COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

August 6, 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=

To access the meeting by phone:

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

Access Code: 161 558 7390

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	Ι	CALL TO ORDER		J. Lanza
	Π	APPROVAL OF AGENDA		
8:05	III	 APPROVAL OF BOARD MINUTES Draft of July 23, 2021 Regular Session Minutes 		

8:10	IV	 REPORTS 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	FLEXPharmacy issues related to Covid-19 and the state of emergency	
8:20		 APPLICATIONS Whittier Street Health Center – New Community Pharmacy Oakmontscript Wholesale Distributor – Wholesale Distributor 	
8:45		 POLICIES Rescind Staff Action Policy 16-04: Staff Action to Handle Above Action Level Results 	
9:00	VI	FILE REVIEW 1 CAS-2021-0249 SA-INV-17648 Walgreens #17214, DS90117 2 CAS-2021-0170 PHA-2021-0012 Big Y #66, DS3257 3 CAS-2021-0193 SA-INV-17572 Galaxy Pharmacy, DS90257 4 CAS-2021-0253 PHA-2021-0019 CVS #1157, DS89752 5 CAS-2021-0273 PHA-2021-0021 CVS #1306, DS3559	
9:30	VII	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.	CLOSED SESSION
10:00	VIII	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION
10:45	IX	ADJOURNMENT	

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting August 6, 2021

Board Members Present

Julie Lanza, CPhT, President (leaves meeting at 10:00 AM) Sebastian Hamilton, Pharm D, MBA, RPh President-Elect Carly Jean-Francois, RN, NP Secretary Andrew Stein, Pharm D Susan Cornacchio, JD, RN (leaves meeting at 9:52 AM) Caryn Belisle, RPh, MBA Leah Giambarresi, Pharm D, RPh Jennifer Chin, RPh Dr. Richard Lopez, MD (arrives meeting 8:30 AM)

Board Members Not Present

Timothy Fensky, RPh Dawn Perry, JD Katie Thornell, RPh, MBA

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 Julienne Tran, PharmD, Investigator Christina Mogni, RPh, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:02 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; C. Belisle, yes; A. Stein; C. Jean-Francois, yes. L. Giambarresi, yes; J. Chin, yes; S. Cornacchio, yes; R. Lopez (arrives at meeting 8:30 AM)

Topic II.

Approval of Agenda

Agenda 8/6/21

DISCUSSION:

ACTION:

Motion by L. Giambarresi, seconded by C. Jean-Francois and voted unanimously by those present to approve the agenda with noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:04 AM

Minutes

1. Draft 7/23/21

Change: Remove William Frisch board staff list as being present, he was not in attendance.

Action:

Motion by L. Giambarresi seconded C. Jean-Francois and voted unanimously to approve the regular session minutes of 7/23/21 with no noted change by roll call vote. J. Chin and C. Belisle abstain.

TOPIC IV

Reports

Applications approved pursuant to Licensure Policy 13-01Time: 8:05 AMDiscussion: R. HARRIS reported there were twenty-one (21) Change of Manager applications approved
pursuant to Licensure Policy 13-01.Time: 8:05 AM

So noted				
ΤΟΡΙϹ ΙV	REPORTS			
Monthly Report from Probation			Time: 8:06 AM	
Discussion, D. LADDIC supplied the July	. 2 2024 1.1		Dhamman, Daard Drahatian Manthh	

Discussion: R. HARRIS provided the July 2, 2021 – July 30, 2021, Pharmacy Board Probation Monthly Report, which noted that zero (0) report(s) from probation have been reported since last Board meeting. There are currently 27 active cases.

So noted

ΤΟΡΙϹ ΙV	REPORTS	
Monthly Report from BDR pursuant to	o Policy 14-02	Time: 8:06 AM

Discussion: R. HARRIS noted that there was two (2) Board Delegated Review case heard on June 10, 2021, and two (2) heard on July 22, 2021. One June 10, 2021, the first was a Reported Loss of Controlled

Substance (PHA-2021-0024) which was referred to the Office of Prosecution for an Order to Show Cause and authorizes resolution with a Consent Agreement for Non-Disciplinary Stayed Probation for One Year, with terms to follow the loss protocol, including exactly monthly counts of all benzodiazepines. The second was a CE self-disclosure (SA-INV-17282) which was closed with discipline not warranted, No Violation.

On July 22, 2021, the first was a CE self-disclosure (SA-INV-17997) which was closed with discipline not warranted, Remediation Complete. The second was a Waiver Renewal (DS90042.) The Board Delegated Review session was attended by Julie Lanza as the Board President, W. FRISCH Director of Pharmacy Compliance, H. ENGMAN as Board Counsel, and Executive Director D. SENCABAUGH.

