

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

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

September 7, 2017  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

**Agenda**

<b>Time</b>	<b>#</b>	<b>Item</b>	<b>Contact</b>
<b>8:30</b>	<b>I</b>	<b>CALL TO ORDER</b>	T. Fensky
<b>8:30</b>	<b>II</b>	<b>APPROVAL OF AGENDA</b> <ul style="list-style-type: none"> <li>• Introduction of Intern: Tiffany Wong</li> </ul>	
<b>8:35</b>	<b>III</b>	<b>APPROVAL OF BOARD MINUTES</b> <ul style="list-style-type: none"> <li>• Draft of August 3, 2017 Regular Session Minutes</li> </ul>	
<b>8:40</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 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
<b>8:45</b>	<b>V</b>	<b>APPLICATIONS</b> <ul style="list-style-type: none"> <li>• Baxter Healthcare Corporation – Petition to Waiver</li> <li>• Triad Isotopes (NU00019) – Transfer of Ownership</li> <li>• Allied Pharmacy, Inc. – New Community Pharmacy</li> <li>• Cardinal Health – Wholesale Distributor</li> </ul>	
<b>9:30</b>	<b>VI</b>	<b>PILOT PROJECT</b> <ul style="list-style-type: none"> <li>• Brigham &amp; Women’s/Bay State Medical Center Technology check Technician Pilot Project</li> </ul>	
<b>10:00</b>	<b>VII</b>	<b>CVS HEALTH PROPOSAL FOR REMEDIATION OF UNKNOWN LOSSES</b>	

<b>10:30</b>	<b>VIII</b>	<b>DETERMINATION OF COMPLIANCE</b> <ul style="list-style-type: none"> <li>• Atef Ayoub, PH 233456, PHA-2017-0036</li> <li>• St. George Pharmacy, DS90034, PHA-2017-0035</li> </ul>																														
<b>10:40</b>	<b>IX</b>	<b>VIOLATION OF CONSENT AGREEMENT FOR STAYED PROBATION</b> <ul style="list-style-type: none"> <li>• CVS #433; DS89796; PHA-2016-0184</li> </ul>																														
<b>10:50</b>	<b>X</b>	<b>FLEX</b> <ul style="list-style-type: none"> <li>• 2018 Board meeting dates</li> <li>• PSUD Committee</li> <li>• Pharmacy Related Outside Sections in FY18 Budget</li> <li>• NABP District 1 &amp; 2 meeting discussion</li> </ul>																														
<b>11:00</b>	<b>XI</b>	<b>POLICIES</b> <ul style="list-style-type: none"> <li>• Bureau Staff Action Policy 17-03: Petitioning for Retirement Status</li> <li>• Enforcement Policy 17-01: Staff Action Authorization for Consent Agreements for Voluntary Surrender and Consent Agreements not to practice</li> <li>• Retail Pharmacy Participation in Research Studies</li> </ul>	V. Berg M. Chan V. Thaker																													
<b>11:05</b>	<b>XII</b>	<b>REGULATIONS</b> <ul style="list-style-type: none"> <li>• 247 CMR 17.00: Sterile Compounding</li> </ul>																														
		<table border="1"> <tr> <td><b>1</b></td> <td>SA-INV-11414- Nimble RX, Inc- DS90047</td> <td>Morton</td> </tr> <tr> <td><b>2</b></td> <td>PHA-2017-0075- Rite Aid #10145, DS3346</td> <td>Santoro</td> </tr> <tr> <td><b>3</b></td> <td>PHA-2017-0126- Rite Aid #10078, DS3471</td> <td>Mogni</td> </tr> <tr> <td><b>4</b></td> <td>SA-INV-11043- Rite Aid #10085, DS3180</td> <td>Mogni</td> </tr> <tr> <td><b>5</b></td> <td>PHA-2017-0052- Rite Aid #10091, DS2558</td> <td>Seed</td> </tr> <tr> <td><b>6</b></td> <td>PHA-2017-0082- Rite Aid #10207, DS2411</td> <td>Mogni</td> </tr> <tr> <td><b>7</b></td> <td>PHA-2017-0086- Bravo Pharmacy, DS89981</td> <td rowspan="2">Melton</td> </tr> <tr> <td><b>8</b></td> <td>SA-INV-11229- Kevin O'Brien, PH17654</td> </tr> <tr> <td><b>9</b></td> <td>PHA-2017-0103- CVS #117, DS3207</td> <td>Mogni</td> </tr> <tr> <td><b>10</b></td> <td>PHA-2017-0133- CVS #669, DS2846</td> <td>Mogni</td> </tr> </table>	<b>1</b>	SA-INV-11414- Nimble RX, Inc- DS90047	Morton	<b>2</b>	PHA-2017-0075- Rite Aid #10145, DS3346	Santoro	<b>3</b>	PHA-2017-0126- Rite Aid #10078, DS3471	Mogni	<b>4</b>	SA-INV-11043- Rite Aid #10085, DS3180	Mogni	<b>5</b>	PHA-2017-0052- Rite Aid #10091, DS2558	Seed	<b>6</b>	PHA-2017-0082- Rite Aid #10207, DS2411	Mogni	<b>7</b>	PHA-2017-0086- Bravo Pharmacy, DS89981	Melton	<b>8</b>	SA-INV-11229- Kevin O'Brien, PH17654	<b>9</b>	PHA-2017-0103- CVS #117, DS3207	Mogni	<b>10</b>	PHA-2017-0133- CVS #669, DS2846	Mogni	
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<b>11:20</b>	<b>XIII</b>	<b>File Review</b>			
		<b>11</b>	PHA-2017-0077- CVS #769, DS2948		Morton
		<b>12</b>	PHA-2017-0068- Omnicare of Northern Mass, DS89931		Santoro
		<b>13</b>	SA-INV-11236- Rite Aid #10204- DS2577		Melton
		<b>14</b>	PHA-2017-0090- Walgreens #3337, DS2626		Mogni
		<b>15</b>	PHA-2017-0135- Walgreens #2517, DS2106		Mogni
		<b>16</b>	PHA-2017-0116- Walgreens #9011, DS3347		Santoro
		<b>17</b>	PHA-2017-0047- Samuels Pharmacy, DS15095		Murray
		<b>18</b>	PHA-2017-0094- Peter Lyons, PH19225		
		<b>19</b>	PHA-2017-0115- Custom Medicine Pharmcenter, DS3323		Mogni
		<b>20</b>	PHA-2017-0145- Dan's Pharmacy, DS89748		Mogni
<b>21</b>	PHA-2017-0144- Lenox Village Pharmacy, DS3344	Mogni			
<b>12:00</b>		<b>LUNCH BREAK</b>			
<b>1:00</b>	<b>XIV</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 applicants.		<b>CLOSED SESSION</b>	
<b>1:45</b>	<b>XV</b>	<b>ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)</b>		<b>CLOSED SESSION</b>	
<b>2:30</b>	<b>XVI</b>	<b>M.G.L. c. 112, § 65C SESSION</b>		<b>CLOSED SESSION</b>	
<b>5:00</b>	<b>XVII</b>	<b>ADJOURNMENT</b>		<b>CLOSED SESSION</b>	

