

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

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

September 5, 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 August 1, 2019 Regular Session Minutes • Introduction of Interns: <ul style="list-style-type: none"> ○ Anna Orbite – MCPHS ○ Nnenna Iregbu - Husson 		
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"> • Revocation of Board Policies <ul style="list-style-type: none"> ○ Policy 98-010: Policy on Extended Leave ○ Policy 98-011: Policy on Customized Patient Packaging ○ Policy 2000-03: Policy on Pharmacy Operations During the Temporary Absence of a Pharmacist • Policy 2019-01: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing, and Tele-pharmacy 		W. Frisch M. Chan

9:20	VI	APPLICATIONS <ul style="list-style-type: none"> Freedom FP Fertility Pharmacy (DS89716)-Petition for a waiver Walpole Pharmacy – New Community Pharmacy Village Fertility Pharmacy (DS90059)– Petition for a waiver Western Mass Compounding Center (DS89965)- Renovation Pharmacy Corporation of America/PharMerica (DS3599) – Relocation Boulevard Pharma Compounding Center (DS2943) – Transfer of Ownership Wegmans Food Markets (DS89914) – Change of Manager 																																						
10:00	VII	FLEX <ul style="list-style-type: none"> Proposed Resolutions for NABP District I & II Meeting Consent Agreement and Order to Show Cause templates for Fines PSUD Rec Committee Appointment 		D. Sencabaugh V. Berg E. Taglieri																																				
10:30	VIII	INVESTIGATIVE CONFERENCE <ul style="list-style-type: none"> Baystate Pharmacy-DS89896; SA-INV-14965 																																						
11:15	IX	TERMINATION OF PROBATION <ul style="list-style-type: none"> Conley’s Drug Store, DS89731, PHA-2016-0113 		K. Fishman																																				
11:30	X	SANCTION HEARING <ul style="list-style-type: none"> Conley’s Drug Store; DS2654; PHA-2016-0018 Richard Doyle; PH15680; PHA-2017-0017 		H. Engman																																				
12:00	XI	FILE REVIEW <table border="1" data-bbox="293 1220 1247 1856"> <tr> <td>1</td> <td>PHA-2019-0055</td> <td>CVS #137, DS2951</td> </tr> <tr> <td>2</td> <td>PHA-2019-0024</td> <td>CVS #2254, DS2886</td> </tr> <tr> <td>3</td> <td>PHA-2019-0063</td> <td>CVS #1803, DS89888</td> </tr> <tr> <td>4</td> <td>PHA-2019-0026</td> <td>CVS #1056, DS1646</td> </tr> <tr> <td>5</td> <td>PHA-2019-0058</td> <td>CVS #685, DS2646</td> </tr> <tr> <td>6</td> <td>PHA-2019-0015</td> <td>CVS #524, DS2532</td> </tr> <tr> <td>7</td> <td>PHA-2019-0064</td> <td>Walgreens #9538, DS3474</td> </tr> <tr> <td>8</td> <td>PHA-2019-0029</td> <td>Walgreens #15969, DS90068</td> </tr> <tr> <td>9</td> <td>PHA-2019-0070</td> <td>Greater Lawrence Family Health Center, DS90041</td> </tr> <tr> <td>10</td> <td>PHA-2019-0042</td> <td>Apothecare of Cape Cod, DS90071</td> </tr> <tr> <td>11</td> <td>PHA-2019-0067</td> <td>Richmond Pharmacy, DS1650</td> </tr> <tr> <td>12</td> <td>SA-INV-14927</td> <td>Cornerstone Health Solutions, DS90083</td> </tr> </table>	1	PHA-2019-0055	CVS #137, DS2951	2	PHA-2019-0024	CVS #2254, DS2886	3	PHA-2019-0063	CVS #1803, DS89888	4	PHA-2019-0026	CVS #1056, DS1646	5	PHA-2019-0058	CVS #685, DS2646	6	PHA-2019-0015	CVS #524, DS2532	7	PHA-2019-0064	Walgreens #9538, DS3474	8	PHA-2019-0029	Walgreens #15969, DS90068	9	PHA-2019-0070	Greater Lawrence Family Health Center, DS90041	10	PHA-2019-0042	Apothecare of Cape Cod, DS90071	11	PHA-2019-0067	Richmond Pharmacy, DS1650	12	SA-INV-14927	Cornerstone Health Solutions, DS90083		
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12:30				
1:30	XII	<p>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, consider a petition for reinstatement and to evaluate the Good Moral Character as required for registration for pending applicants.</p>		
2:15	XIII	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)		
2:30	XIV	M.G.L. c. 112, § 65C SESSION		
5:00	XV	ADJOURNMENT		

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

**MINUTES OF THE GENERAL SESSION
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts, 02114
September 5, 2019**

Board Members Present

Andrew Stein, Pharm D, RPh. President (Leaves 12:45 PM)
Julie Lanza, CPhT, Secretary
Sebastian Hamilton, Pharm D, RPh
Patrick Gannon, RPh (arrives 9:00 AM)
Leah Giambarresi, Pharm D, RPh
Timothy Fensky, RPh
Michael Godek, RPh
Dawn Perry, JD (arrives 8:47 AM)
Richard Lopez, MD

