

COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

October 23, 2020

Webex Information

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

Access Code: 171 312 5550

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 October 9, 2020 Regular Session Minutes
8:10	IV	APPLICATIONS <ul style="list-style-type: none">GE Healthcare, WD446/Radioisotope Life Science - Transfer of OwnershipSOFIE, NU00021 - Renovation
8:30	V	POLICIES <ul style="list-style-type: none">Policy 2020-05: Proper Storage of Refrigerated and Frozen MedicationsPolicy 2018-06: Retail Pharmacy Participation in Research Drug StudiesPolicy 18-02: Retail Pharmacy Participation in Research Drug StudiesResearch Drug Study Tracking Report

8:45	VI	<p>FLEX</p> <ul style="list-style-type: none"> • Pharmacy issues related to Covid-19 and the state of emergency • Election of Board Officers • Pharmacy Advisory Committee Meeting – November 10, 2020 • Pharmacist renewal reminders for 2022 • 2021 Board Meeting Calendar 									
9:15	VII	<p>FILE REVIEW</p> <table border="1" data-bbox="331 478 1398 632"> <tr> <td data-bbox="331 478 375 527">1</td> <td data-bbox="375 478 602 527">SA-INV-16700</td> <td data-bbox="602 478 1398 527">Walgreens #1847, DS1359</td> </tr> <tr> <td data-bbox="331 527 375 575">2</td> <td data-bbox="375 527 602 575">SA-INV-16684</td> <td data-bbox="602 527 1398 575">Pharmscript, DS90251</td> </tr> <tr> <td data-bbox="331 575 375 623">3</td> <td data-bbox="375 575 602 623">SA-INV-16401</td> <td data-bbox="602 575 1398 623">Cornerstone Health Solutions, DS90083</td> </tr> </table>	1	SA-INV-16700	Walgreens #1847, DS1359	2	SA-INV-16684	Pharmscript, DS90251	3	SA-INV-16401	Cornerstone Health Solutions, DS90083
1	SA-INV-16700	Walgreens #1847, DS1359									
2	SA-INV-16684	Pharmscript, DS90251									
3	SA-INV-16401	Cornerstone Health Solutions, DS90083									
9:30	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>									
10:00	X	<p>M.G.L. c. 112, § 65C SESSION</p>									
10:30	XI	<p>ADJOURNMENT</p>									

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

**MINUTES OF THE GENERAL SESSION
Boston, Massachusetts, 02114
WebEx Remote Meeting
October 23, 2020**

Board Members Present

Kim Tanzer, PharmD, RPh. President
Julie Lanza, CPhT, President Elect (arrives 8:15 AM; leaves 10:00 AM)
Leah Giambarresi, Pharm D, RPh, Secretary
Sebastian Hamilton, Pharm D, RPh
Dr. Richard Lopez, MD
Andrew Stein, Pharm D
Susan Cornacchio, JD, RN (Leaves 10:42 AM)
Timothy Fensky, RPh
Katie Thornell, PharmD, RPh
Carly Jean-Francois, RN, NP
Patrick Gannon, RPh (arrives 8:30 AM)
Stephanie Hernandez, Pharm D, BCGP, RPh (leaves: 9:30 AM)
Dawn Perry, JD (Leaves: 10:38 AM)

Board Members Not Present

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 8:04 AM

A quorum of the Board was present, established by roll call. President K. Tanzer chaired the meeting and asked if anyone was recording hearing, no one responded. He explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: K. Tanzer, yes; A. Stein, yes; K. Thornell, yes; S. Hernandez, yes;
D. Perry, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes;
L. Giambarresi, yes; R. Lopez, yes; T. Fensky, yes.

Topic II.

Approval of Agenda

TIME 8:04 AM

Agenda October 23, 2020

DISCUSSION:

Change to Agenda:

1. Defer Research Study Tracking Report

ACTION:

Motion by L. Giambarresi, seconded by S. Hamilton and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:05 AM

Minutes

1. Draft 10/9/20 Session Minutes

No noted Changes.

Action:

Motion by S. Hamilton, seconded L. Giambarresi, and voted unanimously to approve the regular session minutes of 10/9/20 with noted changes by roll call vote.