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

**MINUTES OF THE REGULARLY SCHEDULED MEETING  
239 Causeway Street, Fourth Floor ~ Room 417A  
Boston, Massachusetts, 02114**

**September 7, 2017**

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**Board Members Present**

Timothy Fensky, R.Ph. President  
Michael Godek, R.Ph, President Elect  
Susan Cornacchio, JD, RN, Secretary  
Garrett Cavanaugh, R.Ph.  
Andrew Stein, Pharm D, R.Ph.  
William Cox, CPhT  
Ali Raja, MD, MBA, MPH  
Karen Conley, DNP, RN, AOCN, NEA-BC

**Board Members Not Present**

Richard Tinsley, MBA, Med,  
Patrick Gannon, R.Ph  
Phillippe Bouvier, R.Ph

**Board Staff Present**

David Sencabaugh, R.Ph, Executive Director  
Monica Botto, CPhT, Associate Executive Director  
Heather Engman, JD, MPH, Pharmacy Board Counsel  
Christina Mogni, R.Ph, Investigator  
Michelle Chan, R.Ph, Quality Assurance Pharmacist  
Michael Brosnan, PharmD, R.Ph, Investigator  
Greg Melton, JD, PharmD, BCPS, 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, Contract Pharmacist Fellow  
John Murray, R.Ph, Investigator  
Nathan Van Allen, PharmD, R.Ph.

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**TOPIC I.**

**CALL TO ORDER 8:32 AM**

**DISCUSSION:** A quorum of the Board was present, established 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.

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**TOPIC II.**

**Approval of Agenda**

**TIME: 8:33AM**

**DISCUSSION:** Defer 3 Walgreens cases and Cardinal application to next Board meeting

**ACTION:** Motion by M. GODEK, seconded by K. CONLEY, and voted unanimously by all present to approve the agenda with noted changes.

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D. SENCABAUGH introduces T. WONG as the new intern for the Board of Registration in Pharmacy.

H. ENGMAN introduces A. HIGGINS as the new legal intern for the Board of Registration in Pharmacy.

T. FENSKY asked interns in the audience to stand up and introduce themselves.

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**Topic III.**

**Approval of Board Minutes**

**Minutes Draft, August 3, 2017 Regular Session Minutes**

**TIME: 8:38 AM**

**ACTION:** Motion by K. CONLEY, seconded by M. GODEK, all voted affirmatively by those present, except for A. RAJA and G. CAVANAUGH who abstained, to accept the minutes of the 8/3/2017 General Session minutes with no changes.

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**TOPIC IV.**

**REPORTS**

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

**TIME: 8:39 AM**

**DISCUSSION:** M. BOTTO noted that during the past month there have been thirty two (32) changes of manager, one (1) closed pharmacy, one (1) revocation/expansion, and one (1) new community pharmacy.

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**TOPIC IV.****REPORTS****Monthly Report From Probation****TIME:** 8:39 AM

**DISCUSSION:** D. SENCABAUGH reported that there were fifty two (52) pharmacy licensees on probation and fifteen (15) who have completed probation.

**Monthly Report from BDCR pursuant to Policy 14-02****TIME:** 8:40 AM

There were 6 Board Delegated Review cases heard on August 31, 2017. 4 of the 6 were QREs (PHA-2017-0057, PHA-2017-0058, PHA-2017-0087, PHA-2017-0117) and all of the 4 had been dismissed with discipline not warranted and remediation complete. The other two cases were CE deficiencies (SA-INV-11105, SA-INV-11243) which were closed with no discipline warranted and remediation complete. The Board Delegated Review session was attended by T. FENSKY as the Board Member, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

**Above Action Levels Approved by Staff Action 16-04****TIME:** 8:40 AM

**DISCUSSION:** V. THAKER reported that there were five above action level reports. Three of the five had been escalated to a staff assignment since they were from the same pharmacy, one of the five had been remediated and closed, and the last one was in progress.

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**TOPIC V****APPLICATIONS****1. Baxter Healthcare Corporation- Petition to Waiver****TIME:** 8:40 AM**RECUSAL:** None

**DISCUSSION:** Baxter Healthcare Corporation was not present at the Board meeting. They are petitioning to get a waiver to require a sink in the area. They only store one product there.

