

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

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

February 7, 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 Beth Rabasco, Phone: 617-624-5291 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.

Agenda

Time	#	Item	Page	Contact
8:30	I	CALL TO ORDER		A. Stein
	II	APPROVAL OF AGENDA		
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"> • Draft of January 10, 2019 Regular Session Minutes 		
8:45	IV	REPORTS <ul style="list-style-type: none"> • Applications approved pursuant to Licensure Policy 13-01 • Monthly report from probation • Board Delegated Review pursuant to Licensure Policy 14-02 • Above Action Levels approved by Staff Action 16-04 • PSUD Report-17.03 		
8:50	V	POLICIES and ADVISORIES <ul style="list-style-type: none"> • Shared Pharmacy Service Model Discussion • CDTM advisory • PSUD-Staff Action Policy 17 – 03 		

9:15	VI	<p>APPLICATIONS</p> <ul style="list-style-type: none"> • Partner’s Pharmacy, DS3419 – Pilot Project • Walgreens #16537; DS90079 – Renovation/Expansion • New England Life Care; DS3513 – Renovation/Expansion • Health First Pharmacy- New Community Pharmacy • CVS Pharmacy #260; DS2294 – Change of Manager 														
10:00	VII	<p>FLEX</p> <ul style="list-style-type: none"> • Baystate Medical Center/Brigham & Womens Pilot project update • 2019 NABP Annual Meeting Discussion • NABP Annual Meeting grant opportunity • American Pharmacists Association Institute on Alcoholism and Drug Dependencies (APhA Institute) • 2018 Inquiries 														
10:20	VIII	<p>VIOLATION OF STAYED PROBATION</p> <ul style="list-style-type: none"> • CVS 1009, DS1529,PHA-2017-0169 														
10:30	IX	<p>VIOLATION OF PROBATION</p> <ul style="list-style-type: none"> • Choon Kim, PH27076, OHA-2017-0182 														
10:40	X	<p>FILE REVIEW</p> <table border="1" data-bbox="326 1356 1208 1801"> <tr> <td data-bbox="326 1356 370 1423">1</td> <td data-bbox="370 1356 1208 1423">PHA-2018-0076- CVS #1007, DS90074</td> </tr> <tr> <td data-bbox="326 1423 370 1497">2</td> <td data-bbox="370 1423 1208 1497">PHA-2018-0078- Walgreens #3151, DS2470</td> </tr> <tr> <td data-bbox="326 1497 370 1572">3</td> <td data-bbox="370 1497 1208 1572">PHA-2018-0082- Walgreens #10317, DS89797</td> </tr> <tr> <td data-bbox="326 1572 370 1648">4</td> <td data-bbox="370 1572 1208 1648">PHA-2018-0083- Walgreens #15193, DS89802</td> </tr> <tr> <td data-bbox="326 1648 370 1724">5</td> <td data-bbox="370 1648 1208 1724">SA-INV-14157- Dawn Lynde, PH21814</td> </tr> <tr> <td data-bbox="326 1724 370 1801">6</td> <td data-bbox="370 1724 1208 1801">PHA-2018-0016- Smith Drug, DS2198</td> </tr> </table>	1	PHA-2018-0076- CVS #1007, DS90074	2	PHA-2018-0078- Walgreens #3151, DS2470	3	PHA-2018-0082- Walgreens #10317, DS89797	4	PHA-2018-0083- Walgreens #15193, DS89802	5	SA-INV-14157- Dawn Lynde, PH21814	6	PHA-2018-0016- Smith Drug, DS2198		
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6	PHA-2018-0016- Smith Drug, DS2198															

1:00	XI	<p>EXECUTIVE SESSION</p> <p>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 evaluate the Good Moral Character as required for registration for pending applicants and to receive an update from the Pharmacy Substance Use Disorder Program.</p>		CLOSED SESSION
2:00	XII	ADJUDICATORY SESSION (M.G.L. c. 30A, § 18)		CLOSED SESSION
2:30	XIII	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION
5:00	XIV	ADJOURNMENT		CLOSED SESSION

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

**MINUTES OF THE GENERAL SESSION
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts, 02114
February 7, 2019**

Board Members Present

Andrew Stein, Pharm D, RPh. President
Kim Tanzer, PharmD, RPh. President Elect
Julie Lanza, CPhT, Secretary
Michael Godek, RPh
Timothy Fensky, RPh
Sebastian Hamilton, Pharm D, RPh
Stephanie Hernandez, Pharm D, BCGP, RPh
Susan Cornacchio, JD, RN
Carly Jean-Francois, RN, NP
Patrick Gannon, RPh

Board Members Not Present

Leah Giambarresi, Pharm D, RPh
Dawn Perry, JD

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Associate Executive Director
Heather Engman, JD Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Joanne Trifone, RPh., Director of Pharmacy Investigations
Kimberly Morton, CPhT, Compliance Officer
Greg Melton, JD, PharmD, BCPS, RPh, Investigator
Julienne Tran, Pharm D, RPh Investigator/Quality Assurance Pharmacist
Joseph Santoro, RPh Investigator
Christina Mogni, RPh investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst

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; J. Lanza, yes; M. Godek, yes; S. Hernandez (yes); T. Fensky, yes; P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes

Topic II.

