COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

June 25, 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: 161 280 4542

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
	II	APPROVAL OF AGENDA		
	ш	 APPROVAL OF BOARD MINUTES Draft of June 11, 2021 Regular Session Minutes 		
8:05	IV	 FLEX Pharmacy issues related to Covid-19 and the state of emergency Removal of MA State of Emergency language from Policy 2020-14: COVID-19 Testing 		

8:10	V	 APPLICATIONS Onco360; DS89921- Relocation Gabrielle McCloskey; PTT05250 – Second license extension Koala Pharmacy Boston, LLC – New Community Pharmacy BILH Pharmacy- New Community Pharmacy NIMVAX- New Community Pharmacy 		
8:45	VI	 POLICIES Research Drug Study Report by Staff Action Policy 18-02 Rescission of Staff Action Policy 20-01 to Handle NABP Reports of Licensee Sanctions 		
9:00	VII	FILE REVIEW 1 CAS-2021-0391 SA-INV-17844 Afshin Shamooni, PH25164 2 CAS-2021-0442 SA-INV-17921 James Glass, PH18910 3 CAS-2021-0480 SA-INV-17933 Alexandria Johnson, PH236160 4 CAS-2021-0221 SA-INV-17627 Stop & Shop #2417, DS90070		
9:20	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.		CLOSED SESSION
10:00	IX	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION
10:30	X	ADJOURNMENT		

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE GENERAL SESSION Via Remote WebEx Meeting June 25, 2021

Board Members Present

Board Members Not Present

Julie Lanza, CPhT, President 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 9:51 AM) Caryn Belisle, RPh, MBA Leah Giambarresi, Pharm D, RPh Katie Thornell, RPh, MBA (arrives meeting at 8:05 AM) Jennifer Chin, RPh Dr. Richard Lopez, MD Dawn Perry, JD (leaves meeting at 11:00 AM) Timothy Fensky, 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 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

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, yes; T. Fensky, yes; D. Perry, yes. K. Thornell arrives at meeting 8:05 AM

Approval of Agenda

TIME 8:04 AM

Agenda 6/25/21

DISCUSSION:

Change to Agenda: Defer BILH Pharmacy Application

ACTION:

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

Topic III

Approval of Board Minutes

TIME: 8:05 AM

Minutes

1. Draft 6/11/21

Change: no noted changes

Action:

Motion by L. Giambarresi seconded C. Belisle and voted unanimously to approve the regular session minutes of 6/25/21 with no noted change by roll call vote. D. Perry abstains.

TOPIC IVFlex1. Pharmacy Issues Related to Covid-19 and State of EmergencyTime: 8:05 AM

Presented by: D. SENCABAUGH

Discussion: The state of emergency in Massachusetts has now ended.

Although final guidance is pending, any licenses that have been due to expire since March 10, 2020, must be renewed prior to September 15, 2021. Any Non-Resident Pharmacists / Technicians who have been granted temporary emergency authorization to practice in Massachusetts may do so until September 15, 2021. Anyone wishing to practice in Massachusetts after that date should begin the reciprocation process as soon as possible. No additional emergency authorizations will be issued.

The allowance to the Massachusetts open meeting law permitting video conferenced Board meetings has been extended to April 2022.

The Board is now enforcing the following pre-pandemic requirements:

- supervisory ratios
- perpetual inventory every 10 days
- compounding hand sanitizer without a patient-specific prescription is no longer allowed
- restocking emergency kits in long term care facilities within 48 hours
- ID requirement for picking up a federally controlled substance or gabapentin HOWEVER, ID is not needed to pick up prescriptions for federally scheduled CS and gabapentin in certain circumstances. In order to pick them up post-pandemic, the individual must print their name and address on the reverse side of the prescription and sign it. In the case of an electronic prescription, they must provide an electronic signature. Contact the Drug Control Program for details.

The authority for qualified technicians to vaccinate comes from the federal PREP Act that is still in place. They may continue to vaccinate at this time.

So noted.

2. Removal of MA State of Emergency language from Policy 2020-14: COVID-19 Testing Time: 8:11 AM

Presented by: M. CHAN

Discussion: The language about the Massachusetts state of emergency has been removed from the COVID testing policy now that the emergency period has ended in Massachusetts. No substantive changes to the policy have been made and it has been resent for posting.

No other documents needed updating since they did not contain this language. Other COVID-19 related policies only refer to the federal PREP Act.

So noted.

TOPIC V

Applications

1. ONCO360 DS89921

Relocation

TIME: 8:13AM

Represented by:

Cameron Franklin, Troy Agard (Manager of Record), and Leo Gray

Recusal: N/A Discussion:

MOR Troy indicated that the facility is being updated and relocating down the street with go live on July 19, 2021, with business model still intact. Schedule II through V medications not filled at the pharmacy.

