

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

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

October 3, 2019  
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 Yulanda Kiner, Phone: 617-624-5848 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>
<b>8:30</b>	<b>I</b>	<b>CALL TO ORDER</b>		A. Stein
	<b>II</b>	<b>APPROVAL OF AGENDA</b>	<b>1</b>	
<b>8:40</b>	<b>III</b>	<b>APPROVAL OF BOARD MINUTES</b> <ul style="list-style-type: none"> <li>• Draft of September 5, 2019 Regular Session Minutes</li> <li>• Introduction of Interns:               <ul style="list-style-type: none"> <li>○ Luis Figueroa- Northeastern University</li> <li>○ Olivia Vuong (MCPHS)</li> <li>○ Ryan Davis – Northeastern University</li> </ul> </li> </ul>	<b>4</b>	
<b>8:45</b>	<b>IV</b>	<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> <li>• PSUD Report-Policy 17-03</li> </ul>	<b>23</b> <b>25</b> <b>26</b>	
<b>8:50</b>	<b>V</b>	<b>POLICIES and ADVISORIES</b> <ul style="list-style-type: none"> <li>• Policy 2019-01: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing, and Tele-pharmacy</li> <li>• Joint Policy 2019-06: Compounded Emergency Medications for Veterinarian Use</li> </ul>	<b>27</b> <b>33</b>	W. Frisch  M. Chan

<b>9:20</b>	<b>VI</b>	<b>APPLICATIONS</b>			
		<ul style="list-style-type: none"> <li>Winchester Pharmacy (DS89848) Pilot Program update and extension request</li> </ul>		<b>35</b>	
		<ul style="list-style-type: none"> <li>Brighton Pharmacy (DS89908 )- Relocation</li> </ul>		<b>36</b>	
		<ul style="list-style-type: none"> <li>Capsule Pharmacy Boston – New Community Pharmacy</li> </ul>		<b>46</b>	
		<ul style="list-style-type: none"> <li>Cambridge Health Alliance Specialty Pharmacy- New Community Pharmacy</li> </ul>		<b>60</b>	
<b>10:00</b>	<b>VII</b>	<b>FLEX</b>			
		<ul style="list-style-type: none"> <li>2019-2020 Board meeting dates</li> </ul>		<b>105</b>	
		<ul style="list-style-type: none"> <li>2020 Board officers</li> </ul>			
		<ul style="list-style-type: none"> <li>NABP District I &amp; II Meeting Summary</li> </ul>			
		<ul style="list-style-type: none"> <li>Pharmacy Advisory Committee meeting- October 30 2019 9:00 – 10:30 am</li> </ul>		<b>106</b>	
		<ul style="list-style-type: none"> <li>Nicotine Replacement Therapy</li> </ul>		<b>107</b>	
		<ul style="list-style-type: none"> <li>105 CMR 721.000: ePrescribing regulations</li> </ul>		<b>109</b>	
		<ul style="list-style-type: none"> <li>Implementation of revised USP chapters</li> </ul>		<b>116</b>	
<b>10:30</b>	<b>VIII</b>	<b>INVESTIGATIVE CONFERENCE</b>			
		<ul style="list-style-type: none"> <li>Baystate Pharmacy-DS89896; SA-INV-14965</li> </ul>		<b>118</b>	
<b>11:30</b>	<b>IX</b>	<b>FILE REVIEW</b>			
		1	SA-INV-15068	Stephanie Kochan, PH19741	<b>123</b>
		2	PHA-2019-0074	Walgreens #4393, DS2882	<b>124</b>
		3	PHA-2019-0075	Walgreens #3508, DS2527	<b>127</b>
		4	PHA-2019-0069	CVS #719, DS1906	<b>130</b>
		5	PHA-2019-0025	CVS #75. DS3535	<b>133</b>
		6	PHA-2019-0062	CVS #7232, DS3461	<b>137</b>
		7	PHA-2019-0073	CVS #946, DS3442	<b>140</b>
		8	PHA-2019-0076	CVS #155, DS2471	<b>142</b>
		9	PHA-2018-0015	Preferred Pharmacy Solutions, DS3542	<b>145</b>
<b>12:30</b>	<b>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, consider a petition for reinstatement and to evaluate the Good Moral Character as required for registration for pending applicants.	<b>157</b>	
<b>2:30</b>	<b>XI</b>	<b>ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)</b>	<b>234</b>	
<b>3:00</b>	<b>XII</b>	<b>M.G.L. c. 112, § 65C SESSION</b>	<b>255</b>	
<b>5:00</b>	<b>XIII</b>	<b>ADJOURNMENT</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 3, 2019**

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**Board Members Present**

Andrew Stein, Pharm D, RPh. President  
Kim Tanzer, PharmD, RPh. President Elect  
Julie Lanza, CPhT, Secretary  
Sebastian Hamilton, Pharm D, RPh  
Stephanie Hernandez, Pharm D, BCGP, RPh  
Susan Cornacchio, JD, RN (arrives 8:35 AM)  
Patrick Gannon, RPh  
Timothy Fensky, RPh  
Michael Godek, RPh  
Dr. Richard Lopez, MD

