

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

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

May 3, 2018
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 Beth Rabasco, 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 | | M. Godek |
| | II | APPROVAL OF AGENDA <ul style="list-style-type: none"> • Introduction of Interns | | |
| | III | APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of April 5, 2018 Regular Session Minutes | | |
| 8:40 | IV | REPORTS <ul style="list-style-type: none"> • Applications approved pursuant to Licensure Policy 13-01 • Monthly report from probation • Board Delegated Complaint Review pursuant to licensure policy 14-02 • Above Action Levels approved by Staff Action 16-04 | | R. Harris M. Botto E. Taglieri |
| 8:45 | V | APPLICATIONS <ul style="list-style-type: none"> • Pine Pharmaceutical: Petition for a waiver • Partners Pharmacy – Pilot ADM Program • Island Pharmacy (DS2953)- Transfer of Ownership • Remedium Pharmacy (DS89943) –Renovation/Expansion • Soleo Health (DS89958)- Petition for a Waiver • North Falmouth Pharmacy (DS89831) – Petition for a waiver • New England Life Care – Petition for Waiver • Walgreens 10152 - Change of Manager | | |

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| 9:45 | VI | FLEX <ul style="list-style-type: none"> • CPE Monitor App • Atrius Health: CDTM advisory opinion • Advisory Committee Meeting – May 17, 2018- 9 a.m. – 12 noon | | | | | | | | | | | | | | | | | |
| 10:15 | VII | POLICIES <ul style="list-style-type: none"> • Policy 2018-02: Continuing Education credits for Postgraduate Pharmacy Academic Courses • Staff Action Policy 17-03: Staff Action Policy for Implementation of PSUD revisions • Consent Agreement for PSUD Participants (CAPP) <ul style="list-style-type: none"> ○ CAPP Attachment A: Individualized Rehabilitation Plan (IRP) ○ CAPP Attachment B: PSUD Body Sampling Testing Protocol | H. Engman | | | | | | | | | | | | | | | | |
| 10:45 | VIII | REGULATIONS <ul style="list-style-type: none"> • 247 CMR 16.00: Collaborative Drug Therapy Management • 247 CMR 22.00: Fines (proposed new regulation) | | | | | | | | | | | | | | | | | |
| 12:00 | IX | FILE REVIEW <table border="1" data-bbox="310 863 1161 1457"> <tr> <td data-bbox="310 863 371 930">1</td> <td data-bbox="371 863 1161 930">PHA-2018-0028- Cantrell Drug Company- NO00027</td> </tr> <tr> <td data-bbox="310 930 371 999">2</td> <td data-bbox="371 930 1161 999">PHA-2018-0004- CVS #447- DS3251</td> </tr> <tr> <td data-bbox="310 999 371 1077">3</td> <td data-bbox="371 999 1161 1077">PHA-2018-0006- CVS #257- DS3331</td> </tr> <tr> <td data-bbox="310 1077 371 1152">4</td> <td data-bbox="371 1077 1161 1152">PHA-2017-0219- CVS #1007- DS90074</td> </tr> <tr> <td data-bbox="310 1152 371 1230">5</td> <td data-bbox="371 1152 1161 1230">SA-INV-12422- CVS #0008- DS2926</td> </tr> <tr> <td data-bbox="310 1230 371 1306">6</td> <td data-bbox="371 1230 1161 1306">PHA-2017-0223- Rite Aid #10068- DS2369</td> </tr> <tr> <td data-bbox="310 1306 371 1381">7</td> <td data-bbox="371 1306 1161 1381">PHA-2017-0185- Rite Aid #10206- DS2412</td> </tr> <tr> <td data-bbox="310 1381 371 1457">8</td> <td data-bbox="371 1381 1161 1457">SA-INV-12601- Rite Aid #10110- DS3097</td> </tr> </table> | | 1 | PHA-2018-0028- Cantrell Drug Company- NO00027 | 2 | PHA-2018-0004- CVS #447- DS3251 | 3 | PHA-2018-0006- CVS #257- DS3331 | 4 | PHA-2017-0219- CVS #1007- DS90074 | 5 | SA-INV-12422- CVS #0008- DS2926 | 6 | PHA-2017-0223- Rite Aid #10068- DS2369 | 7 | PHA-2017-0185- Rite Aid #10206- DS2412 | 8 | SA-INV-12601- Rite Aid #10110- DS3097 |
| 1 | PHA-2018-0028- Cantrell Drug Company- NO00027 | | | | | | | | | | | | | | | | | | |
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| 4 | PHA-2017-0219- CVS #1007- DS90074 | | | | | | | | | | | | | | | | | | |
| 5 | SA-INV-12422- CVS #0008- DS2926 | | | | | | | | | | | | | | | | | | |
| 6 | PHA-2017-0223- Rite Aid #10068- DS2369 | | | | | | | | | | | | | | | | | | |
| 7 | PHA-2017-0185- Rite Aid #10206- DS2412 | | | | | | | | | | | | | | | | | | |
| 8 | SA-INV-12601- Rite Aid #10110- DS3097 | | | | | | | | | | | | | | | | | | |

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|------------------------------|-------------|---|-----------------------|
| | 9 | PHA-2017-0217- Walgreens #2309- DS1876 | |
| | 10 | PHA-2017-0218- Walgreens #2861- DS2232 | |
| | 11 | PHA-2017-0202- Ethos Veterinary Health, LLC- DS90035 | |
| | 12 | SA-INV-12421- Hopinkton Drug- DS8191 | |
| | 13 | SA-INV-12720-Blue Hills Pharmacy- DS89900 | |
| | 14 | SA-INV-12085- Prescott Pharmacy- DS90051 | |
| | 15 | SA-INV-12779- Hamid Mohaghegh- PH17643 | |
| | 16 | SA-INV-12679- Seaside Pharmacy- DS89919 | |
| | 17 | SA-INV-12519- Denise DiCiaccio- PH21816 | |
| | 18 | PHA-2017-0216- Stop & Shop #402- DS2260 | |
| | 19 | SA-INV-12623- Baystate Pharmacy- DS89912 | |
| | 20 | SA-INV-12424- Village Fertility Pharmacy, LLC- DS90059 | |
| 12:30 LUNCH BREAK | | | |
| 1:30 | X | EXECUTIVE SESSION The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, the Board will the review a request for the reinstatement of a license, the review of probation compliance and evaluate the Good Moral Character as required for registration for pending applicants. | CLOSED SESSION |
| 2:00 | XI | ADJUDICATORY SESSION (M.G.L. c. 30A, § 18) | |
| 2:50 | XII | M.G.L. c. 112, § 65C SESSION | CLOSED SESSION |
| 5:00 | XIII | ADJOURNMENT | CLOSED SESSION |

