

**COMMONWEALTH OF MASSACHUSETTS
Board of Registration in Pharmacy**

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

January 9, 2020
239 Causeway Street ~ Room 417 A&B
Boston, Massachusetts 02114

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	Contact
8:30	I	CALL TO ORDER	K. Tanzer
	II	APPROVAL OF AGENDA	
8:40	III	APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">• Draft of December 5, 2019 Regular Session Minutes• Introduction of Interns:	
8:45	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	
8:50	V	POLICIES AND ADVISORIES <ul style="list-style-type: none">• Approved CEs Process	M. Chan

9:00	VI	APPLICATIONS <ul style="list-style-type: none"> • Walden Behavioral Care – New Community Pharmacy • McNabb Pharmacy (DS90087)- Renovation • Theragnostics (WD511) – Relocation • Rite Aid 10108 (DS90173) – Change of Manager 										
9:30	VII	FLEX <ul style="list-style-type: none"> • ASHP mid-year update 	J. Lanza									
9:45	VIII	VIOLATION OF STAYED PROBATION <ul style="list-style-type: none"> • CVS 765, DS2910, PHA-2018-0034 										
10:00	IX	FILE REVIEW <table border="1"> <tr> <td>1</td> <td>PHA-2019-0052</td> <td>Walmart Pharmacy #10-1967, DS2737</td> </tr> <tr> <td>2</td> <td>SA-INV-15146</td> <td>Procare LTC of MA, DS90042</td> </tr> <tr> <td>3</td> <td>PHA-2019-0068</td> <td>PharMEDium Services, NO00003</td> </tr> </table>	1	PHA-2019-0052	Walmart Pharmacy #10-1967, DS2737	2	SA-INV-15146	Procare LTC of MA, DS90042	3	PHA-2019-0068	PharMEDium Services, NO00003	
1	PHA-2019-0052	Walmart Pharmacy #10-1967, DS2737										
2	SA-INV-15146	Procare LTC of MA, DS90042										
3	PHA-2019-0068	PharMEDium Services, NO00003										
11:30	X	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 pending applicants.										
12:30		LUNCH BREAK										
1:30	XI	M.G.L. c. 112, § 65C SESSION										
5:00	XII	ADJOURNMENT										

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

**MINUTES OF THE GENERAL SESSION
239 Causeway Street, Fourth Floor ~ Room 417A
Boston, Massachusetts, 02114
January 9, 2020**

Board Members Present

Kim Tanzer, PharmD, RPh. President
Julie Lanza, CPhT, President Elect
Leah Giambarresi, Pharm D, RPh, Secretary
Sebastian Hamilton, Pharm D, RPh
Susan Cornacchio, JD, RN
Dr. Richard Lopez, MD
Andrew Stein, Pharm D
Michael Godek, RPh
Carly Jean-Francois, RN, NP
Dawn Perry, JD

Board Members Not Present

Stephanie Hernandez, Pharm D, BCGP, RPh
Timothy Fensky, RPh (Tim via phone 2:30 PM-3:30)
Patrick Gannon, RPh

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
Stephen Horn, RPh, Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor
Joanna Chow, Office Support Specialist
Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 8:35 AM

A quorum of the Board was present, established by roll call. President K. Tanzer chaired the meeting and asked if anyone was recording hearing, no one responded. She explained that the Board of Pharmacy was recording the meeting.

Roll call attendance: K. Tanzer, yes; J. Lanza, yes; M. Godek, yes; C. Jean-Francois, yes; S. Hamilton, yes; S. Cornacchio, yes; L. Giambarresi, yes; A. Stein, yes; R. Lopez, yes.

Topic II.

Approval of Agenda

TIME 8:35 AM

Agenda January 9, 2020

DISCUSSION:

Change to Agenda:

1. Defer Rite Aide 10108 DS90173 change of manager

ACTION:

Motion by K. Tanzer, seconded by M. Godek and voted unanimously by those present to approve the agenda with noted change.

Dave asks for the Pharmacy Interns to stand and introduce themselves. There are currently no APPE Interns at rotation at the Board this week.

Topic III

Approval of Board Minutes

TIME: 8:35 AM

Minutes

1. Draft, December 5, 2019 minutes

No noted Changes.

Action:

Motion by L. Giambarresi seconded M. Godek, and voted unanimously to approve the regular session minutes of 12/5/19 with noted changes. S. Hamilton and C. Jean-Francois abstained from vote.

