no theft or significant loss of controlled substances in the Pharmacy.
- No corrective actions taken as it was determined that there was no loss.

<u>ACTION</u>: Motion by K. THORNELL, seconded by R. MORELLI, and voted unanimously by those present, to DISMISS the matter (PHA-2022-0058),No Discipline Warranted.

Case #17/CAS-2022-0392

PHA-2022-0083 CVS #2171, DS2865 Time: 10:23 AM

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

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

- RLCS-unknown loss of #274 lorazepam 1mg tablets on or about 02/10/2022 discovered via corporate controlled substance monitoring. Upon conclusion of CVS' internal investigation an additional loss of #800 lorazepam 0.5mg tablets was discovered with no further explanation provided.
- Video footage was reviewed, but it did not identify anything pertaining to the investigation.
- Current MOR Bonthu's response contradicted earlier statements regarding how the loss was discovered. She indicated that the loss of the lorazepam 1mg tablets was identified during the Change in MOR CS inventory on 02/10/2022. She did not speak to the loss of the #800 lorazepam 0.5mg tablets.
- MOR Bonthu indicated that cycle counts of controlled substances are performed on a daily basis and only by pharmacists.
- A retail compliance inspection (ISP-19283) conducted on 08/15/2022 was deemed satisfactory.

<u>ACTION</u>: Motion by J. LOPEZ, seconded by C. BELISLE, and voted unanimously by those present, to consolidate (PHA-2022-0083) with PHA-2022-0114. A second motion was made by C. BELISLE, seconded by S. AHMED, and vote unanimously by those present, to REFER the matter (PHA-2022-0083), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 1 year, with special terms to include the CS loss protocol for all benzodiazepines.

Case #18/CAS-2022-0548

PHA-2022-0114 CVS #2171, DS2865 Time: 10:25 AM

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

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

- During an inspection on 4/27/22, a controlled substance inventory on 2/9/22 for a MOR change was observed but Former MOR Ameyaw was still listed as the MOR on record with the BORP. No change of MOR application had been received.
- Current MOR Bonthu and DL Klaus stated the paperwork for a change of MOR at the Pharmacy had been completed in February 2022 and submitted to the CVS Licensing Team for processing. Once they were made aware of the issue, the application was resubmitted. A copy of the application was provided which showed Former MOR Ameyaw and Current MOR Bonthu signed the attestation on 2/11/22 that a controlled substance inventory was performed. The Notary's copy of the application, which was resigned on 5/25/22 by Current MOR Bonthu, was re-notarized and re-submitted. It was received by the BORP on 6/2/22 with payment processed on 6/10/22.
- A copy of CVS DOC-041422 "Pharmacists in Charge and Powers of Attorney at CVS Health" was submitted that was signed and dated by Current MOR Bonthu confirming review. Going forward, DL Klaus will follow up with the CVS Licensing Team to ensure all MOR changes are timely received and filed with the BORP.

<u>ACTION</u>: Motion by J. LOPEZ, seconded by C. BELISLE, and voted unanimously by those present, to consolidate (PHA-2022-0114) with PHA-2022-0083. A second motion was made by C. BELISLE, seconded by S. AHMED, and vote unanimously by those present, to REFER the matter (PHA-2022-0114), to the

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Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 1 year, with special terms to include the CS loss protocol for all benzodiazepines.

