

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

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

June 27, 2019  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

*If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Nahomi Carlisle, Phone: 617-624-5471 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.*

**Agenda**

<b>Time</b>	<b>#</b>	<b>Item</b>	<b>Page</b>	<b>Contact</b>
<b>8:30</b>	<b>I</b>	<b>CALL TO ORDER</b>		A. Stein
	<b>II</b>	<b>APPROVAL OF AGENDA</b>	<b>1</b>	
<b>8:40</b>	<b>III</b>	<b>APPROVAL OF BOARD MINUTES</b> <ul style="list-style-type: none"> <li>• Draft of June 6, 2019 Regular Session Minutes</li> <li>• Introduction of Interns: Joy Leonard, Northeastern University</li> </ul>	<b>3</b>	
<b>8:45</b>	<b>IV</b>	<b>REPORTS</b> <ul style="list-style-type: none"> <li>• Applications approved pursuant to Licensure Policy 13-01</li> <li>• Monthly report from probation</li> <li>• Board Delegated Review pursuant to Licensure Policy 14-02</li> <li>• Above Action Levels approved by Staff Action 16-04</li> <li>• PSUD Report-Policy 17-03</li> </ul>	<b>18</b>    <b>19</b>	
<b>8:50</b>	<b>V</b>	<b>INVESTIGATIVE CONFERENCE</b> <ul style="list-style-type: none"> <li>• PHA-2018-0088 – Blue Hill Pharmacy, DS89942</li> </ul>	<b>20</b>	
<b>9:30</b>	<b>VI</b>	<b>APPLICATIONS</b> <ul style="list-style-type: none"> <li>• Amerita Home Infusion- New Community Pharmacy</li> <li>• Johnson Compounding &amp; Wellness Center (DS90089)-Shared Services</li> <li>• Chirlie Silver(PH237577) : Petition for CDTM education</li> <li>• Jo-Ann, Muise – Pharmacy Technician in Training applicant: Waiver</li> </ul>	<b>22</b> <b>63</b>  <b>72</b> <b>75</b>	

<b>10:15</b>	<b>VII</b>	<b>FLEX</b> <ul style="list-style-type: none"> <li>Circular: DCP 19-6-107 - Pharmacist Administration of Medications for the treatment of Mental Illness and Substance Use Disorder.</li> </ul>	<b>76</b>																																													
<b>11:00</b>	<b>VIII</b>	<b>FILE REVIEW</b> <table border="1"> <tr> <td><b>1</b></td> <td>SA-INV-18839</td> <td>CVS #1867, DS89648</td> <td><b>80</b></td> </tr> <tr> <td><b>2</b></td> <td>PHA-2019-0032</td> <td>CVS #1845, DS3595</td> <td><b>82</b></td> </tr> <tr> <td><b>3</b></td> <td>SA-INV-14934</td> <td>Hung Tran, PH232660</td> <td><b>88</b></td> </tr> <tr> <td><b>4</b></td> <td>PHA-2019-0039</td> <td>CVS #703, DS24412</td> <td><b>91</b></td> </tr> <tr> <td><b>5</b></td> <td>PHA-2019-0034</td> <td>CVS #686, DS89903</td> <td><b>94</b></td> </tr> <tr> <td><b>6</b></td> <td>SA-INV-14838</td> <td>CVS #5493, DS89634</td> <td><b>96</b></td> </tr> <tr> <td><b>7</b></td> <td>SA-INV-14994</td> <td>Eilene Wegge, PH232602</td> <td><b>97</b></td> </tr> <tr> <td><b>8</b></td> <td>SA-INV-13377</td> <td>Greater Lawrence Family Health Center, DS90041</td> <td><b>109</b></td> </tr> <tr> <td><b>9</b></td> <td>PHA-2019-0047</td> <td>Southwick Pharma, DS90050</td> <td><b>112</b></td> </tr> <tr> <td><b>10</b></td> <td>PHA-2019-0048</td> <td>Thomas McGee, PH18763</td> <td></td> </tr> <tr> <td><b>11</b></td> <td>PHA-2019-0027</td> <td>BioScrip Infusion Services, DS3486</td> <td></td> </tr> </table>	<b>1</b>	SA-INV-18839	CVS #1867, DS89648	<b>80</b>	<b>2</b>	PHA-2019-0032	CVS #1845, DS3595	<b>82</b>	<b>3</b>	SA-INV-14934	Hung Tran, PH232660	<b>88</b>	<b>4</b>	PHA-2019-0039	CVS #703, DS24412	<b>91</b>	<b>5</b>	PHA-2019-0034	CVS #686, DS89903	<b>94</b>	<b>6</b>	SA-INV-14838	CVS #5493, DS89634	<b>96</b>	<b>7</b>	SA-INV-14994	Eilene Wegge, PH232602	<b>97</b>	<b>8</b>	SA-INV-13377	Greater Lawrence Family Health Center, DS90041	<b>109</b>	<b>9</b>	PHA-2019-0047	Southwick Pharma, DS90050	<b>112</b>	<b>10</b>	PHA-2019-0048	Thomas McGee, PH18763		<b>11</b>	PHA-2019-0027	BioScrip Infusion Services, DS3486			
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<b>12:00</b>	<b>LUNCH</b>																																															
<b>1:00</b>	<b>IX</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, to approve admission to the PSUD program and to evaluate the Good Moral Character as required for registration for pending applicants.	<b>118</b>																																													
<b>2:00</b>	<b>X</b>	<b>M.G.L. c. 112, § 65C SESSION</b>	<b>181</b>																																													
<b>5:00</b>	<b>XI</b>	<b>ADJOURNMENT</b>																																														