Approval of Agenda

TIME 8:32 AM

Agenda February 7, 2019

DISCUSSION:

Change to Agenda:

1. Defer Applications: Walgreens #16537; DS90079; Renovation/Expansion

ACTION:

Motion by P. Gannon, seconded by T. Fensky and voted unanimously by those present to approve the agenda with noted change.

Dave asks for the Pharmacy Interns to stand and introduce themselves.

Topic III

Approval of Board Minutes

TIME: 8:36 AM

Minutes

1. Draft, January 10, 2019 Session Minutes

Changes:

1. Reports, Probation, change word "cute" to "cure"
2. Adjudicatory and 65C votes to enter; change from "M. Godek" to "A. Stein" president

Action:

Motion by M. Godek, seconded K. Tanzer, and voted unanimously to approve the regular session minutes of January 10, 2019 with noted changes.

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 thirty-five (35) changes of manager on record (MOR) and seven (7) renovation expansion applications approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:39 AM

Discussion: M. BOTTO provided the January 1, 2019 - January 30, 2019, Board of Pharmacy Statistics Report for the Probation monitor, which noted that one (1) licensee satisfactorily completed probations, one (1) was issued a final notice by board counsel, and there are currently thirty-nine (39) licensees on probation.

So noted

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

REPORTS

Time: 8:39 AM

Discussion: M.BOTTO noted that there were six (6) Board Delegated Review cases heard on February 4, 2019, all of the cases were CE deficiencies (SA-INV-14227, SA-INV-14303, SA-INV-14305, SA-INV-13304, SA-INV-14350, and SA-INV-14348) which were closed with no discipline warranted and remediation complete. The Board Delegated Review session was attended by A. STEIN as the Board Member, M. CHAN as delegate for Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

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

REPORTS

Time: 8:40 AM

Discussion: K. MORTON noted that two (2) above action level reports have been reported since last Board meeting pursuant to Licensure Policy 16-04.

So noted

TOPIC IV
PSUD Report by Staff Action 17-03

REPORTS

Time: 8:40 AM

Discussion: E. TAGLIERI noted that in January 2019, two (2) total applicants have been approved for PSUD admission in 1/19. In January 2019 there was (1) admission, (1) pending admission and one (1) withdrew prior to admission. There were also three (3) IRP changes pursuant to Staff action policy 17-03 and one IRP change which required board vote.

So noted

TOPIC V
Policies and Advisories

Time: 8:41 AM

1. Shared Pharmacy Service Model Discussion

Presented by: W. FRISCH

Discussion:

- W. FRISCH explained that this policy has been developed from information obtained from the NABP model act, ASHP, and stakeholders (BMC), as well as other states' regulations. The Advisory Committee's valuable input helped to shape the definitions and service models. We have had many discussions and revisions on this drafted policy and are now seeking the Board's input.
- Before we get started, there has been an edit to the second paragraph under Purpose and Scope eliminating the "cost effective manner" verbiage.
- In addition to general mandates for all shared services, specific provisions were also made for each service model. The central fill, central processing, and telepharmacy definitions have been developed with feedback from the Advisory Committee.
- Generally, Central fill would follow DEA requirements, but pharmacies must petition the Board before engaging in this activity. Of note, sterile and complex non-sterile central fill would not be permitted unless specifically approved by the Board.

- Central processing activities would only be permitted if the process is verified by a MA licensed pharmacist or done in a MA licensed pharmacy (this is for the eventual non-resident pharmacies that may not have all their pharmacists licensed in MA).
 - Telepharmacy is very narrowly defined as either using an on-site pharmacist who may not be near the filling area (such as cameras in a clean room) or pharmacists performing remote patient counseling. The Advisory Committee felt strongly that the widely accepted definition of allowing technicians to work in remote locations is not needed and should not be permitted in Massachusetts.
 - We are not seeking a vote on this today, but are asking for input to improve this policy.
-
- **Action:** No action warranted.

2. CDTM Advisory

Time: 8:45AM

Presented by: J. TRAN

Discussion: J. TRAN explained the statute and regulation require “5 years of experience as a licensed pharmacist or the equivalent”, we have reached out to several stakeholders to help equate certain educational experiences. Atrius Health, Mass College of Pharmacy, and our own Kim Tanzer were key players in the development of this advisory.

Since the requirement is only for experience as a “licensed pharmacist”, we elected to not get into specific clinical experiences leaving room for the hiring institution to decide compatibility with the practice.

Generally, a pharmacist would need either a BPS certification, or a 1 -2-year residency with additional work experience, as well as a credentialing and training program.

There has been one minor change: under Requirements, section B, in the first statement, the “less than 5 years of experience” was removed to make it clear that the credentialing program can be applied to all CDTM pharmacists.

In the way of background, in order to pursue a BPS in ambulatory care, the educational requirements are **4 years** of practice or PGY-1 plus 1 year of practice.