Case #19/CAS-2022-0638

PHA-2022-0125 CVS #272, DS90325 Time: 10:33 AM

RECUSAL: J. ROCCHIO recused and was 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 unknown loss of 100 methadone 10mg tablets reported as discovered on 5/9/22 during a change
 of MOR controlled substance inventory which actually occurred on 4/12/22 as indicated in the
 response and on the application.
- Former DL Wolowicz determined the loss was a dispensing error after reviewing video on 4/12/22. He had Loss Prevention close the case as a known loss over Former MOR Shaw's objection. He went on an extended vacation and resigned. On 5/9/22, Former MOR Shaw expressed her concern regarding the loss to DL Skinner. Video is retained for 14 days so it was no longer available. Former MOR Shaw stated patients were contacted but no calls were returned.
- The perpetual inventory did not reconcile with the response. It indicated adjustments of -100 on 4/8/22 as a "Confirmed Dispensing Error"; -100 on 05/10/22 as "Further Investigation Required"; and +100 on 5/19/22 as "BOH Count Error". Orders were received on 4/5/22 (#600) and 4/7/22 (#300). On 7/12/22, Former MOR Shaw clarified the response stating she identified the discrepancy on 4/8/22 during CII count ahead of the change of MOR inventory and notified DL Wolowicz. She searched the entire safe, look-alike drugs on the shelves, and the trash. She reviewed video of the prescriptions she filled since 3/27/22 with DL Wolowicz. On 4/1/22, she had filled a prescription for #420 tablets at which time she is seen removing 5 bottles from the safe. She believed they there were in agreement there was no error, but DL Wolowicz had Pharmacist Hebert adjust the perpetual inventory on 4/8/22.
- In an attempt to document the loss, the perpetual inventory was adjusted on 5/10/22 causing 100 tablets to be removed that were added back in on 5/19/22. The only patient contacted and not reached was the one who was dispensed #420 tablets from 4/1/22. Former MOR Shaw theorized the 2 orders received may have been incorrectly entered or one bottle inadvertently discarded. The Pharmacy confirmed the two orders were received correctly. Former MOR Shaw left employment at the Pharmacy on 7/7/22.
- A statement signed and dated by all Pharmacy staff was provided attesting all policies and procedure for the proper storage and handling of controlled substances had been reviewed.

<u>ACTION</u>: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2022-0125), 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-2022-0666

PHA-2022-0127 CVS #1248, DS2875 Time: 10:38 AM

RECUSAL: J. ROCCHIO recused and was 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.

- Untimely RLCS for an unknown loss of #60 hydromorphone 2mg tablets reported as discovered on 4/27/22. Former MOR El Khoury responded the loss was discovered on Sunday, 4/24/22 when the prescription could not be found in the waiting bin and was reported internally on 4/27/22.
- Floater Pharmacist Fletcher filled, back counted, bagged, and verified the prescription on 4/20/22.
 Both he and Former MOR El Khoury reviewed video confirming his actions. Former MOR El Khoury stated the waiting bins and trash were searched. No calls were received from patients about a commingled prescription. No edits were made to the prescription after it was completed. Diversion was not suspected.
- After being alerted the prescription could not be located on 4/24/22, Floater Pharmacist Goulet
 conducted a thorough search of the Pharmacy with the pharmacy technicians. Waiting bins were
 searched up to three times in two hours. She notified Former MOR El Khoury and DL Knight and left a
 detailed note for follow up the next day. She confirmed the patient had a sufficient supply of
 medication until next day when the prescriber could be contacted.
- Former MOR El Khoury spoke with Pharmacy staff ensuring they were aware of proper pick-up etiquette including checking prescriptions they are selling for commingled bags. Pharmacy staff and Floater Pharmacist Fletcher confirmed all policies and procedure for the proper storage and handling of controlled substances were reviewed.

<u>ACTION</u>: Motion by S. AHMED, seconded by K. THORNELL, and voted unanimously by those present, to consolidate the matter (PHA-2022-0127) with PHA-2022-0136. A second motion was made by S. HAMILTON, seconded by S. AHMED, and vote unanimously by those present, to REFER the matter (PHA-2022-0127), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #21/CAS-2022-0751

