COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

October 9, 2020

Webex Information

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

Access Code: 171 096 7636

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 |
|------|-----|---|
| 8:00 | I | CALL TO ORDER |
| | II | APPROVAL OF AGENDA |
| 8:05 | III | APPROVAL OF BOARD MINUTES Draft of September 25, 2020 Regular Session Minutes |
| 8:10 | IV | REPORTS Applications approved pursuant to Licensure Policy 13-01 Monthly report from probation Board Delegated Review pursuant to Licensure Policy 14-02 Above Action Levels approved by Staff Action 16-04 PSUD Report-Policy 17-03 |
| 8:15 | V | APPLICATIONS Central Admixture Pharmacy Services; DS3312 – Change of Manager Spectra Medical Devices: WD487 - Relocation |
| 8:30 | VI | FLEX Pharmacy issues related to Covid-19 and the state of emergency Nomination of Board Officers |

| 8:45 | VII | ADVISORY • Controlled Substance Prescriptions |
|-------|------|---|
| 8:50 | VIII | FILE REVIEW 1. SA-INV-16857 Mary Stevens, PH237024 |
| 9:00 | IX | 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. |
| 9:30 | X | M.G.L. c. 112, § 65C SESSION |
| 10:30 | XI | ADJOURNMENT |

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Remote WebEx Meeting Boston, Massachusetts, 02114 October 9, 2020

Board Members Present

Board Members Not Present

Kim Tanzer, PharmD, RPh. President
Julie Lanza, CPhT, President Elect (leaves 9:30 AM)
Leah Giambarresi, Pharm D, RPh, Secretary
Patrick Gannon, RPh (leaves 9:55 AM)
Sebastian Hamilton, Pharm D, RPh
Dr. Richard Lopez, MD
Andrew Stein, Pharm D
Susan Cornacchio, JD, RN
Timothy Fensky, RPh
Stephanie Hernandez, Pharm D, BCGP, RPh
Katie Thornell, PharmD, RPh
Carly Jean-Francois, RN, NP
Dawn Perry, JD

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
Julienne Tran, PharmD RPh, Investigator
Gregory Melton, Pharm D, JD, RPh Investigator
Christina Mogni, RPh Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:01 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: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; K. Thornell, yes; S. Hernandez (yes); D. Perry, yes; P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky; Dr. Lopez, yes.

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Draft Minutes General Session: 10/9/2020

Topic II. Approval of Agenda TIME 8:03 AM

Agenda: 10/9/20

DISCUSSION:

Change to Agenda:

1. Defer flex: SA-INV-16857 Mary Stevens, PH237024

ACTION:

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

Topic III Approval of Board Minutes TIME: 8:04 AM

Minutes

1. Draft, 9/25/20 Session Minutes

Changes:

Edit vote on Coram PHA-2020-0048 to clarify as follows.

<u>ACTION</u>: Motion by L. GIAMBARRESI, seconded by S. Hamilton, and voted unanimously by those present, to refer the matter (PHA-2020-0048), to the Office of Prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for STAYED PROBATION for a period of 6 Months with conditions of monthly environmental monitoring by a party vendor and immediate (within 1 day) notification to the Board of any above action level results or defect malfunctions.

Action:

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

TOPIC IV Reports
Applications approved pursuant to Licensure Policy 13-01

Discussion: R. HARRIS noted that there have been eighteen (18) Change of Managers applications, zero (0) New Pharmacies and two (2) Renovation applications approved pursuant to Licensure Policy 13-01.

Time: 8:05 AM

So noted

TOPIC IV REPORTS

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Draft Minutes General Session: 10/9/2020

Monthly Report from Probation

Discussion: R. HARRIS noted that one (1) licensee cured; one (1) probation monitoring successfully competed and thirty (30) active cases on probation.

Time: 8:06 AM

Time: 8:06 AM

Time: 8:06 AM

Time: 8:06 AM

So noted

TOPIC IV REPORTS

Monthly Report from BDR pursuant to Policy 14-02

Discussion: M. BOTTO noted there were not BDR to report on this month.

So noted

TOPIC IV REPORTS

Above Action Levels Approved by Staff Action 16-04

Discussion: J. TRAN noted that three (2) above action level report has been reported pursuant to Licensure Policy 16-04, all reports had been successfully remediated and closed

So noted

TOPIC IV REPORTS

PSUD Report by Staff Action 17-03

Discussion: E. TAGLIERI noted that there were twelve (12) active participants and that all active participants would attend the quarterly REC meeting in October.

So noted

TOPIC V Applications

1. Central Admixture Pharmacy Services DS3312 Change of Manager of Record Time: 8:07 AM

Presented by: Mina Saied and Eunice Chang

Discussion: The Board questioned the proposed Manager of Record on his training, competence and background regarding USP 797; USP 795 and Manager of Record duties. Also reviewed were his past duties in previous jobs as a pharmacist.