So noted			
TOPIC IV	REPORTS		
Above Action Levels A	pproved by Staff Action 16-04	Time: 8	3:07 AM
	oted that there was five (5) above actior st Board meeting pursuant to Licensure	•	t has been remediated
So noted			
TOPIC IV	REPORTS		
PSUD Report by Staff	Action 17-03	Time:	8:07 AM
Discussion : E. TAGLIEF (13) active participants So noted	RI noted that in July 2021, there were tw 5.	vo (2) pending ad	missions and thirteen
TOPIC V Pharmacy Issues Relat	Flex red to Covid-19 and State of Emergency	Time: 8	3:08 AM
Presented by D. SENC/	ABAUGH		
The recently released	amendment to the PREP Act now aut	horizes qualified	pharmacy technicians to

The recently released amendment to the PREP Act now authorizes qualified pharmacy technicians to administer flu shots to adults. They can therefore administer flu shots to all ages 3 years and older. No allowances for other vaccinations or age groups were made.

So noted.

TOPIC VIApplications1. Whittier Street Health CenterNew Community Pharmacy

<u>REPRESENTED BY</u>: Frederica Williams, CEO; Dr. Stephen Wright, Medical Director. Sabya Abdul Rauf, MOR

RECUSAL: S. HAMILTON

<u>DISCUSSION</u>: Whittier Health Center is a community health center in Roxbury. The pharmacy would like to service Whittier patients and non-patients. The intention is to convert the clinic pharmacy to a retail pharmacy. Preliminary inspection from the Board confirms the clinic pharmacy passes retail inspection qualification. A new set of blueprints have been requested, the waiting area and counseling room cannot be included in the square footage of the prescription area. Whittier confirms they have the proper set up for 340B compliance. Security for the pharmacy includes upgrades recommended by the Board during the preliminary inspection in June. The Board is still awaiting confirmation of HCQ approval for the existence of a proposed retail pharmacy within the licensed clinic space. Whittier has an answering service that will direct patients where to go if they need assistance off hours. MOR Rauf is a first time Manager of Record and satisfactorily answered all the Board members questions.

<u>ACTION:</u> Motion by L. GIAMBARRESI, seconded by A. STEIN, voted unanimously by those present to approve the application for a new community pharmacy pending a successful inspection, updated blueprint and approval from HCQ. R. LOPEZ was not present for the vote. S. HAMILTON recused for the vote.

2. Oakmontscript

Wholesale Distributor

TIME: 8:27 AM

REPRESENTED BY: Shirley Shi, Owner

RECUSAL: NONE

<u>DISCUSSION</u>: Oakmontscript is applying for a Wholesale Distributor license, their business model is to distribute to pharmaceutical companies that conducts research on generic medications. Oakmontscript previously held a DEA and MCSR registration from DCP. On 6/11/2021, an administrative law judge for the DEA issued a recommended ruling of Oakmontscripts registration. Recommended ruling contained many findings of fact including record keeping violations and shipping drugs to end users who did not have authority to accept the drugs. Additionally, the evidence indicates Oakmontscript falsified its DEA registration to acquire controlled substances. MCSR terminated Oakmontscript's registration schedules II-VI, Oakmontscript reapplied for schedule VI and was denied. Shirley Shi indicated the falsification occurred in 2017 and the recording keeping violations due to improper staff training.

<u>ACTION:</u> Motion by S. CORNACCHIO, seconded by S. HAMILTON, voted unanimously by those present to deny the application for Wholesale Distributor.

TOPIC VII

Policies

Staff Action Policy 16-04: Staff Action to Handle Above Action Level Results

Time: 8:46 AM

Presented by M. CHAN

Discussion: This past April, the procedure for above action levels found in sterile compounding environments was changed to become a more self-directed process. The pharmacy notifies Board staff of the occurrence and attests that it will be remediated.

This process has now been incorporated into Board staff's internal procedure making the staff action policy unnecessary.

Reports of closures of internal files will no longer be presented at Board meetings. Concerning AAL reports will continue to be escalated and brought before the Board.