From this we determined that **5 years** of practice would equivalent to PGY-1 with an additional 2 years of practice or PGY-2 with 1 year of practice.

In lieu of the extra practice years, a facility could develop a monitoring program where a current CDTM pharmacist could direct the new CDTM pharmacist and show him the “ropes.”

They would not need to be experts in the same field to provide such direction.

This is not an all-encompassing advisory, so if someone feels they might have another equivalent situation, they may petition the Board for consideration.

Action: Motion by T. FENSKY, seconded by S. HAMILTON and voted unanimously by all those present to approve the updated policy.

3. PSUD-Staff Action Policy 17-03

Time: 8:59AM

Presented by: E. TAGLIERI

Discussion: E. TAGLIERI explained the policy to implement routine aspects of the pharmacy Substance User Disorder rehabilitation program with noted change that the PSUD supervisor shall report to the Board a summary of all actions taken pursuant to this policy.

Action: Motion by P. GANNON, seconded by S. HERNANDEZ and voted unanimously by all those present to approve the updated policy.

TOPIC VI

APPLICATIONS

Time: 9:00 AM

1. Partner's Pharmacy DS3419 Pilot Project Update/Waiver Request

Presented by: N. BRUNETTE and J. FENELON

Discussion: N. BRUNETTE, RPh manager of Partner's Pharmacy and J. FENELON, compliance director of Partner's Pharmacy presented the discussion. N. BRUNETTE asked the Board for approval of adding more locations for implementation of the AP Passport machine. M. GODEK asked how long the teams that assist with the machine are present for. J. FENELON states the first team is present before the machine is at the institution, and the second team is there with the machine ranging anywhere from days-weeks at a time. N. BRUNETTE asked the Board for approval of adding more locations for implementation of the AP Passport machine. Specifically: Beaumont of Worcester, Northbridge, Westborough and Northborough, The Stone Institute and Southwood at Norwell (see presentation for exact schedule). Also, Partner's discussed they are approaching the year point and would like to come back in a month to discuss formal approval of the program and to leave the pilot state. E. TAGLIERI stated that Board of Registration in Pharmacy, Drug Control Program, and Healthcare Quality need to first initiate a guideline and policy pertaining to ADM use in Long Term Care, and that the pilot project will need to request extension at March Board meeting because this guideline is not yet ready. A. STEIN asked if the Board should consider extending the project now, E. TAGLIERI agrees. T. FENSKY states that Healthcare Quality already has regulations in place for machines such as this, however they specifically are for emergency boxes, not medication administration. E. TAGLIERI clarifies by stating that waivers are necessary from Healthcare Quality due to where the machine is being placed. D. SENCABAUGH asks the Board if project can be extended until June 2019. M. GODEK specifies for the of June 2019. S. HERNANDEZ states that the approval should go through until June subsequent if all other facilities are running successful. K. TANZER asks about one of the locations being removed from the AP Passport list they saw a few months back. N. BRUNETTE states that location is no longer affiliated with the program.

ACTION: Motion by T. FENSKY, seconded by S. HAMILTON and voted unanimously by all those present to approve stage four of the pilot program as described in the provided documentation, Specifically: Beaumont of Worcester, Northbridge, Westborough and Northborough, The Stone Institute and Southwood at Norwell (see presentation for exact schedule) be added, with each AP Passport rollout

being contingent on the successful rollout of the previous AP Passport implementation, and to extend the pilot project until June 30, 2019.

2. Walgreens #16537; DS90079 Renovation/Expansion

Discussion: Deferred

3. New England Life Care; DS3513

Time: 9:15 AM

Renovation/Expansion

Presented by: L. RUSSO & M. SMITH

Discussion: L. RUSSO stated the request is in anticipation of new USP <797> & <800>, and new regulations. A. STEIN asks if the clean room in which they wish to expand is still currently operating, and what the estimated date of expansion will take place. L. RUSSO states that the clean room is still operating the expansion is expected to take place in June of 2019. T. FENSKY asks where the loss of the 400 square feet will come from. L. RUSSO states that the pharmacy will lose the square footage to add to the renovation to the cleanroom. T. FENSKY asks how the cleanroom is going to be clean of debris during construction. L. RUSSO states they will be utilizing duct systems, rubber stoppers, particle counts, and weekly checks. T. FENSKY suggests at least monthly viable checks of containments. M. GODEK asks about the layout and if the pharmacy currently has two floors. L. RUSSO states that one diagram is the floor layout and the other diagram is the HVAC diagram and that the pharmacy is only one floor. A. STEIN asks if this type of construction has been completed before by presenters. L. RUSSO states that they have completed somewhere between 30-40 compounding facilities. T. FENSKY asks if the <797> clean room and <800> clean room will be right next to each other. L. RUSSO states that they will be separated by the two buffer rooms of each unit, which are next to each other.

ACTION: Motion by P. GANNON, seconded by K. TANZER and voted unanimously by all those present to approve the renovation pending a successful inspection.

