

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

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

June 12, 2020

Webex Information

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

Access Code: 161 177 2140

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"> • Draft of June 5, 2020 Regular Session Minutes 		
8:40	IV	REPORTS <ul style="list-style-type: none"> • Applications approved pursuant to Licensure Policy 13-01 • Monthly report from probation • Board Delegated Review pursuant to Licensure Policy 14-02 • PSUD Report-Policy 17-03 		
8:45	V	POLICIES and ADVISORIES <ul style="list-style-type: none"> • Advisory on Remediation Considerations for Handling Above Action Level Environmental Monitoring (EM) Results 		W. Frisch M. Chan

9:00	VI	APPLICATIONS <ul style="list-style-type: none"> • Genoa Healthcare(Chelsea)- New Pharmacy • Hamilton Pharmacy – New Pharmacy 														
9:45	VII	FLEX <ul style="list-style-type: none"> • Pharmacy issues related to Covid-19 and the state of emergency <ul style="list-style-type: none"> ➤ Pharmacist Scope of Practice Expansion with COVID-19 Issues • Advisory Committee (PAC) Recommendation Document 20-01 														
10:00	VIII	FILE REVIEW <table border="1"> <tr> <td>1</td> <td>PHA-2020-0013</td> <td>Walgreens #11119, DS89657</td> </tr> <tr> <td>2</td> <td>SA-INV-16399</td> <td>Lynn Patsis, PH234839</td> </tr> <tr> <td>3</td> <td>PHA-2019-0105</td> <td>CVS #4471, DS3552</td> </tr> <tr> <td>4</td> <td>PHA-2020-0019</td> <td>Plainville Prescription Center, DS1584</td> </tr> </table>	1	PHA-2020-0013	Walgreens #11119, DS89657	2	SA-INV-16399	Lynn Patsis, PH234839	3	PHA-2019-0105	CVS #4471, DS3552	4	PHA-2020-0019	Plainville Prescription Center, DS1584		
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3	PHA-2019-0105	CVS #4471, DS3552														
4	PHA-2020-0019	Plainville Prescription Center, DS1584														
10:20	IX	ADJUDICATORY SESSION (M.G.L. ch. 30A, §18)														
10:30	X	ADJOURNMENT														

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

MINUTES OF THE GENERAL SESSION

Meeting held via WebEx remotely

Boston, Massachusetts, 02114

June 12, 2020

Board Members Present

Kim Tanzer, PharmD, RPh. President
Julie Lanza, CPhT, President Elect
Sebastian Hamilton, Pharm D, RPh
Carly Jean-Francois, RN, NP
Leah Giambarresi, Pharm D, RPh, Secretary
Dr. Richard Lopez, MD
Katie Thornell, RPh
Patrick Gannon, RPh
Susan Cornacchio JD, RN
Timothy Fensky, RPh
Stephanie Hernandez, Pharm D, BCGP, RPh
Andrew Stein, Pharm D

Board Members Not Present

Dawn Perry, JD

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
Richard Geaney, RPh Investigator
Leo McKenna, RPh Investigator

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; A. Stein, yes; S. Hernandez, yes; Carly Jean-Francois, no response

**Topic II. Approval of Agenda
Agenda June 12, 2020**

TIME 8:31 AM

DISCUSSION:

Change to Agenda:

- No draft minutes for 6/5/20 Board

ACTION:

Motion by S. P. GANNON, seconded by T. FENSKY and voted unanimously by those present to approve the agenda with the changes.

Topic III.

Approval of Board Minutes

TIME

No minutes to approve.

ACTION:

TOPIC IV

REPORTS2

TOPIC IV

Reports

Applications approved pursuant to Licensure Policy 13-01

Time: 8:32 AM

Discussion: M. BOTTO reported Change of Manager applications, Renovation applications, and New Community Pharmacies applications approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:33 AM

Discussion: M. Botto reviewed the Probation report.

So noted

TOPIC IV

REPORTS

Monthly Report from BDR pursuant to Policy 14-02

Discussion: no report at this time.

So noted

TOPIC IV

REPORTS

Above Action Levels Approved by Staff Action 16-04

Discussion: no report at this time.

So noted

TOPIC IV

REPORTS

PSUD Report by Staff Action 17-03

Time: 8:33 AM

Discussion: E. TAGLIERI reviewed the PSUD report.

So noted

TOPIC V

Policies and Advisories

1. Advisory on Remediation Considerations for Handling Above Action Level Environmental Monitoring (EM) Results

Time: 8:34 AM

Presented by: M. CHAN

Recusal: None

Discussion: A general overhaul was made to the *Advisory on Remediation Considerations for Handling Above Action Level Environmental Monitoring (EM) Results*. The language was changed to be consistent with the policy on *Sterile Compounding Pharmacy Response to Above Action Level Environmental Monitoring Results* that was converted from an advisory last November. The conversion of that advisory to policy changed some recommendations to mandates.

