

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

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

February 1, 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		T. Fensky
	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 January 22, 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 • PSUD Monthly Reports • Walgreens-Rite Aid Transfer of Ownership 		R. Harris D. Sencabaugh E. Taglieri
8:50	V	APPLICATIONS <ul style="list-style-type: none"> • Arxcare/Pharmascript-Transfer of Ownership • Crown Colony Pharmacy – New Community Pharmacy • Community, A Walgreens Pharmacy (DS89805)- Change of Manager • Walmart Pharmacy 10-2336 (DS3400) – Change of Manager 		

9:15	VI	FLEX <ul style="list-style-type: none"> • Pharmacy Technician in Training Rollout • New waiver process rollout • NABP <ul style="list-style-type: none"> ○ annual meeting, ○ MPJE writing opportunities ○ APHA Institute 																						
9:30	VII	POLICIES <ul style="list-style-type: none"> • Policy: 2018-0#: Complaints against an expired pharmacy intern license 																						
9:45	VIII	ADVISORY <ul style="list-style-type: none"> • Advisory on Pharmacy Response to Failed HEPA Filters in ISO-Classified Environments 																						
10:00	IX	REGULATIONS <ul style="list-style-type: none"> • 247 CMR 6.00: Registration, Management and Operation of a Pharmacy • 247 CMR 9.00: Professional Practice Standards • 247 CMR 20.00: Reporting 																						
12:00		LUNCH BREAK																						
1:00	XI	FILE REVIEW <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20px; text-align: center;">1</td> <td>PHA-2017-0200- Walgreens #11602, DS3520</td> </tr> <tr> <td style="text-align: center;">2</td> <td>PHA-2017-0198- Walgreens #10427, DS3611</td> </tr> <tr> <td style="text-align: center;">3</td> <td>PHA-2017-0116- Walgreens #9011, DS3347</td> </tr> <tr> <td style="text-align: center;">4</td> <td>SA-INV-12522- Walgreens #9011, DS3347</td> </tr> <tr> <td style="text-align: center;">5</td> <td>SA-INV-12111- Walgreens #3151, DS2470</td> </tr> <tr> <td style="text-align: center;">6</td> <td>PHA-2017-0204- Rite Aid #10152, DS3145</td> </tr> <tr> <td style="text-align: center;">7</td> <td>SA-INV-12274- Rite Aid #10110, DS3097</td> </tr> <tr> <td style="text-align: center;">8</td> <td>SA-INV-12428- Rite Aid #10141, DS3119</td> </tr> <tr> <td style="text-align: center;">9</td> <td>PHA-2017-0208- Walmart Pharmacy #10-2683, DS2952</td> </tr> <tr> <td style="text-align: center;">10</td> <td>SA-INV-12085- Prescott Pharmacy, DS90051</td> </tr> </table>	1	PHA-2017-0200- Walgreens #11602, DS3520	2	PHA-2017-0198- Walgreens #10427, DS3611	3	PHA-2017-0116- Walgreens #9011, DS3347	4	SA-INV-12522- Walgreens #9011, DS3347	5	SA-INV-12111- Walgreens #3151, DS2470	6	PHA-2017-0204- Rite Aid #10152, DS3145	7	SA-INV-12274- Rite Aid #10110, DS3097	8	SA-INV-12428- Rite Aid #10141, DS3119	9	PHA-2017-0208- Walmart Pharmacy #10-2683, DS2952	10	SA-INV-12085- Prescott Pharmacy, DS90051		
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		11	SA-INV-11663- Triad Isotopes, Inc., NU00019	
		12	PHA-2017-0151- CVS #746, DS2818	
		13	PHA-2017-0195- CVS #707, DS24373	
		14	PHA-2017-0197- CVS #43, DS3025	
2:00	VIII	EXECUTIVE SESSION The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, the Board will evaluate Probation Compliance, reinstatement of a license and evaluate the Good Moral Character as required for registration for pending applicants.		CLOSED SESSION
2:45	X	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)		CLOSED SESSION
3:15	XI	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION
5:00	XII	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**

February 1, 2018

Board Members Present

Michael Godek, RPh, President
Andrew Stein, Pharm D, RPh, President Elect
Kim Tanzer, PharmD, RPh, Secretary
Susan Cornacchio, JD, RN
Stephanie Hernandez, Pharm D, BCGP, RPh
Patrick Gannon, RPh (via phone)
Timothy Fensky, RPh
Julie Lanza, CPhT
Carly Jean-Francois, RN, NP
Leah Giambarresi, Pharm D, RPh
Ali Raja, MD, MBA, MPH
Phillippe Bouvier, RPh