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

**MINUTES OF THE GENERAL SESSION  
239 Causeway Street, Fourth Floor ~ Room 417A  
Boston, Massachusetts, 02114  
June 27, 2019**

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**Board Members Present**

Andrew Stein, Pharm D, RPh. President  
Kim Tanzer, PharmD, RPh. President Elect  
Sebastian Hamilton, Pharm D, RPh  
Stephanie Hernandez, Pharm D, BCGP, RPh  
Susan Cornacchio, JD, RN  
Patrick Gannon, RPh  
Leah Giambarresi, Pharm D, RPh  
Timothy Fensky, RPh (leaves 1:00 PM)  
Carly Jean-Francois, RN, NP  
Michael Godek, RPh  
Dawn Perry, JD

**Board Members Not Present**

Julie Lanza, CPhT, Secretary

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Monica Botto, CPhT, Associate Executive Director  
Heather Engman, JD Board Counsel  
Joanne Trifone, RPh., Director of Pharmacy Investigations  
Joanna Chow, CPhT, Office Support Specialist  
Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist  
Joseph Santoro, RPh Investigator  
Christina Mogni, RPh investigator  
Gregory Melton, PharmD, RPh, investigator  
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor  
Richard Harris, Program Analyst

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**TOPIC I.** Attendance by roll call:

**CALL TO ORDER 8:34 AM**

A quorum of the Board was present, established by roll call. President A. Stein chaired the meeting and asked if anyone was recording hearing, no one responded. He explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; M. Godek, yes; S. Hernandez yes; P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky, yes; D. Perry, yes (Joins at 8:45 AM)

**Topic II.**

**Approval of Agenda**

**TIME 8:34 AM**

**Agenda June 27, 2019**

**DISCUSSION:**

Change to Agenda: None

**ACTION:**

Motion by M. Godek, seconded by L. Giambarresi and voted unanimously by those present to approve the agenda with no noted changes

Dave asks for the Pharmacy Interns to stand and introduce themselves and also introduces the Northeastern University student, Joy Leonard.

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**Topic III**

**Approval of Board Minutes**

**TIME: 8:34 A**

**Minutes**

**1. Draft, June 6, 2019 Session Minutes**

No noted Changes.

**Action:**

Motion by L. Giambarresi, seconded K. Tanzer, and voted unanimously to approve the regular session minutes of June 6, 2019 with noted changes.

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**TOPIC IV**

**REPORTS**

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

**Time: 8:37 AM**

**Discussion:** M. BOTTO noted that during the past month there have been seventeen (17) changes of Manager of Record (MOR), one (1) renovation/expansion applications, zero (0) new community pharmacy application and five (5) pharmacy closings approved pursuant to Licensure Policy 13-01.

So noted

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**Monthly Report from Probation**

**Time: 8:37 AM**

**Discussion:** M. BOTTO noted there are no new updates for the Board of Pharmacy Statistics Report for the Probation monitor

So noted

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

**Time: 8:37 AM**

**Discussion:** M. BOTTO noted that there were no Board Delegated Review cases heard prior to the meeting this month.

So noted

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

**Time: 8:37 AM**

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

So noted

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

**Time: 8:37 AM**

**Discussion:** E. TAGLIERI noted that in June 2019, one (1) new application was received, and there are currently fourteen (14) active participants. There have been four (4) job offers to PSUD participants.

So noted

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**TOPIC V**

**INVESTIGATIVE CONFERENCE**

**1. PHA-2018-0088**

**Blue Hill Pharmacy DS89942**

**Time: 8:39am**

**PRESENTED BY: Victoria Okeke, Owner and MOR**

**RECUSAL: None**

**DISCUSSION:** Victoria Okeke, owner of Blue Hill Pharmacy, appeared before the board to provide clarity on recent absenteeism and failure to be open during posted business hours. Blue Hill pharmacy has failed to be open several times upon investigators appearing at the pharmacy. Okeke claims that she has had to close the pharmacy during scheduled business hours due to a family medical emergency and patient medication deliveries. Okeke notes that her patients are elderly and mostly home bound, so a vast majority of her scripts are delivered. She states that although she has hired delivery drivers, most of her patients only feel comfortable when she delivers the medications. Okeke states that she plans to change her hours of operation to reflect the needs of her patients in order to make the necessary deliveries. She notes that she has implemented a call forwarding system to get calls on her cell phone when she is absent from the pharmacy as well as after hours. M. GODEK questions the number of hours she is open and her current hours of operation. D. SENCABAUGH stresses the importance of having accurately posted hours on the pharmacy for the public and not necessarily the number of hours she is open. A. STEIN notes that he would like a policy in place when she needs to step away from the pharmacy. S. CORNACCHIO states that she must change her hours of operation on her website in order to reflect the hours of operation. Okeke says she will plan to be open Monday, Wednesday and Friday from 10-6 and Tuesday and Thursday from 12-6 to make the necessary deliveries.