**Board Members Not Present**

Dawn Perry, JD  
Carly Jean-Francois, RN, NP  
Leah Giambarresi, Pharm D, RPh

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Heather Engman, JD Board Counsel  
William Frisch, RPh Director of Pharmacy Compliance  
Michelle Chan, RPh Quality Assurance Pharmacist  
Joanne Trifone, RPh., Director of Pharmacy Investigations  
Joanna Chow, CPhT, Office Support Specialist  
Julienne Tran, Pharm D, RPh Investigator  
Gregory Melton, Pharm D, RPh Investigator  
Christina Mogni, 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 8:31 AM**

A quorum of the Board was present, established by roll call. President A. Stein 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; J. Lanza, yes; M. Godek, yes; S. Hernandez (yes);  
P. Gannon, yes; S. Hamilton, yes; T. Fensky, yes; R. Lopez, yes;  
S. Cornacchio arrives at 8:25 after vote

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**Topic II.**

**Approval of Agenda**

**TIME 8:32 AM**

**Agenda October 3, 2019**

**DISCUSSION:**

Change to Agenda:

1. None

**ACTION:**

Motion by M. Godek, seconded by S. Hamilton and voted unanimously by those present to approve the agenda with noted change.

Ed introduces the APPE students on rotation at the Board: Luis Figueroa and Ryan Davis, Northeastern University; Olivia Vuong, MCP SH Boston.

Andy then asks for the Pharmacy Students in the audience to stand and introduce themselves.

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**Topic III**

**Approval of Board Minutes**

**TIME: 8:35 AM**

**Minutes**

**1. Draft, September 5, 2019 Session Minutes**

No noted Changes.

**Action:**

Motion by M. Godek, seconded S. Hamilton, and voted unanimously to approve the regular session minutes of September 5, 2019 with no noted changes.

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**TOPIC IV**

**REPORTS**

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

**Time: 8:34 AM**

**Discussion:** E. TAGLIERI noted that there have been twenty-two (22) Change of Managers and two (2) pharmacy renovations applications and one (1) new community pharmacy application approved pursuant to Licensure Policy 13-01.

So noted

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**TOPIC IV**

**REPORTS**

**Monthly Report from Probation**

**Time: 8:34 AM**

**Discussion:** E. TAGLIERI provided the August 24, 2019 – September 25, 2019 Pharmacy Board Probation Monthly Report, which noted that five (5) licensees satisfactorily completed probations, twenty-six (26) year-to-date completions and there are currently twenty-seven (27) licensees on probation.

So noted

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**TOPIC IV**  
**Monthly Report from BDR pursuant to Policy 14-02**

**REPORTS**

**Time: 8:35 AM**

**Discussion:** E. TAGLIERI noted that there was one (1) Board Delegated Review case heard on September 27, 2019. The case was a CE self-disclosure (SA-INV-15309) which was closed with discipline not warranted and remediation complete. The Board Delegated Review session was attended by A.STEIN as the Board Member, W. FRISCH Director of Pharmacy Compliance, M.CHAN as Quality Assurance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

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**TOPIC IV**  
**Above Action Levels Approved by Staff Action 16-04**

**REPORTS**

**Time: 8:35 AM**

**Discussion:** E. TAGLIERI noted that no above action level reports have been closed since last Board meeting pursuant to Licensure Policy 16-04.

So noted

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**TOPIC IV**  
**PSUD Report by Staff Action 17-03**

**REPORTS**

**Time: 8:35 AM**

**Discussion:** E. TAGLIERI noted that in September 2019, there was one (1) inquiry with application mailed, and fifteen (15) active participants.

So noted

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**TOPIC V**  
**Policies and Advisories**

**1. Policy 2019:01: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing and Telepharmacy**  
**Presented by: M. CHAN**

**Time: 8:37 AM**

**Discussion:** Policy 2019-01 on Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing, and Telepharmacy, was edited to provide minimum standards for telepharmacy. A. STEIN expressed his concern for the definition of telepharmacy and how it applies across all pharmacy settings.

**Action:** Motion by S. HAMILTON, seconded by K. TANZER, and voted by the majority of those present to approve the telepharmacy addition to Policy 2019-01. A. STEIN voted against this action.

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**2. Joint Policy 2019-06: Compounded Emergency Medications for Veterinarian Use**

**Time: 8:40 AM**

**Presented by: M. CHAN**

**Discussion:** Joint Policy 2019-06 on Compounded Emergency Medications for Veterinary Use, would allow Board-licensed pharmacies to dispense limited quantities of compounded medications to veterinarians for emergency use. Among other requirements, the compounded medications provided

may only include schedule VI drugs, and patient-specific prescriptions must be issued for each medication administered and/or dispensed.

**Action:** Motion by M. GODEK, seconded by T. FENSKY, and voted unanimously by those present to approve the new joint policy.

