

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

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

**November 20, 2020**

**Webex Information**

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

Access Code: 178 384 2029

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**

<b>Time</b>	<b>#</b>	<b>Item</b>
<b>8:00</b>	<b>I</b>	<b>CALL TO ORDER</b>
	<b>II</b>	<b>APPROVAL OF AGENDA</b>
<b>8:05</b>	<b>III</b>	<b>APPROVAL OF BOARD MINUTES</b> <ul style="list-style-type: none"><li>• Draft of November 4, 2020 Emergency Meeting Regular Session Minutes</li><li>• Draft of November 6, 2020 Regular Session Minutes</li></ul>
<b>8:10</b>	<b>IV</b>	<b>APPLICATIONS</b> <ul style="list-style-type: none"><li>• Luis Resto - Pharmacy Technician in Training</li><li>• Hopkinton Drug; DS8191 - Waivers</li><li>• Meena Huh; PI163522 – Request for an application extension</li></ul>
<b>8:20</b>	<b>V</b>	<b>FLEX</b> <ul style="list-style-type: none"><li>• Pharmacy issues related to Covid-19 and the state of emergency</li></ul>

	<b>VI</b>	<p><b>POLICIES &amp; ADVISORIES</b></p> <ul style="list-style-type: none"> <li>• Advisory: Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding</li> <li>• Staff Action Policy 20-01: Staff Action to Handle NABP Reports of Licensee Sanctions</li> <li>• Policy 2020-02: Compounding Copies of Commercially Available Drugs</li> <li>• Joint Policy 2020-12: Vaccine Administration by Qualified Pharmacy Technicians</li> <li>• Joint Policy 2020-13: Administration of FDA-Authorized, FDA-Licensed, and Investigational COVID-19 Vaccines</li> </ul>						
<b>8:30</b>	<b>VII</b>	<p><b>FILE REVIEW</b></p> <table border="1"> <tr> <td><b>1</b></td> <td>PHA-2020-0057</td> <td>David Del Giudice, PH236272</td> </tr> <tr> <td><b>2</b></td> <td>SA-INV-16894</td> <td>Khalid Boukhatem, PH237644</td> </tr> </table>	<b>1</b>	PHA-2020-0057	David Del Giudice, PH236272	<b>2</b>	SA-INV-16894	Khalid Boukhatem, PH237644
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<b>2</b>	SA-INV-16894	Khalid Boukhatem, PH237644						
<b>9:00</b>	<b>VIII</b>	<p><b>EXECUTIVE SESSION</b></p> <p>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.</p>						
<b>10:15</b>	<b>IX</b>	<b>M.G.L. c. 112, § 65C SESSION</b>						
<b>10:30</b>	<b>X</b>	<b>ADJOURNMENT</b>						

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

**MINUTES OF THE GENERAL SESSION  
Boston, Massachusetts, 02114  
WebEx Remote Meeting  
November 20, 2020**

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**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  
Andrew Stein, Pharm D  
Susan Cornacchio, JD, RN (Leaves 9:45 AM)  
Timothy Fensky, RPh  
Katie Thornell, PharmD, RPh  
Dawn Perry, JD (arrives 8:40 AM; leaves 10:30 AM)

**Board Members Not Present**

Patrick Gannon, RPh  
Carly Jean-Francois, RN, NP

**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  
Joanna Chow, Office Support Specialist  
Richard Harris, Program Analyst

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

**CALL TO ORDER 8:00 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; A. Stein, yes; K. Thornell, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; R. Lopez, yes; T. Fensky, yes; J. Lanza, yes. D. Perry joins meeting at 8:40 AM

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**Topic II.**

**Approval of Agenda**

**TIME 8:01 AM**

**Agenda 11/20/2020**

**DISCUSSION:**

Change to Agenda:

1. none

**ACTION:**

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

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**Topic III**

**Approval of Board Minutes**

**TIME: 8:01 AM**

**Minutes**

**1. Draft 11/4/20 Session Minutes**

No noted Changes.

**Action:**

Motion by S. Hamilton, seconded L. Giambarresi, and voted unanimously to approve the regular session minutes of 11/4/20 with noted changes by roll call vote. J. Lanza abstains.

**1. Draft 11/6/20 Session Minutes**

No noted Changes.

**Action:**

Motion by S. Hamilton, seconded L. Giambarresi, and voted unanimously to approve the regular session minutes of 11/6/20 with noted changes by roll call vote.

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**TOPIC IV**

**Applications**

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**TOPIC V**

**FLEX**

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

**TIME: 8:28 AM**

**PRESENTED BY: D. SENCABAUGH**

**DISCUSSION:** Pharmacies are reminded to provide at least one dedicated hour each day in the early morning, for adults 60 years of age and older. The Massachusetts document *Workplace Safety Standards For Retail Businesses To Address COVID-19* that was updated 11/5/20 has more details.

So noted.

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**TOPIC VI**

**POLICIES and ADVISORIES**

- 1. Advisory: Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding** **TIME 8:30 AM**

**PRESENTED BY:** M. CHAN

**DISCUSSION:** Some minor language edits regarding relocation of the C-PEC were made. Moving or replacing a C-PEC is not permitted under this advisory. An *Application for Remodeling, Change in Configuration, or Change in Square Footage* must be submitted for this change.

**ACTION:** Motion by S. HAMILTON, seconded by J. LANZA, voted unanimously by roll call to approve the updated advisory.

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- 2. Policy 2020-02: Compounding Copies of Commercially Available Drugs** **TIME 8:31 AM**

**PRESENTED BY:** M. CHAN

**DISCUSSION:** This policy was edited for clarity and primarily refers to the FDA guidance document *Compounded Drug Products that are Essentially Copies of a Commercially Available Drug Product*.

