

COMMONWEALTH OF MASSACHUSETTS  
Board of Registration in Pharmacy

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

May 28, 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: 161 512 6598

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		
	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none"><li>Draft of May 14, 2021 Regular Session Minutes</li></ul>		
8:05	IV	APPLICATIONS <ul style="list-style-type: none"><li>Long Term Pharmacy Solutions; DS90330 – Waivers</li></ul>		

8:10	V	<p><b>FLEX</b></p> <ul style="list-style-type: none"> <li>Pharmacy issues related to Covid-19 and the state of emergency</li> <li>Update on the Pharmacy Advisory Committee meeting of May 4, 2021</li> <li>NABP Annual Meeting Summary</li> <li>Rescission of the Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding</li> <li>Revised Application for Pharmacy Modifications Including Remodeling, Change in Configuration, or Change in Square Footage</li> </ul>		<p>S. Hamilton C. Belisle</p> <p>W. Frisch M. Chan</p>						
8:30	VI	<p><b>FILE REVIEW</b></p> <table border="1" data-bbox="331 695 1133 800"> <tr> <td data-bbox="331 695 380 743">1</td> <td data-bbox="380 695 618 743">PHA-2021-0002</td> <td data-bbox="618 695 1133 743">CVS #1095, DS2787</td> </tr> <tr> <td data-bbox="331 743 380 800">2</td> <td data-bbox="380 743 618 800">SA-INV-17226</td> <td data-bbox="618 743 1133 800">Brandee Lam, PH239657</td> </tr> </table>	1	PHA-2021-0002	CVS #1095, DS2787	2	SA-INV-17226	Brandee Lam, PH239657		
1	PHA-2021-0002	CVS #1095, DS2787								
2	SA-INV-17226	Brandee Lam, PH239657								
8:45	VII	<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>		CLOSED SESSION						
9:30	VIII	<p><b>M.G.L. c. 112, § 65C SESSION</b></p>		CLOSED SESSION						
10:15	IX	<p><b>ADJOURNMENT</b></p>								

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

**MINUTES OF THE GENERAL SESSION**

**Via Remote WebEx Meeting**

**May 28, 2021**

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**Board Members Present**

Julie Lanza, CPhT, President  
Sebastian Hamilton, Pharm D, MBA, RPh President-Elect  
Carly Jean-Francois, RN, NP Secretary  
Andrew Stein, Pharm D  
Susan Cornacchio, JD, RN  
Timothy Fensky, RPh (Leaves meeting 8:48 AM; returns meeting 9:45 AM)  
Caryn Belisle, RPh, MBA  
Leah Giambarresi, Pharm D, RPh  
Katie Thornell, RPh, MBA  
Jennifer Chin, RPh  
Dawn Perry, JD (Leaves meeting 8:48 AM)

**Board Members Not Present**

Dr. Richard Lopez, MD

**Board Staff Present**

David Sencabaugh, RPh, Executive Director  
Monica Botto, CPhT, Assistant Executive Director  
Heather Engman, JD, Board Counsel  
William Frisch, RPh Director of Pharmacy Compliance  
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

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

**CALL TO ORDER 8:03 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; T. Fensky, yes; C. Belisle, yes; A. Stein; K. Thornell, yes; D. Perry, yes; C. Jean-Francois, yes, L. Giambarresi, yes; J. Chin, yes. S. Cornacchio joins meeting at 8:07 AM.

**Topic II.**

**Approval of Agenda**

**TIME 8:04 AM**

**Agenda 5/28/21**

**DISCUSSION:**

Change to Agenda:  
Flex will be done prior to applications.

**ACTION:**

Motion by T. Fensky, seconded by S. Hamilton 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: 8:05 AM**

Minutes

1. Draft 5/14/21

Change: no noted changes

Action:

Motion by K. Thornell seconded L. Giambarresi and voted unanimously to approve the regular session minutes of 5/14/21 with no noted change by roll call vote.

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**TOPIC IV**

**Applications**

**1. Long Term Pharmacy Solutions DS90330**

**Waivers**

**TIME: 8:30 AM**

REPRESENTED BY: Mike Rice, MOR

RECUSAL: None

DISCUSSION: Long Term Pharmacy Solutions petitioned the Board to renew their waivers. The waivers were originally approved in 2016 and the pharmacy has changed ownership. They requested to renew four out of the six waivers. W. Frisch confirmed if they would still like to waive the compounding of customarily available medications. MOR Rice agreed with withdraw the waiver for 247 CMR 9.01(16).

ACTION: Motion by S. HAMILTON seconded by T. FENSKY, voted unanimously by those present to approve the waivers for 247 CMR 6.02(4), 6.02(5) and 9.01(15).