**ACTION:** Motion by M. GODEK, seconded by W. COX, and voted unanimously by all present to approve the waiver.

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**2. Triad Isotopes, NU00019 - Transfer of Ownership****TIME:** 8:41 AM**RECUSAL:** None

**DISCUSSION:** Triad Isotopes is now owned by Jubilant Pharmacy with no change in management.

**ACTION:** Motion by K. CONLEY, seconded by W. COX, and voted unanimously by all present to approve the transfer of ownership.

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**3. Allied Pharmacy, Inc. - New Community Pharmacy**

**TIME:** 8:45 AM

**RECUSAL:** None

**DISCUSSION:** Allied Pharmacy was represented by Olga C Tejada and Juana Elizabeth Tejada (MOR). They answered the Board members' questions to their satisfaction.

- Compounding: magic mouthwash, omeprazole, and creams
- MOR has been an MOR previously at another location for 2 ½ years. Familiar with the responsibilities.
- There will be no hazardous non-sterile compounding.
- There will be 3 pharmacists and 1 technician employed at the pharmacy. The technician will be required to be PTCB certified.
- The MOR is immunization certified and also has access to PMP.
- They are using Pharmaserv computer system.
- Plan on delivering medication to home with tamper evident packaging.
- In the future they hope to be making blister-packs.

**ACTION:** Motion by W. COX, seconded by G. CAVANAUGH, and voted unanimously by all present to approve the new community pharmacy, pending inspection.

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**4. Cardinal Health - Wholesale Distributor (DEFERRED)**

**TIME:** 8:50 AM

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**TOPIC VI**

**Pilot Project**

**Brigham & Womens / Bay State Medical Center - "Technology-Check-Technician"**

**TIME:** 9:04 AM

**RECUSAL:** None

**DISCUSSION:** Brigham and Women's Hospital and Bay State Medical Center were represented by Caryn Belisle, Erin Taylor, Aaron Michellicci to present a "technology-check-tech" pilot project.

- Propose stock medications to be transferred from the central pharmacy to the hospital wards by certified technicians. Verification of non-patient specific products would not be done by a pharmacist, but by technology. Bar code scanning would occur at several steps in the stocking process, including bedside verification scanning by a nurse.
- This will be a 1 year pilot with monthly audits performed by a pharmacist.
- The purpose is to free up pharmacist time for clinical activities.

- Only schedule VI medications will be included in the pilot. Schedule II-V, patient specific, and compounded medications will not be included.
- All technicians will be certified (CPhT)
- They will be comparing pre and post data to see the benefits of implementing the program.

**ACTION:** Motion by M. GODEK, seconded by W. COX, and voted unanimously by all those present to approve the pilot pending approval from Health Care Safety and Quality and/or DCP.

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## **TOPIC VII**

**CVS Health Proposal for Remediation of Unknown Losses.**

**TIME:** 9:52 AM

**RECUSAL:** None

**DISCUSSION:** CVS Proposal: Stayed Probation Orders; Unknown Losses represented by John N. Rocchio.

- Board's current sanction of a controlled substance loss is a 6 month perpetual inventory for the drug class involved
- Proposal is a 1 year plan including:
  - Initial exact count as well as exact count every 30 days for the drugs in question
  - Periodic cycle counts are done for CVS's high theft drugs
  - Increase supervisor visit to check balance on hand sheets every 30 days
  - CVS has had success in other states with this plan
  - A separate CII waiting bin has been implemented in certain stores at the MOR's discretion
  - CVS is considering moving to an annual count instead of biennial

**ACTION:** No vote at this time. Consideration of proposal will be implemented on a case-by-case basis.

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## **VIII Determination of Compliance**

**TIME:** 10:22 AM

**Atef Ayoub, PH233456**

**RECUSAL:** None

**DISCUSSION:** Atef Ayoub of St. George Pharmacy presented by K. FISHMAN.

- Consent agreement states that he may not act as a MOR and may not supervise interns
- Need to determine whether he is permitted to supervise interns he may be working with even though he is not acting as the preceptor
- (S. CORNACCHIO): Is the new MOR aware of the consent agreement
  - New MOR only works 6 hours a week



**ACTION:** Motion by A. STEIN, seconded by M. GODEK, and voted unanimously by those present to modify consent agreement to indicate that Atef Ayoub may not precept nor supervise interns, and to attest to having read the DEA Pharmacists Manual

**St. George Pharmacy, DS90034, PHA-2017-0035**

**RECUSAL:** None

**DISCUSSION:** St. George Pharmacy represented by K.FISHMAN

- On August 11, 2017 upon inspection, deficiencies were noted
  - CII prescriptions are not being canceled
  - 3 foreign student interns on duty with one pharmacist

**ACTION:** Motion by G.CAVANAUGH, seconded by K. CONLEY, and voted unanimously by those present to acknowledge the violation, but that no further discipline was required.

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**IX Violation of Consent Agreement for Stayed Probation TIME: 10:38 AM**

**CVS #433; DS89796; PHA-2016-0184**

**RECUSAL:** S. CORNACCHIO

**DICUSSION:** S.LEADHOLM discussed the discovery that CVS #433 has not performed exact counts of benzodiazepine products per their consent agreement.

- Inspected on April 28, 2017 and it was discovered that CVS #433 missed a perpetual benzodiazepine count by 12 days
- MOR acknowledged the violation and submitted a plan of correction
- No losses reported since the inspection

**ACTION:** Motion by A. STEIN, seconded by G. CAVANAUGH, and voted unanimously by all present to acknowledge the violation, but that no further discipline was required.

