

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

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

June 15, 2017  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

**Agenda**

<b>Time</b>	<b>#</b>	<b>Item</b>	<b>Contact</b>
8:30	I	<b>CALL TO ORDER</b>	T. Fensky
8:30	II	<b>APPROVAL OF AGENDA</b> <ul style="list-style-type: none"> <li>• Introduction of Intern Hinal Patel</li> </ul>	
8:35	III	<b>APPROVAL OF BOARD MINUTES</b> <ul style="list-style-type: none"> <li>• Draft of May 4, 2017 Regular Session Minutes</li> </ul>	D.Sencabaugh
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 Complaint Review pursuant to licensure policy 14-02</li> <li>• Above Action Levels approved by Staff Action 16-04</li> </ul>	M. Botto K. Fishman V. Thaker
8:45	V	<b>REQUEST FOR REINSTATEMENT</b> <ul style="list-style-type: none"> <li>• James Nahill, PH21521: PHA-2012-0171, PHA-2013-0039, PHA-2013-0038</li> </ul>	L. Ferguson
9:00	VI	<b>SANCTION HEARING</b> <ul style="list-style-type: none"> <li>• Todd Matthews-PHA-2015-0147; PH24657</li> </ul>	S. Leadholm
9:30	VII	<b>ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)</b>	

10:00	VIII	<b>APPLICATIONS</b> <ul style="list-style-type: none"> <li>• Central Admixture Pharmacy Services- DS3312- Petition for Waiver</li> <li>• Letourneau’s Pharmacy-DS3377- Change of Business Model</li> <li>• Heritage Biologics, DS89956 – Petition for Waiver</li> <li>• Johnson Compounding and Wellness-DS3579 -Transfer of Ownership</li> <li>• Preferred Pharmacy Solutions-DS3542-Renovation/Expansion</li> <li>• OptionCare – DS3584 - Relocation</li> </ul>															
11:00	IX	<b>FLEX</b> <ul style="list-style-type: none"> <li>• Narcan Mobile Initiative</li> <li>• 795 Compliance Inspection Tool</li> <li>• Guidance document for non-sterile compounding</li> <li>• The Future of Board Packets</li> </ul>	M. Chan N. Van Allen  R. Harris														
11:30	X	<b>ADVISORY</b> <ul style="list-style-type: none"> <li>• Advisory: Reporting Defective Drug Preparations <ul style="list-style-type: none"> <li>○ Mandated Reporting Form: Defective Drug Preparation Reporting Form</li> </ul> </li> </ul>	M. Chan W. Frisch V. Thaker														
11:45	XI	<b>POLICIES</b> <ul style="list-style-type: none"> <li>• Pharmacy Report of Serious Adverse Drug Event or Improper Drug Dispensing</li> <li>• Mandated Reporting Form: Pharmacy Report of Serious Reportable Event</li> <li>• Referrals to the Office of the Attorney General</li> </ul>	M. Chan W. Frisch V. Thaker H. Engman														
12:15		<b>LUNCH BREAK</b>															
1:15	XII	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 5%; text-align: center;">1</td> <td>PHA-2017-0050- CVS Pharmacy #318- DS21288</td> </tr> <tr> <td style="text-align: center;">2</td> <td>PHA-2017-0080- CVS Pharmacy #915- DS3395</td> </tr> <tr> <td style="text-align: center;">3</td> <td>PHA-2016-0191- CVS Pharmacy #2322- DS2827</td> </tr> <tr> <td style="text-align: center;">4</td> <td>PHA-2017-0069-CVS Pharmacy #2322- DS2827</td> </tr> <tr> <td style="text-align: center;">5</td> <td>PHA-2017-0015- CVS Pharmacy #615- DS3493</td> </tr> <tr> <td style="text-align: center;">6</td> <td>PHA-2017-0054- Walgreens #9233- DS3407</td> </tr> <tr> <td style="text-align: center;">7</td> <td>PHA-2017-0031- Walgreens #4595- DS2970</td> </tr> </table>	1	PHA-2017-0050- CVS Pharmacy #318- DS21288	2	PHA-2017-0080- CVS Pharmacy #915- DS3395	3	PHA-2016-0191- CVS Pharmacy #2322- DS2827	4	PHA-2017-0069-CVS Pharmacy #2322- DS2827	5	PHA-2017-0015- CVS Pharmacy #615- DS3493	6	PHA-2017-0054- Walgreens #9233- DS3407	7	PHA-2017-0031- Walgreens #4595- DS2970	
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		<b>8</b>	PHA-2017-0051- Rite Aid Pharmacy #10060- DS3036			
		<b>9</b>	SA-INV-10701: Rite Aid #10078- DS3471			
		<b>10</b>	PHA-2016-0127- Cardinal Health Nuclear Pharmacy #414-NU11			
		<b>11</b>	SA-INV-11414- Nimble RX, Inc- DS90047			
		<b>12</b>	SA-INV-10593- Holyoke Health Center Pharmacy- DS3491			
		<b>13</b>	PHA-20117-0018: IVG Veterinary Compounding Pharmacy- DS90035			
		<b>14</b>	SA-INV-10881: Partners of Massachusetts- DS3419			
<b>2: 15</b>	<b>XIII</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, the Board will discuss and evaluate the Good Moral Character as required for registration for pending applicant and review of evaluative report.			<b>CLOSED SESSION</b>	
<b>2:45</b>	<b>XIV</b>	<b>ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)</b>			<b>CLOSED SESSION</b>	
<b>3:30</b>	<b>XV</b>	<b>M.G.L. c. 112, § 65C SESSION</b>			<b>CLOSED SESSION</b>	
<b>5:00</b>	<b>XVI</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**