W. FRISCH asked oncology medications with manipulation and if following under USP 800. MOR Troy said that they do not do any USP 800 manipulation. W. FRISCH indicated that if the

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pharmacy stores oncology medications with no manipulation, it requires that they follow USP 800 requiring oncology medications stored under negative pressure and noted that it can be addressed offline. M. CHAN indicated that the pharmacy should re-submit waivers for 247 CMR 6.01 (5) (a) (4)- balance, 247 CMR 6.02 (4) – sufficient variety of chemicals, 247 CMR 9.01 (15) – limiting services to segment of public, and 247 CMR 9.01 (16) – cannot refuse to compound.

<u>ACTION:</u> Motion by C. BELISLE seconded by T. FENSKY, voted unanimously by those present to approve the application pending a successful inspection, adhering to USP 800 standards, and re-submit waiver applications for 247 CMR 6.01 (5) (a) (4)- balance, 247 CMR 6.02 (4) – sufficient variety of chemicals, 247 CMR 9.01 (15) – limiting services to segment of public, and 247 CMR 9.01 (16) – cannot refuse to compound.

 2. Gabrielle McCloskey PTT05250
 Second Extension license
 TIME: 8:21AM

 Represented by: Gabrielle McCloskey

Recusal: N/A

Discussion:

Gabrielle requires a second extension for her Pharmacy Technician Trainee (PTT) license which expires on 6/30/2021. She completed nominal hours in 2019 and does not meet the 500 hours. Gabrielle noted that during the first year, she was only able to work 50 hours and unable to complete the hours. She is a full-time student at UMass-Boston and does not work from September through May. She noted that she would need 50 weeks to complete the 500-hour requirement and would be working in the fall.

E. TAGLIERI indicated that the Board is working on an updated extension policy for PTT licenses for consistency. He noted that the vote for the second extension for Gabrielle be deferred until the policy is brought forth to the board on or around September 15, 2021. H. ENGMAN indicated that we need a policy to standardize the extensions. R. HARRIS indicated that her license is current, and she is able to continue to work until September 15, 2021. The Board will reach out to Gabrielle once the policy is reviewed by the Board.

<u>ACTION:</u> Motion by T. FENSKY, seconded by L. GIAMBARESSI, voted unanimously by those present to defer this PTT second license extension until the PTT extension policy is brought forth to the Board for review.

3.	Koala Pharmacy Boston, LLC	New Community Pharmacy	TIME:

8:31AM

Represented by: Dane Osmanski, proposed Manager of Record.

Recusal: N/A

Discussion:

Dane indicated graduating in 2014 from Northeastern University. The business model is a non-compounding veterinary pharmacy that will be located in South Station. T. FENSKY inquired if this is a chain pharmacy. Dane indicated that this is a first startup company. T.

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FENSKY said that consultation area is not included in the square footage. W. FRISCH noted that the drawing needs to be re-casted to include the prescription area, storage for the pharmacy. T. FENSKY said that veterinary pharmacy usually compound and how he would address that issue. Dane indicated that they would like to specialize in adherence packaging and work with other pharmacies. A. STEIN indicated that he had concerns with partnership with other pharmacies and potentially re-dispensing. C. BELISLE indicated if the licensee is compounding under 20 compounds per day and thought it had to be answered. L. GIAMBARESSI indicated that there are about 10 doors to the pharmacy. Dane indicated that all the controlled substances will be secure. T. FENSKY indicated where the pharmacy is located. Dane noted that the pharmacy is located on the first floor of the 4-story building with different tenants above and noted that there is wood between each floor. Dane indicated that he is the only employee with plans to hire a per-diem pharmacist and certified pharmacy technician. C. BELISLE indicated that if only one pharmacist is allowed. And it was noted that the pharmacy must have a continuity of care plan in the event that the public cannot be served.

Dane noted that the pharmacy is projected to open in the middle of July 2021.

<u>ACTION:</u> Motion by L. GIAMBARESSI, seconded by C. BELISLE, voted unanimously by those present to approve the application with conditions of recasting drawing of the pharmacy area, successful inspection, 3 waivers submitted including 247 CMR 6.01 (5) (a) (4)- balance, 247 CMR 6.02 (4) – sufficient variety of chemicals, 247 CMR 9.01 (15) – limiting services to segment of public, and 247 CMR 9.01 (16) – cannot refuse to compound.

4. BILH Pharmacy New Community Pharmacy DEFERRED

5. NIMVAX New Community Pharmacy TIME: 8:48AM

Represented by: Nimit Deocampo (proposed Manager of Record), Lindsay Wall (Pharmacy Consultant), Daniel Ritchie (QA consultant)

Recusal: N/A

Discussion:

Founder Deocampo indicated that this is a new immunization independent pharmacy to help improve immunization delivery. This is a new, innovative immunizations for a positive experience. We operate Tues-Sunday 9-5pm by appointment and streamline process and spend the time with the patient. Nimit is the only pharmacist with two certified pharmacy technicians. W. FRISCH indicated that the pharmacy drawing be redone. C. BELISLE asked regarding the setup of the pharmacy.