TOPIC IV

REPORTS

Applications approved pursuant to Licensure Policy 13-01

Time: 8:38 AM

Discussion: M. BOTTO noted that there have been fifty-two (52) Change of Managers applications approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV

REPORTS

Monthly Report from Probation

Time: 8:38 AM

Discussion: M. BOTTO provided the November 26, 2019 – January 07, 2020 Pharmacy Board Probation Monthly Report, which noted that two (2) licensees satisfactorily completed probations, zero (0) was issued final notice, and there are currently thirty (30) licensees on probation.

So noted

TOPIC IV

REPORTS

Monthly Report from BDR pursuant to Policy 14-02

Time: 8:38 AM

Discussion: M. BOTTO noted that there was three (3) Board Delegated Review case heard on January 6, 2020. There were two CE self-disclosures (SA-INV-15639, SA-INV-15662) which were closed with discipline not warranted and remediation complete. There was one QRE (SA-INV-15608) which was closed with discipline not warranted, pending results of inspection (i.e. Confirmation of Remediation Complete.) 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: 8:39 AM**

Discussion: J. TRAN 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: 8:39 AM**

Discussion: E. TAGLIERI noted that in December 2019, there was one (1) new application was received with admission and fourteen (14) active participants.

So noted

TOPIC V **Policies and Advisories**
1. New Board Approved CE Process **TIME: 8:39 AM**
PRESENTED BY: M. CHAN

DISCUSSION: In preparation for the new licensing regulations and the workload that it will bring to Board staff, some changes to the approval process for “Board approved CE” were proposed. Effective 7/1/20, a 60-day notice would be required for live programs and the option for home-study would be eliminated.

ACTION: Motion by M. GODEK, seconded by S. HAMILTON, and voted unanimously by those present to approve the new CE approval procedure.

TOPIC VI **APPLICATIONS**
1. Walden Behavioral Care New community Pharmacy **TIME: 8:41 AM**

REPRESENTED BY: Matthew Moen (Manager of Record), Michael Tocco (Chief Executive Officer of Integrated Pharmacy Solutions)

RECUSAL: None

technician check technician. J. LANZA also presented on technician practice advancement and expanded roles.

TOPIC VIII

Violation of Probation:

1. PHA-2018-0034 CVS #765, DS2910

Time: 9:31am

Presented by: Karen Fishman

Recusal: Cornacchio

Discussion:

K. FISHMAN indicated that this matter comes before the Board as a notification of the Registrant's violation(s) of the *Consent Agreement for [One year] Stayed Probation* ("Agreement"), which the pharmacy entered with the Board, effective March 25, 2019. (Attachment 1) The Registrant is subject to this Agreement due to an unknown loss of 1,668 1 mg tablets of alprazolam in August 2018. Terms and conditions include those which have now become the standard terms for retail pharmacy cases with unknown losses (see *Terms and Conditions* section below for a detailed review) in addition to the standard term contained in all Agreements: Paragraph 4a: The Registrant must comply with all laws and regulations governing the practice of pharmacy in Massachusetts. In this case, it appears that CVS #765 violated paragraph 4a of the Agreement. The Manager of Record was directly involved in the violations. (See attached documentation.)

Action: Motion by S. HAMILTON, seconded by M. GODEK voted unanimously by those present, that the pharmacy violated the terms of the consent agreement but maintain the current consent agreement and complete a repeat retail compliance inspection.

TOPIC IX

FILE REVIEW

Case #1

PHA-2019--0052

Walmart Pharmacy #10-1967, DS2737 Time: 9:03 AM

RECUSAL: NONE

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

- During a retail compliance inspection (ISP-11907) on April 2, 2019, investigators discovered that Loudine Denize, Kimberly Alvarado, and Fernando Molina worked as a Pharmacy Technician in Training without a license at the Pharmacy.
- MOR Lebeau noted that the Pharmacy Trainees identified as Ms. Denize, Mr. Molina and Ms. Alvarado were removed from the pharmacy and not allowed to work in the pharmacy.
- The affected individuals promptly completed their Technician in Training applications and sent them to the Board of Pharmacy. He noted that each associate will have the proper licensure and proper designation on their name badge prior to performing any work in the licensed space.
- Of note, Ms. Denize had her PTT issued on 04/12/2019 and her PT issued on 08/08/2019. Ms. Alvarado had her PTT issued on 04/12/2019 and her PT issued on 05/29/2019. Mr. Molina, PTT license issued on 4/12/19 and is now working in a non-pharmacy role.

