COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

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

June 29, 2017 239 Causeway Street ~ Room 417 A&B Boston, Massachusetts 02114

Agenda

Time	#	Item	Contact
8:30	I	CALL TO ORDER	T. Fensky
	II	 APPROVAL OF THE AGENDA Introduction of Pharmacy Intern: Ryan Fan 	
8:35	III	 APPROVAL OF BOARD MINUTES Draft of June 15, 2017 Regular Session Minutes 	
8:40	IV	 APPLICATIONS Partners Healthcare – New community pharmacy Teamsters Care (DS2493)-Renovation/Expansion Birds Hill Pharmacy (DS10374)-Transfer of Ownership 	
9:40	V	 REPORTS Applications approved pursuant to Licensure Policy 13-01 Board Delegated Complaint Review pursuant to licensure policy 14-02 Above Action Levels approved by Staff Action 16-04 	R. Harris M. Botto K. Fishman V. Thaker
9:45	VI	ADVISORYAmendment to staff ratios for institutions	M. Chan W. Frisch
10:00	VII	FILE REVIEW SA-INV-10485- Heritage Biologics Inc- DS89956	J. Trifone

10:15	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, the Board will discuss and evaluate the Good Moral Character as required for registration for pending applicant.	CLOSED SESSION
10:40	IX	ADJUDICATORY SESSION (M.G.L. c. 30A, §` 18)	CLOSED SESSION
11:00	X	M.G.L. c. 112, § 65C SESSION	CLOSED SESSION
11:30	XI	ADJOURNMENT	CLOSED SESSION

COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

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

June 29, 2017

Board Members Present

Timothy Fensky, R.Ph. President Phillippe Bouvier, R.Ph. Susan Cornacchio, JD, RN, Secretary Patrick Gannon, R.Ph Catherine Basile, Pharm D, R.Ph Garret Cavanaugh, R.Ph. Andrew Stein, Pharm D, R.Ph. Richard Tinsley, MBA, Med, Ed Taglieri Jr., R.Ph. President William Cox, CPhT Ali Raja, MD, MBA, MPH

Board Members Not Present

Michael Godek, R.Ph., President-Elect Karen Conley, DNP, RN, AOCN, NEA-BC

Board Staff Present

David Sencabaugh, R.Ph, Executive Director Monica Botto, CPhT, Associate Executive Director Heather Engman, JD, MPH, Pharmacy Board Counsel Michelle Chan, R.Ph. Quality Assurance Pharmacist Joanne Trifone, R.Ph., Director of Pharmacy Investigations Joe Santoro, R.Ph. Contract Investigator Kimberly Morton, CPhT, Compliance Officer Vishal Thaker, PharmD, Pharmacist Christina Mogni, R.Ph., Investigator Julienne Tran, R.Ph., Investigator

TOPIC I.

CALL TO ORDER 8:30 AM

<u>DISCUSSION</u>: A quorum of the Board was present, established by roll call. President T. FENSKY chaired the meeting and asked if anyone was recording. Hearing "no", he explained that the Board of Pharmacy was recording the meeting.

TOPIC II.

APPROVAL OF AGENDA

DISCUSSION: None

ACTION:

Motion by C. BASILE, seconded by A. STEIN, and voted unanimously to approve the agenda.

- D. SENCABAUGH introduced R. FAN and R. LO as the newest APPE rotation students.
- D. SENCABAUGH advised the Board that it was C. BASILE'S last Board Meeting.
- T. FENSKY asked interns in the audience to stand up and introduce themselves.

TOPIC III:

APPROVAL OF BOARD MINUTES

1. Draft June 15, 2017, Regular Session Minutes

<u>DISCUSSION</u>: Change in Flex Session – G. CAVANAUGH did not recuse from

Mobile Narcan/Sullivan's topic.

ACTION:

Motion by P. GANNON, seconded by C. BASILE, and voted affirmatively to accept the minutes of the 6/15/2017 General Session minutes, with noted change. A. RAJA and P. BOUVIER abstained.

