

COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy

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

June 11, 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=](https://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: 161 512 6598

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	I	CALL TO ORDER		J. Lanza
	II	APPROVAL OF AGENDA		
8:05	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">Draft of May 28, 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 • Above Action Levels approved by Staff Action 16-04 • PSUD Report-Policy 17-03 								
8:15	V	FLEX <ul style="list-style-type: none"> • Pharmacy issues related to Covid-19 and the state of emergency • BILH Pilot Project 								
8:45	VI	FILE REVIEW <table border="1" data-bbox="321 642 1192 768"> <tr> <td data-bbox="321 642 367 716">1</td> <td data-bbox="367 642 620 716">SA-INV-17702</td> <td data-bbox="620 642 1192 716">V-Care Pharmacy and Surgical Supplies, DS89813</td> </tr> <tr> <td data-bbox="321 716 367 768">2</td> <td data-bbox="367 716 620 768">PHA-2021-0006</td> <td data-bbox="620 716 1192 768">CVS #10852, DS90095</td> </tr> </table>	1	SA-INV-17702	V-Care Pharmacy and Surgical Supplies, DS89813	2	PHA-2021-0006	CVS #10852, DS90095		
1	SA-INV-17702	V-Care Pharmacy and Surgical Supplies, DS89813								
2	PHA-2021-0006	CVS #10852, DS90095								
9:00	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						
9:45	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

June 11, 2021

Board Members 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 9:07 AM)
Caryn Belisle, RPh, MBA
Leah Giambarresi, Pharm D, RPh
Katie Thornell, RPh, MBA
Jennifer Chin, RPh
Dr. Richard Lopez, MD

Board Members Not Present

Dawn Perry, JD
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 8:01 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; K. Thornell, yes; C. Jean-Francois, yes; L. Giambarresi, yes; J. Chin, yes. S. Cornacchio, yes; R. Lopez, yes.

Topic II.

Approval of Agenda

TIME 8:03 AM

Agenda 6/11/21

DISCUSSION:

Change to Agenda:
none

ACTION:

Motion by L. Giambarresi, seconded by S. Hamilton 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 5/28/21

Change: no noted changes

Action:

Motion by C. Jean-Francois seconded C. Belisle and voted unanimously to approve the regular session minutes of 5/28/21 with no noted change by roll call vote. R. Lopez abstains.

TOPIC IV

Reports

Applications approved pursuant to Licensure Policy 13-01

Time: 8:05 AM

Discussion: R. HARRIS noted that there have been thirty (30) Change of Managers applications, one (1) Closure and one (1) Renovation application approved pursuant to Licensure Policy 13-01.

So noted.

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:05 AM

Discussion: M. BOTTO provided the May 5, 2021 – June 8, 2021, Board of Pharmacy Statistics Report for the Probation monitor, which noted that one (1) licensee satisfactorily completed probation and there are currently twenty-seven (27) licensees on probation.

So noted.

TOPIC IV

REPORTS

Monthly Report from BDR pursuant to Policy 14-02

Time: 8:05 AM

Discussion: D. SENCABAUGH noted that there were two (2) Board Delegated Review cases heard on May 14, 2021, and May 27, 2021. Both were Reported Loss of Controlled Substances which were referred to the Office of Prosecution for a Stayed Probation following the typical loss protocol. 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 Approved by Staff Action 16-04

Time: 8:07 AM

Discussion: N. ALEID noted that zero (0) 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: 8:07 AM

Discussion: E. TAGLIERI noted that there are thirteen (13) active participants and two (2) pending admissions. The next quarterly meeting is in July.

So noted.

TOPIC V

Flex

1. Pharmacy Issues Related to Covid-19 and State of Emergency

Time: 8:07 AM

Presented by: D. SENCABAUGH

Discussion: The Board meeting on July 9 has been canceled. It is a holiday week, and the state of emergency workload is up to date.

So noted.

2. BILH Pilot Project

Time: 8:09 AM

Presented by: W. FRISCH

Recusals: J. LANZA, H. ENGMAN

Discussion: Last month, representatives from BILH Specialty Pharmacy and BILH Direct Pharmacy presented their final pilot project presentation to the Board regarding the operation of their two

separate pharmacies in the same physical space at the Westwood, MA location. They requested to end the pilot project and maintain operations as they have under the pilot project.

After collaboration with Board staff, BILH representatives have submitted several petitions for waivers as a means to the end the pilot project and continue in their current mode of operation.

Action: Motion by C. BELISLE, seconded by J. CHIN, and voted unanimously by roll call by all those present to formally end the pilot project for the BILH Specialty (DS90335) and BILH Direct (DS90336) pharmacies and to continue in their current mode of operation contingent on the Board's approval of the partial security waivers submitted by each pharmacy and the stipulation that Board approval would be needed for any change in the mode of operation between the two pharmacies including any change to the hours of operation of one side.

Action: Motion by C. BELISLE, seconded by K. THORNELL, and voted unanimously by roll call by all those present to grant a partial waiver of 247 CMR 6.02(6)(d) to BILH Specialty Pharmacy (DS90335). Specifically, the requirement for a separate alarm is being waived, not the substantive requirement to have an alarm.

Action: Motion by A. STEIN, seconded by C. BELISLE, and voted unanimously by roll call by all those present to grant a partial waiver of 247 CMR 6.02(6)(e) to BILH Specialty Pharmacy (DS90335). Specifically, the requirement for a secure floor to ceiling barrier between the two pharmacies and a separate alarm is being waived, not the substantive requirement to have an alarm or for the other walls of the pharmacy to have floor to ceiling barriers.

