

COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

March 19, 2021

Webex Information

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

Access Code: 178 321 6261

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		J. Lanza
	II	APPROVAL OF AGENDA		
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">Draft of March 5, 2021 Regular Session Minutes		
8:10	IV	FLEX <ul style="list-style-type: none">Pharmacy issues related to Covid-19 and the state of emergency		
8:15	V	REGULATIONS <ul style="list-style-type: none">247 CMR 18.00: Non-Sterile Compounding		

8:30	VI	FILE REVIEW				
		1	PHA-2020-0067	Remedium Pharmacy, DS89943		
		2	PHA-2020-0059	Walgreens #3130, DS2338		
		3	PHA-2020-0075	Walgreens #17540, DS90234		
		4	PHA-2020-0076	Walgreens #17584, DS90229		
		5	SA-INV-17349	Thomas Reitano, PH20523		
9:15	VII	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	
9:45	VIII	M.G.L. c. 112, § 65C SESSION			CLOSED SESSION	
10:30	IX	ADJOURNMENT				

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

March 19, 2021

Board Members Present

Julie Lanza, CPhT, President
Sebastian Hamilton, Pharm D, RPh President-elect
Carly Jean-Francois, RN, NP Secretary
Dr. Richard Lopez, MD
Susan Cornacchio, JD, RN (Leaves meeting 9:24 AM)
Timothy Fensky, RPh
Andrew Stein, PharmD
Caryn Belisle, RPh, MBA
Jennifer Chin, RPh
Katie Thornell, RPh, MBA (leaves meeting 10:00 AM)
Dawn Perry, JD (leaves meeting 10:27 AM)
Leah Giambarresi, Pharm D, RPh

Board Members Not Present

Board Staff Present

David Sencabaugh, RPh, Executive Director
Heather Engman, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Richard Harris, Program Analyst
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Joanna Chow, Office Support Specialist
Joanne Trifone, RPh, Director of Investigation
Julienne Tran, PharmD RPh, Investigator
Gregory Melton, PharmD, JD, Investigator
Christina Mogni, RPh, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:01 AM

A quorum of the Board was present, established by roll call. President J. Lanza chaired the meeting and she explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: J. Lanza, yes; Dr. Lopez, yes; S. Hamilton, yes; S. Cornacchio, yes; T. Fensky, yes; C. Belisle, yes; A. Stein; K. Thornell, yes; J. Chin, yes, D. Perry, yes; C. Jean-Francois, yes, L. Giambarresi, yes.

Topic II.

Approval of Agenda

TIME 8:02 AM

Agenda 3/19/21

DISCUSSION:

Change to Agenda:
No changes

ACTION:

Motion by C. Jean-Francois, seconded by K. Thornell and voted unanimously by those present to approve the agenda with no noted changes by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:02AM

Minutes

1. Draft 3/5/21

Change: Update credentials on C. Belisle to RPh, MBA.

Action:

Motion by C. Jean-Francoise seconded K. Thornell and voted unanimously to approve the regular session minutes of 3/5/21 with noted change by roll call vote.

TOPIC IV

FLEX

1. Pharmacy Issues Related to Covid-19 and State of Emergency

Time: 8:05 AM

PRESENTED BY: D. SENCABAUGH

The DPH Commissioner has issued a new order allowing additional persons, including various students with appropriate training, to vaccinate for influenza and COVID-19. This is in addition to the pharmacists, interns, and qualified pharmacy technicians who are already permitted to vaccinate.

So noted.

TOPIC V

REGULATIONS

247 CMR 18.00: Non-Sterile Compounding

Time: 8:08 AM

Presented by W. FRISCH, M. CHAN

Discussion: This regulation has been completely reworked and includes some of the coming changes to USP <795>. Standards from USP <800> and 247 CMR 19.00 Hazardous Drugs have also been added. A request for the Board to rescind 247 CMR 19.00 will be brought in the future.

Institutional pharmacies will not be required to obtain a complex non-sterile license. Only resident and non-resident drug store pharmacies will need to obtain this license, as applicable. However, practice standards may apply to Board of Pharmacy licensed persons.

Compounding of hazardous drugs must be performed in a separate hood and room from non-hazardous compounding according to communications from USP to Board staff.

A request was made to rework the daily requirement to review and document pressure differential continuous monitoring device reports. A separate standard requiring remediation and documentation of responses to pressure differential excursions was also requested.

Definitions are all included in 247 CMR 2.00 Definitions including one for complex non-sterile compounding.

