

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

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

November 6, 2020

Webex Information

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

Access Code: 171 162 6480

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		
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">Draft of October 23, 2020 Regular Session Minutes		
8:10	IV	REPORTS <ul style="list-style-type: none">Applications approved pursuant to Licensure Policy 13-01Monthly report from probationBoard Delegated Review pursuant to Licensure Policy 14-02Above Action Levels approved by Staff Action 16-04PSUD Report-Policy 17-03Research Drug Study Report		
8:20	V	FLEX <ul style="list-style-type: none">Pharmacy issues related to Covid-19 and the state of emergencyDiscontinuation of the Board approved CE programs		

8:35	VI	FILE REVIEW			
		1	RMG Pharmacy, DS90308		
		2	Walgreens #10802, DS3558		
		3	County Square Pharmacy, DS15805		
8:50	VII	REVIEW OF COMPLIANCE <ul style="list-style-type: none"> Preferred Pharmacy Solutions; DS3452; PHA-2018-0015 			K. Fishman
9:00	VIII	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.			CLOSED SESSION
9:15	IX	M.G.L. c. 112, § 65C SESSION			CLOSED SESSION
10:30	X	ADJOURNMENT			

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

MINUTES OF THE GENERAL SESSION

Boston, Massachusetts, 02114

Via Remote WebEx Meeting

November 6, 2020

Board Members Present

Kim Tanzer, PharmD, RPh, President
Julie Lanza, CPhT, President Elect (leaves 9:30 AM)
Leah Giambarresi, Pharm D, RPh, Secretary
Patrick Gannon, RPh (leaves 9:55 AM)
Sebastian Hamilton, Pharm D, RPh
Dr. Richard Lopez, MD
Andrew Stein, Pharm D
Susan Cornacchio, JD, RN
Timothy Fensky, RPh
Stephanie Hernandez, Pharm D, BCGP, RPh
Katie Thornell, PharmD, RPh
Carly Jean-Francois, RN, NP
Dawn Perry, JD

Board Members Not Present

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, Assistant 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 Investigator
Julienne Tran, PharmD RPh, Investigator
Cheryl Lathum, Pharm D, JD, RPh Investigator
Christina Mogni, RPh Investigator
Nathaniel VanAllen, PharmD, Investigator
Gregory Melton, PharmD, JD, Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Joanna Chow, Office Support Specialist

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:04 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: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; K. Thornell, yes; S. Hernandez (yes); D. Perry, yes; P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky, yes; R. Lopez, yes.

Topic II.**Approval of Agenda****TIME 8:04 AM****Agenda: 11/6/20****DISCUSSION:**

Change to Agenda:

1. none

ACTION:

Motion by S. Hamilton, seconded by P. Gannon and voted unanimously by roll call vote of all those present to approve the agenda with no noted change.

Ed Taglieri introduces the APPE Student Alexander Huynh from MCP Boston.

Topic III**Approval of Board Minutes****TIME: 8:05 AM****Minutes****1. 10/23/20**

Changes:

1. date of Agenda is 10/23/20; minutes state 10/23/19

Action:

Motion by L. Giambarresi, seconded S. Hamilton, and voted unanimously by roll call vote to approve the regular session minutes of 10/23/20 with noted changes.

TOPIC IV**REPORTS****Applications approved pursuant to Licensure Policy 13-01****Time: 8:08 AM**

Discussion: M. BOTTO noted that there have been thirteen (12) Change of Managers applications approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV**REPORTS****Monthly Report from Probation****Time: 8:08 AM**

Discussion: M. BOTTO provided the September 23, 2020 – October 28, 2020, Board of Pharmacy Statistics Report for the Probation monitor, which noted that two (2) licensees satisfactorily completed probations and there are currently thirty (30) licensees on probation.

So noted

TOPIC IV**REPORTS****Monthly Report from BDR pursuant to Policy 14-02****Time: 8:08 AM**

Discussion: M. BOTTO noted that there were three (3) Board Delegated Review cases heard since the last Board meeting. All three (3) were CE self-disclosures which were closed with discipline not warranted and remediation complete. The Board Delegated Review session was attended by Kim Tanzer

as the Board President, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted

TOPIC IV	REPORTS	
Above Action Levels Approved by Staff Action 16-04		Time: 8:08 AM

Discussion: N. ALEID noted that four (4) above action level report has been reported since last Board meeting pursuant to Licensure Policy 16-04.