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

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

May 3, 2018

Board Members Present

Michael Godek, RPh. President
Andrew Stein, Pharm D, RPh. Pres Elect (left 12:40P)
Kim Tanzer, PharmD, RPh, Secretary
Susan Cornacchio, JD, RN
Stephanie Hernandez, Pharm D, BCGP, RPh
Patrick Gannon, RPh
Julie Lanza, CPhT
Dawn Perry, JD (left 11:30 AM)
Leah Giambarresi, Pharm D, RPh
Ali Raja, MD, MBA, MPH
Phillippe Bouvier, RPh

Board Members Not Present

Timothy Fensky, RPh
Carly Jean-Francois, RN, NP

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Associate Executive Director
Heather Engman, JD Board Council
Michelle Chan, RPh. Quality Assurance Pharmacist
William Frisch, RPh Director of Pharmacy Compliance
Joanne Trifone, RPh., Director of Pharmacy Investigations
Kimberly Morton, CPhT, Compliance Officer
Greg Melton, JD, PharmD, BCPS, RPh, Investigator
Julienne Tran, Pharm D, RPh Investigator
Christina Mogni, RPh Investigator
Joseph Santoro, RPh Investigator
Ed Taglieri, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:30 AM

A quorum of the Board was present, established by roll call. President M. Godek 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: M. Godek, yes; A. Stein, yes; K. Tanzer, yes;
S. Hernandez, yes; P. Gannon, yes; J. Lanza, yes; A. Raja, yes; L. Giambarresi, yes;
D. Perry, yes; S. Cornacchio, yes; P. Bouvier, yes

Moment of silence done in honor of the Officer Sean Gannon, killed in the line of duty, and for the Gannon Family. Patrick Gannon is a member of the Board of Pharmacy and the father of Sean Gannon.

Topic II. Approval of Agenda TIME 8:33 AM

Agenda May 3, 2018

DISCUSSION:

Defer: applications: Soleo Health (DS2953)
Defer: flex: CPE Monitor App
Defer: file review: PHA-2018-0006 CVS #257 DS3331

ACTION:

Motion by P. Gannon, seconded by K. Tanzer, and voted unanimously approve the agenda.

Currently no interns to introduce, it is transition of years and none are on rotations at this time.

Topic III Approval of Board Minutes TIME: 8:35 AM

Minutes

Draft, April 5, 2018 Regular Session Minutes

Changes:

None

Action:

Motion by A. Stein, seconded by L. Giambarresi, and voted unanimously to approve the regular session minutes of April 5, 2018. P. Bouvier abstained.

TOPIC IV REPORTS Time: 8:35 AM

Applications approved pursuant to Licensure Policy 13-01 Time: 8:35AM

Discussion: M. BOTTO noted that during the past month there have been twenty-four (24) changes of manager on record (MOR), and three (3) renovation expansion applications approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:36AM

Discussion: M. BOTTO provided the March 29, 2018 – April 25, 2018, Board of Pharmacy Statistics Report for the Probation monitor, which noted that there are currently fifty-six (56) licensees on probation, and four (4) licensees satisfactorily completed probations.

So noted

TOPIC IV

REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

Time: 8:36AM

Discussion: M. BOTTO provided that there were six (6) Board Delegated Review cases heard on April 30, 2018. Five of the cases were CE deficiencies (SA-INV-128972, SA-INV-12791, SA-INV-12684, SA-INV-12631, and SA-INV-12792) which were closed with no discipline warranted and remediation complete. There was one consumer grievance (SA-INV-11906), which was closed with insufficient evidence. The Board Delegated Review session was attended by M. GODEK as the Board Member, J. TRAN Pharmacy Investigator, as a delegate of the 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: 8:36AM

Discussion: K. MORTON reported that there were three (3) above action level reports successfully remediated and closed since last month's board meeting.

So noted

Topic V:

APPLICATIONS

Time: 8:38AM

1. Pine Pharmaceuticals Petition for Waiver 503B

TIME: 8:38 AM

RECUSAL: None

DISCUSSION:

- W. FRISCH provided an update on the application as this is a non-resident outsourcing facility required a FDA inspection prior to having the license issued.
- The FDA inspection was conducted from April 11, 2018 through April 26, 2018 and the facility received a Form 483.
- A license was issued for the relocated facility and the issue has been resolved.

ACTION: No Action Warranted.

2. Partners Pharmacy Pilot ADM Program

TIME: 8:41AM

RECUSAL: None

DISCUSSION: Partners Pharmacy was represented by Anthony Spero, Chief Operating Officer – Partners Pharmacy; Jody Fenelon, RPh, Director of Compliance; Jim Moncrief, Co-Founder AP PassPort System; Frank Wang, RPh, VP Operations; Derek Corriveau, PharmD, RPh, Pharmacy Director; Nicholas Brunette, PharmD, RPh, Manager of Record; and Bill Bogdanovich, President and CEO Broad Reach Healthcare and Liberty Commons.

- J. FENELON provided over the AP PassPort History which included a deployment 2002 in Texas at Advanced Pharmacy.
- Over 130 AP PassPort systems currently deployed to over 15,000+ residents, 60,000,000+ medication dispensed annually and 8,961 tablets dispensed in 5707 individual patient envelopes at Liberty Commons over 14 days.
- B. BOGDANOVICH provided his experience from his facility’s perspective. He spoke favorably about the technology, the improved workflow and increase in patient safety.
- J. FENELON indicated that AP Passport has been approved by multiple states. She also spoke about the technology was a unique industry leading onsite medication packaging system installed within a facility to provide safe, accurate, and economical dispensing. Improves nursing staff efficiency.
- F. WANG discussed the workflow similarities and changes between the current process in long-term care versus the Liberty Commons pilot. The only difference being that in the current process, the pharmacy technician packages the blister card while in the pilot project, the fill technician loads the refill cartridges.

