

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

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

April 5, 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 March 1, 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 		R. Harris M. Botto E. Taglieri
8:50	V	APPLICATIONS <ul style="list-style-type: none"> • Genoa Healthcare – Greenfield, MA- New Community Pharmacy • Genoa Healthcare-Charlestown, Petition Waiver • Pine Pharmaceutical – Petition to Waiver • Pharmscript (DS90242) - Relocation • CVS Pharmacy #2592 (DS3011) – Change of Manager 		

9:15	VI	<p>FLEX</p> <ul style="list-style-type: none"> • Sterile Compounding Tool • Appointment of New REC member (Public Seat) • Plans of Correction Data • 2017 Inquiries Data 		<p>Van Allen Trifone</p> <p>Taglieri</p> <p>Morton</p> <p>Casalino</p>																									
9:30	VII	<p>POLICIES</p> <ul style="list-style-type: none"> • Staff Action Policy 13-01: Licensure applications and notices 		<p>M. Chan W. Frisch</p>																									
10:00	VIII	<p>REGULATIONS</p> <ul style="list-style-type: none"> • 247 CMR 9:00: Professional Practice Standard 																											
11:00	IX	<p>FILE REVIEW</p> <table border="1" data-bbox="402 890 1287 1871"> <tr> <td data-bbox="402 890 464 968">1</td> <td data-bbox="464 890 1287 968">SA-INV-12109- Big Y Distribution Center, WD497</td> </tr> <tr> <td data-bbox="402 968 464 1045">2</td> <td data-bbox="464 968 1287 1045">SA-INV-12318- Preferred Pharmacy Solutions, LLC, DS3542</td> </tr> <tr> <td data-bbox="402 1045 464 1123">3</td> <td data-bbox="464 1045 1287 1123">SA-INV-12252- Metro West Pharmacy, DS90075</td> </tr> <tr> <td data-bbox="402 1123 464 1201">4</td> <td data-bbox="464 1123 1287 1201">SA-INV-12423- Caring Pharmacy, DS89747</td> </tr> <tr> <td data-bbox="402 1201 464 1278">5</td> <td data-bbox="464 1201 1287 1278">PHA-2017-0212- CVS #1882, DS3047</td> </tr> <tr> <td data-bbox="402 1278 464 1356">6</td> <td data-bbox="464 1278 1287 1356">PHA-2017-0222- CVS #2054, DS2588</td> </tr> <tr> <td data-bbox="402 1356 464 1434">7</td> <td data-bbox="464 1356 1287 1434">PHA-2017-0210- CVS #2054, DS2588</td> </tr> <tr> <td data-bbox="402 1434 464 1512">8</td> <td data-bbox="464 1434 1287 1512">SA-INV-12250- Stop & Shop #17, DS3084</td> </tr> <tr> <td data-bbox="402 1512 464 1589">9</td> <td data-bbox="464 1512 1287 1589">SA-INV-12248- Stop & Shop #55, DS3290</td> </tr> <tr> <td data-bbox="402 1589 464 1667">10</td> <td data-bbox="464 1589 1287 1667">SA-INV-12249- Stop and Shop #416, DS3440</td> </tr> <tr> <td data-bbox="402 1667 464 1745">11</td> <td data-bbox="464 1667 1287 1745">SA-INV-12251- Costco Pharmacy #302, DS1946</td> </tr> <tr> <td data-bbox="402 1745 464 1822">12</td> <td data-bbox="464 1745 1287 1822">PHA-2017-0196- CVS #2600, DS3083</td> </tr> <tr> <td data-bbox="402 1822 464 1900">13</td> <td data-bbox="464 1822 1287 1900">PHA-2017-0191- Remedium Pharmacy, LLC., DS89943</td> </tr> </table>	1	SA-INV-12109- Big Y Distribution Center, WD497	2	SA-INV-12318- Preferred Pharmacy Solutions, LLC, DS3542	3	SA-INV-12252- Metro West Pharmacy, DS90075	4	SA-INV-12423- Caring Pharmacy, DS89747	5	PHA-2017-0212- CVS #1882, DS3047	6	PHA-2017-0222- CVS #2054, DS2588	7	PHA-2017-0210- CVS #2054, DS2588	8	SA-INV-12250- Stop & Shop #17, DS3084	9	SA-INV-12248- Stop & Shop #55, DS3290	10	SA-INV-12249- Stop and Shop #416, DS3440	11	SA-INV-12251- Costco Pharmacy #302, DS1946	12	PHA-2017-0196- CVS #2600, DS3083	13	PHA-2017-0191- Remedium Pharmacy, LLC., DS89943	
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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
	XI	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)			
2:30	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**