Action: Motion by L. GIAMBARRESI, seconded by C. JEAN-FRANCOIS, and voted unanimously by roll call by all those present to grant a partial waiver of 247 CMR 6.02(6)(d) to BILH Direct Pharmacy (DS90336). Specifically, the requirement for a separate alarm is being waived, not the substantive requirement to have an alarm.

Action: Motion by L. GIAMBARRESI, seconded by A. STEIN, and voted unanimously by roll call by all those present to grant a partial waiver of 247 CMR 6.02(6)(e) to BILH Direct Pharmacy (DS90336). Specifically, the requirement for a secure floor to ceiling barrier between the two pharmacies and a separate alarm is being waived, not the substantive requirement to have an alarm or for the other walls of the pharmacy to have floor to ceiling barriers.

Action: Motion by C. BELISLE, seconded by A. STEIN, and voted unanimously by roll call by all those present to grant the following three waivers to BILH Specialty Pharmacy (DS90335) for the requirements to engage in compounding and carry commonly prescribed medications: 247 CMR 6.01(5)(a)(4); 6.02(4); and 9.01(16)

TOPIC VI**File Review**

Case #1

SA-INV-17702

V-Care Pharmacy and Surgical Supplies, DS89813

Time: 08:26 AM

RECUSAL: NONE

DISCUSSION: G. MELTON presented and summarized the investigative report that pertained to these matters.

- Background - At the time of this incident, V-Care and VRx Solutions were located next to each other and physically connected by a secure door. V-Care and VRx Solutions shared common ownership. In March 2021, a site visit was conducted at VRx Solutions to evaluate its operational status after BORP learned that the pharmacy was not open for business after being issued a license in January 2020.
- During the site visit at VRx Solutions, a BORP investigator discovered that V-Care was using VRx Solutions' space to prepare V-Care's prescriptions drugs for reverse distribution. A POC was issued to VRx Solutions and all of V-Care's prescriptions drugs were removed from VRx Solutions. BORP then opened this investigation concerning V-Care.
- MOR Vipul Patel of V-Care indicated that VRx solutions space was used on a one-time basis to prepare prescription drugs for reverse distribution so staff could maintain distancing for COVID-19. MOR Patel indicated that the intern who was tasked with preparing the reverse distributor worked under the supervision of a pharmacist at all times. MOR Patel confirmed that all of V-Care's drugs were removed from VRx solutions. He also confirmed that the practice of sharing licensed space between V-Care and VRx Solutions shall cease going forward.

ACTION: Motion by K. THORNELL, seconded by L. GIAMBARRESI, and voted unanimously by those present, to CLOSE the matter (SA-INV-17702), No Discipline Warranted, Remediation Complete.

Case #2

PHA-2021-0006

CVS #10852, DS90095

Time: 08:33 AM

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

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

- On January 27, 2021, during a retail compliance inspection, it was observed that Pharmacist Tony Majid Habchi assumed the role of MOR on or about 2/16/2020 until about 12/2020 but no change of MOR application was filed. After Pharmacist Habchi left, no interim MOR and/or MOR was appointed, and no change in MOR application was filed.
- Additionally, during ISP-15145, pharmacy technician-in-training (PTT) Laurie Wardwell had an expired license (Expired: 8/29/2019) and was observed helping patients conduct COVID testing at the drive thru window.
- In a response dated March 19, 2021, MOR Hess stated that he became the interim MOR of CVS Pharmacy #10852 on December 27, 2020. A change in PIC controlled substance inventory for C2 and

C3-C5 was provided with the response and was signed by current MOR Hess on 1/30/2021 at closing of business.

- Pharmacist Habchi responded that he was MOR from 2/1/2020 through 12/27/2020. A change in PIC controlled substance inventory for C2 and C3-C5 was provided with the response and was signed by pharmacist Habchi on 2/16/2020 at closing of business. The inventory was completed with outgoing MOR Wallace.
- MOR Hess stated that Laurie Wardwell was working under the supervision of a Nurse Practitioner, who works for the Minute Clinic.
- On March 1, 2021, MOR Hess reviewed and signed the *Advisory on New Managers of Record*.
- On March 1, 2021, MOR Hess, pharmacist Cheng, and lead technician Nicole J. Wright reviewed and signed BORP Policy 2020-14: *COVID-19 Testing*.

ACTION: Motion by S. HAMILTON, seconded by A. STEIN, and voted unanimously by those present, to refer the matter (PHA-2021-0006), 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 VII: Executive Session Call to Order: Time: 8:37AM
By: J. Lanza

ACTION: Motion by, C. Belisle, 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; K. Thornell, yes; C. Jean-Francois, yes, L. Giambarresi, yes; J. Chin, yes. S. Cornacchio, yes; R. Lopez, yes.

S. Cornacchio leaves meeting 9:07 AM

Topic VIII: 65C Sessions MGL c. 112 section 65C Time: 9:27 AM

DISCUSSION: None

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

At 9:27 AM L. Giambarresi, seconded by S. Hamilton and voted unanimously by all those present to enter 65C by roll call vote.

Topic IX ADJOURNMENT OF MEETING TIME: 9:47 AM

ACTION: Motion by L. Giambarresi seconded by J. Chin 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 6/11/21 General Session
2. Draft Minutes of the 5/28/21 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. BILH Pilot Project request and waivers
9. SA-INV-17702 V-Care Pharmacy and Surgical Supplies, DS89813
10. PHA-2021-0006 CVS #10852, DS90095

Respectfully Submitted,
Carly Jean-Francois, NP, Secretary

DRAFT