

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

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

August 3, 2023

Webex Information

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

For video access click on the following link:

<https://eohhs.webex.com/eohhs/j.php?MTID=m9d520940f3950b9db3ed611809b10100>

To access the meeting by phone:

Call in Number: 1-650-479-3208

Access Code: 2531 639 9289

*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		C. Belisle
8:02	II	APPROVAL OF AGENDA		
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of June 1, 2023 Regular Session Minutes		
8:10	IV	REPORTS <ul style="list-style-type: none">• Applications approved pursuant to Licensure Policy 13-01• Monthly report from Probation• Board Delegated Review pursuant to Licensure Policy 14-02• PSUD Report-Policy 17-03• Research Drug Study report pursuant to Staff Action Policy 18-02		

8:15	V	FLEX <ul style="list-style-type: none"> Prosecutorial Discretion Policy and Alford Plea Language Presentation Resolutions for this year's NABP District 1 and 2 meeting 		J. Uhing-Luedde																																																												
8:45	VI	APPLICATION <ul style="list-style-type: none"> Genoa Leominster – New Community Pharmacy Genoa Northampton – New Community Pharmacy 																																																														
9:15	VII	FILE REVIEW <table border="1"> <tr> <td>1</td> <td>CAS-2023-0300</td> <td>SA-INV-21788</td> <td>Big Y Distribution Center, WD497</td> </tr> <tr> <td>2</td> <td>CAS-2023-0124</td> <td>PHA-2023-0034</td> <td>Walgreens #17728, DS90161</td> </tr> <tr> <td>3</td> <td>CAS-2022-0249</td> <td>PHA-2023-0040</td> <td>Mohammad Shakeri, PH19962</td> </tr> <tr> <td>4</td> <td>CAS-2023-0213</td> <td>PHA-2023-0055</td> <td>Walgreens #2710, DS2126</td> </tr> <tr> <td>5</td> <td>CAS-2022-1234</td> <td>PHA-2023-0084</td> <td>Thoa Pham, PH238708</td> </tr> <tr> <td>6</td> <td>CAS-2022-1567</td> <td>PHA-2023-0002</td> <td>Walgreens #3548, DS2713</td> </tr> <tr> <td>7</td> <td>CAS-2023-0308</td> <td>PHA-2023-0072</td> <td>Walgreens #9477, DS89668</td> </tr> <tr> <td>8</td> <td>CAS-2023-0402</td> <td>PHA-2023-0079</td> <td>Walgreens #3016, DS2277</td> </tr> <tr> <td>9</td> <td>CAS-2023-0038</td> <td>PHA-2023-0085</td> <td>Pharmacy Amanecer, DS90354</td> </tr> <tr> <td>10</td> <td>CAS-2022-1630</td> <td>PHA-2023-0095</td> <td>Qualgen, NO00042</td> </tr> <tr> <td>11</td> <td>CAS-2022-1538</td> <td>PHA-2022-0222</td> <td>Galaxy Pharmacy, DS90257</td> </tr> <tr> <td>12</td> <td>CAS-2023-0078</td> <td>PHA-2023-0076</td> <td>Taylor Bird, PH238575</td> </tr> <tr> <td>13</td> <td>CAS-2023-0004</td> <td>PHA-2023-0016</td> <td>CVS #2112, DS2667</td> </tr> <tr> <td>14</td> <td>CAS-2023-0246</td> <td>PHA-2023-0246</td> <td>CVS #2878, DS3092</td> </tr> <tr> <td>15</td> <td>CAS-2023-0553</td> <td>PHA-2023-0104</td> <td>CVS #26, DS2912</td> </tr> </table>	1	CAS-2023-0300	SA-INV-21788	Big Y Distribution Center, WD497	2	CAS-2023-0124	PHA-2023-0034	Walgreens #17728, DS90161	3	CAS-2022-0249	PHA-2023-0040	Mohammad Shakeri, PH19962	4	CAS-2023-0213	PHA-2023-0055	Walgreens #2710, DS2126	5	CAS-2022-1234	PHA-2023-0084	Thoa Pham, PH238708	6	CAS-2022-1567	PHA-2023-0002	Walgreens #3548, DS2713	7	CAS-2023-0308	PHA-2023-0072	Walgreens #9477, DS89668	8	CAS-2023-0402	PHA-2023-0079	Walgreens #3016, DS2277	9	CAS-2023-0038	PHA-2023-0085	Pharmacy Amanecer, DS90354	10	CAS-2022-1630	PHA-2023-0095	Qualgen, NO00042	11	CAS-2022-1538	PHA-2022-0222	Galaxy Pharmacy, DS90257	12	CAS-2023-0078	PHA-2023-0076	Taylor Bird, PH238575	13	CAS-2023-0004	PHA-2023-0016	CVS #2112, DS2667	14	CAS-2023-0246	PHA-2023-0246	CVS #2878, DS3092	15	CAS-2023-0553	PHA-2023-0104	CVS #26, DS2912		
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11:00	VIII	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.																																																														
12:00	LUNCH BREAK																																																															

1:00	IX	M.G.L. c. 112, § 65C SESSION		
4:00	X	ADJOURNMENT		

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

August 3, 2022

Board Members Present

Caryn Belisle, RPh, MBA, President
Jennifer Chin, RPh Secretary
Katie Thornell, RPh, MBA President Elect
Dr. Richard Lopez, MD
John Rocchio, RPh, PharmD
Sami Ahmed, PharmD., RPh, BCPS, BCSCP
Rita Morelli, PharmD, BCACP, RPh
Johanna Lopez, MS
Julie Lanza, CPhT
Carly Jean-Francois, RN, NP
Delilah Barnes, RPh