**ACTION:** Motion by L. GIAMBARRESI, seconded S. HERNANDEZ, and voted unanimously by all those present to defer the vote pending a policy in place during absenteeism and change of hours of operation both online and posted on front door.

**TOPIC VI**

**APPLICATIONS**

**1. Amerita Home Infusion**

**New Pharmacy**

**TIME: 8:58 AM**

REPRESENTED BY: Joseph Ferraro, Audrey Hammond, Andrew Depalma

RECUSAL: None

DISCUSSION: Amerita Home Infusion will be a closed-door pharmacy in Hudson, MA and will provide its patients continuity of care by providing pharmacy services specializing in TPN, antibiotics, pain and specialty compounded products. It will not offer hazardous compounding services. Amerita has petitioned for eight waivers: 247 CMR 6.01(5)(a)(4); 247 CMR 6.01(5)(d); 247 CMR 6.02(4); 247 CMR 6.02(4)(a); 247 CMR 6.02(8)(a); 247 CMR 9.01(15); 247 CMR 9.01(16); and 247 CMR 9.07(3)(c). Amerita will be open 5 days a week with twenty-four/ seven calling services. The compounding company will use the Providence location as a back-up and have dually licensed pharmacists. Amerita answered all the Board's questions to their satisfaction.

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

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**2. Johnson Compounding/Wellness Center- Request Central Fill**

**TIME: 9:07 AM**

REPRESENTED BY: John Walczyk, Jodi Barry

RECUSAL: A. STEIN and C. JEAN FRANCOIS recused and were not present for the discussion or vote on this matter.

DISCUSSION: Johnson's Compounding and Village Fertility hope to come together and utilize a central fill model. Village is unable to remodel to fulfill the upcoming changes in USP <800 and they are seeking Johnson's to compound their hazardous medications. Village and Johnson's are located only 2 miles apart and patients will be able to pick up their compounded preparations at either location. The compounding centers will be utilizing a VPN system for their patients. The patients at Village will be notified that medications will be filled at Johnson's and have the option to opt out. The central fill agreement is limited to only certain medications. The label will be a Johnson's label and contain Village's contact information for patient questions. Johnsons and Village answered all the Board's questions to their satisfaction.

ACTION: Motion by L. GIAMBARRESI, seconded by M. GODEK, voted unanimously by those present to approve the application.

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**3. Chirlie Silver**

**CDTM petition for education Waive**

**TIME: 9:21 AM**

REPRESENTED BY: Chirlie Silver

RECUSAL: None

DISCUSSION: Chirlie Silver is petitioning the board's CDTM requirement. Silver has completed a PGY1 residency at Cambridge Health Alliance. She is also an adjunct professor at MCPHS and Brigham and Women's hospital. Many board members felt that this training was not adequate enough to meet the advisory. L. GIAMBARESSI states that she doesn't want to give her an open ticket for CDTM practice agreements. Silver notes that she has a potential job offer that is pending based on the board's decision. T. FENSKY notes that in the past a petition was granted to an individual who had a focused PGY1 in a particular area. S. HERNANDEZ states that in her personal practice she believes that it takes at least one year to get a grip on the disease state. Board members debated whether her training was adequate enough to meet the requirement.

ACTION: Motion by S. CORNACCHIO, seconded by A. STEIN and voted by the majority of those present to approve the CDTM application pending preceptor recommendation, potential employer's description of the role and training, and a current offer. D. PERRY, L. GIAMBARESSI, T. FENSKY, M. GODEK and S. HAMILTON voted against this action.

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**4. . Jo-Ann Muise**

**PTT Waiver Request**

**TIME: 9:53 AM**

REPRESENTED BY: None

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

DISCUSSION: Jo-Ann Muise is a Walgreens clerk who seeks to waive the high school requirement. She is an elderly woman who never completed high school years ago.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY and voted unanimously by those present to approve the waiver request.

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**TOPIC VII**

**FLEX**

**Time: 10:07 AM**

1. Circular: DCP 19-06-107 Pharmacist Administration of Medications for the treatment of Mental Illness and SUD (update)

RECUSAL: None

DISCUSSION: J. TRAN presented that the Drug Control Program added the drug Perseris (risperidone ER injectable suspension) to the list of medications that pharmacists can administer.

ACTION: None.