April 5, 2018

Board Members Present

Michael Godek, RPh. President
Andrew Stein, Pharm D, RPh. President Elect
Susan Cornacchio, JD, RN, (arrived 8:55AM)
Kim Tanzer, PharmD, RPh. Secretary
Stephanie Hernandez, Pharm D, BCGP, RPh
Patrick Gannon, RPh
Timothy Fensky, RPh
Carly Jean-Francois, RN, NP
Julie Lanza, CPhT
Dawn Perry, JD

Board Members Not Present

Leah Giambarresi, Pharm D, RPh
Ali Raja, MD, MBA, MPH
Phillippe Bouvier, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Associate Executive Director
Heather Engman, JD Chief 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
Nathan Van Allen, Pharm D, RPh Investigator
Ed Taglieri, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:34 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; T. Fensky, yes; C. Jean-Francois, yes; J. Lanza, yes;
D. Perry, yes. (S. Cornacchio no present, arrived 8:55 AM)

TOPIC II. Approval of Agenda TIME 8:35 AM

Agenda April 5, 2018

DISCUSSION:

No changes to the agenda.

ACTION:

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

Executive Director, D. Sencabaugh, introduced 3 new Interns: Patsy Casalino, MCPHS Boston (past intern back to present work he did today), Jenny Lee, NE and Dana Du, MCPHS; Godek called all the other interns in attendance to stand up and introduce themselves.

Topic III Approval of Board Minutes TIME: 8:36 am

Minutes

Draft, March 1, 2018 Regular Session Minutes

Changes:

None

Action:

Motion by P. Gannon, seconded by T. Fensky, and voted unanimously to approve the regular session minutes of March 1, 2018.

TOPIC IV REPORTS

Applications approved pursuant to Licensure Policy 13-01 Time: 8:37AM

Discussion: M. BOTTO noted that during the past month there have been forty-six (16) changes of manager on record (MOR), one (1) renovation expansion, and three (3) outsourcing facilities.

So noted

TOPIC IV **REPORTS**

Monthly Report from Probation

Time: 8:37AM

Discussion: M. BOTTO provided the March 1, 2018 – March 28, 2018, Board of Pharmacy Statistics Report for the Probation monitor, which noted that there are currently fifty-seven (57) 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: 8:37AM

Discussion: There were twelve (12) Board Delegated Review cases heard on March 30, 2018. All twelve of the cases were CE deficiencies (SA-INV-12685, SA-INV-12627, SA-INV-12625, SA-INV-12681, SA-INV-12751, SA-INV-12683, SA-INV-12752, SA-INV-12790, SA-INV-12118, SA-INV-12789, SA-INV-12804, and SA-INV-12876) which were closed with no discipline warranted and remediation complete. The Board Delegated Review session was attended by M. GODEK as the Board Member, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

TOPIC IV **REPORTS**

Above Action Levels Approved by Staff Action 16-04

Time: 8:37AM

Discussion: K. MORTON reported that there were no above action level reports successfully remediated and closed since last month's board meeting.

So noted

TOPIC IV **REPORTS**

PSUD Monthly Report

Time: 8:38AM

Discussion: M. BOTTO reported that there are a total of eleven (11) participants, with one (1) discharge, and three (3) Individualized Rehabilitation Plan's requiring a board vote.

So Noted

TOPIC V:

APPLICATIONS

1. Genoa Healthcare, Greenfield New Community Pharmacy Time: 8:39 am

RECUSAL: None

DISCUSSION: Genoa was represented by Jason Kan and Kevin O’Connell.

Genoa came before the Board of Pharmacy, petitioning for a new community pharmacy with waivers to be consistent across all of their facilities. The waivers were for 247 CMR 6.02 (5) – Signage, 247 CMR 9.01 (15) – Limited Service, 247 CMR 6.01 (5)(a)(8) – OTC Drugs, 247 CMR 6.01(5)(a)(4) – Balance-Compounding, 247 CMR 9.01 (16) – Compounding, 247 CMR 6.02 (4) – Chemicals – Compounding.

F. Fensky asked for a description of what was next to this pharmacy and J. Kan gave a description. P. Gannon asked if the same business model as the other Genoa Healthcare’s and then answer was yes.

