

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

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

June 7, 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 Pharmacy Interns: • Introduction of Legal Intern: 		
	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of May 3, 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"> • North Falmouth Pharmacy – Waivers • Soleo – Waivers • Flynn Pharmacy – Transfer of Ownership • Ayer Family Pharmacy – New Community Pharmacy • Remedium- Transfer of Ownership • Ethos Veterinary – Renovation/Expansion 		

10:00	VI	FLEX <ul style="list-style-type: none"> • CPE Monitor App • Advisory Committee Meeting – May 17, 2018- 9 a.m. – 12 noon • CDTM – advisory opinion 	T. Fensky E. Taglieri K. Tanzer																																				
10:20	VII	POLICIES <ul style="list-style-type: none"> • Policy 2018-04: Naloxone Dispensing via Standing Order • Policy 2018-03: Pharmacist Continuing Education (CE) Requirements 	M. Chan W. Frisch																																				
10:40	VIII	REQUEST FOR REINSTATEMENT <ul style="list-style-type: none"> • Agnes Rubin; PH25022; PHA-2012-0006 																																					
11:00	IX	FILE REVIEW <table border="1" data-bbox="354 600 1263 1860"> <tr><td>1</td><td>PHA-2018-0028- Cantrell Drug Company- NO00027</td></tr> <tr><td>2</td><td>PHA-2018-0002- Rite Aid #10203, DS2570</td></tr> <tr><td>3</td><td>PHA-2018-0005- Rite Aid #10204, DS2577</td></tr> <tr><td>4</td><td>SA-INV-12525- Rite Aid #10067, DS2552</td></tr> <tr><td>5</td><td>SA-INV-12622- Walgreens #7704, DS3413</td></tr> <tr><td>6</td><td>SA-INV-13014- Stop & Shop #398, DS3368</td></tr> <tr><td>7</td><td>SA-INV-13012- Partners of MA, LLC, DS3419</td></tr> <tr><td>8</td><td>SA-INV-12425- Prescription Center Pharmacy-University-Campus, DS89788</td></tr> <tr><td>9</td><td>SA-INV-12513- Omnicare of Northern MA, DS89931</td></tr> <tr><td>10</td><td>PHA-2018-0008- CVS #1855, DS2901</td></tr> <tr><td>11</td><td>PHA-2018-0037- CVS #937, DS3444</td></tr> <tr><td>12</td><td>PHA-2018-0006- CVS #257, DS3331</td></tr> <tr><td>13</td><td>PHA-2018-0017- CVS #257, DS3331</td></tr> <tr><td>14</td><td>PHA-2018-0012 CVS Specialty #48036, DS3416</td></tr> <tr><td>15</td><td>SA-INV-12918 Rachel Marshall, PT17918</td></tr> <tr><td>16</td><td>PHA-2017-0215- CVS #5874, DS3293</td></tr> <tr><td>17</td><td>SA-INV-11104- Southwick Pharma, LLC, DS90050</td></tr> <tr><td>18</td><td>DS-98-005-Little’s HSC Pharmacy; DS2551</td></tr> </table>	1	PHA-2018-0028- Cantrell Drug Company- NO00027	2	PHA-2018-0002- Rite Aid #10203, DS2570	3	PHA-2018-0005- Rite Aid #10204, DS2577	4	SA-INV-12525- Rite Aid #10067, DS2552	5	SA-INV-12622- Walgreens #7704, DS3413	6	SA-INV-13014- Stop & Shop #398, DS3368	7	SA-INV-13012- Partners of MA, LLC, DS3419	8	SA-INV-12425- Prescription Center Pharmacy-University-Campus, DS89788	9	SA-INV-12513- Omnicare of Northern MA, DS89931	10	PHA-2018-0008- CVS #1855, DS2901	11	PHA-2018-0037- CVS #937, DS3444	12	PHA-2018-0006- CVS #257, DS3331	13	PHA-2018-0017- CVS #257, DS3331	14	PHA-2018-0012 CVS Specialty #48036, DS3416	15	SA-INV-12918 Rachel Marshall, PT17918	16	PHA-2017-0215- CVS #5874, DS3293	17	SA-INV-11104- Southwick Pharma, LLC, DS90050	18	DS-98-005-Little’s HSC Pharmacy; DS2551	
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**12:30
LUNCH BREAK**

1:30	X	<p>EXECUTIVE SESSION The Board will meet in Executive Session as authorized pursuant to M.G.L. c. 30A, § 21(a)(1) for the purpose of discussing the reputation, character, physical condition or mental health, rather than professional competence, of an individual, or to discuss the discipline or dismissal of, or complaints or charges brought against, a public officer, employee, staff member or individual. Specifically, the Board will the review a request for the reinstatement of a license, and evaluate the Good Moral Character as required for registration for pending applicants.</p>		CLOSED SESSION
3:00	XI	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)		
3:30	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
June 7, 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
Julie Lanza, CPhT
Phillippe Bouvier, RPh
Leah Giambarresi, Pharm D, RPh
Timothy Fensky, RPh
Carly Jean-Francois, RN, NP

Board Members Not Present

Ali Raja, MD, MBA, MPH
Dawn Perry, JD

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; L. Giambarresi, yes; S. Cornacchio, yes; P. Bouvier, yes;
T. Fensky, yes; C. Jean-Francois, yes

Topic II.

