

COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

January 6, 2022

Webex Information

The regular session is open to the public by video or phone.

For video access click on the following link:

<https://eohhs.webex.com/eohhs/onstage/g.php?MTID=e270cb7bebbb341df4af285c3ab36798f>

To access the meeting by phone:

Call in Number: 1-650-479-3208

Access Code: 2533 829 1570

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
8:00	I	CALL TO ORDER		S. Hamilton
	II	APPROVAL OF AGENDA		
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">Draft of December 17, 2021 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 • PSUD Report-Policy 17-03 • Research Drug Study Report 		
8:15	V	FLEX <ul style="list-style-type: none"> • Pharmacy issues related to Covid-19 and the state of emergency 		
8:20	VI	APPLICATIONS <ul style="list-style-type: none"> • Sebela Pharma RxDirect – New Community Pharmacy 		
8:35	VII	PTT LICENSE EXTENSION REQUEST <u>PTT09116 Harlow, Haley</u> Issue Date: 08/24/2020 Expiration Date: 08/24/2021 10 hours – CVS <u>PTT10098 Jones, Nichole</u> Issue Date: 12/09/2020 Expiration Date: 12/09/2021 60 hours – CVS <u>PTT09800 Carroll, Sophia</u> Issue Date: 11/10/2020 Expiration Date: 11/10/2021 204 hours – CVS <u>PTT07082 Privott, Tiana</u> Issue Date: 12/13/2019 Expiration Date: 12/13/2020 204 hours – CVS <u>PTT09666 Shaikh, Qurratulane</u> Issue Date: 10/29/2020 Expiration Date: 10/29/2021 120 hours <u>PTT06654 Leboeuf, Katelynn</u> Issue Date: 10/28/2019 Expiration Date: 10/28/2020 5 hours - IWP		

9:10	VIII	FILE REVIEW					
		1	CAS-2021-0750	PHA-2021-0067			Westminster Pharmacy, DS1710
		2	CAS-2021-0696	PHA-2021-0062			CVS #1291, DS3303
		3	CAS-2021-0657	PHA-2021-0054			CVS #7232, DS3461
9:30	VI	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	
10:30	X	M.G.L. c. 112, § 65C SESSION				CLOSED SESSION	
11:00	XI	ADJOURNMENT					

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

MINUTES OF THE GENERAL SESSION

Via Remote WebEx Meeting

January 6, 2022

Board Members Present

Sebastian Hamilton, Pharm D, MBA, RPh President

Caryn Belisle, RPh, MBA, President-Elect

Carly Jean-Francois, RN, NP Secretary (Arrives 8:06 AM)

Julie Lanza, CPhT

Susan Cornacchio, JD, RN (arrives at 9:25 AM/leaves 9:52 AM)

John Rocchio, RPh, PharmD (leaves meeting 9:52 AM)

Dr. Richard Lopez, MD

Sami Ahmed, Pharm.D., RPh, BCPS, BCSCP (present for meeting but was unable to begin voting until 8:41 AM due to technical difficulties)

Katie Thornell, RPh, MBA

Delilah Barnes, RPh

Rita Morelli, PharmD, BCACP, RPh

Dawn Perry, JD

Board Members Not Present

Jennifer Chin, RPh

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

Richard Harris, Program Analyst

Joanna Chow, Office Support Specialist

Taylor Lee, Office Support Specialist

Joanne Trifone, RPh, Director of Investigations

Nancy Aleid, Compliance Officer

Christina Mogni, RPh, Investigator

Gregory Melton, RPh, Investigator

Julienne Tran, PharmD, Investigator

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:03 AM

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

Roll call attendance: S. Hamilton, yes; C. Belisle, yes; D. Barnes; J. Rocchio, yes; R. Lopez, yes; D. Perry, yes. K. Thornell, yes J. Lanza, yes; R. Morelli, yes; C. Jean-Francois.

Topic II.

Approval of Agenda

TIME 8:04 AM

Agenda 1/6/22

DISCUSSION:

Defer: none

Michelle introduces APPE Students: Nickayal Page, Western New England College of Pharmacy

ACTION:

Motion by J. Lanza, seconded by K. Thornell and voted unanimously by those present to approve the agenda with no noted change by roll call vote.