**TOPIC VIII****FILE REVIEW**

Case #1

SA-INV-18839

CVS #1867, DS89648

Time: 10:10 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 on or about 01/15/2019 of an untimely, unknown loss of #326 diphenoxylate/atropine 2.5/0325 mg tablets identified via corporate controlled substance monitoring and occurred sometime between 05/01/18 and 01/15/2019 during which time over 60 prescriptions were dispensed.
- MOR Tran confirmed review of cycle counts, biennial inventories, staffing schedules and inventory reports but the reason for the loss could not be determined. They suspect the loss most likely occurred during the filling of a prescription. Video footage was reviewed and diversion was not suspected. CA: pharmacy staff completed training modules regarding proper handling of controlled substances in the pharmacy; pharmacy technicians were re-trained to double count all controlled substances; the balance on hand modification and order adjustment reports will be reviewed weekly to assist in identifying any inventory areas of concern to prevent future drug losses; CVS corporate prompted cycle counts of controlled substances will be performed weekly.

**ACTION:** Motion by M. GODEK, seconded by K. TANZER, and voted unanimously by those present, to CLOSE the matter (SA-INV-18839), No Discipline Warranted, Remediation Complete.

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Case #2

PHA-2019-0032

CVS #1845, DS3595

Time: 10:12AM

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

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

- Previously a staff assignment, SA-INV-13701, the BORP opened a complaint on 1/10/2019 against the Pharmacy due to a consumer complaint of an alleged over-dispense of #45 methylphenidate 10mg tablets as well as a failure to fill a prescription properly, in which clomiphene citrate was dispensed as clomipramine. Additionally, included in the complaint is a failure to implement a Plan of Correction and repeat inspectional deficiencies observed during a retail compliance inspection.
- The unknown loss of #45 methylphenidate 10mg tablets was discovered during state count and is suspected to be due to an over-dispense. It is believed that a stock bottle of 75 tablets was dispensed instead of the prescribed 30 tablets.
- MOR Tran Identified himself as the verification pharmacist and Technician Neov as the data entry technician that entered clomipramine 25mg instead of the prescribed clomiphene citrate 25 mg. Of note, On the verification screen there was a "quality alert" cautioning the pharmacist of the look-alike/sound-alike between clomiphene citrate and clomipramine.



- On 12/6/18 the BORP requested additional information from the pharmacy including a more comprehensive plan of correction including additional corrective action by involved licensees
- On 12/27/18 CVS #1845 submitted documentation showing all involved licensees completed 2 CE's of patient safety and attested to reading 247 CMR 15. They also included additional corrective action, stating a list of LASA drugs has been posted at data entry and is readily available at verification, and staff has been coached to check with the RPh on duty to confirm the medication on the hardcopy when a prescription is received for a medication on the LASA list, and/or every time a LASA warning message is prompted at drug selection.
- On January 4, 2019, OPP Investigator, Christina Mogni observed repeat deficiencies during a Retail Compliance Inspection (ISP-11268). The deficiencies observed were cited from original inspection (ISP-7461 and ISP-9777) for failure to reconcile the perpetual inventory every 10 days and (ISP-9777) for not completing 222 forms when CII's are received. She also noted that there are currently no look alike/sound alike shelf tags on shelves and no look alike/sound alike references at the work station as noted in the corrective action submitted in response to SA-INV-13701. A satisfactory POC was received on 1/29/2109.
- On April 29, 2019, During the investigation concerning PHA-2018-0032, this OPP Investigator reviewed MOR Tran's CPE Monitor to verify CEU's completed in medication safety. His 2017 CPE monitor indicated that he completed 21 CE credits but had a deficiency of 1-law. His 2018 CPE Monitor indicated that he completed 23 CE credits but had a deficiency of 2-live CE credits. Upon further investigation, it was discovered that MOR Tran was also deficient by 1 CE credit in an immunization related topic and 3 complex non-sterile compounding in both 2017 and 2018. Remediation complete.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2019-0032) 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

SA-INV-14934

Hung Tran, PH232660

Time: 10:23 AM

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

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

- Previously a staff assignment, SA-INV-13701, the BORP opened a complaint on 1/10/2019 against the Pharmacy due to a consumer complaint of an alleged over-dispense of #45 methylphenidate 10mg tablets as well as a failure to fill a prescription properly, in which clomiphene citrate was dispensed as clomipramine. Additionally, included in the complaint is a failure to implement a Plan of Correction and repeat inspectional deficiencies observed during a retail compliance inspection.
- The unknown loss of #45 methylphenidate 10mg tablets was discovered during state count and is suspected to be due to an over-dispense. It is believed that a stock bottle of 75 tablets was dispensed instead of the prescribed 30 tablets.
- MOR Tran Identified himself as the verification pharmacist and Technician Neov as the data entry technician that entered clomipramine 25mg instead of the prescribed clomiphene citrate 25 mg. Of

note, On the verification screen there was a “quality alert” cautioning the pharmacist of the look-alike/sound-alike between clomiphene citrate and clomipramine.

