

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

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

May 29, 2020

**The Regular Session of this meeting is open to the public
and will be heard via Webex Conference Call**

Webex Information

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

Access Code: 619 320 526

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 |
|-------------|------------|---|-------------|----------------|
| 8:30 | I | CALL TO ORDER | | K. Tanzer |
| | II | APPROVAL OF AGENDA | | |
| 8:35 | III | APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• May 7, 2020 General Session Minutes• May 15, 2020 General Session Minutes | | |
| 8:40 | IV | REPORTS <ul style="list-style-type: none">• Board Delegated Review pursuant to Licensure Policy 14-02 | | |

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|-------|---------------|--|---|----------------------|---------------------------|---|---------------|-------------------------|--|--|
| 8:45 | V | POLICIES and ADVISORIES <ul style="list-style-type: none"> Policy 2020-04: Board-Approved Pharmacy Technician Licensing Examinations and Pharmacy Technician Training Programs Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding | | W. Frisch M. Chan | | | | | | |
| 9:00 | VI | APPLICATIONS <ul style="list-style-type: none"> East Boston Neighborhood Center – New Community Pharmacy | | | | | | | | |
| 9:15 | VII | FLEX <ul style="list-style-type: none"> Pharmacy issues related to Covid-19 and the state of emergency Boulevard Pharmacy Inspection – DS90300 | | | | | | | | |
| 9:20 | VIII | FILE REVIEW <table border="1"> <tr> <td>1</td> <td>SA-INV-16308</td> <td>Stop and Shop #71, DS2789</td> </tr> <tr> <td>2</td> <td>PHA-2020-0025</td> <td>Rite Aid #10206, DS2412</td> </tr> </table> | 1 | SA-INV-16308 | Stop and Shop #71, DS2789 | 2 | PHA-2020-0025 | Rite Aid #10206, DS2412 | | |
| 1 | SA-INV-16308 | Stop and Shop #71, DS2789 | | | | | | | | |
| 2 | PHA-2020-0025 | Rite Aid #10206, DS2412 | | | | | | | | |
| 9:30 | 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. | | | | | | | | |
| 9:45 | X | ADJUDICATORY SESSION(M.G.L. ch. 30A, §18) | | | | | | | | |
| 10:00 | XI | ADJOURNMENT | | | | | | | | |

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE REGULARLY SCHEDULED MEETING
May 29, 2020

The Regular Session of this meeting is open to the public
and will be heard via WebEx Conference Call

Board Members Present

Kim Tanzer, PharmD, RPh. President
Julie Lanza, CPhT, President Elect
Dawn Perry, JD
Leah Giambarresi, Pharm D, RPh, Secretary
Andrew Stein, Pharm D
Sebastian Hamilton, Pharm D, RPh
Dr. Richard Lopez, MD
Katie Thornell, RPh
Patrick Gannon, RPh
Susan Cornacchio JD, RN
Timothy Fensky, RPh

Board Members Not Present

Carly Jean-Francois, RN, NP
Stephanie Hernandez, Pharm D, BCGP, 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
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
John Murray, RPh Investigator
Leo McKenna, RPh Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:30 AM

A quorum of the Board was present, established by roll call. President K. Tanzer chaired the meeting. Notification of "This meeting is being recorded."

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

Topic II.
Agenda May 29, 2020

Approval of Agenda

TIME 8:31 AM

DISCUSSION:

Change to Agenda:

- No Board Delegated Review Session
- No Adjudicatory Session

ACTION:

Motion by S. HAMILTON, seconded by L. GIAMBARRESI and voted unanimously by those present to approve the agenda with the changes.

Topic III.

Approval of Board Minutes

TIME 8:33 AM

Minutes

1. Draft, 5/7/20 Session Minutes

No noted changes.

ACTION:

Motion by S. HAMILTON, seconded by J. LANZA and voted unanimously by those present to approve the agenda.

2. Draft, 5/15/20 Session Minutes

No noted changes.

ACTION:

Motion by S. HAMILTON, seconded by J. LANZA and voted unanimously by those present to approve the agenda.

GENERAL

TOPIC V

POLICIES and ADVISORIES

1. Policy 2020-04: Board-Approved Pharmacy Technician Licensing Examinations and Pharmacy Technician Training Programs

Time: 8:34 AM

Presented by: M. CHAN

Recusal: None

Discussion: Since PTCB has recently made changes to their technician exam blueprint, the current policy was revised to update the exam requirements and to clarify other issues.

Among some structural revisions, the policy now details which nationally recognized exams and training programs are considered Board approved. There are also updates to the licensing exam to model those of PTCB with only four overarching knowledge-based sections including Pharmacology, Pharmacy Laws and Regulations, Patient Safety and Quality Assurance, and Order Entry and Processing.

No changes were made to the training program requirements.

This policy replaces Policy 2017-01: Guidance for Board-Approved Pharmacy Technician Training Programs and Examinations.