So noted

TOPIC IV	REPORTS	
PSUD Report by Staff Action 17-03		Time: 8:08 AM

Discussion: E. TAGLIERI noted that there were twelve (12) active participants and no pending applications.

So noted

TOPIC IV	REPORTS	
Research Drug Study Report by Staff Action Policy 18-02		Time: 8:09 AM

Discussion: W. FRISCH noted there are fourteen (14) Research Drug Studies from June 2017 through October 2020 and two (2) pharmacies participating.

So noted

TOPIC V	FLEX	
1. Pharmacy issues related to COVID-19 and state of emergency		TIME: 8:09 AM

PRESENTED BY: D.SENCABAUGH

Nothing new to report.

2. Discussion of Board approved CE programs	TIME: 8:10 AM
--	----------------------

PRESENTED BY: M.CHAN

DISCUSSION: Last January, the Board voted to amend the procedure for Board approved CE to require 60 days' notice for review and approval. However, due to operational demands, the Board staff will no longer be able to provide this free service as of April 1, 2021.

The initial plan was to sunset the program in December, but due to COVID, it has been extended until April. Those who have been taking advantage of this service will be notified that an ACPE provider can assist with any future programming.

The Board will continue to accept CE approved by any US Board of Pharmacy.

So noted

TOPIC VI

FILE REVIEW

Case #1

SA-INV-16540

RMG Pharmacy, DS90308

Time:08:12 AM

RECUSAL: NONE

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

- OPP received a complaint from the Attorney for Cure Aid Pharmacy alleging that RMG Pharmacy was transferring patients' prescriptions without consent and providing false advertisement of partnership with Cure-Aid Pharmacy.
- RMG Pharmacy officially opened its business on March 17, 2020 with Pharmacist Babilonia employed as a MOR. RMG's Attorney stated that prior to RMG Pharmacy opening, Renaissance Medical Group's founder and president, Jesus Suarez was a partial owner of Cure-Aid Pharmacy along with the owner of Cure-Aid Pharmacy. However, when RMG Pharmacy opened, the partnership at Cure-Aid Pharmacy was dissolved. The Attorney indicated that as a result of the dissolution of the partnership at Cure-Aid Pharmacy between Mr. Suarez and the owner of Cure-Aid Pharmacy, there was acrimony, possibly motivating Cure-Aid's owner to submit a false complaint against RMG Pharmacy.
- MOR Babilonia indicated that patients who wanted to transfer their prescriptions to RMG Pharmacy had to fill out the prescription transfer form and MOR Babilonia shared that form with their existing pharmacy. The Attorney noted that when MOR Babilonia called Cure-Aid Pharmacy to transfer the prescriptions of patients who wanted to come to RMG Pharmacy, they were denied from Cure-Aid's owner with a suggestion that the patient signature on the forms could have been forged.
- The Attorney indicated that one of the allegation's is a third-hand, hearsay account from a patient through her personal care attendant to the Cure-Aid owner. The Attorney also indicated that said Patient did consent to transfer her prescriptions from Cure-Aid Pharmacy to RMG Pharmacy earlier in the year. However, said Patient decided to go back to Cure-Aid Pharmacy because it was closer to her home. The Attorney noted that RMG Pharmacy fully cooperated to transfer her prescriptions back to Cure-Aid Pharmacy.
- RMG's Attorney stated that it appears that the inclusion of Cure-Aid Pharmacy's address on the Renaissance Medical Group's website was an administrative oversight and it seems that after the relationship between the two entities ended the webmaster for Renaissance Medical Group forgot to remove the reference to Cure-Aid as a partner pharmacy. In June 2020, once notified Renaissance Medical Group took immediate action to remove the reference to Cure-Aid's address.

ACTION: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted unanimously by those present, to CLOSE the matter (SA-INV-16540), No Discipline Warranted.

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

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

- Unknown loss of #50 oxycodone/apap 5mg/325mg tablets.
- MOR Pease indicated that the loss was discovered on July 1, 2020 while performing the perpetual inventory reconciliation.
- MOR Pease noted that the video footage was reviewed. Based on the video footage, MOR Pease noted that it appears that the dispensing pharmacist, Pharmacist Onyeukwu who no longer works for Walgreens, was back-counting the stock bottle after filling the prescription and accidentally added some of that medication to the prescription bottle. The patient was contacted. However, the patient would not confirm receiving extra medication.
- Pharmacist Onyeukwu was contacted for a response, but she denied knowing that there were any issues related to the prescription that she verified.
- MOR Pease stated, "I have gone over our policies and procedures regarding the handling of controlled substances with my staff and specifically reiterated the importance of double-counting C2 prescriptions. I have also placed a sign on the safe and counting station indicating as much to any district pharmacists that come through my store."

