

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

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

July 17, 2020

Webex Information

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

Access Code: 161 759 5995

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 July 10, 2020 Regular Session Minutes		
8:10	IV	APPLICATIONS <ul style="list-style-type: none">• Kabafusion-DS89700 – Relocation• St. Mary’s Pharmacy – New Community Pharmacy• BIDMC Pharmacy – New Community Pharmacy• Anchor Home Medical & Pharmacy – New Community Pharmacyc• Baker Pharmacy; DS12518- Transfer of Ownership		

8:55	V	FLEX <ul style="list-style-type: none"> Pharmacy issues related to Covid-19 and the state of emergency 		
9:00	VI	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION
10:15	VII	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)		CLOSED SESSION
10:30	VIII	ADJOURNMENT		

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

MINUTES OF THE GENERAL SESSION

Meeting held via WEBEX remotely

Boston, Massachusetts, 02114

July 17, 2020

Board Members Present

Kim Tanzer, PharmD, RPh. President
Julie Lanza, CPhT, President Elect
Leah Giambarresi, Pharm D, RPh, Secretary
Sebastian Hamilton, Pharm D, RPh
Dr. Richard Lopez, MD
Timothy Fensky, RPh (leaves at 10:30 AM)
Patrick Gannon, RPh (leave 9:30-10:30 AM; back 10:30 AM-11:00AM)
Susan Cornacchio JD, RN
Katie Thornell, RPh
Dawn Perry, JD (Leave at 10:22 AM)
Carly Jean-Francois, RN, NP (leave at 10:10 AM)
Andrew Stein, Pharm D (leaves at 9:11 AM)
Stephanie Hernandez, Pharm D, BCGP, RPh (leave at 10:30 AM)

Board Members Not Present

Board Staff Present

David Sencabaugh, Executive Director
Monica Botto, Assistant Executive Director
Heather Engman, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance (not present for 65C)
Michelle Chan, RPh Quality Assurance Pharmacist
Julienne Tran, PharmD RPh, Investigator
Gregory Melton, Pharm D, JD, RPh Investigator
Christina Mogni, RPh Investigator
John Murray, RPh Investigator
Nathan VanAllen, PharmD, RPh Investigator
Michael Brosnan, PharmD, 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; J. Lanza, yes; L. Giambarresi, yes; D. Perry, yes; P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes, Dr. Lopez, yes; T. Fensky, yes; K. Thornell; S. Hernandez, yes; Andy Stein, yes.

Topic II.

Approval of Agenda

TIME 8:03 AM

Agenda July 17, 2020

DISCUSSION:

Change to Agenda:

1. Defer application Anchor Home Medical and Pharmacy
2. Defer application Baker Pharmacy DS12518

ACTION:

Motion by L. Lanza, seconded by C. Jean Francois and voted unanimously by those present by roll call vote to approve the agenda with no changes.

Kim asks Michelle to introduce the APPE Pharmacy students Cara O'Toole From WNE and Kyle Blomster from URI.

Topic III

Approval of Board Minutes

TIME: 8:04 AM

Minutes

1. Draft 7/10/20 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 7/10/20 with no noted changes; A. Stein abstains.

Topic IV

Applications:

1. Kabafusion DS89700

Relocation

Time: 8:06 AM

Represented by: John Leary MOR, Attorney Paul Garbarini

Recusal: None

Discussion: Pharmacy desires to relocate from Shrewsbury to Lexington. It is a 7,000 sq. ft. design, with 400 sq. ft. for the clean room. This is a home infusion pharmacy that specializes in IG therapy. Mr. Leary has had MOR experience at several other pharmacies, but he started with Kabafusion in April, 2020. Leary has limited experience with sterile compounding, as he has more regulatory background. Kabafusion has a robust training program including videos, online courses and modules, and didactic learning. On his own, Leary has also been taking courses through ASHP and on USP. Fran McAteer has

had a role in training on environmental monitoring. Leary and the previous MOR, Fidelis Fynn did a self-inspection together. Now, Mr. Fynn has passed the MOR role onto Leary, and Fynn has become the director of operations for Kabafusion. Kabafusion is open Monday – Friday. They plan to be moving everything on the weekend, although all the new equipment will be already in the Lexington location. When they are closed, Kabafusion has 24-hour access to an on call pharmacist and nurse, and other facilities as backup.

Action: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted unanimously by roll call by those present to approve the relocation pending successful inspection.

