

COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

April 30, 2021

Webex Information

The regular session is open to the public by video or phone.

For video access click on the following link:

[://statema.webex.com/statema/onstage/g.php?MTID=](https://statema.webex.com/statema/onstage/g.php?MTID=)

For phone access

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

Access Code: 185 739 7940

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 April 16, 2021 Regular Session Minutes		
8:20	IV	FLEX <ul style="list-style-type: none">Pharmacy issues related to Covid-19 and the state of emergency		

8:30	V	APPLICATIONS <ul style="list-style-type: none"> • Ash Pharmacy – New Community Pharmacy • Central Street Pharmacy; DS89950 – Relocation • Resilience Boston – Wholesale Distributor • Preferred Pharmacy Solutions; DS3542 - Transfer of Ownership 		
9:00	VI	REGULATIONS <ul style="list-style-type: none"> • 247 CMR 17.00: Sterile Compounding 		
10:00	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
10:15	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

April 30, 2021

Board Members Present

Julie Lanza, CPhT, President
Sebastian Hamilton, Pharm D, MBA, RPh President-Elect
Carly Jean-Francois, RN, NP Secretary
Andrew Stein, Pharm D
Susan Cornacchio, JD, RN (leaves meeting 10:01 AM)
Timothy Fensky, RPh
Caryn Belisle, RPh, MBA
Leah Giambarresi, Pharm D, RPh (Leaves meeting 10:01 AM)
Katie Thornell, RPh, MBA
Dawn Perry, JD (Leaves meeting 8:46 AM)

Board Members Not Present

Dr. Richard Lopez, MD
Jennifer Chin, RPh

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
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst
Joanna Chow, Office Support Specialist
Joanne Trifone, RPh, Director of Investigation
Gregory Melton, PharmD, JD, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:04 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; S. Hamilton, yes; S. Cornacchio, yes; T. Fensky, yes;
C. Belisle, yes; A. Stein; K. Thornell, yes; D. Perry, yes; C. Jean-Francois, yes, L. Giambarresi, yes.

Topic II.

Approval of Agenda

TIME 8:04 AM

Agenda 4/30/21

DISCUSSION:

Change to Agenda:

Will not hear Application: Central Street Pharmacy DS89950

ACTION:

Motion by L. Giambarresi, seconded by C. Jean-Francois and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:05 AM

Minutes

1. Draft 4/16/21

Change: no noted changes

Action:

Motion by L. Giambarresi seconded D. Perry and voted unanimously to approve the regular session minutes of 4/16/21 with no noted change by roll call vote.

TOPIC IV

FLEX

1. Pharmacy Issues Related to Covid-19 and State of Emergency Time: 8:06 AM

Presented by D. SENCABAUGH

Due to COVID restrictions, the APhA Institute on Substance Use Disorders is offering its annual training program virtually. A grant has been offered for one person to attend. The Board members will let D. SENCABAUGH know if they would like to attend.

So noted.

TOPIC V

Applications

1. Ash Pharmacy

New Community Pharmacy

TIME: 8:26 AM

REPRESENTED BY: Sampson Tona, MOR; Paul Garbarini, Attorney

RECUSAL: None

DISCUSSION: Sampson Tona is the manager and owner of Ash Pharmacy. The pharmacy is a standalone building in Worcester. The community they wish to service will be comprised of low income, Spanish community, homeless shelter and in the high-rise buildings. MOR Tona confirmed the prescription area and immunization area is separate. W. FRISCH has made the recommendation to move the controlled substance storage area, counter space of 10 sq. ft and no carpet in the non-sterile compounding area. MOR Tona has taken the steps to start meeting those recommendations. They plan to levigate ointments. The second entrance leads to Main Street with security cameras pointing to doors. There are nine cameras total. Pharmacy staff will include two more pharmacists. MOR Tona answered all the Board members questions to satisfaction.

ACTION: Motion by L. GIAMBARRESI seconded by T. FENSKY, voted unanimously by those present to approve the application pending a successful inspection.