ACTION:

Motion by T. Fensky, seconded by S. Hernandez, and voted unanimously in the affirmative to approve this application for a new community pharmacy with waivers listed for Genoa Healthcare, Greenfield pending successful inspection.

2. Genoa Healthcare, Charlestown Petition for Waiver Time: 8:42 am

RECUSAL: None

DISCUSSION: Genoa was represented by Jason Kan and Kevin O’Connell.

Genoa came before the Board of Pharmacy, petitioning for waivers, since a name change occurred, and in an effort to be consistent across all of their facilities. The waivers were for 247 CMR 6.02 (5) – Signage, 247 CMR 9.01 (15) – Limited Service, 247 CMR 6.01 (5)(a)(8) – OTC Drugs, 247 CMR 6.01(5)(a)(4) – Balance-Compounding, 247 CMR 9.01 (16) – Compounding, 247 CMR 6.02 (4) – Chemicals – Compounding.

Other Genoa locations were presented last month, this one is being presented now to have all locations aligned consistently.

ACTION:

Motion by T. Fensky, seconded by S. Hernandez, and voted unanimously in the affirmative to approve the applications for Waiver listed above for Genoa HealthCare, Charlestown.

3. Pharmscript, DS90242 Relocation Time: 8:44 am

RECUSAL: None

DISCUSSION: Genoa was represented by Steven Anderson, MOR and Jennifer Caruso, Chief Corp Officer.

Pharmscript specialized in long term care pharmacy and is moving to a location in Marlborough with 7500 sq feet. The new location is one of another pharmacy that closed. The new location will have a clean room, they will not do sterile compounding now, but will consider in future and at that time seek BOP approval.

ACTION:

Motion by P. Gannon, seconded by K. Tanzer, and voted unanimously in the affirmative to approve the relocation of Pharmscript.

4. CVS Pharmacy #2592 Change of Manager Time: 8:45 am

RECUSAL: None

DISCUSSION: Jeffery Suriyodom, PH237843, MOR was present for this.

Jeffery has not had any previous MOR experience. Jeffery felt he was ready now and up for the challenge. Jeffery stated he has support around him with experience people in the store as well as management and has reviewed information on the BOP webpage. The BOP offered support and education regarding: ratios, tech in training, controlled substance record keeping and looking at past inspections of the store for knowledge.

ACTION:

Motion by T. Fensky, seconded by S. A. Stein, and voted unanimously in the affirmative to approve this change of manager at CVS Pharmacy #2592.

S. Cornachio arrives at 8:55 AM

**5. Pine Pharmaceutical Petition for Waiver Time: 9:00 am
(done at 9:00 AM out of order due to scheduled conference call)**

RECUSAL: None

DISCUSSION: Nicolas Pusateri, Esq and Allison Gentile, Pharmacist

Pine is a 503B outsourcing facility in New York who has recently relocated. The BOP of New York has inspected; however, Massachusetts regulations require the FDA to inspect new

locations prior to items being shipped to the state. With 503b outsourcing facilities being a new category in Massachusetts, this is the first time this type of situation has occurred involving a relocation. Pine Pharmaceuticals has a history of providing compounded pharmaceuticals not commercially available to Massachusetts residents at institutions like Mass Eye and Ear. The goal is to not interrupt these needed treatments at the same time as ensuring safety for patients. This waiver for petition request would allow Pine Pharmaceuticals to continue to ship into Massachusetts until 5/3/18 while waiting for a pending FDA inspection. If the inspection is not completed by 5/3/18, the BOP would reconsider extending the petition at the 5/3/18 meeting.

Nicolas and Allison gave a summary of the forms and request submitted for waiver.

ACTION:

Motion by P. Gannon, seconded by T. Fensky, and voted unanimously in the affirmative to approve the application for Waiver for Pine Pharmaceutical's till 5/3/18.

