

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

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

September 11, 2020

Webex Information

Call in Number: 1-203-607-0564 or toll free 1-866-692-3580
Access Code: 171 428 5047
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													
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 August 28, 2020 Regular Session Minutes 														
8:20	IV	FLEX <ul style="list-style-type: none"> • Pharmacy issues related to Covid-19 and the state of emergency 														
8:30	V	POLICIES <ul style="list-style-type: none"> • Policy 2020-10: Pharmacist Continuing Education (CE) Requirements • Policy 2020-11: Vaccine Administration 		M. Chan												
8:40	VI	FILE REVIEW <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20px; text-align: center;">1</td> <td style="width: 30%;">SA-INV-16188</td> <td>Daniel Lynch Pharmacy, DS1994</td> </tr> <tr> <td style="text-align: center;">2</td> <td>SA-INV-16189</td> <td>Skenderian Apothecary, DS1058</td> </tr> <tr> <td style="text-align: center;">3</td> <td>PHA-2019-0114</td> <td>Stop & Shop #416, DS3440</td> </tr> <tr> <td style="text-align: center;">4</td> <td>PHA-2020-0045</td> <td>Walgreens #9405, DS3475</td> </tr> </table>	1	SA-INV-16188	Daniel Lynch Pharmacy, DS1994	2	SA-INV-16189	Skenderian Apothecary, DS1058	3	PHA-2019-0114	Stop & Shop #416, DS3440	4	PHA-2020-0045	Walgreens #9405, DS3475		
1	SA-INV-16188	Daniel Lynch Pharmacy, DS1994														
2	SA-INV-16189	Skenderian Apothecary, DS1058														
3	PHA-2019-0114	Stop & Shop #416, DS3440														
4	PHA-2020-0045	Walgreens #9405, DS3475														
9:00	VII	M.G.L. c. 112, § 65C SESSION		Closed Session												
10:00	VIII	ADJOURNMENT														

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

MINUTES OF THE GENERAL SESSION

Meeting held via WEBEX remotely

Boston, Massachusetts, 02114

September 11, 2020

Board Members Present

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

Board Members Not Present

Patrick Gannon, RPh
Carly Jean-Francois, RN, NP

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, CPhT, Associate 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 Pharmacy Investigations
Joanna Chow, CPhT, Office Support Specialist
Julienne Tran, Pharm D, RPh Investigator
Christina Mogni, RPh investigator
Gregory Melton, JD, PharmD, RPh, Investigator
Cheryl Lathum, PharmD, RPh, Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:01 AM

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

Roll call attendance: K. Tanzer, yes; J. Lanza, yes; S. Hernandez (yes); D. Perry, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; A. Stein, yes; R. Lopez, yes; K. Thornell, yes; T. Fensky, yes.

Topic II.

Approval of Agenda

TIME 8:02 AM

Agenda September 11, 2020

DISCUSSION:

Change to Agenda:
none

ACTION:

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

Topic III

Approval of Board Minutes

TIME: 8:03 AM

Minutes

1. Draft, August 28, 2020 Session Minutes

No noted Changes.

Action:

Motion by L. Giambarresi, seconded by T. Fensky and voted unanimously by those present by roll call vote to approve the minutes with no noted change.

TOPIC IV

Flex

1. Pharmacy issues related to COVID-19 and the state of emergency Time: 8:05 AM

Presented by: D. Sencabaugh

Discussion:

The only updates for today will be covered in the two policies to be presented to the board. These policies were created to align with the HHS Prep Act. The Board is currently working on policy concerning COVID testing by pharmacists and certified pharmacy technicians to administer vaccinations.

Action: So noted

TOPIC V

Policies

1. Policy 2020-10 Pharmacist Continuing Education (CE) Requirements. Time: 8:06 AM

Presented by: M. Chan

Discussion:

The main change to this policy is that pharmacists will now be required to have 2 CEs for immunization per cycle. This policy will be effective immediately and require that practicing pharmacists who administer immunizations get an 1 additional CE by December 31, 2020.

Action: Motion by T. FENSKY, seconded by S. HAMILTON, and unanimously approved by those present by roll call vote to approve the policy.

2. Policy 2020-11: Vaccine Administration

Time: 8:06 AM

Presented by: M. Chan

Discussion:

Revisions were made to the immunization policy in response to the new HHS declaration under the PREP act that allows pharmacists and interns to immunize children as young as 3 years old.

HHS has made certain mandates to provide immunity from liability when vaccinating children from 3-9 years and the policy has been aligned with those requirements. Some of the revisions include changing the terminology of “pharmacist and intern” to “qualified pharmacy personnel” in the case that technicians will eventually be permitted to immunize. Additionally, ACPE accredited training courses will be required which is stricter than the current policy that allows certain non-ACPE accredited courses.

Immunization training is now required to be ACPE approved for pharmacy personnel to administer vaccines to children less than 9 years of age. Pharmacy personnel who have received other training can still administer to those 9 years of age and above. The CPR certification is now a requirement for pharmacists. It is still the decision of the individual administering the vaccine who they are comfortable giving a vaccination. Of note, pharmacist administration of COVID-19 vaccines will be addressed in a separate future policy.

Action: Motion by T. FENSKY, seconded by S. HAMILTON, and unanimously approved by those present by roll call vote to approve the policy.