Board Members Not Present

Dawn Perry, JD

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Associate Executive Director
Heather Engman, JD, MPH, Pharmacy Board Counsel
Michelle Chan, RPh, Quality Assurance Pharmacist
William Frisch, RPh, Director of Pharmacy Complinace
Joanne Trifone, RPh., Director of Pharmacy Investigations
Kimberly Morton, CPhT, Compliance Officer
Joe Santoro, RPh, Contract Investigator
Nathan Van Allen, PharmD, RPh, Investigator
Greg Melton, JD, PharmD, BCPS, RPh, Investigator
Julienne Tran, Pharm D, RPh Investigator
Samuel Penta, RPh Investigator
Stephen Horn, RPh Investigator
Christina Mogni, RPh Investigator
Ed Taglieri, MSM, NHA, RPh PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:35 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; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; P. Bouvier, yes; C. Jean-Francois, yes; J. Lanza, yes; A. Raja, yes.

TOPIC II. Approval of Agenda TIME 8:37 AM

Agenda February 1, 2018

DISCUSSION:

No changes to the agenda.

ACTION:

Motion by P. Gannon, seconded by T. Fensky, and voted unanimously approve the agenda.

Executive Director, D. Sencabaugh, introduces 2 new Interns: Hannah Boudreau, WNE; Mitchell Price, MCP Boston; Eniola Tuby-Lukan, Northeastern University. Mike call for all the other interns in attendance to stand up and introduce themselves.

Topic III Approval of Board Minutes TIME: 8:40 AM

Minutes

Draft, January 22, 2018 Regular Session Minutes

Changes:

none

Action:

Motion by L. Giambarresi, seconded by S. Hernandez, and voted unanimously to approve the regular session minutes.

TOPIC IV REPORTS Applications approved pursuant to Licensure Policy 13-01 Time: 8:40AM

Discussion: M. BOTTO noted that during the past month there have been sixteen (16) changes of manager on record (MOR), and one hundred (100) changes of ownership (mostly due to change of ownership of Rite Aide to Walgreen's)

So noted

TOPIC IV REPORTS Monthly Report from Probation Time: 8:40AM

TOPIC V:

APPLICATIONS

Time 8:43 AM

1. PharmScript/ARXCare

Transfer of Ownership

RECUSAL: N/A

DISCUSSION: PharmScript was represented by Steven Anderson, proposed MOR for the facility, and Jennifer Krusa, Chief Compliance Officer. PharmScript is a New Jersey-based long term care company, purchasing ARXCARE (Pembroke, MA), and forming PharmScript MA, LLC to establish business in Massachusetts. Although ARXCARE remains open, most of the ARXCARE business is now handled in their Connecticut facility, while they seek a new location in Massachusetts. Steven Anderson, an ARXCARE staff pharmacist, has stayed on to be MOR. Anderson has previous MOR experience with Walgreens. The transfer actually took place on December 20, 2017, but cancellation of a Board Meeting caused the delay in getting it to the Board sooner.

ACTION: Motion by P. GANNON, seconded by P. BOUVIER, and voted unanimously in the affirmative to approve the Transfer of Ownership of ARXCARE to PharmScript MA, LLC.

2. Crown Colony Pharmacy

New Community Pharmacy 8:50 am

RECUSAL: N/A

DISCUSSION: Crown Colony Pharmacy was represented by Thuy Nguyen, proposed MOR, and owner Hung Doan. Doan is also a pharmacist and owner of Blue Hills Pharmacy, which recently had to submit a substantial POC (Plan of Correction) resulting from an inspection, and focused on compounding concerns. With that at the forefront, the Board Members expressed concern with approving a similar business model in a new location.

After answering the Board's questioning, led by T. FENSKY (sterile compounder seat), it was determined that the Board would prefer that they not engage in complex non-sterile compounding, until such time as the previous issues at Blue Hill had been resolved.

ACTION: On a motion made by T. FENSKY and seconded by P. BOUVIER, the Board voted unanimously to approve the application for a new pharmacy for Crown Colony Pharmacy, contingent upon them entering into a non-disciplinary Consent Agreement to refrain from performing non-sterile COMPLEX compounding, until Board Staff is satisfied that they have appropriately resolved the issues at Blue Hill, and pending a successful inspection.