Topic VI

FLEX SESSION

1. Sterile Compounding Tool

Time: 9:10 AM

Presented by: D. SENCABAUGH and N. VAN ALLEN

DISCUSSION: D. SENCABAUGH presented the Sterile Compound Tool that it is in line with 247 CMR 17 and USP 797. D. SENCABAUGH stated it is twice as long as the previous tools and mentioned that the tool has been trialed. N. VAN ALLEN stated the tool is lengthier than the current tool, noting the current tool has 120 questions and the new tool has 350 questions. N. VAN ALLEN explained the tool has been tried in two facilities known to the Board of Pharmacy; one performs high-risk sterile compounding and one performs moderate risk and was remodeled. N. VAN ALLEN stated it took 4 hours to complete the audit (not including the tour of the facility which would be an additional 30-45 minutes) and it would take about 6 hours to complete at an unknown facility. N. VAN ALLEN described the first half of the tool is comparable for all licenses and the second half is more unique so it would not apply to all facilities. N. VAN ALLEN mentioned the tool is well received by the facilities and overall a success; there were no plans of correction issued for the two facilities. T. FENSKY asked if the facility that does not meet the requirements of the best practice questions will result in a citation. N. VAN ALLEN answered the facility will not be cited but documentation will be done. P. GANNON asked to consider clarifying best practice gray areas. K. TANZER asks how documentation is determined. N. VAN ALLEN answered objective data is documented. S. HERNANDEZ asked if there will be public comment on this tool. N. VAN ALLEN answered the tool is based on 247 CMR 17 and D. SENCABAUGH answered public comment will be received with the tool when it is put on the website. A. STEIN asked if a facility can be cited for a plan of correction based on this draft tool. H. ENGMAN answered the best practices are

highlighted gray in the tool and a plan of correction will not be issued for not having the best practices. D. PERRY asked how long an inspection took with the current tool of 120 questions. N. VAN ALLEN answered an inspection with the current tool would take 3 to 3.5 hours. S. CORNACCHIO asked if the facilities receive a copy of the tool prior to the visit. J. TRIFONE answered the facilities receive a copy 2 to 3 weeks in advance. N. VAN ALLEN mentioned there are plans for other investigators to shadow during an inspection to familiarize them with the tool.

ACTION: No action warranted

**2. Appointment of New REC member (Public Seat)
(done out of order reason for time shift)**

Time 8:53 AM

Presented by: E. TAGLIERI

DISCUSSION: E. TAGLIERI stated Shannon left her position due to getting a new job and there being a work conflict. E. TAGLIERI stated Anthony Bashir is recommended for the open position. E. TAGLIERI stated Anthony Bashir has 10-20 years of experience with Substance Use Disorder, is a speech language pathologist, and would be a good asset to the committee.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously to approve the appointment of the new REC member.

3. Plans of Correction Data

Time 9:28 AM

Presented by: K. MORTON

DISCUSSION: K. MORTON presented an overview of the plans of correction data of 2016 versus 2017. K. MORTON stated there was a 15% reduction in plans of correction in retail pharmacies and attributed this to the increase in the number of inspections and increased compliance to the regulations, but mentioned the most common deficiencies found involved staff ratios and controlled substance reporting. K. MORTON noted that the top 3 deficiencies in 2017 remained the same as in 2016: (1) control substance record keeping, (2) equipment and drug storage, and (3) refrigeration temperatures. P. GANNON asked if there was any recommended action to address these common deficiencies. J. TRIFONE answered the deficiencies are addressed by CEs, reference tools, reminding the licensees of the common deficiencies, and via the newsletter. T. FENSKY asked if the data included infusion companies. K. MORTON answered yes if the infusion company was dispensing medication as well. P. GANNON asked if nuclear pharmacies were not included. K. MORTON answered yes, they are not included.

ACTION: No Action warranted

4. 2017 Inquiries Data

Time 9:34 AM

Presented by P. CASALINO

DISCUSSION: P. CASALINO stated the statistics of the 2017 inquiries data. P. CASALINO stated for the 1,422 inquiries logged, the time to answer was an average of 120 hours, but when

outliers were excluded, the time to answer was about 40.5 hours, with the median time of 24 hours. P. CASALINO also mentioned that the time to answer inquires also included non-business hours. P. CASALINO presented the pie graph relating to the inquiries received in 2017. P. CASALINO stated of the 24 keywords, DME, mail order, MTM and outsource was 0% of the inquires while licensing was the largest at 29% and non-resident at 10%. P. CASALINO stated that a new column was created in the spreadsheet to better track when the QA team receive the question to time the QA team answered the question. P. CASALINO also mentioned some of the keywords being tracked may no longer be relevant so they should be assessed at the end of the year. P. CASALINO also noted that the miscellaneous category was 8% of the pie chart and so it would be worth looking through to see if most of the questions asked pertained to a possible new keyword. P. GANNON asked how outliers were determined. P. CASALINO answered the outliers were determined via using excel to identify the quartiles first and identifying the ones that fell outside the quartiles, which there were 5-6 that did.