Board Members Not Present

Dawn Perry, JD
Sebastian Hamilton, Pharm D, MBA,RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, Associate Executive Director
Jacqueline Petrillo, PharmD, RPh, JD, Board Counsel
Michael Egan, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh, Quality Assurance Pharmacist
Richard Harris, Program Analyst
Joanna Chow, Program Analyst
Taylor Lee, Office Support Specialist
Joanne Trifone, RPh, Director of Investigations
Gregory Melton, JD, PharmD, BCPS, Investigator
Julienne Tran, RPh PharmD, Investigator
Christina Mogni, RPh, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 AM

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

Roll call attendance: J. Lanza, yes; J. Rocchio, yes; J. Chin, yes; S. Ahmed, yes; R. Morelli, yes; K. Thornell, yes. J. Lopez, yes; D. Barnes, yes; C. Belisle, yes; C. Jean-Francois joins meeting 8:05 AM; R. Lopez joins meeting at 8:11 AM.

TOPIC II.

Approval of Agenda

TIME 8:03 AM

Agenda 08/03/23

DISCUSSION:

None

ACTION:

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

TOPIC III

Approval of Board Minutes

TIME: 8:03 AM

Minutes

1. Draft 6/1/23

Change: No changes

Action:

Motion by J. Lanza seconded S. Ahmed and voted unanimously to approve the regular session minutes of 6/1/23 with no noted changes by roll call vote.

TOPIC IV

REPORTS

Applications approved pursuant to Licensure Policy 13-01

TIME: 8:03 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported 58 Change of Manager applications and 2 facility transfers of ownership that have been approved via Staff Action since the June 1st Board meeting.

So noted.

TOPIC IV.

REPORTS

Monthly Report from Probation

TIME: 8:03 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto indicated 18 active probation cases, 5 of which have successfully completed probation monitoring since the June 1st Board meeting.

So noted.

TOPIC IV.

REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

TIME: 8:04 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported 7 Continuing Education discrepancies, all of which have been closed with no discipline warranted. 3 inspectional deficiencies were reported, each of which were issued a reprimand. 3 waiver renewal requests have been approved since the last Board meeting.

So noted.

TOPIC IV.

REPORTS

PSUD report by Staff Action 17-03

TIME: 8:05 AM

PRESENTED BY: M. BOTTO

DISCUSSION: M. Botto reported a total of 8 active members in the PSUD program. There have been three successful admissions and two successful completions of the program since the June 1st Board meeting. Currently, there are no admissions pending.

So noted.

TOPIC IV.

REPORTS

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

TIME: 8:05 AM

PRESENTED BY: M. CHAN

DISCUSSION: M. Chan reported 2 pharmacies participating in drug studies. There are currently 12 active studies, 5 of which include investigational drug studies. 9 studies have been concluded and there are currently no new reports.

So noted.

TOPIC V

FLEX

Prosecutorial Discretion Policy and Alford Plea Language Presentation

Time: 8:27 AM

Presented by: J. UHING-LUEDDE

Discussion: These policies would allow the prosecutors to settle discipline more efficiently. The first policy “softens” language in the standard consent agreements (“Alford Plea Language”) so that it does not force the licensee to admit to a violation. The second policy would not allow the prosecutors to change Board-issued discipline or monitoring terms, but would allow them, after consultation with the Board Executive Director and Board counsel, to remove allegations that are not supported by the fact pattern, as well as add other relevant regulations that the licensee’s specific action also violated.

Action: Motion by J. CHIN, seconded by J. ROCCHIO, and voted unanimously by roll call of those present, to approve the Alford Plea Language.

Action: Motion by C. BELISLE, seconded by J. LOPEZ, and voted unanimously by roll call of those present, to approve the Prosecutorial Discretion Policy and to report back to the Board if any significant changes are made to the discipline settlement.

Resolutions for this year's NABP District 1 and 2 meeting

Time: 8:07 AM

Presented by: D. SENCABAUGH, W. FRISCH

Discussion: Resolutions for next month's District meeting are due August 31st. Board staff will draft a resolution requesting for drug shortages, specifically stimulants, be studied for potential solutions at the pharmacy and patient level. Final language will be distributed at September's Board meeting.

Action: Motion by C. BELISLE, seconded by J. LOPEZ, and voted unanimously by roll call of those present, to approve the resolution.

TOPIC VI

Applications

1. Genoa

New Community Pharmacy Leominster, MA

TIME 8:20am

Represented by: Megan Garrity, Regional Director Of Operations at Genoa Healthcare & Julia Burkhardt, Genoa Healthcare Site Manager

Recusal: None

Discussion: MEGAN GARRITY petitioned for approval of an application for a new Genoa Healthcare Pharmacy in Leominster, MA as described in the Board Packet on pages 25 to 57. She apologized for the confusion during the applications process for the Genoa Healthcare's Leominster and Northampton sites. GARRITY indicated that an additional level of review by a regulatory specialist prior to submission of any further applications to BORP was now standard operating procedure. GARRITY also petitioned for waivers of the following regulations: 247 CMR: 247 CMR 6.01(5)(a)(4), 247 CMR 6.01(5)(a)(8), 247 CMR 6.02(4), 247 CMR 6.02(5), 247 CMR 9.01(15), and 247 CMR 9.01(16) as described in Genoa Healthcare's application for the Leominster site.