Board Members Not Present

Susan Cornacchio, JD, RN
Carly Jean-Francois, RN, NP
Kim Tanzer, PharmD, RPh. Pres-Elect
Stephanie Hernandez, Pharm D, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Heather Engman, JD Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Joanne Trifone, RPh., Director of Pharmacy Investigations (12:30 PM to end of meeting)
Samuel Penta, RPh, Supervisor of Pharmacy Investigations (8:30 AM to 2:00 PM)
Joanna Chow, CPhT, Office Support Specialist
Christina Mogni, RPh investigator
Gregory Melton, PharmD, RPh investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:42 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; J. Lanza, yes; M. Godek, yes; S. Hamilton, yes; R. Lopez, yes;
L. Giambarresi, yes; T. Fensky, yes (D. Perry joins meeting 8:47 AM; P. Gannon joins meeting 9:00 AM)

Topic II.

Approval of Agenda

TIME 8:44 AM

Agenda September 5, 2019

DISCUSSION:

Change to Agenda:

1. Defer: Policies/Advisories: Policy 2019-01: Shared Pharmacy Services

- 2. Investigative Conference: Baystate Pharmacy DS89896; SA-INV-14965
- 3. PHA-2019-0026 CVS #1056, DS1646

ACTION:

Motion by M. Godek, seconded by T. Fensky 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 Intern: Anna Orbite and Husson University Intern: Nnenna Iregubu

Topic III **Approval of Board Minutes** **TIME: 8:44 AM**

Minutes

1. Draft, August 1, 2019 Session Minutes

No noted Changes.

Action:

Motion by M. Godek, seconded T. Fensky, and voted unanimously to approve the regular session minutes of February 7, 2019 with noted changes.

TOPIC IV **REPORTS** **Time: 8:48 AM**
Applications approved pursuant to Licensure Policy 13-01

Discussion: E. TAGLIERI noted that there have been thirty-two (32) Change of Managers and three (3) pharmacy renovations applications approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV **REPORTS** **Time: 8:48 AM**
Monthly Report from Probation

Discussion: D. SENCABAUGH provided the July 26, 2019 – August 23, 2019 Pharmacy Board Probation Monthly Report, which noted that seven (7) licensees satisfactorily completed probations. There are currently thirty-two (32) licensees on probation.

So noted

TOPIC IV **REPORTS** **Time: 8:48 AM**
Monthly Report from BDR pursuant to Policy 14-02

Discussion: D. SENCABAUGH noted that there were two (2) Board Delegated Review cases heard on August 29, 2019. There were two CE self-disclosures (SA-INV-15184, SA-INV-15069) which were closed with no discipline not warranted and remediation complete. The Board Delegated Review session was attended by J. LANZA as the Board Member, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

DISCUSSION: Freedom FP Fertility Pharmacy came before the Board of Pharmacy requesting waivers for 247 CMR 9.01 (16) and 247 CMR 6.02 (4). The representatives stated that their pharmacy is located adjacent to their sister company, Freedom Fertility Pharmacy, which offers non-sterile and sterile compounding facilities. There would be no problem for any patient that presents a prescription to Freedom FP Fertility Pharmacy to have their compounded prescription dispensed at Freedom Fertility Pharmacy. Both pharmacies have similar hours.

ACTION: Motion by T. FENSKY, seconded by L. GIAMBARRESI, voted unanimously to approve the application for the waivers.

2. Walpole Pharmacy

New Community Pharmacy

TIME: 8:55 AM

REPRESENTED BY: Elaine Brunelle (MOR/Owner), Steve McNeil (Consultant/Owner)

RECUSAL: NONE

DISCUSSION: Elaine Brunelle, MOR and owner of Walpole Pharmacy, has been licensed for 30 years. She stated that the public has expressed a need for a pharmacy that will service group homes and assisted living facilities in Walpole. MOR Brunelle successfully answered questions from the Board members about the location and security of the pharmacy. Eight alarm units were installed and a locked floor to ceiling closet for CII medications. Walpole Pharmacy plans to do simple and moderate compounding and will edit application accordingly. When asked about other pharmacy staff, MOR Brunelle stated that she plans on hiring another part time pharmacist. There are currently two pharmacy technicians and two delivery drivers that have expressed interest. She also stated that all pharmacy technicians will be required to be nationally certified.

ACTION: Motioned by S. HAMILTON, seconded by M. GODEK, voted unanimously by those present to approve application pending a successful inspection.

3. Village Fertility Pharmacy DS90059

Petition for a waiver

TIME: 9:06 AM

REPRESENTED BY: Steven P

RECUSAL: NONE

DISCUSSION: Steve P., Vice President of Operations came before the Board to request waivers for 247 CMR 6.01 (5)(a)(4), 247 CMR 6.02(4) and 247 CMR 9.01 (16) for the closing of Village Fertility Pharmacy's clean room. W.FRISCH clarified that the pharmacy will be outsourcing its compounding to Johnson Compounding Pharmacy.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, voted unanimously by those present to approve the petition for the waivers.