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**TOPIC VI**

**APPLICATIONS**

**1. Winchester Pharmacy DS89848**

**Pilot Project**

**TIME: 8:40 AM**

REPRESENTED BY: Ed Taglieri

RECUSAL: None

DISCUSSION: E. TAGLIERI discussed the pilot project being conducted by Winchester Pharmacy. Winchester's CEO/President's requested for an extension until February 29th, 2020, due to personal medical concerns/procedures. This extension will provide the continuation of the same project/protocol, thus allowing Winchester Pharmacy to provide monthly reports on the accuracy of their omniceil for multi-dose packaging. Winchester Pharmacy will continue to conduct their 10% RPh verification check on all adherence cards, which is validated by the VBM. E. TAGLIERI noted that Winchester's reports for July, August, and September provided monthly accuracy data for all of adherent cards which reported to have a 0% error rate.

ACTION: Motion by T. FENSKY, seconded by S. HERNANDEZ, voted unanimously by those present to approve the request for an extension until 02/29/2020.

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**2. Brighton Pharmacy DS89908**

**Relocation**

**TIME: 8:43 AM**

REPRESENTED BY: Paul Garbarini (Attorney,) Igor Kuzmin (Proposed Manager of Record)

RECUSAL: None

DISCUSSION: Brighton Pharmacy is seeking to relocate in Brighton, MA. A. STEIN inquired about the plan and reason for relocation. P. Guarini stated that a draft layout of the pharmacy will be submitted to the Board. Brighton Pharmacy stated they are seeking to operate in a new location that is closer to public transportation for patient ease of access. M. GODEK expressed concern regarding patient continuity of care and inquires. Patients will receive a hand-stapled notice on each prescription bag at least 14 days prior to relocation and a notice will be on the website. Applicant needs to circle will/will not on page 6 of application and res submit.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, voted unanimously by those present to approve the relocation application pending a successful inspection.

**3. Capsule Pharmacy Boston New community Pharmacy**

**TIME: 8:55 AM**

REPRESENTED BY: Jeff Garlewicz, (Head of Pharmacy Operations)

RECUSAL: None

DISCUSSION: Capsule Pharmacy is seeking to operate in the Commonwealth of Massachusetts. J. Garlewicz stated that Capsule Pharmacy will be using the same model that is being utilized in the original location in New York. He explained that Capsule Pharmacy follows a basic model, provides delivery (same day delivery), and utilizes technology such as their app, phone calls, and emails provide access to the pharmacy in a private manner.

Further questions were followed by this discussion:

P. GANNON asked to elaborate on the “apps” and how it is used to communicate with the pharmacy; J. Garlewicz explained the Capsule Pharmacy has its own HIPAA compliant app which patients can use to chat with technicians/pharmacists, request refills, check on statuses of their prescriptions, etc.,

A. STEIN asked about support staff; J. Garlewicz explained that the MOR resides in MA and will be in charge of the day to day pharmacy operations. He states that the current support staff consists of a staff pharmacist, and that the rest of the support staff is soon to be established.

A. STEIN also asked about the delivery services and if these services are compliant with HIPAA; J. Garlewicz explains that all delivery personnel involved in the delivery service (i.e. pharmacy to patient) are Capsule Pharmacy HIPAA trained employees, and that they do not utilize any outsource delivery companies.

P. GANNON also inquired about the tracking mechanism that the pharmacy uses for their deliveries; J. Garlewicz explained that their logistics team keeps track of the delivery orders and that they utilize scanning/barcodes as well as electronic signatures which is then relayed back to the pharmacy system. He also added that the vehicles they use for transportation contains no branding (i.e. no Capsule Pharmacy logo), no personal or medication information is seen (Capsule Pharmacy utilizes brown bags to cover any patient information), in order to preserve safety and privacy.

M. GODEK asked J. Garlewicz where he is based and how the MOR will be able to communicate with him about operations; J. Garlewicz explains that although he resides in NJ, MOR will be reporting to him, and if approved, during the start of the new pharmacy, Garlewicz will be visiting the pharmacy on a monthly basis.

ACTION: Motion by S. HAMILTON, seconded by K. TANZER, voted unanimously to approve the application for the new community pharmacy.

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**4. Cambridge Health Alliance Specialty New Community Pharmacy TIME: 9:05 AM**

REPRESENTED BY: Kenneth Hanlon, (Manager of Operations) Kate Magro, (Proposed Manager of Record)

RECUSAL: None

DISCUSSION: Kenneth Hanlon, Manager of Operations and Kate Magro, Proposed Manager of Record is seeking to operate a new specialty pharmacy in Malden, MA that will be modeled after Cambridge Health Alliance Pharmacy. P. GANNON inquired about the location of the new pharmacy. K. Margo



explained the new pharmacy will be located on the 6th floor of an office building and will require badges to gain access to the premise. K. Magro noted that there will be a separate call center located adjacent to the pharmacy where technicians will carry out customer service related tasks, a pharmacist will be present. They plan to apply for specialty accreditation.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present to approve the application pending a successful inspection.

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**5. VRx Solutions**

**New community Pharmacy**

**TIME: 9:14 AM**

REPRESENTED BY: Yung-En Fung, (Proposed Manager of Record.) Vimal Patel, (Manager of Record.)

RECUSAL: None

DISCUSSION: VCare Pharmacy is an independent pharmacy located in Framingham, MA that fulfills both compounded and non-compounded medication orders. Y. Fung and V. Patel explained the need for an independent specialty pharmacy in order to offer personalized care and expressed their patients' request for a separate pharmacy focused only on specialty medications.