4. Health First Pharmacy

Time: 9:23 AM

New Community Pharmacy

Presented by: M. CHAUDHARY & P. GARBARINI

Discussion: Proposed MOR M. CHAUDHARY asked by A. STEIN asks if the operator or owner are currently licensed pharmacists. M. CHAUDHARY states that the owners are her parents and they are not pharmacists, but rather just investors. A. STEIN asks if presenter has been a manager of record in the past. M. CHAUDHARY states that she has not. A. STEIN asks if presenter is familiar with the self-inspection tool, the Prescription Monitoring Program, and immunization requirements. M. CHAUDHARY states that she is familiar with all of the above. T. FENSKY asks if presenter is familiar with compounding. M. CHAUDHARY states that she is only familiar with non-sterile compounding from school and previous rotations. M. CHAUDHARY also states that she is aware of the differences between hazardous drugs and non-hazardous drugs. M. GODEK asks if there are any staff pharmacists already in place. M. CHAUDHARY states that she has two colleagues that are interested in working at this pharmacy, but both may not be full-time employees. M. GODEK asks if there are any technicians in place for when the pharmacy opens. M. CHAUDHARY states that they do not have any technicians yet, as she would like to operate the pharmacy for a month or so first to see how much staffing she would need. M. GODEK recommends that presenter familiarize herself with the new policy in place regarding technicians in training licensing, as well as staffing ratios. W. FRISCH asks if the pharmacy will be a stand-alone pharmacy, or if it will be in a strip mall location. M. CHAUDHARY states that it will be in a strip mall location. W. FRISCH asks if the

pharmacy will have floor to ceiling barriers. M. CHAUDHARY states that it will. K. TANZER asks if the pharmacy will be interested in providing a delivery service. M. CHAUDHARY states that the pharmacy will have delivery service that will have electronic tracking devices on the drivers so they can track the time and date the medication is received, as well as the patient signature. A. STEIN asks what software will be used for the delivery service tracking. M. CHAUDHARY states they will be using BestRX. P. GANNON asks if pharmacy will be providing immunizations as well as blister packing for patient needs. M. CHAUDHARY states that the pharmacy will immunize, and will blister pack based on patients' needs. T. FENSKY asks if the pharmacy will have security cameras. M. CHAUDHARY states that the pharmacy will have security cameras. There will be two-three in the prescription area, one on the front gate, and one in the waiting area. A. STEIN asks if the parents will be helping in any way inside the pharmacy. M. CHAUDHARY states that they will not. M. GODEK asks if anybody will be working in the front store due to large setup. M. CHAUDHARY states that they will have employees working in the front store; however, they will not be technicians.

ACTION: Motion by T. FENSKY, seconded by M. GODEK and voted unanimously by all those present to approve the new community pharmacy pending a successful inspection.

5. CVS Pharmacy #260; DS294

Time: 9:32 AM

Change of Manager

Presented by: JAMIE PAPAIONNOU

Discussion: Proposed MOR J. PAPAIONNOU indicated she was returning from a maternity leave, and was the MOR of CVS #260 prior to her maternity leave. She is up to date on CE requirements, registered with PMP, and a registered immunizer.

ACTION: Motion by T. FENSKY, seconded by P. GANNON and voted unanimously by all those present to approve the Change of Manager application.

TOPIC VII

FLEX

Time 9:51 AM

1. Baystate Medical Center/Brigham & Women's Pilot Project Update

Presented by: W. FRISCH

Recusal: None

Discussion:

- Seeking vote for Baystate and B&W to come off of the pilot project to end one-year pilot project.
- Also, to continue with technology-check-technician.
- Guidance document will be drafted as a joint policy.

Action: Motion by M. GODEK, seconded by K. TANZER, and voted unanimously by those present, to approve to end the one-year pilot project and continue the technology-check-technician project.

2. 2019 NABP Annual Meeting Discussion

TIME: 9:57 AM

Presented by: D. SENCABAUGH

Recusal: None

Discussion:

- K. Tanzer would like to be the delegate.
- S. Hamilton will be the alternative.

Action: Motion by A. STEIN, seconded by J. LANZA, and voted unanimously by those present, to approve the delegate.

Action: Motion by M. GODEK, seconded by A. STEIN, and voted unanimously by those present, to approve the alternate.

3. NABP Annual Meeting grant opportunity

TIME: 10:00 AM

Presented by: D. SENCABAUGH

Recusal: None

Discussion:

- There will be one reimbursement opportunity. Applicants who would not get reimbursement should notify Dave for the grant.

Action: Motion by M. GODEK, seconded by A. STEIN, and voted unanimously by those present, to approve the NABP Annual Meeting grant opportunity.

4. APhA Institute on Alcoholism and Drug Dependencies

TIME: 10:02 AM

Presented by: D. SENCABAUGH

Recusal: None

Discussion:

- S. HERNANDEZ and S. HAMILTON would like to attend.

Action: No action warranted.