WILLIAM FRISCH indicated that new blueprints were sent by Genoa Healthcare on just prior to the board meeting and he did not have a chance to review the blueprints. He also indicated that Genoa was located within other DMH or DPH licensed facilities such as BHCSQ would need additional approvals from those departments or bureaus.

Action: JOHN ROCCHIO motioned to approve the (1) new pharmacy application for Genoa Healthcare's Leominster site contingent upon submission of satisfactory blueprints, obtainment of additional licensing from other departments or bureaus as necessary, and a successful new pharmacy inspection,

and (2) waivers of 247 CMR: 247 CMR 6.01(5)(a)(4), 247 CMR 6.01(5)(a)(8), 247 CMR 6.02(4), 247 CMR 6.02(5), 247 CMR 9.01(15), and 247 CMR 9.01(16); Motion was seconded by SAMI AHMED then approved unanimously by roll-call vote by BORP members present.

2. Genoa New Community Pharmacy – Northampton, MA TIME 8:25am

Represented by: Megan Garrity, Regional Director Of Operations at Genoa Healthcare & Julia Burkhardt, Genoa Healthcare Site Manager

Recusal: None

Discussion: MEGAN GARRITY petitioned for approval of an application for a new Genoa Healthcare Pharmacy in Northampton, MA as described in the Board Packet on pages 58 to 68. GARRITY also petitioned for waivers of the following regulations: 247 CMR: 247 CMR 6.01(5)(a)(4), 247 CMR 6.01(5)(a)(8), 247 CMR 6.02(4), 247 CMR 6.02(5), 247 CMR 9.01(15), and 247 CMR 9.01(16) as described in Genoa Healthcare’s application for the Northampton site.

WILLIAM FRISCH indicated that new blueprints were sent by Genoa Healthcare on just prior to the board meeting and he did not have a chance to review the blueprints. He also indicated that Genoa was located within other DMH or DPH licensed facilities such as BHCSQ would need additional approvals from those departments or bureaus.

Action: JENNIFER CHIN motioned to approve the (1) new pharmacy application for Genoa Healthcare’s Leominster site contingent upon submission of satisfactory blueprints, obtainment of additional licensing from other departments or bureaus as necessary, and a successful new pharmacy inspection, and (2) waivers of 247 CMR: 247 CMR 6.01(5)(a)(4), 247 CMR 6.01(5)(a)(8), 247 CMR 6.02(4), 247 CMR 6.02(5), 247 CMR 9.01(15), and 247 CMR 9.01(16); Motion was seconded by RITA MORELLI, then approved unanimously by roll-call vote by BORP members present.

TOPIC VII

File Review

Case #1 /CAS-2023-0300

SA-INV-21788

Big Y Distribution Center WD497

Time: 09:17 AM

RECUSAL: NONE

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

- On January 19, 2023, Big Y DC submitted an initial report of an unknown loss of 100 alprazolam 0.5mg tablets discovered on January 16, 2023. Big Y DC continued its internal investigation of the incident until the alprazolam was recovered from Big Y’s warehouse on March 21, 2023. At that time, Big Y DC retracted the loss.

- SM Pappas explained that delivery trucks were loaded with supplies for multiple stores including pharmacy supplies. The trucks were loaded according to the delivery route except for pharmacy supplies which were loaded at the tail of the truck regardless of route. This required pharmacy supplies to be off-loaded and reloaded depending on the route. SM Pappas also explained that the Big Y Supermarket in North Haven did not operate a pharmacy, so staff did not realize the purple tote signified pharmacy supplies when the pharmacy supplies were off-loaded and left at the store. Thus, the pharmacy tote was handled as a regular return to Big Y DC's warehouse where the order was lost until March 21, 2023.
- CA: SM Pappas described that the pharmacy totes were now placed in the truck with the store's order instead of the tail of the truck to avoid off-loading at the wrong store which occurred in this incident. In addition, SM Pappas described that a sticker was created and placed on all pharmacy totes which "instructs someone that may have received the wrong tote to call our Asset Protection department for instructions on next actions."

ACTION: Motion by R. MORELLI, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to CLOSE the matter (SA-INV-21788), No Discipline Warranted, Remediation Complete.

Case #2/CAS-2023-0124

PHA-2023-0034

Walgreens #17728, DS90161

Time: 09:20 AM

RECUSAL: NONE

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

- On December 30, 2022, WAG 117728 notified BORP about a loss of 50 Vyvanse 30mg capsules (Schedule II, 100 capsule stock bottle) discovered by MOR Natalie Covino during a back count on December 27, 2022. MOR Covino surmised that "after a thorough investigation, I believe the open bottle of Vyvanse 30mg containing #50 was throw[n] out by accident. It was used to fill a prescription and in haste discarded in the HIPPA trash..."
- MOR Covino then indicated that the HIPAA trash was already removed for disposal by the time the loss was discovered and "all other trash and the entire pharmacy examined."
- However, WAG 17728 later admitted and video footage revealed that the pharmacy was unable to determine whether the bottle was discarded in a refuse receptacle as MOR Covino surmised in the RLCS. Thus, the actual cause of the loss was unknown.
- CA: WAG 17728 indicated that "Our standard operating procedures have been reinforced. Our SOP was not followed by leaving medications on counter. SOP has been reviewed with [Pharmacist Veasna]. All policies have been reviewed with staff."

