

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

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

August 28, 2020

Webex Information

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

Access Code: 171 618 6356

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 August 21, 2020 Regular Session Minutes		
8:10	IV	APPLICATIONS <ul style="list-style-type: none">• Acnos Pharmacy – Wholesale Distributor		
8:20	V	FLEX <ul style="list-style-type: none">• Pharmacy issues related to Covid-19 and the state of emergency• NEU & GLFHC Opioid Bring-Back program• BIDMC Pharmacy – Pilot Project metrics		

8:30	VI	FILE REVIEW				
		1	SA-INV-16563	David Walters, PH16971		
		2	PHA-2019-0095	Walgreens #10127, DS3495		
8:45	VII	REVIEW OF COMPLIANCE Western Mass Compounding Center-DS89965; PHA-2016-0108			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	
9:45	IX	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)				
10:15	X	M.G.L. c. 112, § 65C SESSION			CLOSED SESSION	
10:30	XI	ADJOURNMENT				

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

MINUTES OF THE GENERAL SESSION

Meeting held via WEBEX remotely

Boston, Massachusetts, 02114

August 28, 2020

Board Members Present

Kim Tanzer, PharmD, RPh. President
Sebastian Hamilton, Pharm D, RPh
Leah Giambarresi, Pharm D, RPh, Secretary
Dr. Richard Lopez, MD
Andrew Stein, Pharm D
Katie Thornell, RPh
Susan Cornacchio JD, RN (leaves at 9:19 am)
Carly Jean-Francois, RN, NP (leaves at 9:00 am)
Stephanie Hernandez, Pharm D, BCGP, RPh
Timothy Fensky, RPh
Dawn Perry, JD (leaves at 10:05 AM)

Board Members Not Present

Julie Lanza, CPhT, President Elect
Patrick Gannon, RPh

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
Gregory Melton, Pharm D, JD, RPh Investigator
Christina Mogni, RPh Investigator
John Murray, RPh Investigator
Julienne Tran, PharmD, RPh Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor

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, C. Jean-Francois: yes, S. CORNACCHIO: yes, K. THORNELL: yes, T. Fensky: yes, D. PERRY: yes. Dr. Lopez joins at 8:03 AM and S. Hernandez joins at 8:05 AM.

Topic II.

Approval of Agenda

TIME 8:03 AM

Agenda August 2, 2020

DISCUSSION:

Change to Agenda:

1. none

ACTION:

Motion by S. Hamilton, seconded by J. Giambarresi and voted unanimously by those present by roll call vote to approve the agenda with no noted changes.

Topic III

Approval of Board Minutes

TIME: 8:03 AM

Minutes

1. Draft 8/21/20 General Session Minutes

No noted Changes.

Action:

Motion by S. Hamilton, seconded by L. Giambarresi and voted unanimously by roll call vote to approve the regular session minutes of 8/21/20 with no noted changes. T. Fensky abstains.

TOPIC IV

Applications

Acnos Pharmacy

New Wholesale Distributor

Time: 8:04 AM

Presented by: Leah Brown, Tammy Bishop

Discussion: Applying for new wholesale distributor license and will be leasing unlicensed space in a building that houses another wholesaler. The entrance to the space is secure and will only be accessible by Acnos staff.

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

V: Flex:

1. Pharmacy issues related to COVID-19 and the state of emergency Time: 8:10 AM

Presented by: D. SENCABAUGH

Discussion: In response to the HHS declaration allowing pharmacist immunization of children from ages 3-9 years, a revised immunization policy has been drafted but has not yet been finalized. It will be sent out early next week.

Pharmacist administration of any FDA approved COVID-19 vaccine before it has been added to the ACIP list is still under consideration.

So noted.

2. NEU & GLFHC Opioid Bring Back Program

Time: 8:17 AM

Presented by: Alicia Mam DaCunha, Alicia Modestino

Discussion: Review of a randomized controlled trial to incentivize secure disposal of controlled substances at GLFHC pharmacies using enhanced communication and financial incentives.

The study is currently on hold due to COVID-19 but will restart in October without the financial incentives since that did not appear to be a motivator for patients.

Money that has been freed up will be used to provide postage paid envelopes for medication disposal.

So noted.

3. BIDMC Pharmacy Pilot Project Metrics

Time: 8:38 AM

Presented by: W. FRISCH

Discussion: The vote by the Board on the previously approved pilot project asked for performance metrics to be worked out with Board staff. The list has been provided.

Action: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and unanimously approved by those present by roll call vote to ratify the metrics for the pilot program.

VI: File Review:

Case #1

SA-INV-16563

David Walters, PH16971

Time: 08:42 AM

RECUSAL: K. THORNELL 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.