A. STEIN inquired about the new location. Y. Fung explained that the space for VRx (153 Cochituate Road) is currently unoccupied and that VRx will be located next door from the original VCare Pharmacy (151 Cochituate Road). M. GODEK inquired about the number of support staff members that will be working at VRx. Y. Fung replied and stated that there will be 1-2 technicians at VRx. Y. Fung has been a licensed pharmacist for 4 years, this is his first time as MOR.

ACTION: Motion by M. GODEK, seconded by T. FENSKY, and voted unanimously by those present to approve the application and waivers pending a successful inspection.

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**TOPIC VII**

**FLEX**

**1. 2020 Board Meeting Dates**

**Time: 10:00 AM**

**Presented by:** D. SENCABAUGH

**Discussion:** D. SENCABAUGH presented proposed meeting dates for the 2020 calendar year. The Board meetings will be held on the first Thursdays of the month. The January meeting will be moved to 1/9/2020 to allow extra time after the holidays and there would be no scheduled August meeting.

**Action:** Motion by P. GANNON, seconded by K. TANZER, and voted unanimously by those present to approve the proposed 2020 Board meeting dates.

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## 2. 2020 Board officers

Time: 10:04 AM

**Presented by:** D. SENCABAUGH

**Discussion:** K. TANZER is president-elect for 2020. Nominations for the 2020 secretary and president-elect for 2021 will be held in November and the vote will occur in December. Members may nominate themselves and vote by proxy if they are not present at the meeting. It was noted that the vote is not done via secret ballot.

**Action:** No action warranted.

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## 3. NABP District I/II Meeting Summary

Time: 10:06 AM

**Presented by:** D. SENCABAUGH, M. GODEK, T. FENSKY, S. HAMILTON

**Discussion:** A comprehensive summary of the District I/II meeting was presented. S. HAMILTON reported events and discussions that took place throughout the meeting including states that have expanded the role of technicians (tech-check-tech, immunization delivery) and NABP round table discussions regarding USP chapters <795> and <797>. Also discussed were making naloxone OTC and differentiating license types for clinical pharmacists.

**Action:** No action warranted.

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## 4. Pharmacy Advisory Committee meeting 10/30/19

Time: 10:19 AM

**Presented by:** E. TAGLIERI

**Discussion:** A brief overview was given of the duties of the Pharmacy Advisory Committee. For the upcoming meeting on October 30, it was proposed that the Board request the committee to provide advice on environmental monitoring excursions in sterile compounding, implementation of the USP chapters, and the shared services policy. J. LANZA offered to present the Board's request at the meeting.

**Action:** Motion by T. FENSKY, seconded by S. HERNANDEZ, and voted unanimously by those present for J. LANZA to present the Board's request to the Pharmacy Advisory Committee on 10/30/2019.

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## 5. Nicotine Replacement Therapy

Time: 10:22 AM

**Presented by:** W. FRISCH

**Discussion:** In response to the public health emergency regarding e-cigarettes and vaping products, the sale of these products has been prohibited in Massachusetts. To adjust to this change, a standing order for nicotine replacement therapy (NRT) products has been issued requiring pharmacies to make a reasonable effort to determine if a purchaser's insurance covers an FDA approved OTC NRT. Individuals 18 years or older may receive NRT under the standing order. Patient-specific prescriptions may be issued for persons under 18 years old.

**Action:** No action warranted.

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## 6. 105 CMR 721.000 e-prescribing regulation

Time: 9:38 AM

**Presented by:** L. NELSON, D. JOHNSON

**Discussion:** D. JOHNSON from the Drug Control Program (DCP) presented changes to 105 CMR 721.000 including e-prescribing requirements. Starting 1/1/2020, there will be a 1-year grace period in order to provide health care providers time to transition. The purpose of this grace period is also to begin the waiver application process for all health care providers who seek to waive these regulations before implementation. 105 CMR 721.000 states that in the Commonwealth of Massachusetts, all prescriptions must be e-prescribed unless a provider meets one of the exceptions listed within the regulation. Some exceptions include Schedule VI drugs, compounded drugs, veterinary prescriptions, and durable medical equipment.

T. FENSKY asked about incentives for providers to follow the regulation. D. JOHNSON responded that DCP and the licensing boards can take action.

Pharmacies who receive an otherwise valid prescription that is not electronic are not required to verify that it falls under an e-prescribing waiver or exception.

**Action:** No action warranted.

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## 7. Implementation of revised USP chapters

Time: 10:26 AM

**Presented by:** W. FRISCH, M.CHAN

**Discussion:** Although there are appeals on certain provisions in the revised USP <795>, <797>, and <825> chapters, USP <800> is not subject to them and will become official on December 1, 2019. During the postponement and pending resolution of the appeals, USP considers <800> to be informational and not compendially applicable. There have been several inquiries on the Board's stance of USP <800> in regard to enforcement. It was suggested to enforce USP <800> through coaching during non-punitive inspections. T. FENSKY advised to strongly recommend USP <800>.

**Action:** Motion by T. FENSKY, seconded by J. LANZA, and voted unanimously by those present to inspect pharmacies on USP <800> with the intention of directing pharmacies to develop an action plan to work towards compliance. Discipline will not be issued at this time.