Topic III

Approval of Board Minutes

TIME: 8:06 AM

Minutes

1. Draft 12/17/21

Change: no changes

Action:

Motion by J. Lanza seconded C. Belise and voted unanimously to approve the regular session minutes of 12/17/21 with no noted change by roll call vote. D. Perry and C. Belisle abstain.

TOPIC IV

REPORTS

Applications approved pursuant to Licensure Policy 13-01

Time: 8:07 AM

Presented by: R. HARRIS

Discussion: R. HARRIS noted the report in the Board packet reflects Change of Manager applications approved by Staff Action since the last meeting.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:07 AM

Presented by: R. HARRIS

Discussion: R. HARRIS reported that there have been 2 successful completions of probation monitoring since the last meeting. Currently, there are 19 active cases.

So noted

TOPIC IV

REPORTS

Monthly Report from BDCR pursuant to Policy 14-02

Time: 8:07 AM

Presented by: D. SENCABAUGH

Discussion: D. SENCABAUGH reported that there were 3 cases of self-reported CE deficiencies since the December 2nd Board Delegated Review that have since been remediated and closed with no disciplinary action warranted.

So noted

TOPIC IV

REPORTS

PSUD report by Staff Action 17-03

Time: 8:08 AM

Presented by: E. TAGLIERI

Discussion: E. TAGLIERI noted that there are currently 14 active participants and no pending admissions. There were 15 participants, but one individual decided to pursue a different career and voluntarily withdrew from the program.

So noted

TOPIC IV

REPORTS

Research Drug Study Report

Time: 8:09 AM

Presented by: W. FRISCH, M. CHAN

Discussion: M. CHAN reported that there have been 4 new studies approved by Board Staff since the last meeting. 4 pharmacies are currently participating with a total of 16 studies: 15 using commercially available drugs and 1 using investigational available drugs.

So noted

TOPIC V

Flex

1. Pharmacy Issues related to COVID-19 and state of emergency

Time: 8:10 AM

Presented by: D. SENCABAUGH

Discussion: The FDA and CDC have approved COVID boosters to be given 5 months after the primary series for children aged 12-15 years.

In response to the public health need for vaccinations and resulting from several store closures, the Board will not be enforcing the supervisory ratios at this time for licensed pharmacies that are providing vaccination services provided that the following conditions are met:

- A maximum ratio of 1 pharmacist to 6 support staff is not exceeded; and
- at least 3 support staff are interns and / or certified licensed pharmacy technicians.

So noted.

TOPIC VI**Applications****1. Sebela Pharma RXDirect****New Community Pharmacy****TIME: 8:06 AM****Represented by: Lisa Harpel, Rob Raleigh, Dean Bartello, Ernie Gates****Recusal:****Discussion:**

BOP counsel H. Engman stated on October 29, 2021, BOP considered application for a retail pharmacy license. Board Counsel indicated that Sebela was petitioning the board for a series of waivers previously discussed on October 29th. Sebela also had the opportunity to respond to questions raised by board staff at a previous meeting. Board Counsel stated that based on the information that was presented at the October 29th meeting, the board voted to issue a preliminary denial of the application for licensure because the board members expressed concern for the following reasons 1. The pharmacy would only stock and dispense bowl prep medications manufactured by a company under common ownership and would not stock any other medications. 2. The pharmacy would not be accepting health insurance 3. The pharmacy would require significant waivers of board regulations especially 247 CMR 9.01 (15) and 247 CMR 6.02(4). Board counsel stated that the board members were concerned that this business model would result in polypharmacy, would reduce the ability to perform drug utilization review, would unnecessarily narrow the scope of pharmacy practice, and would not be in the best interest of patients. On December 22, 2021, board staff received correspondence from Sebela indicating that they wished to withdraw their petitions of 4 waivers and instead would like to operate a full-service pharmacy. L. Harpel indicated that they hope to open a community retail pharmacy to deliver medications to patients' homes but also offer them the opportunity to be able to pick up. L. Harpel stated that offering delivery services may be especially advantageous to patients given the uptick of COVID cases. S. Hamilton stated that the application may need to be amended to include controls class 2-4 as it is currently for class 6. L. Harpel confirmed they would be making those changes and applying for their DEA license to be able to stock all medications. Board member C. Belisle asked for clarification as to whether the model for bowl prep is still going to be the same. L. Harpel responds that after hearing the board's concerns they are willing to serve a larger population with their mail order pharmacy service. Board staff S. Hamilton asked for clarification on their mail order model. L. Harpel responds by stating that she is contracting with UPS and USPS to send packages to patients that are integrated with their pharmacy systems. Board member R. Morelli inquired as to whether Sebela would be doing immunizations at their pharmacy to which L. Harpel responds that they will not be doing immunizations at this time, but that she does have certified immunizers if that was a prospect that she wanted to explore in the future.