ACTION: No Action warranted

Topic VII. POLICIES

1. Policy 13-01: Licensure Applications and Notices (done out of order reason for time shift)

Time: 8:50 AM

DISCUSSION: Presented by M. CHAN

There was a section left off from the revised policy regarding transfer of ownership. The original language that had been approved by the Board in June of 2016 was restored.

ACTION: Motion by P. GANNON, seconded by K. TANZER, and voted unanimously to approve the noted reinstatement of section in Policy 13-01: Licensure Applications and Notices.

Topic VIII. REGULATIONS

1. 247 CMR 9.00: Professional Practice Standards

Time: 10:03 AM

DISCUSSION: Presented by W. FRISCH and M. CHAN

Since last Board meeting, reviewed public comment grid and made formatting and wording changes. Red text indicated the text from the last time the Board reviewed the text, blue text indicated changes after public comment, and highlighted text indicated changes since the Board last reviewed the text. P. GANNON offered feedback about the draft. Changes made to the draft during the discussion include:

- 9.05: changed “Naloxone Pamphlet” to “Opioid Antagonist Informational Pamphlet” for consistency
- 9.08: statement about multidrug single dose packaging will be separated into 2 separate standards for clarity
- 9.22: refrigeration temperatures will be in accordance with the Board policies

- 9.14 (4)(b): wording pertaining to the transferring of prescriptions clarified to transfer the maximum refills left on the prescription
- 9.15 (1): wording from “PMP” to “MassPAT” may possibly change to ensure it is aligned with current standards

Action: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously to adopt draft 247 CMR 9.00 Professional Practice Standards and proceed to final administrative review and promulgation.

IX. Open File Review Time: 10:28 am

Case #1
 SA-INV-12109 Big Y Distribution Center, WD408 Time: 10:28 am

RECUSAL: none

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

- RLCS due to theft by an outside vendor from Big Y Pharmacies #22, 23, 25, and 37 when shipping containers delivered by an outside vendor arrived damaged and missing 100-count bottles of gabapentin or zolpidem.
- Upon inspection, OPP Investigators observed a robust security system. The wholesale distribution area was secured with an electronic lock and access was restricted to approximately 10 employees. Schedule IV-V CS’s were further segregated by a walk-in vault with its own electronic lock, cameras, and motions sensors.
- Staff inside the WD area performed order picking only. All P&O’s were sent electronically to the inside by a staff member that remained outside the WD area and segregated from the inside staff to reduce chance of collusion. Big Y Asset Protection routinely audited the inventory. The outside vendor was not allowed in the WD area. WD staff escorted the CS’s to the receiving area where the numbers of containers were confirmed and the containers were inspected by the outside vendor and WD staff prior to transfer of custody to outside vendor.
- CA – Big Y DC used tamper evident tape to seal boxes. In addition, they plan to begin distributing CS’s using their own drivers as soon as a solid logistics plan is settled.

ACTION: Motion by P. GANNON, seconded by K. Tanzer, and voted unanimously by those present, to close SA-INV-12109, no discipline warranted, remediation complete.

Case #2
 SA-INV-12318 Preferred Pharmacy Solutions, LLC, DS3542 Time: 10:30 am

RECUSAL: None

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

- During a site visit on 10/31/17, pharmacy generator failed resulting in loss of power from approximately 9 am to 11:20 am;
 - POC indicated CPhT began cleaning a half hour after power restored and was observed compounding fentanyl at 12:41 pm without adequately cleaning prior to compounding;
 - CPhT diluted RTU Sporicidin and stated contact time was 30 seconds;
 - PPS completed a monthly clean, EM testing, reduced BUDs to high risk 72-hour refrigerated, segregated fentanyl compound;
 - Continuum of Care created for power outages and staff retrained;
- 797 inspection on 11/2/17 with no deficiencies

ACTION: Motion by T. Fensky, seconded by K. Tanzer, and voted unanimously by those present, to close SA-INV-12318 with no discipline warranted and remediation complete.