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## 8. Fine Default Amounts

Time: 10:37 AM

**Presented by:** H. ENGMAN

**Discussion:** H. ENGMAN led the discussion about the implementation of issuing fines to people who practice without a license or with an expired license. At the last Board meeting, there was no consensus for a default fine amount. The statute has a maximum first-time offense of \$1,000. Since this is not a common occurrence, the Board concluded that they will handle fines on a case-by-case basis and fines will range from \$1,000 for first time offense to \$2,500 any time after the first offense.

**Action:** Motion by K. TANZER, seconded by P.GANNON, voted unanimously to handle this issue on a case-by-case basis with no set default fine amount.

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**TOPIC VIII** **INVESTIGATIVE CONFERENCE**  
**SA-INV-14965** **Baystate Pharmacy DS89896** **Time: 10:53am**  
**Presented by: Kathy Sheehan, Janice Lavigne, Kevin Miller, Gary Kerr**

**Recusal: N/A**

**Discussion:**

Led by J. Lavigne and K. Miller whom both read their statements which included all of the steps that were taken to remediate the issue that had occurred and to prevent it from happening in the future. J. Lavigne explained that Baystate wanted to reduce their abundance of oxycodone/acetaminophen 5/325mg and switch over to using oxycodone 5mg tablets. She explained that they were simply trying to complete a transfer between two pharmacies (Baystate to Baystate) but utilized Rx30 to establish the transfer forms and have it on record. By using this software, it didn't appear as a typical transfer, but as a prescription which created the discrepancy that was reported to the Board of Pharmacy. When the incident occurred J. Lavigne stated that Baystate had the appropriate forms (i.e. 222 Form) for the transfer and that it was simply a technological error/data entry error. Soon after, Baystate halted all medication transfers until it was remediated and reviewed by the Board of Pharmacy.

Their plan of action also included contacting the PMP support team to remove the discrepancy from PMP. Also, a signed copy of 247 CMR 9.02 Transfer of Prescriptions was submitted attesting it was reviewed by the pharmacy staff, as well as a copy of 247 CMR 9 was printed for reference and review by covering Baystate Pharmacy staff members. They noted that they did not use 340B drugs to fill the retail prescriptions. They found that Rx30 treats the transfers as prescriptions and reports them to PMP. However, they are no longer using Rx30 for transfers and uses the 222 forms to transfer CII's.

A.STEIN's only concern, which was also a concern of S. HAMILTON, was that the Board of Pharmacy wanted to assure that if the pharmacy was a 340B pharmacy, that they were following 340B regulations. G. Kerr responded that they have been through protocols and observations, and confirmed that they were indeed not a 340B pharmacy; they had a virtual replenishment model as well as neutral inventory.

P. GANNON asked about future use of Rx30 with transfers, to which J. Lavigne confirmed that they will no longer be using Rx30 for transfers.

T. FENSKY asked if the pharmacies documented the appropriate 222 Forms, to which they did.

**Action:** Motion by T.FENSKY, seconded by K. TANZER voted unanimously by those present, to close the staff assignment with no discipline warranted with remediation complete.

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**TOPIC IX****FILE REVIEW**

Case #1

SA-INV-15068

Stephanie Kochan, PH19741

Time: 11:17 AM

RECUSAL: NONE

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

- Self-report on 5/14/19 of 20 CE credits deficient including 5 live and 2 law for 2018 (repeat deficiency);
- Pharmacist Kochan has not practiced as a pharmacist in any state since 2006.
- She stated the CE deficiencies occurred because she had to take care of her elderly mother which was the same reason for her previous deficiencies for 2015 and 2016 (SA- INV- 11477).
- All deficiencies were remediated and all CEs for 2019 have been completed

ACTION: Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present, to CLOSE the matter (SA-INV-15068), No Discipline Warranted, Remediation Complete.

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Case #2

PHA-2019-0074

Walgreens #4393, DS2882

Time: 11:19 AM

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.

- Incomplete RLCS for #108 oxycodone 5mg discovered with only a DEA 106 submitted on 5/28/19 without the BORP's required documents;
- Pharmacist Caso identified a discrepancy of 1x100 oxycodone 5mg tablets during the perpetual inventory reconciliation on 5/20/19. MOR Muniz stated the additional net loss of 8 tablets were due to variances between 9/15/18 and 4/7/19 attributed to miscounts.
- Investigation included a search of all safes and review of the perpetual inventory and purchase orders. Patients who had been dispensed the medication since the last reconciliation on 5/10/19 were contacted and all denied an over-dispense. Security footage was reviewed but was inconclusive.
- Although the DEA 106 reported the loss as "Employee Theft (or Suspected)" which could not be ruled out, MOR Muniz believed the bottle of 100 tablets was accidentally discarded either during the filling process or when the order was being stored into the safe.
- CA: CII's are put away immediately after receipt and confirmation of receipt by the pharmacist and the verifying pharmacist must complete a back count of all Schedule II medications.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2019-0074) to the Office of 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-2019-0075

Walgreens #3508, DS2527

Time: 11:22 AM

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.

