COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

May 7, 2020

Regular Session is open to the public and will be heard via Webex Conference Call

Webex information:

Call in Number: 1-203-607-0564 or toll free 1-866-692-3580 Access Code: 615 536 987

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
9:00	I	CALL TO ORDER		K. Tanzer
	II	APPROVAL OF AGENDA		
9:10	Ш	 APPROVAL OF BOARD MINUTES Draft of March 5, 2020 Regular Session Minutes 		
9:15	VI	 FLEX Virtual Board Meeting Schedule NABP Annual Conference: Resolutions and Candidates for Office Potential testing at pharmacies Pharmacy issues related to Covid-19 and the state of emergency 		

10:00	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 		
10:15	V	 APPLICATIONS MyLyfe Specialty Pharmacy –New Community Pharmacy AllCare Plus; DS89984 – Transfer of Ownership Amber Pharmacy – New Community Pharmacy Radioisotope Life Sciences (WD446) Transfer of Ownership Genoa Healthcare LLC- New Community Pharmacy 		
11:00	VII	FILE REVIEW 1 PHA-2019-0103 Stop & Shop #87, DS2322 2 PHA-2020-0016 CVS #2377, DS3090 3 PHA-2020-0017 CVS #447, DS3251 4 PHA-2020-0015 CVS #1094, DS1627 5 PHA-2020-0018 CVS #2125, DS2763		
11:30	VIII	BREAK		
12:00	IX	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 hear a petition for reinstatement and a request to take NAPLEX and to evaluate the Good Moral Character as required for registration for a pending applicant.	Closed Session	
1:00	X	M.G.L. c. 112, § 65C SESSION		
5:00	XI	ADJOURNMENT		

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE REGULARLY SCHEDULED MEETING May 7, 2020

The Regular Session of this meeting is open to the public and will be heard via Webex Conference Call

Board Members Present

Kim Tanzer, PharmD, RPh. President
Julie Lanza, CPhT, President Elect
Leah Giambarresi, Pharm D, RPh, Secretary
Sebastian Hamilton, Pharm D, RPh
Dr. Richard Lopez, MD
Timothy Fensky, RPh
Katie Thornell, RPh
Stephanie Hernandez, Pharm D, BCGP, RPh
Patrick Gannon, RPh
Susan Cornacchio JD, RN

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
Gregory Melton, Pharm D, JD, RPh Investigator
Christina Mogni, RPh Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Joanna Chow, Office Support Specialist
Richard Harris, Program Analyst
John Murray, RPh Investigator
Richard Geaney, RPh Investigator
Leo McKenna, RPh Investigator

Board Members Not Present

Carly Jean-Francois, RN, NP Dawn Perry, JD Andrew Stein, Pharm D

GENERAL

TOPIC I. Attendance by roll call:

CALL TO ORDER 9:00 AM

TOPIC I. Attendance by roll call: Roll call attendance: K. Tanzer, yes; J. Lanza, yes; L. Giambarresi, yes; S. Hamilton, yes; R Lopez, online; but not responded; T. Fensky, yes; K. Thornell, yes; S. Hernandez, yes; P. Gannon, yes; S. Cornacchio, yes;

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

All votes are to be done by roll call and use of the chat function in Webex is not permitted.

TOPIC II. Approval of Agenda TIME: 9:04

Agenda: May 7, 2020

Changes: No changes

It is noted that C. JEAN-FRANCOIS, D. PERRY and A. STEIN are not present at 9:07 AM.

ACTION: Motion by L. GIAMBARRESI, seconded by K. THORNELL and voted unanimously by those present to approve the agenda. R. LOPEZ did not respond during roll call

Topic III Approval of Board Minutes

1. Minutes Time: 9:08 AM

Draft March 5, 020

Changes: No Changes.

ACTION: Motion by L. GIAMBARRESI, seconded by T. FENSKY and voted unanimously by those present to approve the agenda. R. LOPEZ and S. HERNANDEZ did not respond during roll call.

GENERAL

Topic IV FLEX

1. Virtual Board Meeting Schedule

Presented by: D. SENCABAUGH

Discussion: Due to the pandemic emergency period, D. SENCABAUGH discussed the need to have virtual board meetings at least through the end of July, 2020. Except for May 22 and July 3, virtual Board meetings will occur weekly on Fridays. The usual monthly Thursday meetings will not be held during this time. Agendas will continue to be posted on the website prior to the meetings.

TIME: 9:08 AM

TIME: 9:16 AM

2. NABP Annual Conference: Resolutions and Candidates for Office TIME: 9:11 AM

Presented by: D. SENCABAUGH

Discussion: Since the live NABP meeting has been canceled, a virtual one-day meeting will be held on May 14. T. FENSKY will be installed as the new NABP president and the delegate will be L. GIAMBARRESI with S. HAMILTON as the back-up. T. FENSKY announced that since USP <795> and <797> are under appeal, the proposed resolution regarding them has been rescinded.

