

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

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

July 31, 2020

Webex Information

Call in Number: 1-203-607-0564 or toll free 1-866-692-3580

Access Code: 161 970 8358

Attendee: #

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator Yulanda Kiner, Phone: 617-624-5848 in advance of the meeting. While the Board will do its best to accommodate you, certain accommodations may require distinctive requests or the hiring of outside contractors and may not be available if requested immediately before the meeting.

Agenda

Time	#	Item	Page	Contact
8:00	I	CALL TO ORDER		K. Tanzer
	II	APPROVAL OF AGENDA		
	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of July 24, 2020 Regular Session Minutes		
8:05	IV	APPLICATIONS <ul style="list-style-type: none">• EssentialRx – Transfer of Ownership• Williamstown Apothecary (DS90328) – Change in application• Baker Pharmacy (DS12518) – Transfer of Ownership		
8:35	V	FLEX <ul style="list-style-type: none">• Pharmacy issues related to Covid-19 and the state of emergency		

8:45	VI	<p>POLICIES AND ADVISORIES</p> <ul style="list-style-type: none"> • Ratification of the approved language for Joint Policy 2020-06: Continuation of Drug Therapy upon Discontinuation of a Prescriber’s Practice – ratify approved final language • Ratification of the approved language for Policy 2020-07: Naloxone Dispensing- • Joint Policy 2020-08: Expedited Partner Therapy Prescriptions • Joint Policy 2020-09: Emergency Contraception Standing Order • Advisory: Sterile Compounding Pharmacy Response to HVAC Excursions • Advisory: Pharmacy Response to Failed HEPA Filters in ISO-Classified Environments • Memo regarding Revocation of Board Policy 2010-02: Joint Guidelines for the Use of Automated Pharmacy Systems for the Storage and Dispensing of Schedule VI Controlled Substance Prescriptions in Pharmacies 											
9:30	VII	<p>FILE REVIEW</p> <table border="1" data-bbox="323 915 1192 1071"> <tr> <td data-bbox="323 915 391 966">1</td> <td data-bbox="391 915 667 966">PHA-2020-0027</td> <td data-bbox="667 915 1192 966">Rite Aid #10084, DS2780</td> </tr> <tr> <td data-bbox="323 966 391 1016">2</td> <td data-bbox="391 966 667 1016">PHA-2020-0030</td> <td data-bbox="667 966 1192 1016">Walgreens #19107, DS90154</td> </tr> <tr> <td data-bbox="323 1016 391 1071">3</td> <td data-bbox="391 1016 667 1071">PHA-2020-0031</td> <td data-bbox="667 1016 1192 1071">Walgreens #17927, DS90136</td> </tr> </table>	1	PHA-2020-0027	Rite Aid #10084, DS2780	2	PHA-2020-0030	Walgreens #19107, DS90154	3	PHA-2020-0031	Walgreens #17927, DS90136		
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2	PHA-2020-0030	Walgreens #19107, DS90154											
3	PHA-2020-0031	Walgreens #17927, DS90136											
9:45	VIII	<p>EXECUTIVE SESSION 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 a pending applicant.</p>											
10:00	IX	<p>M.G.L. c. 112, § 65C SESSION</p>											
10:30	X	<p>ADJOURNMENT</p>											

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

MINUTES OF THE GENERAL SESSION

Meeting held via WEBEX remotely

Boston, Massachusetts, 02114

July 31, 2020

Board Members Present

Kim Tanzer, PharmD, RPh. President
Leah Giambarresi, Pharm D, RPh, Secretary
Sebastian Hamilton, Pharm D, RPh
Dr. Richard Lopez, MD
Andrew Stein, Pharm D
Timothy Fensky, RPh
Katie Thornell, RPh
Susan Cornacchio JD, RN
Stephanie Hernandez, Pharm D, BCGP, RPh
Patrick Gannon, RPh
Dawn Perry, JD

Board Members Not Present

Julie Lanza, CPhT, President Elect
Carly Jean-Francois, RN, NP

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, Assistant Executive Director
Heather Engman, JD, Board Counsel
Michelle Chan, RPh Quality Assurance Pharmacist
Joanne Trifone, RPh, Director of Investigator
Richard Geaney RPh, Investigator
Gregory Melton, Pharm D, JD, RPh Investigator
Christina Mogni, RPh Investigator
Cheryl Lathum, PharmD, RPh Investigator
Leo McKenna, PharmD, RPh Investigator
John Murray, RPh Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Joanna Chow, Office Support Specialist
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 AM

A quorum of the Board was present, established by roll call. President K. Tanzer chaired the meeting. She explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: K. TANZER: yes, L. GIAMBARRESI: yes, A. STEIN: yes, S. HAMILTON: yes, D. PERRY: yes, S. CORNACCHIO: yes, S. HERNANDEZ: yes, T. FENSKY: yes, R. LOPEZ: yes; P. GANNON: yes, K. THORNELL: yes.

