

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

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

June 6, 2019
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Nahomi Carlisle, Phone: 617-624-5291 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	Contact
8:30	I	CALL TO ORDER		A. Stein
	II	APPROVAL OF AGENDA		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of May 2, 2019 Regular Session Minutes • Introduction of Interns <ul style="list-style-type: none"> ○ Joanna Tam- Northeastern University ○ Celeste LaHaie- Northeastern University ○ Sherry Zaki- MCPHS 		
8:45	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 • Above Action Levels approved by Staff Action 16-04 • PSUD Report-Policy 17-03 		
8:50	V	POLICIES and ADVISORIES <ul style="list-style-type: none"> • Policy 2019-04: Transfer of Unfilled Prescriptions • Joint Policy 2018- 01: Permitted Prescription Changes and Additions 		
9:30	VI	APPLICATIONS <ul style="list-style-type: none"> • CVS Pharmacy #11301 (Dimock Health Ctr.) – New Pharmacy • Genoa Healthcare-Worcester – New Pharmacy • ProCare LTC of MA (DS90042) – Renovation 		

10:00	VII	<p>FLEX</p> <ul style="list-style-type: none"> • Educating New Pharmacy Managers about Regulatory Compliance and Best Practices to Prevent Opioid Misuse/Abuse • NABP Annual Meeting update <ul style="list-style-type: none"> ○ Timothy D. Fensky elected NABP President-Elect at NABP Annual Meeting ○ NABP Executive Committee Names Anita Young the 2019 Honorary President 		<p>C. Lathum</p> <p>K. Tanzer S. Hamilton</p>																																							
10:30	VIII	<p>FILE REVIEW</p> <table border="1" data-bbox="321 537 1208 1199"> <tr><td>1</td><td>PHA-2019-0028</td><td>Pharmacy Corp of America, DS3599</td></tr> <tr><td>2</td><td>PHA-2019-0027</td><td>BioScrip Infusion Services, DS3486</td></tr> <tr><td>3</td><td>PHA-2019-0037</td><td>Tyngsboro Family Pharmacy, DS89899</td></tr> <tr><td>4</td><td>SA-INV-14768</td><td>Pharmscript of MA, LLC, DS90251</td></tr> <tr><td>5</td><td>SA-INV-14712</td><td>CVS #1022, DS1556</td></tr> <tr><td>6</td><td>PHA-2019-0009</td><td>CVS #610, DS24018</td></tr> <tr><td>7</td><td>SA-INV-14297</td><td>CVS #714, DS3299</td></tr> <tr><td>8</td><td>SA-INV-14301</td><td>CVS #5939, DS3576</td></tr> <tr><td>9</td><td>PHA-2019-0038</td><td>CVS #1882, DS3047</td></tr> <tr><td>10</td><td>PHA-2019-0010</td><td>CVS #207, DS2864</td></tr> <tr><td>11</td><td>SA-INV-14441</td><td>Partners of MA, DS3419</td></tr> <tr><td>12</td><td>PHA-2018-0088</td><td>Blue Hill Pharmacy, DS89942</td></tr> <tr><td>13</td><td>SA-INV-14769</td><td>Preferred Pharmacy Services, DS3542</td></tr> </table>	1	PHA-2019-0028	Pharmacy Corp of America, DS3599	2	PHA-2019-0027	BioScrip Infusion Services, DS3486	3	PHA-2019-0037	Tyngsboro Family Pharmacy, DS89899	4	SA-INV-14768	Pharmscript of MA, LLC, DS90251	5	SA-INV-14712	CVS #1022, DS1556	6	PHA-2019-0009	CVS #610, DS24018	7	SA-INV-14297	CVS #714, DS3299	8	SA-INV-14301	CVS #5939, DS3576	9	PHA-2019-0038	CVS #1882, DS3047	10	PHA-2019-0010	CVS #207, DS2864	11	SA-INV-14441	Partners of MA, DS3419	12	PHA-2018-0088	Blue Hill Pharmacy, DS89942	13	SA-INV-14769	Preferred Pharmacy Services, DS3542		
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12:00																																											
1:00	IX	<p>EXECUTIVE SESSION</p> <p>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 ratify a decision of the Rehabilitation Evaluation Committee (REC) and to evaluate the good moral character as required for registration for pending applicants.</p>																																									
2:00	X	M.G.L. c. 112, § 65C SESSION																																									
5:00	XI	ADJOURNMENT																																									