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**TOPIC V**

**Flex**

**1. Pharmacy Issues Related to Covid-19 and State of Emergency**      **Time: 8:06 AM**

**Presented by:** D. SENCABAUGH

**Discussion:** The Board has received many questions about the governor's end to the emergency period. The current FAQ document on the website is still in effect, but the emergency orders and guidance documents are under review. Updated information will be distributed when available.

**So noted.**

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**2. Update on the Pharmacy Advisory Committee meeting of May 4, 2021**      **Time: 8:07 AM**

**Presented by:** T. FENSKY

**Discussion:** A draft advisory on "Smoke Visualization Studies in ISO-Classified Areas" was brought forward with the goal of developing a final guidance document that will describe the purpose as well as emphasize the value of properly conducted smoke studies. Rather than just serving as a check box for compliance on a certification report, how the results of smoke studies can be used to improve the compounding process and the compounding environment. The next steps are for Board staff to review the input and make edits to the draft document to bring to the Board in the near future.

The discussion on Point-of-Care Testing / Scope of Practice centered around the possible expansion of licensee scope of practice for pharmacy-based CLIA-waived point-of-care testing beyond the currently allowed Health Promotions Screening and COVID-19 testing, which are already included in the Board's Policy on Licensee Scope of Practice. With the federal PREP Act authorizing the conducting of aspects of COVID-19 testing for pharmacists, interns, and qualified pharmacy technicians, the timing is good to discuss other types of testing that could be conducted by licensees in pharmacies. One of the six resolutions just passed at NABP's Annual Meeting encouraged states to continue to allow pharmacists to provide point-of-care testing and vaccinations post-pandemic as well as plan for future pandemics and other natural disasters.

As for other states, the authority and requirements to order, conduct, interpret, and prescribe medications for pharmacy point-of care testing vary widely. In Massachusetts, only pharmacists engaged in a CDTM may only order tests associated with drug therapy, but there are no other provisions for any other pharmacists to order any other tests (other than COVID-19 tests). Regulatory / statutory changes would likely be needed for aspects of testing such as ordering, evaluating, and initiating drug therapy. It is also important to note that pharmacy point-of-care testing requires licensure / approval from DPH's Clinical Laboratory Program.

Next steps include Board staff reviewing feedback received from the Advisory Committee, continuing to research the topic (including other states), and discussing with stakeholders before bringing any recommendations to the Board. Board staff cannot make statutory changes, so others are encouraged to approach legislators.

**So noted.**

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### 3. NABP Annual Meeting Summary

Time: 8:13 AM

Presented by: C. BELISLE, S. HAMILTON

**Discussion:** Topics at the meeting included pharmacist working conditions, FDA Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products, point-of-care testing, technician immunization, tech-check-tech, white bagging, and a “Just Culture” regulatory approach.

So noted.

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### 4. Rescission of the Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding

Time: 8:27 AM

Presented by: M. CHAN

**Discussion:** This advisory address situation where a compounding pharmacy would not necessarily need a renovation application to perform emergent repairs or minor upgrades, as well as some limited guidance for risk assessment and mitigation. These scenarios have been added to the renovation application and the guidance will be incorporated into a more overarching risk assessment and mitigation document that will be brought forward in the future. With these changes, the advisory is no longer necessary.

**Action:** Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by roll call by all those present to rescind the advisory.

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### 5. Revised Application for Pharmacy Modifications Including Remodeling, Change in Configuration, or Change in Square Footage

Time: 8:27 AM

Presented by: M. CHAN

**Discussion:** Scenarios that do not require a renovation application as noted in the *Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding* have been incorporated into the *Application for Pharmacy Modifications Including Remodeling, Change in Configuration, or Change in Square Footage* which is now available on the website.

So noted.

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**TOPIC VI****File Review**

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Case #1

PHA-2021-0002

CVS #1095, DS2787

Time: 08:43 AM

**RECUSAL:** S. CORNACCHIO and L. GIAMBARRESI recused and were not present for the discussion or vote in this matter.

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

- RLCS for 2 unknown losses - loss of #90 amphetamine salts ER 15mg capsules allegedly identified during a controlled substance inventory for a change of MOR on 10/07/2020 (no documentation provided) with the actual inventory performed on 10/16/2020. Despite MOR Soverow attesting all recordkeeping was reviewed and determining the reason for the loss could not be determined, perpetual inventories provided showed no loss. The Pharmacy was asked to report to the BORP there was no loss and withdraw the DEA 106 and CVS complied on 3/11/21.
- RLCS for an unknown loss of #340 Ativan® 0.5mg tablets identified on via corporate controlled substance monitoring on 01/21/2021. Documentation of weekly cycle counts for all NDCs of lorazepam 0.5mg tablets (brand and generic) were provided from 11/07/2020 to 03/06/2021. From 11/07/2020 through 12/5/2020, the BOH for Ativan® 0.5 mg was recorded as #340 with none in stock after 12/5/2020. A reconciliation of all NDCs of lorazepam 0.5mg 4/30/2020 to 2/14/2021 showed an overall discrepancy of -606 tablets. Although the exact reason for this loss was unknown, MOR Soverow contended it was possible there may have been an undocumented return of outdated medication.
- All loss prevention policy and procedures, including diligent inventory management, were reviewed with the pharmacy team to prevent future losses. MOR Soverow indicated, "I have implemented a plan that only pharmacists or my inventory specialists will be cycle counting controlled medications". The Pharmacy team provided a signed and dated attestation that all policies and procedures for the proper storage and handling of controlled substances were reviewed.