Action: Motion by T. FENSKY, seconded by P. GANNON, and voted unanimously by roll call of those present, to allow the delegate to vote on the resolutions on behalf of the Board members.

3. Potential Testing at Pharmacies

Presented by: D. SENCABAUGH, W. FRISCH

Discussion: Board staff has received several inquiries regarding the pharmacist administration of COVID-19 tests and has been diligently discussing the matter with other state bureaus including the Bureau of Infectious Disease and Laboratory Sciences (BIDLS) and Health Care Safety and Quality (HCSQ). Although staff believes that pharmacists should be involved, it will take time to be sure that any procedures that are put in place would be in line with Massachusetts laws and the overall state testing plan.

At this time, pharmacists are permitted to observe and collect test samples that have been self-administered by patients, but pharmacists may not administer or evaluate COVID-19 tests.

As staff learns more about the issue, the Board members will be updated and the information will be communicated through the distribution list and added to the FAQ document.

4. Pharmacy Issues Related to COVID-19 and the State of Emergency

TIME: 9:19 AM

Presented by: W. FRISCH

Discussion: Since the COVID-19 crisis began, pharmacy investigators and Board staff have been working diligently to provide guidance and assistance to its licensees whenever possible.

Draft minutes 5/7/20 BOP approved: 5/15/20 and 5/29/20 The pharmacy investigators have been reaching out to pharmacies to provide support and answer questions and Board staff has developed a frequently updated FAQ document encompassing all the guidance and links to date. Some of the guidance refer to the Commissioner's orders that allow, among other things, permission to compound hand sanitizer, offer emergency refills, and conserve compounding garb.

Under a specialized program, pharmacists and technicians from other states are also permitted to practice in Massachusetts during the emergency period.

Additionally, interagency work has also produced an insurance information document to further guide licensees. The FAQ document and other documents are located on the Board's homepage.

TOPIC IV REPORTS

Applications approved pursuant to Licensure Policy 13-01 Time: 9:23 AM

Discussion: R. HARRIS noted that there have been forty-four (44) Change of Managers applications, five (5) Renovation applications, two (2) New Community Pharmacies applications, one (1) Relocation application and seven (7) pharmacy closings approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV REPORTS

Monthly Report from Probation Time: 9:24 AM

Discussion: R. HARRIS noted that zero (0) report(s) from probation have been reported since last Board meeting.

So noted

TOPIC IV REPORTS

Monthly Report from BDR pursuant to Policy 14-02 Time: 9:25 AM

Discussion: D. SENCABAUGH noted that there was eleven (11) Board Delegated Review case heard on May 4, 2020. There were ten CE self-disclosures (SA-INV-16029, SA-INV-16145, SA-INV-16146, SA-INV-16187, SA-INV-16028, SA-INV-16033, SA-INV-16034, SA-INV-16035, SA-INV-16078, SA-INV-16223) which were closed with discipline not warranted and remediation complete. There was one consumer grievance (SA-INV-15915) which was closed with no violation. The Board Delegated Review session was attended by K. TANZER as the Board President, D. SENCABAUGH as Executive Director, W. FRISCH as Director of Pharmacy Compliance, and H. ENGMAN as Board Counsel.

So noted

TOPIC IV REPORTS

Above Action Levels Approved by Staff Action 16-04 Time: 9:26 AM

Discussion: J. TRAN noted that three (3) above action level report has been reported since last Board meeting pursuant to Licensure Policy 16-04.

So noted

TOPIC IV REPORTS

PSUD Report by Staff Action 17-03 Time: 9:26 AM

Discussion: Defer

So noted

1. MyLyfe Specialty Pharmacy

New Community Pharmacy

TIME: 9:28

Represented by: Adam Mulgary President

Recusal: None, Susan Cornacchio had technical issues

Discussion:

Kim Tanzer: Walk us thru the pharmacy services and what type of services are you going to offer.

Applicant: Operating as a independent retail pharmacy located in a standalone building open to the public.

This is a second location our first pharmacy is in Connecticut.

Pharmacy Signage will be visible to the public.

Mr Knight is the Manager of Record

Patrick: Are you operating the pharmacy as a traditional pharmacy

Mr. Mulgary: The pharmacy will be providing services to a wider range of disease states.

Patrick: asked if Mr. Knight is a first time MOR, and recommended reviewing the Boards guidelines for Manager of record published on the Board's website

Tim: Ask questions related to non-sterile compounding attestation specifically question #16 to verify that the pharmacy will only be compounding with commercially available products.