3. Walgreens DS89805 Change of Manager 9:36 am

RECUSAL: M. GODEK

DISCUSSION: Walgreens Pharmacy DS89805 submitted a Change of manager application, and was randomly selected to petition the Board in person. New Manager Michael Van Houten, who has had previous MOR experience was questioned by members, answering all of their questions to their satisfaction.

ACTION: On a motion by P. GANNON, seconded by T. FENSKY, the Board voted unanimously to approve Michael Van Houten as the new manager of Walgreens 89805

4. Walmart Pharmacy 10-2336 DS3400 Change of Manager 9:45 am

RECUSAL: M. GODEK

DISCUSSION: Walmart Pharmacy DS3400 submitted a Change of manager application, and was randomly selected to petition the Board in person. New Manager Balasubramanian Vaitilingam, who has been serving as Interim MOR, answered all of the Board Member's questions to their satisfaction.

ACTION: On a motion by P. GANNON, seconded by K. TANZER, the Board voted unanimously to approve Balasubramanian Vaitilingam as the new manager of Walmart10-2336.

TOPIC VI FLEX SESSION 10:03 AM

1. Pharmacy Technician in Training Rollout

Presented by: M.BOTTO, E. TAGLIERI

Discussion:

The Board of Registration in Pharmacy ("Board") recently amended 247 CMR 8.03 Registration Requirements for Pharmacy Technician in Training. **The revised regulation requires all Pharmacy Technician Trainees to be licensed by the Board.**

- EFFECTIVE MARCH 1, 2018: No individual may serve as a pharmacy technician trainee without holding a valid Pharmacy Technician Trainee License from the Board.

- They will be required to fill out an online application and receive their technician in training license in order to work as a trainee.
- Trainees should not be involved with assisting pharmacists in handling any medications without a license, but they can do computer training and etc.
- Pharmacist must exercise judgment in training. This clarification must be added to the memo. We should send out memo on distribution lists and to other organizations.

Action: Motion by T. FENSKY, seconded by K. TANZER and voted unanimously by those present, to approve memo with suggested change

2. New Waiver Process rollout

Presented by: M.BOTTO, E. TAGLIERI

Discussion:

All Petitions for Waiver must address:

- There is a compelling public interest which would be served by granting the waiver.
- The petitioner's adherence to the waived regulatory requirement would be impractical and unduly burdensome and that there are other sufficient practices in place.
- There are sufficient safeguards to protect the public health, welfare and safety without the petitioner's compliance with the regulatory requirement.

Application: It was recommended that the application be completed by the licensee. Additional comments to include limiting the number of characters the applicant can use to answer to the questions but it was ultimately decided to leave it at the discretion of the applicant. Another recommendation was made for the form should be a fillable online application.

Action: Motion by T. FENSKY, seconded by P. BOUVIER and voted unanimously by those present, to approve the memo and application with suggested changes.

3. NABP update by Dave Scencabaugh

Time: 10:18AM

A. Annual Meeting

Discussion:

Delegate voted by Board: Stephanie Hernandez will represent the MA Board of Pharmacy as the delegate with Mike Godek as the backup delegate.

Motion by A. STEIN, seconded by K. TANZER and voted unanimously by those present, to approve NABP delegate.

So noted:

B. MPJE writing opportunities

Discussion: K. TANZER will be attending the MPJE writing session along with Michelle.

So noted:

C. APHA Institute

Discussion: Carly volunteered to attend the APhA Institute on Alcohol and Drug Dependency and the grant is pending approval.

So noted:

TOPIC VII:

Policies

Time: 10:34 AM

(Note: S. Hernandez was out of the room and returned at 10:35 AM)

Policy 2018-0#: Complaints against an expired pharmacy intern license

Present by: Heather Engman

Discussion: Heather gave an overview of the proposed policy and discussed the unique nature of a pharmacy intern's license and the need for such a policy. Also reviewed was the attached chart with this.

ACTION: Motion by P.GANNON, seconded by T.FENSKY, voted unanimously to adopt the policy 2018-0# and the associated chart.

TOPIC VIII:

Advisory

Time: 10:47 AM

Advisory on Pharmacy Response to Failed HEPA Filters in ISO-Classified Environments

Presented by: W. FRISCH

DISCUSSION: Since there is no guidance on this issue in USP <797> or elsewhere, the draft "Advisory on Pharmacy Response to Failed HEPA Filters in ISO-Classified Environments" was developed for situations where the filter cannot be immediately remediated. It was presented to the Advisory Committee to the Board on November 16, 2017 for their expert guidance and the document presented today is reflective of the input received.

