

COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

July 23, 2021

WebEx Information

The regular session is open to the public by video or phone.

For video access click on the following link:

[://statema.webex.com/statema/onstage/g.php?MTID=](https://statema.webex.com/statema/onstage/g.php?MTID=)

To access the meeting by phone:

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

Access Code: 161 802 4716

Attendee: #

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator, 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		J. Lanza
	II	APPROVAL OF AGENDA <ul style="list-style-type: none">• Introduction of Intern: Andrew Whitley (MCPHS)		
	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of June 25, 2021 Regular Session Minutes		
8:05	IV	FLEX <ul style="list-style-type: none">• Pharmacy issues related to Covid-19 and the state of emergency		

8:10	V	APPLICATIONS <ul style="list-style-type: none"> • Nantucket Cottage Pharmacy revised floor plan • NIMVAX- New Community Pharmacy/Pilot Project • Boston Children’s Solutions RX – New Community Pharmacy • ONCO 360; DS89921– USP Storage Requirements • Edward M. Kennedy Community Health Care/Framingham – New Community Pharmacy 										
9:00	VI	POLICIES <ul style="list-style-type: none"> • Staff Action Policy 13-01 Licensure Applications and Notices 										
9:15	VII	FILE REVIEW <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 5%; text-align: center;">1</td> <td style="width: 25%;">CAS-2021-0419</td> <td style="width: 25%;">PHA-2021-0030</td> <td style="width: 45%;">Stop and Shop #91, DS2660</td> </tr> <tr> <td style="text-align: center;">2</td> <td>CAS-2021-0114</td> <td>PHA-2021-0008</td> <td>CVS #1049, DS1716</td> </tr> </table>	1	CAS-2021-0419	PHA-2021-0030	Stop and Shop #91, DS2660	2	CAS-2021-0114	PHA-2021-0008	CVS #1049, DS1716		
1	CAS-2021-0419	PHA-2021-0030	Stop and Shop #91, DS2660									
2	CAS-2021-0114	PHA-2021-0008	CVS #1049, DS1716									
9:30	VIII	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								
10:00	IX	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION								
10:30	X	ADJOURNMENT										

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

June 23, 2021

Board Members Present

Julie Lanza, CPhT, President
Sebastian Hamilton, Pharm D, MBA, RPh President-Elect
Carly Jean-Francois, RN, NP Secretary (leaves meeting at 10:00 AM)
Andrew Stein, Pharm D
Susan Cornacchio, JD, RN (leaves meeting at 10:38 AM)
Leah Giambarresi, Pharm D, RPh (arrives meeting 8:25 AM)
Katie Thornell, RPh, MBA
Dr. Richard Lopez, MD
Dawn Perry, JD
Timothy Fensky, RPh

Board Members Not Present

Jennifer Chin, RPh
Caryn Belisle, RPh, MBA

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Assistant Executive Director
Heather Engman, JD, Board Counsel
Michelle Chan, RPh Quality Assurance Pharmacist
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst
Joanna Chow, Office Support Specialist
Joanne Trifone, RPh, Director of Investigation
Gregory Melton, PharmD, JD, Investigator
Cheryl Lathum, PharmD, Investigator
Julienne Tran, PharmD, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 AM

A quorum of the Board was present, established by roll call. President J. Lanza chaired the meeting and she explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: J. Lanza, yes; S. Hamilton, yes; A. Stein; C. Jean-Francois, yes; S. Cornacchio, yes. R. Lopez, yes; T. Fensky, yes; D. Perry, yes. K. Thornell, yes. L. Giambarresi joins meeting at 8:25 AM.

Topic II.

Approval of Agenda

TIME 8:03 AM

Agenda 7/23/21

DISCUSSION:

No changes

ACTION:

Motion by T. Fensky, seconded by S. Hamilton and voted unanimously by those present to approve the agenda with no noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:05 AM

Minutes

1. Draft 6/25/21

Change: no noted changes

Action:

Motion by S. Hamilton seconded C. Jean-Francois and voted unanimously to approve the regular session minutes of 6/25/21 with no noted change by roll call vote by all present.

TOPIC IV

Flex

Pharmacy Issues Related to Covid-19 and State of Emergency

Time: 8:06 AM

Nothing to report.

TOPIC V

Applications

1. Nantucket Cottage Pharmacy

Revised Floor Plan

TIME: 8:06 AM

REPRESENTED BY: R. HARRIS

RECUSAL: None

DISCUSSION: Nantucket Cottage Pharmacy submitted a revised floor plan. They are removing the counseling room and replacing it with a privacy area that includes a half wall.

ACTION: Motion by T. FENSKY, seconded by K. THORNELL, voted unanimously by those present to approve the revised floor plan.

2. NIMVAX**New Community Pharmacy/Pilot Program****TIME: 8:11 AM**

REPRESENTED BY: Nimit Deocampo, MOR; Daniel Ritchie, QA consultant

RECUSAL: None

DISCUSSION: NIMVAX Vaccination Pharmacy provides only immunization services for patients based on CDC Guidelines and ACIP. The pilot will last 18 months, starting on September 1, 2021. NIMVAX has also applied with HCQ for a clinic license.