4. Western Mass Compounding Center DS89965

Renovation

TIME: 9:09 AM

REPRESENTED BY: Brad Sprecher (MOR)

RECUSAL: NONE

DISCUSSION: Brad Sprecher, MOR, came before the Board to request approval for a renovation. The renovation is to be in compliance with USP 800 standards for compounding hazardous drugs and greater temperature control. The renovations would include 1) connect current hazardous drug powder containment hood to the current external exhaust system, 2) paint walls with non-porous, moisture resistant epoxy, 3) repair countertop laminate to maintain non-porous surface, 4) install wall-mounted ductless AC's in hazard and non-hazard compounding rooms. Construction will last for 4-5 days and the pharmacy will be closed. During the time of renovations, appropriate measures would be made to preserve the integrity of equipment and medications within the pharmacy. They do not expect any patients to be affected, but for emergent cases, patients will be directed to Compounded Solutions in Pharmacy in CT.

ACTION: Motion by P.GANNON, seconded by S. HAMILTON, voted unanimously by all those present to approve the application for renovation.

5. Pharmacy Corporation of America/PharMerica DS3599 Relocation TIME: 9:16 AM

REPRESENTED BY: Heather Cardona (MOR), Jeffery Lynch (Director/Previous MOR), Steve Coffey (Regional Director)

RECUSAL: NONE

DISCUSSION: Construction at the new location has started; there will be a new sterile IV room. T. FENSKY asked the group to clarify on what a space on the blueprint would be used for; J. Lynch replied that it would be a gowning room. J. Lynch also indicated that pharmacy will be doing simple and moderate compounding. The Board staff will consult with chief counsel on keeping the same DS number in order to keep probation status and records. T. FENSKY expressed a concern about filters being replaced around sterile materials and recommended the use of a pre- filter.

ACTION: Motion by T. FENSKY, seconded by M. GODEK, voted unanimously to approve the application for relocation pending a successful inspection.

6. Boulevard Pharma Compounding Center DS2943 Transfer of Ownership TIME: 9:52 AM

REPRESENTED BY: Khalid Boukhatem (Owner), David Del Giudice (MOR)

RECUSAL: A.STEIN

DISCUSSION: J. LANZA asked K. Boukhotem about the anticipated changes for the pharmacy. K. Boukhotem stated that all aspects of the pharmacy besides ownership will remain the same. P. GANNON asked the pharmacy representatives if they were aware of any probationary actions, staff ratio, controlled substance diversion, or record keeping issues; MOR Del Giudice stated that he was not aware of any issues or actions against the pharmacy. P. GANNON questioned the pharmacy's probation status; MOR Del Giudice confirmed the pharmacy is on stayed probation until October 2019. T. FENSKY stated that if the pharmacy plans to only compound, a waiver may be required and to review outstanding waivers that the pharmacy would need to reapply for. D. SENCABAUGH stated that he would work with the pharmacy staff to get the necessary waivers and bring back to the Board as an FYI.

ACTION: Motioned by T. FENSKY, seconded by M. GODEK., voted unanimously to approve the application for the transfer of ownership.

7. Wegmans Food Markets DS89914

Change of Manager

TIME: 9:28 AM

REPRESENTED BY: Kerry Laboski (MOR), Brian Pompo (Operations Manager), Andrew Felter (Operations Manager)

RECUSAL: NONE

DISCUSSION: Kerry Laboski is a first time MOR with 8 years of experience as a pharmacist at Wegmans. A. STEIN also asked MOR Laboski if she would have help from other pharmacy managers; she stated that other managers in her division are very supportive and would help her with any problems or concerns that she may have. She has been working with the schedule the last 6 months and will resume that task with an attention to staff ratio. P. GANNON asked MOR Laboski if she was aware of any central loss prevention programs and she mentioned that there is a centralized loss prevention representative for each store and a regional representative that will be overseeing the division.

ACTION: Motion by S. HAMILTON, seconded L. GIAMBARRESI, voted unanimously by those present to approve the application for change of manager.

TOPIC VII

FLEX

1. Proposed Resolutions for NABP District I & II Meeting

Time: 10:01 AM

Presented by: D. SENCABAUGH

Discussion:

NABP provides resources to convene task groups and address issues, and the Board should decide on the best resolutions to bring to the District I & II Meeting for task force consideration. In the future, as results of previous resolutions are received, that information will be circulated back to the Board.

P. GANNON presented the following resolutions for consideration:

- Developing a standard structure between pharmacies, prescribers, and electronic prescribing systems to specify “do not enroll in auto refill” based on certain patient or drug scenarios to reduce the overall cost of healthcare and avoid patients having stock piles of unneeded medication.
- Implement national standard for communication to a patient’s pharmacy when a prescriber discontinues a prescription in an electronic health record so a patient does not accidentally refill a discontinued medication.
- “DIR fees” associated with PBMs and payers prevent retail pharmacies from knowing the true cost of a medication until the resolution.