P. GANNON asked Board staff to clarify the use of the pronoun “it” throughout the document.

Action: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously by roll call by those present to approve the *Advisory on Remediation Considerations for Handling Above Action Level Environmental Monitoring (EM) Results* with requested edits.

TOPIC VI

Applications

1. Hamilton Pharmacy

Time: 8:39AM

Represented by: Marjan Mottaghi, MOR

Recusal: Leah

Discussion:

K. Tanzer asked Ms. Mottaghi, MOR to give the Board an overview of what happened to the pharmacy Phoenix Pharmacy application that was approved approximately two years ago. Ms. Mottaghi stated unfortunately it never opened due to health and financial problems. Ms. Mottaghi was notified by the Board that due to the time lapse of approximately 2 years she would need to reapply for a new Pharmacy license.

Ms. Mottaghi stated that she is applying for a new Store License that will be located at the same location on the corner of Hamilton and Bowden St. Dorchester, MA., with a new name of Hamilton Pharmacy.

K. Tanzer stated the square footage of the pharmacy was within the regulatory requirements and asked Ms. Mottaghi to explain the pharmacy location and if apartments are located above the store and what security systems are in place at the pharmacy.

Ms. Mottaghi stated it is a standalone building with two apartments above the pharmacy and the pharmacy is alarmed with eight security cameras with in the pharmacy.

K. TANZER asked if Ms. Mottahi is planning on providing immunizations, specialty packaging and whether or not she has functioned as a Manager of Record (MOR).

MS Mottaghi replied she would be providing immunizations and specialty packaging and stated additionally that she has not been a MOR.

K. Tanzer recommended that Ms. Mottaghi review the New Manager of Record guidance on the Board's website and inquired about the pharmacy plans for staffing and plans on how the pharmacy would serve patients after hours.

Ms. Mottaghi stated that the pharmacy will be open 80 hours a week and it will be shared with another pharmacist for a total of 40 hours each. The pharmacy will service patients after hours by means of the Pharmacy website. Additional pharmacists will be hired as pharmacy becomes profitable. Initially there will be one pharmacy technician and Ms. Mottahi understands that the pharmacy technician will have a technician in training license before coming into the pharmacy and the pharmacy technicians will be certified. Hamilton Pharmacy plans to set up a virtual technology available to pharmacy's after hours which, has the capacity to provide facetime with patients and email correspondence. In addition, there will be a delivery provision and is currently investigating the local delivery systems and ensure the delivery person is vetted and that each delivery is completed.

K. Tanzer asked for clarification of the pharmacy's plans for compounding. Because the application checked off simple and compounding.

Ms. Mottaghi indicated that the pharmacy would be doing simple compounding with no plans for complex compounding. Note: The application will be amended to reflect simple compounding.

Action: Approve after a successful inspection

Motion: Sebastian

Second: Patrick

Vote: Julie, Andrew, Sebastian, Dr. Lopez, Katie, Patrick, Susan, Tim, Carly, Stephanie, Kim

2. Genoa Healthcare (Chelsea) New Community Pharmacy

Time: 8:53 AM

Represented by: Jason Kan, MOR
Kevin O’Connell, Director of Operations

Recusal: Leah

Discussion:

K. Tanzer: asked Mr. O’Connell if they were here for a new Genoa Pharmacy in Chelsea with the usual Genoa Waivers.

K. O’Connell: replied “Yes” with one amendment to the waivers on 247 CMR 901:16 related to limited need general public clause updated with Monica and a waiver for the right to refuse general compounding.

K.Tanzer: Are there additional questions from the Board members. I hear a motion from the Board to approve.

P. Gannon: Made a motion to approve after a successful inspection.

Jean-Francois: Second the motion

Role Call:

Action: Motion by P. GANNON ,

Seconded: Jean- Francois, and voted unanimously by roll call by those present.

Vote: Unanimously by roll call

TOPIC VII

Flex

Time: 8:56 AM

1. Pharmacist Scope of Practice Expansion with COVID-19 Issues

Presented by: D. SENCABAUGH, W. FRISCH

Recusal: None

Discussion: A memo was presented to expand the pharmacist’s scope of practice to include ordering and testing for COVID-19 as well as the administration of investigational COVID-19 vaccines.

Implementation of this scope of practice change would be contingent on further Board guidance if the Board votes to accept it.