ACTION: Motion by S .AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0034), 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 #3/CAS-2023-0249

PHA-2023-0040

Mohammad Shakeri, PH19962

Time: 09:22 AM

RECUSAL: NONE

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

- WAG 17169 reported unknown losses of multiple Schedule II CS including 793 amphetamine mixed salts tablets of various strengths, 73 methylphenidate 20mg tablets, and 130 oxycodone 5mg tablets were discovered on 12-21-2021. Ultimately, WAG was unable to resolve the discrepancies or determine a cause for the losses. However, WAG indicated that no evidence of diversion was uncovered, and no further discrepancies occurred since the losses discovered on 12-21-2021.
- DEA and BORP inspected the pharmacy after learning of the above-mentioned losses. DEA indicated that most discrepancies occurred when Former MOR Shakeri was MOR. DEA indicated that WAG would have been issued an LOA and would have requested Former MOR Shakeri be terminated from employment had he still been MOR due to very poor recordkeeping. DEA did not suspect diversion just terrible recordkeeping by Former MOR Shakeri. Of note, DEA was also unable to reconcile WAG's inventory.
- DEA chose not to issue a LOA because Current MOR Patel had done an outstanding job reconciling the past controlled substance inventory while maintaining good order for current recordkeeping during his tenure as MOR.
- Former MOR Shakeri responded, "After reviewing your email, the issue of lost control substances were handled by Walgreens loss prevention manager and it was determined that it was more of computer error than an actual loss. I left Walgreens shortly after and I do not recall much of the details about this specific drug loss. Walgreens should be able to provide more details about this loss. I m not sure if this was an internal thief or a computer issue. The schedule II were in a safe accessible only by pharmacist. The pharmacy dispensed large quantities of Adderall and sometimes there was a waiting list of people waiting for the shipment because the store reached the limit of ordering."

ACTION: Motion by J. LOPEZ, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2023-0040), 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.

Case #4/CAS-2023-0213

PHA-2023-0055

Walgreens #2710, DS2126

Time: 09:25 AM

RECUSAL: NONE

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

- During a RCI on 02-01-2023, Investigator Brosnan discovered that WAG 2710's freezer was broken from December 15, 2022 to December 23, 2022 and the pharmacy was also unable to provide temperature logs for another refrigerator.
- According to pharmacy staff, vaccines were stored during the period when the freezer was broken "in a Styrofoam cooler and moved to an unsecured walk-in food freezer in the front of the store, outside of the pharmacy space." In addition, the pharmacy did not monitor the temperature inside the Styrofoam cooler during that period. Instead, a front store manager monitored the temperature in the walk-in freezer. Of note, the vaccines were later moved back to the pharmacy's freezer on December 26,2022 after the freezer was repaired on December 22, 2022.

- Accordingly, Investigator Brosnan issued a plan of correction (POC) to the pharmacy. In addition, he requested that the pharmacy “refrain from using the remaining vaccines stored in the pharmacy freezer until it can be determined whether or not these items can still be used according to Board Policy 2020-05.”
- POC/CA: MOR Oney indicated that she contacted Moderna’s medical information team and excursion team regarding the vaccines and confirmed the vaccines were able to be used. MOR Oney indicated that the freezer was repaired. She also indicated that medication would be transferred to another pharmacy location in the event of another refrigerator or freezer failure to ensure proper storage and monitoring of the medication. MOR Oney also provided a temperature report from 07-31-2022 to 02-02-2023 for the other refrigerator. The temperature report did not reveal any temperature excursions.
- Lastly, MOR Oney indicated that she would “make sure we are regularly monitoring the online temperature monitoring system to ensure everything is being transmitted and logged correctly and that there have been no recent excursions that need to be looked into.”

ACTION: Motion by R. LOPEZ, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0055), 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 REPRIMAND.

Case #5 /CAS-2023-1234

PHA-2023-0084

Thao Pham, PH238708

Time: 09:29 AM

RECUSAL: NONE

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

- BORP opened this complaint after review of SA-INV-20885 during the April 2023 Board Meeting regarding a citation issued to Pharmacist Pham by CA BOP after an inspection and subsequent investigation at Paseo Oak Pharmacy in California during 2020. During the investigation, CA BOP discovered that Pharmacist Pham was PIC at Paseo from July 18, 2018 to January 10, 2019. During that period, Paseo dispensed multiple compounded drug preparations which were copies of commercially available drug products without documentation of a shortage or specific medical need. Pharmacist Pham was initially fined \$3,500.00 but the fine was reduced to \$1,500.00 after she appealed.
- Pharmacist Pham described that she was hired as a PIC at Paseo as a new graduate. However, she only worked one or two days a week. Pharmacist Pham explained that “[she] did not feel comfortable working there so [she] left, and [her] last date of employment was on around November 15th, 2018. Paseo’s owner indicated that he would hire a replacement, but he failed to do so. Ultimately, Pharmacist Pham notified CA BOP that she was no longer PIC at Paseo on January 10, 2019.
- Pharmacist Pham described that she was not physically present in the pharmacy on fourteen occasions when prescriptions were purportedly approved by her. According to Pharmacist Pham, she conveyed this to CA BOP during a phone conference in October 2020. As a result, CA BOP reduced her fine to \$1,500.00.
- CA: Corrective action “included notifying/emailing the Board of Pharmacy immediately on my last date of employment as PIC so that my name/license is not abused and forged with prescriptions. I have also read over the laws and regulations more carefully under the Board’s website so I can be

knowledgeable about the laws and to not take any Pharmacist in Charge/Manager of Record positions until I am fully comfortable, and I have more oversight physically at the pharmacy.” No additional information was provided in response to this complaint.