Action: Edits will be made on the requested sections and will be brought back to a future Board meeting.

Topic VI:

File Review:

Case #1

PHA-2020-0067

Remedium Pharmacy, DS89943

Time: 08:41 AM

RECUSAL: NONE

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

- BORP opened this complaint after Remedium and the Massachusetts Attorney General entered into a settlement agreement after the Attorney General alleged it identified evidence that Remedium was not in compliance with certain laws, regulations, and/or rules governing Remedium when refilling and billing for certain pharmaceutical prescription drugs, compounds and medications paid for by or on behalf of MassHealth, resulting in overpayments for which the Attorney General has made demand.
- Remedium agreed to pay \$500,000 in restitution, and, at its own expense, contract with an independent compliance reviewer agreed upon by Remedium and the Attorney General to implement and administer a compliance and monitoring program at Remedium for a three-year period. As part of the program, the independent reviewer will conduct on-site audits and submit written reports to Remedium and the Attorney General every six months for the first year then every year for the remaining compliance period. Remedium must repay any overpayments identified during those audits.
- Remedium indicated that it did not admit to any facts in the settlement agreement. Remedium explained that the laws and regulations governing automatic refills were ambiguous. The pharmacy

agreed to settle to avoid costly litigation and avoid future investigations caused by the ambiguity of the laws and regulations governing automatic refills. Remedium indicated that they had complied with the terms and condition in the settle agreement and follow all federal and state laws and regulations governing refills and billing for MassHealth.

ACTION: Motion by T. FENSKY, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2020-0067), 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 PROBATION for a period of one year with special terms to include having the pharmacy submit copies of the independent compliance reviewer's reports.

Case #2

PHA-2020-0059

Walgreens #3130, DS2338

Time: 08:50 AM

RECUSAL: NONE

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

- OPP received notification that the Pharmacy had an unknown loss of #100 methylphenidate 5mg tablets occurring on or about August 8, 2020 and an unknown loss of #35 methadone 5mg tablets, #41 d-amphetamine salt combo 10mg tablets, and #10 Vyvanse 20mg capsules occurring on or about November 16, 2020.
- First loss, Former MOR Le indicated that the loss was discovered while the pharmacist was conducting the weekly CII inventory on August 8, 2020. Former MOR Le indicated that in her review of the video surveillance from 07/31/2020, the day that the CII order in question was received, she noted the medication bottles were being separated from the package inserts by the certified pharmacy technician and stated that the methylphenidate bottle may have been mistakenly thrown away with the package inserts.
- Second loss, Former MOR Le stated that upon learning that additional medications had been lost, "We have also learned that at least one technician was counting by 3s and 4s, which we believe led to the miscounts of medications. We have since made sure that each person only counts by five, unless it is less than five tablets/capsules. We have had meetings regarding miscounts with this technician on November 9th and November 17th [2020]".
- Corrective action included only having pharmacists put away CII orders after performing a second check against the invoice.
- Additionally, Former MOR Le stated, "Moving forward, the filling technician will double count his/her work and a second technician will also double count the CII. The pharmacist will double count if another technician is not available. At all times, there must be two technicians counting for the same CII and they must both initial the bottle to show it was double counted twice."
- Walgreens #3130 has no prior loss history.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2020-0059), 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 and to have a pharmacy investigator perform a controlled substance site visit.

RECUSAL: NONE

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

- Complaint against Walgreens Pharmacy #17540 located in West Springfield, MA for failure to comply with a change in MOR and Board Policy 98-010 for an extended leave of a MOR.
- Current MOR Truong assumed the role of MOR on October 15, 2020 and she completed the controlled substance inventory count on October 19, 2020. An application for change in MOR was submitted on 10/23/2020.
- MOR Truong also provided documentation that a change in MOR application was delivered to BOP on 04/16/2020 for Interim MOR Danehey.
- MOR Truong stated, "Areas where I believe could have contributed to this misunderstanding are as follow; a shipping error by FedEx, a clerical error due to shortage of administrative personnel brought upon by the COVID-19 crisis, and/or not contacting the BOP via other means such as email, phone and follow-up on the receivable and processing fees."
- DM Carreira stated, "The MOR change in this location occurred prior to my appointment of District Manager on 04/01/20. I was unaware of the store's failure to comply."
- MOR Truong stated, "I did was (sic) communicating with Board Staff for my change of MOR application and follow through with phone calls and emails to get my store license."