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

TOPIC VIII	File Review	
Case #1/CAS-2021-0249		
SA-INV-17648	Walgreens #17214, DS90117	Time: 08:48 AM

RECUSAL: NONE

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

- •On March 14, 2021, MOR Kohut reached out to Investigator Horn requesting guidance on midprescription label changes for prescriptions dispensed to group homes under MAP.
- •On March 16, 2021, it was related during a site visit (ISP-15541) to Investigator Horn that the Pharmacy relabels blister cards without a valid order for group homes.
- •New medications are filled by prescriptions sent from the prescriber. Mid-prescription direction changes are faxed to the pharmacy by group home staff as a prescription list. The list typically contains about 5-10 medications, all on the same page, stating the change in direction and faxed to the pharmacy titled "label changes". The pharmacist places the new label over the previously filled blister card in the presence of the group home advocate.
- •MOR Kohut noted that going forward, a new prescription is required to be sent in directly from the prescriber. Any form of label changes are not to occur. Patients who have refills remaining on any medication orders will only be filled once more, and then closed. A new prescription from the prescriber will be required for any future refill.
- •MOR Kohut submitted a signed attestation that the pharmacy staff reviewed Circular #DCP 20-3-110: Medication Administration Program (MAP) – Patient Prescribing Directives, and Board Policy 98-011: Policy on Customized Patient Packaging.

On July 6, 2021, Investigator Horn conducted a retail compliance inspection (ISP-16361) that was deemed satisfactory.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by L. GIAMBARRESI, and voted unanimously by those present, to CLOSE the matter (SA-INV-17648), No Discipline Warranted, Remediation Complete.

Case #2/CAS-2021-0170		
PHA-2021-0012	Big Y #66, DS3257	Time: 08:51 AM

RECUSAL: NONE

<u>DISCUSSION</u>: C. LATHUM presented and summarized the investigative report that pertained to these matters.

- Big Y 66 reported the loss of #100 morphine sulfate 30 mg ER tablets on 01/28/2021 and #15ml morphine sulfate 20mg/ml solution on 01/29/2021.
- The loss of the #100 morphine sulfate 30 mg ER tablets occurred on 01/28/2021 while MOR Masciadrelli was unpacking the Schedule II order on the pharmacy bench; one full bottle of morphine sulfate 30 mg ER tablets was never removed from the security bag and thrown into the trash.
- The loss of the morphine 20 mg/ml occurred on the last dispense of the medication. The prescription was written for 150 ml (10 x 15ml). On 1/18, staff pharmacist Sam Baidoo dispensed 30 ml (2 x15ml) to the patient and ordered more for the next day. On 1/19, MOR Masciadrelli was supposed to dispense 120ml (8 x 15 ml), but instead dispensed 9 boxes of 15ml.
- Both losses were reportedly confirmed by review of video footage.
- Pharmacy staff reviewed and signed Big Y's Policy on *Controlled Drug Security* and *CII Safe Responsibilities* on March 12, 2021.
- Pharmacist Masciadrelli received progressive discipline.
- The Pharmacy now saves all controlled substance packing material until after the next weekly C2 inventory to ensure this kind of loss is not repeated.
- An incident report was filed with APMS (Alliance for Patient Medication Safety) which is the program Big Y utilizes for continuous quality improvement.
- MOR Masciadrelli completed an additional 2-hour continuing education program titled *Medication Safety: Practical Approaches to Preventing Medication Errors in Health System Pharmacy,* over and above the minimum yearly requirement set forth by the BORP, and attested to reading and reviewing 247 CMR 15, Continuous Quality Improvement.

<u>ACTION</u>: Motion by A. STEIN, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2021-0012), 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 #3/CAS-2021-0193	
SA-INV-17572	Galaxy Pharmacy, DS90257

Time: 08:53 AM

RECUSAL: NONE

<u>DISCUSSION</u>: C. LATHUM presented and summarized the investigative report that pertained to these matters

•Summary of deficiencies cited on 1/12/21:

- a. Expired Schedule II controlled substances were not reconciled every 10 days. Expired methadone 5 mg tablets #76 and methadone 10 mg tablets #92 were removed from the perpetual inventory on 01/03/2020 but were not reverse distributed until 12/17/2020.
- b. Two balances were last sealed in September 2019.
- c. Freezer temperature logs recorded out of range temperatures from 8°F to 11°F from July 31, 2020-December 31, 2020. Varivax has a storage range of 5°F to -58°F. Two doses of Varivax[®] were administered. One dose was administered on 8/1/2020, and Merck's data supported the vaccine's potency and effectiveness. The second dose was administered on 12/28/2020 and Merck's data did <u>not</u> support the vaccine's potency and effectiveness.
- A plan-of-correction (POC) was received on January 28, 2021:
 - a. All expired medications will be included in the perpetual inventory until reverse distributed. The log was updated to include columns for when medications are received, dispensed, and reverse distributed.
 - b. Both scales were sealed on January 13, 2021.
 - c. The remaining Varivax vaccine was quarantined and returned to an authorized vendor on March 3, 2021. The patient who received the vaccine on 12/28/2020 was contacted, received a full refund, and offered revaccination at no cost. The patient reported no adverse effects. MOR Truong also reviewed the importance of recording and maintaining proper refrigeration and freezer temperatures with all staff.
- On 07/02/2021, a retail compliance site visit was conducted. A plan-of-correction was issued due to expired Schedule II controlled substances not being maintained in perpetual inventory until reverse distributed and a temperature excursion on May 25, 2021 May 26, 2021, with a low reading of -1.73C in the main medication refrigerator. The excursion lasted approximately 15 hours and there was no record of any action taken by staff to ensure medications were not adversely affected by the excursion and were safe for dispensing.
- All staff reviewed and signed the Pharmacy's Policy # 5.17: *Refrigerator and Freezer Temperature Maintenance* and Board Policy 2020-05: *Proper Storage of Refrigerated and Frozen Medications*.

