COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

December 3, 2021

Webex Information

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

For video access click on the following link:

https://statema.webex.com/statema/onstage/g.php?MTID=e08442ae69e1d578052a939d0f6e769e2

To access the meeting by phone:

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

Access Code: 2423 505 9565

Attendee: #

If you need reasonable accommodations in order to participate in the meeting, contact the DPH ADA Coordinator <u>Yulanda Kiner</u>, 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
	II	APPROVAL OF AGENDA		
8:05	Ш	 APPROVAL OF BOARD MINUTES Draft of November 12, 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• PSUD Report-Policy 17-03		
8:15	V	FLEX Pharmacy issues related to Covid-19 and the state of emergency Update on the Pharmacy Advisory Committee Meeting Nomination of Board Officers Pharmacy Advisory Committee Appointment – Timothy Fensky Introduction of new Board member: Rita Morelli		
8:45	VI	 POLICIES Policy 2021-04: Continuing Education (CE) Requirements 		
9:00	VII	PETITION FOR WAIVER • Davila Sachalyz – Pharmacy Technician in Training		
9:10	VIII	PTT LICENSE EXTENSION REQUESTPTT08535 Deas, Cody Issue Date: 07/02/2020Expiration Date: 07/02/2021200 hoursExpiration Date: 07/02/2021PTT08884 Masterton-Jones, Valrie Issue Date:08/05/2020Expiration Date:08/05/2021PTT08884 Masterton-Jones, Valrie Issue Date:08/05/2020Expiration Date:08/05/2021PTT08684 Masterton-Jones, Valrie Issue Date:08/05/2020Expiration Date:08/05/2021PTT7264 Joseph, Junia Issue Date:01/10/2020Expiration Date: 01/10/2021Zero hoursExpiration Date: 01/10/2021PITT07145 Lussier, Brianna Issue Date:12/23/2019Expiration Date:12/23/2020Zero hoursPTT08633 Chy, Jennifer Issue Date:07/09/2020PTT08633 Chy, Jennifer Issue Date:07/09/2020Expiration Date:07/09/2021		

		FILE REVIEW		
9:20		1 CAS-2021-0741 SA-INV-	-18278 Dan's Pharmacy, DS89748	
	IX	2 CAS-2021-0692 PHA-202	21-0059 Walgreens #17177, DS90123	
		3 CAS-2021-0594 PHA-202	21-0045 Walgreens #11885, DS89774	
		EXECUTIVE SESSION		
9:40	X	The Board will meet in Executive M.G.L. c. 30A, § 21(a)(1) for the p character, physical condition or m competence, of an individual, or to of, or complaints or charges broug employee, staff member or individ Good Moral Character as required applicant.	CLOSED SESSION	
10:00	XI	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION
10:30	XII	ADJOURNMENT		

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting December 3, 2021

Board Members PresentBJulie Lanza, CPhT, PresidentRCarly Jean-Francois, RN, NP Secretary (leaves meeting 10:10 AM)Sebastian Hamilton, Pharm D, MBA, RPh President-ElectSusan Cornacchio, JD, RN (leaves meeting 10:29 AM)Jennifer Chin, RPhJohn Rocchio, RPh, PharmD (leaves meeting 10:29 AM)Dr. Richard Lopez, MDCaryn Belisle, RPh, MBASami Ahmed, Pharm.D., RPh, BCPS, BCSCPKatie Thornell, RPh, MBADawn Perry, JDDelilah Barnes, 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 Christina Mogni, RPh, Investigator Gregory Melton, RPh, Investigator Julienne Tran, PharmD, 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 Julie 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; J. Rocchio, yes; J. Chin, yes; S. Cornacchio, yes; R. Lopez, yes; D. Perry, yes. K. Thornell, yes; C. Jean-Francois, yes; S. Ahmed, yes; D. Barnes, yes.

Board Members Not Present Rita Morelli, PharmD, BCACP, RPh Topic II.

Approval of Agenda

TIME 8:03 AM

Agenda 12/3/21

DISCUSSION:

Defer: none

ACTION:

Motion by K. Thornell, seconded by C. Jean-Francois 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: 8:04 AM

Minutes

1. Draft 11/12/21

Change: #4 GMC add S. Ahmed as recused; MA Society Health System Appeal: add recusals: Ahmed, Belisle, Lanza, Rocchio.

Action:

Motion by J. Chin seconded S. Hamilton and voted unanimously to approve the regular session minutes of 11/17/21 with noted change by roll call vote. D. Perry and D. Barnes abstain.

