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

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

#### **January 8, 2021**

#### **Webex Information**

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

Access Code: 178 278 0844

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  ■ Introduction of New Board Members  ○ Caryn Belisle – Hospital Seat  ○ Jennifer Chin – Long-term Care Seat		J. Lanza
	II	APPROVAL OF AGENDA		
8:05	III	<ul> <li>APPROVAL OF BOARD MINUTES</li> <li>Draft of December 18, 2020 Regular Session Minutes</li> </ul>		
8:10	IV	<ul> <li>Applications approved pursuant to Licensure Policy 13-01</li> <li>Monthly report from probation</li> <li>Board Delegated Review pursuant to Licensure Policy 14-02</li> <li>Above Action Levels approved by Staff Action 16-04</li> <li>PSUD Report-Policy 17-03</li> <li>Research Drug Study Report</li> <li>Board Approved Continuing Education Programs</li> </ul>		

8:15	V	<ul><li>APPLICATIONS</li><li>● Omnicare of Northern MA (DS89931) – Renovation</li></ul>	
8:25	VI	<ul> <li>FLEX</li> <li>Pharmacy issues related to Covid-19 and the state of emergency</li> <li>Candidate for pharmacy advisory committee sterility USP &lt;71&gt;         Seat     </li> </ul>	
8:30	VII	FILE REVIEW  1 SA-INV-16892 CVS #703, DS24412	
8:45	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
10:00	X	ADJOURNMENT	

### COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

# MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting January 8, 2021

#### **Board Members Present**

Julie Lanza, CPhT, President
Sebastian Hamilton, Pharm D, RPh President-elect
Carly Jean-Francois, RN, NP Secretary
Leah Giambarresi, Pharm D, RPh
Dr. Richard Lopez, MD
Susan Cornacchio, JD, RN (Leaves meeting 9:41 AM)
Timothy Fensky, RPh
Andrew Stein, PharmD
Dawn Perry, JD (arrives at meeting at 8:05 AM)
Caryn Belisle, PharmD, RPh
Jennifer Chin, 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
Richard Harris, Program Analyst
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Joanna Chow, Office Support Specialist
Joanne Trifone, RPh, Director of Investigator
Julienne Tran, PharmD RPh, Investigator
Gregory Melton, PharmD, JD, Investigator
Paul Seed, PharmD, RPh, Investigator
Michael Brosnan, PharmD, RPh, Investigator

#### **Board Members Not Present**

Katie Thornell, PharmD, RPh Kim Tanzer, PharmD, RPh

#### **TOPIC I.** Attendance by roll call:

#### **CALL TO ORDER 8:02 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; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky, yes; J. Chin, yes; C. Belisle, yes; A. Stein (D. Perry joins meeting at 8:05 AM)

Draft Minutes General Session: 1/8/21

Topic II.

#### **Approval of Agenda**

**TIME 8:03 AM** 

#### Agenda 1/8/21

#### **DISCUSSION:**

Change to Agenda:

1. defer Flex appointment Pharmacy Advisory Committee

#### **ACTION:**

Motion by L. Giambarresi, seconded by S. Hamilton and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Dave thanks P. Gannon for her service on the board and welcomes J. Chin and C. Belisle Ed introduces the MCP APPE Intern A. Elias

**Topic III** 

**Approval of Board Minutes** 

TIME: 8:13 AM

#### **Minutes**

1. Draft 12/18/20

No noted Changes.

#### Action:

Motion by L. Giambarresi, seconded S. Hamilton, and voted unanimously to approve the regular session minutes of 12/18/20 with no changes by roll call vote. Chin and Belisle abstain.

**TOPIC IV** 

REPORTS

Applications approved pursuant to Licensure Policy 13-01

**Discussion**: R. HARRIS noted Change of Managers applications approved pursuant to Licensure Policy 13-01.

So noted.

**TOPIC IV** 

**REPORTS** 

**Monthly Report from Probation** 

**Discussion**: R. HARRIS provided the December 2, 2020 – December 31, 2020, Board of Pharmacy Statistics Report for the Probation monitor, which noted that one (1) licensee was given the opportunity to cure; three (3) licensees satisfactorily completed probations and there are currently twenty-six (26) licensees on probation.

So noted.

**TOPIC IV** 

**REPORTS** 

Monthly Report from BDR pursuant to Policy 14-02

Time: 8:15 AM

Time: 8:14 AM

Time: 8:15 AM

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Draft Minutes General Session: 1/8/21

**Discussion**: M. BOTTO noted that there were four (4) Board Delegated Review cases heard since the last Board meeting. All four (4) staff assignments 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: 8:15 AM

**Discussion**: J. TRIFONE noted that the above action level reports has been closed as part of a complaint since last Board meeting pursuant to Licensure Policy 16-04.

So noted.

TOPIC IV REPORTS

PSUD Report by Staff Action 17-03 Time: 8:16 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: 8:17 AM

**Discussion**: W. FRISCH noted there are twelve (12) active Research Drug Studies since the last report in November and two (2) new pharmacies approved. The report will be presented quarterly.

So noted.

TOPIC IV REPORTS

Board Approved Continuing Education Programs Time: 8:17 AM

**Discussion**: M. CHAN noted there were one hundred and forty-seven (147) CE's approved in 2020, 5 in sterile compounding and 10 in law.

So noted.