TOPIC IV

Applications

1. **GE Healthcare WD446/Radioisotope Life Science Transfer of Ownership** TIME 8:06 AM

REPRESENTED BY: Anne Siewko, MOR

RECUSAL: A. Stein

DISCUSSION: Ann was present to represent GE via telephone. Anne explained that on September 1, 2020 all GE pharmacies were purchased by Radioisotope Life Science located in South Africa.

K. TANZER reminded the Board that back in March they approved GE's nuclear pharmacy and that this time they will just be looking to approve the wholesale distributor.

ACTION: Motion by L. GIAMBARESSI seconded by S. HAMILTON and voted unanimously by those present to approve the application for transfer of ownership.

2. SOFIE, NU00021

Renovation

TIME 8:09 AM

REPRESENTED BY: Carey Thomas, MOR

RECUSAL: None

DISCUSSION: Bill Frisch presented the background information regarding SOFIE and that it is a nuclear pharmacy renovation which is not able to be approved by staff action. Bill explained to the Board that SOFIE is looking to install ports into their HEPA filters.

MOR Thomas explained to the Board what environmental monitoring they would do upon completion of the project including having a party conduct ISO7 certification, particle counts for ISO 5 and air sampling for ISO 5, 7 and 8. In addition, SOFIE will complete their own particle counts as well.

Bill asked to clarify that particle counts will occur for all ISO 5, 7, and 8 areas. MOR Thomas confirmed that yes this would occur before all manufacturing begins.

ACTION: Motion by T. FENSKY, seconded by L. GIAMBARESSI, voted unanimously by roll call of those present to approve the application for renovation pending successful inspection.

Julie Lanza, CPhT, President Elect (arrives 8:15 AM; leaves 10:00 AM)

TOPIC V

Policies and Advisories

1. Policy 2020-05 Proper Storage of Refrigerated and Frozen Medications **TIME: 8:12 AM**

PRESENTED BY: M.CHAN

DISCUSSION: Revisions to the refrigerator policy included some clarifications regarding freezer units and frost buildup in anticipation of the COVID-19 vaccine special storage requirements (deep freeze). Per the CDC, an allowance was made to add water bottles for temperature stabilization as long as they are labeled as a non-food product. A link was also added to the FDA's definition of a "biologic".

ACTION: Motion by T. FENSKY, seconded by C. JEAN-FRANCOIS, and voted unanimously by roll call of those present to approve the updated policy.

2. Policy 2018-06 Retail Pharmacy Participation in Research Drug Studies **TIME: 8:14 AM**

PRESENTED BY: M.CHAN and W.FRISCH

DISCUSSION: There were some verbiage edits, and a requirement was added to notify the Board when a study has ended or if the pharmacy is no longer participating. T.FENSKY asked what the timeframe would be holding on to documentation for the studies. M.CHAN clarified that the documentation would need to be retained for 2 years.

ACTION: Motioned by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by roll call of those present to approve the updated policy.

3. Policy 18-02 Retail Pharmacy Participation in Research Drug Studies **TIME: 8:16 AM**

PRESENTED BY: M.CHAN and W.FRISCH

DISCUSSION: There were some verbiage edits and the requirement to report approvals for pharmacies to participate in research studies was changed to every 3 months from every month. With the limited of number of studies received for approval, quarterly reporting of any new studies is more appropriate.

ACTION: Motion by L. GIAMBARESSI, seconded by T. FENSKY, and voted unanimously by roll call of those present to approve the updated policy.

4. Research Drug Study Tracking Report

Deferred

Patrick Gannon, RPh (arrives 8:30 AM)

TOPIC VI

Flex

1. Pharmacy Issues Related to Covid-19 and State of Emergency **TIME: 8:17 AM**

PRESENTED BY: D.SENCABAUGH

DISCUSSION: An HHS PREP Act update was released allowing pharmacy technicians to provide certain immunizations. Board staff is aware and working on guidance.

So noted.

2. Election of Board Officers for 2021 **TIME: 8:40 AM**

PRESENTED BY: D.SENCABAUGH

DISCUSSION: L. GIAMBARESSI spoke regarding her experiences over her past 3 years on the Board. She mentioned the opportunities to attend NABP meeting both in person and virtually and even having the chance to serve as the state's delegate. S. HAMILTON requested unity amongst the Board and asked that all of those who were supporting him to support Leah instead.

