

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

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

October 4, 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**

<b>Time</b>	<b>#</b>	<b>Item</b>	<b>Page</b>	<b>Contact</b>
8:30	I	<b>CALL TO ORDER</b>		M. Godek
	II	<b>APPROVAL OF AGENDA</b> <ul style="list-style-type: none"> <li>• Introduction of new interns:               <ul style="list-style-type: none"> <li>○ Caitlin Demmett: Northeastern University</li> <li>○ Jeffrey Dumond: Western New England University</li> <li>○ Thanh Dieu: MA College of Pharmacy and Health Sciences</li> </ul> </li> </ul>		
	III	<b>APPROVAL OF BOARD MINUTES</b> <ul style="list-style-type: none"> <li>• Draft of September 6, 2018 Regular Session Minutes</li> </ul>		
8:40	IV	<b>REPORTS</b> <ul style="list-style-type: none"> <li>• Applications approved pursuant to Licensure Policy 13-01</li> <li>• Monthly report from probation</li> <li>• Board Delegated Review pursuant to Licensure Policy 14-02</li> <li>• Above Action Levels approved by Staff Action 16-04</li> </ul>		
8:45	V	<b>POLICIES and ADVISORIES</b> <ul style="list-style-type: none"> <li>• Circular Letter: Schedule II Opioids: Prescription Form Requirements and Patient Requests for Partial Fill</li> <li>• Advisory on the Sale of Hypodermic Syringes and Needles</li> </ul>		

9:15	VI	<p><b>APPLICATIONS</b></p> <ul style="list-style-type: none"> <li>Winchester Pharmacy pilot project petition to Board; DS89848</li> <li>Fenway Pharmacy DS89656 – Change of Manager</li> <li>Standard Pharmacy @ Healthfirst; DS89814 – Transfer of Ownership</li> <li>Bouvier Pharmacy; DS90037 – Renovation/Expansion</li> <li>ACC Apothecare, DS3530- Renovation/Expansion</li> <li>Maida Pharmacy- DS2822 – Renovation/Expansion</li> <li>Benzer Pharmacy/Southwick Pharmacy (DS90050) –Transfer of Ownership</li> </ul>		
10:15	VII	<p><b>FLEX</b></p> <ul style="list-style-type: none"> <li>CDTM Advisory Opinion</li> <li>FDA 50 state meeting update</li> <li>NABP Executive Director Forum update</li> <li>NABP District 1 &amp; 2 meeting update</li> <li>Commonwealth Performance Recognition Award: Michelle Chan</li> <li>Update on AP Passport Pilot Project.</li> <li>Pharmacy Substance Use Disorder Program(PSUD)- Appointment of Pharmacy Technician to the Rehabilitation Evaluation Committee</li> <li>Bowl of Hygeia award</li> </ul>		
10:30	F	<p><b>Violation of Probation</b></p> <ul style="list-style-type: none"> <li>CVS 257; DS 3331 - PHA-2018-0006 &amp; PHA-2018-0017</li> </ul> <p><b>Violation of Stayed Probation</b></p> <ul style="list-style-type: none"> <li>CVS 299; DS3596 – PHA-2016-0237</li> </ul>		
10:45	VIII	<p><b>REGULATIONS</b></p> <ul style="list-style-type: none"> <li>247 CMR 17.00 – Sterile Compounding</li> </ul>		

<b>12:00</b>	<b>IX</b>	<b>FILE REVIEW</b>			
		<b>1</b>	PHA-2018-0041- Omnicare of Northern MA- DS89931		
		<b>2</b>	PHA-2018-0052- CVS #1889- DS2816		
		<b>3</b>	PHA-2018-0051- CVS #844- DS1402		
		<b>4</b>	PHA-2018-0057- CVS #1870- DS90040		
		<b>5</b>	PHA-2018-0050- CVS #714- DS3299		
		<b>6</b>	PHA-2018-0058- CVS #665- DS1198		
		<b>7</b>	PHA-2018-0033- CVS #1866- DS2956		
		<b>8</b>	SA-INV-13378- Walgreens #2471- DS3536		
		<b>9</b>	SA-INV-12803- Rite Aid #10205- DS2573		
<b>12:30 LUNCH BREAK</b>					
<b>1:30</b>	<b>X</b>	<b>EXECUTIVE SESSION</b>  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, review requests for reinstatement, review a violation of probation, review a violation of stayed probation, review a violation of Board agreement and to evaluate the Good Moral Character as required for registration for pending applicants.			<b>CLOSED SESSION</b>
<b>3:00</b>	<b>XI</b>	<b>M.G.L. c. 112, § 65C SESSION</b>			<b>CLOSED SESSION</b>
<b>5:00</b>	<b>XII</b>	<b>ADJOURNMENT</b>			<b>CLOSED SESSION</b>

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

**MINUTES OF THE GENERAL SESSION  
239 Causeway Street, Fourth Floor ~ Room 417A  
Boston, Massachusetts, 02114  
October 4, 2018**