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**Flex Session**

**2018 Board Meeting Dates**

**TIME: 9:01 AM**

**ACTION:** Motion by K. CONLEY, seconded by W. COX, and voted unanimously by those present to approve the 2018 Board Meeting dates.

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**PSUD Committee****TIME: 8:51 AM**

**DISCUSSION:** E.TAGLIERI discussed that the Board is responsible for appointing the PSUD committee. PSUD is a non-disciplinary alternative for all pharmacy licensees to accept a consent agreement for substance abuse treatment instead of discipline. A FAQ sheet will go out on the distribution list.

**Pharmacy Related Outside Sections in FY18 Budget****TIME: 8:52 AM**

**DISCUSSION:** Approval of two amendments presented by H. ENGMAN.

- M.G.L. ch. 94c § 7 – virtual manufactures/distributers with headquarters in Massachusetts may register with DCP
- M.G.L. ch. 94c § 18 D ½ - pharmacies may fill CII prescriptions written by a midlevel practitioners for patients admitted to a LTCF in the contiguous states only if the medications are delivered directly to the LTCF.
- H. Engman summarized amendments to 94C, but there was no “approval” of them.

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**NABP District 1 and 2 Meeting****TIME: 8:53 AM****RESOLUTIONS:**

- Mandate e-prescribing for controlled substances
- Adequate counseling for certain compounded preparations with Black Box Warnings and active ingredients
- Allow refill authorizations by default prescriber in hospital setting, with Electronic Health Records with hospitals in place.

**ACTION:** Motion by M. GODEK, seconded by W. COX, and voted unanimously by all present to send all three resolutions to the district meeting.

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**XI POLICIES****Bureau Staff Action Policy 17-03****TIME: 10:42 AM****Petitioning for Retirement Status:**

**DISCUSSION:** Allow the Executive Director to grant a change to retirement status for licensees without actions on his/her license. This is for individuals at least 50 years old or on a case-by-case basis presented to the Board. There will be requirements for licensees to reactivate their license if one wishes to practice again (i.e. make-up CEs, take MPJE or NABLEX)

**ACTION:** Motion by A. STEIN, seconded by K.CONLEY, and voted unanimously by all present to adopt the staff action policy.

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**Enforcement Policy 17-01: Staff Action Consent Agreements for Voluntary Surrender and Consent Agreements Not to Practice** **TIME: 10:49 AM**

**DISCUSSION:** For licensees who are practicing while impaired or have admitted to drug diversion, this policy would allow the Executive Director to execute a voluntary surrender and consent agreement for a licensee to not to practice and/or enter into the PSUD program.

**ACTION:** Motion by A. STEIN, seconded by W. COX, voted unanimously by all present to adopt the staff action policy.

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**Retail Pharmacy Participation in Research Studies** **TIME: 10:51 AM**

**DISCUSSION:** V. THAKER presented a new policy to allow pharmacy participation in research studies.

- The policy delineates how a pharmacy can become involved in research.
- If a pharmacy is currently involved with a research study, the Principal Investigator must edit the MCSR application and send it to the Drug Control Program (DCP) for approval.

**ACTION:** Motion by M. GODEK seconded by A. STEIN, voted unanimously by all present to approve the policy.  
Board Members: Add to next newsletter

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**XII: REGULATIONS** **TIME: 10:59 AM**

**247 CMR 17.00**

**DISCUSSION:** H.ENGSMAN discussed that ANF has made stylistic changes to 247 CMR 17:00. Section 17 will go out for public comment in Fall, 2017.

**ACTION:** Motion by A. STEIN, seconded by W. COX, voted unanimously by all present to approve the changes to 247 CMR 17.00 and send for public comment.

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Case #1

SA-INV-11414

Nimble Rx, Inc., DS90047

Time: 11:12 AM

**RECUSAL:** NONE

**DISCUSSION:** K. MORTON presented and summarized the investigative 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 had been pushed back to Q4 of 2017
- On June 15, 2017, the board voted to authorize for a letter to be sent to Nimble RX, Inc. requesting they operate as a pharmacy or close within 60 days.
- On August 22, 2017, the Board of Pharmacy received notice from Nimble RX, Inc. that they were closing, effective that day.

ACTION: Motion by A. STEIN, seconded by W. COX, and voted unanimously by those present, to CLOSE (SA-INV-11414) due to No Discipline Warranted, Remediation Complete.

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Case #2

PHA-2017-0075

Rite Aid #10145, DS3346

Time: 11:14AM

RECUSAL: G. CAVANAUGH 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.

- RLCS, #60 methylphenidate CD 20mg capsules, #20 alprazolam 0.25mg tablets, and #90 Lyrica 225mg capsules
- The loss of #60 methylphenidate CD 20mg capsules was discovered on 11/27/2016 during weekly CII inventory
- MOR indicated that Pharmacist Garron filled two methylphenidate CD 20mg prescriptions on 11/22/16. Both patients were contacted and stated they received the correct amount. It is believed the partial bottle was not secured in the safe after the prescriptions were filled and may have been thrown into the trash
- MOR indicated that Lyrica was discovered missing on 11/17/16 when there was insufficient quantity to fill a prescription and that she discovered the loss of alprazolam over the course of the next week during an inspection of the inventory for routine cycle counts.
- It is assumed that the bottles may have accidentally ended up in trash.
- MOR indicated that the pharmacy staff was counseled on proper operational procedures regarding the handling of controlled substances and implemented changes that would limit the

General Session Minutes 9/7/17, approved on October 5, 2017.

number of baskets on the bench at any given time, and moved trash cans further away from the bench to prevent any accidental trashing of bottles.