<u>ACTION</u>: Motion by L. GIAMBARRESI, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to ELEVATE the matter (SA-INV-17572), to a complaint.

Case #4/CAS-2021-0253		
PHA-2021-0019	CVS #1157, DS89752	Time: 08:58 AM

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

<u>DISCUSSION</u>: C. LATHUM presented and summarized the investigative report that pertained to these matters.

- On March 17, 2021, CVS #1157 reported an unknown loss of #324 lorazepam 0.5 mg tablets discovered via corporate controlled substance monitoring on 1/21/2021.
- MOR Knox stated that the loss occurred due to inaccurate cycle counting by technicians and inaccurate NDC counting.
- Pharmacy staff reviewed and signed CVS Policy Pharmacy Colleague Asset Analytics and Insights/Drug Diversion and CVS Policy Federal Regulations and CVS Guidelines for Controlled Substances.

<u>ACTION</u>: Motion by L. GIAMBARRESI, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2021-0019), 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 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 benzodiazepines 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 #5/CAS-2021-0273		
PHA-2021-0021	CVS #1306, DS3559	Time: 09:00 AM

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

<u>DISCUSSION</u>: C. LATHUM presented and summarized the investigative report that pertained to these matters.

- The Pharmacy reported an unknown loss of #60 dextroamphetamine 15 mg ER capsules on 01/30/2021.
- Pharmacist Lachance stated that a pharmacy technician trainee alerted her that the prescription could not be located in the waiting bins. After a thorough search the prescription was redispensed.
- All technicians and staff pharmacists were counseled on CVS policies and procedures for maintaining controlled substances and proper storage and handling of controlled substances
- Pharmacy staff read and signed CVS policy Filling/Dispensing Prescriptions/Stores with Two Step Verification Workflow.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by J. CHIN, and voted unanimously by those present, to refer the matter (PHA-2021-0021), 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.

Executive Session Call to Order:

Time: 9:03 AM

Topic IX: By: J. Lanza

<u>ACTION</u>: Motion by, L. Giambarresi, seconded by C. Jean-Francois, all voted affirmatively by those present to enter executive session.

Roll call attendance: J. Lanza, yes; S. Hamilton, yes; C. Belisle, yes; A. Stein; C. Jean-Francois, yes. L. Giambarresi, yes; J. Chin, yes; R. Lopez, yes. S. Cornacchio was recused at the time and was not in attendance for this vote.

Topic X:

DISCUSSION: None

<u>ACTION</u>: President J. Lanza request a motion to enter 65C.

At 9:44 AM L. Giambarresi, seconded by S. Hamilton and voted unanimously by all those present to enter 65C by roll call vote.

S. Cornacchio leaves meeting at 9:52 AM J. Lanza leaves meeting at 10:00 AM

Topic XI

ADJOURMENT OF MEETING

TIME: 10:12 AM

ACTION: Motion by L. Giambarresi seconded by C. Jean-Francois 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 8/6/21 General Session
- 2. Draft Minutes of the 7/23/21 Meeting
- 3. Report on Applications approved pursuant to Licensure Policy 13-01
- 4. Report on probation
- 5. Report on Board Delegated Complaint Review to licensure policy 14-02
- 6. Report on Above Action Levels approved by Staff Action 16-04
- 7. Report on PSUD 17-03
- 8. Application: Whittier Street Health Center-New Community Pharmacy
- 9. Application: Oakmontscript Wholesale Distributor- Wholesale Distributor
- 10. Staff Action Policy 16-04: Staff Action to Handle Above Action Level Results
- 11. CAS-2021-0249 SA-INV-17648 Walgreens #17214, DS90117
- 12. CAS-2021-0170 PHA-2021-0012 Big Y #66, DS3257
- 13. CAS-2021-0193 SA-INV-17572 Galaxy Pharmacy, DS90257
- 14. CAS-2021-0253 PHA-2021-0019 CVS #1157, DS89752
- 15. CAS-2021-0273 PHA-2021-0021 CVS #1306, DS3559

Respectfully Submitted, Carly Jean-Francois, NP, Secretary