**June 15, 2017**

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**Board Members Present**

Timothy Fensky, R.Ph. President  
Michael Godek, R.Ph., President-Elect  
Susan Cornacchio, JD, RN, Secretary  
Patrick Gannon, R.Ph  
Catherine Basile, Pharm D, R.Ph  
Garret Cavanaugh, R.Ph.  
Andrew Stein, Pharm D, R.Ph.  
Richard Tinsley, MBA, Med,  
Ed Taglieri Jr., R.Ph. President  
William Cox, CPhT

**Board Members Not Present**

Ali Raja, MD, MBA, MPH  
Phillippe Bouvier, R.Ph.  
Karen Conley, DNP, RN, AOCN, NEA-BC

**Board Staff Present**

David Sencabaugh, R.Ph, Executive Director  
Monica Botto, CPhT, Associate Executive Director  
Heather Engman, JD, MPH, Pharmacy Board Counsel  
William E. Frisch, Jr., R.Ph., Director of Compliance  
Michelle Chan, R.Ph. Quality Assurance Pharmacist  
Greg Melton, JD, R.Ph., Investigator  
Joanne Trifone, R.Ph., Director of Pharmacy Investigations  
Joe Santoro, R.Ph. Contract Investigator  
Kimberly Morton, CPhT, Compliance Officer  
Vishal Thaker, PharmD, Pharmacist  
Nathan Van Allen, PharmD, R.Ph.  
John Murray, R.Ph., Investigator  
Julienne Tran, R.Ph., Investigator

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**TOPIC I. CALL TO ORDER 8:30 am**

**DISCUSSION:** A quorum of the Board was present, established by roll call. President T. FENSKY chaired the meeting and asked if anyone was recording. Hearing “no”, he explained that the Board of Pharmacy was recording the meeting.

**TOPIC II. APPROVAL OF AGENDA**

**DISCUSSION:** None

**ACTION:**

1. Motion by P. GANNON, seconded by E. TAGLIERI, and voted unanimously to approve the agenda.
2. D. SENCABAUGH introduced H. PATEL as the newest APPE rotation student from MCPHS University. T. FENSKY asked interns in the audience to stand up and introduce themselves.

**TOPIC III:**

**APPROVAL OF BOARD MINUTES**

1. Draft May 4, 2017, Regular Session Minutes

DISCUSSION: Change title for Susan Cornacchio to, RN, JD, and Secretary

ACTION:

3. Motion by E. TAGLIERI, seconded by C. BASILE, and voted affirmatively to accept the minutes of the 5/4/2017 General Session minutes, with noted change. M. GODEK and G.CAVANAUGH abstained.

#### **TOPIC IV: REPORTS**

**Applications Approved Pursuant to Licensure Policy 13-01, Time: 8:34 am**

DISCUSSION: M. BOTTO noted that since the last Board Meeting, there have been forty-seven (47) change-of-managers, seven (7) renovation/expansions, and two (2) closings approved by staff. So noted

#### **Report of activities Probation Monitor**

DISCUSSION: D. SENCABAUGH (for K.FISHMAN) provided the April 22, 2017 – May 29, 2017, Board of Pharmacy Statistics Report for the Probation monitor, which noted that there are forty-eight (48) licensees on probation, one (1) extension granted, and six (6) licensees satisfactorily completed probation monitoring.

#### **Board Delegated Review Pursuant to BDCR Policy**

There were 6 Board Delegated Review (all Staff Assignments) cases heard on June 12, 2017. 5 of the 6 were self-reports of a CE deficiency (SA-INV-10600, SA-INV-11422, SA-INV-11242, SA-INV-10800, SA-INV-10617) and all of the 5 had been successfully remediated. The 6<sup>th</sup> case was a consumer grievance SA-INV-10717, which, after investigation, was “closed- no violation.”

**The Board Delegated Review session** was attended by T. FENSKY as the Board Member, H. ENGMAN as Board Counsel, W. FRISCH, Director of Pharmacy Compliance, and Executive Director D. SENCABAUGH.

ACTION: So noted

#### **REPORTS**

**Staff Action to Handle Above Action Level reports pursuant to 16-04:**

DISCUSSION: V. THAKER reported that there were five (5) above action level reports, and all had remediated and closed.

ACTION: So noted

#### **TOPIC V: REQUEST FOR REINSTATEMENT**

**PHA-2012-0171, PHA-2013-0039, PHA-2013-0038 James Nahill Time: 9:46 AM**

RECUSAL: none.

DISCUSSION: Presented by Board Paralegal L.FERGUSON. J. NAHILL has met all requirements for license reinstatement except for passing the MPJE, for which he needs board approval.

Presented by J. NAHILL. He described his experience thus far as “humbling”. Currently, he has been working in pharmacy consulting, and in construction. J. NAHILL indicated he was assisted in beginning pharmacy consulting by D. TRINKS. His future plans are to work as a pharmacist in a non-dispensary role.

ACTION: Motion by G. CAVANAUGH, seconded by E. TAGLIERI, and voted by those present, to accept applicant's request for reinstatement with conditions. J. NAHILL must pass the MPJE to be reinstated. A 3-year probation period will follow reinstatement. The conditions of probation state that J. NAHILL may not serve as a Manager of Record or a preceptor. He may not own or have interest a pharmacy or engage in sterile or non-sterile compounding. He may consult in the area of compounding but may not compound, verify compounds, dispense compounds, or authorize any policy and/ or procedures relating to compounding. M. GODEK opposed the motion.

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## **TOPIC VI**

### **TOPIC VI: SANCTION HEARING**

**PHA-2015-0147**

**Todd Mathews**

**Time: 8:51 am**

**Presented by S. LEADHOLM, Board Counsel**

**T. MATHEWS was represented by D. TRINKS, Consultant, and P. GARBARINI, Attorney**

RECUSAL: C. BASILE and E. TAGLIERI recused and were not present for the discussion or vote on this matter. Also, Board Staff, H. ENGMAN, M. CHAN, and M. BOTTO recused and were not present for the discussion or vote on this matter.