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

**MINUTES OF THE GENERAL SESSION
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts, 02114
June 6, 2019**

Board Members Present

Andrew Stein, Pharm D, RPh. President
Kim Tanzer, PharmD, RPh. President Elect
Julie Lanza, CPhT, Secretary
Sebastian Hamilton, Pharm D, RPh
Stephanie Hernandez, Pharm D, BCGP, RPh
Susan Cornacchio, JD, RN
Patrick Gannon, RPh
Leah Giambarresi, Pharm D, RPh
Timothy Fensky, RPh
Carly Jean-Francois, RN, NP

Board Members Not Present

Dawn Perry, JD
Michael Godek, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Associate Executive Director
Heather Engman, JD Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Samuel Penta, RPh., Senior Investigator
Joanna Chow, CPhT, Office Support Specialist
Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist
Joseph Santoro, RPh Investigator
Christina Mogni, RPh investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:33 AM

A quorum of the Board was present, established by roll call. President A. Stein chaired the meeting and asked if anyone was recording hearing, no one responded. He explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; S. Hernandez (yes); P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky (yes)

Topic II.

Approval of Agenda

TIME 8:35 AM

Agenda June 6, 2019

DISCUSSION:

Change to Agenda:

1. Defer BioScript Infusion Services, DS3486 PHA-2019-0027

ACTION:

Motion by P. Gannon, seconded by L. Giambarresi and voted unanimously by those present to approve the agenda with noted change.

Dave asks for the Pharmacy Interns to stand and introduce themselves and also introduces the MCPHS Boston APPE Intern: Shery Zaki; Northeastern APPE Intern: Joanna Tam and Celeste LaHaie

Topic III

Approval of Board Minutes

TIME: 8:37 AM

Minutes

1. Draft, May 2, 2019 Session Minutes

Changes:

Change K.Fensky to T.Fensky under Adjudicatory Session

Action:

Motion by S. Hamilton, seconded P. Gannon, and voted unanimously to approve the regular session minutes of 5/2/19 with noted changes.

TOPIC IV

REPORTS

Applications approved pursuant to Licensure Policy 13-01

Time: 8:34 AM

Discussion: M. BOTTO noted that during the past month there have been twenty-six (26) changes of Manager of Record (MOR), three (3) renovation/expansion applications, one (1) new community pharmacy application approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:35 AM

Discussion: M. BOTTO provided the April 24, 2019 – May 30, 2019, Board of Pharmacy Statistics Report for the Probation monitor, which noted that one (1) licensee satisfactorily completed probations, zero (0) was issued final notice, and there are currently thirty-nine (39) licensees on probation.

So noted

TOPIC IV

REPORTS

Monthly Report from BDR pursuant to Policy 14-02

Time: 8:35 AM

Discussion: M.BOTTO noted that there were two (2) Board Delegated Review cases heard on June 3, 2019, all of the cases were CE deficiencies (SA-INV-14772, SA-INV-14799) which were closed with no discipline warranted and remediation complete. The Board Delegated Review session was attended by A. STEIN as the Board President, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

TOPIC IV

REPORTS

Above Action Levels Approved by Staff Action 16-04

Time: 8:36 AM

Discussion: J. TRAN noted that one (1) above action level report has been reported since last Board meeting pursuant to Licensure Policy 16-04.

So noted

TOPIC IV

REPORTS

PSUD Report by Staff Action 17-03

Time: 8:36 AM

Discussion: E. TAGLIERI noted that in May 2019, one (1) new application was received and returned, there are currently fourteen (14) active participants.

So noted

TOPIC V

Policies and Advisories

1. Policy 2019-04: Transfer of Unfilled Prescriptions

Time: 8:43 AM

Presented by: M. CHAN

Discussion: This policy replaces *Policy 2010-01: Authorizing Transfer of an Original Schedule VI Prescription Not Dispensed*. It permits the transfer of unfilled electronic medications for all schedules. The pharmacy must follow the DEA and rules and policies to transfer these prescriptions.

L. GIAMBARRESI shared a concern that pharmacists would print and fax these unfilled prescriptions. D. SENCABAUGH noted that a faxed electronic prescription would not fit the definition of an electronic prescription and would not be valid.

Action: Motion by S. HAMILTON, seconded T. FENSKY, and voted unanimously by all those present to approve Policy 2019-04: Transfer of Unfilled Prescriptions

2. Joint Policy 2018-01: Permitted Prescription Changes and Additions Time: 8:38 AM

Presented by: M. CHAN

Discussion: Prescribers have shared concerns with days' supply changes, especially with mental health drugs. The updated policy advises pharmacists to check with prescribers on behavioral and narrow therapeutic index drugs before making any quantity changes.