**ACTION:** Motion by S. HAMILTON, seconded by D. PERRY, and voted unanimously by those present, to refer the matter (PHA-2021-0002), 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 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 benzodiazepine 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.

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Case #2

SA-INV-17226

Brandee Lam, PH239657

Time: 08:39 AM

**RECUSAL:** NONE

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

- In December 2020, pharmacist Lam self-reported that she was disciplined in Kentucky, Louisiana, Michigan, and Alabama due to a continuing education audit originating in Kentucky.
- The Kentucky Board of Pharmacy found that pharmacist Lam completed 1 of the 15 required continuing education hours between January 1, 2017, and December 31, 2017. Pharmacist Lam stated, "I thought the time frame of the audit would include 3/1/17 through 2/28/18. I had logged 32 hours within this timeframe." Pharmacist Lam was ordered to pay a \$500 fine and complete 28 continuing education hours on or before June 10, 2018, that could not be used to satisfy continuing education requirements needed for renewal.
- In May 2019, she was disciplined by the Louisiana Board of Pharmacy for her failure to disclose the June 2018 disciplinary action taken by the Kentucky Board of Pharmacy. Pharmacist Lam received a Letter of Reprimand and assessed a fine of \$1,000.00 plus additional administrative costs (totaling \$1250).
- In February 2020, pharmacist Lam signed a Consent order with the Michigan Board of Pharmacy due to her discipline in Kentucky. She was ordered to pay a fine of \$250.
- In October 2020, pharmacist Lam was disciplined by the Alabama Board of Pharmacy for failure to disclose prior discipline in Oregon on her 2017/2018 renewal application in Alabama. On May 15, 2015, pharmacist Lam entered into a Consent Order with the Oregon Board of Pharmacy and was ordered by Oregon to pay a civil penalty and obtain three (3) additional continuing education in pharmacy law or ethics. Pharmacist Lam was also disciplined in Alabama due to the sanctions imposed on her by Kentucky, Louisiana, and Michigan and was ordered to pay a \$4000 fine.
- Pharmacist Lam explained that while she was in the process of applying for licensure in Oregon, she provided a positive response to the question of whether a candidate has engaged in the unlawful use of a controlled substance. She stated that she had a history of marijuana possession in 1993. Pharmacist Lam was ordered to complete extra continuing credit along with the payment of a fine of \$150.

**ACTION:** Motion by T.FENSKY, seconded by S. HAMILTON, and voted unanimously by those present, to CLOSE the matter (SA-INV-17226), No Discipline Warranted, Remediation Complete.

**D. Perry leaves meeting at 8:48 AM**  
**T. Fensky leaves meeting at 8:48 AM**

**Topic VII: Executive Session Call to Order: Time: 8:48 AM**  
 By: J. Lanza

**ACTION:** Motion by, C. Jean-Francois, seconded by K. Thornell, all voted affirmatively by those present to enter executive session.

Roll call attendance: J. Lanza, yes; S. Hamilton, yes; T. Fensky, yes; C. Belisle, yes; A. Stein; K. Thornell, yes; D. Perry, yes; C. Jean-Francois, yes, L. Giambarresi, yes; J. Chin, yes. S. Cornacchio, yes.

**Topic VIII:**

**65C Sessions MGL c. 112 section 65C**

**Time: 9:36 AM**

DISCUSSION: None

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

At 9:36 AM S. Hamilton, seconded by L. Giambarresi and voted unanimously by all those present to enter 65C by roll call vote.

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**T. Fensky rejoins meeting at 9:45 AM**

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**Topic IX**

**ADJOURNMENT OF MEETING**

**TIME: 10:14 AM**

ACTION: Motion by K. Thornell 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 5/28/21 General Session
2. Draft Minutes of the 5/14/21 Meeting
3. Application: Long Term Pharmacy Solutions DS90330 Waivers
4. NABP Annual Meeting Presentation
5. Recission of the Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding
6. Revised Application for Pharmacy Modifications Including Remodeling, Change in Configuration, or Change in Square Footage
7. PHA-2021-0002 CVS #1095 DS2787
8. SA-INV-17226 Brandee Lam PH239657

Respectfully Submitted,  
Carly Jean-Francois, NP, Secretary