ACTION: Vote by roll call by the majority of those present for S. HAMILTON to be President Elect for 2021.

ACTION: Voted unanimously by roll call of those present for C. JEAN-FRANCOIS to be Secretary for 2021.

3. Pharmacy Advisory Committee Recommendation 20-02

TIME: 8:18 AM

PRESENTED BY: E.TAGLIERI

DISCUSSION: This is a formal request to the Advisory Committee for their input on a non-sterile compounding advisory and a request for a Board member to attend. The Advisory Committee meeting is scheduled for November at 10 AM.

ACTION: Motion by T. FENSKY, seconded by L. GIAMBARRESI, and voted unanimously by roll call of those present to approve sending the request to the committee and for A. STEIN to be the delegate.

4. Pharmacist Renewal Reminders for 2022

TIME: 8:23 AM

PRESENTED BY: R.HARRIS and D.SENCABAUGH

DISCUSSION: Currently paper reminder notices are sent to licensees for renewal. It was noted that this involves a great deal of printing and mail. Because this process is obsolete and expensive, the Board will move to email reminders in 2022. Going forward, the Board will need updated valid emails from all licensees.

There will be several reminders in the next two years including on newsletters, at stakeholder meetings, CE presentations.

D. PERRY asked if the website would require licensees to update their email before proceeding with their task on the website. R. HARRIS noted this was not possible for this renewal cycle but would be in the future whenever someone logs in to make any changes.

A. STEIN asked if there was a way to prevent this email from going to spam. He also asked if other Massachusetts Boards are doing this and if it has been successful.

M.BOTTO replied saying that they would have to ask IT in regard to preventing spam, but that other Boards have been very successful in doing this.

K. TANZER noted that Massachusetts is the only state to still send paper reminders out of all the states where she is licensed.

So noted.

5. 2021 Board Meeting Calendar

Time: 8:29 AM

PRESENTED BY: R.HARRIS

DISCUSSION: Next year’s calendar has been distributed so Board members so they can mark their calendars and ensure availability. He noted that the calendar assumes continuing to meet virtually every 2 weeks due to the current COVID circumstances. The calendar will be posted to the Board website.

So noted.

TOPIC VII

FILE REVIEW

Case #1

SA-INV-16700

Walgreens #1847, DS12359

08:14 AM

RECUSAL: J. TRIFONE 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 8/3/2020, an application for a change of MOR dated 7/21/2020 was received with the proposed MOR as Pharmacist Nguyen who was issued an emergency authorization to practice as a pharmacist in MA on 5/27/2020. The application included a statement indicating Former MOR Jesinkey’s last day was on 3/26/2020 and Interim MOR Alves’ last day was 05/14/2020. No change in MOR application was submitted for Interim MOR Alves.
- DM Knight responded that Pharmacist Nguyen was hired internally and was transferring from TX. DM Knight indicated that the emergency order did not specifically prohibit pharmacists licensed pursuant to the emergency order from being MOR and on-boarded him as MOR of the Pharmacy starting 6/17/2020 after that license was issued. Once DM Knight was made aware Pharmacist Nguyen could not be MOR, MOR Duong assumed the position on 8/17/2020.
- After Interim MOR Alves left employment at the Pharmacy, there was no interim MOR in place for 95 days. MOR Duong’s application for a change of MOR listed Former MOR Jesinkey as the outgoing MOR whose last day of employment was 136 prior on 4/3/2020.
- MOR Duong indicated that any future proposed MOR at the Pharmacy will be reminded to fully complete and submit the “Application for Change in Manager of Record”. DM Knight stated that in the future when starting a new MOR, she will require they send her a copy of their application for MOR so she can confirm completion.

ACTION: Motion by T. Fensky, seconded by S. Hamilton, and voted unanimously by those present, to CLOSE the matter (SA-INV-16700), No Discipline Warranted and send a custom advisory about the importance of naming an interim Manager immediately, going forward. C. Jean-Francois was not present for the vote.