M. GODEK presented the following resolution for consideration:

- Pharmacy staffed by technicians with offsite pharmacists available for counseling.

S. HAMILTON presented the following resolution for consideration:

- Naloxone to be available as an OTC medication.

W. FRISCH presented the following resolution for consideration:

- Informing retail pharmacies of necessary compliance to USP <800> by elaborating on how to apply it to that practice.

Action: Motion by P. GANNON, seconded by M. GODEK and voted unanimously by those present for T. FENSKY to bring all six ideas to the NABP staff to determine the most viable ideas to submit, and to submit those resolutions.

2. Consent Agreement and Order to Show Cause Templates for Fines Time: 10:26 AM

Presented by: V. BERG

Discussion:

V. BERG presented a proposed draft to implement a fining process that all Boards have had the authority to do since 2004. All Boards may impose a capped fine for unlicensed practice:

- Individual had a license that has been since suspended or revoked.
- Individual never had a license.

First violation fine may be up to \$1,000 and second violation fine may be up to \$2,500. There is no definition of violation duration in statute. Other boards have considered a violation to be each incidence where the individual has been discovered, not each day without a license.

Pharmacy Board should consider default fine amounts for different licenses, since the fine amount for the license type may be unreasonable. This is an option for the Board, not a required action. This has no correlation with the Board of Pharmacy’s proposed fining regulation at 247 CMR 22.00.

Action: Motion by P. GANNON, seconded by T. FENSKY and voted unanimously by those present to authorize to move these templates forward.

3. PSUD REC Committee Appointment

Time: 10:41 AM

Presented by: E. TAGLIERI

Discussion:

The pharmacy technician member has resigned from PSUD REC Committee. Tracy Cardwell, a certified technician, has been successful in her application to be appointed this role.

Action: Motion by P. GANNON, seconded by J. LANZA and voted unanimously by those present to appoint Tracy Cardwell to a four-year term on PSUD REC Committee.

TOPIC VIII

INVESTIGATIVE CONFERENCE

**SA-INV-14965 Baystate Pharmacy DS89896
DEFERRED**

TOPIC IX

TERMINATION OF PROBATION

PHA-2016-0113 Conley's Drug Store: DS89731

Time: 10:43 AM

Presented by: K. FISHMAN

Recusal: NONE

Discussion:

Conley's Drug Store business was sold to CVS and closed in August 2018. This pharmacy complaint was related to inspectional deficiencies and the sale of compounded non-sterile products without patient prescriptions and was resolved with a consent agreement on 3/20/2019. The MOR at the time also entered into the agreement and will remain on full probation until 3/20/2020.

Action: Motion by M. GODEK, seconded by T. FENSKY, and voted unanimously by those present to terminate the store's probation due to the closure of the business.

TOPIC X

SANTION HEARING

11:55 AM

**PHA-2018-0018 Conley's Drug Store DS2654
PHA-2017-0017 Richard Doyle PH15680**

Recusals: None

Presented by: Heather Engman and Richard Banks

Present: Richard Doyle, Paul Garbarini, JD, Mrs. Doyle

Discussion:

- Heather Summarized and reviewed the process of a Sanction Hearing
- Heather provided an overview of the Memo which summarized these two cases
- R. Doyle presented:

- Was told to stop compounding products of concern; immediately did and removed from shelves
- No longer does OTC compounding; only with a prescription
- All inspections since have been in full compliance
- Acknowledges and agrees with all facts in case
- Requests is for a non-disciplinary sanction vs. a disciplinary sanction
- Board members than questioned R. Doyle
 - A. Stein: What would he feel would be an appropriate sanction? R. Doyle reply a non-disciplinary warning
 - S. Hamilton: Did you or have you had the services of a consultant to help and ensure compliance? R. Doyle: no, have used his son who is a Pharmacist.
- Hearing then ended. Deliberation and vote will take place in Adjudicatory Session later in the agenda

So Noted

TOPIC XI:

FILE REVIEW

Case #1

PHA-2019-0055

CVS #137, DS2951

Time: 11:03 AM

RECUSAL: Nnenna Iregbu, PI 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.

- 2 RLCS – untimely reports for unknown loss of #90 amphetamine salts 20 mg tablets discovered on 03/17/19 and for a loss of #13 Suboxone 8mg/2mg films on 04/16/19 due to customer theft.
- CVS Corporate response indicated on 3/15/19 Pharmacist Powell filled a prescription for #90 amphetamine salts 20 mg tablets and was seen on video footage putting it in the waiting bin. Review of security footage provided with the response showed it was put in a basket next to the verification station.
- 3/17/19 the patient presented at the Pharmacy to pick up the medication and it could not be located; Pharmacist Powell reprints a label and fills the same prescription again which was confirmed on review of the security footage. The Pharmacy was searched but the original prescription fill was never located.
- 3/20/19 MOR Finn adjusted the perpetual inventory (-) 90 tablets with no notation to account for the discrepancy of the BOH.
- Internal investigation included review of security footage which had no direct line of sight to the waiting bins, but CVS Asset Prevention determined there was no evidence of employee theft.
- 4/16/19 while point of sale of #13 Suboxone 8/2mg films was being conducted, the customer took the medication and fled the pharmacy; the police were notified, and the customer was arrested but the medication was not recovered.
- CA: All documentation will be submitted in a timely manner going forward. Loss Prevention policy and procedures were reviewed with the Pharmacy Team, including the importance of ensuring point of