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**Board Members Present**

Michael Godek, RPh. President  
Andrew Stein, Pharm D, RPh. President Elect  
Kim Tanzer, PharmD, RPh. Secretary  
Leah Giambarresi, Pharm D, RPh  
Patrick Gannon, RPh (out of meeting 9:00 AM to 9:30 AM)  
Julie Lanza, CPhT  
Timothy Fensky, RPh  
Ali Raja, MD, MBA, MPH  
Sebastian Hamilton, MBA, Pharm D, RPh  
Stephanie Hernandez, Pharm D, BCGP, RPh

**Board Members Not Present**

Carly Jean-Francois, RN, NP  
Susan Cornacchio, JD, RN  
Dawn Perry, JD

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Monica Botto, CPhT, Associate Executive Director  
Heather Engman, JD Board Council  
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/Quality Assurance Pharmacist  
Christina Mogni, RPh Investigator  
Joseph Santoro, RPh Investigator  
Nathan Van Allen, PharmD, RPh Investigator  
Ed Taglieri, MSM, NHA, RPh PSUD Supervisor  
Richard Harris, Program Analyst

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**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: A. Stein, yes; K. Tanzer, yes; S. Hernandez, yes; J. Lanza, yes; P. Gannon, yes; T. Fensky, yes; A. Raja, yes; S. Hamilton, yes; L. Giambarresi, yes, M. Godek, yes

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**Topic II.**

**Approval of Agenda**

**TIME 8:37 AM**

**Agenda October 4, 2018**

**DISCUSSION:**

Change to Agenda:

1. Defer Benzer Pharmacy/Southwick Pharmacy transfer of ownership
2. Defer PSUD Appointment of Pharmacy Technician to the Rehabilitation Evaluation Committee

**ACTION:**

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

Dave introduced the 3 interns: Caitlin Demmett, Northeastern University, Jeffrey Dummon, Western New England University, Thanh Dieu, MCPHS Boston. Dave asked all students in the audience to stand and introduce themselves. Lastly, Dave thanked Dr. Raja for her service and contributions to the Board. This is his last meeting in his term and he will be unable to continue for another term due to scheduling conflicts.

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**Topic III**

**Approval of Board Minutes**

**TIME: 8:40 AM**

**Minutes**

**Draft, September 6, 2018 Regular Session Minutes**

Changes:

1. Page 5, correct spelling of S. Cornacchio
2. Page 6, item 6, P. Gannon was out of room and did not participate, he was not recused

**Action:**

Motion by P. Gannon, seconded S. Hamilton, and voted unanimously to approve the regular session minutes of September 6, 2018 with noted changes.

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**TOPIC IV**

**REPORTS**

**Applications approved pursuant to Licensure Policy 13-01**

**Time: 8:41 AM**

Discussion: M. BOTTO noted that during the past month there have been thirty-two (32) changes of manager on record (MOR) and twenty-two (22) closed pharmacies.

So noted

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**TOPIC IV****REPORTS****Monthly Report from Probation****Time: 8:41 AM**

Discussion: M. BOTTO provided the July 26, 2018 – August 24, 2018, Board of Pharmacy Statistics Report for the Probation monitor, which noted that one (1) licensee was given the opportunity to cure, and that there are currently fifty (50) licensees on probation.

So noted

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**TOPIC IV****REPORTS****Monthly Report from BDCR pursuant to Policy 14-02****Time: 8:42 AM**

Discussion: M.BOTTO noted that during the past month there have been four (4) staff actions for board delegated reviews. The first two were regarding CE deficiencies (SA-INV-13858, SA-INV-13857), the last two being a quality related events (SA-INV-13619 & SA-INV-13616). All staff assignments were closed with discipline not warranted and remediation complete.

So noted

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**TOPIC IV****REPORTS****Above Action Levels Approved by Staff Action 16-04****Time: 8:42 AM**

Discussion: K.MORTON noted that during the past month there were two (2) above action level results, which were successfully remediated and closed pursuant to licensure Policy 16-04.

So noted

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**TOPIC V****Policies and Advisories****Time: 8:44AM****1. Circular Letter Update: CII Partial Filling****Discussion:**

M. CHAN presented this revised document as a result of the newly signed Act for Prevention and Access to Appropriate Care and Treatment. This circular letter updates the partial fill language for Schedule II medications. Instead of schedule II opioid remainders becoming void after patients elect partial fills, the new change will apply to all Schedule II medications and allows partial fills within 5 days of script issuance without the remainder becoming void. The patient must fill the remainder within 30 days, and it can only be filled by the pharmacy that originally filled it. Patients may not be charged any additional payments, including copays.

**Action:** Motion by A. STEIN, seconded by K. TANZER, and voted unanimously by those present, to approve the circular letter revision.

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## **2. Advisory Update: Sale of Hypodermic Syringes**

**Time: 8:45AM**

### **Discussion:**

M. CHAN presented this revised document as a result of the newly signed Act for Prevention and Access to Appropriate Care and Treatment. The revised advisory on the sale of hypodermic needles and syringes removes the age and identification requirements for purchasing these items without a prescription. Before this update, the requirement was proof of at least 18 years of age. M. CHAN also stated another change, which was to add information on syringe and waste disposal that can be given to patients upon purchase. The hyperlink will be changed to the full URL for use in the event of technological issues.

**Action:** Motion by S. HERNANDEZ, seconded by T. FENSKY, and voted unanimously by those present, to approve the advisory update.