P. GANNON asked if exams and programs currently under review would be subject to the new policy. M. CHAN clarified that although the exam changes simplified the requirements, the one exam that is under review would not be required to adhere to the new policy.

Action: Motion by S. HAMILTON, seconded by J. LANZA, and voted unanimously by roll call by those present to approve Policy 2020-04: Board-Approved Pharmacy Technician Licensing Examinations and Pharmacy Technician Training Programs.

2. Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding

Time: 8:36 AM

Presented by: W. FRISCH

Recusal: None

Discussion: There were some minor changes to the document currently in use, but most significantly, a section was added advising hospital sterile compounders that they must still notify and obtain any necessary approvals from the (DPH-HCQ) Massachusetts Department of Public Health, Division of Health Care Facility Licensure and Certification before conducting repairs once they are licensed by the Board.

Although, the Board does not yet license institutional sterile compounders, edits to this advisory will make it clear for the future.

Additionally, the advisory only allows the removal or addition of primary engineering controls that are not used for hazardous compounding. HVAC systems are involved with changes to hazardous compounding primary engineering controls and would require a renovation application.

Action: Motion by T. FENSKY, seconded by J. LANZA, and voted unanimously by roll call by those present to approve the revisions to the Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding.

GENERAL

VI: Applications:

1. East Boston Neighborhood Center – New Community Pharmacy Represented by: Donna Zaloumis

TIME 8:42

Recusal:

Discussion:

East Boston Neighborhood Center is submitting an application for a new community pharmacy. The East Boston Neighborhood Center had been in a longstanding pharmacy services contract with Eaton. Two years ago, Eaton sold the business to CVS and CVS carried over the contract. The contract was up for renegotiations, but CVS and East Boston Neighborhood Center was unable to negotiate a new contract therefore the agreement was terminated and expired. The East Boston Neighborhood Center located at 20 Maverick Square location in East Boston is requesting to open the space as a pharmacy to service the East Boston Neighborhood Center patients with an intent to re-establish services, non-health center patients can have their prescriptions filled.

The application indicates a request for simple compounding but in fact moderate compounding will be done therefore the application will be amended to reflect moderate compounding. Donna Zaloumis will be the MOR and is currently manages the 10 Gold St. location. Ms. Zaloumis indicated that no special packaging will be done at the East Boston Neighborhood location.

Action: Motion by S. HAMILTON, seconded by A.STEIN, and voted unanimously by roll call by those present to approve application for new community pharmacy for East Boston Neighborhood Center.

GENERAL

VII: Flex:

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

TIME: 8:47

Presented by Dave

Recusal:

Discussion:

The Board was posed the question as to whether or not a pharmacy technician can oversee a COVID-19 test under the supervision of a nurse practitioner. Issues to consider:

- Drive through draw must be sanitized each time the draw is used.
- Pharmacy technicians will be supervised by a nurse practitioner for this particular function only and the pharmacy technician will still be under the direct supervision of a pharmacist for any pharmacy related tasks.
- The nurse practitioner will now have oversight of the test process and in the event, there is an issue with the testing process, the nurse practitioner can enter the pharmacy space to go to the window.
- Pharmacy technician will need appropriate training.
- This process could be beneficial to the pharmacist who is filling prescriptions.

This process has been approved and is currently in practice.

The pharmacy technicians are part of the ratio and at the time during the current situation ratios are relaxed but if this practice becomes routine, the ratio issue may be revisited.

There have been numerous questions from associations and pharmacists about pharmacist's ability to administer the antibody test. HHS nationally came out with a ruling that said they could, and that HHS will preempt the state regarding whether the pharmacist could conduct the testing or not. The states do have the ability to establish guidelines and the state is currently discussing this and looking at an overall state policy. The discussion is taking place collaboratively with other state agencies who may be involved.

2. New FAQ #29 – Extending BUD in an emergency. FAQ document has been updated which includes 2 additions, one being the relaxation of BUD's in order to conserve drug supplies based on recent guidance that was published by USP. Most notably in the relaxation of the BUDs was the extension of BUDs for controlled room temperature for 4 days. The second update in the FAQ was guidance for when there was a COVID-19 positive employee in the pharmacy. The guidance was sent out previously and now the guidance are incorporated into the FAQ.