D. SENCABAUGH stated that Board staff are researching this and understand that pharmacists can and want to be a part of testing, not just observe. However, this is something that has not historically been viewed as within the of scope of pharmacist practice.

P. GANNON asked whether FDA approved vaccines could be added. W. FRISCH mentioned that FDA approved vaccines will likely be added to the ACIP guidelines and pharmacists are able to administer vaccines on that list. L. GIAMBARRESI stated that there is usually a lag before an FDA vaccine is added to the ACIP guidelines.

The interpretation of results was discussed, but the definition of “interpret” was deemed to be too broad in this scenario.

Action: Motion by S. CORNACCHIO, seconded by A. Stein, and voted unanimously by roll call by those present (except by D. PERRY who did not respond) to expand the scope of practice for pharmacists and

pharmacy interns to include ordering, administration, reading, and reporting of authorized COVID-19 tests. Also approved was to allow the administration of FDA approved and investigational COVID-19 vaccines.

2. Advisory Committee (PAC) Recommendation Document 2001

Presented by: E. TAGLIERI, W. FRISCH

Recusal: None

Discussion: The recommendation document is to have the Advisory Committee provide input for various documents for future Board consideration. A June 24 meeting with the Advisory Committee is planned and input is requested for a scope of practice advisory. Also needed is a Board member to be present for the meeting.

Discussions included expanding the pharmacist's role in Medication Assisted Treatment. W. FRISCH discussed that this advisory is to review activities that are already considered part of the scope of practice.

Action: Motion by L. GIAMBARRESI, seconded by A. STEIN, and voted unanimously by roll call by those present (except by J. LANZA, R. LOPEZ, and D. PERRY who did not respond) to approve the recommendation document requesting the Advisory Committee's input for a scope of practice advisory as well as for T. FENSKY to be the Board liaison at the Advisory Committee meeting.

TOPIC VIII

FILE REVIEW

Case #1

PHA-2020-0013

Walgreens #11119, DS89657

Time: 9:58 AM

RECUSAL: NONE

DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to these matters.

- RLCS- a loss of #60 d-amphetamine salt combo 30mg tablets occurring on or about December 22, 2019 due to an unknown loss.
- MOR Richardson indicated that he completed the following: ensuring all prescriptions were logged correctly in the perpetual inventory, checked all areas in the pharmacy to ensure that the medication bottle was not misplaced, personally called all the patients that received the medication in the week prior to verify possible mis fill, verified that all prescriptions dispensed matched the perpetual inventory, reviewed video footage at various times to see if there was an error that may have occurred, checked in the prescription bins to ensure that an old prescription was not filled or in the system for too long and the medication could not be located. M
- MOR Richardson noted that the perpetual inventory for the week ending December 25, 2019 was accurate with no missing inventory.
- MOR Richardson indicated that the video footage did not reveal anything unusual.
- MOR Richardson stated, "Since the incident the pharmacy has counted the significant loss drug daily at the end of the day to continue to track it, continued to make sure only pharmacists are counting CII medications, practicing better methods of filling a CII medication and immediately placing it back in the safe, as well as continuing to follow Walgreens/State policy of weekly CII inventory counts with no missing inventory."

ACTION: Motion by T. FENSKY, seconded by L. GIAMBARRESI, and voted unanimously by those present, to refer the matter (PHA-2020-0013), 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

SA-INV-16399

Lynn Patsis, PH234839

Time: 10:00 AM

RECUSAL: NONE

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

- Repeat CE deficiency: The Licensee reported on 04/23/2020 that she realized she was deficient for her 2019 CEs. The Licensee stated 4.25 CEs completed were not ACPE accredited for pharmacists in Massachusetts. The Licensee indicated that she is also licensed in Texas. The Licensee apologized for the misunderstanding on her part.
- CA: A review of the Licensee's CPE Monitor e-Profile showed remediation on 4.5 CEs as of 03/15/2020. The Licensee indicated she understood any CEs completed for remediation do not count for her 2020 CE requirements.

ACTION: Motion by L. GIAMBARRESI, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to CLOSE the matter (SA-INV-16399), No Discipline Warranted, Remediation Complete.

Case #3

PHA-2019-0105

CVS #4471, DS3552

Time: 10:04 AM

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

DISCUSSION: R. GEANEY presented and summarized the investigative report that pertained to these matters.