- This staff assignment is a companion complaint to PHA-2019-0103, Stop & Shop #87, a reported loss of controlled substances of #100 hydrocodone/APAP 5mg/325mg tablets occurring on or about September 21, 2019.
- During the course of the investigation (PHA-2019-0103), it was discovered that Pharmacist Walters failed to complete the perpetual inventory yet signed the record. The Board voted to open this SA on PH Walters for failure to provide a response to PHA-2019-0103.
- On July 3, 2020, Pharmacist Walters was notified that a staff assignment had been opened.
- On July 10, 2020, the OPP Investigator received a response to the staff assignment investigation. In his response, Pharmacist Walters stated, "Please be advised that I do attest to having read and reviewed sections 247 CMR 6 and 247 CMR 9 in their entirety".

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE the matter (SA-INV-16563), No Discipline Warranted, Remediation Complete.

Case #2

PHA-2019-0095

Walgreens #10127, DS3495

Time: 08:44 AM

RECUSAL: NONE

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

- Walgreens #10127 reported a series of losses of Schedule II controlled substances on three separate occasions in March 2019 and April 2019. The reason for the first and second losses was initially reported as unknown. However, an amendment was filed in May 2019 after the third loss changing the reasons for all three losses to theft by employee pilferage. In addition, the first loss was reported in an untimely manner.
- MOR indicated that an internal investigation was started after the second loss was discovered. However, the investigation was complex because surveillance video was not useful, and the diversion involved the use of duplicate serial numbers for prescriptions logged into the perpetual inventories of various strengths of oxycodone products. In addition, MOR's supervisors required her to keep her suspicions and the internal investigation secret.
- In August 2019, Walgreens #10127 submitted an untimely report of additional losses caused by the employee pilferage. Walgreens #10127 indicated that the additional losses were discovered by the United States Drug Enforcement Administration audited the pharmacy as part of its investigation into the diversion reported in May 2019.
- MOR implemented plans of corrections including adding a number of Schedule III & IV drugs to the perpetual inventory and reconciliations of perpetual inventory on an increased frequency. She also retrained staff members on proper handling of controlled substances. The pharmacy performs random and/or daily audits when variances arise or questionable activity. Additionally, Asset Protection Managers monitor high risk drug reporting and communicate and work together with the Pharmacy Manager to investigate any losses or questionable activity. MOR also indicated that she reviewed

“Asset Protection reports weekly to ensure no deviations or anomalies exist.” In addition, staff must submit to pre-employment and random drug testing.

ACTION: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0095), No Discipline Warranted, Remediation Complete.

VII. Review of Compliance

PHA-2016-0108 Western Mass Compounding Center DS89965 Time: 8:46 AM

Presented by: K. FISHMAN

Discussion: WMCC has requested to end their term of probation, however investigators have found certain products that should not have compounded since they appeared to essentially be copies of commercially available drugs. They make a significant amount of veterinary compounds and it was noted that they have made significant progress towards compliance.

The documentation is not yet where it needs to be, but they could be taken out of probation contingent on an attestation regarding documentation and only to make appropriately needed compounded medications, individualize documents, and stop using blanket prescriber approvals. They also need to update their veterinary references.

Action: Motion by T. FENSKY, seconded by A. STEIN, and unanimously approved by those present by roll call vote to end the probationary period with the conditions of increased inspections, an attestation to adhere to Board policy on compounding commercially available products, have policies and procedures in place to comply with compounding documentation standards, and obtain patient specific documentation validating the reason each compound.

C. Jean-Francois leaves meeting at 9:00 AM

Kim Tanzer announces at 9:08 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: 9:08AM

By: K. Tanzer

ACTION: Motion by S. Hamilton seconded by T. Fensky and voted unanimously by roll call to call the 8/28/20 meeting of the Executive Session to order.

Roll call attendance: K. TANZER: yes, L. GIAMBARRESI: yes, A. STEIN: yes, S. HAMILTON: yes, C. Jean-Francois: yes, S. CORNACCHIO: yes, K. THORNELL: yes, T. Fensky: yes, D. PERRY: yes. Dr. Lopez: yes, S. Hernandez: yes.

S. Cornacchio leave meeting at 9:18 AM

Topic IX:

Adjudicatory Session

Time: 9:43 AM

DISCUSSION: None

ACTION: President K. Tanzer request a motion to enter Adjudicatory Session.

At 9:43 AM S. Hamilton, seconded by L. Giambarresi and voted unanimously by all those present to enter Adjudicatory Session:

Topic X:

M.G.L. 65 C #1

Time: 9:58 AM

DISCUSSION: None

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

At 9:58 AM T. Fensky, seconded by S. Hamilton and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

D. Perry leave meeting at 10:05 AM

Topic XI:

ADJOURNMENT OF MEETING

TIME: 10:24 AM

ACTION: Motion by S. Hamilton seconded by L. Giambarresi, 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 8/28/20 General Session
2. Draft Minutes of the 8/21/20 Meeting
3. Applications: Acnos Pharmacy Wholesale Distributor

4. BIDMS Pharmacy Pilot Project Metrics
5. NEU & GLFHC Opioid Bring Back program
6. SA-INV-16563 David Walters PH16971
7. PHA-2019-0095 Walgreens #10127 DS3492
8. PHA-20016-0108 Western Mass Compounding Center DS89965

Respectfully Submitted,
Leah Giambarresi, PharmD, RPh, Secretary