ACTION: Motion by J. CHIN, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2023-0084), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #6/CAS-2023-1567

PHA-2023-0002

Walgreens #3548, DS2713

Time: 09:32 AM

RECUSAL: NONE

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

- During a retail compliance inspection on 12/15/22, it was noted that the pharmacy had an unlicensed inventory specialist handling drug inventory
- MOR Robert indicated that she failed to ensure PTT Christopher O’Keefe had an active license with the Board. She noted that PTT O’Keefe was hired and completed his training before she even met him. MOR Robert incorrectly thought that his license application was already approved. She indicated that the company system regularly alerts the MOR to any license that expires and if the staff has no license. However, PTT O’Keefe was coded in the system as a technician and the system did not alert her of any issues regarding his license.
- From 09/09/2022 through 01/26/2023, his cashier hours completed were 760 hours as an unlicensed staff.
- The MOR indicated that she will work closely with my front store management to ensure that the PTT application is the first form a new pharmacy employee fills out. She created a file that contains the PTT application as well as blank sheets to record the tech in training hours. It also contains a quick reference of all pharmacy team members including their license numbers and expiration dates.

ACTION: Motion by K. THORNELL, seconded by J. LOPEZ, and voted unanimously by those present, to refer the matter (PHA-2023-0002), 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-2023-0308

PHA-2023-0072

Walgreens #9477, DS89668

Time: 09:35 AM

RECUSAL: NONE

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

- RLCS for unknown losses of #8 amphetamine salts 20mg tablets identified on 12/11/22 during the reconciliation of the perpetual inventory. An audit identified additional unknown losses of #6 amphetamine salts 10mg tablets and #89 amphetamine salts 30mg. Controlled substance recordkeeping was reviewed for the 3 drugs from 6/10/22-12/11/22. Video was not reviewed.
- Pharmacist Tuleva first identified the 20mg discrepancy on 12/9/22 when filling a prescription. She assumed a prescription was logged incorrectly and would find the error when she did the inventory on

12/10/22. Contrary to the RLCS, she determined a discrepancy of #12 tablets and adjusted BOH on 12/11/22.

- MOR Mackey reviewed the perpetual inventory since the previous reconciliation on 12/2/22. She contacted patients who had been dispensed 20mg tablets with no overages reported. APM Borosavage initiated daily counts on 12/13/22 then added counts for all strengths of amphetamine salt tablets over the next 4 weeks. An internal audit identified the losses of #6 amphetamine salts 10mg and #89 amphetamine salts 30mg. MOR Mackey believed the losses for the 10mg and 20mg tablets were due to counting errors.
- Perpetual inventories for 11/8/21-12/19/22 for the 10mg and 30mg tablets were provided. A review for the 10mg tablets identified the BOH was adjusted -6 on 11/20/21. A review of the 30mg tablets identified +137 on 11/21/22 but no loss of 89 tablets. A review for the 20mg tablets identified an adjustment of -12 and the Pharmacy was asked to file an amended DEA 106. The Pharmacy was also asked to provide the perpetual inventory showing the 30mg loss. No additional documentation was provided but MOR Mackey stated those loss quantities were based on an audit.
- DM Feeney reviewed Pharmacy operations regarding drug accuracy with MOR Mackey. Going forward, only pharmacists will count CII with back-counts of all stock bottles excluding 500-count.

ACTION: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0072), 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-2023-0402

PHA-2023-0079

Walgreens #3016, DS2277

Time: 09:39 AM

RECUSAL: NONE

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

- Repeat inspectional deficiencies cited on 3/21/23 for Former MOR Tony Nguyen still on record as MOR but left employment on 2/5/23, controlled substance recordkeeping violations, and insanitary conditions that were not remediated in POCs previously provided. The matter of PHA-2022-0047 was heard on 10/13/23 for no MOR at the Pharmacy from 2/16/21-11/13/21 cited during a site visit on 3/7/22. The Board members voted for a Reprimand. During inspections on 6/14/22 and 12/14/22, the Pharmacy was cited for repeat deficiencies of controlled substance recordkeeping violations and insanitary conditions.
- DM Mattia related he became DM on 3/13/23 and did not know why the Former DM Carreira did not notify the BORP of a MOR change. DM Mattia appointed Current MOR Thomas Nguyen as MOR and an application was completed on 4/14/23. All deficiencies were immediately addressed by Current MOR Thomas Nguyen including completing the perpetual inventory every 10 days, re-organizing records to be readily retrievable, returning expired CII, and cleaning the Pharmacy. Current MOR Thomas Nguyen stated the perpetual inventory had not been completed previously every 10 days due to a lack of communication between the absent MOR and the district pharmacists who worked at the Pharmacy.
- DM Mattia and Current MOR Thomas Nguyen will ensure all requirements are met and will work with the Store Manager to address any additional janitorial concerns. Current MOR Thomas Nguyen will ensure the perpetual inventory is completed every 10 days and the Pharmacy's compliance to all deficiencies per the POC. Current MOR Thomas Nguyen and Pharmacist Monzavi signed the copies of

SOP “Pharmacist-in-Charge Change Notifications” and “INMAR Rx Solutions - CII and CIII-V Claims” confirming review. Current MOR Thomas Nguyen, Pharmacist Monzavi, and CPHT Slade signed the copy of “Controlled Substance Perpetual Inventory and Reconciliations Procedures” confirming review.