- OPP received notification that they had a loss of #496 tramadol 50mg tablets on or about July 15, 2019 and #90 oxycodone 10mg tablets on or about October 16, 2019
 - DL Miklasiewicz indicated that the loss of the tramadol 50mg was discovered via corporate controlled substance monitoring. The cause of the loss is unknown at this time
 - DL Miklasiewicz indicated that the loss of the oxycodone 10mg was discovered on September 19, 2019 and reported by the prior pharmacy manager. A prescription could not be located in the waiting bin and after searching for the prescription with no luck the pharmacy re-dispensed the medication. It is suspected that the patient was given the prescription twice, however the patient denied having received a duplicate prescription
 - DL Miklasiewicz noted that during this investigation the Former MOR Roxo was on suspension and terminated on or about October 10, 2019 for unrelated issues. Former MOR Roxo was the MOR during the 2018/2019 biennial counts and responsible for their completeness. A new MOR has since been appointed. All loss prevention policy and procedures, including diligent inventory management has been reviewed with the new MOR and pharmacy team to prevent future losses.
-

ACTION: Motion by T. FENSKY, seconded by L. GIAMBARRESI, and voted unanimously by those present, to refer the matter (PHA-2019-0105), 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 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.

Case #4

PHA-2020-0019

Plainville Prescription Center, DS1584

Time: 9:34 AM

RECUSAL: NONE

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

- Inspectional Deficiencies from a retail inspection (ISP-13970) conducted on 01/21/2020 included perpetual inventory not available/complete; CII biennial inventory not available for review; CIIs not entered into the perpetual inventory on the date received; no temperature monitoring while drugs are stored in the refrigerator; no entries in the temperature log since March 2019.
- The same controlled substance recordkeeping deficiencies were previously cited on 02/28/2018 and 01/08/2019. A Plan of Correction (POC) was not submitted. Of note, the Pharmacy was on probation from 1/4/16 to 1/3/18 for failure to remediate inspectional deficiencies.
- A follow-up site visit (ISP-14151) was conducted on 2/25/2020 with continued deficiencies observed including no perpetual inventory reconciliations or refrigeration temperature log entries since the last inspection in January 2020 and no CII biennial inventory available. A POC was requested to include all deficiencies cited on 1/21/2020 and 2/25/2020.
- On 03/30/2020, notification was received that Owner/MOR Stanley had engaged an Attorney to provide a response to the complaint. After granting multiple requests for extensions for a response, on 05/11/2020 the Attorney submitted an email notification stating that due to an irretrievable breakdown in the attorney – client relationship, he no longer represented the Pharmacy. MOR Stanley was provided the opportunity to respond.
- On 5/14/2020, MOR Stanley provided a POC only which indicated the 2018 perpetual inventory had been located and will be updated to include the date CIIs are received, the daily recording of refrigerator temperature will be policy, and a daily temperature log will be kept current. A complaint was opened for MOR Stanley. On 6/3/2020, a second site visit (ISP-14329) was performed at which time MOR Stanley indicated that she would be transferring her specialty packaging patients to another pharmacy and is attempting to sell her business.
- CA: As of March 2020, the perpetual inventory will be kept in the records box, the perpetual inventory will be kept current, and the record of refrigerator temperatures will be monitored daily.

ACTION: Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously by those present, to refer the matter (PHA-2020-0019), 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 PROBATION for a period of 2 years, with special terms to include, current MOR can no longer serve as MOR and a new MOR must be in place within 30 days.

Topic IX

EXECUTIVE SESSION

No executive session

Topic X:

Adjudicatory Session (M.G.L. ch 30A § 18)

Time: 10:09 AM

DISCUSSION: None

ACTION: President K. Tanzer request a motion to enter Adjudicatory Session.

At 10:09 AM L. Giambarresi, seconded by T. Fensky and voted unanimously by all those present to enter Adjudicatory Session:

Topic XI:

M.G.L. 65 C

No MGL 65C session

Topic XII

ADJOURNMENT OF MEETING

TIME: 10:10 AM

ACTION: Motion by T. Fensky seconded by L. Giambarresi, and voted unanimously by those present, to adjourn from General Session.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 6/12/20 General Session
2. Report on Applications approved pursuant to Licensure Policy 13-01
3. Report on probation
4. Report on PSUD Report-Policy 17-03
5. Advisory on Remediation Considerations for Handling Above Action Level Environmental Monitoring (EM) Results
6. Applications: Genoa Healthcare(Chelsea)- New Pharmacy
7. Applications: Hamilton Pharmacy – New Pharmacy
8. Pharmacist Scope of Practice Expansion with COVID-19 Issues
9. Advisory Committee (PAC) Recommendation Document 20-01
10. PHA-2020-0013: Walgreens #11119, DS89657
11. SA-INV-16399: Lynn Patsis, PharmD, RPh, PH234839
12. PHA-2019-0105: CVS Pharmacy #4471, DS3552
13. PHA-2020-0019: Plainville Prescription Center, DS1584

Respectfully Submitted,

Leah Giambarresi, PharmD, RPh, Secretary