DISCUSSION: Presented by S. LEADHOLM: The parties stipulated to certain facts and violations. There is no dispute regarding the underlying facts of violations in this case. During the Sanction Hearing, both parties will have an opportunity to present evidence of mitigating and/or aggravating circumstances and the board will determine the appropriate sanction.

T. MATHEWS claimed that he made good faith efforts to implement the Plan of Corrections but was often unsuccessful due to lack of support from owners.

Presented by D. TRINKS, who attested to T. Mathew's efforts. Attempted to assist Mathews with the implementation of a new labeling system, but they were unsuccessful due to lack of support from pharmacy owners.

Presented by E. LANGNER. LANGNER indicates the previous vote by the Board of Pharmacy was for two-year probation with terms that T. MATTHEWS may not serve as Manager of Record or a preceptor during the probationary period. E. LANGNER indicated the original discipline is appropriate. Despite the lack of support from ownership, the Manager of Record is still responsible for following rules and regulations. Repeated inspections over a one year period showed consistent violations each time. These repeated violations show a lack of responsiveness from Manager of Record T. MATHEWS.

Board members discussed that deficiencies such as staff ratios and re-dispensing of medications were well within T. MATHEWS'S control. These deficiencies were also consistent over a period of time. T. MATHEWS proceeded to explain to Board members the actions that he would take differently now based on his experience thus far.

**TOPIC VII** At 9:25 am, on a motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously to enter **Adjudicatory session.**

Back to General Session at 9:46am

**Topic IX**  
**Narcan Mobile Initiative / Sullivan's Pharmacy**

**Flex Session**

**Time: 11:00 am**

Recusal: T. FENSKY and G. CAVANAUGH recused and were not present for the discussion or vote in this matter.

**This Topic was chaired by President-Elect M. GODEK**

Discussion: J. NGUYEN and A. BURNS presented a pilot project program where End Mass Overdose would partner with Sullivan's Pharmacy to create mobile Narcan kiosks at various health fairs and events to increase the availability of the medication to the public as part of a two year pilot project. J. NGUYEN stated that while Sullivan's Pharmacy would be partnering with End Mass Overdose, the pharmacy would be responsible for procurement, security, transport and dispensing of the medication as well as billing. J. NGUYEN stated that the medication would be stored in lock boxes in a segregated area from the public and protected by Sullivan's Pharmacy employees. These medications would be dispensed pursuant to a standing order signed by a physician.

Sullivan's Health care will collect data per event to include the communities where the events are held, number of naloxone rescue products dispensed, number of people requesting additional information on naloxone products and number of people requesting information on substance use disorder and recovery services. This data will be reported to the Board on a quarterly basis.

The petition for a pilot project does not include a request for waiver of any Board Regulations.

Action: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously by those present, to approve the pilot project for a period from 1 August 2017 through 1 February 2019.

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**795 Compliance Inspection Tool**

**Flex Session**

**Time: 11:27 am**

Recusal: NONE

Presented By: N. VAN ALLEN

Discussion: N. VAN ALLEN presented and discussed information related to the 795 Compliance Inspection Tool. He stated it is based off of proposed 247 CMR Section 18 and the current version of USP <795>. It will allow Board Staff to be more efficient in the inspection process and allow licensees to self-inspect. He proposes a soft-rollout by posting the tool on the Board website before holding licensees to the criteria set forth in the document. Prior to enforcement of the inspection tool, there will be changes to reflect any updates to 247 CMR Section 18 once it is promulgated.

Action: Motion by A. STEIN, seconded by W. COX, and voted unanimously by those present, to approve the 797 Compliance Inspection Tool with the noted changes.

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**Flex Session**

**Time: 11:33 am**

**Guidance Document for Non-Sterile Compounding**

Recusal: NONE

Presented By: M. CHAN

Discussion: M. CHAN presented a document to differentiate simple/moderate non-sterile compounding from complex non-sterile compounding to aid licensees in the upcoming licensure process of complex non-sterile compounding pharmacies in the Commonwealth. This is to serve as a guidance document for the licensees to help them obtain appropriate policies, procedures, facilities, and practices for the appropriate type of compounding they perform.

Action: Motion by E. TAGLIERI, seconded by M. GODEK, and voted unanimously by those present, to approve the Guidance Document for Non-Sterile Compounding.

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**Flex Session**

**Time: 11:34 am**

**Discussion of Board Packets**

Recusal: NONE

Presented By: R. HARRIS

Discussion: R. HARRIS presented to the Board regarding the modernization of Board packets. Starting in August 2017, Board members will receive a virtual Board packet through a secure email address in place of the current hard copy Board packets. There will be a limited number of physical Board packets available for the Board members at Board meetings. R. TINSLEY suggested that there be compilation of the PDF files so as to limit the number of files sent to the Board members.

**Topic X**

**Advisory**

**Time: 11:45 am**

**Reporting Defective Compounds Advisory**

**Defective Drug Preparation Reporting Form**

Discussion: V. THAKER presented an advisory and a form designed to satisfy the requirements set forth in M.G.L. 112 S. 39 that calls for pharmacies licensed by the Board to report defective drug preparations to the Board.

Action: Motion by M. GODEK, seconded by E. TAGLIERI, and voted unanimously by those present to approve the Reporting Defective Compounds Advisory with the noted changes. A second motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously by those present to approve the Defective Drug Preparation Form.

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**Topic XI**

**Policies**

**Time: 11:48 am**

**Pharmacy Report of Serious Adverse Drug Event or Improper Dispensing**

Discussion: V. THAKER presented a form designed to satisfy the requirements in M.G.L. 112 Section 39 that calls for pharmacies licensed by the Board to report any serious adverse drug event or any improper dispensing of a prescription drug that results in serious injury or death. S. CORNNACHIO suggested that the definition for serious reportable event be aligned with the definition in M.G.L. 111 Section 51H.