Topic II.

Approval of Agenda

TIME 8:03 AM

Agenda July 31, 2020

DISCUSSION:

Change to Agenda:

1. Baker Pharmacy resolved remove from agenda
2. Defer PHA-2020-0031 Walgreens #17927 DS90136

ACTION:

Motion by S. Hamilton, seconded by T. Fensky and voted unanimously by those present by roll call vote to approve the agenda with noted changes.

Topic III

Approval of Board Minutes

TIME: 8:05 AM

Minutes

1. Draft 7/24/20 General Session Minutes

No noted Changes.

Action:

Motion by L. Giambarresi, seconded by S. Hamilton and voted unanimously by roll call vote to approve the regular session minutes of 7/24/20 with no noted changes.

TOPIC IV

Applications

1. EssentialRx

Transfer of Ownership

Time: 8:05 AM

Represented by: Khalid Boukhatem, owner; Kerry Sam, MOR; Ernest Gates, Gates Healthcare Associates

Recusal: None

Discussion: Transfer of ownership of Saint Vincent Pharmacy at Saint Vincent Hospital. Kerry Sam, the MOR at Saint Vincent Pharmacy, will be staying as the MOR of EssentialRx. A waiver to not compound was submitted with the application. They do not compound, but they do use First Kits to prepare Magic Mouthwash. The Board informed the applicants that use of the First Compounding Kits is compounding requiring a designated compounding area and completion of a compounding record. They cannot waive compounding due to their use of the First Kits. It was recommended that they refer people to the nearest compounding pharmacy. The pharmacy already has a list of compounding pharmacies to give to the patients. When asked,

Mr. Boukhatem responded that he did own Boulevard Pharmacy, but they would not be connected.

Action: Motion by T. FENSKY, seconded by L. GIAMBARESSI, and voted unanimously by roll call by those present to approve the application for transfer of ownership pending the withdrawal of the compounding waiver.

2. Williamstown Apothecary Change to Application Time: 8:13 AM

Represented by: Keith Preston, David MacHaffie, and Sarah Roberts

Recusal: None

Discussion: The Board received confirmation of implementation of updated security measures this week; a panic alarm has been installed in the vestibule and written confirmation that security is monitoring in real time 24/7. The panic alarm button signal goes to the Williamstown Police Department and they will respond. The live security camera monitoring is done by BMC security. The door to the vestibule can be locked, if for some reason security or video monitoring is down.

Action: Motion by T. FENSKY, seconded by L. GIAMBARRESI, and voted unanimously by roll call by those present to approve the application, pending successful inspection.

3. Baker Pharmacy DS12518 Transfer of Ownership

DEFERRED

V: Flex:

1. Pharmacy issues related to Covid-19 and the state of emergency

Presented by: Dave

Recusal: None

Discussion: None]

TOPIC VI Policy and Advisory

1. Joint Policy 2020-06: Continuation of Drug Therapy upon Discontinuation of a Prescriber's Practice

Time: 8:18 AM

Presented by: M. CHAN

Discussion: This policy describes the conditions by which a pharmacist can continue established medication therapy after a prescriber ceases to practice. The limit to dispensing was removed as long as the script was issued when a proper patient-prescriber relationship existed. Language was also added to allow for continued therapy after the prescription has expired or has no remaining refills. This is the same language in draft regulation 247 CMR 9.00.

Action: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by roll call by all those present to ratify the language changes.

2. Policy 2020-07: Naloxone Dispensing

Time: 8:19 AM

Presented by M. CHAN

Discussion: This policy combines the two existing naloxone policies: the one that allows off-site dispensing and the one that describes the general dispensing and reporting requirements. In response to the comments from last week, a statement was added to allow for a generic “naloxone rescue kit” label in place of the name and address when the purchaser uses their insurance.

Action: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted unanimously by roll call by all those present to ratify the language changes.

3. Joint Policy 2020-08: Expedited Partner Therapy Prescriptions

Time: 8:21 AM

Presented by M. CHAN

Discussion: The language has been updated and simplified for the treatment of chlamydia using the Expedited Partner Therapy Prescription process.