K. TANZER and other Board members suggested editing the language to specifically address mental health drugs and other drugs where a change in the days' supply dispensed could cause a clinical concern. S. CORNACCHIO wanted to ensure that the policy will not pose a barrier to medication access.

Action: Motion by S. HERNANDEZ, seconded P. GANNON, and voted unanimously by all those present to update Joint Policy 2018-01: Permitted Prescription Changes and Additions with noted changes.

TOPIC VI

APPLICATIONS

1. CVS Pharmacy #11301 (Dimock Health Ctr) New Pharmacy TIME: 8:50AM

Represented by: Stacy Longo, Manager of Record

Recusal: S. CORNACCIO recused and was not present for the discussion or vote on this matter.

DISCUSSION: CVS pharmacy is seeking to operate in the Dimock Health Community Health Center. CVS is seeking to change a clinic to a retail pharmacy. Medications previously held by the clinic will be returned by the clinic. CVS will apply for a new drug store license and receive new medications through that license.

A. STEIN advises changing the compounding assentation to MOD. B. FRISCH advises connecting with HCQ administrator on the transfer process and discusses the necessary firewall between a retail and clinic pharmacy.

ACTION: Motion by S. HERNANDEZ, seconded by K. TANZER, and voted unanimously by those present to approve the application with noted changes pending a successful inspection.

2. Genoa Healthcare-Worcester

New Pharmacy

TIME: 8:57AM

Represented by: Jillian Curt, Manager of Record and Corey Po, Site Development

Recusal: None

DISCUSSION: Genoa Healthcare in Worcester, MA was represented will be a closed-door pharmacy located below a community mental health center and will provide its patients continuity of care by providing pharmacy services specializing in psychotropic drugs. It will not offer compounding services. Genoa has petitioned for six waivers: 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). Genoa Healthcare answered all the Board's questions to their satisfaction.

P. GANNON expressed concern with the location of the fireplace. Gordon assured P. GANNON that the fireplace is not in the licensed space and will be permanently blocked off.

ACTION: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted unanimously by those present to approve the application and waivers pending a successful inspection.

3. ProCare LTC of MA DS90042

Renovation

TIME: 9:02AM

Represented by: Donna Gorka, Manager of Record

Recusal: NONE

DISCUSSION: ProCare LTC operations have more than doubled since first starting operations. It now has 7000 beds and has outgrown its physical space. It plans to renovate by taking available space next door. The pharmacy will continue to operate during construction.

W. FRISCH advises additional risk mitigation strategies due to an increase in particle count that is near the compounding area.

ACTION: Motion by S. HERNANDEZ, seconded by T. FENSKY, and voted unanimously by those present to approve the renovation application.

TOPIC VII

FLEX

1. Educating New Pharmacy Managers about Regulatory Compliance and Best Practices to Prevent Opioid Misuse/Abuse

Time: 9:20 AM

Presented by: C. LATHUM

Discussion: C. LATHUM presented an overview of her project which involved educating new pharmacy managers during educational site visits, rather than during regulatory enforcement inspections. Topics included proactive naloxone dispensing, counseling efforts, and PMP reminders. The pharmacy managers were appreciative and provided positive feedback.

So noted

2. NABP Annual Meeting Update

Time: 9:31 AM

- **T. Fensky President Elect**
- **A. Young Honorary President**
- **Summary of Meeting**

Presented by: D. SENCABAUGH, S. HAMILTON, K. TANZER

Discussion: The topics regarding technicians administering immunizations and artificial intelligence were discussed. Five resolutions were accepted including: de-prescribing efforts, education requirements for technicians, request for the FDA to clarify recall procedures in 503b, and identify impact of workload on patient safety outcomes (ISMP/AACP). Members who have passed away were also recognized. Brad Hamilton will be District 1 leader, Caroline Juran will be treasurer, Tim Fensky is president elect, and Jake Campbell is the incoming president.