The Advisory includes recommendations on a pharmacy's course of action when presented with these situations. Specifically, recommended conditions for sterile compounding depending on the location of the failed HEPA filter(s) and the pharmacy's risk assessment.

Per the Board's recommendations, Board staff will change "qualified microbiologist" to "other qualified vendor" and add 12 hours or less BUD because room is essentially a segregated compounding room. P.GANNON suggested moving mandate of 7 days to report to the top of the document to separate the mandate from the advisory section.

ACTION: Motion by P.GANNON, seconded by T.FENSKY, voted unanimously to adopt the advisory with the noted changes.

TOPIC IX. REGULATIONS TIME: 10:50 AM

1. 247 CMR 20.00 Reporting Time: 10:50 AM

Presented By: H. Engman

Discussion:

- H. Engman clarified the Wholesaler drug loss reporting and that it was included in 247 CMF 7.
- Public comment was reviewed by H. Engman via the tracking change tool distributed

Changes:

none

Action:

Motion by P. Gannon, seconded by K. Tanzer, and voted unanimously to approve final draft of 247 CMR 20.00 Reporting and proceed to final administrative review and promulgation.

2. 247 CMR 6.00 Registrations, Management and Operation of a Pharmacy

Time: 10:55 AM

Presented by: H. Engman

Discussion:

- H. Engman reviewed the changes in blue to 247 CMR 6.00 which were distributed and an attachment to the minutes
- Discussion on 247 CMR 6.02 (4) to clarify and understand what "in charge" meant. This is part of statute thus cannot be changed. It was agreed to clarify in guidance documents any clarification needed.
- Public comment was reviewed by H. Engman via the tracking change tool distributed

Changes:

none

Action:

Motion by T. Fensky, seconded by S. Hernandez, and voted unanimously to approve final draft of 247 CMR 6.00 Registrations, Management and Operation of a Pharmacy and proceed to final administrative review and promulgation.

4. 247 CMR 9.00 Professional Practice Standards

Time: 11:10 AM

Presented by: H. Engman

Discussion:

- Public comment was reviewed by H. Engman via the tracking change tool distributed
- Input from the Board was noted on the tracking tool for the following:
 - 9.01(6) (16) (23)
 - 9.01 (2) (3) (4)
 - 9.04 (1) (4) (14) (16)
 - 9.07
 - 9.08 (4)
- This section ended at this time, work will continue at a future meeting.
- No action taken at this time.

So noted

TOPIC X:

Lunch

Time: 12:00 PM to 1:00 PM

TOPIC XI.

Open File Review

Time: 2:15 PM

Case #1

PHA-2017-0200

Walgreens #11602, DS3520

Time: 2:15 PM

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

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

- Loss report of #72 oxycodone/ acetaminophen 5/325mg tablets on or about September 14, 2017.
- The loss was a result of a return to stock bottle with #70 oxycodone/ acetaminophen 5/325mg tablets being misplaced, as well as an unknown loss of #2 oxycodone/ acetaminophen 5/325mg tablets discovered during an inventory audit.
- Corrective action includes a policy that only the pharmacist can remove schedule II prescriptions from the will call if they need to be put back to stock and that pharmacists must make it priority to ensure the schedule II medication is put immediately back into the safe.
- Walgreens #11602 has one prior reported loss.
- A retail compliance inspection was conducted on September 12, 2017 with no deficiencies noted.

ACTION: Motion by T. FENSKY, seconded by P.GANNON, and voted unanimously by those present, to refer the matter to the office of prosecution for the issuance of an order to show cause and authorize a consent agreement for reprimand.

Case #2

PHA-2017-0198

Walgreens #10427, DS3611

Time: 2:17 PM

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

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

- Loss report of #100 Oxycontin CR 20mg tablets on or about August 31, 2017.
- A discrepancy in the inventory was discovered when a patient brought in a prescription for Oxycontin CR 20mg tablets, and the stock bottle received earlier that day was not in the safe.
- MOR indicated that while the nature of the loss is unknown, it may have been possible that the medication was accidentally discarded into the trash during the receiving process. Security footage was reviewed and all areas of the pharmacy were searched.
- Corrective actions include all controlled substances must now always be received and handled under direct surveillance that will allow full vision, including any trash, around the corresponding area. In addition, interns and certified technicians are no longer allowed to handle CII medications.
- Walgreens #10427 has one prior reported loss.
- A retail compliance inspection was conducted on August 25, 2017 with no deficiencies noted.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter to the office of prosecution for the issuance of an order to show cause and authorize a consent agreement for reprimand.