GENERAL

VII: Flex:

2. Boulevard Pharmacy Inspection – DS90300

TIME: 8:57

Recusal:

Discussion:

On May 20, 2020 a 797-site visit was performed as part of an ongoing Board investigation into inspectional deficiencies observed during a 797 inspection that was conducted on February 24, 2020 at Boulevard Pharmaceutical Compounding Center in Worcester. They also did a site visit early March 2020. That standard review documentation at the site visit to assess deficiencies from the previous inspections were addressed and corrected. There was a list of 24 deficiencies. Two thirds of them had been remediated with 8 remaining. The deficiencies that were still identified were related to incubation temperatures and humidity monitoring with a recent documentation showing out of specification results during the most recent sampling of April to May . The EM, both bacterial and fungal were incubated during this time frame and the data collected during the time period is invalid due to incorrect temperature range. The incubation temperature setting has not been corrected since the last inspection with 2 temperature systems with contradicting data. The pharmacy does not have sufficient data to support an adequate level of quality stability insurance for CSPs (compounded sterile products) dispensed putting patients at increased risk. Additionally, there were observed high risk compounds, sterile compounding logs describing compounding of non-hazardous medications within a negative pressure hazardous compounding room in primary engineering control increasing the risk of cross contamination and no labeling to identify such hazards. With a recommendation made on site included ceasing sterile compounding until the deficiencies could be corrected and a proper level of quality and sterility insurance could be provided with complete and accurate documentation of all CSPs with an expiratory or recall. They've contracted with a third party to perform the monthly EM (Environmental Monitoring). They hired a consultant to make corrections to the deficiencies. The licensee agreed to the recommendations including stopping all USP797 compounding and a continuity of care plan was put in place. Next steps would be to have the complaint PHA 20-0028 to come before the Board for a vote before the licensee could resume sterile compounding.

This is an informational stage and once completed the investigator will present the case to the Board's next meeting.

VIII: File Review

May 29, 2020 Board Meeting

TOPIC VIII

Open File Review

TIME: 09:04 AM

Case #1

SA-INV-16308

Stop and Shop #71, DS2789

Time: 9:04 AM

RECUSAL: K. THORNELL 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.

- On 3/17/2020, an untimely RLCS of #120 Concerta 36mg discovered on 2/28/2020 when 2 prescriptions of #60 Concerta 36mg for siblings filled on 2/27/2020 could not be located at pick up.
- Pharmacist Matos-Reis stated the loss was discovered on 2/28/2020 when the patients' mother presented at the Pharmacy to pick up the prescriptions and they could not be located. Pharmacist Matos-Reis alleged that security footage showed the prescription bags were placed in the trash on 2/27/2020 and

remained there untouched. The trash bag was closed at 4:30pm on 02/27/2020 and remained in view in the Pharmacy until 3:30pm on 02/28/2020 when it was removed for disposal by a store employee and put in the store's trash compactor.

- A review of security footage (7:56am to 3:39pm) from 2/27/2020 that was provided confirmed Pharmacist Matos-Reis, who had filled and verified the prescriptions, inadvertently placed them in a trash bin located next to a bin for filled prescriptions.
- The prescription bins for filled prescriptions were moved from the floor to the pharmacy counter and the trash bin was relocated out of the verification area to avoid future occurrences. The prescriber was contacted for new prescriptions which were issued and filled on 03/02/2020.

ACTION: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by those present, to CLOSE the matter (SA-INV-16308), No Discipline Warranted, Remediation Complete.

Case #2

PHA-2020-0025

Rite Aid #10206, DS2412

Time: 9:07 AM

RECUSAL: NONE

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

- An unknown loss of #133 tramadol 50 mg tablets discovered on 03/01/2020 during a change of MOR inventory and reported 03/19/2020. The Pharmacy listed 18 additional CII, CIII, CIV controlled substances as losses on the BOP RLCS but the DEA 106 listed only #133 tramadol 50mg.
- In a response received on 05/01/2020, MOR Dias contended, there was an error in reporting resulting in a duplicate report of a loss of #133 tramadol 50 mg tablets. MOR Dias stated, "After further investigation, all losses related to this case were deemed not reportable". MOR Dias indicated, "This was a clerical error, and had we looked in the controlled substance record keeping box for 2019 at the store, we would have known this was previously reported". RPL Bagni confirmed with loss prevention that this was a duplicate reporting of a loss of #132 tramadol 50mg submitted on 11/11/2019 (PHA-2019-0113 heard at 02/06/2020 Board meeting).
- MOR Dias mandated that each controlled substance be double counted by the pharmacy technician then counted again by the pharmacist prior to dispensing. Rite Aid Policy #POP.01.08.v5 "Controlled Substance Loss (Reporting & Compliance)" was provided and was signed by all pharmacy staff acknowledging that it had been reviewed.

ACTION: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by those present, to DISMISS the matter (PHA-2020-0025), No Violation.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 5/29/20 General Session
2. Draft Minutes of the 5/7/20 Meeting
3. Draft Minutes of the 5/15/20 Meeting
4. Applications: East Boston Neighborhood Center – New Community Pharmacy
5. Policy 2020-04: Board-Approved Pharmacy Technician Licensing Examinations and Pharmacy Technician Training Programs

6. Advisory on Conducting Repairs or Services to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding
7. SA-INV-16308 Stop & Shop #71, DS2789
8. PHA-2020-0025 Rite Aid #10206, DS2412