A motion was made by K. Belisle to approve the application with the edit of including controlled substances 2-5 in their application contingent upon a satisfactory board inspection; Seconded by J. Lanza; then board members voted unanimously by roll call to approve motion.

TOPIC VII**PTT License Extension Request****1. PTT07082 Privott, Tiana****Time: 8:28 AM****Represented by: Self****Recusal: S. CORNACCHIO, J. ROCCHIO**

Discussion: T. PRIVOTT petitioned for an extension of her pharmacy technician trainee license. COVID restrictions began shortly upon PRIVOTT accepting employment with CVS and she was unable to continue training in the pharmacy prior to license expiration. She is now able to begin work upon approval of an extension of her license.

Action: A motion was made by C. BELISLE to extend the expiration date of T. PRIVOTT'S pharmacy technician trainee license by one year; Seconded by D. PERRY, then Board Members present voted unanimously by rollcall to approve motion except S. CORNACCHIO and J. ROCCHIO who recused.

2. PTT09116 Harlow, Haley

Time: 8:31 AM

Represented by: Self

Recusal: S. CORNACCHIO, J. ROCCHIO

Discussion: H. HARLOW petitioned for an extension of her pharmacy technician trainee license. She was previously employed as front-store staff and relocated to the pharmacy to assist with staffing. The front of the store didn't have enough staff to allow for H. HARLOW to obtain adequate hours in the pharmacy. HARLOW has recently been given the opportunity to continue training as a pharmacy technician.

Action: A motion was made by C. JEAN-FRANCOIS to extend the expiration date of H. HARLOW'S pharmacy technician trainee license by one year; Seconded by J. LANZA, the Board Members present voted unanimously by rollcall to approve motion except S. CORNACCHIO and J. ROCCHIO who recused.

3. PTT10098 Jones, Nichole

Time: 8:35 AM

Represented by: Self

Recusal: S. CORNACCHIO, J. ROCCHIO

Discussion: N. JONES petitioned for an extension of her pharmacy technician trainee license. JONES was previously a front-store employee and began working in the pharmacy due to staffing shortages caused by COVID restrictions. She has nearly completed her training and was offered the opportunity to continue training as a pharmacy technician.

Action: A motion was made by C. BELISLE to extend the expiration date of N. JONE'S pharmacy technician trainee license by one year; Seconded by K. THORNELL, then Board Members present voted unanimously by rollcall to approve motion except S. CORNACCHIO and J. ROCCHIO who recused.

4. PTT09800 Carroll, Sophia

Time: 8:37 AM

Represented by: Self

Recusal: S. CORNACCHIO, J. ROCCHIO

Discussion: S. CARROLL petitioned for an extension of her pharmacy technician trainee license. She trained in the pharmacy as a pharmacy technician at CVS for 5 months before falling ill. S. CARROLL is also a nursing student and is eager to continue training in the pharmacy upon approval of her extension request.

Action: A motion was made by C. BELISLE to extend the expiration date of S. CARROLL'S pharmacy technician trainee license by one year; Seconded by J. LANZA, then Board Members present voted unanimously by rollcall to approve motion except S. CORNACCHIO and J. ROCCHIO who recused.

5. PTT09666 Shaikh, Qurratulane

Time: 8:41 AM

Represented by: Self

Recusal: None

Discussion: Q. SHAIKH petitioned for an extension of her pharmacy technician trainee license. The licensee had fallen ill shortly upon accepting employment and was unable to access transportation to get to work. SHAIKH now has access to transportation and was given the opportunity to continue training in the pharmacy as a pharmacy technician.