Action: Motion by M. GODEK, seconded by E. TAGLIERI, and voted unanimously by those present to approve the reporting form with the noted changes.

**Topic XI**

**Policies**

**Time: 11:57 am**

**Referrals to the Office of the Attorney General**

Discussion: H. ENGMAN presented Bureau Staff Action Policy 17-02 to facilitate referrals to the Office of the Attorney General concerning unlicensed practice, practice after revocation or suspension, practice under a false name, false use of credentials, or potential Medicaid fraud, in order to protect the health and safety of the public, or the integrity of the Medicaid Program.

Action: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously by those present to approve the reporting form with the noted changes.



TOPIC VII

**Adjudicatory Session**

DISCUSSION: None

ACTION: At 9:25 am, on a motion by P. GANNON, seconded by G. CAVANAUGH, the members voted unanimously to enter into Adjudicatory session. C. BASILE and E. TAGLIERI were still recused.

TOPIC VIII:

**APPLICATIONS**

**Time: 8:39am**

**1. Heritage Biologics, Inc. Petition for Waiver**

RECUSAL: None

DISCUSSION: Heritage Biologics was represented by Katie Pederson, who explained that the business model for Heritage was such that it takes a long time to build a customer base, and that is why they had not yet ordered drugs. Heritage presented several waiver requests, but after the Board Members asked their questions, they decided to withdraw 5 of them, having to do with required equipment, square footage, storage of controlled substances, perpetual inventory record keeping, and the requirement for a registered pharmacist to be present at all times the pharmacy is open. Heritage answered the Board members' questions to their satisfaction.

ACTION: Motion by C. BASILE, seconded by E. TAGLIERI, and voted unanimously in the affirmative to approve Heritage Biologics, Inc. continuation of operations and approved their other waiver requests.

**2. Letourneau's - Change in Business Model**

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

DISCUSSION: Letourneau's was represented by Shawn McKallagat, Owner and MOR. Letourneau's sold most of their business; files and inventory, to CVS, but wish to remain open as a non-sterile compounding pharmacy, and to administer immunizations. Currently, they also serve the basic pharmacy needs for Phillips Academy, but that will be ending soon. Mr. McKallagat answered the Board members' questions to their satisfaction.

ACTION: Motion by A. STEIN, seconded by M. GODEK, and voted unanimously in the affirmative to approve the change in business model of Letourneau's Pharmacy.

**3. Johnson's Compound and Wellness Center – Transfer of Ownership Time: 10:43 am**

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

DISCUSSION: Johnson's was represented by John Walczyk, MOR and President. He explained that there is no intent to change the business model at this time. Walczyk answered the Board Members' questions to their satisfaction.

ACTION: Motion by M. GODEK, seconded by C. BASILE, and voted unanimously to approve the transfer of ownership of Johnson's Compounding and Wellness center to A & J Compounding, Inc.

**4. Preferred Pharmacy Solutions Renovation / Expansion Time: 10:46 am**

RECUSAL: None

DISCUSSION: Preferred Pharmacy Solutions was represented by Dennis Lyons, Consultant, and Anthony Rozzi, MOR. They are planning to essentially double the space of the pharmacy, by expanding to two floors, since they have experienced a large increase in volume recently.

Mr. Lyons and Mr. Rozzi described their plans, reviewed the blueprint, and answered the Board members' questions to their satisfaction. They are still awaiting a permit from Haverhill.

ACTION: Motion by C. BASILE, seconded by P. GANNON, and voted unanimously in the affirmative to approve the renovation plans for the start of construction at Preferred Pharmacy. The Pharmacy will continue to communicate progress with the Board.

## 5. OptionCare - Relocation

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

DISCUSSION: OptionCare was represented by Scott Shepard, Director of Pharmacy and MOR, and Karen Rowley, Senior Director of Operations. They are planning to relocate from 257 Turnpike Road in Southborough, MA to 734 Forest Street in Marlborough, MA, sometime in late October or early November, 2017. They will require an inspection prior to using the facility.

ACTION: Motion by P. GANNON, seconded by E. TAGLIERI, and voted unanimously in the affirmative to approve the relocation of OptionCare, pending a successful inspection.

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### TOPIC IX

### FLEX SESSION

#### Topic IX

#### Flex Session

**Time: 11:00 am**

#### **Narcan Mobile Initiative / Sullivan's Pharmacy**

Recusal: T. FENSKY and G. CAVANAUGH recused and were not present for the discussion or vote in this matter.

Discussion: J. NGUYEN and A. BURNS presented a pilot project program where End Mass Overdose would partner with Sullivan's Pharmacy to create mobile Narcan kiosks at various health fairs and events to increase the availability of the medication to the public as part of a two year pilot project. J. NGUYEN stated that while Sullivan's Pharmacy would be partnering with End Mass Overdose, the pharmacy would be responsible for procurement, security, transport and dispensing of the medication as well as billing. J. NGUYEN stated that the medication would be stored in lock boxes in a segregated area from the public and protected by Sullivan's Pharmacy employees. These medications would be dispensed pursuant to a standing order signed by a physician.

Sullivan's Health care will collect data per event to include the communities where the events are held, number of naloxone rescue products dispensed, number of people requesting additional information on naloxone products and number of people requesting information on substance use disorder and recovery services. This data will be reported to the Board on a quarterly basis.

The petition for a pilot project does not include a request for waiver of any Board Regulations.

Action: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously by those present, to approve the pilot project for a period from 1 August 2017 through 1 February 2019.