TOPIC IVReportsApplications approved pursuant to Licensure Policy 13-01Time: 8:06 AMDiscussion: R. HARRIS noted the report in the Board packet reflects the applications that were processed since the last meeting.				
So noted				
ΤΟΡΙϹ ΙV	REPORTS			
Monthly Report from Probatio	on	Time: 8:06 AM		
Discussion : R. HARRIS provided the November 09, 2021 – November 24, 2021, Pharmacy Board Probation Monthly Report, which noted one (1) licensee Successfully Completed probation Monitoring, there are currently 21 active cases.				
So noted				
ΤΟΡΙϹ ΙV	REPORTS			
Monthly Report from BDR pur	suant to Policy 14-02	Time: 8:06 AM		
	Page 2 of 10			
Draft Minutes General Sessi	on: 12/3/21			
BOP Approved: 12/17/21				

Discussion: D. SENCABAUGH noted there is no BDR report.

So not	ed		
TOPIC PSUD	IV REPORTS Report by Staff Action 17-03	Time:	8:07 AM
	sion : E. TAGLIERI noted that in November 2021, there are fifteen applications.	n (15) ac	tive participants and no
So not	ed		
ΤΟΡΙϹ	V Flex		
1.	Pharmacy Issues related to Covid-19 and state of emergency.		Time: 8:07 AM
	Presented by: D. SENCABAUGH		
	Nothing to report.		
2.	Update on Pharmacy Advisory Committee Meeting		Time: 8:10 AM
	Presented by: C. BELISLE, W. FRISCH		
	Discussion: The Advisory Committee to the Board of Pharmac development of an advisory for media fill testing. These tests h sterile compounding personnel.		
	So noted.		
3.	Nomination of Officers		Time: 8:26 AM
	Presented by: D. SENCABAUGH		
	Discussion: Nominations for Secretary and President-elect for vote will take place at the December 17, 2021, Board meetin ballot.		
	President-Elect Nominee 1: C. BELISLE Nominated by: J. LANZA, seconded by S. HAMILTON and voted to approve this nomination.	unanim	ously by all those present

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<u>President-Elect Nominee 2</u>: C. JEAN-FRANCOIS Nominated by: C. BELISLE, seconded by K. THORNELL and voted unanimously by all those present to approve this nomination.

President-Elect Nominee 3: K. THORNELL

Nominated by: D. PERRY, seconded by S. HAMILTON and voted unanimously by all those present to approve this nomination.

<u>Secretary Nominee 1</u>: C. JEAN-FRANCOIS Nominated by: S. CORNACCHIO, seconded by S. HAMILTON and voted unanimously by all those present to approve this nomination.

<u>Secretary Nominee 2</u>: J. CHIN Nominated by: S. HAMILTON, seconded by J. LANZA and voted unanimously by all those present to approve this nomination.

4. Pharmacy Advisory Committee Appointment Tim Fensky

Time: 8:17 AM

Presented by: E. TAGLIERI

Discussion: Now that S. AHMED has been appointed to the Board, his seat opened up on the Advisory Committee. Timothy Fensky has applied for that open seat and has already been vetted through DEA, NABP Clearinghouse, CORI, and the OIG's office.

Action: Motion by S. HAMILTON, seconded by D. PERRY, and voted unanimously by those present, to approve T. FENSKY's appointment to the Advisory Committee.

5. Introduction of New Board Members

Time: 8:07 AM

Presented by: D. SENCABAUGH

Discussion: Delilah Barnes from Sullivan's Pharmacy has been appointed to the independent seat that has been vacated by Andrew Stein. Rita Morelli from MCPHS has been appointed to the vacant academic seat.

R. LOPEZ has been reappointed for another term.

So noted.

TOPIC VI

Policies

1. Policy 2021-04 Continuing Educations (CE) Requirements Time: 8:34 AM

Presented by: M. CHAN

Discussion: After receiving some stakeholder feedback, some edits have been made to this policy.

With input from the legal team to help interpret the CDTM statute, edits were made to clearly state that only an additional 5 CEU's per calendar year are required for CDTM pharmacists.

For the compounding CE criteria, specific terms for program titles were added to assist licensees with program selection as well as enforcement. The titles are the only way for Board staff to determine if the program meets either the sterile or complex non-sterile compounding requirement. ACPE's "compounding" designator is nonspecific to either compounding type so, it cannot be used as the sole indicator of compliance.

As the Board members cannot delegate its discretion to the staff, the specific terms are necessary, but the policy can be updated with additional terms as needed.

A licensee could always petition the Board for approval of a compounding CE without one of these words if they feel it meets the spirit of the statute.

Action: Motion by S. HAMILTON, seconded by C. BELISLE, and voted unanimously by those present, to approve the policy changes.