sale accuracy and waiting bin accuracy. The point of sale procedure was reviewed with the pharmacy staff reminding them not to place an unsold prescription on the counter in front of the customer. Instead, the prescription should be placed directly into a plastic bag or on the counter behind the register. The “Numeric Waiting Bin” system was implemented on 04/21/2019.

ACTION: Motion by T. Fensky, seconded by M. Godek, and voted unanimously by those present to refer the matter (PHA-2019-0055) 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-2019-0024

CVS #2254, DS2886

Time: 11:06 AM

RECUSAL: Nnenna Iregbu, PI 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.

- Untimely RLCS on 2/20/19 for a loss of 90 methylphenidate 20 mg tablets discovered on 2/7/19; during the review of the 14-day post fill report for medications to be returned to stock the prescription was identified but the medication was not in the CII waiting bin.
- MOR Kommineni searched the waiting bin and reviewed security footage which confirmed the prescription was filled and placed in the waiting bin.
- Internal investigation could not determine the cause of the loss, but it is believed the prescription was dispensed without being sold through the register.
- CA: baseline loss prevention procedures were reviewed with staff, specifically those that prevent drug diversion; pharmacy staff were trained “on not selling prescriptions that are expired as the register will not allow them to be scanned”; POS system was recently updated and will not allow CII prescriptions that are expired beyond 30 days of date prescribed to be scanned for sale.

ACTION: Motion by M. Godek, seconded by T. Fensky, and voted unanimously by those present to refer the matter (PHA-2019-0024) 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 #3

PHA-2019-0063

CVS #1803, DS89888

Time: 11:08 AM

RECUSAL: Nnenna Iregbu, PI 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.

- Untimely RLCS on 5/9/19 for an unknown loss of #3 fentanyl 75mcg patches discovered on 2/10/19 during the reconciliation of the perpetual inventory.
- Internal investigation included a search of the CII safes and the trash, review of dispensing reports, and the patient who received fentanyl 75mcg patches was contacted and denied an over-dispensing. Security footage was reviewed but was inconclusive. No cause could be determined.

- CA: Pharmacist on duty will only remove the quantity needed to fill the prescription from the safe, produce the prescription using the production safety zone mat, and return the medication to the safe immediately after use.

ACTION: Motion by S. Hamilton, seconded by T. Fensky, and voted unanimously by those present to refer the matter(PHA-2019-0063) 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 #4

PHA-2019-0026

CVS #1056, DS1646

Case Deferred

Case #5

PHA-2019-0058

CVS #685, DS2646

Time: 11:09 AM

RECUSAL: Nnenna Iregbu, PI 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

- RLCS on 05/15/2019, submitted an untimely report of an unknown loss of #440 clonazepam 0.5 mg tablets identified via corporate monitoring on 02/12/2019 and was deemed a “liquid variance over a long period of time”. The loss represents 27.7% of the total clonazepam 0.5mg tablets dispensed over the past year.
- CVS Asset Protection performed exact counts in the pharmacy using the 2018 biennial as the initial BOH and initiated daily cycle counts of all NDCs of clonazepam 0.5 mg tablets that occurred for 2 weeks.
- Current MOR Meneses indicated the investigation was prompted from the corporate loss team based off a 9-month balance on hand inquiry for the NDC and was not a store identified drug loss. The investigation did not conclude until 5/15/19.
- Biennial inventories performed in 2018 and 2019 were exact counts and clonazepam is hand counted; clonazepam is not in an automation unit in the Pharmacy.
- Three letters of continuation addressed to the DEA dated 03/13/2019, 04/11/2019, and 05/10/2019 were provided but were not sent to the BORP.
- CA: The Pharmacy will ensure back counts are consistently performed. If any loss is identified, it will be investigated and reported immediately. The safe is to remain closed at all times. BOH modification reporting will be reviewed weekly by the pharmacy staff with strict adherence to state counts and CVS prompted cycle counts.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0058) 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 STAYED PROBATION and to implement the CVS protocol for all benzo-diazepams for 12 months.

Case #6

RECUSAL: Nnenna Iregbu, PI 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.

- CVS #524 was inspected on 12/26/2018 and repeat violations were observed from prior POC issued on 05/08/2018 involving the failure to maintain proper temperature ranges for refrigerated prescription drugs.
- Upon further investigation, CVS #524 used an analogue thermometer to monitor temperature in their refrigerators and freezers and recorded the temperature twice daily on handwritten logs as required. These logs were within acceptable range with minor deviations on three occasions in 08/2018. However, investigators relied on the results of an unmonitored and unused electronic thermometer which showed out of range temperatures from 12/15/2018 through 12/26/2018.
- CA: Internal policy and procedures for temperatures excursions were reviewed with staff. Refrigerators were cleaned and reorganized to allow better air flow. Thermometers were repositioned. Investigator Melton also reviewed temperatures logs from 01/2019 through 03/2019 and learned that the pharmacy responded appropriately during a temperature excursion in 02/2019 after training was reviewed with staff.