5. 2018 Inquiries

TIME: 10:02 AM

Presented by: J. TRAN

Recusal: None

Discussion:

- The pie chart breaks down the 1,375 inquiries that were received and logged by Board staff in 2018.
- Licensing and non-resident licensing remain a large portion of the questions received, followed closely by controlled substances questions.
- The labels that are outlined with a box represent very low numbers and thus are not labeled on the chart.
- The average time to respond was 23.55, hours however this time includes non-business hours such as weekends, evenings, and holidays.
- This is down from our median time to completion in 2017 which was 24.26 hours.
- A. STEIN recommended that the common questions should be addressed through the NABP newsletter.
- To decrease the percentage of miscellaneous, more keywords will be added for more clarification.
- P. GANNON recommends publishing range as well as median.

Action: No action warranted.

VIII: Violation of Stayed Probation

1. PHA-2017-0169

CVS #1009, DS1529

TIME: 10:13AM

Represented by: K. FISHMAN

Recusal: Cornacchio

Discussion: K. FISHMAN summarized the facts regarding the violation of stayed probation. This matter comes before the Board as a notification of the Registrant's violation(s) of the Consent Agreement for [One year] Stayed Probation ("Agreement"), which the pharmacy entered into with the Board, effective December 20, 2017. (Attachment 1) The Registrant is subject to this Agreement due to an unknown loss of 1,588 tablets of tramadol 50mg in August 2017. Terms and conditions include those which have now become the standard terms for retail pharmacy cases with unknown losses (see Terms and Conditions section below for a detailed review) in addition to the standard term contained in all Agreements: Paragraph 4a: The Registrant must comply with all laws and regulations governing the practice of pharmacy in Massachusetts. In this case, it appears that CVS #1009 violated paragraph 4a of the Agreement.

Specifically, a retail pharmacy inspection was performed on November 7, 2018. The Board's inspector noted that the Registrant was in compliance with those standard terms of the Agreement specific to the unknown loss; however, other problems were noted. Specifically, the inspector issued a Plan of Correction for documentation of discrepancies in controlled substance returns sent back to Genco, the reverse distribution vendor used by CVS.

Three (3) letters were mailed to the pharmacy by Genco regarding the following discrepancies:

Testosterone 50mg/5gm had a discrepancy of -14.5 boxes on the 4/14/18 return to Genco;
Lorazepam 2mg/ml vials had a discrepancy of -90 vials on the 5/18/18 return to Genco;
Tramadol/APAP 37.5/325mg had a discrepancy of -403 tablets on the 5/18/18 return to Genco.

However, the inspector reported that there was no documentation of investigation or response to Genco for the reported discrepancies. As noted above, the Tramadol/APAP 37.5/325mg was one of the medications they were counting as part of their Agreement.

On November 11, 2018, the inspector received the Plan of Correction. The Registrant was able to account for two (2) of the three (3) discrepancies for which Genco notified them. However, the pharmacy was unable to account for the Tramadol/APAP 37.5/325mg.

Earliest Release Date: December 20, 2018

Options for the Board to Consider: Paragraph 7 of the Agreement states that if the Registrant does not comply with each requirement of this Agreement, or if the Board opens a Subsequent Complaint during the Stayed Probation Period, the Registrant agrees to the following:

- a. The Board may upon written notice to the Registrant as warranted to protect the public health, safety or welfare:
 - i. LIFT the stay, resulting in the imposition of PROBATION and rendering this Agreement disciplinary;
 - ii. EXTEND the Stayed Probation Period or, if the stay is lifted, the Probationary Period; and/or
 - iii. MODIFY the Stayed Probation Agreement requirements; and/or
 - iv. IMMEDIATELY SUSPEND the Pharmacy's registration.

Recommended Board Action: Probation Department Coordinator defers to the Board.

Action: Motion by P. GANNON, seconded by M. GODEK and voted unanimously by all those present to offer 30 days to cure with documentation requested until the March board meeting.

IX: Violation of Probation

1. PHA-2017-0182

Choon Kim PH27076

TIME: 10:25AM

Represented by: K. FISHMAN

Recusal: None

Discussion: K. FISHMAN explained matter comes before the Board as a notification of Licensee’s non-compliance with the *Consent Agreement (for Two Years) Probation* (“Agreement”) he entered with the Board, **effective March 21, 2018. (Attachment 1)** Specifically, Licensee did not comply with the Agreement at paragraph 5 (b) -(d), which requires him to submit a total of 140 CEs consistent with the requirements at 247 CMR 4.03, to count towards renewal deficiencies in 2015, 2016 and 2017. Despite several written communications via email to include an offer for Licensee to submit a Request for Extension, the Licensee has not complied with the requirements.

Basis for Probation: The Board and Licensee acknowledge and agree that:

- a. In or about February 2017, Licensee submitted an application to the Nevada Board of Registration in Pharmacy (“Nevada Board”) for a pharmacist license by reciprocity (“application”).
- b. On or about April 12, 2017, the Nevada Board considered and denied on various grounds Licensee’s application based on Licensee’s submission of a Voucher as to Moral Character that contained a forged signature.
- c. On July 20, 2017, the Nevada Board heard Licensee’s petition for reconsideration and voted to uphold its decision to deny him a license; wherefore with respect to his License:
 - i. Licensee violated 247 CMR 10.03 (1) (1) and (o), by submitting a Voucher as to Moral Character with his application that contained a forged signature.
 - ii. Licensee violated 247 CMR 10.03 (1)(a), through violating 247 CMR 40.3(4), by failing to complete as a precondition for renewal of his License 20 CEs for each of 2015 and 2016 prior to renewing his license in November 2016.
 - iii. Licensee violated 247 CMR 10.03(1)(a), through violating 247 CMR 40.3(3), by attesting to completing 40 CEs when renewing his license in November 2016.