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## **3. Policy Update: Naloxone**

**Time: 8:47AM**

### **Discussion:**

M. CHAN presented an update to the naloxone policy as a result of the newly signed Act for Prevention and Access to Appropriate Care and Treatment. A statewide standing order will be issued by DPH and the pharmacist training requirement has been eliminated. Details on the statewide order will be sent out once finalized.

**Action:** Motion by S. HAMILTON, seconded by L. GIAMBARRESSI, and voted unanimously by those present, to approve the policy update.

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**1. Winchester Pharmacy DS89848 Pilot project petition****TIME: 8:48AM**

**Presented by:** Stephen McNeil- Owner, Winchester Pharmacy, William Maguire- Omnicell, Charles Frame- Omnicell

Recusal: M. BOTTO

Discussion: S. MCNEIL presents request for Board Approval to implement a new Omnicell VBM 200F at Winchester Pharmacy, and to waive the pharmacist final patient dispensing process verification, allowing a certified technician to perform the final patient dispensing process verification. S. MCNEIL explains that VBM is located in the pharmacy, uses RFID/Barcoding, photographs and records and documents all steps of filling, and pharmacist is still checking which medications are going into the VBM machine. The end goal of the new machine is to make the pharmacy technician the final checker. S. MCNEIL begins YouTube video and slide show presentation and explains the accuracy and safety of the machine.

P. GANNON expresses concern over pharmacist entering medications and asks if there is a double checking where no duplicate or wrong medication will be entered into the VBM since the pharmacist is manually entering the medication. S. MCNEIL replies that the VBM machine takes photographs from every angle, and also used NDC barcoding, and recognizes the entire barcode and not just part of it, and applies to vitamins as well as OTC medications. S. MCNEIL also indicated that the pharmacist will only enter one bottle at a time to ensure accuracy. This quality assurance measure will increase accuracy and decrease any chance for error.

S.HAMILTON asks if there are any other machines like this implemented in any other sites, and is there sufficient data to support the accuracy of the device. W. MAGUIRE states that there are some devices within the country that have machines that are less sophisticated than the Omnicell VBM 200F, and other pharmacies across the country have this model installed.

L. GIAMBARRESI asked if there is a known error rate for the Omnicell VBM 200F. W. MAGUIRE states that there was a small case study conducted over a three-month period with 60 patients. No pills were damaged, no malfunctions were reported.

M. GODEK asked S. MCNEIL if patients will be notified that a final patient dispensing process verification was conducted by a certified technician, and not a pharmacist. S. MCNEIL indicated that they can notify patients and allow for patients to opt out of the pilot if they choose to.

S. HAMILTON inquired about the training the certified technicians undergo to participate in this pilot, and suggested they complete extra patient safety CE's. S. MCNEIL indicated the certified technicians undergo the same level of training as the pharmacists, and that he would consider requiring extra patient safety CE's.

M. GODEK, S. HAMILTON, T. FENSKY, and P. GANNON express concern that more data collection is necessary in order to review implementation of new technology.



Action: No action taken. Pilot project petition will be taken under advisement. Unanimous decision to perform a 90-day data collection period and return in February 2019 for further advisement.

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**TOPIC VI**

**APPLICATIONS**

**2. Fenway Pharmacy**

**Change of Manager**

**TIME: 9:35AM**

**Presented by:** Joel Itkowite, RPh; Sinclair Lau (Acting Director)

Recusal: None

Discussion: J. ITKOWITE presents to the Board today to request approval in a change of manager. J. ITKOWITE has been a pharmacist since 1999, worked at Walgreens as an MOR and district manager, worked at Cambridge Health Alliance as well, and is currently at Fenway Pharmacy. He has performed a self-inspection has noted no drug losses, no compounding issues, only compounding he does is miracle mouthwash. The pharmacy specializes in HIV patients as well as general patients. States all technicians currently employed are certified.

Action: Motion by T. FENSKY, seconded by L. GIAMBARRESI, and voted unanimously of those present, to APPROVE the application for change of manager.

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**TOPIC VI**

**APPLICATIONS**

**3. Standard Pharmacy @Healthfirst DS89814 Transfer of Ownership TIME: 9:40AM**

**Presented by:** Thomas Cory (Partial Owner); Brian Memeses (Manager of Record and Partial Owner)

Recusal: None

Discussion: T. CORY presents to the Board requesting transfer of ownership. T. CORY is the owner of 2 stores, states that Standard Pharmacy is his second store. Brian is the MOR at the second store, Standard Pharmacy @Healthfirst (DS89814).

Action: Motion by T. FENSKY, seconded by P. GANNON, and voted by unanimously of those present, to APPROVE the application for transfer of ownership

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**TOPIC VI**

**APPLICATIONS**

**4. Bouvier Pharmacy DS90037 Renovation/Expansion**

**TIME: 9:42AM**

**Presented by:** Brian Bouvier (Owner)

Recusal: None

Discussion: B. BOUVIER presents to the Board seeking approval for plans for renovation/expansion. The current building he occupies has two floors, and his pharmacy operates on the first floor. He requests to expand to the second floor due to small work spaces. B. BOUVIER states that all stairwell doors have keypad locks that lock automatically when closed, and doors deadlock after hours. Both floors have security systems, and security monitoring is able to be conducted on either floor, but will mostly take place on the first floor. B. BOUVIER also states that a pharmacist will be present and supervising staff on both floors.