Case #2

SA-INV-16684

Pharmscript, DS90251

Time: 08:48 AM

RECUSAL: NONE

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

- RLCS of 30mL morphine sulfate 20mg/mL from an E-kit at a LTCF discovered on 7/15/2020 and a loss of #2 lorazepam 0.5mg tablets from an E-kit at the same LTCF on or about 8/9/2020. Both losses were realized during the replenishment and reconciliation of the E-kit after return to the Pharmacy.
- On 7/15/2020, CPhT James noticed two 15mL bottles of morphine sulfate 20mg/mL were leaking in the E-kit and notified Pharmacist Kim and MOR Gancarz. The shrink-wrap on the bottles for tamper deterrence had been peeled away then covertly tucked back over the caps. When the caps were removed, MOR Gancarz noticed a needle-sized hole in the manufacturer seals that was allowing the contents to gradually drip out. Additionally, the contents appeared diluted (lighter blue when compared to a stock bottle). The LTCF was notified. The internal investigation did not identify any deficiency in the Pharmacy's processes or diversion during transit. A review of the Pharmacy's security footage of the controlled substance room showed no evidence of diversion during the replenishment of the E-kit with the morphine sulfate oral solution loss. MOR Gancarz concluded the diversion likely occurred at the LTCF. The Pharmacy does not repackage morphine sulfate 20mg/mL into an individually packaged, single dose form.
- On 8/12/2020, CPhT James discovered #2 lorazepam 0.5mg tablets were removed without authorization from an E-kit at the same LTCF and was documented as "popped in error" on 8/9/2020. She reported it to Pharmacist Szydlik. Documentation provided showed 4 authorized withdrawals of oxycodone 5mg tablets. MOR Gancarz indicated that although an authorized withdrawal of oxycodone and the removal of the lorazepam occurred for the same patient on 08/09/2020 at 10:52PM, the handwriting, nurse's signature, and prescriber's name appear different. The LTCF was notified and MOR Gancarz discussed the loss with DCP. Initially the LTCF stated documentation for the destruction of the lorazepam tablets would be provided but later admitted no documentation existed. MOR Gancarz reported both losses to the local police department since the LTCF failed to do so.
- The LTCF was provided a "tackle box" E-kit with two serialized tags to reseal the E-kit after removal of a medication. The E-kit is allegedly double locked within a locked narcotic box located in a locked medication cart located on the primary nursing floor. Only authorized LTCF nursing staff are allowed access to the medication carts and locked narcotic boxes. After the lorazepam loss, the [LTCF] was provided with 4 additional yellow serialized tag for the E-kit that are documented when used on the inside of the E-kit.
- CA: The Pharmacy intends to implement the use of automated dispensing machines for emergency-controlled substances in all serviced facilities which will allow for tighter accountability and security of controlled substances. Once completely implemented, controlled substances will no longer be stored in "tackle box" E-kits. MOR Gancarz indicated that the pandemic has delayed the implementation of use due to restricted access at the LTCF.

ACTION: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously by those present, to CLOSE the matter (SA-INV-16684), No Discipline Warranted, Remediation Complete, and have the DS maintain the previous practice of shrink wrapping the product, as well as refer to DCP for review *Circular Letter: DHCQ 18-6-679* for "Controlled Substances in Schedule II-V Approved for Inclusion in Long Term Care Facility Emergency Kits".

Case #3

RECUSAL: S. HAMILTON and P. GANNON 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.