ACTION: Motion by M. GODEK, seconded by S. HAMILTON, and voted unanimously by those present, to DISMISS the matter (PHA-2019-0052), Discipline Not Warranted, Remediation Complete.

Case #2

SA-INV-15146

Procure LTC of MA, DS90042

Time: 9:05 AM

RECUSAL: NONE

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

- A USP <797> (ISP-12488) inspection was conducted on June 17, 2019, it was observed that the pharmacy failed to timely report an above action level on or about May 22, 2019.
- MOR Gorka indicated that the monthly environmental monitoring was completed on May 22, 2019 and the sample plate was checked on May 30th at 6:04am but it was never sent out for identification. On June 18, 2019, a monthly triple clean was performed. On June 19, 2019, an environmental monitoring sampling of the room was repeated.
- On June 21, 2019, the results from the 1 CFU fungal plate from 5/22/19 showed that it was normal flora of the skin (micrococcus/kocuria). On June 22, 2019, a repeated environmental monitoring sampling for bacteria were completed and showed no CFU. On June 25, 2019, the final environmental monitoring report was sent to the Board of Pharmacy with a plan of correction. On June 26, 2019, the repeat sample of the fungal plates were read with no CFU.
- MOR Gorka noted that she does take full responsibility and that in the future, she would treat any CFU as if it was a fungal so as to not make this mistake again. She indicated that she has set-up calendar reminders on the day the samples are scheduled to be taken, read, and sent. MOR Gorka noted that she has shared this calendar with the IV Technician Supervisor as a backup.

ACTION: Motion by S. HAMILTON, seconded by M. GODEK, and voted unanimously by those present, to CLOSE the matter (SA-INV-15146), Discipline Not Warranted, Remediation Complete.

Case #3

PHA-2019-0068

PharMEDium Services, NO00003

Time: 9:07 AM

RECUSAL: NONE

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

- Consent decree of permanent injunction today between the United States and PharMEDium Services in May 2019. The company has four registered outsourcing facilities located in Memphis, TN.; Cleveland, MS; Sugar Land, TX and Dayton, N.J. According to the complaint, despite previous warnings from the U.S. Food and Drug Administration and repeated promises from PharMEDium to correct deficiencies, PharMEDium continued to violate the law.
- The consent decree prohibits PharMEDium from, among other things, manufacturing, holding, or distributing PharMEDium's drugs at or from its Tennessee facility until it completes corrective actions and receives authorization from the FDA. The company has ceased operations at its Mississippi

facility, and its Texas and New Jersey facilities must, among other things, hire an independent expert to review PharMEDium's operations at these facilities to ensure compliance with the law.

- In the consent decree, the FDA alleges that PharMEDium manufactured and distributed drugs intended to be sterile such as oxytocin and morphine sulfate, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act. Drugs prepared, packed or held under insanitary conditions may have been contaminated with filth or may have been rendered injurious to health. The consent decree also alleges that PharMEDium distributed unapproved new drugs and drugs that were misbranded because their labeling did not bear adequate directions for use.

ACTION: Motion by M. GODEK, seconded by S. HAMILTON, and voted unanimously by those present, to refer the matter (PHA-2019-0068) 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 PROBATION for a period concurrent with the FDA's Consent Decree.

Topic X: Executive Session Call to Order:

No Executive Session held

Topic XI: M.G.L. 65 C #1 Time: 9:54 AM

DISCUSSION: None

ACTION: President K. Tanzer request a motion to enter M.G.L 65 c Session.

At 9:54 AM A. Stein, seconded by S. Hamilton and voted unanimously by all those present to enter M.G.L. chapter 65 c Session:

Topic XII ADJOURNMENT OF MEETING TIME: 3:51 PM

ACTION: Motion by M. Godek seconded by K. Tanzer, and voted unanimously by those present, to adjourn from General Session.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

1. Draft Agenda of the 1/9/20 General Session
2. Draft Minutes of the 12/5/19 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. Policy: Approved CEs Process update
9. Applications: Walden Behavioral Care- New Community Pharmacy

10. Applications: McNabb Pharmacy DS90087 Renovation
11. Applications: Theragnostics WD511 Relocation
12. Applications: Rite Aid 10108 DS90173 Change of Manager
13. Violation of Stayed Probation: CVS 765, DS2910, PHA-2018-0034
14. PHA-2019-0052 Walmart Pharmacy #10-1967; DS2737
15. SA-INV-15146 Procure LTC of MA, DS90042
16. PHA-2019-0068 PharMEDium Services, NO00003

Respectfully Submitted,
Leah Giambarresi, PharmD, RPh, Secretary