Action: Motion by A. STEIN, seconded by S. HERNANDEZ, and voted unanimously of those present, to APPROVE the application for renovation/expansion.

**TOPIC VI**

**APPLICATIONS**

**5. ACC Apothecare DS3530**

**Renovation/Expansion**

**TIME: 9:50AM**

**Represented by:** Sara Antell- ACC Apothecare, MOR; Arthur Margolis- ACC Apothecare, Owner; Ernie Gates- Gates Healthcare, Consultant; Bob Falk- Gates Healthcare, Contractor

Recusal: A. STEIN

Discussion: S. MANTEL presents to the Board seeking approval for plans for renovation/expansion in order to fall in compliance with upcoming USP <800> non-sterile compounding. States that non-sterile compounding as well as HD compounding is done as well. M. GODEK asks if S. MANTELL has any experience with reconstruction while the pharmacy is open, and what type of risk mitigation will be implemented. S. MANTELL states she has no prior experience with construction going on while working in a pharmacy. Risk mitigation strategy is to work on reconstruction while the pharmacy is closed on the weekends. Also, room will be blocked off from the Rx checking station. New USP <800> room is not vented outside but contains double filter HEPA filtration and negative pressure.

Action: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously of those present, to approve the application for renovation/expansion.

**TOPIC VI**

**APPLICATIONS**

**6. Maida Pharmacy DS2822**

**Renovation/Expansion**

**TIME:**

This renovation/ expansion application has been deferred from the agenda and will be completed by staff action.

**TOPIC VI**

**APPLICATIONS**

**7. Benzer Pharmacy/Southwick Pharmacy DS90050 Transfer of Ownership TIME:**

This transfer of ownership application has been deferred from the agenda

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**TOPIC VII**

**FLEX**

**1. CDTM Advisory Opinion**

**Presented By: W. FRISCH**

**Time: 10:05 AM**

**DISCUSSION:**

Clinical Directors, Amy Vachon and Tanya Iliadis, from Atrius Health, were introduced to the Board by W. FRISCH. The individuals requested an advisory opinion regarding equivalent experience of pharmacists for an ambulatory care vacancy in their CDTM program. Both individuals explained that they found that their best candidates for pharmacists (who are all required to do CDTM training at Atrius Health) were those that have just completed a PGY-1 residency in Ambulatory Care. However, CDTM regulations state that a pharmacist needs 5 years of experience to perform CDTM. The individuals requested that 1 year of a PGY-1 ambulatory residency, in conjunction with their extensive training program, be deemed equivalent to 5 years of experience for this one case.

K. TANZER asked if they are hiring candidates who have completed the Atrius residency program. The individuals replied that they were not, since their residency program is very small. A large percentage of their pharmacists are external hires.

**ACTION:** Motion by P. GANNON, seconded by A. STEIN, and voted by those present to approve of the equivalency. K. TANZER opposed the motion.

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**2. FDA 50 State Compounding Meeting Update**

**Presented By: W. FRISCH and M. CHAN**

**Time: 10:14 AM**

**DISCUSSION:**

W. FRISCH discussed how he and M. CHAN attended the 50 State 2018 FDA Intergovernmental Working Meeting on Compounding at the FDA headquarters recently. As panel members, W. FRISCH and M. CHAN presented the current progress on draft regulation 247 CMR 17, which will strengthen sterile compounding in the Commonwealth.

W. FRISCH mentioned that there was a review of several FDA guidance and policy documents at the meeting:

- Compounding Commercially Available Medications
- Insanitary Conditions in Compounding Pharmacies
- Compounding with Bulk Drug Substances

- Distribution of Compounded Human Drug Products (memorandum)
  - Outsourcing Facility Oversight Guidance on Compounding and Repackaging of Radiopharmaceuticals
  - Drug Supply Chain Security Act
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### **3. NABP Executive Director Forum Update**

**Presented By: D. SENCABAUGH**

**Time: 10:16 AM**

#### **DISCUSSION:**

D. SENCABAUGH discussed his recent visit to the NABP Conference in Illinois; where there were over 35 Executive Directors present (some of them from Canada).

D. SENCABAUGH appreciated the opportunity to hear ideas and practices from some peers. Topics discussed included opioid drug company lawsuits, disaster plans; CE Monitor for Board approved CEs, investigative strategies as well as various FDA topics.

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### **4. NABP District 1 & 2 Meeting Update**

**Presented By: L. GIAMBARRESI**

**Time: 10:19 AM**

#### **DISCUSSION:**

L. GIAMBARRESI mentioned that there was good representation from both districts at the meeting. Task forces were created for the following:

- Pharmacy technician licensing exams
- Drug losses in transit
- Standardization of 503B drug recalls
- Standardized collaboration between pharmacies and prescribers (if sending new dose of a medication, mention that an old dose is being discontinued)

T. FENSKY and P. GANNON mentioned that there will have to be more backing on the collaboration between pharmacies and prescribers.

L. GIAMBARRESI mentioned that 2 of the resolutions were backed by NABP.

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### **5. Commonwealth Performance Recognition Award: Michelle Chan**

**Presented By: D. SENCABAUGH**

**Time: 10:22 AM**

#### **DISCUSSION:**

On an annual basis, the Commissioner recognizes a member of each bureau that consistently goes above and beyond his/her job description. In 2018, the Bureau of Health Professions Licensure recipient was Quality Assurance Pharmacist Michelle Chan.