NIMVAX addressed concerns that arose during the last Board Meeting. First, the prescription processing area has been revised to meet the requirement, it is now 367 sq. ft. Second, technicians will be monitoring the post vaccination area. Third, NIMVAX stated a Pharmacy license would be more appropriate than a clinic license because Pharmacists are unable to write prescriptions for vaccines. Pharmacists might not be able to operate a clinic. However, a pharmacist can obtain a standing order from a doctor to dispense the vaccines. The vaccines will be billed to insurance through Pharmacy software.

The pilot program will terminate if a clinic license is granted by HCQ.

ACTION: Motion by S. HAMILTON, seconded by S. CORNACCHIO, voted by the majority of those present to approve the pilot project for 18 months with the following conditions: metrics on a monthly basis after the pharmacy opens; metrics should include storage/temperature excursions, filling/administration accuracy, handling of adverse reactions/VAERS, QA processes, as well as the types and number of each vaccine; administrations that occur off-site and pending a successful inspection. J. LANZA, T. FENSKY and L. GIAMBARRESI voted against.

3. Boston Children's Solutions RX**New Community Pharmacy****TIME: 8:59 AM**

REPRESENTED BY: Al Patterson, MOR

RECUSAL: T. FENSKY, D. PERRY, S. CORNACCHIO

DISCUSSION: Boston Children's Solutions provides specialty pharmacy care primarily to Children's Hospital patients. The intent is to serve complex care children that right now have a discontinued care model. There are issues associated with children obtaining specialty med care and staying on the therapy. Boston Children's has applied for three waivers revolving around compounding. The CVS located in the hospital will be compounding for them. They have a plan in place to service patients on the weekends.

ACTION: Motion by A. STEIN, seconded by S. HAMILTON, voted unanimously by those present to approve the application pending a successful inspection and waivers for 247 CMR 6.02(4), 247 CMR 6.01(5)(a)(4) and 247 CMR 6.01(5)(a)(5).

4. ONCO360 DS89921**USP Storage Requirements****TIME: 9:12 AM**

REPRESENTED BY: Troy Agard, MOR; Cameron Franklin, Compliance and Privacy Officer; Christopher Urban, Chief Pharmacy Officer and Leo Gray VP, Pharmacy Operations

RECUSAL: None

DISCUSSION: On the June 25th meeting, the Board approved an application for relocation for ONCO360 pending among other things, adherence to USP 800 storage requirements. In Board staff discussions with the pharmacy, they do not agree on those storage requirements. ONCO 360 stores and dispenses antineoplastic HDs requiring manipulation, however, this is not a compounding pharmacy, and they perform no manipulations to these drugs. They dispense manufacturers' original packages. ONCO 360 contends that USP <800> does not require them to store these drugs in an externally ventilated, negative-pressure room with at least 12 ACPH since they are not the ones doing the manipulation/compounding. Our read of USP <800> is that even if this pharmacy is not doing the manipulation, these drugs are still required to be stored under USP <800> conditions since they are not in their final dosage form. On July 7th, Board staff reached out to the USP expert committee who agreed with our interpretation.

ACTION: Motioned by T. FENSKY, seconded by A. STEIN, voted unanimously by those present to approve the application pending adherence to USP 800 standards.

5. Edward M. Kennedy Community Health Care/Framingham**New Community Pharmacy****TIME: 9:32 AM**

REPRESENTED BY: Matt Moen, Director of Pharmacy Operations

RECUSAL: None

DISCUSSION: Edward M. Kennedy Community Health Care is a retail pharmacy located on the floor of their clinic. There is currently a CVS operating in that space, they intend to vacate the space at the end of October and Edward M. Kennedy Community Health Care plans to take over the space over the weekend. There is a plan in place for emergencies after hours and they do not plan to offer delivery at this moment. Health Care Quality has been notified of the proposed change in service provider for the pharmacy.

ACTION: Motioned by L. GIAMBARRESI, seconded by K. THORNELL, voted unanimously by those present to approve the application pending a successful inspection and final approval from HCQ. S. CORNACCHIO was not present for the vote.

TOPIC VI**Policies**

Presented by M. CHAN

Discussion: This policy grants Board staff the authority to perform certain licensing functions. The intent of the pharmacy technician trainee license is to obtain necessary experience to become a pharmacy technician, however, Board staff has received several extension requests for trainees who have obtained very few hours of training or none at all.

The requested changes are to require at least 250 hours of employment as a pharmacy technician trainee in order for staff to extend the license and also the ability to provide extensions for up to 2 additional years as long as they have met that initial 250-hour threshold.

Action: Motion by T. FENSKY, seconded by K. THORNELL, and voted unanimously by roll call by all those present to approve updates to the policy.

TOPIC VII

File Review

Case #1/CAS-2021-0419

PHA-2021-0030

Stop & Shop #91, DS2660

Time: 09:45 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.