ACTION: Motion by J. ROCCHIO, seconded by K. THORNELL, and voted unanimously by those present, to COMBINE the matter (PHA-2023-0079) with PHA-2022-0047, 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.

Case #9/CAS-2023-0038

PHA-2023-0085

Pharmacy Amanecer, DS90354

Time: 09:44 AM

RECUSAL: NONE

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

- Formerly SA-INV-21385 - Complex non-sterile compounding (NSC) of gabapentin 10%/naproxen 5% multiphasic emulsion from BioPhysics components was observed during an inspection on 12/22/2022. The MFR was incomplete. None of the bases or APIs had expiration dates or open dates on the containers. Expiration dates for components were listed on a component expiration dates sheet provided by BioPhysics. Additionally, the compounding records were incomplete and no SDSs were available. The POC indicated SDSs were obtained and the Pharmacy voluntarily ceased complex NSC on 12/23/22.
- MOR Szarek alleged BioPhysics consulted MOR Beckman at Custom Medicine who told him this was simple compounding, so he had no training in complex-NSC. The MFR was referenced off of an incomplete BioPhysics formulation and when compared, significant discrepancies were identified including mixing speeds and times and containers for the final preparation. A 120 BUD was assigned based on a potency test conducted on a 2021 sample failed at day 150. Although physical changes were noticed on day 60 of the 1/31/22 report and day 30 of the 10/10/22 report for BioPhysics analysis of samples, MOR Szarek contended the lab found no level of degradation. All appropriate PPE in the SDSs was not used.
- Four prescriptions were compounded from 9/21/22 to 12/2/22 and were all issued by Dr. Crowley on pre-printed prescriptions. The prescriptions stated they could only be filled at pharmacies licensed to use the proprietary base and the Pharmacy was specified. MOR Szarek indicated the Pharmacy had no contract or license with BioPhysics.
- MOR Szarek did not complete complex-NSC CEs since he thought this preparation was simple compounding. All P&Ps were obtained from NPSC. He provided a statement dated 8/15/22 indicating he had completed the NPSC compounding training module.
- MOR Szarek stated he would obtain BOP approval prior to resuming complex-NSC and he would engage a compounding consultant. He indicated the Pharmacy would compound requests for simple or moderate compounds. MOR Szarek provided a signed and dated statement confirming review of the Pharmacy’s policies and procedures for non-sterile compounding.
- SA-INV-21385 was heard on 4/6/23 and the Board members voted to elevate it to a complaint. MOR Szarek indicated no additional response to the complaint would be provided.

ACTION: Motion by D. BARNES, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2023-0085), 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-2022-1630

PHA-2023-0095

Qualgen, NO00042

Time: 09:49 AM

RECUSAL: NONE

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

- Report from the FDA that on 12/6/22, a federal court entered a consent decree against Qualgen (a 503B outsourcing facility) prohibiting them from directly or indirectly distributing adulterated drugs in interstate commerce. Qualgen primarily compounded and distributed Bio-Identical Hormone Replacement Therapy pellets. During FDA inspections in 2015, 2017, 2018, 2021 and 2022, Form 483s were issued for CGMP violations. Additionally, the FDA posted a safety alert in 2015 and a warning letter in 2016. Of note, the OK BOP fined Qualgen \$100,000 and issued a 5-year probation on 6/15/16 for multiple state and federal violation including CGMP violations.
- Qualgen's attorney did not provide written responses from CEO Riney and Director of QA Lavoie as requested. A copy of the Consent Decree of Permanent Injunction was submitted. In a letter from the FDA dated 12/19/22, Qualgen was allowed to resume operations for terminally sterilized drugs but not aseptically processed drugs or non-sterile drugs. Recall notices that were dated 10/17/18 for 74 lots of pellets and 5/31/18 for 3 lots of pellets were provided.
- Attorney England stated Qualgen failed to notify the BORP per 247 CMR 21.09(5) of 483s or warning letters since 10/19/17 due to a lack of awareness of the requirement. He contended since 483s are public information freely accessible, Qualgen did not see the benefit of sending what appeared to be additional information. He claimed there was a lack of clarity regarding the requirements considering the fact that FDA inspectional information is public.
- The shipping information into MA beginning on 10/19/17 was requested. The response included from 1/7/21 to 9/29/22 only and indicated 64 testosterone pellets and 96 estradiol pellets were shipped into MA to 3 locations. According to the Qualgen QA Specialist/Customer Complaint Lead, no adverse events have been reported in the history of Qualgen.
- The Qualgen Consent Decree Deadlines and Deliverables provided detailed the compliance activities undertaken. Qualgen agreed to settle the suit with the US District Court and be bound by a consent decree of permanent injunction. Qualgen contracted with RCA to implement 3rd party oversight of cGMP remediation.