2. St. Mary’s Pharmacy

New Community Pharmacy

Time: 8:15 AM

Represented by: Bakheet Shenoda, MOR

Recusal: None

Discussion: Bakheet and the owner will open a new retail pharmacy in North Andover. It is located in a plaza on the end, with one neighbor to the left, a beauty salon. There is no access from the neighboring store and no access from above tenants. Points of entry are limited to a front door and back door, but Bakheet assured the back door will always be closed. Bakheet was previously MOR at NPH Pharmicare pharmacy for 4 months in Whitinsville and was a floater pharmacist for CVS. This pharmacy will be providing vaccinations, with a privacy room area surrounded by curtains. They will be reaching out to nearby nursing homes to assess the need for compliance packaging. They will perform simple compounding, such as oral suspensions. Staffing will be 1 pharmacist and 1 technician to start. They have an after-hours voicemail with access to a pharmacist on call. Training for non-sterile compounding for the pharmacist will be reassessed every 6 months, to inspect compounding area and add safety precautions.

Action: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted unanimously by roll call by those present to approve the relocation pending successful inspection.

3. BIDMC Pharmacy

New Community Pharmacy/Relocation Time: 8:29 AM

Represented by: David Young, Luca Cattaneo, Kim Nguyen

Recusal: J. LANZA and H. ENGMAN recused and were not present for the discussion or vote in this matter.

Discussion: Beth Israel Deaconess Medical Center (BIDMC) is looking to operate 2 separate, licensed pharmacies without a physical barrier and with a shared production area. One pharmacy will be designated as a specialty pharmacy while the other will be a retail pharmacy focusing on central fill for their Boston location. There will be designated areas with signage specific to each pickup. The representatives answered questions from the Board members regarding security measures, including that there will be 73 security cameras in use and 37 of those cameras focused on the production area. Each pharmacy will have its own inventory, physically separated by lines of demarcation and routinely

reconciled. Specifically, cycle counts will occur every Friday for the specialty pharmacy. They do not plan to have any of the same medications in each pharmacy. The specialty side will just keep specialty medications. Each pharmacy will have its own phone number, labels, and signage. There will be 2 DEA numbers and 2 separate MORs. The representatives assured members of the Board that they will not be sharing staff between the 2 spaces. Concerns were raised about accountability and who would be held responsible for this pilot project because this model is unprecedented. Pharmacists Chirag, David Young, and Luca Cattaneo will all be responsible and dedicated to running this project, rather than BIDMC. This facility allows them to expand services and provide a high touch with patients. They can enhance patient management by focusing more efforts on high risk patients. Separate licenses operating in the same pharmacy space is requested because accreditation efforts and costs for the specialty pharmacy are labor intensive, as well as creating opportunity for contracts that are typically restricted to specialty pharmacies.

Action: Motion by L. GIAMBARRESI, seconded by K. THORNELL, and voted unanimously by roll call by those present to approve the central fill petition.

Action: Motion by L. GIAMBARRESI, seconded by P. GANNON, and voted unanimously by roll call by those present to approve the pilot project contingent upon the following conditions:

- Approval of the DEA
- Specific metrics and reporting schedule to be determined in conjunction with Board staff
- Pilot project to begin 6 months from the date both pharmacies are open and operational

Action: Motion by L. GIAMBARRESI, seconded by P. GANNON, and voted unanimously by roll call by those present to approve the relocation of BIDMC Specialty Pharmacy pending a successful inspection.

Action: Motion by L. GIAMBARRESI, seconded by P. GANNON, and voted unanimously by roll call by those present to approve a new retail license for BILH Pharmacy Direct pending a successful inspection.

TOPIC V **Flex:** **Time: 9:11 AM**
Pharmacy Issues related to COVID-19 and the state of emergency:
Presented by: D. Sencabaugh

Dave notes no updates this week.

Kim Tanzer announces the general session will be ending and the Board will be going into private session. The Board will not cover any other general session items today.

Andrew Stein, Pharm D (leaves at 9:11 AM)

Topic VI:

M.G.L. 65 C #1

Time: 9:15 AM

DISCUSSION: None

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

At 9:15 AM L. Giambarresi, seconded by J. Lanza and voted unanimously by roll call vote of all those present to enter M.G.L. chapter 65 c Session:

Carly Jean-Francois, RN, NP (leave at 10:10 AM)

Dawn Perry, JD (Leave at 10:22 AM)

Timothy Fensky, RPh (leaves at 10:30 AM)

Patrick Gannon, RPh (leave 9:30-10:30 AM; back 10:30 am to 11:00 AM)

Stephanie Hernandez, Pharm D, BCGP, RPh (leave at 10:27 AM)

Topic VII:

Adjudicatory Session

Time: 10:51 AM

DISCUSSION: None

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

At 10:51 AM S. Hamilton, seconded by L. Giambarresi and voted unanimously by roll call vote of all those present to enter M.G.L. chapter 65 c Session:

Topic VII

ADJOURNMENT OF MEETING

TIME: 10:54 AM

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

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 7/17/20 General Session
2. Draft Minutes of the 7/10/20 Meeting
3. Applications Kabafusion DS89700 Relocation
4. St. Mary's Pharmacy New Community Pharmacy
5. BIDMC Pharmacy New Community Pharmacy

Respectfully Submitted,
Leah Giambarresi, PharmD, RPh, Secretary