**ACTION:** Motion by S. HAMILTON, seconded by J. LANZA, voted unanimously by roll call to approve the updated policy.

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- 3. Staff Action Policy 20-01: Staff Action to Handle NABP Reports of Licensee Sanctions** **TIME 8:32 AM**

**PRESENTED BY:** M. CHAN

**DISCUSSION:** This policy allows Board staff to handle NABP reports of licensee sanctions in other jurisdictions. Primarily it would allow the triage team to close files and take no further action if the violation is in regard to CE deficiencies, “administrative” deficiencies, and certain criminal proceedings. These actions are similar to the staff action policy that is in place regarding GMC candidates.

**ACTION:** Motion by S. HAMILTON, seconded by J. LANZA, voted unanimously by roll call to approve the staff action policy.

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- 4. Joint Policy 2020-12: Vaccine Administration by Qualified Pharmacy Technicians** **TIME 8:33 AM**

**PRESENTED BY:** M. CHAN

**DISCUSSION:** This policy allows vaccine administration by qualified pharmacy technicians. A qualified pharmacy technician is defined as a licensed certified technician or a licensed pharmacy technician who has worked at least 500 hours after obtaining their license.

Technicians can administer vaccines on the ACIP list for ages 3 – 18 years, or as authorized by the HHS PREP Act. ACPE training is needed as well as direct, on-site supervision of a pharmacist.

Technicians may only prepare and administer vaccines and emergency medications for adverse reactions.

As pharmacies update their vaccine standing orders to include technicians, appropriate epinephrine doses for children under 33 lbs must be addressed. The available epinephrine devices are not suitable for patients under this weight.

**ACTION:** Motion by L. GIAMBARRESI, seconded by J. LANZA, voted unanimously by roll call to ratify the policy as approved by DPH.

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**5. Joint Policy 2020-13: Administration of FDA-Authorized, FDA-Licensed, and Investigational COVID-19 Vaccines** **TIME 8:37 AM**

**PRESENTED BY:** M. CHAN

**DISCUSSION:** This policy allows pharmacists, interns, and qualified pharmacy technicians to administer FDA-licensed or FDA-authorized COVID-19 vaccines for ages 3 years and older in accordance with the HHS PREP Act. A separate policy is required since the Board’s regular vaccine policy only allows vaccines on the ACIP list.

The policy also allows pharmacists and interns to administer investigational COVID-19 vaccines.

**ACTION:** Motion by S. HAMILTON, seconded by L. GIAMBARRESI, voted unanimously by roll call to ratify the policy as approved by DPH.

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**TOPIC VI**

**FILE REVIEW**

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**Topic VIII**

**EXECUTIVE SESSION**

**Time: 9:03 AM**

**Read by K. Tanzer**

DISCUSSION:

ACTION: At 9:03 AM President K. Tanzer read the statement on reasons for Executive Session.

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**Topic VIII: Executive Session**

**A. Call to Order #1:**

**Time: 9:04 AM**

By: K. Tanzer

ACTION: Motion by L. Giambarresi, seconded by P. Gannon, and voted unanimously by roll call to call the 10/23/20 meeting of the Executive Session to order.

Roll call attendance: K. Tanzer, yes; A. Stein, yes; K. Thornell, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; R. Lopez, yes; T. Fensky, yes; J. Lanza, yes; D. Perry, yes.

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**Topic VIII: Executive Session**

**B. Call to Order #2:**

**Time: 9:15 AM**

By: K. Tanzer

ACTION: Motion by L. Giambarresi, seconded by P. Gannon, and voted unanimously by roll call to call the 10/23/20 meeting of the Executive Session to order.

Roll call attendance: K. Tanzer, yes; A. Stein, yes; K. Thornell, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; R. Lopez, yes; T. Fensky, yes; J. Lanza, yes; D. Perry, yes.

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**Topic X:**

**M.G.L. 65 C #1**

**Time: 9:09 AM**

**A. Call to order #1**

DISCUSSION: None

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

At 9:09 AM L. Giambarresi, seconded by S. Hamilton and voted unanimously by all those present to enter M.G.L. chapter 65 c Session by roll call vote.

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**Topic X:**

**M.G.L. 65 C #1**

**Time: 9:35 AM**

**B. Call to order #2**

DISCUSSION: None

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

At 9:35 AM L. Giambarresi, seconded by S. Hamilton and voted unanimously by all those present to enter M.G.L. chapter 65 c Session by roll call vote.

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Susan Cornacchio, JD, RN (Leaves 9:45 AM)

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Dawn Perry (leaves meeting 10:30 AM)

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**Topic XI**

**ADJOURNMENT OF MEETING**

**TIME: 10:39 AM**

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

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EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 11/20/20 General Session
2. Draft Minutes of the 11/4/20 Meeting
3. Draft Minutes of the 11/6/20 Meeting
4. Applications: Luis Resto Pharmacy Technician in Training
5. Applications: Hopkinton Drug DS8191 Waivers
6. Applications: Meena Huh PI163522; request for application extension
7. Advisory: Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding
8. Staff Action Policy 20-01: Staff Action to Handle NABP Reports of Licensee Sanctions
9. Policy 2020-02: Compounding Copies of Commercially Available Drugs
10. Joint Policy 2020-12: Vaccine Administration by Qualified Pharmacy Technicians
11. Joint Policy 2020-13: Administration of FDA-Authorized, FDA-Licensed, and Investigational COVID-19 Vaccines
12. PHA-2020-0057 David Del Giudice, PH236272
13. SA-INV-16894 Khalid Boukhatem, PH237644

Respectfully Submitted,  
Leah Giambarresi, PharmD, RPh, Secretary