ACTION: Motion by R. LOPEZ, seconded by D. BARNES, and voted unanimously by those present, to refer the matter (PHA-2023-0095), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #11/CAS-2022-1538

PHA-2022-0222

Galaxy Pharmacy, DS90257

Time: 09:56 AM

RECUSAL: NONE

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

- RLCS of #80 morphine ER 60mg tablets discovered during an inspection on 12/8/22 that was identified on 11/8/22 during a change of MOR inventory but was not reported as the loss was deemed insignificant. Final reports were submitted on 12/8/22 indicating the internal investigation concluded the drug was inadvertently discarded. Current MOR Le filled a prescription for a patient who received methadone and morphine. He retrieved both medications, but the morphine was too soon to fill. When he discarded the empty methadone bottles, it was alleged the morphine bottle was discarded. On 11/8/22, the Pharmacy and safe was searched. The patient was contacted and confirmed the morphine bottle was not received with the methadone prescription. Counts were performed on 12/8/22, 1/8/23, and 2/8/23 with no further discrepancies. In the POC, SOP 5.05 Theft of Controlled Substances defines an insignificant loss as <5% if average monthly dispensing due to accidental loss.
- Current MOR Le contended that after a thorough investigation, he deemed the loss as insignificant as there was no theft or diversion and the patient confirmed she did not receive it. Once informed that the loss must be reported, former MOR Tran submitted the final reports.
- All bottles will be checked prior to discarding to ensure the bottles are empty. SOP 5.05 for controlled substances loss reporting was updated on 12/12/22. Any future accidental loss will be monitored for at least 90 days to confirm there was no theft or diversion. Current MOR Le stated a new CII safe was purchased and a new camera was installed to monitor the CII safe. A statement that was signed and dated by Current MOR Le and PT Ruan was provided confirming review of the Pharmacy's controlled substances policies.

ACTION: Motion by D. BARNES, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2022-0222), 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, with special terms to include updating their SOP 5.05 to align with the DEA's definition of a significant loss.

Case #12

CAS-2023-0078

PHA-2023-0076

Taylor Bird PH238575

Time: 10:01 AM

RECUSAL: J. ROCCHIO and intern G. LAGUERRE recused and were not present for the vote or discussion in this matter.

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

- During an inspection on 01/10/2023, it was discovered that Pharmacist Bird had administered immunizations with an expired CPR certificate. The POC showed Pharmacist Bird had administered 127 vaccines from 12/19/22-1/10/23.
- Pharmacist Bird realized at the end of December 2022 that his CPR certification had expired and enrolled in next available CPR course which was not until 1/12/23. He stated, "While I did bring up the fact that my certification had expired to the district scheduler when I enrolled in the course, I wasn't instructed to cancel immunization appointments or practice differently". He understood he should have stopped immunizing but was concerned about patient complaints and retaliation from

management. At the time, he was unaware of the ability to cancel patient immunization appointments.

- Pharmacist Bird provided a copy of his CPE Monitor Profile for 2021 and 2022 which showed he completed 2.25 CE's related to immunizations, but only completed 3.25 CE's in 2021. SA-INV-21501 was elevated to PHA-2023-0076 by BORP staff action.
- Pharmacist Bird indicated he misunderstood the CE requirements. Pharmacist Bird stated, "I wrongly assumed that the pharmacist license renewal CE requirement was with each license renewal and not yearly, so I attempted to complete most of the 40 credits in 2022 while failing to do all of 2021's requirement".
- Pharmacist Bird saved reminders in his calendar and at his desk that his CPR certification will expire on 1/12/25. He will not administer immunizations if his CPR certification were to expire in the future. He reviewed 247 CMR 9.01(1), BORP Policy 2020-11 Vaccine Administration and the CE requirements. From 04/02/2023 to 05/11/2023, Pharmacist Bird completed 21.25 CE's including 6 live CE's and 5 law CE's for remediation. He confirmed understanding that the CE's completed for remediation are over and above the minimum yearly requirement of 20 CE's for 2023.

ACTION: Motion by J. LOPEZ, seconded by S. AHMED, and voted unanimously by those present, to refer the matter (PHA-2023-0076), 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-2023-0004

PHA-2023-0016

CVS #2112, DS2667

Time: 10:05 AM

RECUSAL: J. ROCCHIO and intern G. LAGUERRE recused and were not present for the vote or discussion in this matter.

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

- RLCS- unknown loss of #78 mixed dextroamphetamine salt capsules on or about 12/05/2022.
- MOR Abdallah reported that the loss of #78 mixed dextroamphetamine salt capsules was discovered on or about 12/05/2022 while dispensing a prescription.
- Pharmacist Michienzi indicated that on 12/01/2022, she was the floater pharmacist working at the Pharmacy and discovered a shortage. She indicated that she searched the safe, ran a report for the NDC number to see if other prescriptions were filled for the wrong quantity but could not find an error and left a note for the MOR.
- The MOR noted that the prescriptions were recounted, re-checked that they were filled correctly, and as a result there were no patients contacted.
- The Pharmacy confirmed there is still an unknown loss of #48 capsules (suspected to be thrown in the trash) and they deem it insignificant.
- MOR Abdallah attested that she reviewed Loss Prevention policy and procedures with the Pharmacy Team to prevent future losses including diligent inventory management.
- MOR Abdallah submitted a signed attestation that the staff involved in this incident reviewed the proper storage and handling of controlled substances.

ACTION: Motion by S. AHMED, seconded by R. MORELLI, and voted unanimously by those present, to refer the matter (PHA-2023-0016), 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.