- L. GIAMBARESSI asked how the patients receive other drugs not in the med cart. The representative explained that a label is generated for the new drug and sent to the facility.
- P. GANNON asked on the contingency plan in case of a mechanical failure. The representative explained that there is a phone on the unit to call the repair technician and would repair the unit. However, the pharmacy has an internal downtime (EMO) which the pharmacy would package the medication in the pillow packs, filled and delivered to the facility. The units are also monitored and supported remotely.
- S. CORNACCHIO asked if the name and room number for the patients are the only identifiers on the pillow pack of the medication. The representative said that there is a detailed report with an image and the description of the tablet. S. CORNACCHIO indicated that for patient safety, they should also provide another indicator like date of birth. E. TAGLIERI also said that there are patient pictures on the medication administration record which helps to identify the patient. Additionally, if the patient has dementia, you are unable to ask them for their date of birth.
- J. TRIFONE asked the scenario in the event that there is a change in the NDC number due to a different manufacturer. The representative said that top cartridge is disposable and the unit reads the NDC# to match the NDC number by the sensor. Additionally, the representative said that in the event of a recall, the prescription can lock out a unit to immediately address it and that the lot numbers are not comingled.
- D. PERRY asked if the cartridge units are recyclable. The representative said that the units are not recyclable but that they are working on it. Additionally, J. FENELON indicated that the Partners unit has a lower medication error rate than the hospital and retail rates.
- S. HERNANDEZ asked regarding the description of the tablet and the policies and procedures for per diem staff.
- P. GANNON asked how the facility handles the per-diem staff. The representative indicated that the

ACTION: Motion by A.STEIN, seconded by, S. HERNANDEZ, and voted unanimously in the affirmative with the following list of the approved conditions for the pilot project:

- The length of the pilot project is one (1) year.
- A Massachusetts Board-licensed pharmacist from Partners Pharmacy (herein referred to as Partners) in Marlborough is to load the AP Passport for the first 30 days. If no concerns at this point, Partners may change to a Massachusetts Board-licensed Nationally Certified Pharmacy Technician.
- The Massachusetts Board-licensed Nationally Certified Pharmacy Technician may load the machine only with live video surveillance supervision by a Massachusetts Board-licensed pharmacist from Partners Marlborough.
- No federally controlled substances (CII-CV) may be stored in the AP Passport for 60 days. Federally controlled substances may be stored in the AP Passport after 60 days.

- Partners shall assure that any NIOSH drugs stored and dispensed in the AP Passport complies with provisions set forth in USP <800> Hazardous Drugs, Handling in Healthcare Settings.
- Partners is to monitor, track, and tabulate quality, safety, and security metrics during the term of the pilot project.
- After 90 days of successful operations verified by the monitoring reports, Partners may petition the Board to add AP Passport at other Long Term Care Facilities. Partners shall propose a structured roll-out to additional facilities for a controlled implementation.
- Partners shall assure that any interaction with nurses at the facilities or Certified Technicians (at the facility or the Houston Support desk) via video surveillance communication is with a Massachusetts Board-licensed pharmacist from Partners Marlborough.
- Field Technicians performing maintenance or repair of the AP Passport shall be supervised with live video surveillance supervision by a Massachusetts Board-licensed pharmacist from Partners Marlborough.
- All video surveillance recordings of the AP Passport at the Long Term Care Facilities shall be kept for a minimum of 30 days.
- Partners may use the AP Passport for CVI Emergency Drugs. Partners shall assure that these drugs are handled in accordance with DPH Regulations, Policies, and Guidelines for use of Emergency Medication Kits in Long Term Care Facilities.
- Partners shall not use the AP Passport for Emergency Drugs of federally controlled substances (CII-CV) and shall utilize the current system allowed by DPH Regulations, Policies, and Guidelines. Partners will be required to submit a plan on how the AP Passport will comply with Emergency Medication Kit requirements if Partners wishes to use the AP Passport for Emergency Drugs of federally controlled substances. This plan would have to approved by the DPH Bureau of the Health Care Safety and Quality (BHCSQ) and the Bureau of Health Professions Licensure (BHPL).
- 60 days prior to the end of the one (1) year pilot project, Partners shall request Board of Pharmacy final approval with applicable waivers if Partners wishes to continue with implementation and use of AP Passport in Long Term Care Facilities.
- All audit reports and related documentation of the AP Passport shall be readily available for Board inspection.

3. Island Pharmacy (DS2953)

Transfer of Ownership TIME: 9:53AM

RECUSAL: None.

DISCUSSION: Island Pharmacy was represented by Barry Recter who is the proposed Manager of Record and David Trinks (owner).

- Barry detailed his work experience including his previous experience as the Pharmacy Director of Pharmacy at Nantucket Hospital. He has 27 years experience working at Island Pharmacy and his current staff includes one staff pharmacist and five technicians.
- D. TRINKS indicated that since the last retail inspection, the new refrigerator has been replaced with a new sensor to measure the temperature. The pharmacy does

engage in simple and moderate compounding. The store is registered with MassPat and will engage in immunizations.

ACTION: Motion to approve the new application by A.STEIN, seconded by, P. GANNON, and voted unanimously to approve the application.

4. Remedium Pharmacy Renovation/Expansion TIME: 10:01AM

RECUSAL: None.

DISCUSSION: Remedium Pharmacy was represented by Manager of Record Cristina Iepure and Flaviu Iepure (owner). F. IEPURE indicated that the original space was damaged by fire but they would like to get the space renovated and expanded. Additionally, they would like to submit plans for compounding room that will USP <800> compliant.

ACTION: Motion by P. GANNON, seconded by, S. HERNANDEZ, and voted unanimously in the affirmative to approve the renovation, remodeling application.

5. Soleo Health Petition for a Waiver TIME: 10:06AM

RECUSAL: None.

DISCUSSION: DEFERRED.

6. North Falmouth Pharmacy -- Petition for Waiver TIME: 10:07

Deferred

7. New England Life Care – Petition for Waiver TIME: 10:07

RECUSAL: None

DISCUSSION: New England Life Care was represented by Bret Snow, the Manager of Record.

New England Life Care came before the Board of Pharmacy, petitioning for a waiver of 247 CMR 6.01(5)(a)(4)- a balance capable of accurately weighing quantities as small as 13 milligrams, which balance shall be tested and sealed by the state or local sealer of weights and measures annually. MOR Snow explained that the pharmacy does not engage in high risk compounding or weighing of powdered or solid ingredients. All low and medium risk compounding performed is conducted via the reconstitution of premeasured vials direct from the manufacturer.

ACTION: An initial motion by A. STEIN, seconded by K. TANZER to approve the application, was voted unanimously to approve the petition for waiver.

8. Walgreens #10152 – Change of Manager

TIME: 9:34 am

RECUSAL: M. GODEK

DISCUSSION: Daniel Le, PH236377, proposed Manager of Record was present for this.

Daniel has not had any previous MOR experience. He indicated he has been working for Walgreens for five years, and has been a pharmacist for a year and a half. He indicated he was recommended for this position by his manager, and that in preparation he has read the Manager of Record Advisory and completed the self-inspection tool. The BOP offered support and education regarding: ratios, technician in training, and controlled substance recordkeeping.