Consent Agreement: Licensee became subject to Probation for no less than two (2) years, effective March 21, 2018. He is required to submit the above-noted CEs within six (6) months of the Effective Date as noted above.

Compliance Deadline: September 21, 2018

Compliance Status: The Board has not received any CEs or a Request for Extension form from the Licensee.

Action: Motion by M. GODEK, seconded by S. HERNANDEZ and voted unanimously by all those present to suspend his pharmacist license indefinitely until continuing education credits are completed.

TOPIC X

FILE REVIEW

Case #1

PHA-2018-0076

CVS #1007, DS90074

Time: 10:39 AM

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

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

- A complaint against CVS #1007 as a result of a failure to timely report a confirmed loss of controlled substances
- On 9/20/18, OPP received a RLCS initial notification for a suspected loss of #2,087mls promethazine-codeine 10mg-6.25mg/ 5ml that occurred on or about 9/11/18.
- A retail compliance inspection was conducted 10/22/18. During the inspection, OPP Investigator Murray noted the outstanding RLCS report. Pharmacy staff indicated the loss was a result of pilferage, and that the PTT responsible was terminated. OPP Investigator Murray informed pharmacy staff and the District Supervisor that the final RLCS was overdue and asked that they work to complete the submission.
- Investigator Murray contacted District Supervisor Richard on 10/26/18, as the final RLCS had still not been submitted. She indicated she expected the report to be submitted early the next week.
- On 11/6/18, CVS #1007 submitted the final RLCS, 35 days overdue, indicating the investigation concluded on 10/25/18. An investigation was subsequently opened on the licensee involved in the diversion
- On 12/3/18 an untimely response to the complaint was received. MOR Giblin indicated the initial variance was identified via corporate controlled substance monitoring, pharmacists conducted daily counts and the cause of the variance was not identified at that time. She indicated a letter of continuation was submitted to the Board on October 11, 2018 as the loss was still being investigated.
- This OPP Investigator received a copy of this letter obtained by Investigator Murray during the 10/22/18 inspection and reviewed the email inbox used for the submission of RLCS forms. No emails were received in this email inbox on 10/11/2018. All emails received that week were reviewed and confirmed that no letter of continuation was received regarding CVS #1007.
- CA- MOR stated, "Going forward, I will ensure timeline for submission of any drug loss documents are coordinated with field leadership, loss prevention and drug loss team to comply with Massachusetts Board of Pharmacy regulations."

ACTION: Motion by T. FENSKY, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2018-0076) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #2

PHA-2018-0078

Walgreens #3151, DS2470

Time: 10:43 AM

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

- RLCS - unknown loss of #60 Concerta 18 mg tablets on 10/10/18;
- MOR MacDonald indicated the loss was discovered during the perpetual inventory on 10/2/18 and was a possible dispensing error;
- The perpetual inventory provided indicated a reconciliation was conducted on 9/23/18 then on 10/2/18 with BOH as zero with the last transactions occurring on 9/27/18 when 100 tablets were received, Prescription 1 dispensed for #30 and Prescription 2 dispensed for #18 which was the physical balance on hand;

- PI Ahmad indicated she was given an open bottle and an unopen bottle of Concerta 18 mg by MOR MacDonald, double counted 30 tablets for Prescription 1, circled the quantity on the leaflet and vial label on a 10-dram vial, then back counted the remainder in the stock bottle; MOR MacDonald did not double count the quantity;
- The Pharmacy unsuccessfully attempted to confirm that the patient who received Prescription 1 was dispensed 60 additional Concerta 18 mg tablets;
- In an additional response on 12/21/18, MOR MacDonald indicated the patient who received Prescription 2 was not contacted because there were only 18 tablets in stock at the time of fill; this triggered “a red flag that was later confirmed during the weekly perpetual inventory”; therefore, the loss was realized on 9/27/18 contradictory to the reported date of 10/2/18;
- Security footage was reviewed (date not indicated) but was inconclusive;
- CA: Security camera was repositioned to be in view of the new safe, filling procedures were reviewed with staff pharmacists and PI Ahmad. MOR MacDonald completed 2 CEs in medication safety and attested to reviewing 247 CMR 15.
- One prior unknown loss of a CII (reprimand); last inspection on 11/20/18 was deemed satisfactory.

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

ACTION: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2018-0078) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #3

PHA-2018-0082

Walgreens #10317, DS89797

Time: 10:47 AM

RECUSAL: M. GODEK 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.