Action: A motion was made by C. BELISLE to extend the expiration date of Q. SHAIKH's pharmacy technician trainee license by one year; Seconded by C. JEAN-FRANCOIS, then Board Members present voted unanimously by rollcall to approve motion.

6. PTT06654 Leboeuf, Katelynn

Time: 8:44 AM

Represented by: Self

Recusal: None

Discussion: K. LEBOEUF petitioned for an extension of her pharmacy technician trainee license. The licensee initially began employment as an Assistant Manager for Walgreens. Shortly after, she decided to pursue a career as a pharmacy technician at which point her license had expired. LEBOEUF was recently given the opportunity to continue training as a pharmacy technician.

Action: A motion was made by C. BELISLE to extend the expiration date of K. LEBOEUF's pharmacy technician trainee license by one year; Seconded by K. THORNELL, then Board Members present voted unanimously by rollcall to approve motion.

TOPIC VIII

File Review

Case #1/CAS-2021-0750

PHA-2021-0067

Westminster Pharmacy, DS1710

Time: 08:51 AM

RECUSAL: NONE

DISCUSSION: C.MOGNI presented and summarized the investigative report that pertained to this matter.

- Inspectional deficiencies from inspection on 8/4/21 including improper and insanitary storage of Moderna vaccines outside the Pharmacy in an unsecured freezer; missing temperature logs for the freezer and the refrigerator containing J&J vaccines; no standing order for the J&J vaccine. On 08/04/2021, Owner Serio agreed to voluntarily cease and desist administration of all immunizations

and quarantined all refrigerated products until proof of proper storage was obtained. An incomplete POC was submitted.

- Owner Serio responded that the electronic temperature monitoring system would send emails/texts for out-of-range temperatures. The system required that the temperature logs had to be manually downloaded to Google Sheets or Excel spreadsheet or the records were deleted after 14 days. He claimed the freezer range was set more stringently so alerts were received which were used to recreate the manual logs. Although he stated there were no temperature excursions, documentation provided showed 10 excursions above 6°F from 7/26/21-8/4/21 which he stated were false excursions. No documented action was submitted for these excursions. The Pharmacy received 700 doses of Moderna vaccine from 3/8/21-7/22/21. Dispensing reports showed 352 Moderna doses were dispensed beginning 3/17/21.
- Owner Serio stated the Pharmacy has a pharmaceutical grade refrigerator with a built-in thermometer with alarm. The Pharmacy received 465 doses of J&J vaccine from 3/19/21-7/26/21, Dispensing reports showed 343 J&J doses dispensed including 2 doses on 1/30/21. During follow up inspection on 12/3/21, Current MOR Maki stated J&J vaccine was not received until 7/26/21.
- Moderna and J&J vaccines were in stock and dispensed on multiple dates when no refrigeration temperatures were recorded and could not be provided. Owner Serio justified dispensing vaccines indicating no alerts or alarm sounded and that the temperature was observed as appropriate at the time the vaccine was removed from the freezer/refrigerator. During a follow-up site visit on 9/17/21, Owner Serio was instructed to damage the Moderna vaccine and to contact manufacturers of quarantined refrigerated products to determine if safe for dispensing. On 12/3/21, the Moderna vaccine vials were in the Sharps container with no documentation of destruction, documented return for destruction of some refrigerated products, or documented follow up with manufacturers.
- A new Pharmacy freezer was installed, and a new LogTag electronic monitoring system was implemented for the freezer with storage of a temperatures for one year minimum on 8/6/2021. EliTech USB data loggers are used to monitor refrigerator temperatures and temperatures during transport of vaccines for off-site immunizations. Twice daily manual logs are maintained. Pharmacy staff reviewed all P&Ps related to refrigeration and action for excursions and use of the LogTag system.

ACTION: Motion by K. THORNELL, seconded by D. BARNES and voted unanimously by those present, to refer the matter (PHA-2021-0067), 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/CAS-2021-0696

PHA-2021-0062

CVS #1291, DS3303

Time: 08:58 AM

RECUSAL: J. ROCCHIO 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 this matter.