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2020-0052), 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.

RECUSAL: NONE

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

- During a USP 795 inspection conducted on 08/27/2020, it was observed that a powder hood in the negative pressure hazardous compounding room had been vented through the roof to the outside since the last inspection on 10/30/2019. MOR Heroux-Camirand was informed the BORP should have been notified prior to any construction/changes in the Pharmacy.
- MOR Heroux-Camirand indicated during the inspection performed on 10/30/2019, she had discussed with the Investigators plans for USP 800 compliance including venting the existing hazardous powder containment hood to the outside and it was agreed that it would be good practices to comply with upcoming USP regulations. MOR Heroux-Camirand stated, "Sending in a renovation application never occurred to me because it was not discussed during the Oct 2019 inspection, and I just simply did not think of it". Although she contracted with an HVAC company in September 2018, the work was not completed until 03/02/2020. On 03/04/2020, an in-line booster fan was installed to enhance ventilation. The powder hood was recertified on 03/10/2020.

- From 03/03/2020 through 03/06/2020, the Pharmacy compounded 10 hazardous non-sterile compounds prior to the recertification of the powder hood on 03/10/2020. MOR Heroux-Camirand contended there was not a need for a continuity of care plan because there were only a few hours of interruption during the construction and she resumed compounding once the area was cleaned and functional again.
- The “Testing and Certification Report” provided from 03/10/2020 did not document that the powder hood was placed in a room with at least 12 ACPH and did not include magnahelic gauge readings that showed negative pressure as required per USP 800. MOR Heroux-Camirand indicated the room had never been certified and contended, “As far as I am aware, USP 800 was still in draft phase and was simply guidance on best practices”. Although she could not previously find a company to certify the rooms, MOR Heroux-Camirand indicated that she was able to contract with a company that is scheduled to certify the rooms on 10/22/2020.

ACTION: Motion by L. GIAMBARRESI, seconded by A.STEIN, and voted unanimously by those present, to CLOSE the matter (SA-INV-16771), No Discipline Warranted.

TOPIC VII **Review of Compliance**

PHA-2018-0015 Preferred Pharmacy Solutions, DS3542

Time: 8:25 AM

PRESENTED BY: H. ENGMAN

RECUSAL: NONE

DISCUSSION: ENGMAN indicated that Preferred Pharmacy Solutions (PPS) petitioned to terminate its probation. ENGMAN recommended that BORP terminate probation as requested because PPS complied with all terms and conditions of its probation agreement.

ACTION: Motion by T. FENSKY to terminate probation, seconded by S. HAMILTON, and voted unanimously by those present to terminate probation by roll call vote.

Topic IX

EXECUTIVE SESSION

Time: 8:35 AM

Read by K. Tanzer

DISCUSSION:

ACTION: At 8:35 AM President A. Tanzer read the statement on reasons for Executive Session.

Topic VIII:

Executive Session Call to Order:

Time: 8:41 AM

By: A. Stein

ACTION: Motion by P. Gannon, seconded by S. Hamilton, and voted unanimously by roll call to call the 11/6/20 meeting of the Executive Session to order.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; K. Thornell, yes; S. Hernandez (yes); D. Perry, yes; P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky, yes; R. Lopez, yes.

Topic IX:

M.G.L. 65 C #1

Time: 9:00 AM

DISCUSSION: None

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

At 9:00 AM L. Giambarresi, seconded by J. Lanza and voted unanimously by all those present to enter M.G.L. chapter 65 c Session by roll call vote.

Topic X

ADJOURMENT OF MEETING

TIME: 10:49 AM

ACTION: Motion by L. Giambarresi seconded by A. Stein, and voted unanimously by those present, to adjourn from General Session by roll call vote.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 11/6/20 General Session
2. Draft Minutes of the 10/23/20 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. Report on Research Drug Study
9. RMG Pharmacy DS90308 SA-INV-16540
10. Walgreens #1082 DS3558 PHA-2020-0052
11. County Square Pharmacy DS15805 SA-INV-16771
12. Preferred Pharmacy Solutions DS3452 PHA-2018-0015

Respectfully Submitted,
Leah Giambarresi, PharmD, RPh, Secretary