Approval of Agenda

TIME 8:35 AM

Agenda June 8, 2018

DISCUSSION:

Change to Agenda: Applications: Ayer Family Pharmacy new community pharmacy done by staff action, thus removed from the agenda.

ACTION:

Motion by P. Gannon, seconded by K. Tanzer, and voted unanimously to approve the agenda with noted changes.

Dave introduced the 3 interns, Curt Kim from Northeastern Pharmacy Program, Alana DeSimone from MCP Boston Pharmacy Program and Jordan Smith the new DCP Intern. Heather introduced Hannah Levine the Legal Intern. Mike asked all students in the audience to stand and introduce themselves. Dave acknowledged the retirement of Lau Kwan on 5/31/18 after 24 years with the Board and thanked her for her dedication and service.

Topic III

Approval of Board Minutes

TIME: 8:35 AM

Minutes

Draft, May 3, 2018 Regular Session Minutes

Changes:

Change spelling of Sean Gannon's name in Topic I, draft listed it as "Shawn" correct spelling Sean

Action:

Motion by L. Giambarresi, seconded P. Bouvier, and voted unanimously to approve the regular session minutes of May 3, 2018 with noted changes. T. Fensky and C. Jean-Francois abstaining from vote.

TOPIC IV

REPORTS

Time: 8:35 AM

Applications approved pursuant to Licensure Policy 13-01

Time: 8:35AM

Discussion: R. HARRIS noted that during the past month there have been twenty-five (25) changes of manager on record (MOR) and one (1) renovation expansion applications approved pursuant to Licensure Policy 13-01.

So noted

Topic V:

APPLICATIONS

Time: 8:38AM

1. Soleo Health, Petition for waiver

Time: 8:38 am

RECUSAL: None

DISCUSSION: Soleo Health was represented by Nkiruka Agu.

Soleo Health came before the Board of Pharmacy, petitioning for waivers for the consultation area sign, balance, and performing 795 compounding, as they are a Home Infusion, closed-door pharmacy. The waivers were for 247 CMR 9.07 A – Signage, 247 CMR 9.01 (lock boxes sign) – 247 CMR 6.01 (5)(d), 247 CMR 6.05 (a) Balance, and 247 CMR 9.01(3) – 795-Compounding,

ACTION:

Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously in the affirmative to approve this application for 3 waivers for Soleo Health.

2. Ethos Veterinary, Woburn Renovation / Expansion

Time: 8:43 am

RECUSAL: None

DISCUSSION: Ethos Veterinary was represented by Patrick Welch, Bob Fallon + Ernest Gates, Gates Healthcare, and proposed MOR Matthew Chan.

Ethos came before the Board of Pharmacy, petitioning for an approval for their renovation and expansion plans, as they plan to renovate within the same building. The goal is to prepare for compliance with new USP 800 regulations. The representatives answered all the Board Members' questions to their satisfaction.

ACTION:

Motion by A. STEIN, seconded by S. HERNANDEZ, and voted unanimously in the affirmative to approve the renovation and expansion plans for Ethos, pending a successful inspection.

ACTION:

Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously in the affirmative to approve Mathew Chan as MOR of this facility.

3. North Falmouth Pharmacy, DS89895 Petition for Waiver Time: 8:54 am

RECUSAL: None

DISCUSSION: North Falmouth Pharmacy was represented by Srinivas Rathnam, MOR

North Falmouth Pharmacy, in consideration of its business model, petitioned the Board for 10 specific waivers. North Falmouth serves mostly Long-Term Care facilities, including assisted living facilities and group homes, and has no walk-in patients.

Waiver requests included: 247 CMR 6.01 (5)(a)(4), balance 247 CMR 6.01 (5)(d)(1), patient consultation area, 247 CMR 9.07(3)(c), counselling sign, 247 CMR 8.04(2)(a), Certified Pharmacy Technician name tag, 247 CMR 6.02(8)(a)posting of hours of operation, 247 CMR 6.02(7) MOR name posted, 247 CMR 8.01(11) pharmacy intern badge, 247 CMR 8.04(3)(a) Pharmacy Technician name tag, 247 CMR 8.023(2)(a) pharmacy technician trainee name tag, and 247 CMR 6.02 (5) pharmacy sign.