- On July 30, 2021, CVS 1291 submitted a final report of an unknown loss of #100 oxycodone 5mg tablets discovered on April 7, 2021. CVS 1291 explained that the losses were discovered by a staff pharmacist during reconciliation of inventory for Schedule II controlled substances.

- The staff pharmacist looked in both safes and was unable to find the missing bottle or determine a reason for the loss. An internal investigation was initiated at that time which lasted until July 22, 2021 . CVS 1291 indicated a change in staff at asset protection delayed the investigation.
- CVS 1291 indicated that loss prevention policies would be reviewed with pharmacy staff including “diligent inventory management and dispensing standards” to mitigate recurrence of a similar loss of controlled substance.

ACTION: Motion by S. HAMILTON, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2021-0062), 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-2021-0657

PHA-2021-0054

CVS #7232, DS3461

Time: 09:01 AM

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

DISCUSSION: J. TRAN presented and summarized the investigative report that pertained to this matter.

- Investigator Horn conducted a retail compliance inspection on 07/02/2021 and observed a violation of supervisory ratios and a PTT administering COVID vaccinations without a pharmacy technician license.
- MOR Bozoian indicated that PTT Shor began administering vaccines on or about June 7, 2021, after completing all of the required trainings. During the July 2, 2021, inspection, the Investigator brought to MOR Bozoian’s attention that PTT Shor’s PT license had not posted to the Board of Pharmacy website, so PTT Shot stopped administering vaccinations.
- The MOR alleges that the PTT application was sent but never posted on the Board’s website. BORP records indicate that a PT Registration Application was received, and was dated, notarized, and postmarked 06/10/2021 (prior to the 07/02/2021 inspection). PTT Shor’s PT license was issued on 07/16/2021.
- MOR Bozoian indicated that moving forward she will adhere to the staffing ratio. She noted that she is working with and supporting current technicians towards achieving national certification. Additionally, she has gained two national certified technicians since the violation was observed and two additional technicians who have begun to prepare for their exams.

ACTION: Motion by C. BELISLE, seconded by C. JEAN-FRANCOIS, and voted unanimously by those present, to refer the matter (PHA-2021-0054), 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.

Topic IX:

Executive Session Call to Order:

Time: 9:06 AM

By: S. Hamilton

Action: A motion was made by to K. Thornell enter Executive Session; Seconded by C. Jean-Francois and Board Members present voted unanimously by roll call to approve motion. Roll call attendance: S. Hamilton, yes; C. Belisle, yes; D. Barnes; J. Rocchio, yes; R. Lopez, yes; D. Perry, yes. K. Thornell, yes; J. Lanza, yes; R. Morelli, yes; C. Jean-Francois; S. Amid, yes.

S. Cornacchio joins meeting 9:25 AM

Topic X:

65C Sessions MGL c. 112 section 65C

Time: 9:25 AM

DISCUSSION: None

ACTION: President S. Hamilton request a motion to enter 65C.

At 9:25 AM K. Thornell, seconded by C. Jean-Francois and voted unanimously by all those present to enter 65C by roll call vote.

S. Cornacchio leaves meeting 9:52 AM

J. Rocchio leaves meeting 9:52 AM

Topic XI

ADJOURNMENT OF MEETING

TIME: 9:55 AM

ACTION: Motion by K. Thornell seconded by R. Morelli 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 1/6/22 General Session
2. Draft Minutes of the 12/17/21 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. Research Drug Study Report
9. Applications: Sebel Pharma RxDirect, new community pharmacy
10. PTT Extensions:
 - a. PTT09116 Harlow, Haley
 - b. PTT10098 Jones, Nichole
 - c. PTT09800 Carroll, Sophia
 - d. PTT07082 Pivott, Tiana
 - e. PTT09666 Shaikh, Qurratulane
 - f. PTT06654 Leboeuf, Katelynn
11. CAS-2021-0750 PHA-2021-0067 Westminster Pharmacy DS1710
12. CAS-2021-0696 PHA-2021-0062 CVS #1291DS3303
13. CAS-2021-0657 PHA-2021-0054 CVS #7232 DS3461

Respectfully Submitted,
Carly Jean-Francois, NP, Secretary