ACTION: Motion by W.COX, seconded by K. CONLEY, and voted unanimously by those present, to refer the matter (PHA-2017-0075) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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Case #3

PHA-2017-0126

Rite Aid #10078, DS3471

Time: 11:17 AM

RECUSAL: G. CAVANAUGH 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.

- RLCS, #100 oxycodone 30mg tablets on 11/20/2016 due to a miscount reported 29 days after discovery of the loss on 12/19/2016;
- 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 but loss could not be confirmed;
- 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 M. GODEK, seconded by K. CONLEY, and voted unanimously by those present, to refer the matter (PHA-2017-0126) 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 #4

SA-INV-11043

Rite Aid #10085, DS3180

Time: 11:19 AM

RECUSAL: G. CAVANAUGH 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.

- RLCS discovered on 12/5/16 and reported 1/27/17 (violation of the 7-day reporting requirement);

- Losses included 127 clonazepam 1mg, 32 lorazepam 0.5mg, 5 lorazepam 1mg, 5 alprazolam 0.25mg, 72 alprazolam 0.5mg;
- Initial loss of clonazepam 1 mg discovered on 12/3/16;
- Thorough internal investigation conducted during which additional discrepancies were determined;
- Determined to be operational losses which were defined to be losses due to miscounts by floater pharmacists or medications inadvertently discarded in trash;
- CA included new procedure for handling controlled substances in which only pharmacists can count controlled substances, with double counting, back counts that are recorded on the stock bottle, reconciliation of amount on hand with balance in computer prior to returning medication to shelf, only one stock bottle on shelf with surplus stored in locked safe, and any discrepancy reported immediately;
- Pharmacy has 5 previous losses reported from 3/24/14 to 5/4/15

ACTION: Motion by M. GODEK, seconded by A. STEIN, and voted unanimously by those present, to CLOSE (SA-INV-11043) with an advisory letter recommending an exact count CIII-CV Controlled Substances Inventory.

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Case #5

PHA-2017-0052

Rite Aid #10091, DS2558

Time: 11:25 AM

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

DISCUSSION: P. SEED presented and summarized the investigative report that pertained to these matters.

- RLCS discovered on 12/5/16 and reported 1/27/17 (violation of the 7-day reporting requirement);
- Losses included 127 clonazepam 1mg, 32 lorazepam 0.5mg, 5 lorazepam 1mg, 5 alprazolam 0.25mg, 72 alprazolam 0.5mg;
- Initial loss of clonazepam 1 mg discovered on 12/3/16;
- Thorough internal investigation conducted during which additional discrepancies were determined;
- Determined to be operational losses which were defined to be losses due to miscounts by floater pharmacists or medications inadvertently discarded in trash;

General Session Minutes 9/7/17, approved on October 5, 2017.

- CA included new procedure for handling controlled substances in which only pharmacists can count controlled substances, with double counting, back counts that are recorded on the stock bottle, reconciliation of amount on hand with balance in computer prior to returning medication to shelf, only one stock bottle on shelf with surplus stored in locked safe, and any discrepancy reported immediately;

- Pharmacy has 5 previous losses reported from 3/24/14 to 5/4/15

ACTION: Motion by T. FENSKY, seconded by W. COX, to refer the matter (PHA-2017-0052) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION with special terms to include staff retraining, read and attest to having read 247 CMR 9, and for the MOR to read and attest to having read the Board Advisory on New Managers of Record and to DISMISS (PHA-2017-0052) upon receipt of proof of the special terms for STAYED PROBATION having been met.

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Case #6

PHA-2017-0082

Rite Aid #10207, DS2411

Time: 11:28 AM

RECUSAL: G. CAVANAUGH 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.

- Inspectional deficiencies on 4 consecutive inspections 1/11/16 to 3/1/17 under MOR Almeida;
- Repeat deficiencies for expired CII record keeping and USP 795 compounding with incorrect BUDs and not labeled as compounds;
- Inadequate POCs submitted as deficiencies not fully corrected;
- CA with new method for accounting for expired/damaged CIIs and retraining staff regarding USP 795 compounding requirements;
- Compounding logs provided with response dated April 2017 show incorrect BUDs and missing label for "this is a compounded preparation" (repeat deficiencies).
- Inspected 7/19/17 with no deficiencies cited.

ACTION: Motion by M. GODEK, seconded by K. CONLEY, and voted unanimously by those present, to refer the matter (PHA-2017-0082) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION for 6 months with special terms to include having the staff read and

attest to reading 247 CMR 9 and USP <795> and to DISMISS (PHA-2017-0082) upon receipt of proof of the special terms for STAYED PROBATION having been met.

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Case #7

PHA-2017-0086

Bravo Pharmacy, DS89981

Time: 11:34 AM

RECUSAL: NONE

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

- During an inspection on March 29, 2017, OPP Investigators learned that a change in MOR had occurred in November of 2016 but the application was not submitted until March 27, 2017. Specifically, former MOR O'Brien resigned in November of 2016 and current MOR Donald Burns was promoted. MOR Burns indicated that he repeatedly reminded the owner of Bravo that the application needed to be completed but the application was still filed late.

- Bravo indicated that a B&E occurred at the pharmacy on October 24, 2016 and former MOR O'Brien resigned the next week. The owner indicated that he had never dealt with a B&E before and had a difficult time addressing all the issues that needed to be resolved. This caused the delay in the submission of the application for the change in MOR.

- Of note, former MOR O'Brien failed to respond to numerous attempts to contact him by certified mail, email, and phone and his pharmacist license expired on December 31, 2016.