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### **795 Compliance Inspection Tool**

### **Flex Session**

**Time: 11:27 am**

Recusal: NONE

Presented By: N. VAN ALLEN

Discussion: N. VAN ALLEN presented and discussed information related to the 795 Compliance Inspection Tool. He stated it is based off of proposed 247 CMR Section 18 and the current version of USP <795>. It will allow Board Staff to be more efficient in the inspection process and allow licensees to self-inspect. He proposes a soft-rollout by posting the tool on the Board website before holding licensees to the criteria set forth in the

document. Prior to enforcement of the inspection tool, there will be changes to reflect any updates to 247 CMR Section 18 once it is promulgated.

Action: Motion by A. STEIN, seconded by W. COX, and voted unanimously by those present, to approve the 797 Compliance Inspection Tool with the noted changes.

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**Guidance Document for Non-Sterile Compounding**

**Time: 11:33 am**

Recusal: NONE

Presented By: M. CHAN

Discussion: M. CHAN presented a document to differentiate simple/moderate non-sterile compounding from complex non-sterile compounding to aid licensees in the upcoming licensure process of complex non-sterile compounding pharmacies in the Commonwealth. This is to serve as a guidance document for the licensees to help them obtain appropriate policies, procedures, facilities, and practices for the appropriate type of compounding they perform.

Action: Motion by E. TAGLIERI, seconded by M. GODEK, and voted unanimously by those present, to approve the Guidance Document for Non-Sterile Compounding.

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**Discussion of Board Packets**

**Time: 11:34 am**

Recusal: NONE

Presented By: R. HARRIS

Discussion: R. HARRIS presented to the Board regarding the modernization of Board packets. Starting in August 2017, Board members will receive a virtual Board packet through a secure email address in place of the current hard copy Board packets. There will be a limited number of physical Board packets available for the Board members at Board meetings. R. TINSLEY suggested that there be compilation of the PDF files so as to limit the number of files sent to the Board members.

**Topic X**

**Advisory**

**Time: 11:45 am**

**Reporting Defective Compounds Advisory**

**Defective Drug Preparation Reporting Form**

Discussion: V. THAKER presented an advisory and a form designed to satisfy the requirements set forth in M.G.L. 112 S. 39 that calls for pharmacies licensed by the Board to report defective drug preparations to the Board.

Action: Motion by M. GODEK, seconded by E. TAGLIERI, and voted unanimously by those present to approve the Reporting Defective Compounds Advisory with the noted changes. A second motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously by those present to approve the Defective Drug Preparation Form.

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**Topic XI**

**Policies**

**Time: 11:48 am**

**Pharmacy Report of Serious Adverse Drug Event or Improper Dispensing**

Discussion: V. THAKER presented a form designed to satisfy the requirements in M.G.L. 112 Section 39 that calls for pharmacies licensed by the Board to report any serious adverse drug event or any improper dispensing of a prescription drug that results in serious injury or death. S. CORNNACHIO suggested that the definition for serious reportable event be aligned with the definition in M.G.L. 111 Section 51H.

Action: Motion by M. GODEK, seconded by E. TAGLIERI, and voted unanimously by those present to approve the reporting form with the noted changes.

**Topic XI**

**Policies**

**Time: 11:57 am**

**Referrals to the Office of the Attorney General**

Discussion: H. ENGMAN presented Bureau Staff Action Policy 17-02 to facilitate referrals to the Office of the Attorney General concerning unlicensed practice, practice after revocation or suspension, practice under a false name, false use of credentials, or potential Medicaid fraud, in order to protect the health and safety of the public, or the integrity of the Medicaid Program.

Action: Motion by P. GANNON, seconded by C. BASILE, and voted unanimously by those present to approve the reporting form with the noted changes.

**TOPIC XII: OPEN FILE REVIEW**

**Case #1**

**PHA-2017-0050**

**CVS Pharmacy #318- DS21288**

**Time: 12:10 am**

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

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

- Reported loss of #5 Fentanyl 12 mcg patches discovered while performing a perpetual inventory on 11/7/2016
- On April 3, 2017, CVS Pharmacy Supervisor sent an email to OPP investigator indicating the missing #5 Fentanyl patches were found stuck between the doors of the safe
- CVS Corporate Drug Loss Team sent a clarification letter addressed to the DEA withdrawing the original DEA-106
- On April 13, 2017, this OPP investigator received a copy of the amended DEA-106 form.

ACTION: Motion by M. GODEK, seconded by C. BASILE, and voted unanimously by those present, to Dismiss PHA-2017-0050, no violation.

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**Case #2**

**PHA-2017-0080**

**CVS Pharmacy #915- DS3395**

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

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

- RLCS of #627 tramadol 50mg tablets on or about December 9, 2016.

- Loss was identified via corporate controlled substance monitoring. An investigation has not uncovered a reason for the loss.
- Corrective action was taken by MOR
- A Retail Compliance inspection (ISP-6641) was conducted on February 1, 2017 with deficiencies noted. The deficiency noted was expired CII medications not reconciled every 10 days until they are reverse distributed. A successful plan of correction was submitted.
- CVS Pharmacy #915 has three prior reported losses.

ACTION: Motion by E.TAGLIERI, seconded by M. GODEK, and voted unanimously to Dismiss PHA-2017-0080, no discipline warranted, upon receipt of exact count inventory of all Tramadol products in 9/2017.

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**Case #3**

**PHA-2016-0191                      CVS Pharmacy #2322, DS2827**

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

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

- RLCS of #283 tramadol 50mg tablets around August 15, 2016 and a loss of #60 amphetamine 10mg tablets around March 4, 2017.
- Tramadol loss was identified via corporate controlled substance monitoring and amphetamine via a patient pickup.
- CVS conducted a full investigation and the loss for tramadol was unknown. Video footage was not reviewed as time-frame could not be determined. Video footage was reviewed for amphetamine loss with no suspicious activities.
- Policies and procedures were submitted to the OPP related to controlled substance accountability and management and they were reviewed with staff.
- A Retail Compliance inspection (ISP- 7106) was completed on April 4, 2017 with no deficiencies noted.
- CVS Pharmacy #2322 has three prior reported losses.