10 ACTIONS:

Motion by P. Gannon, seconded by A. STEIN, and voted unanimously in the affirmative to approve the Waiver for requiring a balance 247 CMR 6.01 (5)(a)(4).

Motion by T. FENSKY, seconded by P. BOUVIER, and voted unanimously in the affirmative to approve the Waiver for requiring a consultation sign 247 CMR 9.07 (3)(c).

Motion by T. FENSKY, seconded by S. HERNANDEZ, and voted unanimously in the affirmative to approve the Waiver for requiring a patient consultation area 247 CMR 9.07 (5)(d)(1).

Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously in the affirmative to approve the Waiver for requiring a pharmacy sign 247 CMR 6.02 (5).

Motion by P. GANNON, seconded by L. GIAMBARRESI. Tanzer, and voted unanimously in the affirmative to approve the Waiver for requiring posting hours of operation 247 CMR 6.02 (8)(a).

Motion by T. FENSKY, seconded by S. HERNANDEZ, and voted unanimously in the affirmative to DENY the Waiver for requiring a certified technician name badge 247 CMR 8.04(2)(a),.

Motion by T. FENSKY, seconded by P. BOUVIER, and voted unanimously in the affirmative to DENY the Waiver for requiring a technician name badge 247 CMR 8.04(3)(a).

Motion by T. FENSKY, seconded by P. BOUVIER, and voted unanimously in the affirmative to DENY the Waiver for requiring a technician in training name badge 247 CMR 8.023(2)(a).

Motion by T. FENSKY, seconded by P. BOUVIER, and voted unanimously in the affirmative to DENY the Waiver for requiring a pharmacy intern name badge 247 CMR 8.01(11).

Motion by T. FENSKY, seconded by P. BOUVIER, and voted unanimously in the affirmative to DENY the Waiver for requiring posting of the MOR's name 247 CMR 6.02(7).

4. Flynn Pharmacy Transfer of Ownership

Time: 9:38 am

RECUSAL: None

DISCUSSION: No representative from Flynn Pharmacy attended the meeting.

Thomas Flynn is transferring the ownership of Flynn's Pharmacy in Pittsfield, MA to his son Christopher.

ACTION:

Motion by A. STEIN, seconded by P. BOUVIER, and voted unanimously in the affirmative to approve this transfer of ownership.

5. Remedium Transfer of Ownership

Time: 9:58 am

RECUSAL: Susan Cornacchio

DISCUSSION: Remedium was represented by Atty Paul Garbarini, Owner Flaviv Iepure, and MOR Christina Iepure.

Remedium had applied for a change of ownership, but Attorney Garbarini characterized the transaction as a "transfer of membership", while requesting that the DS and CS numbers remained the same. Board Counsel H. ENGMAN stated that the transfer is unclear, and requested further documentation from Garbarini, to be submitted by 6/18/18, in order to get on the 6/28/18 Board agenda.

ACTION:

Motion by T. FENSKY, seconded by P. BOUVIER, and voted unanimously in the affirmative to table the discussion of this matter until June 28, 2018.

Topic VI

FLEX SESSION

Time: 9:07 AM

1. CPE Monitor App

Presented by: T. FENSKY

Discussion:

NABP has created an app for self-monitoring of CE's. It will be free to upload ACPE credits but will require payment for non-ACPE uploads. The cost is \$30 a year. Paper CE's can be uploaded through the app. The app can send alerts for deadlines, which should help ensure that pharmacists keep up with their CE's.

ACTION: So noted

2. Advisory Committee Meeting May 17, 2018 Update

Presented by: E. TAGLIERI and K. TANZER

Discussion:

Emerging models in pharmacy practice were discussed and a draft policy was brought forward for discussion. Board staff will edit the policy based on the discussions with the goal to bring it to the Board in the near future.

ACTION: So noted

3. CDTM – Advisory Opinion

Presented by: M. CHAN and W. FRISCH

Discussion:

Board staff anticipates developing a formal guidance document regarding pharmacist qualifications for CDTM. However, until formal guidance is developed, Board staff recommends the following:

The completion of at least two years of nationally accredited postgraduate pharmacy residency, to include at least one year of psychopharmacology residency, along with clinical competency training, clinical assessment training, didactic training, and national and internal clinical guidelines training described above, sufficiently qualifies a pharmacist, in accordance with 247 CMR 16.02(1)(c), to enter into a CDTM agreement in the area of Behavioral Health. This advisory opinion is limited to the position of Behavioral Health Clinical Pharmacist at Atrius Health and to the training described in Atrius Health's May 30, 2018 letter, attached hereto.

ACTION: Motion by S. HERNANDEZ, seconded by T. FENSKY, and voted unanimously to agree with the proposed advisory opinion.

Topic VII.