PHA-2022-0136 CVS #1248, DS2875 Time: 10:40 AM

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

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

- Inspectional deficiencies on 6/22/22 for Former MOR El Khoury still on file as MOR. Also PTT Meas' license expired on 4/29/22 and PTT Bazile's license expired on 05/17/2022. Interim MOR Wagner stated MOR El Khoury left in early June and Current MOR Elkadi was starting on 6/27/22. No CS inventory completed by MOR El Khoury as outgoing MOR was on file. PTT Meas worked 245.94 hours and PTT Bazile worked 84.92 hours in the Pharmacy with an expired license.
- Former MOR El Khoury's last day was 6/4/22, Interim MOR Wagner served 6/5/22-06/25/2022, and Current MOR Elkadi started on 6/27/22 when a CS inventory was completed. The BORP received the change of MOR application on 7/12/22. Both PTT Meas and PTT Bazile were not aware of the expiration dates of their PTT licenses. PTT Meas had completed over 500 hours and applied for a PT license which was issued 6/29/22. PTT Bazile stated she only worked as a cashier after notified his license expired. She applied for an extension on 7/21/22.
- Ms. Furtado alleged there is no formal process for tracking PTT hours, but the MOR monitors them.

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• The POC stated the MOR will monitor PTT hours and license expirations monthly and will conduct a quarterly BORP self-audit to ensure compliance. In the response, Current MOR provided a signed and dated statement confirming review of 247 CMR 8.03(2), (4)(c), and (5) pertaining to PTTs. The expiration date for PTT Bazile's license was extended to 1/17/23.

ACTION: Motion by S. AHMED, seconded by K. THORNELL, and voted unanimously by those present, to consolidate the matter (PHA-2022-0136) with PHA-2022-0127. A second motion was made by S. HAMILTON, seconded by S. AHMED, and vote unanimously by those present, to REFER the matter (PHA-2022-0136), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #22/CAS-2022-0705

PHA-2022-0129 CVS #8437, DS3549 Time: 10:45 AM

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

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

- During an inspection on 6/9/22, it was observed that a controlled substance inventory for a change of MOR was completed on 2/26/22 but Former MOR Ruiz was still listed as the MOR. Current MOR Norphel stated he assumed the MOR role on 2/27/22 after completing a controlled substance inventory on 2/26/22. Copies of the CS inventories that were only signed by Current MOR Norphel were provided. He indicated an application was completed on 3/17/22 and was given to DL Vachon to submit.
- DL Vachon stated the application was returned to his satellite office in Wellesley which he infrequently
 visits. He did not follow up to verify the application was received. DL Vachon claimed, "Going
 forward, I will take corrective action to ensure I validate the proper application was received by the
 MA Board of Pharmacy and uploaded properly via the Board's website". On 7/22/22, DL Vachon and
 CVS Regulatory were asked to follow up with BORP staff regarding the change of MOR application as
 MLO still reflected Former MOR Ruiz.
- On 7/27/22, it was determined that Former MOR Ruiz was no longer employed by CVS. She was informed by email that she was still listed as the MOR of the Pharmacy and was reminded she was required to notify the BORP within 10 business days of leaving the position. DL Vachon confirmed the CS inventories were completed by both Current MOR Tenzin and Former MOR Ruiz on 2/26/22.
- In the 7/19/22 response, Current MOR Norphel stated, "Going forward, I will ensure licensing
 applications are received timely and validate through the applicable channels". A copy of CVS DOC041422 Pharmacist in Charge and Powers of Attorney at CVS Health was submitted that was signed by
 the staff pharmacists confirming review.

<u>ACTION</u>: Motion by J. CHIN, seconded by S, AHMED, and voted unanimously by those present, to refer the matter (PHA-2022-0129), 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.

Topic X: Executive Session Call to Order: Time: 10:49 AM

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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 R. Morelli enter Executive Session; Seconded by D. Barnes and Board Members present voted unanimously by roll call to approve motion.

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

Lunch 12:15 to 12:45 PM

Topic XI: Adjudicatory Session Time: 12:47 PM

DISCUSSION: None

ACTION: President S. Hamilton request a motion to enter Adjudicatory Session.