D. SENCABAUGH mentioned that every action M. CHAN takes is related to protecting the public. She is great at multitasking and an unsung hero here at the Bureau.

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## **6. Update on AP Passport Pilot Project**

**Presented By: E. TAGLIERI**

**Time: 10:25 AM**

### **DISCUSSION:**

E. TAGLIERI brought to the Board's attention that the Director of Pharmacy involved with the AP Passport pilot project was planning to slow the process of expanding to other nursing facilities.

- Defer deployment date to early 2019 to ensure proper training for success.
  - The Director of Pharmacy will keep the Board updated via E. TAGLIERI.
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## **7. PSUD REC Committee Appointment**

**Topic was deferred.**

**Time: 10:26 AM**

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## **8. Bowl of Hygeia Award: David Sencabaugh**

**Presented By: E. TAGLIERI**

**Time: 10:26 AM**

### **DISCUSSION:**

E. TAGLIERI explained the significance of the Bowl of Hygeia. E. TAGLIERI then read a speech that was read at the awards ceremony for the 2018 recipient, David Sencabaugh.

D. SENCABAUGH was awarded for his outstanding work at the Board and dedication to the profession.

E. TAGLIERI, as well as other Board members/staff, shared their stories and gratitude for D.

SENCABAUGH and believed that the award was well deserved.

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## **TOPIC VIII: VIOLATION OF PROBATION**

### **1. CVS #257 DS3331 PHA-2018-0006 & PHA-2018-0017**

**Time: 10:35 AM**

**Presented by:** Karen Fishman

RECUSAL: None

### DISCUSSION:

- The underlying issues are related to drug losses at this pharmacy.
- Terms of the probation:
  - A retraining plan was to be completed – this has been submitted
- Probation violation:
  - POC submitted late.
  - CII returns were not being reconciled every 10 days
  - Temperature logs for the months of July and August were missing entries
  - One pharmacist CPR certification was expired on August 2018. However, he administered a vaccination during the inspection.
  - No immunization training certificates or CPR training cards were available for any pharmacist.

ACTION: Motion by S. HERNANDEZ, seconded by T. FENSKY, and voted unanimously by those present to extend probation by 2 months. Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present to open a staff action on the MOR.

**2. CVS #2299 DS3596 PHA-2016-0237**  
**Presented by:** Karen Fishman

**Time:** 10:54 AM

RECUSAL: None

DISCUSSION: Deferred to November Board meeting.

ACTION: Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously by those present to defer until another inspection is completed before November 2018.

**TOPIC IX: REGULATIONS**

**1. 247 CMR 17.00 Sterile Compounding**

**Time:** 11:00 AM

**Presented by:** W. FRISCH, M. CHAN and H. ENGMAN

DISCUSSION:

- W. FRISCH reminded everyone that there will be a nighttime meeting on October to discuss the draft regulation of 247 CMR 17 and further address the public comments. The plan after that is to bring a revised draft to the November Board meeting, then have a final vote on a final version at the December Board meeting.
- While W. FRISCH read the public comments on each section, M. CHAN took note of the Board's decisions/suggestions.
- 17.13 (9)(d): W. FRISCH felt that USP <825> should be dealt with separately. P. GANNON suggested making this section a best practice, as opposed to a regulation. T. FENSKY agreed with this statement. W. FRISCH mentioned that there should be mention of a HEPA filter for negative pressure, and that maybe that could be addressed in 247 CMR 19.
  - Motion by P. GANNON, seconded by A. STEIN, and voted unanimously by those present to strike section and publish as a best practice recommendation.

- 17.14 (5): T. FENSKY suggested that the language should stay the same, and that licensees should show control and apply for a waiver as needed.
    - No motion necessary.
  - 17.15 (1)(a): W. FRISCH mentioned that some states require an area minimum (i.e. NJ has a minimum requirement of 100 square feet). Currently, the requirement is a minimum of 72 square feet. W. FRISCH stated that this requirement would be more for new constructions, with a grandfathering provision/wavier if not meeting the requirement. T. FENSKY suggested a minimum requirement of 100 square feet, then the licensee can apply for a waiver if wanted. H. ENGMAN expressed concern that the Board cannot be accepting so many waivers.
    - Motion by T. FENSKY, seconded by J. LANZA, and voted unanimously by those present to have a minimum requirement of 100 square feet.
  - 17.15 (2)(d): Reduce size to 72 square feet and include grandfathering provision related to renovations or new builds, with a waiver process available.
    - Motion by T. FENSKY, seconded by J. LANZA, and voted unanimously by those present to have a minimum requirement of 72 square feet.
  - 17.21 (1) & (2): T. FENSKY suggested to have the Advisory Committee provide guidance. D. SENCABAUGH agreed, suggesting the section be left as-is until hearing from the Advisory Committee.
  - 17.22 (3): T. FENSKY and P. GANNON both suggested to strike the entire section.
    - Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present to strike the section.
- 17.23 (1)(c): P. GANNON suggested changing the section to have smoke-study “with each PEC certification or recertification.”
- Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously by those present to accept the recommendation.
- 17.24 (7): Strike section (j), ask Advisory Committee to review section (d), add “contaminated CSP” on section (h), defer section (g) to meeting on October
    - No motion was made.
  - 17.34 (3): T. FENSKY requested to reword the term “glove failure” and the frequency. W. FRISCH said that the Board staff will redefine/reword this.
    - Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously by those present to accept the changes.
  - 17.34 (6): Section will be reworked to include “GFS after completing daily compounding” in best practices.
    - No motion was made.
  - 17.35: Align with GFS frequency.
    - No motion was made.
  - 17.40 (1): Will be discussed further, to come to agreement on a certain number of packages, at the meeting on October .
  - W. FRISCH said at the meeting on October , the Board will go through the remainder of the 247 CMR 17 public comments, then go over them all quickly once more.