Case #3

PHA-2017-0116

Walgreens #9011, DS3347

Time: 2:18 PM

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

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

- Walgreens #9011 submitted an initial loss form (RLCS) for an unknown loss of 683 tramadol 50mg tablets on February 24, 2017. On May 9, 2017, a final RLCS for an unknown loss of 375 tablets was reported. The final report used an exact count of tramadol 50mg tablets taken on June 9, 2016 during 2016 Annual Inventory. Cycle counts were increased and covert cameras installed. The investigation resulted in Asset Protection interviewing a technician for suspicious behavior recorded on the covert cameras but Asset Protection cleared the technician after the interview.

- During the investigation into the loss of tramadol, a retail compliance inspection (ISP-7765) conducted on July 27, 2017 revealed unresolved losses of 30 amphetamine 20mg mixed-salts tablets and 20 amphetamine 5mg mixed-salts extended release (ER) capsules. In addition, the pharmacy failed to report the amphetamine losses. The complaint was amended to include these violations.
- Walgreens #9011 determined that both losses were caused by miscounts by pharmacists using footage from surveillance footage. The amphetamine 5mg mixed-salt ER capsules was caused by the pharmacist simultaneously preparing multiple prescriptions and failing to follow standard operating procedures when filling controlled prescriptions (double counts). The MOR admonished the pharmacist on record.
- The loss of the amphetamine 20mg mixed-salts tablets was due to the pharmacist being distracted by the telephone and pick-up windows. The MOR included the incident in the Monthly Peer Review notes for the pharmacy and reinforced the existing internal policy requiring double counts for all Schedule II medications with staff.
- Lastly, MOR Kocur submitted a Board of Pharmacy RLCS and a DEA-106 for the losses in the response to the amended complaint.

ACTION: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously by those present, to dismiss complaint, no discipline warranted after pharmacy submits documentation that they continued tramadol perpetual inventory for an additional 90 days.

Case #4

SA-INV-12522

Walgreens #9011, DS3347

Time: 2:21 PM

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

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

- RLCS-a loss of 32 tramadol 50mg tablets due to an over dispense of 30 tablets and the recovery of 2 tablets located behind the pharmacy scale.
- Video footage was used by front store manager to determine that a tech in training counted 90 instead of the correct quantity of 60 tablets for a prescription dispensed on 10/27/17.
- MOR admitted that she failed to properly verify the prescription dispensed on 10/27/17. Tech in training admitted that she counted the incorrect quantity and failed to double count according to policy because she didn't realize tramadol was a C-IV.
- Corrective action was for all technicians to double count federally scheduled controlled substances. Also, tramadol 50mg tablets were placed in the safe to help with management of perpetual inventory.

ACTION: Motion by T. FENSKY, seconded by K.TANZER, and voted unanimously by those present, to CLOSE SA-INV-12522, no discipline warranted.

Case #5

SA-INV-12111

Walgreens #3151, DS2470

Time: 2:25 PM

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

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

- Pharmacy Technician Trainee (PTT) Elizabeth Azizian submitted an application dated August 18, 2017, for pharmacy technician licensure with 1250 hours.
- MOR MacDonald indicated that the store will use a PTT tracking log which will be kept in a binder at the store and each trainee will be responsible for logging their shift. MOR MacDonald indicated that either he or the store manager will reconcile the PTT tracking log monthly against time/attendance sheets.
 - Walgreens' Corporate Support Center was contacted to see if any updates can be made to the current system or procedures so that PTT hours can be monitored electronically and notifications can be sent to the appropriate parties at designated intervals.
 - Technician Azizian was licensed on 10/04/2017.

ACTION: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by those present, to CLOSE SA-INV-7694, no discipline warranted, and remediation complete.