ACTION: Motion by T. Fensky, seconded by J. Lanza, and voted unanimously by those present, to dismiss compliant PHA-2019-0015 with no violation.

Case #7

PHA-2019-0064

Walgreens #9538, DS3474

Time: 11:15 AM

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

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

- During a retail compliance inspection (ISP-12331) on 5/14/19, the Pharmacy was cited for PTT Parker working as a PTT without a license;
- Current MOR Tran had only commenced employment as MOR on 5/6/19. Former MOR Nguyen indicated there was a miscommunication with the front store manager regarding the submission of PTT Parker's application to the BORP.
- Documentation provided showed PTT Parker worked a total of 195 hours in the Pharmacy while unlicensed from 04/05/2019 to 05/14/2019. Current MOR Tran confirmed PTT Parker had performed PTT duties during this time.
- CA: PTT Parker was issued a PTT license on 5/20/19. Current MOR Tran will ensure name-tabs will not be issued to pharmacy staff without proof of licensure; all pharmacy staff licenses were reviewed; a self-inspection heavily focused on licensing was performed on 06/15/2019 with additional self-inspections planned for 09/15/2019, 12/15/2019, and every 3 months thereafter. Current MOR Tran

will confirm current licensure for all new hires in the Pharmacy. PTT Parker will ensure she is properly licensed at all times.

ACTION: Motion by S. Hamilton, seconded by P. Gannon, and voted unanimously by those present, to refer the matter (PHA-2019-0064) the matter 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

PHA-2019-0029

Walgreens #15969, DS90068

Time: 11:18 AM

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

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

- Incomplete RLCS on 2/11/19 with only the DEA 106 submitted for an unknown loss of #100 amphetamine salts 20 mg tablets on or about 02/05/2019.
- The shortage was discovered on 1/25/19 by Pharmacist Sokolovskaya during the reconciliation of the perpetual inventory. Since the last reconciliation on 1/20/19, 7 prescriptions were filled and 13x100 amphetamine salts 20 mg tablets were received.
- Internal investigation included a search of the Pharmacy for a misplaced stock bottle and review of security footage of the filling of the prescriptions and the receipt of the order. There was no evidence of diversion.
- Current MOR Duong speculated, “The most likely scenario is that we were shorted one bottle by the distributor” but “no cause could be determined and there is no discernable pattern at this time”.
- The wholesale distributor was contacted and confirmed 13x100 amphetamine salts 20 mg tablets were sent to the Pharmacy and no discrepancies were reported for amphetamine salts 20 mg tablets. A review of the PMP confirmed all prescriptions dispensed 1/21/19 – 1/25/19.
- CA: Will double check the inventory count at the end of each shift and will double check that inventory received matches the invoices.

ACTION: Motion by T. Fensky, seconded by J. Lanza, and voted unanimously by those present, to refer the matter (PHA-2019-0029) 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 #9