ACTION: Motion by L. GIAMBARRESI, seconded by K. TANZER, and voted unanimously to approve this change of manager at Walgreens #10152

Topic VI

FLEX SESSION

Time: 10:11 AM

1. CPE Monitor App

DEFER to June

2. Atrius Health: CDTM Advisory Opinion

Time: 10:11AM

Discussion:

Kathy Keough, Director, Government Relations, Amy Vachon, PharmD, Director, Clinical Pharmacy Program, and Tanya Iliadis, Assistant Director, Clinical Pharmacy Program, from Atrius Health appeared before the Board to seek an advisory opinion (written request submitted April 5, 2018) regarding Collaborative Drug Therapy Management (CDTM) experience requirements as set forth in 247 CMR 16.02 (1)(c)(2). Kathy Keough, Director, Government Relations, provided an overview of Atrius Health and the high value placed on the Clinical Pharmacy Program as part of the overall health care team in managing patient drug therapy. Currently there are 14 Clinical Pharmacists participating in CDTM Agreements. Amy Vachon, PharmD, Director, Clinical Pharmacy Program, explained that only pharmacists that have completed residencies (PGY1 or PGY2) are considered for CDTM positions and that Atrius has a robust competency training program. Atrius Health is requesting an advisory opinion from the Board on the five (5) year experience requirement as a licensed pharmacist to enter a CDTM agreement since candidates fresh out of residency programs would not meet this requirement. Specifically, can the completed residency program and the organization's clinical pharmacy training program be considered equivalent to five (5) years experience as a licensed pharmacist?

Board President M. Godek thanked Atrius Health representatives for their presentation and informed them that the Board would take the request under advisement. Board Counsel H. Engman suggested that the Board develop an advisory opinion to be considered at a future

meeting outlining specific criteria and parameters for experience equivalency. Discussion among Board members centered around assuring that the residency programs provide a sufficient level of exposure to the skills and qualifications required of the position.

ACTION: No vote taken.

3. Advisory Committee Meeting: May 17, 2018 9 AM to 12 Noon

Time: 10:27AM

Discussion:

E. Taglieri, PSUD Program Supervisor, informed the Board that the next meeting of the Advisory Committee to the Board will be held on May 17, 2018, from 9AM to 12 Noon. The agenda will primarily be focused on discussing a draft policy centered around Emerging Models of Pharmacy Practice including Central Fill Pharmacy, Central Processing Pharmacy, and Telepharmacy (Shared Service). For the benefit of newer Board members, E. Taglieri provided background on the legislative mandate for the Board to form the Advisory Committee and the tasks that the Committee was required to address. Investigating emerging models of coordinated, remote, and shared pharmacy services was among the tasks required of the Advisory Committee and was the subject of four (4) prior meetings of the Advisory Committee. E. Taglieri requested that the Board adopt Advisory Committee Recommendation Document 18-01, Emerging Models of Pharmacy Practice (shared services), and recommend that the Advisory Committee develop a draft policy on the shared pharmacy service models for future consideration by the Board. Also requested was that a Board member present the recommendation document at the Advisory Committee meeting. Board member K. Tanzer volunteered to present the recommendation document.

ACTION: Motion by P. Gannon, seconded by S. Hernandez, and voted unanimously by those present, to adopt Advisory Committee Recommendation Document 18-01 and recommend that the Advisory Committee develop a draft policy on the shared pharmacy service models for future consideration by the Board.

Topic VII.

POLICIES

Time: 10:33 AM

1. Policy 2018-02: Continuing Education Credits for Postgraduate Pharmacy Academic Courses

TIME: 10:33 AM

Presented by: M. CHAN

Discussion: M. CHAN explained that the intent of this new policy is to allow CE credit to be awarded to pharmacists who are taking postgraduate pharmacy classes in accordance with our regulations.

Adapted from the criteria for Board-approved CE programs, this provides a formal process for awarding those credits.

Since ACPE now allows non-ACPE credit to be submitted to CPE Monitor, having this system in place will allow licensees to have all credits in one place as well as make the Board's auditing process smoother.

Approval of this policy would supersede Policy 98-004 that exempts pharmacists who are enrolled in a non-traditional Pharm.D program from having to obtain CE hours.

As written, the policy offers 3 contact hours of CE for every 1 academic credit.

Certain wording changes were suggested by K. TANZER as well as a request to add clarification that all other CE requirements still apply (i.e. 2 hours of law, 5 hours of live instruction, etc.)

ACTION: Motion by L. GIAMBARRESI, seconded by P. GANNON and voted unanimously by all those present to approve the policy with the noted changes.

2. Staff Action Policy 2017-03: Staff Action for implementation of PSUD Revision

Time: 10:45 AM

Presented by: E. Taglieri

Discussion: E. Taglieri discussed the update to this Staff Action Plan to reflect the current practice of the program. When the Staff Action Plan was first approved, it was based off a theoretical process that had not been implemented. Now that the program has been operational for 8 months, it was time to update the Board and request for some clarifications in the Staff Action Policy. E. Taglieri discussed the proposed policy and the changes. Of Major note are:

1. Clarification on authority to change license status as participants progress in the program.
2. Change in philosophy to body sample testing versus urine testing
3. Clarification on vacations, allowing participants to utilize the 7 days every 6 months intermittently, not all at once.
4. On page 5, updates and additions to guidance allowed by the Rehabilitation Evaluation Committee (REC) to alter participants rehabilitation plans.
5. Authority to REC to alter the participants requirements with the addition of evidence of drug diversion and urine test results with low creatinine or concerns of adulterated body sample (page 6).

The Board requested some of the acronyms to be added to definitions as well as to clarify the language on page 5 to ensure the second chart is represented correctly with not allowing dates of meetings and signatures after 2-3 years, but requiring them prior to that.

ACTION: Motion by P. Gannon, seconded by P. Bouvier and voted unanimously by all those present to approve the policy with the noted changes and adjustment of wording on grid page 5 as well as adding the definition of acronyms.

3. Consent Agreement for PSUD Participants (CAPP) with: Attachment A: Individualized Rehabilitation Plan (IRP) Attachment B: PSUD Body Sample Testing Protocol

Time: 10:52 AM

Presented by: E. Taglieri

Discussion: E. Taglieri discussed the update to the CAPP and Attachment A & B to reflect the current practice of the program. When these were first approved, it was based off a theoretical process that had not been implemented. Now that the program has been operational for 8 months, it was time to update the Board and request for some clarifications. E. Taglieri discussed the proposed changes. Of Major note are:

1. Language in CAPP was clarified
2. Attachment A updated to reflect changes in IRP allowed by REC
3. Attachment B updated to reflect observed vs. supervised urines and the need for additional body sample testing is urine creatinine was below 20 mg/dl.

No additional changes or clarifications were requested of the Board.

ACTION: Motion by P. Gannon, seconded by K. Tanzer and voted unanimously by all those present to approve the updated CAPP as well as Attachment A and B.

Topic VIII.