**TOPIC X****FILE REVIEW**

Case #1

PHA-2018-0041 Omnicare of Northern MA, DS89931

Time: 12:10 PM

RECUSAL: NONE

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

- Omnicare reported on 5/8/18 and on 5/17/18, an in-transit loss of multiple CII-IV's in a narcotic kit and on unknown loss of 3 fentanyl 25 mcg/hr patches, respectively.
- CA for in transit loss – Omnicare reported the in-transit loss to UPS. UPS investigated the loss but was informed the pharmacy that they were “not able to recover” the shipment. Omnicare now requires LTC facilities to include their email in the tracking number report, so they have real time access to delivery status of used and outdated kits being shipped from the facility to Omnicare.
- CA for unknown loss - Omnicare’s evening narcotic pharmacist “reset expectations with the pharmacy team around performing back counts and maintaining accuracy of the perpetual inventory after each dispense.”

ACTION: Motion by A. STEIN, seconded by P. GANNON, and voted unanimously by those present, to DISMISS the matter (PHA-2018-0041) upon receipt of a more robust POC to include delivery procedures of e-kits via common courier arranged by Omnicare.

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Case #2

PHA-2018-0052 CVS #1889, DS2816

Time: 12:24 PM

RECUSAL: NONE

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

- RLCS-unknown loss of #60 amphetamine ER 20mg capsules on or about March 17, 2018
- An investigation concluded on April 13, 2018 was reported back to the DEA indicating that there was no theft or significant loss of controlled substances at this Pharmacy, based on CVS's interpretation of the DEA's criteria for significant.
- The loss was discovered on March 17, 2018 when a patient came into the pharmacy to pick up his prescription for #60 amphetamine ER 20mg capsules and the pharmacy team could not locate the prescription in the waiting bin.
- Video footage from the date of fill (3/13/18) until the time of pickup did not reveal any evidence of internal theft however, it was discovered that there was limited camera coverage on the waiting bins and no camera coverage on the actual waiting bin in which the script was placed.
- Technicians were reminded to make sure they are putting the prescription in the correct alphabetical slot in the waiting bin and were retrained on waiting bin and POS procedures. Cameras were adjusted to improve coverage on the waiting bins and the disconnected camera is now connected to the DVR and operating properly.



ACTION: Motion by A. STEIN, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2018-0052) 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.

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Case #3

PHA-2018-0051

CVS #844, DS1402

Time: 12:26 PM

RECUSAL: NONE

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

- RLCS- #523 clonazepam 0.5mg tablets on or about May 15, 2018, discovered after the 2018 biennial inventory in which the inventory flagged a possible drug loss.
- Loss believed to be due to poor counts during an acquisition in October 2017 and inaccurate count in the 2017 biennial inventory.
- Reconciliation report was provided by Loss Prevention for clonazepam 0.5mg tablets
- MOR will review weekly Pharmacy Balance on Hand and Order Adjustment Reports and work in tandem with Asset Protection to help better identify inventory areas of concern and help prevent any further drug losses. All baseline loss prevention procedures were reviewed with staff. This includes diligent inventory management and dispensing standards.

ACTION: Motion by A. STEIN, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2018-0051) 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 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.

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Case #4

PHA-2018-0057

CVS #1870, DS90040

Time: 12:29 PM

RECUSAL: NONE

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

- RLCS-unknown loss of #100 oxycodone 5mg tablets on or about June 7, 2018 loss was discovered during routine count on June 7, 2018
- There were four prescriptions for oxycodone 5mg tablets filled between the time of the state count on June 02, 2018 and cycle count on June 07, 2018. An attempt was made to contact the patients who received the two most recent fills prior to the discovery of the loss. A voice mail was left for the first patient who did not call back. The second patient's contact information was not up to date and therefore was unable to contact that patient.

- All pharmacist who work in the Pharmacy, including the visiting pharmacist, were retrained on the proper procedures when filling prescriptions for Schedule II controlled substances. Pharmacists were encouraged to count the medication prior to filling the prescription to ensure that it matches the perpetual inventory. Pharmacist were also asked to calculate how much medication will remain after filling the prescription and then perform a back-count to ensure that it matches the calculated amount. A final check of the perpetual inventory is encouraged to make sure it matches.
- CVS Pharmacy #1870 has no prior losses dating back to 2013 and a retail compliance inspection (ISP-8698) conducted on 11/15/2017 was deemed satisfactory.

**ACTION:** Motion by A. STEIN, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2018-0057) 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.