Case #3

SA-INV-12252

Metro West Pharmacy, DS90075

Time: 10:34 am

RECUSAL: None

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

- Inspectional deficiencies from ISP-8200 for hazardous compounding on 9/12/17 with master formulations not matching compounding logs, lack of SOPs and training documentation, non-compliance with the handling and storage of HDs, BUDs recorded as month/year.
- Additional deficiencies for ISP-7734 on 09/12/2017 for dead insects on shelves and no hot water.
- An extensive POC was submitted including development of new SOPs, updating of master formulations, quality assurance checks on compounds, and pest control.
- The pharmacy ceased compounding HDs.
Site Visit ISP-8517 on 10/24/17 found the POC to be substantially implemented and retail inspection ISP-8763 and 795 inspection ISP-9083 were conducted on 1/23/18 with no deficiencies cited.
- T. Fensky discussed concerns that the pharmacy did not appear to have a good understanding of categories of compounding (simple, moderate, complex) as well as what was categorized as hazardous compounding. The board discussed this further and seemed in agreement. C. Mogni responded that on initial inspection, she would have agreed, but after the inspection and pharmacy educating staff she felt confident they did understand on re-inspection.

ACTION: Motion by P. Gannon seconded by L. Fensky, and voted unanimously by those present, to close SA-INV-12252 with no discipline warranted, but increase the frequency of inspections at the Inspector's discretion.

Case #4

SA-INV-12423

Caring Pharmacy, DS89747

Time: 10:44 am

RECUSAL: none

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

- Inspectional deficiencies on 10/31/17 for failure to store medications within the pharmacy and lack of hot water.
- At least 12 boxes of drugs (mostly in-date) were observed in the finished basement and another 6 boxes of expired drugs in multiple locations in the unfinished basement.
- MOR Phan indicated the pharmacy was in process of rearranging to install new carpet and to accommodate a ScriptPro and the hot water had been temporarily disconnected.
- MOR Phan returned the expired drugs; proof was submitted; pictures provided show the pharmacy and basement has been cleaned and rearranged.

ACTION: Motion by T. Fensky , seconded by S. Hernandez, and voted unanimously by those present, to close SA-INV-12423, no discipline warranted, remediation complete.

Case #5

PHA-2017-0212

CVS #1882, DS3047

Time: 10:45 am

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

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

- RLCS- #100 methadone 10mg tablets discovered by staff pharmacist while performing state count on August 18, 2017
- Prescriptions were dispensed to two patients between state counts and one of the two patients was ruled out as having received the extra tablets
- The verification pharmacist contributes the suspected dispensing error to his failure to perform a complete back count and identified contributing factors such as location, space allocation and disruptions
- MOR Barone indicated that a dedicated work area with a blue mat was established to count Schedule II medications. A computer was placed in the area to verify the prescription and back count on the perpetual inventory. She also indicated that there was a discussion with the pharmacists regarding the importance of following CVS process for filling and dispensing CII medications and the importance of working in a neat and organized manner.

- Pharmacist Cola attests to having read 247 CMR 15 on Continuous Quality Improvement Program and completed two CE contact hours in medication safety.

ACTION: Motion by T. Fensky, seconded by K Tanzer, 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 #6

PHA-2017-0222

CVS #2054, DS2588

Time: 10:47 am

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

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

- RLCS- #100 methylphenidate 10mg tablet discovered on 10/28/2017 while performing the state count.
- Video footage was reviewed and patients called for all seven prescriptions filled between the state counts on 10/14/2017 and 10/28/2017. There were no significant findings.
- The loss is assumed to be a result of a full bottle being thrown in the trash
- Loss Prevention policy and procedures were reviewed with the pharmacy team which includes diligent inventory management and dispensing standards. Staff reviewed the process of back counting of all narcotics at the time of dispensing to ensure accuracy. MOR indicated that back counts will be done after every CII prescription is filled and noted on the stock bottle and the back tag of the prescription hard copy. A back count will also be performed on open and sealed bottles in the safe.

ACTION: Motion by T. Fensky, seconded by S. Hernandez, 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 #7

PHA-2017-0210

CVS #2054, DS2588

Time: 10:44 AM

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.

- An over-dispense of #80 oxycodone 5mg tablets occurred on 7/03/2017.
- Security cameras were reviewed and it was determined that Pharmacist Abdoubakr dispensed the entire contents of a full #100 count stock bottle instead of the #20 tablets prescribed.

- Pharmacist Abdoubakr indicated that she did the back count but failed to document it on the back tag of the prescription and instead of pouring the back counted drug into the stock bottle, she poured it into the patient's vial.
- An unsuccessful attempt was made to reach the patient to retrieve the over-dispensed medication.
- MOR Eskarous indicated that the pharmacist team was retrained regarding the safe production process. Pharmacist Abdoubakr met with her pharmacy manager and discussed the importance of adhering to workflow, including safe production practices and proper measures to utilize when verifying the quantity of CII's dispensed.
- Pharmacist Abdoubakr completed 2 CE contact hours in, "Preventing Medication Errors", and reviewed 247 CMR 15, Continuous Quality Improvement program.