- Timely incomplete RLCS on 7/8/19 for an unknown loss of #100 oxycodone 15mg tablets discovered on 6/27/19 during the reconciliation of the perpetual inventory.
- Pharmacist Williams checked all logged prescriptions, all orders received, all dispensed prescriptions and all empty bottles thrown in the trash or DPI disposal boxes. The shelves, floor, and drawers were searched to see if the bottle had been misplaced or fell.
- MOR Patel (Turner) stated patients who had been dispensed the medication since the last reconciliation were contacted and all denied an over-dispense. Security footage was viewed but was inconclusive. MOR Patel (Turner) stated the loss may have been caused by employee theft but it could not be confirmed so no pharmacy staff member was named as a suspect.
- Daily on-hand counts of oxycodone 15mg will be done for the next 2 months and the pharmacist will triple count any prescriptions dispensed for this drug.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2019-0075) to the Office of 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 #4

PHA-2019-0069

CVS #719, DS1906

Time: 11:24 AM

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

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

- During retail inspection ISP-12501 on 6/13/19, the Pharmacy was cited for having no MOR in place since Former MOR Patel exited employment on 3/28/19 with no controlled substance inventory completed. A POC was due on 7/8/19 but was not received until 8/7/19 with no extension requested.
- A complaint was opened on 7/1/19 that was not responded to by 7/25/19 with no extension requested. A request for response to both the POC and complaint was sent to CVS Regulatory Affairs and DL Hope on 7/31/19. CVS Regulatory Affairs indicated on 8/1/19 that they had not received a copy of the inspection.
- On 8/6/19, Current MOR St. Marie was contacted and he stated that he has been the only staff pharmacist in the Pharmacy since Former MOR Patel left. Although he had been performing the duties of a MOR and had verbally agreed to becoming MOR, no formal agreement was previously made. He indicated he was in process of becoming MOR and provided a copy of the controlled substance inventory that he alone performed on 7/22/19 as the incoming MOR.
- On 8/7/19, CVS provided a response which included the POC. According to the POC, Current MOR St. Marie was made MOR of the Pharmacy on 8/6/19. DL Hope took responsibility for not assigning a MOR to the Pharmacy. She stated she had two candidates that she was ultimately unable to hire then

asked Current MOR St. Marie to assume the position. According to the response, Current MOR St. Marie started as MOR on 7/7/19. A copy of the application for a change of MOR dated 8/6/19 was also provided.

- CA: Going forward, DL Hope will ensure that a new MOR will be assigned in a timely manner and a change of MOR application with a controlled substance inventory will be submitted to the BORP within the required timeframe.

ACTION: Motion by K. TANZER, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0069) 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-2019-0025

CVS #75, DS3535

Time: 11:27 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

- Untimely RLCS on 2/7/19 of an unknown loss of #100 oxycodone 5 mg tablets discovered on 11/29/18 during reconciliation of the perpetual inventory.
- Former MOR Dionne stated that the loss was attributed to an unconfirmed dispensing error of 100 additional tablets to a patient who was contacted but would not verify receipt of additional tablets. Former MOR Dionne felt the patient was lying and did not involve CVS Loss Prevention in the investigation.
- Former MOR Dionne identified Pharmacist Lu as the person responsible for the unconfirmed dispensing error since he filled a prescription for #240 oxycodone 5mg on 11/27/18. Pharmacist Lu responded that he did not recall the incident but the dispensing error was “most likely attributed to constant distractions in the pharmacy”. He indicated that he may have counted 40 tablets, added 100 tablets, was interrupted, then added 200 additional tablets to the vial but was unsure. A back count was not documented.
- CA: Former MOR Dionne stated, “I did formal write ups for both staff pharmacists to make sure we were following internal protocols regarding back counting narcotic prescriptions” as it was determined both staff pharmacists had not been performing back counts. A copy of the formal write up for Pharmacist Lu was submitted. All pharmacists attested to reviewing 247 CMR 15 in its entirety.
- During the investigation of the complaint, Former MOR Dionne indicated the Pharmacy had a backlog of approximately 1,500 prescriptions in the queue as of 7/12/19 resulting from the acquisitions of Osco Pharmacy #578 (2/6/19) and Eaton Apothecary #2035 (5/7/19) with no added staffing.
- On 7/22/19, a Site Visit (ISP-12732) was performed at which time 4 pharmacists and 6 pharmacy technicians were observed working with approximately 105 prescriptions in the queue. It was noted that it is not uncommon to have an average of 500-600 prescriptions outstanding in the queue daily based on historical volume. A minimum of 3 pharmacists and 6 support staff was recommended to keep pace with prescription fulfillment while maintaining adequate standards of safety.
- A response from CVS Corporate on 8/16/19 reiterated the backlog of prescriptions was due to the acquisitions of 2 pharmacies. The Pharmacy had a significant increase in weekly volume of

prescriptions with the same amount of staffing prior to the acquisitions while waiting for new hires to complete the hiring process.