POLICIES

Time: 9:27 AM

1. Policy 2018-04: Naloxone Dispensing via Standing Order

TIME: 9:27 am

DISCUSSION: Presented by: M. CHAN

All naloxone information currently found in several different places on the website have been consolidated into this one policy that now has 2 appendices: one is the “opioid antagonist information pamphlet” and the other is an example standing order.

Dispensing requirements, including the list of approved training programs have been removed from the example order and consolidated into the policy. The language was updated throughout using the same phrases that were recently voted upon for use in 247 CMR 9.

The only other notable change was the clarification that only in-state pharmacies need to comply. The example standing order has been simplified.

P.GANNON: Suggested making a few changes in the pamphlet on rescue position and rescue breathing due to possible confusion. They are written in consecutive order, which may lead the person administering the drug to the patient to think that rescue breathing has to be done in the rescue position.

ACTION: Motion by T. FENSKY, seconded by K. TANZER, and voted unanimously to approve the updates to Policy 2018-04: Naloxone Dispensing via Standing Order.

2. Policy 2018-03: Pharmacist Continuing Education (CE) Requirements TIME: 9:35 am

DISCUSSION: Presented by M. CHAN

This update allows newly licensed pharmacists who received their license after Oct. 1, to have a “grace period” to get their required CE for that calendar year. An allowance for reciprocity is already in place.

Two other changes will also be added:

The first would be to add a note in the newly licensed section to clarify that this does not apply to those who have graduated in the same calendar year as licensure.

The second would be to change the wording in regards to CPE Monitor since the new app allows certificates for CME category 1 and Board approved programs to be uploaded.

ACTION: Motion by A. STEIN, seconded by K. TANZER, and voted unanimously to approve updates to Policy 2018-03: Pharmacist Continuing Education (CE) Requirements with the noted changes.

Topic VIII.

REQUEST FOR REINSTATEMENT

Time: 10:13 AM

1. Agnes Rubin PH25022; PHA-2012-0006

Presented by: Heather Engman

Recusals: None

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

DISCUSSION: J.TRAN presented the investigation report.

- RLCS- #120 buprenorphine/naloxone films on or around September 21, 2017
- On August 17, 2017, an internal analyst reviewing the report titled “RX Net CC Suboxone-Buprenorphine” flagged the pharmacy as having buprenorphine-naloxone drug loss between the timeframe of January 1, 2017 through July , 2017.
- On September , 2017, PDM Maloof conducted a covert count of suboxone in which 749 suboxone films were counted and the estimated on-hand quantity was 773. On November 11, 2017 PDM Maloof filed a DEA 106 with no diversion suspected but the store will continue with the covert counts as it was reported that there was a total loss of 120 films.
- DL Rock indicated that the pharmacy manager reviewed procedures for the accurate handling, dispensing, and accountability of controlled drugs with the associates. Also, the pharmacists now keep all of the suboxone in the safe separated from the regular inventory and only pharmacists are handling it. They double count and back count every single medication.
- Investigator Murray conducted a retail inspection (ISP-9009) on January 22, 2018 with no deficiencies noted.
- J.TRAN recommends dismissal of complaint with no discipline warranted, remediation complete.

ACTION: Motion by K.TANZER, seconded by P.BOUVIER, and voted unanimously to dismiss complaint with no discipline warranted.

Case #3

PHA-2018-0005

Rite Aid #10204 DS2577

Time: 10:37 am

DISCUSSION: J.TRAN presented the investigational report.

- RLCS- #90 Oxycontin 60 mg tablets 12/20/17 due to suspected dispensing error.
- The error was discovered three days after it occurred when the weekly inventory was conducted and with further research, they were able to discover the patient that received the over-dispensing of the Oxycontin 60 mg tablets.
- The dispensing pharmacist was filling two narcotic prescriptions for the same patient. One prescription was written for a quantity of 180 and the second prescription was written for a quantity of 90. The pharmacist inadvertently counted 180 tablets instead of 90 tablets for the Oxycontin 60 mg prescription. Additionally, the perpetual inventory was logged incorrectly for 180 tablets instead of the prescribed 90 tablets.
- No video footage was reviewed
- Corrective action included having the MOR discuss with the dispensing pharmacist better procedures on filling schedule II medications to prevent errors, filling one prescription at a time so there is only one label out or, if the patient has multiple narcotics prescriptions only working on one at a time.

- Investigator Horn conducted a retail compliance inspection (ISP-8696) on November 10, 2017 with no deficiencies noted.
- J.TRAN recommends a reprimand.

ACTION: Motion by A.STEIN, seconded by T.FENSKY, and voted on unanimously to refer to the Office of Prosecution for the issuance of an Order to Show Cause, and to authorize a Consent Agreement for Reprimand.

Case #4

SA-INV-12525

Rite Aid #10067 DS2552

Time: 10:42 am

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

DISCUSSION: K.MORTON presented the investigational report.