ACTION: Motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously by those present, to refer the matter (PHA-2016-0191) 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, placing all Tramadol products on perpetual inventory for 6 months.

**Case #4**

**PHA-2017-0069                      CVS Pharmacy #2322, DS2827**

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

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

- During a routine Retail Compliance inspection (ISP-5121) conducted on November 21, 2016, OPP investigator cited multiple repeat deficiencies including; expired CII not being inventoried every 10 days (23 different drugs), insanitary conditions, and compounding deficiencies to include; incorrect BUDs (1 year when

should've been 30 days) and incomplete or missing compounding records

- Other deficiencies noted in report; current MOR's name not posted, current MOR's paperwork for controlled substances not complete, no running hot water from the sink, the MOR was unable to produce refrigerator logs prior to 11/1/2016.
- Satisfactory POC was submitted 12/11/2016
- On April 4, 2017, OPP performed a follow-up Retail Compliance Inspection (ISP-7106) which was deemed satisfactory, no deficiencies observed.

ACTION: Motion by P. GANNON, seconded by W. COX, and voted unanimously by those present, to Dismiss PHA-2017-0069, no discipline warranted, already remediated.

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**Case #5**

**PHA-2017-0015**

**CVS Pharmacy #615, DS3493**

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

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

- On March 1, 2016, CVS #615 reported an unknown loss of 1,948ml of guaifenesin-codeine 100mg-10mg/5ml oral liquid discovered on February 19, 2016, subsequently amended to 1,387ml.
  - On April 13, 2016 and on June 20, 2016, BORP Staff requested additional information to clarify the circumstances of the loss. On June 29, 2016, a staff-assignment investigation (SA-INV-10401) was opened.
  - According to former MOR Dahbour, the quantity of loss changed depending on the period of time reviewed. Reconciliations were completed for several months, and the variances were small in comparison to the volume of scripts dispensed. The suspected loss is believed to be due to excess poured when dispensing of scripts, as well as the loss of a couple ml's every time the pharmacist poured out and measured this drug over the past couple of months.
  - Former MOR Dahbour's corrective action included closer scrutiny of inventory records to more quickly identify a loss, double counting all CS's, retraining in SOP for damages/outdates and loss prevention.
  - BORP opened a complaint during the January 2017 Meeting. CVS #615 did not have any further information to add. Of note, the loss represented 1.8% of the annual inventory.
  - CVS #615 has had four additional reports of loss (2 of 4 were unknown losses) during former MOR Dahbour's term of service.
  - CVS Pharmacy #615 has not reported a loss or theft since August of 2016.
- ACTION: Motion by M. GODEK, seconded by A. STEIN, and voted unanimously by those present, to Dismiss PHA-2017-0015, no violation.

**Case #6**

**PHA-2017-0054**

**Walgreens #9233, DS3407**

RECUSAL: M. GODEK, and W. COX recused and were not present for the discussion or vote on this matter.

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

- RLCS-Self-report loss of #66 oxycodone 20mg reported on December 16, 2016 and #30 morphine sulfate ER 15mg tablets reported on January 18, 2017.
- Both losses were discovered during weekly perpetual inventory
- In a review of video footage of the first loss, it appears that the #66 oxycodone tablets may have been thrown into the trash
- A review of video footage of the second loss showed Pharmacist Nguyen filling prescriptions for # 90 oxycodone 5mg tablets along with a second prescription for #60 morphine 15mg SR tablets. It appeared that he counted #90 tablets for both the oxycodone and morphine SR
- MOR MacDonald indicated that filling procedures were reviewed with staff and reminded them that all CII medications are to be doubled counted by the pharmacist and CPhT and circled on the bottle.
- Pharmacist Nguyen completed 2 hours of CE with a focus on Safety/Med error prevention and attested to reading 247 CMR 15 in its entirety.

ACTION: Motion by A. STEIN, seconded by R. TINSLEY and voted unanimously by those present, to refer the matter (PHA-2017-0054) 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 #7**

**PHA-2017-0031**

**Walgreens #4595, DS2970**

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

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

RLCS-Self-reported loss of #180 D-Amphetamine Salt Combo 20mg tablets on or about January 15, 2017, later amended to #90 after further investigation

- MOR Tram indicated that there was an initial loss of #30 tablets discovered on January 15, 2017, by the pharmacist performing the CII perpetual inventory
- LP ran the Item Movement Report and ultimately determined that #90 tablets were missing, dating back to the Annual CS Inventory taken on June 9, 2016
- MOR Tram initiated an action plan help prevent further losses of this nature.
- MOR Tram will be responsible for printing a bi-weekly report of controlled substances that would highlight and evaluate the dollar amounts and negative adjustments. She will also be responsible for monitoring for accurate receiving by initialing as well as circling the amount of controlled product received.
- MOR Tram indicated that the pharmacist will perform a daily "Smart" count on 6-10 randomized controlled drugs. MOR Tram will also monitor exceptions with ordering and analyze overbuys for controls.

ACTION: Motion by A. STEIN, seconded by C. BASILE and voted unanimously by those present, to refer the matter (PHA-2017-0031) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for Reprimand.

