

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

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

December 4, 2020

Webex Information

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

Access Code: 178 957 9534

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 November 20, 2020 Regular Session Minutes
8:10	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• Above Action Levels approved by Staff Action 16-04• PSUD Report-Policy 17-03
8:15	V	APPLICATIONS <ul style="list-style-type: none">• AllCare Plus Pharmacy LLC DS90322 - Waivers
8:25	VI	FLEX <ul style="list-style-type: none">• Pharmacy issues related to Covid-19 and the state of emergency• Nov. Pharmacy Advisory Committee Meeting update

8:30	VII	FILE REVIEW	
		1	PHA-2020-0054 Rite Aid #10209, DS2899
		2	PHA-2020-0060 CVS #159, DS16605
		3	SA-INV-16891 Cardinal Health #414, NU11
9:00	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.	
9:30	IX	M.G.L. c. 112, § 65C SESSION	
10:30	X	ADJOURNMENT	

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

December 4, 2020

Board Members Present

Kim Tanzer, PharmD, RPh. President
Julie Lanza, CPhT, President Elect (left meeting 9:30 to 10:00 AM)
Leah Giambarresi, Pharm D, RPh, Secretary
Patrick Gannon, RPh
Sebastian Hamilton, Pharm D, RPh (leaves meeting 10:00 AM)
Dr. Richard Lopez, MD
Susan Cornacchio, JD, RN (leaves meeting at 9:00 AM)
Timothy Fensky, RPh
Katie Thornell, PharmD, RPh
Carly Jean-Francois, RN, NP (Leaves meeting at 10:05 AM)
Dawn Perry, JD

Board Members Not Present

Andrew Stein, PharmD

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
Christina Mogni, RPh Investigator
Gregory Melton, PharmD, JD, Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Joanna Chow, Office Support Specialist

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 AM

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

Roll call attendance: K. Tanzer, yes; J. Lanza, yes; K. Thornell, yes; D. Perry, yes; Dr. Lopez, yes; P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky yes.

Topic II.

Approval of Agenda

TIME 8:03 AM

Agenda December 4, 2020

DISCUSSION:

Change to Agenda:

1. none

ACTION:

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

Dave thanks K. Tanzer for her service this year and presents a gavel to memorialize the event.

Topic III

Approval of Board Minutes

TIME: 8:08 AM

Minutes

1. Draft 11/20/20

No noted Changes.

Action:

Motion by L. Giambarresi, seconded S. Hamilton, and voted unanimously to approve the regular session minutes of 11/20/20 with no changes by roll call vote. Gannon and Jean-Francois abstain.

TOPIC IV

REPORTS

Applications approved pursuant to Licensure Policy 13-01

Time: 8:09 AM

Discussion: R. HARRIS noted that all applications approved pursuant to Licensure Policy 13-01 are Change of Managers.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:09 AM

Discussion: R. HARRIS provided the October 20, 2020 – December 1, 2020, Board of Pharmacy Statistics Report for the Probation monitor, which noted that two (2) licensees satisfactorily completed probations and there are currently twenty-eight (28) licensees on probation.

So noted

TOPIC IV

REPORTS

Monthly Report from BDR pursuant to Policy 14-02

Time: 8:09 AM

Discussion: R. HARRIS noted that there were no Board Delegated Review cases heard prior to the meeting.

So noted

There is a separate DPH group that will determine allocation of COVID-19 vaccines to pharmacies. The Board will provide details as they become available.

So noted.

2. November 10, 2020 Pharmacy Advisory Committee Meeting update

TIME: 8:16 AM

PRESENTED BY: E. TAGLIERI

DISCUSSION:

At the second Pharmacy Advisory Committee Meeting of 2020, M. CHAN and W. FRISCH reviewed an initial draft of a non-sterile compounding advisory. Among other suggestions, the Committee recommended to review the FDA's guidance on insanitary conditions.

So noted

TOPIC VII

FILE REVIEW

Case #1

PHA-2020-0054

Rite Aid #10209, DS2899

Time: 08:18 AM

RECUSAL: NONE

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

- RLCS- loss of #100 oxycodone 10mg tablets on or about June 26, 2020 as a result of an unknown loss.
- The loss was discovered on June 26, 2020 during a routine dispensing. MOR Weisburgh indicated that he searched the dumpster on the day of the loss, without success. MOR Weisburgh stated patients were contacted who were dispensed the medication between June 16, 2020 through June 26, 2020 and no patients admitted to receiving extra tablets. He noted that the video footage was reviewed. The security cameras provided a view of the registers but was inconclusive. The counts of the drug were completed multiple times between June 26, 2020 through July 16, 2020 and 3 additional drugs did not show additional shortages.
- MOR Weisburgh indicated that the Loss Prevention Manager instructed him to conduct drug audits on the oxycodone 10mg tablets prior to the opening and after closing the pharmacy. The MOR indicated that he conducted these audits for about two weeks without any further discrepancies.
- MOR Weisburgh stated, "The pharmacy reviewed procedures for the accurate handling, dispensing and accountability of controlled drugs with the associates. Store will continue to follow policy and procedures in regard to the controlled substances handling and storage. Only the pharmacist will double count CII's; initial on the prescription label; and back count. A weekly control count will continue to be conducted to ensure the highest level of accuracy of controlled substance inventory in accordance with MA regulations."