Nimit indicated that there is a 24/7 monitoring of the pharmacy space. He indicated that there is 1 large and 1 small refrigerator. T. FENSKY asked the location of the pharmacy. Nimit indicated it is located in Cummings Park in Beverly, MA and in a corner unit in a shopping plaza. On the first floor, there are 6-7 businesses.

S. CORNACCHIO indicated that this is a large business within mixed use of businesses and asked if the patients can be observed. Nimit will have 2 pharmacy technicians to go between the 2 rooms to check the patients. The doors will be open to observe patients. T. FENSKY indicated that this does

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not fit within a pharmacy model but rather a clinic. He noted that this model requires a different type of license rather than a pharmacy license. S. HAMILTON indicated that he would like to consider a pilot project for this model. S. CORNACCHIO noted that a pilot project should be considered in a safe manner to see if this innovation will work. Of note, they have numerous waivers beginning on page 72 of the Board packet.

<u>ACTION:</u> Motion by C. BELISLE, seconded by S. CORNACCHIO, voted unanimously by those present to

defer this matter to a further meeting for consideration.

1. Research Drug Study Report by Staff Action Policy 18-02

TOPIC VI

Policies

Time: 9:30 AM

Presented by M. CHAN

Discussion: There are 3 pharmacies participating in a total 12 active research studies, one of which involves an investigational drug.

So noted.

2. Rescission of Staff Action Policy 20-01 to Handle NABP Reports of Licensee Sanctions Time: 9:31 AM

Presented by M. CHAN

Discussion: This staff action policy was approved last November to grant Board staff the ability to manage NABP Clearinghouse reports of Board-licensee sanctions issued in other jurisdictions. It included language to handle CE violations as well as certain administrative and criminal violations. However, since it has been difficult to apply the policy to the many different scenarios, staff would like to handle these reports through the normal triage process. A triage policy is now under revision to address these reports and will be brought forward in the near future.

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

ΤΟΡΙϹ VII	File Review	
Case #1/CAS-2021-0291		
SA-INV-17844	Afshin Shamooni, PH25164	Time: 09:33 AM
<u>RECUSAL</u> : NONE		
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Draft Minutes General Se	ession: 6/25/21	
BOP Approved: Pending		

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

- Pharmacist Shamooni's MA license was issued 8/10/2001 and expired 12/31/2006.
- NABP Clearinghouse report of discipline in CA as PIC of the Pharmacy for failure to provide all documents requested by the CBOP and for dispensing prescriptions to customers in Florida without proper licensure as a nonresident pharmacy. Pharmacist Shamooni's CA license was placed on probation for 5 years effective 8/26/2020.
- The Accusation included with the report indicated four causes of discipline for unprofessional conduct were cited including Subverting a Board Investigation; Violation of Statute; Failure to Produce Records; and Dishonesty, Fraud, or Deceit.
- In response to the notification of the MA OPP investigation on 5/3/2021, Pharmacist Shamooni's Attorney first inquired what the consequences would be in the event Pharmacist Shamooni chose not to reply. He was informed, "As the notification states: If you do not submit a response regarding the investigation..., OPP and Board staff will assess the complaint based on the information in their possession". On 5/4/2021, the Attorney responded, "We are authorized by Mr. Shamooni to inform you of his decision to submit his Massachusetts pharmacist license for cancellation. As such, he will not be responding to your inquiry".

<u>ACTION</u>: Motion by T. FENSKY, seconded by A. STEIN, and voted unanimously by those present, to ELEVATE the matter (SA-INV-17844) to a complaint, and refer 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 REVOCATION.

Case #2/CAS-2021-0442		
SA-INV-17921	James Glass, PH18910	Time: 09:43 AM

RECUSAL: NONE

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

- The BORP received a report of discipline in another jurisdiction for Pharmacist Glass. A Consent Order from the NABP Clearinghouse dated 8/29/2013 for discipline of a fine of \$200.00 imposed by the TNBOP on Pharmacist's Glass' license for allowing an unlicensed person to work as a pharmacy technician from 7/1/2012-11/20/2012. Pharmacist Glass stated the unlicensed individual has just passed his NAPLEX exam and he had been aware the person was unlicensed. Pharmacist Glass was in the process of disciplining him when the TNBOP performed an inspection at the pharmacy.
- Additionally, during the investigation, it was determined Pharmacist Glass failed to complete any CEs in 2019 which he indicated was resolved with the TNBOP. Pharmacist Glass attested that 12 CEs of his 32 CEs including 5 live and 2 law completed in 2020 and 8 CEs completed on 3/6/2021 would be considered as remediation of his 2019 deficiency. Pharmacist Glass confirmed he understood any CEs completed for remediation cannot be used to fulfill his 2021 CE requirements.