REGULATIONS

Time: 10:56 AM

1. 247 CMR 16.00: Collaborative Drug Therapy Management

Time: 10:56 am

DISCUSSION: Presented by H. ENGMAN

When 247 CMR 16:00 was last revised, section 16.02, requiring specific qualifications to enter into a collaborative practice agreement, established a “grandfathering” date for those who earned a doctor of pharmacy degree and entered into a collaborative practice agreement on or before June 30, 2017. Since the promulgation took longer than expected, the date needed to be moved to 12/15/17, otherwise the regulation would have made some people retroactively non-compliant.

Action: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously to authorize Board staff to waive 247 CMR 16.02 (1) (c) date, and change the date to 12/15/2017.

2. 247 CMR 22.00: Fining

Time: 11:15 am

DISCUSSION: Presented by H. ENGMAN, D. SENCABAUGH

247 CMR 22.00 was first introduced several months prior to this meeting as being a new section that would be one of the last sections of 247 CMR to be presented to the Board as a result of sweeping pharmacy reform legislation, and under authority granted to the Board by M.G.L. c. 112, sections 24A and 42D.. Board Counsel H. ENGMAN provided a structure of the section which is a draft of a proposed outline of the “process” of fining, with the thought that specific violations and fines would live in a section that could more easily be revised over time.

Action: No vote on section 22.00 was taken at this meeting. P. GANNON said he would hope to see a “phase-in” approach to fining, and the idea of putting together a “fining” sub-committee of the Board was mentioned by some members for consideration. Board staff committed to dedicating time to the fining issue, and bring suggestions to a future Board meeting, to include a matrix for offenses and dollar amounts for fines that would reflect the severity of violations.

11:30 AM: Dawn Perry leaves meeting for the remainder of the day

Topic IX. OPEN FILE REVIE Time: 11:40 AM

Case #1
PHA-2017-0028 Cantrell Drug Company NO00027 Time: 11:40 AM

RECUSAL: none

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

- Cantrell's FDA registration is no longer "current," as the facility is prohibited from distributing products.
- Cantrell failed on more than one occasion to report FDA inspections.
- The FDA has suspended operations at Cantrell at this time based off inspection, and thus they are not currently shipping into Massachusetts.
- Pharmacy OPP will continue to monitor and update Board in the event this situation changes

ACTION: None at this time, Cantrell is currently not able to operate and ship items into Massachusetts with the FDA ceasing operations.

Case #2
PHA-2018-0004 CVS #447 DS3251 Time: 11:42 AM

RECUSAL: S. Cornacchio

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

- During an inspection 11/3/2017 an individual wearing a pharmacy technician badge could not provide a technician license and none could be verified;
- In the POC, MOR Wheeler attested a copy of the license was now posted in the pharmacy but was not provided;
- CVS Regulatory Affairs submitted the response which indicated the person in question is a pharmacy technician trainee at 571 hours as of 1/27/18.
- MOR will verify licensure/number of hours worked for support staff.

ACTION: Motion by P. Gannon, seconded by P. Bourvier, and voted unanimously by those present to dismiss PHA-2018-0004, with no discipline warranted, remediation complete.

Deferred

Case #4

PHA-2017-0219

CVS #1007 DS90074

Time: 11:44 AM

RECUSAL: S. Cornacchio

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

- RLCS- #100 oxycodone 5mg tablets was discovered during the state count on September 01, 2017.
- The state count prior to the loss on 08/28/2017 was deemed accurate and there were 14 prescriptions filled between the two state counts
- Video footage was reviewed for all 14 scripts. The cameras showed the original prescription being filled and verified, and then placed with other medications to be filed into the ready bin. Asset protection could not determine the cause of the loss and indicated that there was no question of diversion.
- The MOR indicated that he could not recall exactly which patients were contacted, but the patients that were contacted stated that they did not receive the extra medication
- All Loss Prevention Policy and Procedures, including the practice of documenting residual on the back of hard copies were reviewed with the Pharmacy Team to prevent future losses. This included diligent inventory management and dispensing standards. There was also a review of back counting of all Schedule II's at the time of dispensing.

ACTION: Motion by A. Stein, seconded by L. Giambarresi, and voted unanimously by those present to refer PHA-2017-0219 to the Office of Prosecution for an issuance of an order to show cause and authorize a consent agreement for reprimand.

Case #5

SA-INV-12422

CVS #0008 DS2926

Time: 11:46 AM

RECUSAL: S. Cornacchio

DISCUSSION: K. Morton presented and summarized the investigative report that pertained to these matters.

- RLCS- an unknown loss of #311 tramadol HCL 50mg tablets on or about September 05, 2017.
- MOR indicated the medication is produced by an automated counting system and though not definitively proven, automation mechanical issues may have culminated in the residual loss of tramadol.
- For corrective action, MOR indicated the automation vendor recalibrated system and the pharmacy team is performing routine maintenance and accuracy checks on prescriptions produced by the automation system.

- CVS #0008 has three prior reported losses

A retail compliance inspection was conducted on December 13, 2017 with deficiencies noted, including gaps in the perpetual inventory exceeding 10 days. A successful plan of correction was submitted.

ACTION: Motion by L. Giambarresi, seconded by P. Gannon and voted unanimously by those present to close SA-INV-12422, with no discipline warranted, remediation complete.

Case #6

PHA-2017-0223

Rite Aid #10068 DS2369

Time: 11:52 AM

RECUSAL: M. Godek

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

- RLCS- #100 oxycodone 15mg tablets discovered missing on November 11, 2017 while performing the weekly Schedule II count
- The perpetual inventory log indicated that there were two prescriptions filled for two different patients between the state count on 11/03/2017 and 11/12/2017 as well as #400 oxycodone 15mg tablets received on 11/10/2017
- Both patients were called and both patients said they had no extra tablets
- There are currently no security cameras in the pharmacy.
- MOR reviewed procedures for accurate, handling, dispensing and accountability of controlled substances with the pharmacy staff. He informed the staff that they will be held accountable for following procedures and had the staff sign a document stating they will, count, double count and back count the stock bottles for exact counts. He noted that the staff will minimize narcotics on the work bench at one time. He indicated that Schedule II drugs can only be ordered and checked in by a pharmacist with Power of Attorney. The receiving pharmacist will now circle and initial quantities received on all invoices. MOR Guettler indicated that he will perform random audits to ensure accurate handling, dispensing and accountability of controlled drugs.

ACTION: Motion by P. Gannon, seconded by K. Tanzer and voted unanimously by those present to dismiss PHA-2017-0223, with no discipline warranted

Case #7

PHA-2017-0185

Rite Aid #10206 DS2412

Time: 11:48 AM

RECUSAL: none

DISCUSSION: K. Morton presented and summarized the investigative report that pertained to these matters.

- Complaint opened a result of a failure to timely report a confirmed loss of controlled substances and a failure to properly maintain controlled substance perpetual inventory logs.