**Case #8**

**PHA-2017-0051**

**Rite Aid Pharmacy #10060, DS3036**

**Time: 1:44 PM**

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

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

- RLCS for a loss of #100 Oxycodone HCL 5mg tablets on or about November 20, 2016 due to a suspected prescription miscount.
- The loss was discovered while conducting a controlled substances count. Pharmacy staff immediately conducted an internal audit, comparing the order history and drug dispensing records for the oxycodone 5mg tablets and checked the shelves to ensure the bottle was not accidentally misplaced.
- The staff pharmacist was able to recover 8 empty bottles for Oxycodone 5mg from the trash. When adding those 8 bottles to the 7 bottles that remained in the C-II safe and comparing it with the totals from the internal audit program- it indicated a dispensing error.
- MOR contacted all patients who received Oxycodone 5mg tablets during the period the loss could have occurred to see if anyone received extra tablets but the error was not able to be confirmed.
- Pharmacy staff adjusted C-II verification process to reduce likelihood of miscounts, and the District Supervisor reviewed the loss policies and procedures surrounding controlled substance inventory management with the floater pharmacist who may have conducted the miscount.

ACTION: Motion by A. STEIN, seconded by C. BASILE, and voted unanimously by those present, to refer the matter to the office of prosecution for the issuance of an order to show cause and authorize a consent agreement for reprimand to the drug store.

**Case #9**

**SA-INV-10701**

**Rite Aid Pharmacy #10078, DS3471**

**Time: 1:46 PM**

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

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

- Loss of 100 oxycodone 30mg tablets due to a suspected prescription miscount
- The loss was reported 29 days after discovery
- MOR LaRoche filled a prescription for 280 tablets with a returned to stock bottle of 168, counted 180 total then added 2 full bottles of 100
- Patient was identified and contacted but did not return the medication
- No theft/diversion suspected
- Perpetual inventory indicated entries input after the fact
- CA includes double counting, back counting with documentation, logging entries immediately
- P&P for filling CII prescriptions was reviewed with MOR LaRoche.

ACTION: Motion by P. GANNON, seconded by W. COX, and voted unanimously by those present, to open a complaint.

**Case #10**

**PHA-2016-0127**

**Cardinal Health Nuclear Pharmacy #414- NU11**

**Time: 1:55 PM**

RECUSAL: None



DISCUSSION: N. VAN ALLEN presented and summarized the investigation report that pertained to these matters:

- Cardinal Health Nuclear voluntarily ceased compounding on September 2nd, 2016 subsequent to inspectional deficiencies of their certification for both PECs and SECs and environmental state of control issues identified during a NABP Inspection on June 23rd-24th, 2016.
- The facility remained closed while undergoing a complete renovation of their sterile compounding facility and establishing a compliant ISO Class 7 cleanroom suite.
- Cardinal Health Nuclear successfully remediated the deficiencies cited, by achieving a full certification of both PECs and SECs and maintaining an environmental state of control.
- Cardinal Health Nuclear resumed compounding operations on March 11th, 2017.

ACTION: Motion by M. GODEK, seconded by E. TAGLIERI, and voted unanimously by those present, to dismiss PHA-2016-0127, no discipline warranted, remediation complete.

**Case #11**

**SA-INV-11414**

**Nimble RX, Inc., DS90047**

**Time: 1:56 PM**

RECUSAL: none

DISCUSSION: K. Morton presented and summarized the investigation report that pertained to these matters:

- On March 31, 2017, OPP Investigators attempted to conduct a retail compliance inspection at Nimble Rx, Inc. but were not able to gain access to the pharmacy, as it had never opened for business.
- Nimble RX Inc. indicated that when they went through the licensing process in June of 2016 they had anticipated beginning operations at that location in Q4 of 2016. They then decided to focus the company's efforts on improving the quality of their patient experience in their currently active locations before expanding to new markets. The new expected start date has been pushed back to Q4 of 2017
- Nimble RX Inc. confirmed that medications had never been ordered, stored, or dispensed there and that they have not yet obtained any insurance contracts in the state of Massachusetts, but they do have a wholesaler contract with Cardinal Health.
- They also indicated that their current Manager of Record, Richard Ploude is in an idle role since operations are inactive. When OPP investigator contacted Richard Ploude he indicated that he ended his relationship with Nimble RX, Inc. in July of 2016 due to the pharmacy not opening and that he no longer has contact with Nimble RX, Inc.
- When asked about the conflicting information Nimble RX Inc. responded by stating, "Richard Ploude is our Manager of Record on file. We are in pursuit of a new Manger of Record as we approach our Q4 opening date."

ACTION: Motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously by those present, to receive notification from E.D. Sencabaugh to Nimble RX, Inc. to open within 60 days with a valid MOR or open a complaint.

**Case #12**

**SA-INV-10593**

**Holyoke Health Center Pharmacy, DS3491**

**Time: 2:03 PM**

RECUSAL: None

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

- On November 9, 2016, OPP Inspectors conducted a routine retail compliance inspection (ISP-6255) that was deemed satisfactory. However, three unlicensed staff members called Pharmacy Community Health (PCH) Workers were observed working in the pharmacy during the inspection. OPP Inspectors did not observe any violations involving the PCH Workers during the inspection. OPP opened an SA-INV to further examine the matter.
- A job description was obtained from the pharmacy. The job description was partly consistent with descriptions of medical interpreters with additional duties similar to pharmacy clerks. The PCH Workers do not handle controlled substances other than to process patients at the POS. The pharmacy stressed that patient do not provide cognitive services to patients.
- MOR Lori Lewicki stated that the PCH Workers assist patents in obtaining and coordinating pharmacy services.
- PCH Workers facilitate, but do not dispense, prepare or package medications, or call for refills.
- MOR Lewicki also stated one of the reasons they utilize PCH Workers is that she no luck in procuring the services of pharmacists or pharmacy technicians who are truly bilingual.
- The pharmacy also has 16 separate high tech cameras in place to detect improper actions by persons employed at the pharmacy.

ACTION: Motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously by those present, to close SA after receiving detailed formalized policies and procedures from Holyoke Health Center Pharmacy on maintaining security and safety in the pharmacy in the presence of PCH workers.