- RLCS- an unknown loss of #159 Tramadol 50 mg tablets on or around 10/30/17.
- MOR indicated that the loss of tramadol 50 mg was discovered during a monthly count and their investigation did not uncover the reason for the loss.
- In his response MOR indicated that controlled substance prescriptions are double counted and the amount dispensed is circled. He also indicated that four additional counts were completed with no additional losses.
- Rite Aid #10067 has one prior reported loss.
- A retail compliance inspection was conducted on March 5, 2018 with deficiencies noted, including temperature monitoring issues and insanitary conditions. A successful plan of correction was submitted.
- K.MORTON recommends closing the staff assignment with no discipline warranted.

ACTION: Motion by P.GANNON, seconded by L.GIAMBARRESI, and voted on unanimously to close staff assignment, no discipline warranted.

Case #5

SA-INV-12622

Walgreens #7704 DS3413

Time: 10:44 am

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

DISCUSSION: J.SANTORO presented the investigational report.

- RLCS- Unknown loss of #1303 lorazepam 1mg tablets on or about 9/3/17.
- An investigation was concluded on October 4, 2017 and identified a Pharmacy Designated Hitter (DH) who allegedly engaged in pilferage.
- Loss was first discovered by a technician at the initiation of a weekly negative adjustment inventory.
- DH was confronted about the losses that were consecutive with the shifts she worked. The DH denied stealing lorazepam but admitted to stealing four prednisone tablets for her dog. DH was fired for the theft of the prednisone tablets and subsequent counts after her dismissal showed no additional shortages.
- All benzodiazepines were added to the perpetual inventory list and will be an ongoing practice to count them with the weekly inventory. The counts will be continuously monitored with additional random spot checks.
- No prior or additional losses reported.
- J.SANTORO recommends further discussion.

ACTION: Motion by P.GANNON, seconded by K.TANZER, and voted on unanimously to dismiss the staff assignment with no discipline warranted.

Case #6

SA-INV-13014

Stop and Shop #398 DS3368

Time: 10:46 am

DISCUSSION: J.SANTORO presented the investigational report.

- During a retail compliance inspection (ISP-8681) conducted on 11/29/2017 the MOR was unable to provide hours for a Pharmacy Technician Trainee. On 02/17/2018, MOR submitted a POC which indicated that the PTT applied for her Pharmacy Technician license on 02/17/2018 with 1750 hours.
- PTT did not apply for her PT license on 02/17/2018 as indicated and Stop & Shop's Training Coordinator was unable to produce the PTT's passing grade
- PTT was rescheduled for exam on May 6, 2018 but did not pass and was immediately reclassified to a pharmacy clerk.
- BORP Policies and regulations related to Pharmacy Interns and Technicians were reviewed with the staff. All posted licensees will be monitored quarterly for expiration dates. Stop & Shop has deployed a new compliance policy incorporating IMS One Key Pharmacy software that will alert licensees and MOR's of expiring licenses. The Pharmacy will keep detailed records of associate time spent as a clerk as well as time spent in the role of a PTT. There will be increased personal vigilance by the MOR during the training and licensing phase to insure all documents are processed in a timely manner.
- J.SANTORO recommends closing the staff assignment with no discipline warranted, remediation complete.

ACTION: Motion by P.GANNON, seconded by S.HERNANDEZ, and voted unanimously to close staff assignment with no discipline warranted, remediation complete.

Case #7

SA-INV-1301

Partners of MA, LCC DS3419

Time: 10:50 am

RECUSSAL: J.TRIFONE recused and was not present for discussion.

DISCUSSION: J.SANTORO presented the investigational report.

- RLCS, #60 oxycodone HCL 10mg tablets, #30 oxycodone HCL 5mg tablets, #60 morphine sulfate ER 30mg tablets, and #90 hydrocodone/acetaminophen 5-325mg tablets on 10/26/2017.
- It was determined that the Driver of the pharmacy's Courier Service took 21 bags of controlled substances on his route but only 17 bags were delivered.
- Video surveillance showed the Driver leaving the Pharmacy with 21 bags.
- The Driver was charged with 4 counts of larceny of drugs and possession with the intent to distribute the narcotics taken. Policy and procedures related to controlled substance dispensing and delivery of CDS were update and implemented on 10/30/17 with education via meetings and email. The dispensing and delivery of CDS changed by moving from a three (3) part manifest to a four (4) part manifest, which provided a closed- loop method to verify delivery of all CDS medications to facilities.
- J.SANTORO recommends closing the staff assignment; no discipline warranted, remediation complete.

ACTION: Motion by S.HERNANDEZ, seconded by P.BOUVIER, and voted on unanimously to close staff assignment; no discipline warranted, remediation complete.

Case #8

SA-INV-12425

Prescription Center Pharmacy-University Campus DS89788

Time: 10:55 am

DISCUSSION: G.MELTON presented the investigational report.