So noted

TOPIC VIII

FILE REVIEW

Case #1

PHA-2019-0028

Pharmacy Corporation of America, DS3599

Time: 9:40 AM

RECUSAL: NONE

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- RLCS on 1/24/2019 of #42 hydromorphone 2mg tablets attributed to an alleged manufacturer shortage;
- Discrepancy was discovered while CPhT Moore was pre-packaging 10x60 blister cards of hydromorphone 2mg from 6 bottles of 100 tablets and was short #42 tablets;
- CPhT Moore immediately reported the discrepancy to Pharmacist Sullivan who investigated the issue by conducting an inventory of the drug, reviewing prescriptions dispensed since the last reconciliation including contacting the facilities dispensed to and checking the calculations in the perpetual log;
- Security footage was reviewed and MOR Lynch stated CPhT Garin was seen setting up the pre-packaging but did not perform it. CPhT Garin moved the pre-packaging out of the CII cage into the control room and it was left unattended for a period of time. Although the Pharmacy deemed nothing suspicious had occurred, a violation of policy was observed when Pharmacist Korim left CPhT Garin alone in the control room and did not close the CII cage door;
- The manufacturer was contacted and did not report any issues with the lot in question;
- CA: Pharmacists only will open and verify control substances orders including opening all bottles to confirm the seals are intact; pre-packaging jobs will be prepared by pharmacists and will remain in the CII cage until packaging is performed; policies and procedures were reviewed with control room staff; granted access was removed for non-pharmacy employees to the control room, and Pharmacist Korim and CPhT Garin were issued formal warnings for not following policy.

ACTION: Motion by S. Hamilton, seconded by K. Tanzer, and voted unanimously by those present, to refer the matter (PHA-2019-0028) to the office of the 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

PHA-2019-0037

Tyngsboro Family Pharmacy, DS89899

Time: 9:45 AM

RECUSAL: NONE

DISCUSSION C. MOGNI presented and summarized the investigative report that pertained to these matters.

- Inspectional deficiencies for inspection ISP-12000 on 1/7/19 for expired medications in vials used for compliance packaging, expired stock bottles in patient baskets, re-packaging of samples of Xarelto (2 patients), Latuda (1 patient), and Entresto (1 patient), and tablets and capsules removed from multi-dose packaging not properly segregated and disposed of.
- MOR Hubbard responded that prior to the inspection, she had identified a process issue for compliance packaging, began a change in the process, and has since developed a new policy and procedure (dated 1/7/19) for filling patient medications in compliance packaging that included discontinuation of the use of individual patient baskets.
- MOR Hubbard alleged samples were repackaged into multi-dose packaging for 2 patients only which contradicts samples observed in 4 patient baskets.
- CA: All individualized patient baskets were eliminated, active inventory is used for compliance packaging, there is a monthly and quarterly process for the removal of expired medications from active inventory, CII medications have been synchronized with any balance stored in the locked CII cabinet until used for the next cycle, and an expired medication return for CII-CVIs was completed on 2/27/19.

ACTION: Motion by S. Hamilton, seconded by K. Tanzer and voted unanimously by those present, to DISMISS the matter (PHA-2019-0037), No Discipline Warranted, Remediation Complete.

Case #3

SA-INV--14768

Pharmscript of MA, LLC, DS90251

Time: 9:45 AM

RECUSAL: NONE

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- RLCS of 15mL morphine sulfate 100mg/5mL oral solution (blue liquid) from an E-kit discovered on 1/14/19 by Pharmacist Adjei during verification of the contents of the E-kit after replenishment; the contents of the bottle that was visibly tampered with were replaced with an unknown clear liquid.
- The E-kit was returned from the LTCF on 1/6/19 after the authorized dispensing of another medication on 1/4/19. The E-kit was left unsealed at the LTCF in the medication room with no security cameras where anyone with access was able to divert from the E-kit.
- MOR Gancarz conducted a joint investigation with the LTCF which was inconclusive but the LTCF suspected diversion by a staff nurse.

- CA: The Pharmacy now includes 5 sets of tamper evident numbered seals with each E-kit for it to be resealed after each removal of medication occurs; the Pharmacy and the LTFC developed a joint policy for resealing the E-kit; oral morphine sulfate solution bottles are now shrink wrapped; the LTFC stores the E-kit in a locked box in a locked medication cart.

ACTION: Motion by T. Fensky, seconded by S. Hernandez, and voted unanimously by those present, to CLOSE the matter (SA-INV-14768), No Discipline Warranted, Remediation Complete.