- On 8/16/19, the Pharmacy was contacted and Pharmacist Eldib indicated there were approximately 395 prescriptions in the queues with only about 10 prescriptions received daily with PV1 performed at another CVS pharmacy. Pharmacist Eldib estimated the daily volume as 300-400 prior to the acquisitions and provided documentation that the Pharmacy had filled approximately 595 prescriptions/day the week of 8/4/19. The Pharmacy has 3 pharmacists scheduled Monday to Wednesday (8 hours overlap with 2 pharmacists; 1-2 hours overlap with 3 pharmacists) and 2 pharmacists scheduled Thursday and Friday (3 hours overlap).
- CA: According to CVS Corporate, the District Leader set up a team to assist the Pharmacy with catching up. In addition, the District Leader approved more hours for staffing and asked for support from neighboring locations to appropriately manage the Pharmacy's current volume. The current budgeted hours at the Pharmacy for pharmacists is 120 hours per week and for support staff is ~350-400 hours per week (the Pharmacy is open 87 hours/week).

ACTION: Motion by S. HERNANDEZ, seconded by M. GODEK, and voted unanimously by those present, to refer the matter (PHA-2019-0025) 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, with special terms to include that CVS increase oversight visits to the store.

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Case #6

PHA-2019-0062

CVS #7232, DS3461

Time: 11:38 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.

- Untimely RLCS on 5/22/19 for an unknown loss of #60 Aptensio XR 20mg capsules on 4/8/19 due to a dispensing error.
- MOR Antenor claimed the loss was discovered on 4/13/19 during the perpetual inventory count but the electronic perpetual inventory provided showed no entries between 4/8/19 and 4/22/19 when it was next reconciled.
- The Pharmacy received #90 Aptensio XR 20mg capsules for a prescription for #30 filled the same date by Pharmacist McGrath. This was the first and only time this medication had been ordered and dispensed. Pharmacist McGrath could not recall the incident.
- Security footage was reviewed but the quantity dispensed for the prescription could not be determined. Although MOR Antenor contacted the patient/caregiver multiple times with no success, on a subsequent visit to the pharmacy the patient/caregiver confirmed the dispensing error.
- CA: MOR Antenor reviewed proper filling of CII-medications with all staff members, ensuring CII-medications are double counted and the back count is consistently documented. Pharmacy staff will continue to remain extra diligent and adhere to all applicable CVS policies and procedures with regard to the filling and dispensing of controlled substances. A CQI QRE form was provided documenting the medication error. Pharmacist McGrath submitted proof of completion of 3 CEs in the topic of medication errors and confirmed reviewing 247 CMR 15 in its entirety.



ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0062), No Discipline Warranted, Remediation Complete, include an Advisory Letter on Board Policy 2018-05.

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Case #7

PHA-2019-0073

CVS #946, DS3442

Time: 11:41 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.

- Untimely RLCS on 6/18/19 for an unknown loss of #520 lorazepam 0.5 mg tablets discovered on 04/15/2019 with the investigation concluding on 5/17/19.
- MOR Obarowski reported the loss was identified from corporate controlled substance monitoring as a variance on 04/15/2019.
- The investigation initiated by Loss Prevention included twice daily cycle counts at the open and close of business, review of all inventory cycle counts, orders, and returns since the last biennial inventory, and review of security footage which was inconclusive. The lorazepam 0.5mg tablets were removed from the automation unit. MOR Obarowski performed additional twice daily counts at the beginning and end of her shifts for a month.
- MOR Obarowski stated, "At the conclusion of the investigation, it was determined that the loss was a result of inconsistent double counting of the controlled substance and the automation unit dispensing inconsistent quantities".
- Exact CIII-CV biennial inventory counts were conducted in 2018 and 2019.
- CA: All pharmacy staff are compliant on the CVS training modules for the proper handling of controlled substances. Prompted cycle counts are completed daily. All controlled substances are double counted, circled and initialed by the pharmacy staff member at production. MOR Obarowski will review monthly/weekly state counts completed by the pharmacists. "The Balance on Hand modification Red Flag report" will be reviewed weekly with the pharmacy team and any discrepancies will be further reviewed by MOR Obarowski.

ACTION: Motion by M. GODEK, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2019-0073), to the Office of 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 BENZODIAZEPINE 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 #8

PHA-2019-0076

CVS #155, DS2471

Time: 11:44 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.

- Unknown RLCS on 7/11/19 for an unknown loss of #699 tramadol 50 mg tablets discovered on 6/3/19 after review of the BOH modification report.
- Loss Prevention team assisted in the investigation to determine if the loss was due to diversion. Daily counts were conducted, and reconciliations were performed weekly without an additional loss discovered. The investigation determined that the last variance occurred in April 2019 at which time PT Karen Maltais went out on a leave of absence and was unable to be interviewed.
- Exact counts were performed for the CIII-CV biennial inventory in 2018 and 2019. All controlled substances are double counted by hand on a counting tray with quantities circled on the label and initialed.
- CA: Pharmacy staff will review BOH modification reports, ordering and cycle count activity in sufficient detail to quickly identify and prevent drug count discrepancies or diversion. The pharmacy team was reminded to double count all controlled substance medications prior to dispensing. The pharmacist on duty will double check all the most commonly dispensed controlled substance medications and the prescriptions in the waiting bin during all inventories to ensure an accurate count. Pharmacy technicians who handle damages and outdates were re-trained on proper procedures to prevent inaccuracies. MOR O'Brien reviewed all baseline loss prevention procedures, specifically those related to the prevention of drug diversion, with the pharmacy staff.