ACTION: Motion by M. GODEL, seconded by S. CORNACCHIO, and voted unanimously by those present, to refer the matter (PHA-2017-0086) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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Case #8

SA-INV-11229

Kevin O'Brien, PH17654

Time: 11:34 AM

RECUSAL: NONE

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

- During an inspection on March 29, 2017, OPP Investigators learned that a change in MOR had occurred in November of 2016 but the application was not submitted until March 27, 2017. Specifically, former MOR O'Brien resigned in November of 2016 and current MOR Donald Burns was promoted. MOR Burns indicated that he repeatedly reminded the owner of Bravo that the application needed to be completed but the application was still filed late.

- Bravo indicated that a B&E occurred at the pharmacy on October 24, 2016 and former MOR O'Brien resigned the next week. The owner indicated that he had never dealt with a B&E before



and had a difficult time addressing all the issues that needed to be resolved. This caused the delay in the submission of the application for the change in MOR.

- Of note, former MOR O'Brien failed to respond to numerous attempts to contact him by certified mail, email, and phone and his pharmacist license expired on December 31, 2016.

ACTION: Motion by M. GODEK, seconded by K. CONLEY, and voted unanimously by those present, to CLOSE (SA-INV-11229), No Discipline Warranted.

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Case #9

PHA-2017-0103

CVS #117, DS3207

Time: 11:38 AM

RECUSAL: S. CORNACCHIO 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.

- Repeat inspectional deficiencies from on 10/6/16 and on 4/6/17 for controlled substance record keeping for the perpetual inventory including return of CII that had been dispensed and outdates of medications, OTCs, compounding components and vaccines in active stock.

- 3 different MORs from initial inspection to notification of complaint.

- Current MOR Fox provided comprehensive action plan.

- MOR Fox went through all shelves, pulled all outdates/short-dates, reviewed dispensing logs to ensure no expired meds dispensed, reviewed all P&Ps with staff, assigned check of stock monthly for outdates with return generated monthly.

- Expired CII log will be reviewed weekly to ensure compliance.

ACTION: Motion by M. GODEK, seconded by K. CONLEY, and voted unanimously by those present, to refer the matter (PHA-2017-0103) 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 #10

PHA-2017-0133

CVS #669, DS2846

Time: 11:38 AM

RECUSAL: S. CORNACCHIO 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.

- RLCS, #569 clonazepam 0.5 mg with initial loss reported on 4/18/17;

General Session Minutes 9/7/17, approved on October 5, 2017.

- Confirmed loss of #306 clonazepam 0.5mg reported 05/31/2017;
- Loss identified via corporate controlled substance monitoring and based on 5/1/15 biennial inventory compared with dispensed, acquired and returned drug;
- No diversion suspected;
- CA included monitoring of BOH reports, ordering, cycle counts; double count all controls; retraining of staff on handling of control outdates and damages; review of all baseline loss prevention procedures;
- Exact count of CIII-Vs conducted on last biennial inventory on 4/30/17;
- Last inspected 7/27/17 with no deficiencies cited.

**ACTION:** Motion by M. GODEK, seconded by K. CONLEY, and voted unanimously by those present, to refer the matter (PHA-2017-0133) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION with special terms to include staff retraining in the areas of inventory management, prescription production, and waiting bin management, perform an exact count of all benzodiazepines at least once every 30 days for a period of one year, and increase store visits by management above pharmacy manager to at least once every 30 days to validate and sign off on the BOH Modification Red Flag Cover Page.

### **XIII**

### **File Review**

**11. PHA-2017-0077**

**CVS #769, DS2948**

**Time: 11:55 AM**

**RECUSAL:** S. CORNACCHIO

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

- RLCS, #553 alprazolam 1mg tablets on or about December 9, 2016
- An investigation was conducted and the reason for the loss was unable to be determined.
- Corrective action taken included that during the biennial inventory conducted on April 30, 2017, an exact count was conducted on CII-V medications (over #1,000 units), as well as CII-V medications in the pharmacy's automated dispensing machine. He also verified that an exact count was conducted on the alprazolam 1mg tablets.
- CVS has two prior reported losses

**ACTION:** Motion by K. CONLEY, seconded by G. CAVANAUGH, voted unanimously by those present, for stayed probation to perform an initial exact count of CII-V drugs within 30

days, as well as exact benzodiazepine counts every 30 days for 1 year, staff retraining and supervisor to sign count sheets every 30 days.

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**12. PHA-2017-0068                      Omnicare of Northern MA, DS89931                      Time: 11:58 AM**

**RECUSAL: S. CORNACCHIO**

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

- RLCS, # 65 oxycodone/APAP 5/325 UD tablets and 1 fentanyl 12mcg patch on or about February 5, 2017
- #1 fentanyl 12mcg patch was discovered lost on February 5, 2017 during weekly inventory between 1/30/2017 and 2/5/2017
- A loss of #65 oxycodone/APAP 5/325 UD tablets was reported on February 8, 2017, discovered during the weekly perpetual inventory
- LP was unable to determine the cause of the loss
- MOR indicated that pharmacists will rotate through scheduled counts and she will monitor their activities. The pharmacists were encouraged to be diligent when checking/verifying and dispensing orders. She also indicated that oxycodone/APAP 5/325mg tablets will be counted twice weekly and a perpetual back count procedure of the oxycodone 5mg tablets was implemented and will take place after every fill.

**ACTION:** Motion by A. STEIN, seconded by W. COX, voted unanimously by those present, to dismiss the complaint, no discipline warranted.