Case #4

SA-INV-14712

CVS #1022, DS1556

Time: 9:53 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- Consumer complaint of an over-dispensing of #89 oxycodone 5 mg tablets on 2/27/19 instead of a requested partial fill of #10 tablets for a prescription written for #20 tablets.
- 2/28/19 – the Pharmacist on Duty alerted MOR Mui of a discrepancy of the balance on hand of oxycodone 5 mg tablets which indicated #89 but there were only #10 in stock; a dispensing report was run and a prescription for #10 tablets was supposedly dispensed the previous day by Pharmacist Greenleaf.
- MOR Mui contacted Pharmacist Greenleaf who recalled double counting 10 tablets then poured 10 tablets into the stock bottle and 89 tablets into the vial to be dispensed and this was confirmed upon review of video footage;
- The lead pharmacy technician went to the home of the patient to retrieve 79 oxycodone tablets which were double counted and quarantined for return by MOR Mui;
- CA: Over-dispensing was reported to the CVS District Manager, QRE report was filled out, #79 oxycodone 5 mg tablets that were retrieved were returned to the reverse distributor, policies and procedures for CII dispensing were reviewed, Pharmacist Greenleaf changed his practice to re-counting CII in the vial after returning the stock bottle to the safe, MOR Mui and Pharmacist Greenleaf reviewed 247 CMR 15 in its entirety, and Pharmacist Greenleaf completed 5 CEs in patient safety and 1 CE in managing chronic opioid patients.
- CA: Over-dispensing was reported to the CVS District Manager, QRE report was filled out, #79 oxycodone 5 mg tablets that were retrieved were returned to the reverse distributor, policies and procedures for CII dispensing were reviewed, Pharmacist Greenleaf changed his practice to re-counting CII in the vial after returning the stock bottle to the safe, MOR Mui and Pharmacist Greenleaf reviewed 247 CMR 15 in its entirety, and Pharmacist Greenleaf completed 5 CEs in patient safety and 1 CE in managing chronic opioid patients.

ACTION: Motion by S. Hamilton, seconded by P. Gannon and voted unanimously by those present, to CLOSE the matter (SA-INV-14712), No Discipline Warranted, Remediation Complete.

Case #5

PHA-2019-0009

CVS #610, 24018

Time: 9:55 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to these matters.

- On November 6, 2018, a retail compliance inspection (ISP-10904) was conducted at the Pharmacy with deficiencies cited including, but not limited to, failure to maintain refrigerators within proper range, as well as failure to respond to out of range temperatures. Specifically, on fourteen occasions, there were a range of temperature between 30.8°F – 35.7°F. POC indicated products were quarantined following the inspection. Additional information stated they had no documentation to show what actions were taken.
- CVS Pharmacies have a 24 hour electronic temperature monitoring system in addition to twice daily manual logs. MOR Wheaton provided a signed copy of the pharmacy staff attesting that they read the policy and procedure regarding routine temperature monitoring and drug product storage and that they have read the Temp Alert Manual.
- Going forward from 11/6/18, only pharmacists are allowed to record temperatures on the logs twice a day. A work order was also submitted to have the refrigerator inspected to make sure it was in proper working order.

ACTION: Motion by S. Hamilton, seconded by P. Gannon and voted unanimously by those present, to DISMISS the matter (PHA-2019-0009), No Discipline Warranted, Remediation Complete.

Case #6

SA-INV-14297

CVS #714, DS3299

Time: 9:57 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

DISCUSSION: J. SANTORO presented and summarized the investigative report that pertained to these matters.

- Animal Medical Center (AMC) faxed a signed hardcopy for tramadol for a canine patient to CVS #714 and the pharmacist on duty refused the hardcopy.
- The pharmacist's initial explanation to the employee at AMC that the Board of Pharmacy cited them for filling orders that were submitted on hardcopies that displayed VOID when faxed.
- After being informed of this, AMC's manager called to further discuss the reasons for the refusal of the prescription, and this time, the pharmacist at CVS #714 vaguely referenced a recent "corporate policy" that precludes CVS from accepting a faxed hardcopy for controlled substances that displays "VOID".
- The complainant indicated that despite her best efforts to understand the reasons for the refusal, to professionally reason with the pharmacist and to attempt to verbally verify that the hardcopy was legitimate, she refused to fill it and attempted to direct her to the CVS corporate office.
- Several attempts were made to obtain a statement from the MOR, and the recent corporate policy related to "VOID" prescriptions and corrective action but an edited version of the MOR's response was sent by legal with no policy or corrective action.

ACTION: Motion by S. Hernandez, seconded by T. Fensky and voted unanimously by those present, to CLOSE the matter (SA-INV-14297), No Violation.

Case #7

SA-INV-14297

CVS #5939, DS3576

Time: 10:00 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

DISCUSSION J. SANTORO presented and summarized the investigative report that pertained to these matters.