- RLCS-10 oxycodone 30mg tabs due to a medication error in October 2017. The pharmacy then reported two unknown losses of 7 hydrocodone-acetaminophen 5-325mg tablets in February 2018 and of 10 oxycodone-acetaminophen 5-325 in March 2018.
- Former MOR and Current MOR both described that in a change in pharmacy computer system was implemented in October 2017. The change caused a dramatic increase in wait times for patient and in stress level for employees.
- In January 2018, current MOR Stephanie Ventriglia took over specifically to revamp the workflow to increase efficiency. She implemented several changes as part of CA including pharmacist only access to CII Safe, weekly reconciliation of Schedule II CS's by a pharmacist on rotating basis, physical count of all Schedule II Rx's returned to stock b/c patient abandoned prior to placing in the CII Safe, additional security camera, all

CS's reportable to MassPAT must be sealed in clear plastic bag by stapling and tamper evident tape by verification pharmacist.

- G.MELTON recommends closing the staff assignment; no discipline warranted, remediation complete

ACTION: Motion by A.STEIN, seconded by K.TANZER, and voted on unanimously to close staff assignment; no discipline warranted, remediation complete.

Case #9

SA-INV-12513

Omnicare of Northern MA DS89931

Time: 10:58 am

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

DISCUSSION: G.MELTON presented the investigational report.

- Former employee reported substandard CSP practice at the pharmacy. Substandard practice included mold on mats and floor, food in the pharmacy, deviation from policy and procedures for verifying CSPs, untrained staff verifying CSPs, and frozen premixed IV solutions improperly stored.
- Investigator Melton visited the pharmacy and obtained staff rosters, schedules, policy and procedures, compounding records, and dispensing logs for an approximate 8-week period (11/19/17-01/13/2018). He found no evidence of substandard practice as described by the former employee.
- In addition, a USP-797 inspection on 02/20/2018 was completed by OPP Investigators and no deficiencies related to the allegations by the former employee were observed. The inspectional deficiencies that were observed related to problems with correctly documenting products used to clean and the timing of the cleaning.
- G.MELTON recommends closing staff assignment; insufficient evidence.

ACTION: Motion by P.BOUVIER, seconded by T.FENSKY, and voted on unanimously to close staff assignment; insufficient evidence.

Case #10

PHA-2018-0008

CVS #1855, DS2901

Time: 10:59 AM

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.

- Unknown RLCS of 100 oxycodone 5mg tablets on 1-25-18. During internal investigation, MOR indicated that video surveillance showed that she likely discarded a 100-count bottle on 11-29-18. Trash searched without success and patients were contacted to rule out dispensing error.
- Investigator Melton reviewed perpetual inventory log & discovered the state counts completed on 11-25-18 & 12-3-18 showed no discrepancy. The discrepancy was actually discovered during a cycle count on 12-4-18 after the state count on 12-3-18.
- Investigator Melton also noted that no back-counts were conducted on prescriptions dispensed during the same period. This combination of events weakened the conclusion that the loss occurred as reported on 11-29-18 and made any conclusion as to the exact point of the loss challenging.

ACTION: Motion by A. STEIN, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2018-0008) 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 #11

PHA-2018-0037

CVS #937, DS3444

Time: 11:01 AM

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.

- Unknown RLCS of 100 Morphine Sulfate ER 30mg tablets discovered December 6, 2017. In addition, this investigator discover change in MOR application was not submitted for current MOR.
- Patients contacted, surveillance video reviewed, MOR believes he discarded the bottle in the trash.
- CA - Retraining including triple checking and back counting all CII's prior to bagging. Pharmacy also filed change in MOR.

ACTION: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2018-0037) 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.

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

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

- Loss of 91 oxycodone 10mg on 11/14/17 reported on 12/7/17;
- Internal investigation with review of video show Former MOR Sutphin filling multiple CII prescriptions at the same time on 11/8/17 and what appeared to be her discarding the oxycodone 10 mg bottle with other empty bottles;
- Loss discovered on 11/12/17 during a perpetual inventory but later stated loss discovered on 11/10/17 while filling a prescription for oxycodone 10mg and not having an open stock bottle;
- Review of perpetual inventory revealed multiple discrepancies, inaccurate recordkeeping, and reconciliations greater than 10 days from 11/24/17-12/8/17 and 1/3/18-1/14/18;
- Former MOR Sutphin was disciplined by CVS and no longer is employed there as of 1/26/18;
- CVS 257 has 3 prior CII losses and received a reprimand 11/8/17 for drug violations and was cited on 2/26/18 (ISP-9279) for failure to reconcile the perpetual inventory.

ACTION: Motion by A. STEIN, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2018-0006) 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 PROBATION for a period of 1 YEAR 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 benzodiazepine 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 in this matter.