PHA-2019-0070

Greater Lawrence Family Health Center, DS90041

Time: 11:20 AM

RECUSAL: NONE

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

- Allegation by a former employee that the GLFHC Methuen Pharmacy was acting as a “central fill” pharmacy for other GLFHC locations due to an insurance contract denial and they are “rolling prescriptions”. Additionally, during ISP-9768 on 5/14/18, the co-mingling of duties, staff, drug ordering and inventory between the clinic and the Pharmacy was observed.
- The Complainant claimed prescriptions were received at the Lawrence South Pharmacy where they were data entered on the Methuen Pharmacy’s server, it was adjudicated on the Methuen Pharmacy’s server, the label would print at the Methuen Pharmacy where it would be filled and verified, then the prescription would be delivered to the Lawrence South Pharmacy for pickup. This practice could be for any prescription.
- MOR Baccari responded that the Methuen Pharmacy has a Parata Pass unit for specialty packaging and the Methuen Pharmacy does provide that service to GLFHC patients. He contended the prescriptions for specialty packaging are sent to the Methuen Pharmacy, are processed and filled there, then they are either delivered to the patient’s home or to another GLFHC Pharmacy location for pick up.
- The Complainant provided numerous emails from 3/11/10 to 5/14/18 supporting the allegations indicating that if a patient did not have a refill on a maintenance medication, the pharmacist was authorized to dispense a 30-day supply. This practice occurred off and on during this period.
- Emails from the VP of HR Borgesi and VP Martin were provided that acknowledge Cigna and Humana contracts were denied at the Lawrence South Pharmacy and those prescriptions were filled at the Methuen Pharmacy and delivered to the Lawrence South Pharmacy for pickup. They also confirmed allowing a 30-day supply of maintenance medications to be dispensed if there were no refills left and based that procedure on a North Carolina Board of Pharmacy regulation.
- CA: According to MOR Baccari, VP Martin was not aware of the insurance contract issue until April 2018. The practice of filling prescriptions for GLFHC pharmacies without an insurance contract and delivering them to the other GLFHC Pharmacy locations has been discontinued. Patients are offered home delivery.
- ISP-9768: Noted the Methuen Pharmacy filled, billed, and delivered medications to the four other GLFHC sites. Additionally, GLFHC central purchasing agent ordered the medications for all the GLFHC clinics and had them dropped shipped to the Methuen Pharmacy to be stored and distributed.
- MOR Baccari provided invoices from 1/1/18 to 5/31/18 for medications ordered for the clinics which were ordered under the clinic accounts.
- CA: All clinic orders are shipped to the clinic where they will be received by clinic staff. The GLFHC policy was updated to reflect this change in protocol for clinic orders.
- Staff assignment was heard at the 11/1/18 Board meeting and the Board requested additional information.
- Addendum with 11/20/18 response attesting the information provided by MOR Baccari and VP Martin was true and accurate for the Board’s concerns regarding transfer policy, 30-day rollover prescriptions, and insurance contract denials.
- Transfer policy created 11/19/18 was provided which does not fully comply with all requirements of 247 CMR 9.02 and Board Policy 2101-01.
- VP Martin alleged the 30-day rollover was due to a backlog of refill requests in May of 2017 was a temporary option that immediately changed after one week, but emails provided by the Complainant indicate this was an intermittent practice from 03/2010 to 05/2017.
- A Continuity of Care – No Refills policy created on 11/19/18 was provided with options if the patient is out of medication to dispensing a one-time 3-day supply, contacting a clinician for a new prescription, or referring the patient to the clinic for an acute visit,

- Cigna initially denied Lawrence South Pharmacy a contract because the pharmacy was within the clinic. Cigna later denied a contract due to the high percentage of 340B prescriptions at that location. Lawrence South Pharmacy does not accept Cigna patients at that location but offers pharmacy services from the other locations.
- Initially Lawrence South Pharmacy could not negotiate the predatory reimbursement rate for 340B entities with Humana, but eventually accepted a dual 340B/retail contract.
- In response to a request for the previous policies, VP Martin provided a signed response co-signed by the GLFHC SVP & Chief Medical Officer attesting the information was true and accurate.
- The policies provided for the 340B and retail GLFHC pharmacies licensed by the BORP were allegedly informal documents written in April 2015 included in the GLFHC 340B Policy and Procedure Manual and not official policy documents. There was no written continuity of care policy if a patient was out of refills until 11/19/18, but VP Martin attested the “idea was informally, yet uniformly enforced”.
- On 6/27/19, SA-INV-13377 was presented to Board and was converted to a complaint with a request for a P&P for the transfer of prescriptions that complies with all Board requirements.
- On 7/15/2019, a compliant P&P for the transfer of prescriptions was received with no additional response for the complaint.

ACTION: Motion by S. Hamilton, seconded by T. Fensky, and voted unanimously by those present, to refer the matter (PHA-2019-0070) 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

PHA-2019-0042

Apothecare of Cape Cod, DS90083

Time: 11:23 AM

RECUSAL: NONE

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

- Inspectional deficiencies from retail inspection (ISP-11573) on 2/19/19 for clean and sanitary conditions (repeat deficiency), non-sterile compounding (repeat deficiency), controlled substance recordkeeping violations, refrigeration, lack of SOPs and expired compounding components with at least one prescription identified as compounded with expired coal tar solution. The Pharmacy failed to remediate the repeat deficiencies in the POC for ISP-10833 on 10/30/18.
- MOR Zou repeatedly provided untimely and incomplete responses. Requested compounding records were missing, incomplete or altered. All prescriptions with corresponding compounding logs were not provided. A provided dispensing report of compounded medications from 1/1/18 to 2/28/19 listed 516 medications including at least 7 different transdermal gels and 4 different suppositories. About 25 vancomycin suspension formulations were compounded despite stating the Pharmacy stopped compounding vancomycin after the 10/30/18 inspection and after Firvanq became available in 4/2018 (21 of 25). The Pharmacy prepared 11 different compounds for a total of 69 fills from 2/20/2019 to 5/18/2019 with compounding logs missing, incomplete or altered despite addressing in the POC.
- For the compounding deficiencies, MOR Zou responded at the time when these violations occurred he believed that the compounding procedures were correct. The pharmacist in charge of compounding is

no longer employed at the Pharmacy. Vancomycin was compounded because MOR Zou allegedly did not know there was a commercially available product.

- CA: New SOPs were created; expired medications and API were returned to an authorized reverse distributor; new biennial inventory of CII and CIII-CVs was performed; daily cleaning schedule was created; refrigerator temperature log was implemented for the compounding refrigerator. A consultant was hired to assist with non-sterile compounding compliance and staff training. New master formulations were obtained (copies provided). The Pharmacy will install computerized compounding software and will perform a USP 795 gap analysis.
- Re-inspected 7/31/19 with POC issued for 44 of 142 compounds from 3/2019 to 7/2019 with no compounding logs; disorganized records; commercially available vancomycin solution compounded with no documentation as to the reason. Of note, MOR Zou could not provide information as to the status for the compounding from prior to February 2019.