RECUSAL: J. ROCCHIO and intern G. LAGUERRE recused and were not present for the vote or discussion in this matter.

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

- Unknown loss of #90 dextroamphetamine salts 20mg tablets on or about 01/18/2023.
- MOR Pereira reported that the loss of dextroamphetamine salts 20mg tablets was discovered on 01/18/2023 when a patient came in to pick up their prescription. The prescription could not be found in the waiting bin, so the prescription was refilled as the patient never received the initial prescription.
- The MOR noted that a full investigation was conducted, and patients were contacted. No patients admitted to receiving the medication and the Pharmacy is confident that it was not rung through the register and accidentally provided to someone else.
- Video footage showed that the medication was placed in the waiting bin, but video footage is no longer available.
- MOR Pereira provided a signed attestation from the pharmacy staff that the Loss Prevention policy and procedures have been reviewed with the pharmacy team.
- The Pharmacy has 1 pending loss discovered on 04/20/2023 for #404 Suboxone 8mg-2mg SL films (TRG-21621).

ACTION: Motion by C. JEAN-FRANCOIS, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2023-0061), 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.

RECUSAL: J. ROCCHIO and intern G. LAGUERRE recused and were not present for the vote or discussion in this matter.

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

- On March 23, 2023, CVS 26 submitted initial notification of an unknown loss of 437 tramadol 50mg tablets discovered on March 16, 2023. CVS 26 then submitted a final report of loss on April 7, 2023 indicating the investigation concluded on April 1, 2023.
- On May 10, 2023, CVS 26 submitted an amended final report of loss. CVS 26 amended the date the investigation concluded to May 5, 2023 and confirmed the unknown loss of 437 tramadol tablets initially reported on March 23, 2023. CVS 26 then indicated that an additional unknown loss of 457 clonazepam 1mg tablets was discovered during the investigation of the tramadol loss.
- CA: Former MOR Cady wrote, "All Loss Prevention policy and procedures have been reviewed with the Pharmacy Team to prevent future losses. We will also review back counting of all narcotics at the time of dispensing to ensure accuracy."

ACTION: Motion by D. BARNES, seconded by J. LOPEZ, and voted unanimously by those present, to combine the matter (PHA-2023-0104) with PHA-2022-0108 and 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 a 1 year PROBATION, with special terms to include the Controlled Substance Loss Protocol for all benzodiazepines and tramadol containing products.

TOPIC VIII: Executive Session Call to Order: Time: 10:14 AM

By: C. Belisle 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 C. Jean-Francois and Board Members present voted unanimously by roll call to approve motion. Roll call attendance: J. Lanza, yes; J. Rocchio, yes; J. Chin, yes; S. Ahmed, yes; R. Morelli, yes; K. Thornell, yes. J. Lopez, yes; D. Barnes, yes; C. Belisle, yes; C. Jean-Francois, yes; R. Lope, yes.

TOPIC IX: 65C Sessions MGL c. 112 section 65C Time: 10:46 AM

DISCUSSION: None

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

At 10:46 A.M. S. AHMED seconded by D. BARNES and voted unanimously by all those present to enter M.G.L. chapter 65 c Session by roll call vote.

Lunch 11:53 AM to 12:30 pm

S. Ahmed leaves meeting at 12:00 PM

D. Barnes leaves meeting at 2:23 PM

TOPIC X ADJOURNMENT OF MEETING TIME: 3:43 PM

ACTION: Motion by J. Lanza seconded by J. Chin 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 8/3/2023 General Session
2. Draft Minutes of the 6/1/2023 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on probation
5. Report on PSUD 17-03
6. Research Drug Study Report (Staff Action Policy 18-02)
7. Draft Policy on Delegation of Authority re: Drafting Orders to Show Cause and Consent Agreements
8. Draft Policy: Standard Consent Agreement Terms – Alford Plea Language
9. Genoa Health Care application for a new pharmacy in Leominster
10. Genoa Health Care application for a new pharmacy in Northampton
11. CAS-2023-0300 SA-INV-21788 Big Y Distribution Center, WD497
12. CAS-2023-0124 PHA-2023-0034 Walgreens #17728, DS90161
13. CAS-2022-0249 PHA-2023-0040 Mohammad Shakeri, PH19962
14. CAS-2023-0213 PHA-2023-0055 Walgreens #2710, DS2126
15. CAS-2022-1234 PHA-2023-0084 Thoa Pham, PH238708
16. CAS-2022-1567 PHA-2023-0002 Walgreens #3548, DS2713
17. CAS-2023-0308 PHA-2023-0072 Walgreens #9477, DS89668
18. CAS-2023-0402 PHA-2023-0079 Walgreens #3016, DS2277
19. CAS-2023-0038 PHA-2023-0085 Pharmacy Amanecer, DS90354
20. CAS-2022-1630 PHA-2023-0095 Qualgen, NO00042
21. CAS-2022-1538 PHA-2022-0222 Galaxy Pharmacy, DS90257
22. CAS-2023-0078 PHA-2023-0076 Taylor Bird, PH238575
23. CAS-2023-0004 PHA-2023-0016 CVS #2112, DS2667
24. CAS-2023-0246 PHA-2023-0246 CVS #2878, DS3092
25. CAS-2023-0553 PHA-2023-0104 CVS #26, DS2912

Respectfully Submitted,
Jennifer Chin, RPh, Secretary