Action: Motion by T. FENSKY, seconded by L. GIAMBARRESI, and voted unanimously by roll call by all those present to approve the policy changes.

4. Joint Policy 2020-09: Emergency Contraception Standing Order

Time: 8:23 AM

Presented by M. CHAN

Discussion: The policy was simplified to contain just the statutory requirements for offering and reporting emergency contraception dispensed pursuant to a standing order. Links to the Sexual and Reproductive Health Program’s offerings for a model standing order and other current information have been included.

Action: Motion by S. HAMILTON, seconded by T. FENSKY, and voted affirmatively by those present, except P. GANNON who abstained, by roll call to approve the policy changes.

5. Advisory: Sterile Compounding Pharmacy Response to HVAC Excursions

Time: 8:26 AM

Presented by M. CHAN

Discussion: The most notable edits to this advisory are to the suggested beyond use dates during the remediation process and the removal of the recommendation to suspend compounding in the event of a temperature or relative humidity excursion lasting longer than 60 minutes.

Action: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by roll call by all those present to approve the changes to the advisory.

6. Advisory: Pharmacy Response to Failed HEPA Filters in ISO-Classified Environments

Time: 8:27 AM

Presented by M. CHAN

Discussion: The time frame for reporting was removed and now refers only to the reporting form. Once the new regulations are promulgated, the time to report will change to one business day. Also edited were the suggested beyond use dates during remediation.

Action: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by roll call by all those present to approve the changes to the advisory.

7. MEMO regarding Revocation of Board Policy 2010-02: Joint Guidelines for the use of Automated Pharmacy Systems for Storage and Dispensing of Schedule VI Controlled Substance Prescriptions in Pharmacies

Time: 8:30 AM

Presented by M. CHAN

Discussion: This memo requests a vote to rescind Policy 2010-02: Joint Guidelines for the Use of Automated Pharmacy Systems for the Storage and Dispensing of Schedule VI Controlled Substance Prescriptions in Pharmacies once 247 CMR 9.00 is promulgated. Automated pharmacy systems are addressed in those draft regulations and will make this policy obsolete. The regulations will allow Schedule IV – VI prescription dispensing while this policy only allows refills of Schedule VI prescriptions in automated pharmacy systems.

Action: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted unanimously by roll call by all those present to rescind the policy upon promulgation of 247 CMR 9.00.

TOPIC VII

File Review

Case #1

PHA-2020-0027

Rita Aid #10084, DS2780

Time: 08:33 AM

RECUSAL: NONE

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

- On 4/1/2020, untimely, incomplete, inaccurate RLCS for an unknown loss of #61 dextroamphetamine/amphetamine salts 20 mg tablets allegedly discovered on 02/17/2020. In an initial response on 5/28/2020, MOR Fullem stated the loss was discovered during a routine audit on 2/17/20 but the perpetual inventory provided for 2/1/2020 to 4/1/2020 did not show any discrepancies. The corporate reconciliation report showed results for 3 NDCs with 1 overage and 2 shortages with an overall discrepancy of 61 tablets. MOR Fullem was contacted for clarification and she stated that the discrepancy of dextroamphetamine/amphetamine salts 20 mg tablets was discovered sometime in November 2019 and not on 2/17/2020 as reported. A revised response was requested.
- On 6/11/2020, an amended response was received. DL Bagni stated there was a miscommunication between Former DL Courchaine and MOR Fullem regarding when this loss actually occurred with a lack of follow up. The initial notification of the loss was filed on 2/17/20 and forwarded to her upon taking over the position on 3/1/20. When the investigation concluded, she filed the final reports.
- MOR Fullem indicated 2 discrepancies were discovered during the reconciliation of the perpetual inventory and were due to failure to double count and back count the tablets prior to dispensing. Allegedly, there was an unconfirmed dispensing error on 9/25/2019 when it was suspected that a patient received 90 tablets instead of 60 tablets but it “was never successfully confirmed with the patient”. On 11/28/2019, a second discrepancy was identified as a possible over-dispensing “but there were no clues as to which prescription was affected”. Subsequently, the patient disclosed the over-dispensing on 01/24/2020 to MOR Fullem. The one additional tablet that was missing was attributed to a manufacturer shortage in a bottle. Copies of “Replenishment DC Ordering: Drug Detail” reports were provided as the perpetual inventories for 4 NDC numbers of dextroamphetamine/amphetamine salts 20 mg tablets. Additional discrepancies were identified that appear to be attributed to filling prescriptions using partial quantities of two different NDC numbers although this was not documented in the “perpetual inventory”.
- CA: RPL Bagni made corrections to the process for reporting controlled substance losses to be in compliance going forward. MOR Fullem stated all pharmacist must double count CII medications, document the starting balance minus the dispensed quantity and the expected final balance on hand and double check that it matches the on-hand quantity. Since this incident, stock bottles have also been counted prior to dispensing, per Rite Aid policy.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2020-0027), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Case #2

