

**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

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

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

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

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

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

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.

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.

TOPIC IV

Applications

1. Luis Resto

Pharmacy Technician in Training

TIME 8:04 AM

REPRESENTED BY: R. HARRIS

RECUSAL: None

DISCUSSION: R. HARRIS gave an overview of the applicant. The applicant has been working at Integriscript for a while as a delivery man and would like to move into the pharmacy. He did not graduate from high school; is not enrolled in a GED program and does not intend to. Luis is requesting a waiver of that regulation. K. TANZER informed the Board there is precedence for this.

ACTION: Motion by A. STEIN seconded by L. GIAMBARESSI and voted unanimously by those present to approve the application for Pharmacy Technician in Training.

2. Meena Huh; PI163522 Request for an application extension TIME 8:06 AM
REPRESENTED BY: Meena Huh

RECUSAL: None

DISCUSSION: Meena graduated from Northeastern in 2018, took the NAPLEX June 2019 and passed but did not pass the MPJE within a year of taking the NALEX. The Board approved her first extension request to October 31, 2020. On October 27, 2020, she went to sit for the MPJE but ran into a problem with her middle name. Meena's middle name was present on her federal ID but not on her Pearson VUE registration. She has taken MPJE three times in the past and has not had problems. The issue has been resolved. She has been continuously studying and staying up to date. Meena is requesting a second extension.

ACTION: Motion by T. FENSKY, seconded by S. HAMILTON, voted unanimously by roll call of those present to approve the extension.

3. Hopkinton Drug; DS8191 Waivers TIME 8:13 AM
REPRESENTED BY: John Zaia (MOR), Dennis Katz (Owner)

RECUSAL: A. STEIN

DISCUSSION: Hopkinton Drug is a retail pharmacy looking to end the retail portion of their business and focus on their compounding business. MOR Zaia noted the retail business has dropped steadily and it made more economic sense to drop the retail side. They currently fill about 20 scripts a day. The compounding business has taken over and the demand from customers is higher. They are hoping to stop the retail side by January 2021. They plan to notify the patients and transfer the scripts as soon as waivers are approved by the Board. Stock will be returned and any extra will be disposed of when they are expired. Three pharmacists that work in the retail side will be trained to work in the compounding pharmacy.

W. FRISCH questioned use of their current space allocated for the retail business. MOR Zaia stated their intent is to utilize that space for other purposes. They would like to add to that space but understands they will need to submit plans and have them approved. In the short term, the space will be used for storage and intake.

MOR Zaia stated they will maintain the pickup window for compounding orders. Signs will be posted stating they are not available for retail business. OTC meds will be available. Staff will be available at the window for questions from customers.

K. TANZER noted there is a pending FDA 483 report. Hopkinton has sent a response to the 483 to Nathan VanAllen. T. FENSKY suggested acting now only if there is something detrimental in the report.

R.HARRIS requested revised waivers; the waivers submitted were not complete.

ACTION: Motion by L. GIAMBARESSI, seconded by S. HAMILTON, voted unanimously by roll call of those present to approve the waivers pending resubmission of revised waivers for 247 CMR 6.02(4) and 247 CMR 9.01(15).

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.

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.

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.

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.

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.

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.

TOPIC VI

FILE REVIEW

Case #1

PHA-2020-0057

David Del Giudice, PH236272

Time:08:40 AM

RECUSAL: A. STEIN had exited the meeting and was not present for the discussion or vote in this matter.

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- During a USP 797 inspection (ISP-14127) conducted on 02/24/2020 and a follow-up Site Visit (ISP-14244) conducted on 03/03/2020 numerous inspectional deficiencies were observed at the Boulevard Pharmaceutical Compounding Center. Although a POC was submitted, there were continued concerns with sterile compounding at the Pharmacy. On 05/20/2020, a follow-up Site Visit (ISP-14318) was conducted, and ongoing deficiencies were observed. On 05/20/2020, Former MOR Del Giudice provided an attestation of agreement to voluntarily cease sterile compounding, engage a consultant, recall CSPs filled over the previous 50 days, engage a third party EM company to validate EM, and implement a continuity of care plan.
- On 09/25/2020, PHA-2020-0028 for the Pharmacy was heard at the Board meeting. The Board voted to authorize resolution of the matter by a consent agreement for Probation for a period of two years with special terms. The Board also voted to open a complaint for Former MOR Del Giudice for failure to remediate or correct the deficiencies cited by the date specified in the POC.
- On 10/09/2020, the BORP received an "Application for Change in Manager" for a change of manager from Former MOR Del Giudice to Current MOR Patsis signed on 09/28/2020.
- Former MOR Del Giudice indicated that after voluntarily ceasing sterile compounding, all activities in the sterile rooms ceased, including all cleaning and environmental monitoring. There are no plans as of this time to reopen the rooms. If a decision is made to attempt to resume sterile compounding in the future, a consultant will be brought in to assist with updating all aseptic training and policies and procedures for the Pharmacy; both in-house and third party training of Pharmacy staff members will occur per specific policies that have been developed for the Pharmacy; and annual competency checks will be updated to include a review of SOPs. Former MOR Del Giudice stated, "Personally, I have taken the time to step back and reevaluate how I handle myself as a professional on a daily basis. I have personally made improvements by adding many more checks for myself for my daily routines".
- Former MOR Del Giudice contended that following the initial out of range readings for the incubators, the Pharmacy's third-party consultant for microbiology checked the incubators. Supposedly, the incubators were adjusted, and the Pharmacy was provided documentation that showed the incubators were in range. According to MOR Del Giudice, alarms for out of range