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**13. SA-INV-11236                      Rite Aid #10204, DS2577                      Time: \_\_\_\_\_**  
**Deferred**

**14. PHA-2017-0090                      Walgreens #3337, DS2626                      Defer**  
**Deferred**

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**15. PHA-2017-0135                      Walgreens #2517, DS2106                      Defer**  
**Deferred**

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**16. PHA-2017-0116                      Walgreens # 9011, DS3347                      Defer**  
**Deferred**

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**17. PHA-2017-0047                      Samuels Pharmacy, DS15095                      Time: 12: 19 PM**

**RECUSAL:** H. ENGMAN

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

- Pharmacy complaint opened due to discrepancies observed on 1/10/2017 in the perpetual inventory vs. reverse distribution on 9/9/16 for morphine sulfate ER 60mg tablets (+35) and morphine sulfate 15mg tablets (-16).
- On 2/1/17, accompanied DEA investigators during audit in which 6 Schedule II medications were audited and discrepancies were observed in 5 of the 6 medications audited.
- In reviewing the documents submitted for the complaint, it observed that there were 14 instances where partially filled CII's had the remaining quantity dispensed in excess of 72 hours and 4 instances where the quantity of methadone received was not fully entered into the perpetual inventory.
- MOR Lyons identified 13 additional instances of discrepancies in the perpetual inventory logs.
- Samuels Pharmacy closed on 4/14/17.

**ACTION:** Motion by M. GODEK, seconded by A. STEIN, voted unanimously by those present, to dismiss the complaint, no discipline warranted.

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**18. PHA-2017-0094**

**Peter Lyons, PH19225**

**Time:** 12:19 PM

**RECUSAL:** H. ENGMAN

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

- Please see PHA-2017-0047
- P. Lyons is still currently practicing.

**ACTION:** Motion by M. GODEK, seconded by G. CAVANAUGH, voted unanimously by those present, to refer to Office of Prosecution, for an Order to Show Cause to authorize a consent agreement for a reprimand. Mr. Lyons cannot be MOR for 2 years and may not precept any pharmacy interns for 2 years.

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**19. PHA-2017-0115**

**Custom Medicine Pharmacenter, DS3323 Time:** 12:01 PM

**RECUSAL:** None

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

- Failure to submit acceptable POC in violation of 247 CMR 10.03 for retail and USP 795 deficiencies for inspections on 3/15/17 including compounding investigational taste test samples with CIIs for Synopsys, allegedly accepting medications from

General Session Minutes 9/7/17, approved on October 5, 2017.

veterinarians/owners for further compounding, and accepting Focalin XR 30mg dispensed by another pharmacy for further compounding.

- Investigational CII's not consistently counted every 10 days and not on last biennial inventory.
- Documentation obtained during inspection included 6 prescriptions for CII test samples, invoices/DEA 222 forms for investigational CII's, investigational drug inventory logs for CII's, and documentation of vet drug obtained from Atlantic Vet Hospital.
- Voluntarily stopped compounding investigational taste test samples and compounding drugs obtained accepted from patients/owners or veterinarians on 3/17/17.
- MCSR for the Principal Investigator at Senopsys was for "Ind, IV, V, VI".
- MOR Beckman did not provide a POC that included corrective steps, a timetable for the steps, and the date compliance achieved.
- MOR Beckman contended the compounding in question was halted pending Board's resolution of the issue.
- The Attorney alleged the compounding was not compounding, but the skilled preparation of test samples and that no compounding of them had occurred 3/15/16-3/15/17 with no purchasing records during that time.
- From 3/30/16 to 2/21/17, the Pharmacy compounded 4,094 samples for Senopsys and none of these prescriptions were submitted as requested.
- The Pharmacy does not have any MCSR's or a veterinary wholesale license. The 12/12/13 nonsterile compounding attestation states all APIs are from an FDA approved manufacturer or distributor.
- CA included return Focalin XR 30mg to reverse distributor, preparation of test samples has been suspended, compounding of veterinary meds received from another registrant has been halted, compounding CII's purchased from another pharmacy has been discontinued.
- P&P has been adopted for prohibiting further compounding from drugs received from patients and all staff attested to reviewing it.
- Last inspected 8/23/17 with POC issued for investigational drug substance (never used) not stored under appropriate temperature in freezer

**ACTION:** Motion by M. GODEK, seconded by K. CONLEY, voted unanimously by those present, to refer to Office of Prosecution, for an Order to Show Cause to authorize a consent agreement for a stayed probation for 6 months. An advisory is to be sent out stating that the pharmacy cannot receive medications from another pharmacy or prescriber (in this case, veterinarian) to compound medications. The advisory will include the new policy regarding investigational drug studies. The pharmacy staff must read, and attest to having read the following: 247 CMR 9.00 and USP 795.

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**20. PHA-2017-0145**

**Dan's Pharmacy, DS89748**

**Time: 12:12 PM**

**RECUSAL:** None

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

General Session Minutes 9/7/17, approved on October 5, 2017.

- Inspection on 5/8/2017 revealed MOR Balling compounded #60 Cannabidiol (CBD) 25 mg capsules without a prescription.
- FDA does not allow the compounding of CBD products as they are considered new drugs and have not been determined to be safe and effective for any medical condition.
- MA Medical Marijuana Program prohibits the sale of marijuana or marijuana-infused products by anyone other than a Registered Marijuana Dispensary.
- CBD crystals were obtained from a local retail location for the purposes of further compounding.
- The Pharmacy did have an invoice and CoA for the CBD from CBD International.
- Compounding log had no evidence of a validated study or reference for the safety and efficacy of the preparation and no quality assurance check for the weight of the capsules.
- MOR/Owner Balling did not dispense the compound and has no intention of compounding CBD in the future.

**ACTION:** Motion by T. FENSKY seconded by W. COX and voted unanimously by those present, to dismiss the compliant for insufficient evidence. An advisory letter will be sent to Dan's Pharmacy with the FDA's position on compounding CBD products.