Case #6

PHA-2017-0204

Rite Aid #10152, DS3145

Time: 2:25 PM

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

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

- RLCS-#100 hydrocodone/acetaminophen 7.5mg/325mg tablets on or about August 27, 2017 due to a suspected dispensing error.
- The loss was discovered on August 19, 2017 during a weekly CII count showing a loss of #100 hydrocodone/acetaminophen 7.5mg/325mg tablets.
- On August 13, 2017, video footage showed a pharmacist removing three bottles from the right side of the safe where the hydrocodone/acetaminophen 7.5mg/325mg tablets is located. The prescription that she filled called for 120 tablets.
- On September 14, 2017, the Pharmacy District Manager and the Loss Prevention Manager conducted covert counts, reviewed video footage and patient profiles that filled prescription during the course of the day. It revealed that one particular patient who filled a hydrocodone/acetaminophen 7.5mg/325mg prescription on August 13, 2017 was due to pick-up his monthly prescription however he did not his scheduled refill in Sept. It is suspected that he received an over-dispensing of his hydrocodone prescription.
- Ongoing covert counts did not reveal any additional discrepancies.

ACTION: Motion by P. GANNON, seconded by K.TANZER, and voted unanimously by those present, to dismiss the complaint, no discipline warranted, remediation complete.

Case #7

SA-INV-12274

Rite Aid #10110, DS3097

Time: 2:27 PM

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

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

- Pharmacy Technician Trainee submitted an application for his PT license with 1200 hours.
- MOR enrolled the PTT in their corporate training program at 950 hours. It took an extended period of time for the PTT to complete the program. When he was finished he program he was well over 1000 hours

The MOR was under the impression that the corporate training program's exam rendered the technician state certified (licensed).

- PTTs will now record their hours biweekly from the date of hire in a folder placed by the technician's station. The MOR will be responsible to add up the trainee's hours every other week and will schedule the trainee for Rite Aid's Pharmacy Technician University when the trainee approaches 500 hours. Once the classes are completed and the trainee passes the exam the MOR will have them apply for their pharmacy technician license.

ACTION: Motion by S. HERNANDEZ, seconded by P. GANNON, and voted unanimously by those present, to CLOSE SA-INV-12274, no discipline warranted, and remediation complete.

Case #8

SA-INV-12428

Rite Aid #10141, DS3119

Time: 2:30 PM

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

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

- An over-dispense of #60 dextroamphetamine-amphetamine 30mg tablets on 9/15/2017
- The medication was recovered on 09/20/2017 and destroyed

- Pharmacist Bond waited to the end of the night to log the prescription into the CII perpetual inventory book and realized that she had over-dispensed 60 tablets
- MOR indicated that policy and procedures for filling and processing of all controlled substances were reviewed with Pharmacist Bond
- Pharmacist Bond submitted documentation that she completed an additional 5.25 contact hours of continuing education credit focused on medication safety pertaining to this QRE and has reviewed 247 CMR 15, Continuous Quality Improvement Program, in its entirety

ACTION: Motion by S. HERNANDEZ, seconded by K. TANZER, and voted unanimously by those present, to CLOSE SA-INV-12428, No Discipline Warranted, Remediation complete.

Case #9

PHA-2017-0208

Walmart Pharmacy #10-2683,

Time: 2:32 PM

RECUSAL: NONE

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

- Repeat Inspectional deficiency in the area of CS recordkeeping was observed over the past two retail compliance inspections: conducted on 04/12/2017, and 09/15/2017.
- Broken CII tablets were not reconciled on the perpetual inventory log at least once every 10 days and were not deducted from the perpetual inventory properly when sent to the reverse distributor
- In addition, compounding records were not readily retrievable during the inspection on 09/15/2017 and a binder with one compounding record and blanks were on site but incomplete
- A satisfactory Plan of Correction was received by OPP Investigator on 10/12/2017

ACTION: Motion by A. STEIN, seconded by S. HERNANDEZ, and voted unanimously by those present, to DISMISS (PHA-2017-0208), No Discipline Warranted, Remediation complete.

Case #10

SA-INV-12085

Prescott Pharmacy, DS90051

Time: 2:34 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 narcotic 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 Leary could provide no proof;
- Former MOR Leary indicated one kit was used but 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 T. FENSKY, seconded by A. STEIN, and voted unanimously by those present, to open a STAFF ASSIGNMENT on Hamid Mohaghegh to gather his response to the allegations in SA-INV-12085. NO VOTE was taken on SA-INV-12085 at this time.

Case #11

SA-INV-11663

Triad Isotopes, Inc, NU00019

Time: 2:45 PM

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

DISCUSSION: S. PENTA presented and summarized the investigative report that pertained to these matters.