ACTION: Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously by those present to DISMISS PHA-2017-0210 with no discipline warranted and to send a letter as a reminder to document Schedule II counts on paper if the computer system is down.

Case #8

SA-INV-12250

Stop & Shop #17, DS3084

Time: 10:58 AM

RECUSAL: D. PERRY 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.

- Stop & Shop #17, #55, & #416 each reported thefts of 30 buprenorphine-naloxone 8-2mg sublingual films by an outside vendor conducting inventory audits in each pharmacy.
- Internal investigation discovered that the reports of losses occurred after audits. Asset Protection reviewed surveillance video and discovered that one employee of an outside vendor was present at each pharmacy during the audits.
- Stop & Shop set up additional cameras and live surveillance for the next four audits at the pharmacies involved. Person under suspicion was not observed in the pharmacy during the four audits and no additional losses were reported. Stop & Shop confirmed that outside vendor barred employee from conducting pharmacy audits.

ACTION: Motion by P. GANNON, seconded by S. HERNANDEZ, and voted unanimously by those present to close SA-INV-12250, with no discipline warranted, remediation complete.

Case #9

SA-INV-12248

Stop & Shop #55, DS90075

Time: 10:58 AM

RECUSAL: D. PERRY 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.

- Stop & Shop #17, #55, & #416 each reported thefts of 30 buprenorphine-naloxone 8-2mg sublingual films by an outside vendor conducting inventory audits in each pharmacy.
- Internal investigation discovered that the reports of losses occurred after audits. Asset Protection reviewed surveillance video and discovered that one employee of an outside vendor was present at each pharmacy during the audits.
- Stop & Shop set up additional cameras and live surveillance for the next four audits at the pharmacies involved. Person under suspicion was not observed in the pharmacy during the four audits and no additional losses were reported. Stop & Shop confirmed that outside vendor barred employee from conducting pharmacy audits.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present to close SA-INV-12248, with no discipline warranted, remediation complete.

Case #10

SA-INV-12249 Stop & Shop #416, DS3440 Time: 10:58 AM

RECUSAL: D. PERRY 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.

- Stop & Shop #17, #55, & #416 each reported thefts of 30 buprenorphine-naloxone 8-2mg sublingual films by an outside vendor conducting inventory audits in each pharmacy.
- Internal investigation discovered that the reports of losses occurred after audits. Asset Protection reviewed surveillance video and discovered that one employee of outside vendor was present at each pharmacy during the audits.
- Stop & Shop set up additional cameras and live surveillance for the next four audits at the pharmacies involved. Person under suspicion was not observed in the pharmacy during the four audits and no additional losses were reported. Stop & Shop confirmed that outside vendor barred employee from conducting pharmacy audits, remediation complete.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present to close SA-INV-12249, with no discipline warranted.

Case #11

SA-INV-12251 Costco Pharmacy #302, DS1946 Time: 11:00 AM

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

- Unknown loss of 153 zolpidem 10mg tablets discovered on 6/27/2017 according to the electronic inventory system.

- A manual reconciliation was conducted. MOR indicated that the actual count on hand was correct. He attributed the variance between actual count and electronic inventory to the estimated quantity in the biennial for CIII-CV and differences in the way transactions were captured by the electronic system.
- In response, he performed an exact count of all CIII-CV's and placed all CIII-CV on perpetual inventory. He also placed the zolpidem in a locked cabinet to further secure the drug. He reported since the exact count and start of CII-CV's perpetual inventory at the end of June 2017 that his pharmacy has had no additional losses.

ACTION: Motion by A. STEIN, seconded by P. GANNON, and voted unanimously by those present to close SA-INV-12251, with no discipline warranted, remediation complete.

Case #12

PHA-2017-0196 CVS #2600, DS3083 Time: 11:02 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 loss of 168 oxycodone-acetaminophen 5-325mg tablets on 08/09/17. Prescription discovered missing when patient arrived for pick up.
- MOR indicated that internal investigation showed prescription was verified correctly but given to the wrong patient by a technician during POS transaction because of similar patient names and multiple prescriptions. Technician could not recall details of event. MOR purported wrong patient received the oxycodone-acetaminophen 5-325mg tablets but the patient denied receiving them.
- MOR reviewed policy and procedures for transactions at POS. Pharmacy reported no other losses to the BORP from 2 years prior to the 08/17.