- MOR Responded to perpetual inventory logs and indicated when she was cleaning out files, she destroyed all outdated/removed from stock perpetual logs not realizing they needed to be kept. She was a new MOR at this point and still was learning the job.
- In relation to the failure to timely report a RLCS, she indicated the policy on reporting losses was overlooked and that the staff was unfamiliar with the reporting protocol.
- To remediate, MOR Bean stated, the pharmacy has been made aware of the time reporting policies and will follow exact protocol in the future if any other occurrence were to happen.
- In relation to the perpetual inventory logs, MOR Bean submitted a plan of correction indicating that the pharmacy staff pharmacist has been informed of the violation and that going forward, all perpetual inventory log sheets will be maintained for two years. MOR Bean also indicated that from the day of the inspection all records have been kept and all pharmacy employees have been made aware of the requirements for maintenance of perpetual inventory logs.
- MOR Bean attested to reading and reviewing the Board's Advisory on New Managers of Record in its entirety.

ACTION: Motion by A. Stein, seconded by S. Hernandez and voted unanimously by those present to dismiss PHA-2017-0185, with no discipline warranted, remediation complete.

Case #8

SA-INV-12601

Rite Aid #10110 DS3097

Time: 11:55 AM

RECUSAL: M. Godek

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

- RLCS- #30 dextroamphetamine/amphetamine salt ER 20mg capsule discovered by a staff pharmacist on 10/21/2017 during state count
- There were five prescriptions filled and a receipt for #300 capsules received between the correct count on 10/12/2017 and the discovery of the loss on 10/21/2017.
- The MOR called each patient that received the medication during that time but only a couple could confirm that they received the correct quantity.
- Cameras were not angled toward the safe or filling stations, therefore not reviewed
- MOR indicated that modifications were made to workflow to included: triple counts on all Schedule II prescriptions, back counts on all residual CII's in the stock bottles, write the new quantities with marker on the bottles, match the quantities in the computer, log RX immediately after it is verified, instead of at the end of the day, and CII's books will be kept at the verification computer instead of in the back area on top of the safe.

ACTION: Motion by K. Tanzer, seconded by L. Giambarresi and voted unanimously by those present to close SA-INV-12601, with no discipline warranted, remediation complete.

RECUSAL: M. Godek

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

- RLCS- #161 oxycodone 5mg tablets on or about October 27, 2017.
- An initial loss was discovered on August 26, 2017 and not reported because it was deemed insignificant. An additional loss occurred October 27, 2017 for #90 oxycodone 5mg tablets that they could not account for and it was determined that after a pattern of two losses of the same medication that a DEA 106 was submitted.
- Both losses were discovered when the prescription could not be located at the time the patient came in to pick it up.
- Investigation included checking every amber vial inside the bag to make sure it matched the prescription leaflet and video footage was reviewed but it could not be determined when the loss occurred, technicians on duty were interviewed but no staff member admitted to passing, concealing or stealing the medication.
- Video footage was reviewed and it was determined because there was no camera on the ready bins, store leadership and Asset Protection determined this was the point where the medication went missing, most likely due to internal theft.
- Corrective action included adjusting the cameras to now include the pick-up bin area, daily counts of oxycodone are conducted and compared to the perpetual inventory. All bags, lunch boxes are now kept outside the pharmacy in the staff's lockers and checked prior to leaving their shift.

ACTION: Motion by P. Gannon, seconded by P. Bouvier and voted unanimously by those present to refer PHA-2017-0217 to the Office of Prosecution for an issuance of an order to show cause and authorize a consent agreement for reprimand.

RECUSAL: M. Godek

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

- RLCS- #90 dextroamphetamine ER 10mg capsules discovered when the patient came to pick up the prescription and it was unable to be located.
- The ready bins were checked but the prescription could not be found. The pharmacist on duty decided to fill the prescription again and a loss of #90 capsules was generated
- Video footage was unable to determine what happened to the prescription after it was placed with the other prescriptions to be filed into ready bins.
- MOR indicated that window procedures were reviewed with the staff and the importance of verification of the patient's name and address, pin pad verification of telephone number, and

scanning each prescription leaflet. She indicated that a discussion took place with the staff regarding the timely filing of prescriptions into the ready bins and the importance of being consistent and vigilant about filing all the prescriptions into ready bins.

ACTION: Motion by P. Gannon, seconded by P. Bouvier and voted unanimously by those present to refer PHA-2017-0218 to the Office of Prosecution for an issuance of an order to show cause and authorize a consent agreement for reprimand.

Case #11

PHA-2017-0202 Ethos Veterinary Health, LLC, DS90035 Time: 12:03 PM

RECUSAL: NONE

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

- Inspectional deficiencies from retail, USP 795 and USP 797 inspections on 10/18/17 & 10/25/17; Former MOR was on extended medical leave with no interim MOR appointed & Current MOR had no compounding background
- Required records not available during inspections including return records, training documents for compounding and hazardous drugs, QRE reports, staff competencies; hand hygiene occurring in unclassified space due to size of sink in anteroom
- June 2017 fungus was identified in the buffer room with no remediation and was not reported to the BORP
- Ethos voluntarily ceased sterile compounding 10/18/2017 and issued a recall
- Engaged a consultant and staff received extensive training in compounding with new P&Ps created and implemented
- No sterile compounding currently and planning on new pharmacy build out for 2018
- Retail and USP 795 inspections on 1/10/18 with no deficiencies
- USP 797 inspection on 4/10/18 showed marked improvement and currently not compounding.

ACTION: Motion by P. GANNON, seconded by, L. GIAMBARRESI and voted unanimously by those present, to refer the matter (PHA-2017-0202) 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.

ADDITIONAL ACTION: Motion by L. GIAMBARRESI, seconded by S. HERNANDEZ and voted unanimously by those present, to have the proposed MOR and their supervisor appear

before the Board to review the change of MOR application submitted for Ethos Veterinary Health, LLC DS90035.

Case #12

SA-INV-12421

Hopkinton Drug, DS8191

Time: 12:16 PM

RECUSAL: NONE

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

- Inspectional deficiencies for USP 795 inspection on 11/2/17 for missing training documents related to hazardous drugs for a pharmacy intern, missing hazardous risk acknowledgements for 2 pharmacy staff members, and compounding Mimosa Pudica in a powder hood last certified on 2/23/16
- MOR Zaia determined an outdated training list was used and affixed an out of service sign to the powder hood after the inspection
- Annual training including hazardous drugs was completed with acknowledgements on 12/19/17
- CA includes using the current version of the training checklist for new hires; will be reviewing and updating the initial training packet
- Powder hood was re-certified on 1/16/18
- Inspected 3/28/18 ISP-9461 with no POC issued.