- On Jun 14th, 2017, Triad Isotopes, Inc (Nuclear Pharmacy) filed an initial disclosure of above action level results during environmental monitoring on June 5th, 2017.
- These excursions were identified in ISO Class 7 viable air and surfaces and are common environmental and human bacteria.
- Remediation ensued which included cleaning and disinfection and resampling on June 16th, 2017.
- On June 25th, 2017, a second disclosure was filed for above action level results identified during the retesting.
- This excursion was a repeat sampling location from the initial monitoring.

- Remediation was initiated and repeat sampling was conducted on July 3rd, 2017. No above action level results were identified.
- Internal Root Cause Analysis was conducted, and Corrective Action Preventative Action Plan was documented.
- A Site Visit (ISP-8276) was conducted on September 18th, 2017 and it was identified that non-sterile gloves were being used during aseptic compounding and that sterile syringes with needles attached used for compounding were being removed from their packages in worse than ISO Class 5 conditions.
- The MOR provided a response and ordered sterile gloves for use in compounding and instructed compounding staff to open syringes within the ISO Class 5 space. Compounding continued through the course of the remediation with BUDs remaining at 12 hours or less.
- A Site Visit (ISP-8881) was conducted on 12/12/2017 to verify process was maintained. Pharmacy was continuing to follow new process.

ACTION: Motion by T. AFENSKY, seconded by P. GANNON, and voted unanimously by those present, to CLOSE SA-INV-11663, No Discipline Warranted, Remediation complete.

Case #12

PHA-2017-0151

CVS #746, DS2818

Time: 2:47 PM

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

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

- On February 21, 2017, CVS Pharmacy #746 reported that a loss of 60 oxycodone 5mg tablets discovered on February 17, 2017 was under investigation.
- On April 12, 2017, CVS Pharmacy #746 submitted a final report that an unknown loss of 134 oxycodone 5mg tablets and 55 amphetamine mixed-salts 30mg tablets occurred on or about February 16, 2017 and February 17, 2017.
- The pharmacy further described on the final report of losses that 60 of 134 total oxycodone 5mg tablets and 30 of 55 amphetamine mixed-salts 30mg tablets reported as unknown losses were likely due to a suspected employee theft.

- In addition, the remaining losses were based on the CVS corporate partner's inventory rather than the perpetual inventory in the pharmacy. CVS indicated that both counts were accurate but was unable to explain the variances.

ACTION: Motion by T. FENSKY, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2017-0151) 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 #13

PHA-2017-0195

CVS #707, DS24373

Time: 2:50 PM

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

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

- RLCS, a loss of #411 buprenorphine-naloxone 8/2mg SL tablets discovered on or before July 19, 2017
- An investigation was opened as a precaution due to the medication being found away from the area where it is stored.
- LP ran a reconciliation dating back to the 2017 biennial inventory that showed no loss however the 2015 biennial inventory reconciliation showed a loss of #411 tablets.
- LP concluded that the loss is believed to be the results of improper biennial procedure performed in 2015.
- All team members were retrained in biennial inventory procedures and all Loss Prevention Policy and Procedures were reviewed with the pharmacy team to prevent further losses. This includes diligent inventory and dispensing standards

ACTION: Motion by T. FENSKY, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2017-0195) to refer the matter (PHA-2017-0195) 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 with special terms to include conducting an exact count CS inventory for all scheduled 3-5 medications within 30 days, and a monthly exact count of all buprenorphine containing products for 12 months, staff retraining in the areas of inventory management, prescription production, and waiting bin management within 30 days and increased store visits from the Pharmacy Supervisor or Loss Prevention at least once every 30 days to validate and sign off on the BOH report cover page.

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

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

- RLCS-#100 amphetamine salts 30mg tablets on or about August 23, 2017 due to a suspected dispensing error.
- Loss was discovered when the overnight pharmacist discovered a shortage of #100 amphetamine 30mg tablets and an overage of #100 amphetamine 20mg tablets while completing the perpetual inventory. The MOR stated that they are unsure how the loss occurred but may have occurred as a result of undiscovered dispensing error or delivery error from the outside vendor.
- Video footage reviewed but did not reveal over-dispensing of medication.
- MOR DoPham called several patients to confirm the color and printed letter on the pill. We reviewed the camera and called the three patients who had prescriptions for over 100 tablets of amphetamine 20mg on 8/15/17, 8/17/17, 8/19/17.
- MOR DoPham interviewed all staff pharmacists who had access to the C2 inventory regarding the loss.
- Retail compliance inspection on 11/1/17 with no deficiencies noted.