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**21. PHA-2017-0144      Lenox Village Pharmacy. DS3344      Time: 12:16 PM**

**RECUSAL:** None

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

- RLCS, #3 dextroamphetamine 10mg and #1 dextroamphetamine 5mg in December 2016.
- In April 2016, manufacturer's recall of different lots of dextroamphetamine 5mg and 10mg;
- Pharmacy had #20 dextroamphetamine 10mg from recall which was segregated in CII cabinet but not inventoried;
- Recalled meds were discovered in CII cabinet 12/16/2016 but now only contained #19;
- Inventory on 12/29/2016 showed only #17;
- In addition, on 12/24/16 there were #13 dextroamphetamine 5mg on hand but only #12 on next inventory 12/28/2016;
- Investigation was conducted but could not identify cause of loss;
- Pharmacists were leaving the CII keys unattended;
- No separate expired CII log;
- CA includes new SOPs, perpetual inventory conducted by 2 staff members; will double count and back count CII's, expired/damaged CII's will remain in perpetual inventory until shipped, CII keys must be kept on the pharmacist's person, security cameras will be installed.
- Last inspected 6/26/17 with no deficiencies cited.

**ACTION:** Motion by W. COX, seconded by M. GODEK, voted unanimously by those present, to dismiss the compliant, no discipline warranted, remediation complete.

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**TOPIC VIII**

**EXECUTIVE SESSION**

**DISCUSSION:** None

**ACTION:** At 12:24 pm President T. FENSKY read the statement on reasons for Executive Session.

At 1:33, T. FENSKY called for a motion to enter Executive Session: Motion by M. GODEK, seconded by K. CONLEY and voted unanimously by roll call to enter into Executive Session. T. FENSKY; yes, S. CORNACCHIO yes, A. STEIN: yes G. CAVANAUGH: yes; A. RAJA; yes, W.COX; yes, M. GODEK; yes, K. CONLEY; yes.

**TOPIC IX**

**Adjudicatory Session**

**DISCUSSION:** None

**ACTION:** At 1:53 pm motion by A. STEIN, seconded by W. COX and voted unanimously to enter into Adjudicatory session.

**TOPIC X**

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

**DISCUSSION:** None

**ACTION:** At 2:00 pm motion by K. CONLEY, seconded by W. COX and voted unanimously to enter into M.G.L. c. 65C Session.

**TOPIC XI.**

**ADJOURNMENT OF MEETING**

**DISCUSSION:** NONE

**ACTION:** At 3:00 am motion by M. GODEK, seconded by K. CONLEY, and voted unanimously to adjourn the meeting.

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

1. Draft Agenda of the 9/07/2017 General Session
2. Draft Minutes of the 8/03/2017 Meeting
3. Petition to Waiver – Baxter Healthcare Corporation
4. Application of Triad Isotopes – for Change of Ownership
5. Application of Allied Pharmacy, Inc. – for New Community Pharmacy
6. Presentation of Pilot Project Proposal, Bay State Medical Center and Brigham & Womens, Technology - Check - Tech.
7. Presentation by CVS regarding Unknown Losses
8. Report on applications approved pursuant to Licensure Policy 13-01
9. Report of Board Delegated Review Session from 8/31/2017

10. Report of Above Action Level pursuant to Policy 16-04
11. Monthly Report from Probation 7/22/17 – 8/23/17
12. Memo to the Board from Karen Fishman on Determination of Compliance re: Atef Ayoub, PH233456, PHA- 2017-0036, PHA-2015-0098 and St George Pharmacy DS90034, PHA-2017-0035
13. Memo to the Board from Samuel Leadholm re: CVS 433, Violation of Consent Agreement for Stayed Probation PHA-2016-0184.
14. Bureau Staff Action Policy 17-03, Petitioning for Retirement Status
15. Enforcement Policy 17-01; Staff Action Consent Agreements for Voluntary Surrender and Consent Agreements
16. Policy 2017-03; Retail Pharmacy Participation in Research Studies
17. Memo to the Board from Vita Berg re: Pharmacy Related Outside Sections in FY 18 Budget
18. Draft 247 CMR section 17.00 (new section on Sterile Compounding)
19. List of proposed 2018 Board of Pharmacy Meeting dates
20. Investigation report in the matter of SA-INV-11414, Nimble Rx, Inc., DS90047
21. Investigation report in the matter of PHA-2017-0075, Rite Aid #10145, DS3346
22. Investigation report in the matter of PHA-2017-0126, Rite Aid #10078, DS3471
23. Investigation report in the matter of SA-INV-11043, Rite Aid #10085-DS3180
24. Investigation report in the matter of PHA-2017-0052, Rite Aid #10091, DS2558
25. Investigation report in the matter of PHA-2017-0082, Rite Aid #10207, DS2411
26. Investigation report in the matter of PHA-2017-0086, Bravo Pharmacy, DS89981
27. Investigation report in the matter of SA-INV-11229, Kevin O'Brien, PH17654
28. Investigation report in the matter of PHA-2017-0103, CVS #117, DS3207
29. Investigation report in the matter of PHA-2017-0133, CVS#669, DS2846
30. Investigation report in the matter of PHA-2017-0077, CVS #769, DS2948
31. Investigation report in the matter of PHA-2017-0068, Omnicare, DS89931
32. Investigation report in the matter of SA-INV-11236, Rite Aid #10204, DS2577
33. Investigation report in the matter of PHA-2017, Samuels Pharmacy, DS15095
34. Investigation report in the matter of PHA-2017-0094, Peter Lyons, PH19225
35. Investigation report in the matter of PHA-2017-0115, Custom Medicine Pharmcenter, DS3323
36. Investigation report in the matter of PHA-2017-0145, Dan's Pharmacy, DS89748

Respectfully submitted by:

S. CORNACCHIO, JD, RN, Secretary