- Failure to timely report a confirmed loss of controlled substances that occurred on or before July 25, 2018. On November 27, 2018 the Drug Loss submitted the final report indicating that an investigation was concluded on October 25, 2018 and confirmed an unknown loss of #323 Lorazepam 0.5 mg tablets. The investigation did not identify theft or diversion.
- CVS #5939 is currently under a Non-Disciplinary Stayed Probation and performing monthly counts on all benzodiazepines effective 10/8/2018 due to a loss of #443 lorazepam 0.5mg tablets on 4/5/18.
- CVS internal systems identified a potential variance in the balance of Lorazepam 0.5mg tablets during their CS monitoring. It is believed that the bottle may have been missed during the May 1, 2018 biennial count.
DRA Lariviere indicated that the reason for the untimely RLCS was because the investigation was still ongoing and not concluded until the investigators conducted their interviews in November. The gap between the initial and final notification was the time that was used to investigate the issue, hence why we filed the continuation letters with the Board and DEA.
- This OPP Investigator along with the Compliance Officer reviewed the email inbox used for the submission of RLCS forms due to a claim that a letter of continuation was submitted to the Board and confirmed that no letter of continuation was received regarding the investigation at CVS #5939.
- MOR Ward indicated that all technicians and staff pharmacists were retrained on CVS policies and procedures for maintaining controlled substances. In addition, with the assistance of asset protection, lorazepam 0.5mg tablets balance has been monitored to identify an ongoing loss. Lorazepam is now cycle counted by hand rather than using weight scales. Lorazepam was moved to the "fast mover" section which is clearly visible to the pharmacist and security cameras in the pharmacy.
- System prompted cycle counts are conducted weekly along with official monthly counts used for BOP and Loss Prevention. The Pharmacy Manager will sign off on the monthly counts and the pharmacist will sign off on the weekly counts. There will be weekly review of the BOH modification and order adjustment report and will work in tandem to help identify any inventory areas of concern and help prevent any further drug losses. The plan for sending RLCS in a timely manner was not addressed in this plan of correction.

ACTION: Motion by T. Fensky, seconded by S. Hamilton and voted unanimously by those present, to convert the matter (SA-INV-14297) to a complaint and to refer to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND, unless new information is provided in the response to the complaint.

Case #8

PHA-2019-0038

CVS #1882, DS3047

Time: 10:05 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

DISCUSSION J. SANTORO presented and summarized the investigative report that pertained to these matters.

- RLCS- #100 hydrocodone-acetaminophen 10/325mg tablets on or about February 19, 2019 discovered during state count on 2/16/2019.
- Video footage was reviewed and showed a Pharmacist Walsh walking from the verification station to the production station to obtain a 60-dram vial. There were 40-dram vials at the verification station which would have accommodated the prescription quantity of #84 tablets. The pharmacist went out of her way to obtain the larger bottle and is why she suspects that the patient received the extra 100 tablets
- There were 6 prescriptions filled from the correct state count on 2/9/19 to the discovery of loss on 2/16/19. Patients were called about the potential over-dispense, but none confirmed receiving an extra #100 tablets.
- A review of PMP by this OPP Investigator indicated that there was no prescription for #100 hydrocodone-acetaminophen 10/325mg tablets that could have been missed.
- All pharmacy staff have completed training modules regarding proper handling of controlled substances in the pharmacy. The Pharmacy will continue to do weekly cycle counts, signed off by a pharmacist, for system prompted cycle counts and the Pharmacy Manager for monthly count being used for BOH and Loss Prevention.
- There will also be a weekly review of the BOH modification and adjustment reports to work in tandem to help better identify any inventory areas of concern and help prevent any further losses. Pharmacist Walsh completed 2 CE credits in "Preventing Medication Errors" and 2 CE credits in "Preventing Diversion and Promoting Safety with Opioids" and attested to reading 247 CMR 15, Continuous Quality Improvement, in its entirety.

ACTION: Motion by T. Fensky, seconded by P. Gannon, and voted unanimously by those present, to refer the matter (PHA-2019-0038) to the office of the 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

PHA-2019-0010

CVS #207, DS2864

Time: 10:08 AM

RECUSAL: S. CORNACCHIO recused and was not present for the discussion or vote on this matter.

DISCUSSION G. MELTON presented and summarized the investigative report that pertained to these matters.