- On 12/6/18 the BORP requested additional information from the pharmacy including a more comprehensive plan of correction including additional corrective action by involved licensees
- On 12/27/18 CVS #1845 submitted documentation showing all involved licensees completed 2 CE’s of patient safety and attested to reading 247 CMR 15. They also included additional corrective action, stating a list of LASA drugs has been posted at data entry and is readily available at verification, and staff has been coached to check with the RPh on duty to confirm the medication on the hardcopy when a prescription is received for a medication on the LASA list, and/or every time a LASA warning message is prompted at drug selection.
- On January 4, 2019, OPP Investigator, Christina Mogni observed repeat deficiencies during a Retail Compliance Inspection (ISP-11268). The deficiencies observed were cited from original inspection (ISP-7461 and ISP-9777) for failure to reconcile the perpetual inventory every 10 days and (ISP-9777) for not completing 222 forms when CII’s are received. She also noted that there are currently no look alike/sound alike shelf tags on shelves and no look alike/sound alike references at the work station as noted in the corrective action submitted in response to SA-INV-13701. A satisfactory POC was received on 1/29/2109.
- On April 29, 2019, During the investigation concerning PHA-2018-0032, this OPP Investigator reviewed MOR Tran’s CPE Monitor to verify CEU’s completed in medication safety. His 2017 CPE monitor indicated that he completed 21 CE credits but had a deficiency of 1-law. His 2018 CPE Monitor indicated that he completed 23 CE credits but had a deficiency of 2-live CE credits. Upon further investigation, it was discovered that MOR Tran was also deficient by 1 CE credit in an immunization related topic and 3 complex non-sterile compounding in both 2017 and 2018. Remediation complete.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE the matter (SA-INV-14934), No Discipline Warranted, Remediation Complete upon receipt of documentation demonstrating a 3:1 remediation of the CE deficiency by Pharmacist Tran.

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Case #4

PHA-2019-0039

CVS #703, DS24412

Time: 10:26 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.

- Untimely RLCS- of #100 Oxycodone /APAP 5-325mg tablets that occurred on or about December 28, 2018. An investigation was completed on January 23, 2019 and there was no indication of theft or diversion and the loss at the Pharmacy is unknown. The Board staff received notification of the loss on March 15, 2018.
- The loss was discovered when a patient came into the Pharmacy to pick up their prescriptions and one for #100 oxycodone/APAP 5-325mg was missing. The prescriptions were placed in paper bags and the bags placed in a separate waiting bin located in the area where the empty delivery totes are stored. It is

believed that the bag containing the oxycodone/APAP 5/325mg fell in a tote and was sent back to their wholesale distributor.

- MOR Sibailly indicated that a pharmacist called the wholesale distributor but they could not confirm receiving the paper bag of medications.
- SCA Pacia indicated that the untimely reporting of the loss was due to an ongoing investigation in which the investigators conducted their interviews in March 2019. She noted that continuation letters were filed with the Board and DEA. No emails with attached continuation letters were received.
- In response to this event, the waiting bin area has been reorganized and the Pharmacy will no longer store empty totes near the waiting bins. All Pharmacy staff have completed training modules regarding proper handling of controlled substances. Cycle counts will be continued weekly for system prompted cycle counts and signed off by the pharmacist.

The pharmacy manager will complete the monthly count used for BOP and Loss Prevention. There will be weekly review of BOH modification and order adjustment reports to work in tandem to help better identify any inventory areas of concern and help to prevent further losses.

ACTION: Motion by T. FENSKY, seconded by M. GODEK, and voted unanimously by those present, to refer the matter (PHA-2019-0039) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

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Case #5

PHA-2019-0034

CVS #686, DS89903

Time: 10:30 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

- Untimely RLCS- #90 methylphenidate 10mg tablets on or about March 14, 2019. According to the final report submitted on March 28, 2019, an investigation was concluded on March 20, 2019 and there was no theft and the loss at the Pharmacy is unknown.
- On March 5, 2019, a new perpetual inventory sheet was prepared for four bottles of Methylphenidate 10mg tablets received from wholesaler with a different NDC # and added to the inventory. On March 13, 2019, RPH Ying discovered a shortage of 90 tablets and an investigation was run between March 13, 2019 and March 14, 2019.
- A review of PMP from 3/05/2019 to 3/14/2019 for methylphenidate 10mg tablets with the new NDC number confirmed 4 prescriptions were filled as identified on the perpetual inventory log. There were no missing prescriptions. MOR Le indicated that all patients were called but could not confirm an over-dispense.

In response to this event, all Pharmacy staff have completed training modules regarding proper handling of controlled substances. Cycle counts will be continued weekly for system prompted cycle counts and signed off by the pharmacist. The pharmacy manager will complete the monthly count used for BOP and Loss Prevention. There will be a weekly review of the BOH modification and order adjustment reports to work in tandem to help better identify any inventory areas of concern and help to prevent further losses.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2019-0034) 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 #6

SA-INV-14838

CVS #5493, DS89634

Time: 10:32 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.