- Untimely RLCS, #102 oxycodone 15 mg IR tablets on or about 07/28/18
- During a retail Compliance inspection (ISP-11024) conducted on 11/26/2018, OPP Investigator observed a DEA 106 for an unexplained loss of oxycodone IR 15mg tablets and Section A of the Board RLCS
- On December 18, 2018, MOR Chambers-Smith provide a copy of Section B of the Board RLCS and a statement regarding the loss. According to Section B of the RLCS, the investigation concluded on 8/31/2018 and the reason for the loss was unknown.
- There were 5 prescriptions filled from the previous inventory and 3 of the 5 patients verified that their quantities were correct.
- MOR Chambers-Smith indicated that the reason Section A and B were not submitted in a timely manner was due to a break in communication
- Multiple people we’re handling the same issue without communicating what steps had been completed. Additionally, the language of the RX Integrity form regarding the DEA 106 form caused confusion regarding requirements for sections A and B
- MOR Chambers-Smith indicated that the RX Integrity form is being updated so that the wording is less confusing. The Pharmacy will continue to perform checks and balances by conducting weekly

reconciliation of each CII controlled substance. Close attention will be paid to the quantity dispensed and will only receive from the safe what is needed to fill the current prescription, no excess bottles. Medications will not be taken from the safe in advance to fill prescriptions. Unused bottles will be returned to the safe immediately after filling prescription, and empty bottles will not be recapped before disposing them.

ACTION: Motion by S. HERNANDEZ, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2018-0082) 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 REPRIMAND.

Case #4

PHA-2018-0083

Walgreens #15193, DS89802

Time: 10:50 AM

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

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

RLCS- #50 d-amphetamine salts ER 10mg capsules as a result of an unknown loss. No prior reported losses.

- Loss was identified on November 16, 2018 after performing a perpetual inventory reconciliation.
- MOR Blanchette indicated upon review of the video footage, the pharmacist counted the medication and the stock bottle which remained on the pharmacy bench. The video footage appeared inconclusive with verifying where the stock bottle was placed after it was returned to the shelf. He further indicated that the pharmacy was searched, and the medication was not located. On the same day, the district manager and loss prevention were made aware of the loss.
- MOR Blanchette indicated that he reviewed with staff the Walgreens Standard Operating Procedure for filling RX's emphasizing on use of plastic totes for organization and order and reminded staff pharmacist to return CII stock bottles back to safe upon completion of the filling and verifying process as soon as possible.
- A retail compliance inspection (ISP- 11074) was conducted at Walgreens #15193 on December 4, 2018 was deemed satisfactory.

ACTION: Motion by S. HERNANDEZ, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2018-0083) to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #5

SA-INV-14157

Dawn Lynde, PH21814

Time: 10:52 AM

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

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

- Pharmacist Lynde properly reported that she received discipline in another jurisdiction from the Maine BOP for unprofessional conduct after failing to perform DURs on multiple gabapentin Rx's for the same patient. Specifically, the patient received approximately 30 Rx's for 270 gabapentin 300mg

capsules from 3-2017 to 02-2018 from. Pharmacist Lynde verified 23/30 gabapentin Rx's for the patient.

- Significantly, 16/23 Rx's were rejected by Maine Medicaid for being too early to refill and she allowed the patient to pay cash for those early refills. She admitted that she did not perform a DUR on any of the 23 Rx's that she verified. As a result, Pharmacist Lynde entered into a consent agreement for discipline with the Maine BOP in the form of a warning (similar to BORP reprimand) and a \$250.00 civil penalty.
- Pharmacist Lynde reported mitigating circumstances affected her professional conduct. She indicated that she had health issues in 12-2016. She described that she was denied additional leave and was forced to return to work in 01-2017 on light duty. She then was forced to return to regular duty in 02-2017 after only two weeks of light duty. She indicated that she then had an acute illness in 02-2017. She next explained that when she recovered and returned to work the pharmacy's MOR quit because the pharmacy's future was in question after a transfer of ownership to Walgreens.
- CA: Pharmacist Lynde completed additional remediation beyond her consent agreement with the Maine BOP and her annual CE requirements for her MA RPh license. Specifically, she provided proof of completion of 2 hours of CE in patient safety and to reading 247 CMR 15.00.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE the matter (SA-INV-14157), No Discipline Warranted, Remediation Complete.

Case #6

PHA-2018-0016

Smith Drug, DS2198

Time: 10:58 AM

RECUSAL: NONE

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

- Inspectional deficiencies (ISP-9094) on 3/5/18 for controlled substance recordkeeping, expired drugs, issues with refrigeration documentation, repackaging of drugs dispensed from other pharmacies, lack of labeling on multi-dose packaging, and non-compliant labeling on multi-dose packaging;
- Pharmacy dispenses drugs in vials, Dispill, blister cards, and daily primarily to individual residents and assisted living facilities;
- Pharmacy notified of the complaint on 3/30/18;
- POC received on 4/17/18 and the response to the complaint received on 5/25/18 did not adequately address non-compliant labeling deficiencies;
- Re-inspection (ISP-10060) on 7/17/18 cited for controlled substance recordkeeping & security, disposing of controlled substances via police Take-Back box, outdated API, and non-compliant labeling (175 of 400 on Dispill);
- 7/18/18 Board staff recommended the Pharmacy discontinue the use of non-compliant labeling & packaging and no longer accept drugs dispensed from other pharmacies for repackaging in multi-dose packaging which MOR Fournier agreed to on 7/19/18;
- POC received 7/20/18-
 - MOR Fournier responded she reviewed the draft regulations for multi-dose packaging and completed 2 CEU on patient safety;
 - Effective immediately Smith Drug will only dispense package product dispensed by Smith Drug and from no other source;

