COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

May 15, 2020

The Regular Session of this meeting 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: 618 493 755

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.

Time	#	Item	Page	Contact
8:30	Ι	CALL TO ORDER		K. Tanzer
	II	APPROVAL OF AGENDA	1	
	III	 APPROVAL OF BOARD MINUTES Draft of May 7, 2020 Regular Session Minutes 		
8:40	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 	3	

Agenda

8:45	v	 APPLICATIONS Onco360; DS89921- Waivers GE Healthcare; WD510 - Relocation 	4 16	
9:00	VI	 POLICIES Revision of Staff Action Policy 14-02: Board Delegated Review 	33	
9:10	VII	 FLEX Pharmacy issues related to Covid-19 and the state of emergency Summary of NABP virtual Annual Meeting, May 14, 2020 		
		BREAK		
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.	38	Closed Session
9:45	IX	M.G.L. c. 112, § 65C SESSION	105	

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE REGULARLY SCHEDULED MEETING May 15, 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 Andrew Stein, Pharm D Sebastian Hamilton, Pharm D, RPh Timothy Fensky, RPh Dr. Richard Lopez, MD Dawn Perry, JD Stephanie Hernandez, Pharm D, BCGP, RPh Katie Thornell, RPh Patrick Gannon, RPh Susan Cornacchio JD, RN Carly Jean-Francois, RN, NP

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 Leo McKenna, RPh Investigator **TOPIC I**. Attendance by roll call: **CALL TO ORDER 8:30 AM** A quorum of the Board was present, established by roll call. President K. Tanzer chaired the meeting.

Roll call attendance: K. Tanzer, yes; J. Lanza, yes; L. Giambarresi, yes; S. Hamilton, yes; R Lopez, yes; T. Fensky, yes; K. Thornell, yes; S. Hernandez, yes; P. Gannon, yes; S. Cornacchio, yes; C. Jean-Francois, yes; Dawn Perry, yes; A. Stein, yes;

Topic II. Agenda May 7, 2020

Approval of Agenda

TIME 8:33 AM

DISCUSSION: Change to Agenda: No changes

ACTION:

Motion by L. GIAMBARRESI, seconded by J. LANZA and voted unanimously by those present to approve the agenda.

Topic III.

Approval of Board Minutes

TIME 8:34 AM

Minutes 1. Draft, 5/7/20 Session Minutes

No noted changes.

ACTION:

Motion by L. GIAMBARRESI seconded by P. GANNON and voted unanimously by those present to approve the agenda. A. STEIN and C.JEAN-FRANCOIS abstained.

TOPIC IV

REPORTS

Applications approved pursuant to Licensure Policy 13-01Time: 8:35 AMDiscussion: R. HARRIS noted that there have been five (5) Change of Managers applications and one (1)Renovation applications approved pursuant to Licensure Policy 13-01.

So noted

TOPIC IV

REPORTS

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: 8:36 A	Μ
2020. The remediat President	ere were seven (7) CE self-dis ion complete. The Board Del	sclosures which were egated Review sessi	rd Delegated Review case hea e closed with discipline not w on was attended by Kim Tanz . ENGMAN as Board Counsel,	arranted and er as the Board
So noted				
TOPIC IV	I	REPORTS		
Above Ad	tion Levels Approved by Sta	aff Action 16-04	Time: 8:36 A	M
	n: J. TRAN noted that zero (pursuant to Licensure Policy	•	report has been reported sir	nce last Board
So noted				
TOPIC IV		REPORTS		
PSUD Re	oort by Staff Action 17-03		Time: 8:36 AM	
	n: E. TAGLIERI noted that in approved and two (2) grad	•	ere thirteen (13) active partic	ipants, one (1)
So noted				
V: Applic		GENERAL		
1. Onco	360 DS89921	Petitio	on to Waiver	TIME: 8:38
Repre	esented by: B. FRISCH			
	ssion: B. FRISCH presented v val as well as new waivers fo	•	aco360. They submitted exist	ing waivers for

Action: Motion by P. GANNON, second by L. GIAMBARESSI, and voted unanimously by roll call by those present to approve Onco360's request for waivers.

GENERAL

Relocation

V: Applications:

2. GE Healthcare WD510

Represented by:

Recusal: none Discussion: Irina Sobolev to discuss relocation pla	va, QA rep and Cory Romzo, Compliance Leader ns for GE Healthcare.	appeared by Webex phone call
-	on and seconded by L. GIAMBARESSI and voted e application for relocation of GE Healthcare.	l unanimously by roll call by
VI: Policy and Advisory	GENERAL	
ΤΟΡΙϹ VI	POLICIES	
1. Staff Action Policy 14-02:	Board Delegated Review (BDR)	Time: 8:44 AM
Presented by: M. CHAN		
Recusal: None		
Discussion: Updates to this	policy will allow the BDR work group to dispose	of certain cases involving losses

Criteria include: (1) the Pharmacy has not had any Board investigation or Complaint related to a loss of controlled substances within two years; (2) the Pharmacy's license has not previously been disciplined, restricted, or conditioned because of a loss of controlled substances; and (3) the Pharmacy was not able to determine the cause of the loss.

of controlled substances in Schedules III – V involving less than 500 units.

These cases will be disposed of using the "Unknown Loss Protocol": (1) Conduct and maintain documentation of an exact count of all controlled substances in Schedules III – V within 30 days. (2) Conduct and maintain documentation of an exact count of all products in the class of medication that was reported lost at least once every 30 days for a period of one year. (3) Provide documentation demonstrating that all staff have been retrained in areas of inventory management, prescription production, and waiting bin management within 30 days. (4) If applicable, maintain documentation demonstrating that the area pharmacy supervisor or loss prevention manager has reviewed the pharmacy's

TIME_____

balance on hand modification cover pages for all products in the class of medication that was reported lost at least once every 30 days for a period of one year.

Action: Motion by P. GANNON, seconded by S. HAMILTON, and voted unanimously by roll call by those present to approve updates to Staff Action Policy 14-02: Board Delegated Review (BDR).

TOPIC VII

1. Pharmacy issues related to COVID-19 and the state of emergency

Presented by: D. SENCABAUGH and W. FRISCH

Recusal: None

Discussion: This section will remain on each agenda going forward so any new information can be presented by the Board staff.

Since the last meeting, some pharmacies have opened COVID-19 testing sites with pharmacists observing sample collection being performed by patients.

Board staff has continued interagency work to determine how pharmacists could further assist with the overall state testing plan and has sent a memo to state administration outlining the legal framework.

So noted.

2. Summary of NABP Virtual Annual Meeting, May 14, 2020

Presented by: D. SENCABAUGH, L. GIAMBARRESI, and S. HAMILTON

Recusal: None

Discussion: T. FENSKY was installed as the incoming NABP president. All resolutions supported by NABP were passed.

So noted.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. Draft Agenda of the 5/15/20 General Session
- 2. Draft Minutes of the 5/7/20 Meeting
- 3. Applications: Onco360; DS89921 Waivers
- 4. Report on Applications Approved Pursuant to Licensure Policy 13-01

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Time: 8:53 AM

FLEX

Time: 8:46 AM

- 5. Report on PSUD 17-03
- 6. Applications: GE Healthcare; WD510 Relocation
- 7. Policy 14-02: Board Delegated Review Revision