TOPIC VI

FILE REVIEW

Case #1

SA-INV-16188

Daniel Lynch Pharmacy, DS1994

Time: 08:13 AM

RECUSAL: NONE

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

- On February 13, 2020, OPP Investigators accompanied DEA to Daniel L. Lynch Pharmacy on a site visit (ISP-14056) as part of a DEA investigation into standard of practices of an unidentified healthcare practitioner. OPP investigators supported DEA in a professional capacity to ensure patients were not negatively impacted during the visit.
- Significantly, DEA indicated that Daniel L. Lynch Pharmacy involvement in the investigation as incidental. Specifically, Daniel L. Lynch Pharmacy dispensed prescriptions issued by the unidentified healthcare practitioner which were of evidentiary value to DEA. DEA indicated that no criminal activity was uncovered at the pharmacy and no further action was taken upon completion of the site visit.

ACTION: Motion by L. GIAMBARRESI, seconded by A. STEIN, and voted unanimously by those present, to CLOSE the matter (SA-INV-16188), Insufficient Evidence.

Case #2

SA-INV-16189

Skenderian Apothecary, DS1058

Time: 08:15 AM

RECUSAL: NONE

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

- On February 13, 2020, OPP Investigators Richard Geaney and John Murray accompanied DEA to Skenderian Apothecary on a site visit (ISP-14057) as part of a DEA investigation into standard of practices of an unidentified healthcare practitioner. OPP investigators supported DEA in a professional capacity to ensure patients were not negatively impacted during the visit.
- DEA indicated that Skenderian Apothecary's involvement in the investigation was incidental. Specifically, Skenderian Apothecary dispensed prescriptions issued by the unidentified healthcare practitioner which were of evidentiary value to DEA. DEA indicated that no criminal activity was uncovered at the pharmacy and no further action was taken upon completion of the site visit.

ACTION: Motion by L. GIAMBARRESI, seconded by J. LANZA, and voted unanimously by those present, to CLOSE the matter (SA-INV-16189), Insufficient Evidence.

Case #3

PHA-2019-0114

Stop & Shop, DS3440

Time: 08:16 AM

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

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

- S&S #416 reported an unknown loss of 100 buprenorphine 8mg sublingual tablets discovered on 10-8-2019. However, S&S #416 later determined that no loss occurred and retracted the report of an unknown loss.
- S&S #416 explained in the retraction that a "1" was missed during data entry on a prescription issued and filled for 120 buprenorphine 8mg sublingual tablets. Instead, the quantity recorded as dispensed was 20 causing what was initially interpreted as an unknown loss.

ACTION: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0114), No Violation.

Case #4

PHA-2020-0045

Walgreens #9405, DS3475

Time: 08:18 AM

RECUSAL: NONE

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

- On 06/11/2020, the Pharmacy submitted an untimely, inaccurate RLCS for an unknown loss of #82 oxycodone 5 mg tablets allegedly discovered on 5/30/2020 during the reconciliation of the perpetual inventory.
- All documentation provided in the response indicated the discrepancy was for 93 tablets despite MOR Faustino stating that the internal investigation determined one prescription for oxycodone 5 mg tablets was logged incorrectly resulting in a discrepancy of 82 tablets instead of 93 tablets. The discrepancy was actually identified initially on 5/3/2020 and carried over weekly until 5/31/2020. Additionally, the electronic perpetual inventory was documented as reconciled on 4/26/2020 with the next documented reconciliation on 5/31/2020 (35 days). CII weekly count inventory sheets were provided showing additional discrepancies with no reconciliation of those discrepancies i.e. prescriptions dispensed during the count.
- MOR Faustino stated invoices, the perpetual inventory and security camera footage were reviewed but were inconclusive. MOR Faustino indicated patients who had been dispensed oxycodone 5mg tablets were contacted but none reported an over-dispensing. The loss was suspected to be due to accidental disposal of an open bottle of oxycodone 5mg tablets, but theft could not be ruled out.
- CA: All controlled substance policies and procedures and SOPs for filling were reviewed with the pharmacy team to ensure the proper quantity is dispensed for all CII prescriptions including CII prescriptions must be logged into the perpetual inventory promptly after dispensing; all CII prescriptions must be double counted by the pharmacist if it was filled by a certified pharmacy technician; and CII stock bottles be immediately returned to the CII safe. If the time-delay is enabled on the safe, the CII stock bottle must be kept in view at the pharmacist's station until it can be put back. The electronic perpetual inventory will be checked regularly to ensure prescriptions were logged accurately. Additionally, pharmacy staff were encouraged to back count CII bottles as a secondary check for accuracy of the perpetual inventory.

ACTION: Motion by L. GIAMBARRESI, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2020-0045), 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.

Topic VII

M.G.L. 65 C

Time: 8:22 AM

K. Tanzer announces the open session is complete and the Board of Pharmacy will be entering M.G.L. 65C session which is private.

Topic VII:

M.G.L. 65 C #1

Time: 8:22 AM

DISCUSSION: None

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

At 8:22 AM L. Giambarresi, seconded by A. Stein and voted unanimously roll call vote by all those present to enter M.G.L. chapter 65 c Session.

Topic VIII

ADJOURNMENT OF MEETING

TIME: 9:58 AM

ACTION: Motion by L. Giambarresi seconded by S. Hamilton and voted unanimously by roll call vote of those present, to adjourn from General Session.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 9/11/20 General Session
2. Draft Minutes of the 8/28/20 Meeting
3. Policy 2020-10 Pharmacist Continuing Education (CE) Requirements
4. Policy 2020-11: Vaccine Administration
5. SA-INV-16188 Daniel Lynch Pharmacy, DS1994
6. SA-INV-16189 Skenderian Apothecary, DS1058
7. PHA-2019-0114 Stop & Shop #416, DS3440
8. PHA-2020-0045 Walgreens #9405, DS3475

Respectfully Submitted,
Leah Giambarresi, PharmD, RPh, Secretary