Action: Motion by T. Fensky, seconded by P. Gannon, and voted unanimously by all those present by roll call to approve the application for change of Manager.

2. Spectra Medical Devices WD487 Relocation Time: 8:18 AM

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Draft Minutes General Session: 10/9/2020

Presented by: Augustine Turriza

Discussion: The Board questioned the manager on the relocation. He explained they were moving to a different location in Wilmington after 12 years and they only stocked CVI medications. He discussed the need to have both the old and new location open for a short period of time during the move.

Action: Motion by T. Fensky, seconded by L. Giambarresi, and voted by roll call vote unanimously by all those present to approve the relocation.

The Board will work with licensee to have the old location license active until the new location is ready. Board will issue a new license to the site of relocation but leave it inactive until they are ready to operate out of the new location. When the new location is ready, then the old location license will be inactivated, and the new location license will be activated.

TOPIC VI Flex

1. Pharmacy Issues related to Covid-19 and state of emergency TIME: 8:27 AM

PRESENTED BY: D. SENCABAUGH

DISCUSSION: Guidance for testing and immunizing for COVID-19 in pharmacies is still under review. Also, the ability for certified pharmacy technicians to immunize with proper training is still under discussion, but it does not look like it will be resolved soon.

So noted.

2. Nomination of Board Officers for 2021

PRESENTED BY: D. SENCABAUGH

DISCUSSION: Nominations for the positions of Secretary for 2021 and President-Elect for 2021/President for 2022 will be done today and the vote will occur during the October Board meeting. The following Board members have terms expiring soon and should not be nominated since they will be unable to complete the terms of the offices: Patrick Gannon, Tim Fensky, Susan Cornacchio, and Andrew Stein. The vote will be live and not secret. Candidates may give a speech prior to voting if they wish. The vote is not to be discussed between meetings and candidates may not solicit votes from other board members.

TIME: 8:29 AM

ACTION:

Motion by T. FENSKY, seconded by J. LANZA to nominate Sebastian Hamilton for the position of secretary.

Motion by K. TANZER, seconded by S. CORNACCHIO to nominate Carly Jean-Francois for the position of secretary.

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Draft Minutes General Session: 10/9/2020

Motion by K. TANZER, seconded by S. HERNANDEZ and D. PERRY to nominate Sebastian Hamilton for the position of President-Elect.

Motion by J. LANZA, seconded by A. STEIN to nominate Leah Giambarresi for the position of President-Elect.

TOPIC VII ADVISORY

Controlled Substance Prescriptions: TIME 8:36 AM

PRESENTED BY: M. CHAN

DISCUSSION: M. Chan explained to the Board that the Controlled Substance Prescription Advisory has been updated to focus on the validity of the prescription as opposed to the security of controlled substances as it had been previously.

Updates to the Controlled Substances advisory included a change of focus to providing guidance on determining the validity of a prescription rather than drug security.

This guidance refers to NABP's video on "red flags" to help the pharmacist identify potential misuse or diversion.

ACTION: Motion by T. FENSKY, seconded by A. STEIN, voted unanimously by roll call to approve the updated Controlled Substance Prescription Advisory.

Topic IX EXECUTIVE SESSION Time: 8:39 AM

Read by A. Stein

DISCUSSION:

ACTION: At 8:39 AM President K. Tanzer read the statement on reasons for Executive Session.

Topic IX: Executive Session Call to Order: Time: 8:39 AM

By: K. Tanzer

<u>ACTION</u>: Motion by L. Giambarresi, seconded by S. Hamilton, and voted unanimously by roll call to call the 10/9/30 meeting of the Executive Session to order.

Roll call attendance: A. Stein, yes; K. Tanzer, yes; J. Lanza, yes; K. Thornell, yes; S. Hernandez (yes); D. Perry, yes; P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky; Dr. Lopez, yes.

Draft Minutes General Session: 10/9/2020

Topic X: M.G.L. 65 C #1 Time: 8:52 AM

DISCUSSION: None

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

At 8:52 AM P. Gannon, seconded by S. Hamilton and voted by roll call vote unanimously by all those present to enter M.G.L. chapter 65 c Session:

- J. Lanza leaves meeting at 9:30 AM
- P. Gannon and S. Hernandez leave meeting at 10:00 AM

Topic XII ADJOURMENT OF MEETING TIME: 10:06 AM

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

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. Draft Agenda of the 10/9/20 General Session
- 2. Draft Minutes of the 9/25/20 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. Applications: Central Admixture Pharmacy Services DS3312 Change of Manager

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- 9. Applications: Spectra Medical Devices WD487 Relocation
- 10. Advisory: Controlled Substance Prescriptions

Respectfully Submitted, Leah Giambarresi, PharmD, RPh, Secretary