- BORP staff received notice from the Professional Credential Services, Inc. indicating PTT, Charlene Luna submitted a signed application for the pharmacy technician registration with 1852 hours.
- MOR Yann indicated that she failed to follow up with PTT Luna on her hours worked in the pharmacy. She recalls having PTT Luna fill out an application in 2018 when all PTT's had to be registered. At that time, she lost a couple of pharmacy technicians which may have contributed to PTT Luna working approximately 40 hours per week. MOR Yann indicated that PTT Luna's hours quickly approached 1800-hours without notice.
- MOR Yann indicated that as soon as she was notified of PTT Luna's hours, she removed her from the schedule and contacted the district trainer to have her take the state exam. MOR Yann stated, "going forward I will check every month to see how many hours have been worked by pharmacy technician trainees under my supervision. I will ensure that every trainee under my supervision will be state certified before they approach 1000 hours."

ACTION: Motion by M. GODEK, seconded by K. TANZER, and voted unanimously by those present, to CLOSE the matter (SA-INV-14838), No Discipline Warranted, Remediation Complete.

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Case #7

SA-INV-14994

Eilene Wegge, PH232602

Time: 10:35 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.

- CE Deficiency discovered during new retail compliance inspection at CVS #11131 in Provincetown. Licensee is MOR and had a deficiency of 2.5 CE credits in any topic in 2017 and 3 CE credits including 1 CE credit in an immunization related topic in 2018
- Licensee indicated that she got a new computer toward the end of 2018 and believes that she may have lost files during the transfer to the new computer. She could only find one file that was completed in December that was not reported to NABP.
- Remediation complete

ACTION: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously by those present, to CLOSE the matter (SA-INV-14994), No Discipline Warranted, Remediation Complete upon receipt of documentation demonstrating a 3:1 remediation of the CE deficiency by Pharmacist Wegge.

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Case #8

SA-INV-13377      Greater Lawrence Family Health Center, DS90041      Time: 10:39 AM

RECUSAL: NONE

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

- Allegation by a former employee that the GLFHC Methuen Pharmacy was acting as a “central fill” pharmacy for other GLFHC locations due to an insurance contract denial and they are “rolling prescriptions”. Additionally, during ISP-9768 on 5/14/18, the co-mingling of duties, staff, drug ordering and inventory between the clinic and the Pharmacy was observed.
- The Complainant claimed prescriptions were received at the Lawrence South Pharmacy where they were data entered on the Methuen Pharmacy’s server, it was adjudicated on the Methuen Pharmacy’s server, the label would print at the Methuen Pharmacy where it would be filled and verified, then the prescription would be delivered to the Lawrence South Pharmacy for pickup. This practice could be for any prescription.
- MOR Baccari responded that the Methuen Pharmacy has a Parata Pass unit for specialty packaging and the Methuen Pharmacy does provide that service to GLFHC patients. He contended the prescriptions for specialty packaging are sent to the Methuen Pharmacy, are processed and filled there, then they are either delivered to the patient’s home or to another GLFHC Pharmacy location for pick up.
- The Complainant provided numerous emails from 3/11/10 to 5/14/18 supporting the allegations indicating that if a patient did not have a refill on a maintenance medication, the pharmacist was authorized to dispense a 30-day supply. This practice occurred off and on during this period.
- Emails from the VP of HR Borgesi and VP Martin were provided that acknowledge Cigna and Humana contracts were denied at the Lawrence South Pharmacy and those prescriptions were filled at the Methuen Pharmacy and delivered to the Lawrence South Pharmacy for pickup. They also confirmed allowing a 30-day supply of maintenance medications to be dispensed if there were no refills left and based that procedure on a North Carolina Board of Pharmacy regulation.
- CA: According to MOR Baccari, VP Martin was not aware of the insurance contract issue until April 2018. The practice of filling prescriptions for GLFHC pharmacies without an insurance contract and delivering them to the other GLFHC Pharmacy locations has been discontinued. Patients are offered home delivery.
- ISP-9768: Noted the Methuen Pharmacy filled, billed, and delivered medications to the four other GLFHC sites. Additionally, GLFHC central purchasing agent ordered the medications for all the GLFHC clinics and had them dropped shipped to the Methuen Pharmacy to be stored and distributed.
- MOR Baccari provided invoices from 1/1/18 to 5/31/18 for medications ordered for the clinics which were ordered under the clinic accounts.
- CA: All clinic orders are shipped to the clinic where they will be received by clinic staff. The GLFHC policy was updated to reflect this change in protocol for clinic orders.
- Staff assignment was heard at the 11/1/18 Board meeting and the Board requested additional information.