ACTION: Motion by K. TANZER, seconded by A. STEIN, and voted unanimously by those present to DISMISS PHA-2017-0196, with no discipline warranted, remediation complete.

Case #13

PHA-2017-0191 Remedium Pharmacy, LLC, DS89943 Time: 11:05 AM

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

- A New Hampshire pharmacy filed a complaint that staff member at Remedium impersonated a patient to transfer a prescription. Remedium denied the allegation.
- Patient reported that the prescription was intended to be sent to Remedium but was accidentally sent to the NH pharmacy. He requested the transfer to Remedium and the NH pharmacy refused. He then contacted the NH pharmacy himself and the NH pharmacy still refused to transfer the prescription to Remedium.

- Additionally, Remedium was inspected on 09/28/2017 and multiple deficiencies observed including CIV-VI's and PHI stored outside of the pharmacy in an unsecured area, drug samples in the storage area and pharmacy, partial fills completed after permitted time period, no expiration dates on blister packs, trainee badge incorrectly identified her as certified tech, unmonitored refrigerator with CS's in storage area.
- MOR successfully remediated all deficiencies and asserted that the fire at the old pharmacy caused most of the deficiencies in the new pharmacy during the relocation due to limited space in the new area. Also, the drug samples were taken from local MD as a favor to destroy and none were dispensed to patients.

ACTION: Motion by K. TANZER, seconded by T. FENSKY, and voted unanimously by those present to DISMISS PHA-2017-0191, with no discipline warranted, remediation complete.

Topic X: EXECUTIVE SESSION Time: 11:10 AM
Read by M.GODEK

DISCUSSION:

ACTION: At 11:10 AM President M. GODEK read the statement on reasons for Executive Session.

At 11:10 AM, M. GODEK called for a motion to enter Executive Session: Motion by S. HERNANDEZ, seconded by P. GANNON and voted unanimously by roll call to enter Executive Session.

M. Godek, yes; A. Stein, yes; S. Cornacchio, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; C. Jean-Francois, yes; J. Lanza, yes; D. Perry, yes.

Topic XI: Adjudicatory Session (MGL 30A § 18) Time: 11:13AM

DISCUSSION: None

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

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

Topic XII: M.G.L. 65 C Time: 11:30 AM

DISCUSSION: None

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

At 11:30 AM, Motion by P. Gannon, seconded by K. Tanzer and voted unanimously to enter M.G.L. chapter 65 c Session:

Topic XIII: ADJOURNMENT OF MEETING Time: 2:28 PM

ACTION: Motion by T. FENSKY seconded by D. PERRY, 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 4/5/18 General Session
2. Draft Minutes of the 3/1/18 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. Report on Pharmacy Substance Use Disorder Program
8. Application New Community Pharmacy Genoa Healthcare-Greenfield MA
9. Application Waiver Genoa Healthcare-Charlestown, MA
10. Application Waiver Pine Pharmaceutical
11. Application Relocation Pharmscript (DS90242)
12. Application Change of Manager CVS Pharmacy #2592, DS3011
13. Sterile compounding Tool
14. Appointment of New PSUD REC Member Anthony Bashir
15. 2017 Plans of Correction Data Summaries
16. 2017 Inquires Data Summaries
17. Staff Action Policy 13-01: Licensure Applications and Notices
18. Summary of Public Comments 247 CMR 9.00 Professional Practice Standards
19. SA-INV-12109- Big Y Distribution Center, WD497
20. SA-INV-12318- Preferred Pharmacy Solutions, LLC, DS3542
21. SA-INV-12252- Metro West Pharmacy, DS90075
22. SA-INV-12423- Caring Pharmacy, DS89747
23. PHA-2017-0212- CVS #1882, DS3047
24. PHA-2017-0222- CVS #2054, DS2588
25. PHA-2017-0210- CVS #2054, DS2588
26. SA-INV-12250- Stop & Shop #17, DS3084
27. SA-INV-12248- Stop & Shop #55, DS3290
28. SA-INV-12249- Stop and Shop #416, DS3440
29. SA-INV-12251- Costco Pharmacy #302, DS1946
30. PHA-2017-0196- CVS #2600, DS3083
31. PHA-2017-0191- Remedium Pharmacy, LLC., DS89943

Respectfully Submitted,
Kim Tanzer, PharmD, RPh
Secretary