Mr. Mulgary responded correct and reminded the board that he was not a pharmacist and that was his understanding.

Patrick: do you plan on expanding your staffing, Mr Mulgary responded yes over time.

Kim Tanzer: Asked what disease state are you adding to your services.

Mr. Mulgary; responded oncology and disease states blood disorders and Hemophilia.

Patrick: Reminded Mr. Mulgary that the owners are non-pharmacist and would not be allowed in the dispensing area where the license staff are working.

Mr. Mulgary: responded in agreement

Action: **Approve** Deny Other

Conditions Comments

M: Kim, Julie, Leah, Dr. Lopez, Tim, **Sebastian**, Katie, Patrick, Stephanie, Susan

S: Kim, Julie, **Leah**, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie, Susan

V: Kim, Julie, Leah, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie

VI: Applica	ations:
-------------	---------

2. AllCare Plus DS89984

Transfer of Ownership

TIME: 9:42 am

Represented by: Dan L'Italien and John Leyten

Recusal: none, None, Susan Cornacchio had technical issues

Discussion:

John Layten, Director of Pharmacy for ALLCare Pharmacy stated the transfer of ownership is occurring on April 22, 2020 license was issued by the Massachusetts Board of Pharmacy.

- Everything is staying the same the ownership is changing.
- The Pharmacy is operating from the same location.

Action: Approve Deny Other

Conditions Comments

M: Kim, Julie, Leah, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie, Susan
 S: Kim, Julie, Leah, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie, Susan

V Kim, Julie, Leah, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie

NOTE: Susan had technical difficulties making her unable to participate in the vote.

GENERAL

VI: Applications:

3. Amber Pharmacy New Community Pharmacy TIME: 9:48 am

Represented by: Kelly, Department Supervisor Eli, Manager of Records

Recusal: non, Susan had technical difficulties Discussion:

Amber Pharmacy

Represented By: Kelly, Department Supervisor

Eli, Manager of Records

Requesting application for new Pharmacy

· Headquarters in Omaha, Nebaska.

Page 6 of 12

- · Specialize in specialty medications.
- · Open door pharmacy open to the public.
- · Location, Gateway Center, Newton, Massachusetts.
 - o level of the office building with a public entrance and public parking for patients.
 - o Accessible from Main Street.
- Eli was a pharmacist for 8 years at a retail pharmacy, Walmart Board advised Eli to review BOP MOR responsibilities via the Everbrite located on the Board's website.
- · 24 hour toll free number available to call for pharmacy consult.
- · There will be no specialty packaging.
- · There will be no immunizations.
- · The application was updated to include moderate compounding.
- The pharmacy will commercially approved powders and will not use bulk powders.

Action: Approve Deny Other
Conditions Comments

M: Kim, Julie, Leah, Dr. Lopez, **Tim**, Sebastian, Katie, Patrick, Stephanie, Susan

S: Kim, Julie, Leah, Dr. Lopez, Tim, **Sebastian**, Katie, Patrick, Stephanie, Susan

V Kim, Julie, Leah, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie

NOTE: Susan had technical difficulties making her unable to participate in the vote.

GENERAL

VI: Applications:

4. Springfield Pharmacy

New Community Pharmacy

TIME: 9:53 am

Recusal: None Discussion:

New Community Pharmacy – Springfield Pharmacy

- New property located in Holyoke, Massachusetts.
- Open Community Pharmacy.
- Will function the same as the current Springfield Pharmacy in Springfield.
- No deliveries
- Unit dose packaging coming out of the store.
- Addendum to the application to include simple and moderate compounds.
- Located within a multi-unit building with businesses on both sides and apartments on top.
- Pharmacy is located on the level.
- Will use the sample security system company, Beacon protection, as the Springfield Pharmacy.
 - o Doors and safe will be alarmed.
 - o Motion sensors and cameras will be in place.
- MOR is new as MOR
 - Board recommended the MOR review the BOP website pertaining to regulations.
- Staffing
 - o 2 full time pharmacist.

Page 7 of 12

- o 2 technicians one will be multi- lingual.
 - (The Board stated that Technician Trainees become licensed).
- Both Pharmacies will be called "Springfield Pharmacy".

Action: Approve Deny Other Conditions Comments

M: Kim, Julie, Leah, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie, Susan
 S: Kim, Julie, Leah, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie, Susan
 V Kim, Julie, Leah, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie, Susan

GENERAL

VI: Applications:

5. Radioisotope Life Sciences WD446 Transfer of Ownership TIME 9:58

Application Withdrawn

GENERAL

TIME: 10:00

VI: Applications:

6. Genoa Healthcare LLC New Community Pharmacy

Represented by: Kevin O'Connell, Director of Operations

Katherine Moriarty, Manager of Records

Recusal: Leah Discussion:

This pharmacy is their location in the state of Massachusetts.