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to DISMISS the matter (PHA-2020-0075), No Violation.

RECUSAL: NONE

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

- Complaint against Walgreens Pharmacy #17584 (Pharmacy) located in Springfield, MA for failure to comply with the requirements for a change in MOR and Board Policy 98-010 for an extended leave of a MOR.
- MOR Nicole Pone indicated that she assumed the role of pharmacy manager on May 25, 2020 and since it was her first role as pharmacy manager, she was not familiar with the required paperwork.
- MOR Pone noted that there were additional delays caused by obtaining the previous manager of record's signature and the need for obtaining a notarized signature due to reduced bank hours as a result of COVID.
- DM Carreira indicated execution was given to the previous Store Manager who verified completion at the time, and he was unaware of the store's failure to comply until we received notification from the board.

- MOR Pone stated, "I understand that I'm responsible for timely submitting the paperwork. I have since spent time reviewing the requirements and am confident that a similar incident will not occur again."

ACTION: Motion by J.CHIN, seconded by K. THORNELL, and voted unanimously by those present, to DISMISS the matter (PHA-2020-0076), No Discipline Warranted, Remediation Complete.

Case #5

SA-INV-17349

Thomas Reitano, PH20523

Time: 08:58 AM

RECUSAL: NONE

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

- NABP Clearinghouse Report of a 3-month suspension of Pharmacist Reitano's RI license by the RI BOP on 1/16/2020. Pharmacist Reitano was disciplined for failure to properly conduct a DUR on 9/11/17 resulting in a potential therapeutic drug duplication while he was on probation for a similar DUR error. On 2/16/17, Pharmacist Reitano received a 1-year probation for filling and refilling on multiple occasions prescriptions in the same therapeutic class and failed to properly conduct a DUR. He was also required to complete 5 additional CEs in patient safety at that time.
- Pharmacist Reitano responded that he was notified of the most recent allegation 21 months after the prescription at issue had been filled and had no recollection of it. At the time of the incident, he was employed at a Rite Aid central processing location and stated no DUR warning alerted during PV1 verification. Pharmacist Reitano completed 8 CEs in patient safety as remediation between 2/5/17 and 3/5/17.
- Pharmacist Reitano met the terms of his consent agreement and on 4/16/2020, his RI license was returned active status. Additionally, Pharmacist Reitano took it upon himself to complete 5 CEs in the topic of patient safety between 3/4/18 and 5/10/2020 and 2 CEs in the topic of MTM on 11/12/2018.

ACTION: Motion by L. GIAMBARRESI, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to CLOSE the matter (SA-INV-17349), No Discipline Warranted, Remediation Complete

Julie Reads Executive Session Language

Time: 9:06 AM

Topic VII:

Executive Session Call to Order:

Time: 9:06 AM

By: J. Lanza

ACTION: Motion by, K. Thornell, seconded by L. Giambarresi, all voted affirmatively by those present to enter executive session with no changes.

Roll call attendance: J. Lanza, yes; Dr. Lopez, yes; S. Hamilton, yes; S. Cornacchio, yes; T. Fensky, yes; C. Belisle, yes; A. Stein; K. Thornell, yes; J. Chin, yes, D. Perry, yes; C. Jean-Francois, yes, L. Giambarresi, yes.

Topic VIII:

65C Sessions MGL c. 112 section 65C

Time: 10:09 AM

DISCUSSION: None

ACTION: President J. Lanza request a motion to enter 65C.

At 10:09 AM L. Giambarresi, seconded by C. Jean-Francois and voted unanimously by all those present to enter 65C by roll call vote.

K. Thornell leaves meeting at 10:00 AM

S. Cornacchio leaves meeting at 10:24 AM

D. Perry leaves meeting at 10:27 AM

Topic VIII

ADJOURNMENT OF MEETING

TIME: 10:31 AM

ACTION: Motion by L. Giambarresi seconded by T. Fensky 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 3/19/21 General Session
2. Draft Minutes of the 3/5/21 Meeting
3. Draft 247 CMR 18.00 Non-Sterile Compounding
4. SA-INV-17002 Raya Nasim, PH232359
5. PHA-2020-0085 Jeffrey L. Cohen, PH20756
6. SA-INV-16945 Walgreens #13135, DS89732
7. SA-INV-16783 CVS #23, DS90049
8. SA-INV-16947 CVS #117, DS3207

Respectfully Submitted,
Carly Jean-Francois, NP, Secretary