TOPIC VII

Petition for Waiver

1. Davila, SachalyzPTT Waiver RequestRepresented by: SelfRecusal: Cornacchio, Rocchio

TIME 8:36am

Discussion: S. DAVILA petitioned for a waiver of the pharmacy technician trainee education requirement. She indicated that she is a single parent and that she is currently employed by CVS. She believes that receiving a technician license would allow her the flexibility to complete her education and provide for her son.

Action: A motion was made by S. Hamilton to approve the applicant's waiver; Seconded by D. Perry, then Board Members present voted unanimously by rollcall to approve motion except S. Cornacchio and J. Rocchio who recused.

TOPIC VIII

PTT Extension Request

1. PTT08884 Masterton-Jones, Valrie Represented by: Self Recusal: Cornacchio/Rocchio/Sandhal/Jean-Francois/Belisle/Ahmed

Discussion: V. MASTERTON-JONES petitioned for an extension of her pharmacy technician trainee license. Due to COVID restrictions, she was not able to obtain the minimum required hours. She previously appeared before the Board on 11/12/2021 and was deferred due to quorum.

Action: A motion was made by S. Hamilton to extend the expiration date of V. Masterton-Jones's pharmacy technician trainee license by one year; Seconded by J. Chin, then Board Members present voted unanimously by rollcall to approve motion except S. Cornacchio, J. Rocchio, N. Sandhal, C. Jean-Francois, C. Belisle, and S. Ahmed who recused.

2. PTT07264 Joseph, Junia Represented by: Self Recusal: Cornacchio/Rocchio/Sandhal

Discussion: J. JOSEPH petitioned for an extension of her pharmacy technician trainee license. She explained that she completed the Middlesex Community College trainee program in partnership with CVS but could not work in the pharmacy due to COVID restrictions. JOSEPH has recently been offered the opportunity to begin work at CVS as a technician trainee.

Action: A motion was made by C. Belisle to extend the expiration date of J. Joseph's pharmacy technician trainee license by one year; Seconded by D. Barnes, then Board Members present voted unanimously by rollcall to approve motion except S. Cornacchio, J. Rocchio, and N. Sandhal who recused.

3. PTT08633 Chy, Jennifer Represented by: Self Recusal: Cornacchio/Rocchio/Sandhal

Discussion: J. CHY petitioned for an extension of her pharmacy technician trainee license. She indicated that upon starting her training in the pharmacy, some family members became ill and required round-the-clock care. As a result, she was not able to complete her training. CHY is currently employed by CVS and was given the opportunity to begin training as a pharmacy technician.

Action: A motion was made by C. Jean-Francois to extend the expiration date of J. Chy'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, J. Rocchio, and N. Sandhal who recused.

4. PTT07145 Lussier, Brianna

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TIME 8:49am

TIME 8:52am

TIME 8:56am

Represented by: Self Recusal: None

Discussion: B. LUSSIER petitioned for an extension of her pharmacy technician trainee license. She indicated that she was previously employed by Apothecare but fell ill prior to beginning work in the pharmacy and needed intensive care for 6 months. LUSSIER recently began working again and was offered the opportunity at a Walgreens to begin training as a pharmacy technician.

Action: A motion was made by J. Chin to extend the expiration date of B. LUSSIER's pharmacy technician trainee license by one year; Seconded by D. Barnes, then Board Members present voted unanimously by rollcall to approve motion.

TIME 8:59am

5. PTT08535 Deas, Cody Represented by: Self Recusal: None

Discussion: C. DEAS petitioned for an extension of their pharmacy technician trainee license. They are currently employed as front store staff and working towards becoming a store manager and obtaining a pharmacy technician license. They were previously unable to obtain hours in the pharmacy due to staffing shortage. DEAS was offered the opportunity to beginning training in the pharmacy as a pharmacy technician.

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

ΤΟΡΙϹ ΙΧ	File Review	
Case #1/CAS-2021-0741		Time: 09:02 AM
SA-INV-18278	Dan's Pharmacy, DS89748	

RECUSAL: NONE

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

- A PTT was observed administering a COVID-19 test during a retail compliance inspection by Investigator Stephen Horn in July 2021.
- Dan's Pharmacy did not directly address the reason for using a PTT to test in violation of BORP Policy 2020-14 in its response. Instead, Dan's Pharmacy insisted that the activity was authorized by BORP Policy 2020-14 (rev. 02/19/2021). No version of BORP Policy 2020-14 authorized PTTs to administer COVID-19 tests.
- Dan's Pharmacy ceased ordering, administering, processing, reading, and reporting the results of COVID-19 tests at the end of July 2021. The pharmacy provided copies of its standard operating

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procedure (SOP) for COVID-19 testing and manufacturer's instructions for use for the FDAauthorized test used for its testing program.