ACTION: Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present, to refer the matter (PHA-2019-0076), to the Office of 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.

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Case #9

PHA-2018-0015

Preferred Pharmacy Solutions, DS3542

Time: 11:47 AM

RECUSAL: NONE

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

- In January 2018, a joint inspection/investigation began at PPS after reports of issues with controlled substances from various sources. In March 2018, PPS reported an unknown loss of 56 oxycodone ER 10mg tablets and a complaint was opened.
- The complaint was then amended after completion of the joint inspection/investigation in May 2018 to include violations of the Controlled Substance Act (CSA) discovered during the course of the joint inspection/investigation.

- The joint inspection/investigation uncovered multiple violations including incomplete and inaccurate recordkeeping of Schedule II controlled substances, employees diverted controlled substances, practitioner DEA registration numbers were inaccurate, records were stored off site w/o permission, and no hard copies were obtained for Schedule II emergency prescriptions.
- PPS also failed to report in their DEA renewal application that an owner had multiple convictions involving drug offenses and fraud. In addition, the same owner had his Massachusetts pharmacist license revoked as a result of his criminal convictions.
- As a result, DEA and PPS entered into a settlement agreement to resolve the matter. PPS agreed to pay \$75K and enter into a corrective action plan (CAP) for three years. Terms of the CAP included barring the defrocked pharmacist/owner from any contact with the pharmacy, biannual self-evaluations to audit compliance with CSA, and allowing up to three warrantless inspections by DEA without prior notice.
- PPS also must comply with document requests by DEA related to monitoring compliance with the CAP, resolve software issues that allow technicians to enter false DEA numbers, purge false DEA numbers from records, implement policies to discipline employees who enter false DEA numbers.
- In addition, DEA reserved the right to take further administrative or injunctive action against PPS for violations of the CAP including revocation of the pharmacy's licensure.

ACTION: Motion by S. HAMILTON, seconded by M. GODEK, and voted unanimously by those present, to refer the matter (PHA-2018-0015), to the Office of 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 closing out the current probation contingent upon the signing of this new consent agreement for probation.

**Topic IX** **EXECUTIVE SESSION** **Time: 11:45 AM**  
**Read by A. Stein**

DISCUSSION:

ACTION: At 11:55 AM President A. Stein read the statement on reasons for Executive Session.

**Topic X:** **Executive Session Call to Order:** **Time: 1:15 PM**  
 By: A. Stein

ACTION: Motion by K. Tanzer, seconded by P. Gannon, and voted unanimously by roll call to call the 10/3/19 meeting of the Executive Session to order.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; M. Godek, yes; S. Hernandez (yes); P. Gannon, yes; S. Hamilton, yes; T. Fensky, yes; R. Lopez, yes; S. Cornacchio, yes

**Topic XI:** **Adjudicatory Session (M.G.L. ch 30A § 18)** **Time: 1:08 PM**

DISCUSSION: None

ACTION: President A. Stein request a motion to enter Adjudicatory Session.

At 1:08 PM M. Godek seconded by S. Hernandez and voted unanimously by all those present to enter Adjudicatory Session:

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**Topic XII:**

**M.G.L. 65 C #1**

**Time: 2:15 PM**

DISCUSSION: None

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

At 2:15 PM T. Fensky, seconded by S. Hamilton and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

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**Topic XIII**

**ADJOURNMENT OF MEETING**

**TIME: 4:00 PM**

ACTION: Motion by P. Gannon seconded by M. Godek, 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 10/3/19 General Session
2. Draft Minutes of the 9/5/19 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 PSUD 17-03
8. Policy 2019-01: Shared Pharmacy Service Models Including Central Fill, Central and Remote Processing and Tele-pharmacy
9. Joint Policy 2019-06: Compounded Emergency Medications for Veterinarian Use
10. Applications: Winchester Pharmacy DS89848 Pilot Program Extension
11. Applications: Brighton Pharmacy DS89908 Relocation
12. Applications: Capsule Pharmacy Boston; New Community Pharmacy
13. Applications: Cambridge Health Alliance Specia9alty Pharmacy; New Community Pharmacy
14. Application: VRx Solutions; New Community Pharmacy
15. 2019-2020 Board Meeting Dates
16. Pharmacy Advisory Committee Meeting Recommendation 19-02
17. SA-INV-14965 Baystate Pharmacy DS89896 Investigative conference
18. SA-INV-15068 Stephanie Kochan, PH19741
19. PHA-2019-0074 Walgreens #4393, DS2882
20. PHA-2019-0075 Walgreens #3508, DS2527
21. PHA-2019-0069 CVS #719, DS1906
22. PHA-2019-0025 CVS #75. DS3535

23. PHA-2019-0062 CVS #7232, DS3461
24. PHA-2019-0073 CVS #946, DS3442
25. PHA-2019-0076 CVS #155, DS2471
26. PHA-2018-0015 Preferred Pharmacy Solutions, DS3542

Respectfully Submitted,  
Julie Lanza, CPhT, Secretary