

**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	Page	Contact
8:00	I	CALL TO ORDER		K. Tanzer
	II	APPROVAL OF AGENDA		
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of September 25, 2020 Regular Session Minutes		
8:10	IV	REPORTS <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Central Admixture Pharmacy Services; DS3312 – Change of Manager• Spectra Medical Devices: WD487 - Relocation		

8:30	VI	FLEX <ul style="list-style-type: none"> Pharmacy issues related to Covid-19 and the state of emergency Nomination of Board Officers 		
8:45	VII	ADVISORY <ul style="list-style-type: none"> Controlled Substance Prescriptions 		
8:50	VIII	FILE REVIEW <ol style="list-style-type: none"> 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.		CLOSED SESSION
9:30	X	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION
10:30	XI	ADJOURNMENT		

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

MINUTES OF THE GENERAL SESSION

Meeting held via WEBEX remotely

Boston, Massachusetts, 02114

September 25, 2020

Board Members Present

Kim Tanzer, PharmD, RPh. President
Julie Lanza, CPhT, President Elect (leaves meeting at 9:00 AM)
Sebastian Hamilton, Pharm D, RPh
Leah Giambarresi, Pharm D, RPh, Secretary
Dr. Richard Lopez, MD
Andrew Stein, Pharm D
Katie Thornell, RPh (leaves meeting at 10:30 AM)
Susan Cornacchio JD, RN
Stephanie Hernandez, Pharm D, BCGP, RPh
Timothy Fensky, RPh
Dawn Perry, JD (leaves at 10:30 AM)
Patrick Gannon, RPh (leaves meeting at 10:00 AM)

Board Members Not Present

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
Joanne Trifone, RPh, Director of Investigator
Gregory Melton, Pharm D, JD, RPh Investigator
Christina Mogni, RPh Investigator
John Murray, RPh Investigator
Julienne Tran, PharmD, RPh Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Joanna Chow, Office Support Specialist

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 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, J. LANZA: yes, L. GIAMBARRESI: yes, A. STEIN: yes, S. HAMILTON: yes, S. CORNACCHIO: yes, K. THORNELL: yes, T. Fensky: yes, D. PERRY: yes. Dr. Lopez: yes, S. Hernandez: yes, P. GANNON: yes.

Topic II.

Approval of Agenda

TIME 8:04 AM

Agenda September 25, 2020

DISCUSSION:

Change to Agenda:

1. Defer Hopkington Drug to 65C

ACTION:

Motion by P. Gannon, seconded by J. Giambarresi and voted unanimously by those present by roll call vote to approve the agenda with noted changes.

Dave introduces Megan Pantos, WNE APPE Intern and Ed introduces Luella Robles MCP Boston APPE Intern.

Topic III

Approval of Board Minutes

TIME: 8:0 AM

Minutes

1. Draft 9/11/20 General Session Minutes

No noted Changes.

Action:

Motion by L. Giambarresi, seconded by S. Hamilton and voted unanimously by roll call vote to approve the regular session minutes of 9/11/20 with no noted changes. P. Gannon abstains.

TOPIC IV

Reports

Applications approved pursuant to Licensure Policy 13-01

Time: 8:06 AM

Discussion: R. HARRIS noted that there have been thirty (30) Change of Managers applications, three (3) New Pharmacies and seven (7) Renovation applications approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:06 AM

Discussion: R. HARRIS noted that zero (0) report(s) from probation have been reported since last Board meeting.

So noted

2. NABP District I and II meeting Summary

Time: 8:17 AM

Presented by: S. HAMILTON, L. GIAMBARRESI and T. FENSKY

Recusal: None

Discussion: S. HAMILTON noted there were lots of good conversation about COVID-19, vaccines when it becomes available and immunizations. Dave spoke well about where the state of Massachusetts is on immunization. Tim Fensky was the keynote speaker which was well received. He also had a resolution to make sure the lessons we learned from COVID-19, remote pharmacy practices and other key things that happened during COVID; to make sure NABP convenes a subcommittee to make sure we learn those lessons.

L. GIAMBARRESI noted all the resolutions passed and are moving forward.

T. FENSKY noted he compiled all the resolutions into one to present. They are going to take what we learned from COVID-19 and try to get into some model language for future pandemics or natural disasters. District I and II had the most attendees.

So noted.