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Case #5

PHA-2018-0050

CVS #714, DS3299

Time: 12:31 PM

**RECUSAL:** NONE

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

- RLCS-unknown loss of #4614 mls of promethazine-codeine syrup discovered when Asset Protection received corporate system notification of adjustments to the BOH from cycle counts.
- Loss Protection provided a reconciliation report from the Biennial/Annual Inventory on 05/01/2017 to 06/13/2018 for a variance of -4758 ml syrup.
- Loss Prevention identified a lack of adherence to security controls in the pharmacy which included: pharmacist exiting the pharmacy into the receiving area while wearing lab coats; the control safe left open for extended periods of time; excessive amounts of personal belongings stored in the pharmacy; and lack of controls when receiving orders from their wholesale distributor (totes left unattended on the drop-off counter).
- All Staff pharmacist will be printing the Sunday Red Flag report and immediately contacting Loss Prevention in the event there are any unexplained changes to the BOH. Attention will be placed on all store generated cycle counts and any unexplained store generated negative cycle counts or any order adjustments that are unreasonably above dispensing need will be reported to the District Asset Protection Leader. Promethazine -codeine Syrup has been relocated in the Pharmacy so that it is in clear sight of the pharmacist at the verification station.
- The MOR will conduct random spot checks over the next 12 months. MOR has reinforced security controls with all Pharmacy staff which includes that all controlled drug safes are secured when not filling a prescription for a controlled substance medication, ensuring no personal belongings are brought into the Pharmacy and requiring all pharmacy team members to remain vigilant to guard against the diversion of controlled substances. District Asset Protection Manager will continue to monitor adherence to the security controls identified in the investigation

**ACTION:** Motion by S. HERNANDEZ, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2018-0050) 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 one 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 promethazine with codeine 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. Also, all staff read and attest to the CVS Loss Prevention policy.

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Case #6

PHA-2018-0058

CVS #665, DS1198

Time: 12:38 PM

RECUSAL: NONE

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

- RLCS- #1,134 tramadol 50 mg tablets on or about June 5, 2018, discovered by the DAPL during a Health Assessment at the pharmacy. DAPL was reviewing the red flag report and noticed multiple negative variances for tramadol 50mg going back to March 2018
- Loss Prevention team assisted in the investigation to determine if the loss was due to diversion. Counts were conducted daily and reconciliation were performed weekly without any additional variances. The Loss Prevention team was able to rule out active losses or diversion by current team members, however an explanation of the loss was not uncovered
- MOR reviewed applicable CVS policy and procedures regarding drug loss prevention with all pharmacy staff and have taken the following corrective action to prevent future variances: the current daily counts of controlled substances will be conducted by the pharmacist only, and will be hand counted to ensure accuracy
- MOR will ensure all controlled substance drug handling policies are adhered to without exception. This includes making sure no bags, purses, jackets, and other personal belongings are brought into the pharmacy, double counting all controlled substances and ensuring drug orders placed and received are appropriate to dispensing levels
- A new "red flag" report was added to the current BOH report which will highlight any adjustments made that are outside acceptable and reasonable guidelines. This report will be available to the pharmacist weekly and will allow the Pharmacy to immediately reach out to Loss Prevention team if any diversion is suspected

ACTION: Motion by A. STEIN, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2018-0058) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION for a period of one 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 tramadol 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. Also, all staff read and attest to the CVS Loss Prevention policy.

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Case #7

PHA-2018-0033

CVS #1866, DS2956

Time: 12:42 PM

RECUSAL: NONE

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

- RLCS loss of #349 tramadol 50 mg tablets on 01/17/2018 and loss of #100 oxycodone/acetaminophen 10/325 mg tablets due to a suspected dispensing error on 02/01/2018; Loss of tramadol 50mg identified via CVS corporate controlled substance monitoring; internal investigation included review of cycle counts, biennial inventories, staffing schedules and inventory reports and could not identify the reason for the loss; Loss of oxycodone/acetaminophen 10/325mg was identified during a cycle count on 2/2/18
- Internal investigation included review of the perpetual inventory with DEA 222 forms and invoices viewed video
- Of 6 prescriptions dispensed since the last perpetual inventory on 1/27/18, only 5 patients who had been dispensed oxycodone/acetaminophen 10/325mg on 1/31/18 and 2/1/18 were contacted and no one claimed to have received an extra 100 tablets; one patient did not respond, and the Pharmacy suspected he received the over-dispense. Production and verification Pharmacist Boulger alleged there were multiple distractions causing her to possibly add an extra 100 tablets to the suspected patient's prescription fill on 2/1/18.
- CA: CVS policies and procedures reviewed with the pharmacy team and the pharmacist will double count all controlled substances prior to dispensing
- MOR will monitor all medication counts; back counting of CII stock bottles with back count noted on the prescription hardcopy
- MOR Owens completed 2 CEs in safe use of opioids and dispensing of high-alert medications
- Pharmacist Boulger completed 2 CEs in prevention of medication errors and attested to reviewing 247 CMR 15; copy of CVS policy on the production of prescriptions signed by pharmacy team submitted.

ACTION: Motion by S. HERNANDEZ, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2018-0033) 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.