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

- POC issued after deficiencies involving lack of state counts in perpetual inventory log for CS's awaiting RD and outdated MOR signage were observed during an inspection on 2-26-18. Pharmacy responded in a POC that the P&P for perpetual inventory was reviewed and MOR would ensure state counts were completed. In addition, the pharmacy indicated that signage was updated. Investigators discovered that signage was not updated as described in the POC.
- Complaint opened as a result of outdated signage, failure to remediate, and ongoing problems with perpetual inventory including three reports of loss in the last year.
- Investigator Melton discovered that a report of loss for methylphenidate which the pharmacy retracted was an actual loss due to failure to record a prescription. Pharmacy ultimately updated signage after complaint was opened.

ACTION: Motion by A. STEIN, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2018-0017) 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 PROBATION for a period of 1 YEAR 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 benzodiazepine 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

Case #14

PHA-2018-0012

CVS Specialty #48036, DS3416

Time: 11:10 AM

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

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

- On 2/23/2018, PT Marshall contacted the BORP to inquire if her pharmacy technician license required renewal and indicated that she has been employed by CVS Specialty #48036 for 6 years
- PT Marshall was informed that her license expired on 09/03/2016;
- CVS Corporate provided a response on behalf of the pharmacy and PT Marshall (who had not reviewed the response) indicating that PT Marshall's role as a Pharmacy Service Representative (PSR) did not require a pharmacy technician license;
- PT Marshall stated that part of her function as a PSR was processing refills for patients but she does not perform data entry or production of rx's;

- PT Marshall renewed her license on 02/26/2018.
Last inspected 5/24/18 ISP-9601 with no deficiencies

ACTION: Motion by S. HERNANDEZ, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2018-0012) 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 and to include an advisory on technician scope of practice and licensing requirements.

Case #15

SA-INV-12918

Rachel Marshall, PT17918

Time: 11:10 AM

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

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

- On 2/23/2018, PT Marshall contacted the BORP to inquire if her pharmacy technician license required renewal and indicated that she has been employed by CVS Specialty #48036 for 6 years;
- PT Marshall was informed that her license expired on 09/03/2016;
- CVS Corporate provided a response on behalf of the pharmacy and PT Marshall (who had not reviewed the response) indicating that PT Marshall's role as a Pharmacy Service Representative (PSR) did not require a pharmacy technician license;
- PT Marshall stated that part of her function as a PSR was processing refills for patients but she does not perform data entry or production of rx's;
- PT Marshall renewed her license on 02/26/2018.
Last inspected 5/24/18 ISP-9601 with no deficiencies

ACTION: Motion by A. STEIN, seconded by K. TANZER, and voted unanimously by those present, to CLOSE SA-INV-12918, No Discipline Warranted, Remediation Complete.

Case #16

PHA-2017-0215

CVS #5874, DS3293

Time: 11:14 AM

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

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

- RLCS- #1,679MLs of Guaifenesin AC Cough Syrup 100mg-10mg/5ml and #394MLs of G Tussin AC Liquid 100mg-10mg/5ml on or about 7/10/17.
- MOR indicated the loss was identified via corporate controlled substance monitoring after performing inventory reconciliation and #1,054 RX's were dispensed over the reconciliation timeframe.
- MOR also indicated that the cause of the discrepancy is unknown, but it is believed that inventory and dispensing practices, as well as a potential NDC related discrepancy that may have occurred during the previous biennial inventory could have contributed to the loss.
- CVS #5874 has two prior reported losses, and a retail compliance inspection was conducted on April 10, 2018 with no deficiencies noted.
- On 12/5/17, CVS #5874 entered into a Non-Disciplinary Stayed Probation agreement as a result of a previous controlled substance loss.

ACTION: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2017-0215) 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, and recommend the pharmacy include guaifenesin with codeine containing products in the CVS Protocol of monthly counts.

Case #17

SA-INV-11104

Southwick Pharma, LLC, DS90050 Time: 11:24 AM

RECUSAL: NONE

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

- Investigation was opened in response to allegations of an inappropriate prescriber/pharmacy relationship including allegations that prescriptions were being directed to Southwick without patient consent.
- Southwick denied the allegations and indicated they are unaware of any prescriptions are being directed to their pharmacy, and that they believe patients request their prescriptions be sent to their pharmacy because they have a convenient location and also offer delivery services.
- During an inspection conducted on 1/2/18, a report was discovered indicating that a large portion of prescriptions are prescribed by the prescriber identified in the initial staff assignment.
- Following the inspection, the investigation was re-opened. OPP Investigator was unable to substantiate any connection between the owners and/ or MOR of Southwick and the prescriber

in question. Additionally, to date, the Board has not received any consumer complaints in relation to Southwick.

ACTION: Motion by S. HERNANDEZ, seconded by T. FENSKY, and voted unanimously by those present to CLOSE, SA-INV-11104 due to insufficient evidence.