VI: File Review:

Case #1

PHA-2020-0048

Coram CVS/Specialty Infusion Services, DS3601

Time: 08:14 AM

RECUSAL: S. CORNACCHIO and J. TRIFONE recused and were not present for the discussion or vote in this matter

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

- On July 9, 2020, a complaint was opened as a result of SA-INV-16256 due to a repeat above action level on July 15, 2020.
- On July 7, 2020, MOR Quach submitted a Disclosure of Above Action Level Environmental Monitoring Results, Form 1 on 6/24/2020. The above action disclosure was 1cfu surface sample of Alternaria (fungus) in the ISO 7 compounding room -right outside wall of laminar flow hood (LFH) 12497. MOR Quach indicated that BUDs would be reduced to 3 refrigerated and 24 hours at room temperature effective 7/7/20 at 4pm.
- On July 15, 2020, MOR Quach submitted Disclosure of Above Action Level Environmental Monitoring Results, Form 2: Final Reporting Form after monitoring conducted on March 19, 2020 for cleanroom A. MOR Quach submitted a copy of the EM report dated July 8, 2020 for Room B cleanroom which did not show any above action level contamination.
- MOR Quach noted that after the above action level, a triple cleaning was completed in the affected areas and in the ISO 5 areas. The technicians follow Coram's cleaning policy on a daily, weekly and monthly basis and ensure all activities are logged.

- MOR Quach stated, “We also added visual inspection by the production supervisor weekly in ISO 5, ISO 7, and ISO 8. We are now and will continue to wipe the medications, diluents, and empty bags in prep room before transferring into the clean room (ISO 7) and we then wipe down again prior to transferring in the hood (ISO 5). Limited supplies are kept in our clean rooms and the rooms are kept clean and tidy.”

ACTION: 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.

Case #2

PHA-2020-0028 Boulevard Pharmaceutical Compounding Center, DS90300 Time: 08:21 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.

- Formerly SA-INV-16224 that was elevated to a complaint by BORP staff action. During a USP 797 inspection (ISP-14127) conducted on 2/24/2020 and a follow-up Site Visit (ISP-14244) conducted on 3/3/2020 inspectional deficiencies were observed including missing documentation on cleaning logs for multiple days in February, gaps in the dilution logs for cleaning products, unlabeled CSPs in the refrigerator with incomplete accompanying compounding logs, incubator temperatures were inconsistent and out of range (high), using an NST refrigerator thermometer and an oral thermometer in the incubators, incomplete documentation for in-house EM, alprostadil 500mcg/mL stock solution assigned 150 day BUD, and failure to adhere to policy regarding handling of serum vials for autologous serum eye drops when more than one patient was scheduled on the same day. MOR Del Giudice submitted a POC.
- On 4/9/2020, MOR Del Giudice provided a response to SA-INV-16224 indicating he had assumed all responsibilities for the cleanroom including cleaning, EM, and performing all sterile compounding after the sterile compounding technician was recently terminated. He alleged he completed all tasks but failed to document them. The Pharmacy contracts with an outside vendor to complete the monthly clean but that staff was not trained on the Pharmacy’s SOPs. MOR Del Giudice stated the Pharmacy uses a continuous temperature monitoring system but no one checks it.
- Due to the numerous concerns with the Pharmacy’s sterile compounding, SA-INV-16224 was converted to a complaint by BORP staff action on 4/24/2020 and another Site Visit (ISP-14318) was conducted on 5/20/2020. Continued deficiencies were observed for incubation temperature monitoring with out of specification results during the most recent in-house EM sampling. The report stated the data collected was invalid. The Pharmacy had begun compounding high-risk intrathecal CSPs since 3/3/2020. Additionally, the Pharmacy was compounding non-hazardous medications, including autologous serum eye drops, in the hazardous compounding room. It was recommended that the Pharmacy cease sterile compounding. On 5/20/2020, 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.

- In response to the complaint, MOR Del Giudice stated all CSPs are labeled immediately and compounding logs are completed and reviewed. The volume was added to the labels. All EM is being sent to a third party for testing. Cleaning logs were updated, and the monthly cleaning will occur after EM sampling. Cleaning for autologous serum eye drops will be documented on each compounding log. The Pharmacy purchased commercially available alprostadiil solution. The media fill will be reviewed to reflect a complex high-risk preparation. The electronic temperature system will be reviewed and documented daily. The outside cleaning company will be given the Pharmacy's SOPs to review. Future certifications will be reviewed with the certification company with review documented.

ACTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2020-0028), to the office of the prosecution for the issuance of an order to show cause and to authorize resolution of the matter by a consent agreement for PROBATION for a period of 2 YEARS with special terms to include the pharmacy will continue to refrain from sterile compounding for the immediate term until can demonstrate they have made all the necessary changes to sterile compound in compliance, and include monitoring during the probation. Additionally, the pharmacy will need to engage a consultant to address all the deficiencies at which time they will submit the remediation plan to the Board's Quality Assurance Team and then once reviewed by QA, the pharmacy will need to petition the Board to reengage in sterile compounding.

SECOND MOTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to open a COMPLAINT on Pharmacist David Del Giudice, PH236272.

THIRD MOTION: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to open a STAFF ASSIGNMENT on Pharmacist Khalid Boukhatem, PH237644.

Case #3

PHA-2020-0051

Walgreens #4393, DS2882

Time: 08:54 AM

RECUSAL: NONE

DISCUSSION: G. MELTON presented and summarized the investigative report that pertained to these matters.

- Walgreens #4393 reported an unknow loss of 100 methylphenidate 10mg tablets in July 2020. Walgreens #4393 conducted an extensive internal investigation including review of surveillance video, reconciliation of patient's prescription, invoices, and perpetual inventory logs, and investigative support from asset protection.
- However, MOR Muniz for Walgreens #4393 stated, "... It is believed that [sic] bottle may have been inadvertently discarded in the trash or inadvertently sent back in a tote to the vendor when unpacking the weekly CII inventory on 7/8/2020... The point of the loss could not be identified, and a theft cannot be ruled out."
- MOR Muniz stated, "Changes to procedure require pharmacists when receiving a CII order to double check quantity against the invoice in addition to the standard procedure of performing the receiving audit."

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2020-0051), 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 PROBATION for a period of 1 YEAR with special terms to include performing a perpetual inventory of all Schedule II medications every 7 days, restricting the handling of Schedule medications to pharmacists only, and requiring a supervisor to review the perpetual inventory for all schedule II medications once a month.

J. Lanza leaves meeting at 9:00 AM

Kim Tanzer announces at 9:04 AM the general session will be ending, and the Board will be going into Executive Session and reads the reason for entering Executive Session as required. The Board will not cover any other general session items today.

Topic VII: Executive Session Call to Order: Time: 9:05 AM
By: K. Tanzer

ACTION: Motion by L. Giambarresi seconded by P. Gannon and voted unanimously by roll call to call the 9/25/20 meeting of the Executive Session to order.

Roll call attendance: K. TANZER: yes, L. GIAMBARRESI: yes, A. STEIN: yes, S. HAMILTON: yes, S. CORNACCHIO: yes, K. THORNELL: yes, T. Fensky: yes, D. PERRY: yes. Dr. Lopez: yes, S. Hernandez: yes, P. GANNON: yes.

Topic VIII: Adjudicatory Session Time: 9:54 AM

DISCUSSION: None

ACTION: President K. Tanzer request a motion to enter Adjudicatory Session.

At 9:54 AM S. Hamilton, seconded by L. Giambarresi and voted unanimously by all those present to enter Adjudicatory Session:

Topic IX: M.G.L. 65 C #1 Time: 10:00 AM

DISCUSSION: None

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

At 9:58 AM T. Fensky, seconded by S. Hamilton and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

P. Gannon leaves meeting at 10:00 AM
A. Stein leaves meeting at 10:12 AM
K. Thornell leaves meeting at 10:30 AM
D. Perry leaves meeting at 10:30 AM

Topic X:

ADJOURNMENT OF MEETING

TIME: 10:40 AM

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

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 9/25/20 General Session
2. Draft Minutes of the 9/11/20 Meeting
3. Report on Applications approved pursuant to Licensure Policy 13-01
4. Report on Board Delegated Complaint Review to licensure policy 14-02
5. Report on Above Action Levels approved by Staff Action 16-04
6. Report on PSUD 17-03
7. PHA-2019-0166 Hopkinton Drug DS8191
8. PHA-2020-0048 Coram CVS Specialty Pharmacy DS3601
9. PHA-2020-0028 Boulevard Pharmaceutical Compounding Center DS90300
10. PHA-2020-0051 Walgreens #4393 DS2882

Respectfully Submitted,
Leah Giambarresi, PharmD, RPh, Secretary