TOPIC V Applications

1. Omnicare of Northern MA DS89931 Renovation TIME: 8:18am

**Represented by:** John Rocchio, CVS Health Senior Director, James Brewster, Omnicare of Northern MA Interim Manager of Record, Regan Alison Nichols, CVS Health Architecture/Engineer, Brian Feeney, CVS Health Engineer, Sandy Paz, Omnicare of Northern MA Operations Manager

Recusal: Susan Cornacchio

**Discussion:** 

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CVS HEALTH as owner of OMNICARE OF NORTHERN MA (OMINCARE) provided a brief overview of the plan for the renovation of which included HVAC upgrade and use of a segregated compounding area (SCA) with a single compounding aseptic containment isolator (CACI) for compounded sterile preparations (CSP) during the renovation for continuity of care.

W. FRISCH next provided an overview of the plan for renovation according to application submitted by OMNICARE. FRISCH indicated that OMNICARE planned to upgrade the heating, ventilation, and air conditioning (HVAC) system, flooring, and plumbing in the existing cleanroom. During renovation, OMNICARE planned to convert office area in the pharmacy to a SCA to maintain continuity of care for patients. In addition, FRISCH indicated only low-risk compounding would take place in the SCA with reduced beyond use dates (BUD) for CSP of 12 hours for room temperature preparations and 24 hours for refrigerated preparations. FRISCH also indicated that N. VAN ALLEN visited the facility to ensure OMNCARE's renovation plan accurately represented the actual areas in the pharmacy. CVS HEALTH confirmed that FRISCH's overview was accurate.

T. FENSKY expressed concern about the traffic between the garbing area, sink, and SCA. CVS HEALTH indicated that the area would be cleared of all office equipment. In addition, the traffic would be rerouted to restrict access to CSP staff only and emergency egress only for all others. CVS also indicated that only a single technician would staff the CACI at at time. CVS HEALTH reiterated that only low-risk compounding would take place in the SCA with an effort to dispense immediate-use kits (mini-bag kits) much as possible. Furthermore, complex CSP such as TPN would be outsourced.

FENSKY and C. BELISLE inquired about environmental control in the SCA. CVS HEALTH indicated that the CACI would be cleaned daily with Periodox (sporicide) daily. SCA would be cleaned daily alternating LPH and Vesphene (phenolic, acid cleaner) and every two weeks with Periodox (sporicide). The air in the SCA would be positive pressure & HEPA filtered. Surface sampling would be conducted at baseline and every 2 weeks until the project is completed in approximately six weeks. In addition, the SCA would be fitted with epoxy paint on all walls and doors, and a seamless ceiling and flooring. Furthermore, the door would open automatically by an elbow operated pushbutton. CVS HEALTH added that the construction area will be enclosed by a zip-wall system and is located approximately 90 feet from the SCA.

#### Action:

MOTION BY FENSKY to approve application by OMNICARE for renovation pending successful inspections of the areas (EXISTING CLEANROOM & SCA) in the renovation plan; SECONDED by S. HAMILTON; Then, HAMILTON, C. JEAN-FRANCIOS, L. GIAMBARRASI, R. LOPEZ, A. STEIN, FENSKY, D. PERRY, J. CHIN, BELISLE, and J. LANZA voted AYE.

TOPIC VI Flex

1. Pharmacy Issues related to Covid-19 and state of emergency.

Presented by: N/A Recusal: N/A

Discussion: None - Proceeded to File Review without discussion at approximately 8:43am

#### 2. Candidate for Pharmacy Advisory Committee Sterility USP <71>

#### **Deferred**

TOPIC VII FILE REVIEW

Case #1

SA-INV-16892 CVS #703, DS24412 Time: 08:44 AM

<u>RECUSAL</u>: S. CORNACCHIO recused and was not present for the discussion or vote in this matter.

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

- During a Retail Compliance inspection conducted on September 17, 2020 it was observed that the Pharmacy failed to comply with the Order of the Commissioner of Public Health effective 03/25/2020 requiring pharmacies to provide alternative pharmacy hours, at least one hour every day in the early morning, for adults aged 60 years and older to limit their potential exposure to COVID-19.
- MOR Sibailly posted a senior hour sign before the inspection ended indicating, "... dedicating the first hour the pharmacy opens each day to meet our most vulnerable guests and their caregivers". .
- MOR Sibailly stated, "I will continue to ensure that the sign remains posted until further notice."

<u>ACTION</u>: Motion by L. GIAMBARRESI, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to CLOSE the matter (SA-INV-16892), No Discipline Warranted, Remediation Complete.

Topic VIII: Executive Session Call to Order: Time: 8:47 AM

By: J. Lanza

<u>ACTION</u>: Motion by, L. GIAMBARRESI, seconded by D. PERRY, and voted unanimously by roll call for call to order of the executive session.

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

Topic IX: 65C Sessions MGL c. 112 section 65C Time: 9:23 AM

**DISCUSSION: None** 

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

At 9:23 AM L. Giambarresi, seconded by S. Hamilton and voted unanimously by all those present to enter 65C by roll call vote.

Draft Minutes General Session: 1/8/21

TIME: 9:54 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 1/8/21 General Session
- 2. Draft Minutes of the 12/18/20 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 Drug Study
- 9. Report on Continuing Education Programs
- 10. Applications: Omnicare of Northern MA DS8931 Renovation
- 11. SA-INV-16892 CVS #703 DS24412

Respectfully Submitted, Carly Jean-Francois, NP, Secretary



Draft Minutes General Session: 1/8/21 BOP Approved: pending