ACTION: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by those present, to CLOSE (SA-INV-12421), Discipline Not Warranted, Remediation Complete.

Case #13

SA-INV-12720

Blue Hills Pharmacy, DS89900

Time: 12:18 PM

RECUSAL: NONE

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

- Inspectional deficiencies for a re-inspection with repeat deficiencies related to non-sterile compounding in October 2017 including master formulations with no references, extended BUDs with no documentation, missing quality control, lack of 795 and 800 compounding SOPs, lack of training SOPs, no documentation on proper storage and handling of hazardous drugs
- Pharmacy voluntarily ceased compounding hazardous preparations

- POC received did not adequately address the deficiencies
- MOR revised and provided detailed, comprehensive SOPs including 795 and 800 compounding SOPs and compounding staff were retrained on them
- Master formulations were reviewed and revised to include references and correct BUDs

ACTION: Motion by A. STEIN, seconded by K. TANZER, and voted unanimously by those present, to CLOSE (SA-INV-12720), Discipline Not Warranted, Remediation Complete.

Case #14

SA-INV-12085

Prescott Pharmacy, DS90051

Time: 12:25 PM

RECUSAL: NONE

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

- E-kits containing benzodiazepines were dispensed to a substance abuse treatment center which is not allowed by federal law
- 3 rx's were created 10/24/16 and 3 rx's were created 10/26/16 for "Narcotic Kits" containing lorazepam, clonazepam, and alprazolam
- Former VP of Operations Andrea Standring allegedly created the orders and supplied the kit, but Former MOR could provide no proof
- Former MOR Leary indicated one kit was used and CPhT Foresman claimed no kits were actively filled
- Pharmacist Standring denied filling E-kits and stated she had a heated discussion with Hamid Mohaghegh about the legality of supplying E-kits to a NTC and Hamid stated he would take care of it
- Former MOR Collins did not recall supplying any E kits to any facility at that time

ACTION: Motion by A. STEIN, seconded by K. TANZER, and voted unanimously by those present, to CLOSE (SA-INV-12085), Discipline Not Warranted, Remediation Complete.

Case #15

SA-INV-12779

Hamid Mohaghegh, PH17643

Time: 12:25 PM

RECUSAL: NONE

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

- 3/16/2018 monetary settlement with US Attorney's Office for failure to comply with requirements of the Controlled Substance Act
- On probation as of 2/23/18
- Related to SA-INV-12085 for Prescott Pharmacy in Worcester for E-kits containing benzodiazepines dispensed to RCA in October 2016
- Alleged Former VP of Operations Andrea Standring created the orders and supplied the kit, but no proof was provided
- Attorney submitted the response indicating Pharmacist Mohaghegh, the owner of Family Pharmacy and Medserv, has no involvement with Prescott Pharmacy, is not an owner, stockholder, director, or employee of Prescott Pharmacy, and that MOR John Leary should provide a response.

ACTION: Motion by A. STEIN, seconded by K. TANZER, and voted unanimously by those present, to CLOSE (SA-INV-12779), Insufficient Evidence.

Case #16

SA-INV-12679

Seaside Pharmacy, DS89919

Time: 12:31 PM

RECUSAL: NONE

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

- On 1-10-18, multiple deficiencies involving CS's were observed during a site visit. POC was issued as a result. The deficiencies included failing to sign the face of C-II Rx, failing to log C-II transactions in a timely manner, dispensing partial quantity of C-II using a faxed prescription, and allowing a technician in training to log C-II.
- MOR Vo submitted a POC to address the issues. She indicated that she reminded RPh's to sign the face of C-II Rx's and to record C-II transactions on the day of fill. She stopped using faxed prescriptions to partially fill C-II's and will call for emergency Rx if needed going forward. She forbade staff except for RPh's to log the C-II's.

- In addition, MOR Vo responded after receiving notice of this investigation. She reiterated the actions taken in her POC to remediate the observed deficiencies. She also explained that she advanced a small quantity (5 oxycodone 30mg tablets) of a C-II to a patient using a faxed Rx because of an impending storm the next day.

ACTION: Motion by K. TANZER, seconded by P. GANNON, and voted unanimously by those present, to CLOSE (SA-INV-12679), No Discipline Warranted, Remediation Complete.

Case #17

SA-INV-12519

Denise DiCiaccio, PH21816

Time: 12:33 PM

RECUSAL: NONE

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

- Pharmacy and Owner/Former MOR Rubin were placed on probation for 1 year for ISP deficiencies involving C-II recordkeeping effective 08-08-17. Owner/Former MOR Rubin required to stepdown as MOR per consent agreement. He now works as Staff RPh only.
- Current MOR DiCiaccio failed to submit dispensing data on 36 occasions between 08-08-17 and 11-07-17. She indicated that she was not aware of required PMP waiver for days of operation, she relied on Owner/Staff RPh Rubin as staff pharmacist to submit data, and she failed to remember to submit data when Owner/Staff RPh Rubin went on vacation.
- MOR DiCiaccio created written opening and closing procedures for the pharmacy. No further delinquencies from 12-27-17 to 03-15-18.

ACTION: Motion by P. BOUVIER, seconded by S. HERNANDEZ, and voted unanimously by those present, to CLOSE (SA-INV-12519), No Discipline Warranted, Remediation Complete.

Case #18

PHA-2017-0216

Stop & Shop #402, DS2260

Time: 12:35 PM

RECUSAL: NONE

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

- RLCS- #65 oxycodone 15mg tablets, the reason for the loss could not be confirmed. It is suspected that the medication was inadvertently discarded.
- MOR alleges that after filling a prescription for oxycodone 15mg tables on 11/14/2017, he inadvertently discarded the stock bottle. He remembers three bottles on the counter, two of which were empty and the other had #65 tablets.

- After he logged the prescription into the perpetual inventory he picked up the bottles and discarded all three bottles.
- Video was reviewed on 11/21/2017 and was inconclusive. The area in question behind the pharmacy, the safe and counter, was not on camera view.
- On November 29, 2017 the cameras were adjusted to include the area behind the pharmacy to ensure the safe and counters are in view of the cameras. MOR indicated that the Pharmacy will keep empty bottles uncapped and will discard immediately after using, and recap bottles in use and return immediately to the safe. Count backs will be performed after logging prescription on the perpetual inventory. A designated clear area will be instituted for dispensing of CII prescriptions.