<u>ACTION</u>: Motion by J. CHIN, seconded by S. HAMILTON, and voted unanimously by those present, to CLOSE the matter (SA-INV-17921), No Discipline Warranted, Remediation Complete.

Case #3/CAS-2021-0480 SA-INV-17933

Alexandria Johnson, PH236160

Time: 09:46 AM

RECUSAL: NONE

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

On 5/10/2021, Pharmacist Johnson self-reported she was deficient 6 CEs in 2019. Pharmacist Johnson is not currently practicing in MA but wanted to maintain her MA license. After realizing her deficiency in 2020, she self-remediated by completing 6 additional CEs on 12/31/2020 for a total of 26 CEs in 2020. On 06/03/2021, Pharmacist Johnson was notified she could renew her MA pharmacist license.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by T. FENSKY, and voted unanimously by those present, to CLOSE the matter (SA-INV-17933), No Discipline Warranted, Remediation Complete.

Case #4/CAS-2021-0221		
SA-INV-17627	Stop and Shop, DS90070	Time: 09:48 AM

<u>RECUSAL</u>: K. THORNELL 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 02/24/2021, the Pharmacy submitted a final Board Report of Loss of Controlled Substances (RLCS) and DEA Form 106. An investigation was concluded on 2/8/2021, which confirmed the loss of #1 amphetamine mixed salts 10 mg tablets, #4 amphetamine mixed salts 15 mg tablets, and #2 amphetamine mixed salt 30 mg tablets due to employee pilferage occurring from on or about 11/30/2020-02/08/2021.
- MOR at time of the loss Alyson Williams responded that on 1/26/2021 pharmacist Sean Wiggin was returning a prescription for amphetamine 30 mg tablets filled on 1/25/2021 to stock and was verifying the count in the return to stock bottle and observed that the bottle was 1 tablet short. Also, on 2/5/2021, an additional loss for amphetamine 15 mg tablets was noted when pharmacist Williams recounted a prescription in the will call area filled that morning.
- After review of video surveillance, a pharmacy cashier, not licensed by the Board, was interviewed. The associate admitted to taking amphetamine pills approximately 4-5 times for her own use and the use of other family members (mother and spouse). The Bourne police department was contacted.
- The associate's employment was suspended on 02/08/2021, and employment was later terminated. All pharmacy staff read and agreed to uphold Stop and Shop Policy 19-005: *Controlled Substance*.

<u>ACTION</u>: Motion by S. HAMILTON, seconded by J. CHIN, and voted unanimously by those present, to CLOSE the matter (SA-INV-17627), No Discipline Warranted, Remediation Complete.

Topic VII: By: J. Lanza **Executive Session Call to Order:**

Time: 9:51AM

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<u>ACTION</u>: Motion by, L. Giambarresi, seconded by T. Fensky, 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; S. Cornacchio, yes; R. Lopez, yes; T. Fensky, yes; D. Perry, yes. K. Thornell, yes.

S. Cornacchio leaves meeting 9:51 AM

Topic VIII:

65C Sessions MGL c. 112 section 65C

Time: 10:32 AM

DISCUSSION: None

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

At 10:32 AM T. Fensky, seconded by J. Chin and voted unanimously by all those present to enter 65C by roll call vote.

D. Perry leaves meeting at 11:00 AM

Topic IX

ADJOURMENT OF MEETING

TIME: 11:15 AM

ACTION: Motion by T. Fensky seconded by L. Giambarresi 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 6/25/21 General Session
- 2. Draft Minutes of the 6/11/21 Meeting
- 3. Application: Onco360; DS89921- Relocation
- 4. Application: Gabrielle McCloskey; PTT05250 Second license extension
- 5. Application: Koala Pharmacy Boston, LLC New Community Pharmacy
- 6. Application: BILH Pharmacy- New Community Pharmacy
- 7. Application: NIMVAX- New Community Pharmacy
- 8. Research Drug Study Report by Staff Action Policy 18-02
- 9. Rescission of Staff Action Policy 20-01 to Handle NABP Reports of Licensee Sanctions
- 10. CAS-2021-0391 SA-INV-17844 Afshin Shamooni, PH25164
- 11. CAS-2021-0442 SA-INV-17921 James Glass, PH18910
- 12. CAS-2021-0480 SA-INV-17933 Alexandria Johnson, PH236160
- 13. CAS-2021-0221 SA-INV-17627 Stop & Shop #2417, DS90070.

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Draft Minutes General Session: 6/25/21 BOP Approved: Pending Respectfully Submitted, Carly Jean-Francois, NP, Secretary