### **Case #13**

**PHA-2017-0018 IVG Veterinary Compounding Pharmacy, DS90035 Time: 2:05 PM**

RECUSAL: none

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

- 2 reports of a loss of compounded hydrocodone capsules from the "veterinary pharmacy"/hospital dispensary in the hospital.
- Hospital employee diversion suspected.
- Internal investigation could not confirm who pilfered the drugs.
- All compounded medications for pick up are now kept inside the compounding pharmacy or mailed.
- A log book is used to track each controlled substance prescription until it is picked up.
- All controls dispensed for in-patient use are in a locked box in the ICU with monitoring and a log book was implemented for all compounded in-patient prescriptions as well.
- Last inspected 04/05/2017 with no deficiencies (retail and 795).

ACTION: Motion by E. TAGLIERI, seconded by W. COX, and voted unanimously by those present, to dismiss PHA-2017-0018, no discipline warranted, remediation complete and refer to DCP Veterinary Board.

### **Case #14**

RECUSAL: none

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

- Unknown loss of 100 methadone 5 mg tablets found during the overnight shift of the same day on 07/12/2015 while conducting perpetual inventory.
- An internal investigation was conducted including the review of video footage from the CII room.
- Suspect the bottle was discarded inadvertently.
- All empty bottles in the CII room are inspected by a pharmacist before being discarded and the trash is removed by the pharmacist.
- No losses in over 3 years.

ACTION: Motion by M. GODEK, seconded by W. COX, and voted unanimously by those present, to close SA-INV-10881, no discipline warranted.

### **TOPIC XIII**

#### **EXECUTIVE SESSION**

DISCUSSION: None

ACTION: At 2:10 pm President T. FENSKY read the statement on reasons for Executive Session. At 2:18, he called for a motion to enter Executive Session: Motion by P. GANNON, seconded by M. GODEK and voted unanimously by roll call to enter into Executive Session. C. BASILE had left the meeting for the day.

### **TOPIC XIV**

#### **Adjudicatory Session (continued)**

DISCUSSION: None

ACTION: At 2:27 pm, on a motion by M. GODEK, seconded by E. TAGLIERI, the members voted unanimously again, to enter into Adjudicatory session.

### **TOPIC XV**

#### **M.G.L. c. 65C Session**

DISCUSSION: None

ACTION: At 2:50 pm, on a motion by M GODEK, seconded by E. TAGLIERI and voted unanimously to enter into M.G.L. c. 65C Session. W. COX left for the day.

### **TOPIC XVI**

#### **ADJOURNMENT OF MEETING**

DISCUSSION: NONE

ACTION: At 4:50 pm motion by M. GODEK, seconded by P. GANNON, and voted unanimously to adjourn the meeting. R.TINSLEY had left for the day.

#### **EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING**

6. Draft Agenda of the 6/15/2017 General Session
7. Draft Minutes of the 5/4/2017 Pharmacy Board Meeting
8. Draft Advisory on Defective Compounds
9. Draft Defective Drug Preparation Form

10. Board of Pharmacy draft Advisory on Pharmacy Requirements to Maintain Defective Drug Preparation Log
11. Draft Pharmacy Report Form for Serious Adverse Drug Event or Improper Dispensing
12. Memo from Sam Leadholm to Members of the Board of Registration in Pharmacy re Todd Mathews (for sanction hearing.)
13. Application of Letourneau's Compounding Pharmacy to change its business model.
14. Application of Waivers for Heritage Biologics, Inc.
15. Application of A & J Compounding, Inc. for a Transfer of Ownership
16. Application of Preferred Pharmacy for renovation / expansion.
17. Application of Option Care Enterprises, Inc. to relocate their pharmacy.
18. Memo from Karen Fishman, Probation Monitor-Statistics for period 4/22/17 – 5/29/17
19. Report on applications Approved Pursuant to Licensure Policy 13-01
20. Report of Board Delegated Review Session from 6/12/2017
21. Report of Above Action Level pursuant to Policy16-04
22. Bureau Staff Action Policy 17-02 Referrals to the Office of the Attorney General
23. Memo from Sullivan's Pharmacy regarding petition for pilot program approval
24. Board of Registration in Pharmacy draft Advisory on Levels of Non-Sterile Compounding
25. Board of Pharmacy Complex Non-Sterile Compounding Inspection Report
26. Investigation report in the matter of PHA-2017-0050 CVS #318, DS21288
27. Investigation report in the matter of PHA-2017-0080 CVS #915, DS3395
28. Investigation report in the matter of PHA-2016-0191CVS #2322, DS2827
29. Investigation report in the matter of PHA-2017-0069CVS #2322, DS2827
30. Investigation report in the matter of PHA-2017-0015CVS #615, DS3493
31. Investigation report in the matter of PHA-2017-0054, Walgreens #9233, DS3407,
32. Investigation report in the matter of PHA-2017-0031, Walgreens #4595, DS2970
33. Investigation report in the matter of PHA-2017-0051, Rite Aid Pharmacy10060, DS3036
34. Investigation report in the matter of SA-INV-10701, Rite Aid#10078, DS3471
35. Investigation report in the matter of PHA-2016-0127, Cardinal Health Nuclear #414, NU11
36. Investigation report in the matter of SA-INV-11414, Nimble Rx, Inc., DS90047
37. Investigation report in the matter of SA-INV-10593, Holyoke Health Center Pharmacy, DS3491
38. Investigation report in the matter of PHA-2017-0018, IVG Veterinary Compounding Pharmacy, DS90035
39. Investigation report in the matter of SA-INV-10881, Partners of Massachusetts, DS3419

40. Respectfully submitted by:

S. CORNACCHIO, JD, RN, Secretary  
Secretary