- Pharmacist allegation that Cornerstone Health Solutions (CHS) pharmacy interns failed to maintain patient confidentiality.
- Pharmacist indicated that she received a phone call to transfer out a prescription from her pharmacy allegedly from a pharmacy intern calling from her cell phone working from home.
- MOR Phung indicated that the CHS interns were reaching out to at-risk Boston Medical Center Health Plan (BMCHP) patients to reduce exposure to COVID-19 to offer mail order service as an option. She indicated that they had pharmacy interns working remotely to help support the volume of incoming requests to transfer patients to mail order pharmacy services.
- Pharmacy interns contacted pharmacies via encrypted, HIPAA compliant software and requested that the prescriptions be transferred directly to CHS via fax. She indicated that no patient information was sent to an intern's home.
- APPE rotation students were contacted. The pharmacy interns were asked about their interaction with their assigned preceptor and if there was direct preceptor supervision. There were 5 interns who indicated that they had remote supervision with their preceptor via zoom, email, phone calls and messages.
- The Attorney indicated that the pharmacy interns did not contact patients but rather only provided the patient's medication list to the pharmacies while requesting a transfer. The interns had scripts that they read from to contact pharmacies with a request to fax the transferred prescriptions to a pharmacist at CHS.
- The Attorney for CHS responded that the pharmacy interns were supervised by and interacted regularly with an assigned preceptor via email, phone and group discussions. When the assigned preceptor was not available, other supervising pharmacists were available via email, phone and meetings. He indicated that the pharmacy interns were working remotely due to the pandemic while conducting assigned activities related to the project. The Attorney indicated that the supervisory ratio of pharmacist to pharmacy intern during this remote program was 4 pharmacists to 13 pharmacy interns.

ACTION: Motion by L. GIAMBARRESI, seconded by A.STEIN, and voted unanimously by those present, to CLOSE the matter (SA-INV-16401), No Discipline Warranted, and clarify in the closing letter the requirements of the Board's Advisory on "*...Pharmacy Intern Direct Supervision*". Additionally, Board members requested a response from the 3 interns who were contacted as part of this investigation, explaining why they did not provide a response to this investigation.

Stephanie Hernandez, Pharm D, BCGP, RPh (leaves: 9:30 AM)

Topic VIII
Read by K. Tanzer

EXECUTIVE SESSION

Time: 9:30 AM

DISCUSSION:

ACTION: At 9:30 AM President K. Tanzer read the statement on reasons for Executive Session.

Topic VIII: Executive Session

A. Call to Order #1:

Time: 9:30 AM

By: K. Tanzer

ACTION: Motion by L. Giambarresi, seconded by P. Gannon, 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. Hernandez, yes;
D. Perry, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; P. Gannon, yes; J. Lanza, yes;
L. Giambarresi, yes; R. Lopez, yes; T. Fensky, yes.

Julie Lanza, CPhT, President Elect (arrives 8:15 AM; leaves 10:00 AM)

Topic VIII: Executive Session

B. Call to Order #2:

Time: 10:17 AM

By: K. Tanzer

ACTION: Motion by L. Giambarresi, seconded by P. Gannon, 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. Hernandez, yes;
D. Perry, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; P. Gannon, yes; J. Lanza, yes;
L. Giambarresi, yes; R. Lopez, yes; T. Fensky, yes.

Topic X: M.G.L. 65 C #1

Time: 9:36 AM

A. Call to order #1

DISCUSSION: None

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

At 9:36 AM S. Hamilton, seconded by J. Lanza and voted unanimously by all those present to enter M.G.L. chapter 65 c Session by roll call vote.

Topic X:

M.G.L. 65 C #1

Time: 10:37 AM

B. Call to order #2

DISCUSSION: None

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

At 10:37 AM P. Gannon, seconded by S. Hamilton and voted unanimously by all those present to enter M.G.L. chapter 65 c Session by roll call vote.

Dawn Perry, JD (Leaves: 10:38 AM)

Susan Cornacchio, JD, RN (Leaves 10:42 AM)

Topic XI

ADJOURNMENT OF MEETING

TIME: 11:11 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 10/29/20 General Session
2. Draft Minutes of the 10/9/20 Meeting
3. Applications: GE Healthcare, WD446/Radioisotope Life Science-Transfer of Ownership
4. Applications: SOFIE, NU00021, Renovation
5. Policy 2020-05: Proper Storage of Refrigerated and Frozen Medications
6. Policy 2018-06: Retail Pharmacy Participation in Research Drug Studies
7. Policy 18-02: Retail Pharmacy Participation in Research Drug Studies
8. Pharmacy Advisory Committee Recommendation Document 20-02
9. SA-INV-16700 Walgreens #1847; DS1359
10. SA-INV-16684 Pharmscript, DS90251
11. SA-INV-16401 Cornerstone Health Solutions, DS90083

Respectfully Submitted,
Leah Giambarresi, PharmD, RPh, Secretary