- Addendum with 11/20/18 response attesting the information provided by MOR Baccari and VP Martin was true and accurate for the Board's concerns regarding transfer policy, 30-day rollover prescriptions, and insurance contract denials.
- Transfer policy created 11/19/18 was provided which does not fully comply with all requirements of 247 CMR 9.02 and Board Policy 2010-01.
- VP Martin alleged the 30-day rollover was due to a backlog of refill requests in May of 2017 was a temporary option that immediately changed after one week, but emails provided by the Complainant indicate this was an intermittent practice from 03/2010 to 05/2017.
- A Continuity of Care – No Refills policy created on 11/19/18 was provided with options if the patient is out of medication to dispensing a one-time 3-day supply, contacting a clinician for a new prescription, or referring the patient to the clinic for an acute visit,
- Cigna initially denied Lawrence South Pharmacy a contract because the pharmacy was within the clinic. Cigna later denied a contract due to the high percentage of 340B prescriptions at that location. Lawrence South Pharmacy does not accept Cigna patients at that location but offers pharmacy services from the other locations.
- Initially Lawrence South Pharmacy could not negotiate the predatory reimbursement rate for 340B entities with Humana, but eventually accepted a dual 340B/retail contract.
- In response to a request for the previous policies, VP Martin provided a signed response co-signed by the GLFHC SVP & Chief Medical Officer attesting the information was true and accurate. The policies provided for the 340B and retail GLFHC pharmacies licensed by the BORP were allegedly informal documents written in April 2015 included in the GLFHC 340B Policy and Procedure Manual and not official policy documents. There was no written continuity of care policy if a patient was out of refills until 11/19/18, but VP Martin attested the "idea was informally, yet uniformly enforced".

**ACTION:** Motion by P. GANNON, seconded by M. GODEK, and voted unanimously by those present, to elevate the matter (SA-INV-13377) to a complaint.

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Case #9

PHA-2019-0047

Southwick Pharma, DS90050

Time: 10:53 AM

**RECUSAL:** NONE

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

- On 4/25/19, a retail compliance inspection was attempted but the Pharmacy was locked with a sign posted to customers that the Pharmacy was being sold and they had suspended operations; during a site visit on 2/4/19, MOR McGee related the intended transfer of ownership to Benzer Pharmacy was not going to occur and the owners were negotiating a pending sale.
- Owner Dorairaj faxed notification to the BORP on 4/25/19 stating the Pharmacy would be closed for 2 weeks starting 4/22/19 and that patient prescriptions were transferred to other pharmacies.
- On 5/29/19, it was confirmed with MOR McGee that the Pharmacy was still closed, locked and alarmed and controlled substances were still in inventory waiting to be reverse distributed.
- MOR McGee responded he was instructed to suspend operations as of 4/19/19 and with only 2-day notice, contacted the patients to pick up or transfer their prescriptions and conducted a controlled

substance inventory. He stated he was unaware of the regulatory requirements for the closure of a pharmacy but would ensure compliance going forward.

- The BORP received a customer complaint dated 5/13/2019 concerning new prescriptions called in by her physician with her refill requests on 4/21/19 that were not filled because the Pharmacy was closed and the voicemail system accepted the information with no notification of closure.

On 5/31/19, the husband of Owner Dorairaj who helps manage the pharmacy stated the Pharmacy will be closing by the end of June since a buyer could not be found. The owners will work with MOR McGee to reverse distribute the inventory. As of 6/10/19, the BORP had not been notified of the closure of the Pharmacy.

ACTION: Motion by S. HAMILTON, seconded by M. GODEK, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0047), No Discipline Warranted, Remediation Complete.

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Case #10

PHA-2019-0048

Thomas McGee, PH18763

Time: 10:56 AM

RECUSAL: NONE

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

- On 4/25/19, a retail compliance inspection was attempted but the Pharmacy was locked with a sign posted to customers that the Pharmacy was being sold and they had suspended operations; during a site visit on 2/4/19, MOR McGee related the intended transfer of ownership to Benzer Pharmacy was not going to occur and the owners were negotiating a pending sale.

- Owner Dorairaj faxed notification to the BORP on 4/25/19 stating the Pharmacy would be closed for 2 weeks starting 4/22/19 and that patient prescriptions were transferred to other pharmacies.

- On 5/29/19, it was confirmed with MOR McGee that the Pharmacy was still closed, locked and alarmed and controlled substances were still in inventory waiting to be reverse distributed.

- MOR McGee responded he was instructed to suspend operations as of 4/19/19 and with only 2-day notice, contacted the patients to pick up or transfer their prescriptions and conducted a controlled substance inventory. He stated he was unaware of the regulatory requirements for the closure of a pharmacy but would ensure compliance going forward.

- The BORP received a customer complaint dated 5/13/2019 concerning new prescriptions called in by her physician with her refill requests on 4/21/19 that were not filled because the Pharmacy was closed and the voicemail system accepted the information with no notification of closure.

On 5/31/19, the husband of Owner Dorairaj who helps manage the pharmacy stated the Pharmacy will be closing by the end of June since a buyer could not be found. The owners will work with MOR McGee to reverse distribute the inventory. As of 6/10/19, the BORP had not been notified of the closure of the Pharmacy.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0048), No Discipline Warranted, Remediation Complete.