- RLCS for an unknown loss of 52mL opium tincture 10mg/mL discovered on 3/30/2021 by Interim MOR Alicandro during an attempt to fill a prescription. The Pharmacy was searched including the CII cabinet and shelves. The will call bin was checked to ensure the last prescription had not been filled twice. Controlled substance records were reconciled. Video footage was reviewed but was inconclusive.
- According to the responses provided by Interim MOR Alicandro and MOR Kiley, during the reconciliation of the perpetual inventory for liquid CII, the quantities contained in the bottles were not confirmed. They were only checking a bottle was present in the CII cabinet. MOR Kiley had filled the previous prescription on 2/17/2021 and inaccurately stated she used an open bottle and an unopened bottle to fill it. She presumed both bottles were put into the recycling bin. Pharmacist Lee addressed only the reconciliation performed on 3/27/2021 indicating he was working alone which contributed to the oversight in his recording of the BOH. The perpetual inventory documented 52mL as the inventoried BOH from 2/20/2021-3/27/2021.
- Going forward, Interim MOR Alicandro, MOR Kiley, and Pharmacist Lee will visually verify the quantity of CII liquids to ensure the BOH recorded in the perpetual inventory is accurate. MOR Kiley will also ensure all narcotics are returned to the CII cabinet prior to dispensing the CII prescription. Pharmacist Lee will prepare in advance to have an operational strategy for counting CII and will work slowly when counting. If he is working with Pharmacy support staff, he will delegate tasks to maintain Pharmacy operations to allow him to count CII undisturbed. A statement signed and dated by Pharmacy staff was provided confirming Stop and Shop Policy 10-005 "Controlled Substances" and Policy 19-031 "CII Perpetual Inventory" were reviewed.

ACTION: Motion by T. FENSKY, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2021-0030), 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 REPRIMAND.

Case #2/CAS-2021-0114

PHA-2021-0008

CVS #1049, DS1716

Time: 09:41 AM

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

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

- CVS #1049 initially reported the loss of #333 tramadol 50 mg tablets confirmed on 12/14/2020.
- On October 11, 2020, a red flag report identified a discrepancy of tramadol 50 mg.
- A cycle count modification report was created and showed the NDC cycle counted to zero from 333 tablets on September 29, 2020.
- The cause of the loss is unknown.
- Cycle counts are now limited to Inventory and pharmacists. Previously, technicians working production could conduct cycle counts.
- Controls were moved away from the trash bin and dispersed into the bays of the pharmacy.
- Pharmacists will continue to monitor red flags medications weekly and make notes of explanation for each medication.
- Pharmacy staff attested to reviewing the CVS policy on the Filling/Dispensing Prescriptions- Store with Two Step Verification Workflow.

ACTION: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2021-0008), 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 one year, with special terms to include conducting an exact count CS inventory for all scheduled 3-5 medications within 30 days, and a monthly exact count of all tramadol containing products for 12 months, staff retraining in the areas of inventory management, prescription production, and waiting bin management within 30 days and increased store visits from the Pharmacy Supervisor or Loss Prevention at least once every 30 days to validate and sign off on the BOH report cover page.

Topic VII:

Executive Session Call to Order:

Time: 9:49 AM

By: J. Lanza

ACTION: Motion by, L. Giambarresi, seconded by T. Fensky, all voted affirmatively by those present to enter executive session.

Roll call attendance: Roll call attendance: J. Lanza, yes; S. Hamilton, yes; A. Stein; C. Jean-Francois, yes; S. R. Lopez, yes; T. Fensky, yes; D. Perry, yes. K. Thornell, yes; L. Giambarresi, yes. S. Cornacchio not present at time of vote.

C. Jean Francois leaves meeting at 10:00 AM

Topic VIII: 65C Sessions MGL c. 112 section 65C Time: 10:16 AM

DISCUSSION: None

ACTION: President J. Lanza request a motion to enter 65C.

At 10:16 AM L. Giambarresi, seconded by K. Thornell and voted unanimously by all those present to enter 65C by roll call vote.

S. Cornacchio leaves meeting at 10:38 AM

Topic IX ADJOURNMENT OF MEETING TIME: 10:50 AM

ACTION: Motion by S. Hamilton seconded by L. Giambarresi 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 7/23/21 General Session
2. Draft Minutes of the 6/25/21 Meeting
3. Application: Nantucket Cottage Pharmacy Revised Floor Plan
4. Application: NIMVAX New Community Pharmacy/Pilot Project
5. Application: Boston Children's Solutions RX New Community Pharmacy
6. Application: ONCO 360 DS89921 USP Storage Requirements
7. Application: Edward M. Kennedy Community Health Care/Framingham New Community Pharmacy
8. Staff Action Policy 13-01 Licensure Applications and Notices
9. CAS-2021-0419; PHA-2021-0030 Stop and Shop #91 DS2660
10. CAS-2021-0114; PHA-2021-0008 DVS #1049 DS1716

Respectfully Submitted,
Carly Jean-Francois, NP, Secretary