• The SOP did not delineate which staff members may order, administer, process, and report the results of COVID-19 tests. The SOP did require the pharmacist on duty to read results and notify patients who test positive. For negative results, all staff members were authorized to notify patients.

<u>ACTION</u>: Motion by J. ROCCHIO, seconded by S. HAMILTON, and voted unanimously by those present, to CLOSE the matter (SA-INV-18278), No Discipline Warranted, Remediation Complete.

Case #2/CAS-2021-0692		
PHA-2021-0059	Walgreens #17177, DS90123	Time: 09:10 AM

RECUSAL: NONE

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

- On July 20, 2021, OPP Investigator Paul Seed conducted a retail compliance inspection at WAG #17177. At first, WAG #17177 complied with supervisory because one of three technician w/o nationally certification was not being used to fill prescriptions. However, Investigator Seed later observed the technician designated as cashier assist in filling prescriptions when she processed a refill request for a patient. At that instant, WAG #17177 no longer complied with minimum supervisory ratios because three pharmacy technicians without national certification were utilized to fill prescriptions while supervised by one pharmacist.
- In addition, WAG 17177 failed to submit a change in MOR application for the current MOR who has served as MOR since at least July 20, 2021.
- The current MOR indicated that the following corrective action was implemented: Technicians were provided with cashier badges and required to wear their cashier badges when assigned to cashier duties to visually delineate their function. The pharmacy's employee schedule was updated to display which staff member was the designated cashier at all times. In addition, WAG #17177's job description for pharmacy cashiers was posted in the pharmacy so staff may easily reference assigned job duties a cashier may perform. The current MOR also indicated that he reviewed regulations for supervisory ratios with all members of WAG #17177's pharmacy staff. Lastly, two technicians have earned national certification since the incident on July 20, 2021.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by K. THORNELL, and voted unanimously by those present, to refer the matter (PHA-2021-0059), to the office of the 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-2021-0594 PHA-2021-0045 Walgreens #11885, DS89774

Time: 09:12 AM

RECUSAL: NONE

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

- CS loss of #100 oxycodone 30mg tablets on or about June 7, 2021, and the reason for the loss was unknown.
- MOR Galvin indicated that on June 8, 2021, the bottle of 100 oxycodone 30mg was discovered missing while completing a drug inventory count.
- MOR Galvin stated that Pharmacist Cox was seen on video at the fill station processing a prescription for oxycodone 30mg tablets on June 7, 2021. She had 3 stock bottles in a red plastic bin at the time. After production, Pharmacist Cox placed the empty stock bottles into the red bin containing the 3rd bottle and as she walked to the verification screen, she was seen throwing out the contents of the red bin containing the stock bottles in the trash.
- MOR Galvin noted that the patient who had picked up the prescription on June 7, 2021, was contacted and she confirmed that she received the correct quantity of 120 tablets. On June 8, 2021, the District Manager was notified of the suspected loss.
- MOR Galvin indicated that corrective actions would include logging in and back counting on-hands to verify inventory counts are correct right after filling prescriptions and putting stock bottles away immediately after filling prescriptions or as soon as possible if medication is in the time delay portion of the safe.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by D. BARNES, and voted unanimously by those present, to DEFER the vote on the matter (PHA-2021-0045), pending receipt and review of video footage by investigator.

Topic X: By: J. Lanza

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

Time: 9:18 AM

Executive Session Call to Order:

C. Jean-Francois leaves meeting 10:10 AM J. Rocchio and S. Cornacchio leave meeting at 10:29 AM

Topic XI:65C Sessions MGL c. 112 section 65CTime: 10:17 AM

DISCUSSION: None

ACTION: President J. Lanza request a motion to enter 65C.

At 10:17 AM J. Chin, seconded by K. Thornell and voted unanimously by all those present to enter 65C by roll call vote.

ACTION: Motion by S. Hamilton seconded by K. Thornell 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 12/3/21 General Session
- 2. Draft Minutes of the 11/12/21 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 PSUD 17-03
- 7. Policy 2021-04 Continuing Education (CE) Requirements
- 8. PTT Petition for Waiver: Davila Sachalyz
- 9. PTT license extension:
 - a. PTT08535 Deas Cody
 - b. PTT08884 Masteron-Jones, Valrie
 - c. PTT7264 Joseph, Junia
 - d. PTT07145 Lussier, Brianna
 - e. PTT08633 Chy, Jennifer
- 10. CAS-2021-0741 SA-INV-18278 Dan's Pharmacy, DS89748
- 11. CAS-2021-0692 PHA-2021-0059 Walgreens #17177, DS90123
- 12. CAS-2021-0594 PHA-2021-0045 Walgreens #11885, DS89774

Respectfully Submitted, Carly Jean-Francois, NP, Secretary