readings from the electronic monitoring system for temperatures and humidity are documented within the system and the alerts are sent to the Pharmacy staff personal cell phones.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to DISMISS the matter (PHA-2020-0057), No Discipline Warranted, Remediation Complete.

Case #2

SA-INV-16894

Khalid Boukhatem, PH237644

Time: 08:57 AM

RECUSAL: A. STEIN recused and was not present for the discussion or vote in this matter.

DISCUSSION: C. MOGNI presented and summarized the investigative report that pertained to these matters.

- During a USP 797 inspection (ISP-14127) conducted on 02/24/2020 and a follow-up Site Visit (ISP-14244) conducted on 03/03/2020 numerous inspectional deficiencies were observed at the Boulevard Pharmaceutical Compounding Center. Although a POC was submitted, there were continued concerns with sterile compounding at the Pharmacy. On 05/20/2020, a follow-up Site Visit (ISP-14318) was conducted, and ongoing deficiencies were observed. On 05/20/2020, Former MOR Del Giudice provided an attestation of agreement to voluntarily cease sterile compounding, engage a consultant, recall CSPs filled over the previous 50 days, engage a third party EM company to validate EM, and implement a continuity of care plan.
- On 09/25/2020, PHA-2020-0028 for the Pharmacy was heard at the Board meeting. The Board voted to authorize resolution of the matter by a consent agreement for Probation for a period of two years with special terms. The Board also voted to open a staff assignment for Owner Boukhatem for concerns of his lack of formal training/knowledge of 797 sterile compounding.
- Owner Boukhatem stated that as the new owner of the pharmacy, he relied on Former MOR Del Giudice and Current MOR Patsis, who had formal 797 compounding training, to conduct all aspects of sterile compounding. Owner Boukhatem did not recall performing any final verification of sterile products but had performed secondary math verifications for new formulas on two separate occasions. He indicated in addition to completing his annual sterile compounding CE requirements, he had worked at Tufts Medical Center prior to owning the Pharmacy. Therefore, he was confident that he had acquired the knowledge to assist in math verification of master formulary records.
- Owner Boukhatem submitted a copy of his resume indicating he had been employed at Tufts Medical Center as an IV Pharmacist from November 2017 to September 2019. Although Tufts Medical Center provided a verification letter of employment to Owner Boukhatem, they would not provide him the documentation of his sterile compounding in-house training completed. After assuming ownership of the Pharmacy, he did not complete any additional sterile compounding training at the Pharmacy. No additional training was completed as remediation since the Pharmacy had ceased compounding sterile preparations. Owner Boukhatem indicated that the Pharmacy will no longer engage in sterile compounding in the future stating, "We felt we did not have enough sterile compounding volume to sustain the enormous cost associated to continue".
- On 10/09/2020, the BORP received an "Application for Change in Manager" for a change of manager from Former MOR Del Giudice to Current MOR Patsis on 09/28/2020.

ACTION: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by those present, to CLOSE the matter (SA-INV-16894), No Violation.

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.

Topic VIII: **Executive Session** **Time: 9:04 AM**
A. Call to Order #1:
By: K. Tanzer

ACTION: Motion by J. Lanza, seconded by T. Fensky, and voted unanimously by roll call to call the 11/20/20 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.

Topic VIII: **Executive Session** **Time: 9:16 AM**
B. Call to Order #2:
By: K. Tanzer

ACTION: Motion by L. Giambarresi, seconded by S. Hamilton, 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.

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.

Topic X:
B. Call to order #2

M.G.L. 65 C #1

Time: 9:35 AM

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.

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

Dawn Perry (leaves meeting 10:30 AM)

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.

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