Case #18

DS-98-005

Little's HSC Pharmacy, DS2551

Time: 11:25 AM

RECUSAL: NONE

DISCUSSION: H. ENGMAN presented and summarized matter.

- Little's HSC Pharmacy submitted a public records request asking for documentation pertaining to the pharmacy's history of discipline. A comprehensive search revealed the following:
 - The Board opened a Complaint against Little's HSC Pharmacy in 1998 and assigned docket number DS-98-005. The Complaint pertained to problems with controlled substances security and accountability between approximately 1993 and 1995.
 - James Little, PH13718, owned and/or managed Little's HSC Pharmacy in the 1990's. The Board took action against James Little's pharmacist license as a result of the aforementioned problems with controlled substances security and accountability.
 - Notably, Board staff cannot locate any Consent Agreement or Final Decision and Order that imposes discipline on Little's HSC Pharmacy. The 1998 and 1999 Board meeting minutes indicate that the Board intended to discipline James Little; there is no indication in meeting minutes that the Board intended to discipline Little's HSC Pharmacy.
 - Based on the foregoing, it appears the discipline against James Little was incorrectly attributed to Little's HSC Pharmacy in the Board's licensure database, when it should have been attributed to James Little.

ACTION: Motions by S. HERNANDEZ, seconded by P. GANNON, and by separate unanimous votes by those present to:

- 1) Correct Little's HSC Pharmacy (DS2551) licensure history and remove the discipline associated with DS-98-005.
 - 2) Correct James Little's licensure history (PH13718) and add the six months of suspension followed by five years of probation that was associated with Complaint PH-98-005.
-

Topic X:
Read by M.GODEK

EXECUTIVE SESSION

Time: 11:29 PM

DISCUSSION:

ACTION: At 11:29 PM President M. GODEK read the statement on reasons for Executive Session.

12:30 PM to 1:37 PM Lunch Break

Topic X: Executive Session Call to Order:

Time: 1:42 PM

By: M. GODEK

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by roll call to call the June 7, 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; L. GIAMBARRESI, yes; T. FENSKY, yes; C. JEAN-FRANCOIS, yes; A. STEIN, yes.

Topic XI: ADJUDICATORY SESSION (MGL 30A § 18) Time: 11:44 AM

DISCUSSION: None

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

At 11:44 AM, Motion by A. Stein, seconded by K. Tanzer and voted unanimously to enter Adjudicatory Session.

Topic XII:

M.G.L. 65 C

Time: 11:48 AM

DISCUSSION: None

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

At 11:48 AM, Motion by A. Stein, seconded by S. Hernandez and voted unanimously to enter M.G.L. chapter 65 c Session:

Topic XIII:

ADJOURNMENT OF MEETING

Time: 2:59 PM

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

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 6/7/18 General Session
2. Draft Minutes of the 5/3/18 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: North Falmouth Pharmacy (DS89831) Petition for Waiver
8. Application: Soleo Waivers
9. Application: Flynn Pharmacy Transfer of Ownership
10. Application: Ayer Family Pharmacy New Community Pharmacy
11. Application: Remedium Transfer of Ownership
12. Application: Ethos Veterinary Renovation/Expansion
13. Advisory Committee Meeting Recommendation 18-01
14. Atrium Health: CDTM advisory opinion
15. Pharmacy Advisory Committee Meeting draft recommendation and agenda
16. Policy 2018-04; Naloxone Dispensing via Standing Order
17. Policy 2018-03; Pharmacist Continuing Education (CE) Requirements
18. PHA-2012-0006- Agnes Rubin; PH25022
19. PHA-2018-0028- Cantrell Drug Company- NO00027
20. PHA-2018-0002- Rite Aid #10203, DS2570
21. PHA-2018-0005- Rite Aid #10204, DS2577
22. SA-INV-12525- Rite Aid #10067, DS2552
23. SA-INV-12622- Walgreens #7704, DS3413
24. SA-INV-13014- Stop & Shop #398, DS3368
25. SA-INV-13012- Partners of MA, LLC, DS3419
26. SA-INV-12425- Prescription Center Pharmacy-University-Campus, DS89788
27. SA-INV-12513- Omnicare of Northern MA, DS89931
28. PHA-2018-0008- CVS #1855, DS2901
29. PHA-2018-0037- CVS #937, DS3444
30. PHA-2018-0006- CVS #257, DS3331
31. PHA-2018-0017- CVS #257, DS3331
32. PHA-2018-0012 CVS Specialty #48036, DS3416
33. SA-INV-12918 Rachel Marshall, PT17918
34. PHA-2017-0215- CVS #5874, DS3293
35. SA-INV-11104- Southwick Pharma, LLC, DS90050
36. DS-98-005-Little's HSC Pharmacy; DS2551

Respectfully Submitted,
Kim Tanzer, PharmD, RPh
Secretary