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Case #11

PHA-2019-0027

Bioscrip Infusion Services, DS3486

Time: 10:57 AM

RECUSAL: NONE

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

- RLCS for a discrepancy of 8 syringes of morphine sulfate 1mg/ml waste that could not be accounted for after an audit was conducted subsequent to the discovery on 1/4/19 of controlled substances including 20 syringes of morphine sulfate 1mg/mL waste and 40 lorazepam 2mg/ml vials in the office of Former MOR Matthews.
- Former MOR Matthews was interviewed by the Regional GM and the HR Manager but few details were provided as to why the waste had not been returned via the reverse distributor other than she lacked the time to complete the task. Additionally, she alleged the lorazepam was received from Home Solutions after a transfer of ownership, but there were no records. BioScrip contends poor recordkeeping, not diversion, was suspected.
- Compounded controlled substance waste was being disposed of using a DEA Form 41 via the drain, drug disposal waste bin, sharps containers or not indicated at all and none of the methods used rendered the substances 'non-retrievable' as designated by the DEA and drugs were recorded on the forms on various dates.
- Biennial inventory performed on 11/6/18 and change of manager of record controlled substance inventory performed on 1/11/19 did not include expired, damaged, and wasted medications and perpetual inventories including the waste log inventory had not been consistently reconciled every 10 days.
- Review of documentation provided revealed an additional 6 syringes not accounted for; SVP Stalmack responded that the Pharmacy was able to account for all syringes including those reported on the DEA Form 106 but the response associating entries to the DEA Form 41 did not reconcile for 10 of 14 syringes.
- The [Attorney] for Former MOR Matthews alleged that she had little time to deal with compounded waste of controlled substances and attributed her actions to the lack of proper training regarding the handling of controlled substance waste and the uncertainty of how to contend with the lorazepam vials that were not included in the transfer from Home Solutions. According to the [Attorney], Former MOR Matthews segregated the controlled substances from active stock and secured them in her locked desk to prevent dispensing to patients and to reduce the risk of diversion.
- CA: Former MOR Matthews was terminated on 1/11/19. Former MOR Ostrander who assumed the position reviewed BORP regulations and BioScrip policies and procedures to improve understanding of recordkeeping. The perpetual inventory including expired, damaged, and wasted medications is performed every 7 days with revision of the policy on 4/22/19 requiring 2 signatures. All pharmacy staff were trained on the return procedure to the reverse distributor. Current MOR Njoroge assumed the position as MOR on 5/16/19. Former MOR Matthews submitted 3 CEs related to compliance with the Federal Controlled Substance Act and prevention of diversion of opioids and attested to reviewing MGL 94C sections 1-30 and the DEA Pharmacist's Manual in its entirety.

ACTION: Motion by M. GODEK, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter, (PHA-2019-0027), No Discipline Warranted, Remediation Complete.



**Topic IX**  
**Read by A. Stein**

**EXECUTIVE SESSION**

**Time: 11:45 AM**

DISCUSSION:

ACTION: At 11:45 AM President A. Stein read the statement on reasons for Executive Session.

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**Topic IX:**  
By: A. Stein

**Executive Session Call to Order:**

**Time: 12:47 PM**

ACTION: Motion by K. Tanzer, seconded by S. Hamilton, and voted unanimously by roll call to call the 6/27/19 meeting of the Executive Session to order.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; M. Godek, yes; S. Hernandez yes; P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky, yes; D. Perry, yes

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**Topic X:**

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

**Time: 11:07 AM**

DISCUSSION: None

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

At 11:07 AM S. Hamilton, seconded by K. Tanzer and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

**M.G.L. 65 C First Call to Order #2**

**Time: 1:45 PM**

DISCUSSION: None

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

At 1:45 PM M. Godek, seconded by K. Tanzer and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

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**Topic XI**

**ADJOURNMENT OF MEETING**

**TIME: 2:19 PM**

ACTION: Motion by S. Hamilton seconded by K. Tanzer, and voted unanimously by those present, to adjourn from General Session.

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EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 6/27/19 General Session
2. Draft Minutes of the 6/6/19 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on probation
5. Report on Board Delegated Complaint Review to licensure policy 14-02
6. Report on Above Action Levels approved by Staff Action 16-04
7. Report on PSUD 17-03
8. Investigative Conference: PHA-2018-0088 Blue Hill Pharmacy, DS89942
9. Applications: Amerita Home Infusion- New Community Pharmacy
10. Applications: Johnson Compounding & Wellness Center DS90089 Shared Services
11. Applications: Chirlie Silver (PH237577) Petition for CDTM education
12. Applications: Jo-Ann Muise: Pharmacy Technician in Training application: waiver request
13. Circular Letter DCP 19-6-107 Pharmacist Administration of Medications for the treatment of Mental Illness and Substance Use Disorder
14. SA-INV-18839 CVS #1867, DS89648
15. PHA-2019-0032 CVS #1845, DS3595
16. SA-INV-14934 Hung Tran, PH232660
17. PHA-2019-0039 CVS #703, DS24412
18. PHA-2019-0034 CVS #686, DS89903
19. SA-INV-14838 CVS #5493, DS89634
20. SA-INV-14994 Eilene Wegge, PH232602
21. SA-INV-13377 Greater Lawrence Family Health Center, DS90041
22. PHA-2019-0047 Southwick Pharma, DS90050
23. PHA-2019-0048 Thomas McGee, PH18763
24. PHA-2019-0027 BioScrip Infusion Services, DS3486

Respectfully Submitted,  
Julie Lanza, CPhT, Secretary