- · Location: Covington, Massachusetts
- · Integrated closed door pharmacy located in Swift River
 - o Remote location.
 - o 202 bed facility for drug abuse treatment.
 - o No customer window.
 - o Dispense directly to nursing as needed.
 - o Patients will self-administer.
 - Nursing will store the medication.

Page 8 of 12

- · Katherine Moriarty, MOR has been an MOR in Massachusetts since 2012
 - Board recommends she review the BOP regulatory requirements which are located on the BOP website.

Action: <u>Approve</u> Deny Other

Conditions Comments

M: Kim, Julie, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie, Susan
 S: Kim, Julie, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie, Susan
 V Kim, Julie, Dr. Lopez, Tim, Sebastian, Katie, Patrick, Stephanie, Susan

General

VII: File Review

TOPIC VII File Review TIME: 10:01 AM

Case #1
PHA-2019-0103 Stop and Shop #87, DS2322 Time: 10:01 AM

<u>RECUSAL</u>: K. THORNELL 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 these matters.

- OPP received notification that they had a loss of #100 hydrocodone/acetaminophen 5mg/325mg tablets occurring on or about September 21, 2019.
- MOR Lodge indicated that on September 21, 2019, while completing the weekly perpetual inventory, he discovered that the perpetual count was short by #100 tablets of hydrocodone/acetaminophen 5mg/325mg tablets. MOR Lodge noted that the loss was investigated, and the reason for the loss cannot be determined.
- MOR Lodge cannot attest that a reconciliation of the perpetual inventory for all schedule II-controlled substances was conducted by a pharmacist at least every 10 days. It was observed that the staff pharmacist did not perform a perpetual inventory on 9/14/2019 and just signed the book.
- MOR Lodge indicated that as part of his investigation he reviewed copies of the perpetual inventory, DEA 222 forms and invoices for 3 months prior to the loss, on 9/21/2019. Upon review, a discrepancy of #14 tablets was identified as a reported dispensing error that occurred on 8/8/2019.
- The response indicated that "Stop & Shop has investigated the loss and although the reason for the loss could be confirmed, diversion or theft ware not thought to be the cause. It is suspected that the medication was inadvertently discarded in the trash.
- MOR Lodge stated, "As the pharmacy manager, I have taken this opportunity to review the schedule II perpetual inventory and controlled substances policy, focusing on the importance of maintaining accurate inventories with all pharmacy staff."

<u>ACTION</u>: Motion by P. GANNON, seconded by T. FENSKY, and voted unanimously by those present, to refer the matter (PHA-2019-0103) 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.

General

CVS #2377, DS3090

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

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

- On 1/2/2020, the Pharmacy submitted an untimely RLCS for an unknown loss of #100 Adderall 20 mg tablets discovered on 10/18/2019 during the reconciliation of the perpetual inventory.
- The internal investigation included review of the returns log, the dispensing log, the perpetual inventory and a search of the safe and waiting bin. MOR Smith reviewed security camera footage and based on the actions of the pharmacist, it was suspected the drug was returned in an expired medication return to INMAR but was not scanned out properly. As of 12/27/2019, INMAR had not processed the return and the Pharmacy could not confirm it had been received by INMAR.

Time: 10:10 AM

• On 2/26/2020, the BORP was notified after further investigation, the DEA 106 was withdrawn as there was no loss. MOR Smith responded that on 2/24/2020, INMAR confirmed receipt of the missing Adderall 20mg tablets.

<u>ACTION</u>: Motion by P. GANNON, seconded by L. GIAMBARRESI, and voted unanimously by those present, to DISMISS the matter (PHA-2020-0016), No Violation.

Case #3

PHA-2020-0017 CVS #447, DS3251 Time: 10:14 AM

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

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

- RLCS on 12/30/19 for an unknown loss of #461 lorazepam 0.5 mg tablets identified via a Potential Diversion Monitoring Report review by the Asset Protection Team on or about 11/20/2019.
- MOR Foglio indicated the loss was researched and loss prevention performed multiple reconciliations but a reason for the loss could not be identified.
- No additional information regarding the loss was provided in response to the complaint.
- CA: All CVS Loss Prevention policies and procedures were reviewed with the pharmacy staff. CVS Policy "Filling/Dispensing Prescriptions Store with Two Step Verification Workflow" was provided. The policy was signed by the pharmacists indicating it had been reviewed.

ACTION: Motion by T. FENSKY, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2020-0017) 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 Benzodiazepine 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 #4

PHA-2020-0015 CVS #1094, DS1627 Time: 10:16 AM

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

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