At 12:47 PM C. Belisle, seconded by D. Barnes and voted unanimously by all those present to enter adjudicatory session by roll call vote.

Topic XII: 65C Sessions MGL c. 112 section 65C Time: 12:51 PM

DISCUSSION: None

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

At 12:51 PM J. Chin, seconded by K. Thornell and voted unanimously by all those present to enter 65C by roll call vote.

- S. Hamilton leaves meeting at 2:20 PM
- J. Chin leaves meeting at 2:33 PM
- J. Rocchio leave meeting at 2:39 PM

Topic XIII: ADJOURMENT OF MEETING TIME: 3:03 PM

ACTION: Motion by S. Ahmed seconded by K. Thornell 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 10/13/22 General Session
- 2. Draft Minutes of the 9/1/22 Meeting

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- 3. Report on Applications approved pursuant to Licensure Policy 13-01
- 4. Report on probation
- 5. Report on Board Delegated Complaint Review to licensure policy 14-02
- 6. Report on PSUD 17-03
- 7. Report Research Drug Study Report pursuant to Staff Action Policy 18-02
- 8. Policy 2022-02: Extended Absence of a Manager of Record
- 9. Policy 2020-14: COVID-19 Testing
- Petition for waiver 10. Application: Walmart N/A 11. Application: Rite Aid Petition for waiver N/A
- 12. Application: Genoa Healthcare N/A **New Pharmacy & Waivers**
- 13. Application: New Health Charlestown N/A Waiver
- 14. Application: Whittier Health Pharmacy DS89795 Relocation 15. Application: Cornerstone Health Solutions DS90083 Renovation
- 16. Application: MedWiz of Mass, LLC Renovation
- 17. 247 CMR 13.00: Registration requirements and minimal professional standards for nuclear pharmacies
- 18. CAS-2022-2026 PHA-2022-0034 The Baker Pharmacy, DS12518 19. CAS-2022-2026 PHA-2022-0035 Zachary Barrieau, PH238037
- 20. CAS-2022-0278 PHA-2022-0051 Walgreens #19695, DS90174
- 21. CAS-2022-0277 PHA-2022-0047 Walgreens #3016, DS2277 22. CAS-2022-0416 PHA-2022-0085 Walgreens #12399, DS89688
- 23. CAS-2022-0549 PHA-2022-0111 Walgreens #2330, DS1736
- 24. CAS-2022-0701 PHA-2022-0133 Cardinal Health, WD352
- 25. CAS-2021-1166 PHA-2022-0021 Big Y #63, DS3179
- 26. CAS-2022-0333 PHA-2022-0067 Market 32 Pharmacy, DS2526
- 27. CAS-2022-0242 PHA-2022-0045 Option Care, DS90107
- 28. CAS-2022-0237 PHA-2022-0042 CVS #686, DS89903
- 29. CAS-2022-0239 PHA-2022-0033 CVS #2254, DS2866 30. CAS-2022-0189 PHA-2022-0029 CVS #10502, DS90067
- 31. CAS-2022-0249 PHA-2022-0040 CVS #2322, DS2895
- 32. CAS-2022-0281 PHA-2022-0055 CVS #2070, DS2711
- 33. CAS-2022-0285 PHA-2022-0058 CVS #2533, DS2933
- 34. CAS-2022-0392 PHA-2022-0083 CVS #2171, DS2865
- 35. CAS-2022-0548 PHA-2022-0114 CVS #2171, DS2865
- 36. CAS-2022-0638 PHA-2022-0125 CVS #272, DS90325
- 37. CAS-2022-0666 PHA-2022-0127 CVS #1248, DS2875 38. CAS-2022-0751 PHA-2022-0136 CVS #1248, DS2875
- 39. CAS-2022-0705 PHA-2022-0129 CVS #8437, DS3549

Respectfully Submitted, Carly Jean-Francois, NP, Secretary

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