ACTION: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2017-0197) 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.

Topic XII:

EXECUTIVE SESSION

Time: 1:00 PM

DISCUSSION: None

ACTION: At 12:00 PM President M. GODEK read the statement on reasons for Executive Session.

At 12:00 PM, M. GODEK called for a motion to enter Executive Session: Motion by T. Fensky, seconded by A. Stein and voted unanimously by roll call to enter Executive Session. M. Godek, yes; A. Stein, yes; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; P. Bouvier, yes; C. Jean-Francois, yes; J. Lanza, yes; A. Raja, yes.

Topic XIII: ADJUDICATORY SESSION Time: 2:55 PM

DISCUSSION: None

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

At 2:55 PM, M. GODEK called for a motion to enter Adjudicatory Session: Motion by S. Hernandez, seconded by P. Gannon and voted unanimously to enter Adjudicatory Session:

Topic XIV. 65 C Session M.G.L. c. 112 § 65C Time: 3:05 PM

DISCUSSION: None

ACTION: President M. Godek request a motion to enter 65C Session M.G.L. c. 112 § 65C

At 3:05 M. PM motion by P. Gannon, seconded by K. Tanzer and voted unanimously to enter 65 C Session M.G.L. c. 112 § 65C.

P. Gannon leaves the meeting at 4:40 PM

Topic XV: ADJOURMENT OF MEETING Time: 4:41 PM

DISCUSSION: NONE

ACTION: President M. Godek request a motion to Adjourn the General Session Meeting.

At 4:41 M. PM motion by T. Fensky, seconded by S. Hernandez and voted unanimously to adjourn the General Session meeting..

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 2/1/18 General Session
2. Draft Minutes of the 1/22/18 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on probation-none this month
5. Report on Delegated Complaint Review pursuant to licensee policy 14-01-none this month
6. Report on Above Action Levels approved by Staff Action 16-04
7. Report on Pharmacy Substance Use Disorder Program 12/17
8. Application: Arxcare/Pharmascript: Transfer of Ownership
9. Application: Crown Colony Pharmacy: New Community Pharmacy
10. Application: Community, A Walgreen Pharmacy DS89805; Change of Manger
11. Application: Walmart Pharmacy 10-2336 (DS3400); Change of Manager
12. Flex: Petition for a Waiver of the Provisions for 247 CMR 14.01 Application
13. Flex: Petition for Waiver Memo for 247 CMR 14.01
14. Flex: Technician in Training Licensure Memo for 247 CMR 8.03
15. Policy: Memo 1/4/18 Enforcement Actions against an Expired Pharmacy Intern License

16. Advisory: Advisory on Pharmacy Response to Failed HEPA Filters in ISO-classified Environments
17. Regulations 247 CMR 20.00 Reporting
18. Summary of Public Comments 247 CMR 20.00
19. Regulations 247 CMR 6.00 Registration, Management and Operation of a Pharmacy
20. Summary of Public Comments 247 CMR 6.00
21. Regulations 247 CMR 9.00 Professional Practice Standards
22. Summary of Public Comments 247 CMR 9.00
23. Investigation report in the matter PHA-2017-0200- Walgreens #11602, DS3520
24. Investigation report in the matter PHA-2017-0198- Walgreens #10427, DS3611
25. Investigation report in the matter PHA-2017-0116- Walgreens #9011, DS3347
26. Investigation report in the matter SA-INV-12522- Walgreens #9011, DS3347
27. Investigation report in the matter SA-INV-12111- Walgreens #3151, DS2470
28. Investigation report in the matter PHA-2017-0204- Rite Aid #10152, DS3145
29. Investigation report in the matter SA-INV-12274- Rite Aid #10110, DS3097
30. Investigation report in the matter SA-INV-12428- Rite Aid #10141, DS3119
31. Investigation report in the matter PHA-2017-0208- Walmart Pharmacy #10-2683, DS2952
32. Investigation report in the matter SA-INV-12085- Prescott Pharmacy, DS90051
33. Investigation report in the matter SA-INV-11663- Triad Isotopes, Inc., NU00019
34. Investigation report in the matter PHA-2017-0151- CVS #746, DS2818
35. Investigation report in the matter PHA-2017-0195- CVS #707, DS24373
36. Investigation report in the matter PHA-2017-0197- CVS #43, DS3025

Respectfully submitted by:

K. Tanzer, PharmD, RPh, Secretary