- Smith Drug will comply with labeling requirements for multi-dose packaging;
 - Policy/Procedure developed to cleaning daily planners;
 - Use of daily planners is being phased out as soon as possible, with the potential for exceptions requests for a limited number of patients with handicaps that preclude using that system;
- MOR Fournier stated she intended to convert the majority of the multi-dose packaging to Dispill by 7/28/18.
 - Site Visit (ISP-10130) on 8/20/18: although all labeling was not fully compliant, MOR Fournier estimated 320 of 400 patients had been converted to Dispill labeling with some also converted to Dispill packaging;
 - 8/22/18 MOR Fournier indicates she signed a formal agreement to work with a consultant who is aware of the outstanding issues to be addressed for full compliance.
 - Re-inspection conducted on 01/16/19 resulted in a POC with deficiencies including:
 - CII's not locked or dispersed, all on the shelves in one location
 - Pharmacy technician working with an expired license (11/22/18)
 - Standards of practice not maintained (repeat)-staff handling medications with bare hands, dirty bins, dirty planners, reusing of vials, and technicians checking technician for filled Dispill packages prior to dispensing.
 - Medications being returned/disposed of at the police station (repeat).
 - CS return from 2008 not redistributed and not on perpetual inventory, some product as old as 1995. Expired C2 in file cabinet not on perpetual inventory. Expired C2 observed in plastic bag including redacted vials, two with Rite Aid labels.
 - Mediations ready for dispensing/delivery including daily planners with Dispill labeling with incorrect date, non-compliant or no labeling.

ACTION: Motion by M. GODEK, seconded by S. HERNANDEZ, and voted unanimously by those present, to refer the matter (PHA-2018-0016) 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 a STAYED PROBATION for a period of 2 years, with special terms to include appointing a new Manager of Record (MOR) within in the next 30 days, and resolving all outstanding inspectional deficiency issues within 30 days. Board requested a re-inspection 30 day after the new MOR is in place to evaluate progress.

A second motion was made by M. GODEK, seconded by S. HAMILTON, and voted unanimously by those present, to open a complaint on MOR Fournier for failure to correct a deficiency. Additionally, Board members requested that the MOR be notified that she needs to immediately rectify the cleanliness and labeling deficiencies, specifically all labeling must be in compliance and inform her that a re-inspection will occur within 2 weeks of her being notified. Lastly, all other outstanding deficiencies need to be remediated within 30 days.

Topic XI

EXECUTIVE SESSION

Time: 11:30 AM

Read by A. Stein

DISCUSSION:

ACTION: At 11:30 AM President A. Stein read the statement on reasons for Executive Session.

Topic XI: Executive Session Call to Order: Time: 1:33 PM
By: M. Godek

ACTION: Motion by P. Gannon, seconded by T. Fensky, and voted unanimously by roll call to call the February 7, 2019 meeting of the Executive Session to order.

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

Topic XII: Adjudicatory Session (M.G.L. ch 30A § 18) Time: 11:45 AM

DISCUSSION: None

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

At 11:45 AM M. Godek, seconded by K. Tanzer and voted unanimously by all those present to enter Adjudicatory Session:

Topic XIII: M.G.L. 65 C #1 Time: 11:48 AM

DISCUSSION: None

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

At 11:48 AM T. Fensky, seconded by M. Godek and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

Topic XIII: M.G.L. 65 C #2 Time: 2:03 PM

DISCUSSION: None

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

At 2:03 PM T. Fensky, seconded by K. Tanzer and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

LUNCH Time out: 12:25 PM Time back: 1:31 PM

Topic XIV: ADJOURNMENT OF MEETING TIME: 3:35 PM

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

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 2/7/19 General Session
2. Draft Minutes of the 1/10/19 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. Draft Shared Pharmacy Service Model Discussion
9. CDTM Advisory
10. PSUD-Staff Action Policy update 17-03
11. Partner's Pharmacy, DS3419; Pilot Project Expansion Request/Waiver
12. New England Life Care; DS3513; Renovation/Expansion
13. Health First Pharmacy; New Community Pharmacy
14. CVS Pharmacy #260; DS2294; Change of Manager
15. PHA-2017-0169; CVS #1009; DS1529 violation of stayed probation
16. PHA-2017-0182; Choom Kim; PH27076 violation of probation
17. PHA-2018-0076- CVS #1007, DS90074
18. PHA-2018-0078- Walgreens #3151, DS2470
19. PHA-2018-0082- Walgreens #10317, DS89797
20. PHA-2018-0083- Walgreens #15193, DS89802
21. SA-INV-14157- Dawn Lynde, PH21814
22. PHA-2018-0016- Smith Drug, DS2198

Respectfully Submitted,
Julie Lanza, CPhT, Secretary