- On 1-10-19, MOR at CVS #207 informed OPP during a routine retail compliance inspection that a theft of 30 Amphetamine 10mg mixed-salts extended release capsules, 34 Oxycodone 20mg controlled release tablets, and 15 Tramadol 50mg tablets was discovered on 12-21-18. MOR indicated that a pharmacy cashier (non-licensee) admitted to diverting multiple controlled substances. OPP checked records at BHPL and learned that theft was not yet reported. CVS #207 was unaware that the theft was not reported because district office confirmed the report was submitted.
- The district office indicated that the failure to report was unintentional and stressed that the failure was not caused by CVS #207. The district office indicated that the report was held for guidance from corporate after district staff learned of the BORP's adoption of a new policy on 12-6-18 for reporting loss or theft of controlled substances. The district office indicated that district staff were provided training on the new policy to mitigate recurrence of similar incident. In addition, a completed report of theft was submitted by CVS #207 on 1-24-19.

- CVS #207 also implemented corrective action to address the diversion. The pharmacy now locks all completed CII prescriptions in the CII safe until a patient arrives to pick them up. In addition, a renovation is planned to begin in May 2019 with an open design for better sightlines and a new surveillance system that covers entire pharmacy.

ACTION: Motion by K. Tanzer, seconded by P. Gannon and voted unanimously by those present, to DISMISS the matter (PHA-2019-0010), No Discipline Warranted.

Case #10

SA-INV-14441

Partners of MA, DS3419

Time: 10:10 AM

RECUSAL: NONE

DISCUSSION J. SANTORO presented and summarized the investigative report that pertained to these matters.

- BORP staff received notice from the Professional Credential Services, Inc. indicating Pharmacy Technician Trainee (PTT) Benjamin Appiah submitted a signed application dated October 26, 2018, with 2102.19 hours.
- MOR indicated that after he discovered PTT Appiah, had reached 1400 hours, he alert him that he needed to schedule his technician assessment examination to apply for his pharmacy technician license.
- MOR Brunette stated that he failed to ensure this had been completed.
- Policy dated April 2019 indicated that MOR will verify proper licensure for all potential new hires. If the pharmacy employs a pharmacy technician in training, the MOR will record the following on the "Pharmacy Technician in Training Spreadsheet" which is to be reviewed bi-weekly by the MOR;
- Employees full name, Effective date of Pharmacy Technician in Training License, Date of Hire, Number of hours accumulated, Date of Technician Assessment Exam' Effective date of Approved Technician License.
- In addition, once a technician in training accumulates 500 hours they will take the technician assessment exam and the date of the exam is to be recorded on the spreadsheet by the MOR. If a technician in training accumulates 1400 hours, they are to be removed from the schedule until the MOR can verify they had a valid pharmacy technician license with the BORP.
- A retail compliance inspection ISP-11807 conducted on March 20, 2019 was deemed satisfactory.

ACTION: Motion by S. Hernandez, seconded by P. Gannon and voted unanimously by those present, to CLOSE the matter (SA-INV-14441), No discipline warranted, remediation complete.

Case #11

PHA-2018-0088

Blue Hill Pharmacy, DS89942

Time: 10:22 AM

RECUSAL: NONE

DISCUSSION J. SANTORO presented and summarized the investigative report that pertained to these matters.

- Complaint was opened on December 28, 2018 as a result of the Pharmacy not being open for business during posted business hours and failure to implement a plan of correction.
Prior to the complaint, The BORP opened a staff assignment (SA-INV-10879) for not being open for business on multiple days during posted business hours and calls made to the MOR went unanswered.
- BORP voted unanimously to close staff assignment (SA-INV-10879), Discipline Not Warranted, Remediation Complete. The remediation included: If a delivery requires a pharmacist it will be delivered before opening or after closing and there will be a pharmacist cell phone number posted on the door in the case of an emergency.
- On November 28, 2018, Investigator Richard Geaney was unable to perform an inspection due to the Pharmacy being closed.
MOR Okeke indicated that she was late opening that day due to a family medical emergency in which she had to be at the hospital.
MOR Okeke indicated that she plans to hire a part-time pharmacist who would cover for her if she couldn't be in the pharmacy during business hours. Her immediate plan is to make all deliveries between the hours of 5:00pm-7:00pm to accommodate her patient's needs for person to person counseling. She indicated that her future plan is to hire a dedicated delivery person who can make deliveries during work hours.
- MOR Okeke indicated that once her plan is in place she will request a change in hours to 10:00am-5:00pm. MOR Okeke has subsequently hired a part-time delivery person. MOR Okeke noted that she has implemented call forwarding services so that calls will be forwarded to her cell phone in an event that she had to step out of the pharmacy.

ACTION: Motion by P. Gannon, seconded by T. Fensky, and voted unanimously by those present, to defer the matter (PHA-2018-0088), and request an investigative conference with the MOR/Owner.