PHA-2020-0030

Walgreens #19107, DS90154

Time: 08:37 AM

RECUSAL: NONE

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

- On April 21, 2020, the Pharmacy submitted an untimely final Board Report of Loss of Controlled Substances (RLCS) which confirmed the loss of # 179 oxycodone 5 mg tablets on March 8, 2020.
- MOR Berube attested that she completed a perpetual inventory at the end of her shift on March 8, 2020 and discovered the discrepancy. MOR Berube then went on vacation until March 16, 2020. On April 3, 2020, MOR Berube stated that she could not reconcile the loss and contacted her supervisors. She stated that she regretted not working with her leadership sooner so that the loss had been reported more expediently.
- On April 17, 2020, MOR Berube reviewed video footage. She discovered that while filling a prescription on March 7, 2020, she threw a sealed bottle and a half bottle of oxycodone 5 mg into the HIPPA trash.
- MOR reiterated that she inadvertently threw the medication into the HIPPA trash on 3/7/2020 at approximately 17:26. She stated that the HIPPA trash is removed from the Pharmacy by a pharmacist and then placed in a locked receptacle in the stock room. A vendor then removes the HIPPA trash every week on Wednesday morning.
- MOR Berube reviewed workflow and workstation procedures with her staff and understands the importance of focusing on one task at a time. Pharmacists were reminded to promptly return Schedule II medications to the safe and to keep the bench clutter free. In addition, the district manager reviewed with MOR Berube and the other pharmacists the procedures to follow when a loss is suspected and the Walgreens requirement of completing a weekly perpetual inventory.
- Pharmacy staff attested to reviewing the Walgreens' Policy and Procedure on Controlled Substances Inventory.

ACTION: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by those present, to refer the matter (PHA-2020-0030), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for REPRIMAND.

Kim Tanzer announces at 8:41 AM the general session will be ending, and the Board will be going into Executive Session and reads the reason for entering Executive Session as required. The Board will not cover any other general session items today.

Topic VIII:

Executive Session Call to Order:

Time: 8:41 AM

By: K. Tanzer

ACTION: Motion by L. Giambarresi seconded by A. Stein and voted unanimously by roll call to call the 7/31/20 meeting of the Executive Session to order.

Roll call attendance: K. TANZER: yes, L. GIAMBARRESI: yes, A. STEIN: yes, S. HAMILTON: yes, D. PERRY: yes, S. CORNACCHIO: yes, S. HERNANDEZ: yes, T. FENSKY: yes, R. LOPEZ: yes; P. GANNON: yes, K. THORNELL: yes.

S. Cornacchio is not at the meeting from 8:47AM to 8:55 AM

Topic IX:

M.G.L. 65 C #1

Time: 8:47AM

DISCUSSION: None

ACTION: President K. Tanzer request a motion to enter M.G.L 65 c Session.

At 8:47 AM S. Hamilton, seconded by L. Giambarresi and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

Topic XI:

ADJOURNMENT OF MEETING

TIME: 9:24 AM

ACTION: Motion by P. Gannon seconded by S. Hamilton, 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 7/31/20 General Session
2. Draft Minutes of the 7/24/20 Meeting
3. Applications: EssentialRX transfer of ownership
4. Applications: Williamstown Apothecary Change in Application
5. Ratification: Joint Policy 2020-06: Continuation of Drug Therapy upon Discontinuation of a Prescriber's Practice
6. Ratification: Policy 2020-07: Naloxone Dispensing
7. Joint Policy 2020-08: Expedited Partner Therapy Prescriptions
8. Joint Policy 2020-09: Emergency Contraception Standing Order
9. Advisory: Sterile Compounding Pharmacy Response to HVAC Excursions
10. Advisory: Pharmacy Response to Failed HEPA Filters in ISO-Classified Environments
11. Memo regarding Revocation of Board Policy 2010-02: Joint Guidelines for the Use of Automated Pharmacy Systems for the Storage and Dispensing of Schedule VI Controlled Substance Prescriptions in Pharmacies
12. PHA-2020-0027 Rite Aid #10084 DS2780
13. PHA-2020-0030 Walgreens #19107 DS90154

Respectfully Submitted,
Leah Giambarresi, PharmD, RPh, Secretary