2. Central Street Pharmacy DS89950 Relocation TIME:

REPRESENTED BY:

Not presented.

3. Resilience Boston Transfer of Ownership TIME: 8:18 AM

REPRESENTED BY: Christopher Grabowski, Designated representative for facility; Amanda Ashcraft, Director of Quality Assurance; Ori Solomon, General Counsel

RECUSAL: None

DISCUSSION: Sanofi (Genzyme) was acquired by National Resilience. This is a complete takeover of the facility, including manufacturing. The product made by Resilience is still licensed by Sanofi and will be marketed by them. FDA registration has been updated to reflect the change in ownership.

ACTION: Motion by S. HAMILTON seconded by T. FENSKY, voted unanimously by those present to approve the application pending a successful inspection.

4. Advanced Pharmacy Solutions Transfer of Ownership TIME: 8:36 AM

REPRESENTED BY: Anthony Rozzi, MOR; Joseph Calomo, Owner

RECUSAL:

DISCUSSION: Preferred Pharmacy Solutions is a long-term care pharmacy who have been in business for over 12 years. They are closing 5/31/21 and Advanced Pharmacy Solutions will be the new owners. All

the inventory, building security, MOR and staff will remain. J. TRIFONE gave a summary of previous cases for inspectional deficiencies and drug violations against Preferred Pharmacy Solutions that resulted in Probation. Leadership and consulting will be new. Joseph Calomo is aware of past issues and new processes have been implemented to prevent repeat errors.

ACTION: Motion by T. FENSKY seconded by A. STEIN, voted unanimously by those present to approve the application pending a successful inspection.

D. Perry leaves meeting 8:45 AM

TOPIC VI

Regulations

247 CMR 17.00: Sterile Compounding

Time: 8:59 AM

Presented by M. CHAN, W. FRISCH

Discussion: These regulations have already been offered for public comment and resulted in many changes reducing the document to 13 pages. Among the changes were the inclusion of the hazardous drug standards based on USP <800> as well as changes to be consistent with the current draft of USP <797>.

Since the proposed regulations at 247 CMR 19.00 *Hazardous Drugs* have been incorporated into to the drafted non-sterile and sterile regulations, withdrawal of that section was requested.

The updated draft will be posted on the website.

Action: Motion by T. FENSKY, seconded by S. HAMILTON, and voted unanimously by roll call by all those present to advance 247 CMR 17.00 *Sterile Compounding* for the administrative review process and public hearing.

Action: Motion by T. FENSKY, seconded by C. BELISLE, and voted unanimously by roll call by all those present to withdraw 247 CMR 19.00 *Hazardous Drugs* from the administrative review process.

Julie Reads Executive Session Language

Time: 9:23 AM

Topic VII:

Executive Session Call to Order:

Time: 9:24 AM

By: J. Lanza

ACTION: Motion by, L. Giambarresi, seconded by K. Thornell, all voted affirmatively by those present to enter executive session.

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

Topic VIII:

65C Sessions MGL c. 112 section 65C

Time: 9:59 AM

DISCUSSION: None

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

At 9:59 AM S. Hamilton, seconded by T. Fensky and voted unanimously by all those present to enter 65C by roll call vote.

S. Cornacchio leaves meeting at 10:01 AM

L. Giambarresi leaves meeting at 10:01 AM

Topic IX

ADJOURNMENT OF MEETING

TIME: 10:04 AM

ACTION: Motion by T. Fensky seconded by C. Jean-Francois 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 4/30/21 General Session
2. Draft Minutes of the 4/16/21 Meeting
3. Application: Ash Pharmacy New Community Pharmacy
4. Application: Resilience Boston Wholesale Distributor Change of Ownership
5. Application: Preferred Pharmacy Solutions Change of Ownership
6. 247 CMR 17.00 Sterile Compounding

Respectfully Submitted,
Carly Jean-Francois, NP, Secretary