Case #12

SA-INV-14769

Preferred Pharmacy Solutions, DS3542

Time: 10:34 AM

RECUSAL: NONE

DISCUSSION: G. MELTON presented and summarized the investigative report that pertained to these matters.

- In 03/2019, BORP received a report from a third-party vendor responsible for BHPL applications that three technician candidates reported working technician trainee hours at PPS but did not have trainee licenses on record. Current MOR admitted that the three candidates worked 500 hours at PPS as unlicensed trainees. Current MOR explained that the former MOR certified the training prior to resigning in 03/2019.
- In addition, current MOR immediately audited all personnel with technician duties and determined that two additional employees were assigned technician duties without proper licensing as trainees under former MOR. Current MOR immediately reassigned the two unlicensed employees to non-technician duties.
- OPP Investigators audited licensing for all personnel working in in the pharmacy during an unannounced inspection on April 25, 2019 and found all personnel were properly licensed. In addition,

4 of 5 employees in question obtained proper licensing as trainees or technicians as of 5-14-2019. The 5th employee has a pending application.

- CA: Current MOR educated HR, supervisors, assistant managers, & orientation/training personnel about regulations in 247 CMR 8.03. Current MOR updated policy to require MOR to initiate trainee application for new employees who may work in the pharmacy immediately upon hiring. Current MOR also added the trainee application to the new employee in-processing checklist which will be co-administered by HR and MOR.

ACTION: Motion by T. Fensky, seconded by K. Tanzer, and voted unanimously by those present to defer the matter (SA-INV-14769) and schedule an investigative conference with the MOR and Owner.

Topic IX **EXECUTIVE SESSION** **Time: 10:46 AM**
Read by A. Stein

DISCUSSION:

ACTION: At 11:45 AM President A. Stein read the statement on reasons for Executive Session.

Topic IX: **Executive Session Call to Order:** **Time: 11:19 AM**
By: A. Stein

ACTION: Motion by S. HERNANDEZ, seconded by J. LANZA, and voted unanimously by roll call to call the June 6, 2019 meeting of the Executive Session to order.

A. STEIN; yes, K. TANZER; yes, J. LANZA; yes, L. GIAMBARRESI; yes, S. HAMILTON; yes, P. GANNON; yes, S. HERDANDEZ; yes, T. FENSKY; yes, C. JEAN-FRANCOIS; yes, S. CORNACCHIO; yes

Lunch: **Out: 11:45 AM** **Back: 1:00 PM**

Topic X: **M.G.L. 65 C #1** **Time: 11:04 AM**

DISCUSSION: None

ACTION: President A. Stein request a motion to enter M.G.L 65 c Session.

At 11:04 AM T. Fensky, seconded by K. Tanzer and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

Topic XI **ADJOURNMENT OF MEETING** **TIME: 2:20 PM**

ACTION: Motion by S. Hernandez seconded by T. Fensky, and voted unanimously by those present, to adjourn from General Session.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 6/6/19 General Session
2. Draft Minutes of the 5/2/19 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on probation
5. Report on Board Delegated Complaint Review to licensure policy 14-02
6. Report on Above Action Levels approved by Staff Action 16-04
7. Report on PSUD 17-03
8. Staff Action Policy 13-01 (Revision): Licensure Applications and Notices
9. Policy 2019-04: Transfer of Unfilled Prescriptions
10. Joint Policy 2018-01: Permitted Prescription Changes and Additions
11. Applications: CVS Pharmacy #11301 (Dimock Health Ctr.) New Pharmacy
12. Applications: Genoa Healthcare Worcester- New Pharmacy
13. Applications: ProCare LTC of MA (DS90042) Renovation
14. PHA-2019-0028 Pharmacy Corp of America, DS3599
15. PHA-2019-0027 BioScript Infusion Services, DS3486
16. PHA-2019-0037 Tyngsboro Family Pharmacy, DS89899
17. SA-INV-14768 Pharmscript of MA, LLC, DS90251
18. SA-INV-14712 CVS #1022, DS1556
19. PHA-2019-0009 CVS #610, DS24018
20. SA-INV-14297 CVS #714, DS3299
21. SA-INV-14301 CVS #5939, DS3576
22. PHA-2019-0038 CVS #1882, DS3047
23. PHA-2019-0010 CVS #207, DS2864
24. SA-INV-14441 Partners of MA, DS3419
25. PHA-2018-0088 Blue Hill Pharmacy, DS89942
26. SA-INV-14769 Preferred Pharmacy Services, DS3542

Respectfully Submitted,
Julie Lanza, CPhT, Secretary