ACTION: Motion by P. GANNON, seconded by P. BOUVIER, and voted unanimously by those present, to refer the matter (PHA-2017-0216) 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 #19

SA-INV-12623

Baystate Pharmacy, DS89912

Time: 12:37 PM

RECUSAL: NONE

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

- RLCS- suspected over-dispense of #24 oxycodone 15mg tablets on 12/15/2017, that can be accounted for but not recovered
- The loss was discovered while filling a prescription for oxycodone 15mg tablets, the back count on the bottle did not match the balance on hand. A weekly perpetual inventory performed later that day confirmed the loss
- Pharmacist Charron filled/packaged and verified the prescription for #224 tablets using 86 tablets from KVK and 138 tablets from Sun Pharm (100 from an unopened bottle and 38 from another sealed bottle) which should have resulted in a back count of 62, however, the bottle discovered in the safe had been sealed with a back count of 38 tablets indicating inventories were crossed
- Pharmacist Charron was counseled for not reconciling back counts with the perpetual log. Controlled Substance Dispensing Policies were revised to include an additional step to double count all controlled substance prescriptions and was sent out to all Pharmacy staff and locations via email on 01/16/2018. Physical reminders of this policy were hung throughout the pharmacy in the form of neon printed sheets. Additionally, MOR indicated that the Director BH

Retail/Ambulatory Pharmacy Services is working to enhance the pharmacy surveillance system and add additional cameras to the department

- Pharmacist Charron submitted documentation that he completed an additional 2 contact hours of continuing education credit focused on medication safety and attested that he reviewed 247 CMR 15, Continuous Quality Improvement Program, in its entirety

ACTION: Motion by KS> HERNANDEZ, seconded by P. GANNON, and voted unanimously by those present, to CLOSE (SA-INV-12623), No Discipline Warranted, Remediation Complete

Case#20

SA-INV-12424 Village Fertility Pharmacy, LLC, DS90059 Time: 12:39 PM

RECUSAL: NONE

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

- On November 16, 2017, a Disclosure of Above Action Level Environmental Monitoring was submitted.
- Due to the high level of contamination identified, a Site Visit (ISP-8678) was conducted on November 17, 2017 by OPP Investigators.
- Review of facility and documents did not directly identify the root cause.
- The Pharmacy voluntarily ceased compounding and instituted its continuity of care plan.
- Remediation ensued and repeat monitoring was conducted which identified fungal contamination in the anteroom.
- Root Cause Analysis and Corrective Action was conducted which included several facility renovations (replaced humidifier, touch up painting, re-caulking, removal of unnecessary appliances, replacement of ceiling tiles, installation of door sweep).
- Environmental monitoring and cleanroom certification conducted met acceptance criteria.
- Pharmacy resumed compounding on January 26, 2018.

ACTION: Motion by P. GANNON, seconded by L. GIAMBARRESI, and voted unanimously by those present, to CLOSE (SA-INV-12424), No Discipline Warranted, Remediation Complete.

12:40 PM: Andrew Stein leaves meeting for the remainder of the day

Topic X: EXECUTIVE SESSION Time: 12:40 PM

Read by M.GODEK

DISCUSSION:

ACTION: At 12:36 PM President M. GODEK read the statement on reasons for Executive Session.

12:45 PM to 1:37 PM Lunch Break

Topic X: Executive Session Call to Order time: Time: 1:37 PM
By: M. GODEK

ACTION: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by roll call to call the May 3, 2018 meeting of the Executive Session to order.

M. GODEK; **yes**, S. CORNACCHIO; **yes**, K. TANZER; **yes**, S. HERNANDEZ; **yes**, P. GANNON; **yes**, J. LANZA; **yes**, P. BOUVIER, **yes**; A. RAJA, **yes**; L. GIAMBARRESI, **yes**.

Topic XI: ADJUDICATORY SESSION (MGL 30A § 18) Time: 2:00 PM
DISCUSSION: None

ACTION: President M. Godek request a motion to enter Adjudicatory Session.

At 11:30 AM, Motion by P. Gannon, seconded by K. Tanzer and voted unanimously to enter Adjudicatory Session.

Topic XII: M.G.L. 65 C Time: 2:37 PM

DISCUSSION: None

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

At 2:37 PM, Motion by P. Gannon, seconded by L. Giambarresi and voted unanimously to enter M.G.L. chapter 65 c Session:

Topic XIII: ADJOURNMENT OF MEETING Time: 2:53 PM

ACTION: Motion by L. Giambarresi seconded by K. Tanzer, 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 5/3/18 General Session
2. Draft Minutes of the 4/5/18 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. Application: Pine Pharmaceutical: Petition for a waiver
8. Application: Partners Pharmacy- Pilot ADM Program/ Petition for Waiver
9. Application: Island Pharmacy (DS89943) Renovation/Expansion
10. Application: Soleo Health (DS89958) Petition for Waiver
11. Application: North Falmouth Pharmacy (DS89831) Petition for Waiver
12. Application: New England Life Care Petition for Waiver
13. Application: Walgreens 10152 Change of Manager
14. Atrius Health: CDTM advisory opinion
15. Pharmacy Advisory Committee Meeting draft recommendation and agenda
16. Draft policy 2018-02: Continuing Education Credits for Postgraduate Pharmacy Academic courses
17. Draft Revisions: Staff Action Policy 17-03: Staff Action Policy for Implementation of PSUD
18. Updated Consent Agreement for PSUD Participants (CAPP) with:
 - a. Attachment A: individualized Rehabilitation Plan (IRP)
 - b. Attachment B: PSUD Body Sample Testing Protocol
19. 247 CMR 16:00 Collaborative Drug Therapy Management
20. 247 CMR 22.00 Fines
21. PHA-2018-0028- Cantrell Drug Company- NO00027
22. PHA-2018-0004- CVS #447- DS3251
23. PHA-2018-0006- CVS #257- DS3331
24. PHA-2017-0219- CVS #1007- DS90074
25. SA-INV-12422- CVS #0008- DS2926
26. PHA-2017-0223- Rite Aid #10068- DS2369
27. PHA-2017-0185- Rite Aid #10206- DS2412
28. SA-INV-12601- Rite Aid #10110- DS3097
29. PHA-2017-0217- Walgreens #2309- DS1876
30. PHA-2017-0218- Walgreens #2861- DS2232
31. PHA-2017-0202- Ethos Veterinary Health, LLC- DS90035
32. SA-INV-12421- Hopinkton Drug- DS8191
33. SA-INV-12720-Blue Hills Pharmacy- DS89900
34. SA-INV-12085- Prescott Pharmacy- DS90051
35. SA-INV-12779- Hamid Mohaghegh- PH17643
36. SA-INV-12679- Seaside Pharmacy- DS89919
37. SA-INV-12519- Denise DiCiaccio- PH21816
38. PHA-2017-0216- Stop & Shop #402- DS2260
39. SA-INV-12623- Baystate Pharmacy- DS89912
40. SA-INV-12424- Village Fertility Pharmacy, LLC- DS90059

Respectfully Submitted,
Kim Tanzer, PharmD, RPh
Secretary