ACTION: Motion #1 by T. Fensky, seconded by M. Godek, and voted unanimously by those present, to refer the matter (PHA-2019-0042) 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 PROBATION for 2 years; for the Manager of Record to step down and an inspection within the next week.

Motion #2 by M. Godek, seconded by P. Gannon, and voted unanimously by those present, to open a complaint against the Manager of Record.

Case #11

PHA-2019-0067

Richmond Pharmacy, DS1650

Time: 11:44 AM

RECUSAL: NONE

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

- RLCS of 56 oxycodone 5mg tablets on 5/24/2019 allegedly lost in transit with only a DEA 106 and a note submitted. MOR Frassica did not determine the loss to be significant based on the quantity of oxycodone 5mg tablets he dispenses and did not properly report it to the BORP.
- In response to the complaint, Owner/MOR Frassica stated the loss was discovered when the customer reported her prescription had not been delivered. The delivery driver employed by the Pharmacy believes he dropped the bag but didn't know where. There are no security cameras in the parking lot and no search of the premises was indicated.
- A review of the perpetual inventory provided showed it was not reconciled every 10 days on numerous occasions; it was adjusted on 6/10/2019 with a note -56 per 106.
- CA: MOR Frassica discussed the incident with the delivery driver who was given a warning of termination if it happened again; only the head delivery driver will deliver CII; pharmacy staff assign deliveries of CIII-CVs to delivery drivers and track them.

ACTION: Motion by T. Fensky, seconded by P. Gannon, and voted unanimously by those present, to refer the matter (PHA-2019-0067) 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 STAYED PROBATION for 1 year and to tighten up on Policy and procedure on delivery and reconciliation of perpetual inventory.

Case #12

SA-INV-14927

Cornerstone Health Solutions, DS90083

Time: 11:52 AM

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

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

- 4/22/19 - allegation of refusal to transfer a prescription for Epclusa for the Patient from CHS (a BMC operated pharmacy) to Crown Colony Pharmacy where the Patient obtains his medications.
- Crown Colony indicated the Patient requested that his physician, whose practice is in a health center that is affiliated with BMC, send the prescription to them but it was faxed to CHS instead. The pharmacy liaison at the physician's office refused to relay a request from Crown Colony for a new prescription for Epclusa to the physician.
- CHS acknowledged that a request for transfer was received from Crown Colony but alleged the Patient did not authorize the transfer. Furthermore, CHS alleged that Crown Colony adjudicated a claim to the Patient's insurance company for Epclusa without a valid prescription from the physician. Crown Colony denied that allegation. CHS has filled only Epclusa for the Patient and no other medications.
- MOR Phung stated CHS and BMC have a contractual relationship for providing specialty care services and denies any wrongdoing. MOR Phung indicated CHS has no P&P for the transfer of prescriptions.

ACTION: Motion by M. Godek, seconded by P. Gannon, and voted unanimously by those present, to close SA-INV-14927 due to insufficient evidence.

TOPIC XII

EXECUTIVE SESSION

Time: 12:17 PM

Read by A. Stein

DISCUSSION:

ACTION: At 12:17 PM President A. Stein read the statement on reasons for Executive Session.

TOPIC XII

Executive Session Call to Order:

Time: 1:37 PM

By: J. Lanza, Secretary

ACTION: Motion by P. Gannon, seconded by M. Godek, and voted unanimously by roll call to call the September 5, 2019 meeting of the Executive Session to order.

Roll call vote: J. Lanza, yes; M. Godek, yes; S. Hamilton, yes; R. Lopez, yes; L. Giambarresi, yes; T. Fensky, yes; D. Perry, yes; P. Gannon, yes.

21. Sanction Hearing: Richard Doyle, PH15680; PHA-2017-0017
22. Sanction Hearing: Memo from Heather Engman RE: Conley's Drug Store: DS2654 PHA-2016-0018 and Richard Doyle, PH15680; PHA-2017-0017
23. PHA-2019-0055 CVS #137, DS2951
24. PHA-2019-0024 CVS #2254, DS2886
25. PHA-2019-0063 CVS #1803, DS89888
26. PHA-2019-0026 CVS #1056, DS1646
27. PHA-2019-0058 CVS #685, DS2646
28. PHA-2019-0015 CVS #524, DS2532
29. PHA-2019-0064 Walgreens #9538, DS3474
30. PHA-2019-0029 Walgreens #15969, DS90068
31. PHA-2019-0070 Greater Lawrence Family Health Center, DS90041
32. PHA-2019-0042 Apothecare of Cape Cod, DS90071
33. PHA-2019-0067 Richmond Pharmacy, DS1650
34. SA-INV-14927 Cornerstone Health Solutions, DS90083

Respectfully Submitted,
Julie Lanza, CPhT, Secretary