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Case #8

SA-INV-13378

Walgreens #2471, DS3536

Time: 12:45 PM

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

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

- 5/3/18 – Complaint from Former MOR Wisocky alleging the Store Manager entered the pharmacy after hours on 2/26/18 without a pharmacist present to retrieve a POC due on 2/27/18; Former MOR Wisocky and PT Lougee were made aware of the incident on 2/27/18 when the Store Manager (unlicensed) told them she had entered the pharmacy with the Shift Leader (unlicensed) on 2/26/18 after being directed by DM Deleppo (unlicensed) to find the POC
- Former MOR Wisocky contacted Walgreens Loss Prevention regarding the incident and was told there was no Walgreens policy, but it was against the law; PT Lougee provided a statement corroborating

Former MOR Wisocky's allegation indicating DM Deleppo directed the Store Manager to enter the Pharmacy to obtain the POC

- PT Cintron attempted to obtain video footage of the incident, but could not gain access to the office computer and was later questioned about her actions by Walgreens Loss Prevention; Current MOR Mujukian provided a response supporting Former MOR Wisocky's allegation
- The Store Manager admitted to entering the Pharmacy when the Pharmacy was closed in the presence of the Shift Leader to obtain the POC, but was unaware that it was against company policy
- CA: The Store Manager was given a final written warning during a meeting with DM Deleppo and Walgreens Loss Prevention.

ACTION: Motion by T. FENSKY, seconded by K. TANZER, and voted unanimously by those present, to CLOSE SA-INV-13378, No Discipline Warranted upon receipt of a copy of a memo sent to all Massachusetts licensed pharmacies reminding staff about the policy on unlicensed staff in the pharmacy.

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Case #9

SA-INV-12803

Rite Aid #10205, DS2573

Time: 12:51 PM

RECUSAL: M. GODEK 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 of #100 oxycodone HCL 10mg tablets and #100 oxycontin 80mg tablets, which was later amended to include #633 alprazolam 1mg tablets, #1,204 alprazolam 2mg tablets, #338 clonazepam 1mg tablets, #75 dextroamphetamine-amphetamine salts ER 20mg capsules, #65 morphine sulfate ER 200mg tablets, and #999 tramadol 50mg tablets.
- MOR indicated that on December 30, 2017, the loss of #100 oxycodone HCL 10mg tablets and #100 oxycontin 80mg tablets was discovered. Asset Protection District Manager reviewed video footage of the day before and observed a pharmacy technician trainee turning the camera away from the CII safe and bench. The statement indicated that the technician trainee was interviewed and admitted to moving the camera but did not admit to taking any drugs.
- After terminating the technician trainee, a full controlled substance inventory was taken, resulting in the additional reported losses.
- A retail compliance inspection was conducted on March 20, 2018 with no deficiencies noted.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to convert SA-INV-12803 to complaint.

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**Topic XI**

**EXECUTIVE SESSION**

**Time: 12:59 PM**

**Read by M. Godek**

DISCUSSION:

ACTION: At 12:59 PM President M. GODEK read the statement on reasons for Executive Session.

**1:00 PM to 2:00 PM Lunch Break**

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**Topic XI: Executive Session Call to Order:**

**Time: 2:00 PM**

By: M. Godek

ACTION: Motion by P. Gannon, seconded by A. Stein, and voted unanimously by roll call to call the October 4, 2018 meeting of the Executive Session to order.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; S. Hernandez, yes; J. Lanza, yes; P. Gannon, yes; T. Fensky, yes; A. Raja, yes; S. Hamilton, yes; L. Giambarresi, yes, M. Godek, yes

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**Topic XII:**

**M.G.L. 65 C**

**Time: 3:29 PM**

DISCUSSION: None

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

At 3:29 PM, Motion by P. Gannon, seconded by T. Fensky and voted unanimously to enter M.G.L. chapter 65 c Session:

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**Topic XIII:**

**ADJOURNMENT OF MEETING**

**TIME: 4:27 PM**

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

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EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 10/4/18 General Session
2. Draft Minutes of the 9/6/18 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. Winchester Pharmacy Pilot Project Petition to Board DS89848
8. Fenway Pharmacy DS89656 Change of Manager
9. Standard Pharmacy @ Heathfirst DS89814 Transfer of Ownership
10. Bouvier Pharmacy DS90037 Renovation/Expansion
11. ACC Apothecary DS3530 Renovation/Expansion
12. CDTM Advisory Opinion
13. Violation of Probation: CVS 257; DS3331; PHA-2018-006 & PHA-2018-0017
14. Violation of Stayed Probation: CVS 299; DS3596; PHA-2016-0237
15. 247 CMR 17.00 Sterile Compounding Grid Public Comments

16. PHA-2018-0041 Omnicare of Northern MA DS89931
17. PHA-2018-0052 CVS #1889 DS2816
18. PHA-2018-0051 CVS #844 DS1402
19. PHA-2018-0057 CVS #1870 DS90040
20. PHA-2018-0050 CVS #714 DS3299
21. PHA-2018-0058 CVS #665 DS1198
22. PHA-2018-0033 CVS #1866 DS2956
23. SA-INV-13378 Walgreens #2471 DS3536
24. SA-INV-12803 Rite Aid #10205 DS2573

Respectfully Submitted,  
Kim Tanzer, PharmD, RPh  
Secretary