- Rite-Aid Pharmacy #10209 had one prior loss on 11/20/19 – zolpidem 5mg tablets #10 – unknown loss.

ACTION: Motion by S. HAMILTON, seconded by P. GANNON, and voted unanimously by those present, to refer the matter (PHA-2020-0054), 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

PHA-2020-0060

CVS #159, DS16605

Time: 08:21 AM

RECUSAL: S. CORNACCHIO 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.

- Untimely RLCS submitted on 08/31/2020, reporting the loss of #473 lorazepam 0.5mg tablets identified via corporate controlled substance monitoring as a variance on 06/24/2020. Cycle counts, biennial inventories, staffing schedules and inventory reports were reviewed and the reason for the loss could not be determined. Security camera footage was not reviewed.
- MOR Phillips reported that end of day counts, which were performed each night by the pharmacist on duty, were initiated to ensure no further loss had occurred. The counts were reported to CVS Asset Protection for several weeks. MOR Phillips indicated that exact counts of CIII-CVs were performed for both the 2019 annual inventory and 2020 annual inventory and that all controlled substances are double counted by hand. The reconciliation report used to determine the loss showed the 2019 annual inventory was used as the start date despite having performed an exact count in 2019 and 2020 for all controlled substances.
- All loss prevention policies and procedures, including diligent inventory management, were reviewed with the Pharmacy team to prevent future losses (copy provided). MOR Phillips implemented a policy that only the pharmacist can perform cycle counts to decrease the chance of any future losses. During production, all CIII-CV controlled substances are hand counted twice and initialed by the Pharmacy team member and the pharmacist uses the visual verification tray to verify the tablets/capsules.

ACTION: Motion by L. GIAMBARRESI, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2020-0060), 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 a monthly exact count of all BENZODIAZEPINES 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 #3

SA-INV-16891

Cardinal Health #414, NU11

Time: 08:25 AM

RECUSAL: NONE

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

- During a Nuclear Compliance Inspection on 09/17/2020, Investigator Van Allen noted that the Pharmacy installed two BSCs in the WBC buffer room during the certification in January 2020 without notification to the BORP. EM was conducted after installation and prior to use. The previous certification from July 2019 did not include these BSCs on the floor plan.
- In the response, MOR Lamont contended that the installation of the two new BSCs did not meet the notification requirement per the BORP “Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding”. MOR Lamont did not complete an application because the installation of two new BSCs was considered an improvement to sterile compounding at the Pharmacy performed in accordance with the advisory and did not change the configuration or square footage of the buffer room, did not involve BSCs used for hazardous compounding, and did not constitute a “major” repair. According to the advisory, “Major Repair/Major Service is defined as significant modifications, repairs, or service to the compounding pharmacy that may not affect the floor plan but may result in changes to airflow dynamics and/or the generation of environmental contaminants”.
- MOR Lamont indicated that during the installation of the new BSCs, the existing BSC and counter in the WBC room were moved slightly but no remodeling, construction or HVAC work was performed. The certification report for the WBC buffer room and BSCs from 1/28/2020 was provided. According to MOR Lamont, compounding in the WBC room was suspended from 1/28/2020 to 2/11/2020. Since customers were notified weeks in advance, there was minimal inconvenience to them.

ACTION: Motion by T. FENSKY, seconded by S. HAMILTON, and voted by all those present, to CLOSE the matter (SA-INV-16891), No Discipline Warranted and include a copy of the updated *Advisory on Conducting Repairs or Service to Sterile Compounding Facilities or Facilities Engaging in Complex Non-Sterile Compounding* with the closing letter.

Topic VIII **EXECUTIVE SESSION** **Time: 8:28 AM**
Read by K. Tanzer

DISCUSSION:

ACTION: At 8:29 AM President K. Tanzer read the statement on reasons for Executive Session.

Topic VIII: **Executive Session Call to Order:** **Time: 8:29 AM**
 By: K. Tanzer

ACTION: Motion by L. Giambarresi, seconded by S. Hamilton, and voted unanimously by roll call to call the 12/4/20 meeting of the Executive Session to order.

Roll call attendance: K. Tanzer, yes; J. Lanza, yes; K. Thornell, yes; D. Perry, yes; Dr. Lopez, yes; P. Gannon, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; T. Fensky yes.