TIME: 8:36 am

TOPIC IV:

APPLICATIONS

1. Partner's Health Care New Community Pharmacy 8:36 am

<u>RECUSAL</u>: A. RAJA recused and was not present for the discussion and vote on this matter. <u>DISCUSSION</u>: Partners Health Care was represented by Michael Carter, Corporate Director of Specialty Pharmacy, and William Barrows, Program Director. The model is for a pharmacy to service patients and employees of Partners with specialty items. They need to un-check the waiver for complex non-sterile compounding. Carter and Barrows answered the other Board members' questions to their satisfaction.

<u>ACTION:</u> Motion by C. BASILE, seconded by W. COX, and voted unanimously in the affirmative to approve Partners Health Care, with noted change to the waiver, pending successful inspection.

2. Teamsters Renovation

RECUSAL: None

<u>DISCUSSION</u>: Mark Antidormi, Pharmacy Director, represented Teamsters Care. The plans had been reviewed by Board staff and Members, and showed a decrease in space to make way for the construction of a credit union. Security was explained. Antidormi answered the Board members' other questions to their satisfaction.

<u>ACTION:</u> Motion by P. GANNON, seconded by G. CAVANAUGH, and voted unanimously in the affirmative to approve the application to renovate Teamsters care, subject to inspection.

Minutes of the General Session 6/29/2017, approved August 3, 2017

3. Birds Hill Pharmacy – Transfer of Ownership 8:43 am

RECUSAL: A. STEIN recused and was not present for the discussion and vote regarding this matter.

DISCUSSION: Birds Hill is changing ownership to A & J Rx, Inc. Board Member A. STEIN will be co-owner and MOR. No person was present to represent the company.

ACTION: Motion by R. TINSLEY, seconded by W. COX, and voted unanimously to approve the transfer of Ownership of Birds Hill Pharmacy.

TOPIC V:

REPORTS

Applications Approved Pursuant to Licensure Policy 13-01,

DISCUSSION: M. BOTTO noted that since the last Board Meeting, there have been seventeen (17) change-of-managers and one (1) closing approved by staff.

So noted

Board Delegated Review Pursuant to BDCR Policy

There was 1 Board Delegated Review (Staff Assignment) case heard on June 15, 2017. It was a self-report of a CE deficiency (SA-INV-11552) it had been successfully remediated.

The Board Delegated Review session was attended by T. FENSKY as the Board Member, H. ENGMAN as Board Counsel, W. FRISCH, Director of Pharmacy Compliance, and Executive Director D. SENCABAUGH.

ACTION: So noted

REPORTS

Staff Action to Handle Above Action Level reports pursuant to 16-04:

DISCUSSION: V. THAKER reported that there were two (2) above action level reports, and both had remediated and closed.

ACTION: So noted

TOPIC VI: ADVISORY **TIME: 8:46 AM**

Amendment to Staff Ratios

<u>DISCUSSION:</u> Presented by D. SENCABAUGH and V. THAKER, this is an amendment to the existing advisory allowing for and describing situations when a licensed pharmacist preceptor may supervise more than two pharmacy interns. Of note, P. GANNON asked that in addition to the examples provided the Board Staff include a table describing different scenarios and the allowable number of interns under the supervision of the pharmacist.

<u>ACTION:</u> Motion by A. STEIN, seconded by C. BASILE and voted unanimously to approve the advisory with the proposed changes.

TOPIC VII: File Review TIME: 8:50 AM

SA-INV-10485

Heritage Biologics Inc., DS89956

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

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

- On November 8, 2016, investigators went to do a retail compliance inspection but conducted a site visit (ISP-6279). There was no pharmacist on duty or any drug product at the pharmacy. There was only an administrative person at the desk in the reception area.
- November 10, 2016 OPP investigator confirmed with board staff that the MOR change had been completed. Investigators spoke with MOR Gonneville who told him that he works only 10 hours per week at Heritage Biologics, Inc and is the only pharmacist employed. He stated that they have never filled a prescription order or had any medication on site since they were licensed. They were in the process of hiring a sales person to recruit patients. MOR also stated that he is employed as a staff pharmacist elsewhere. Both PMP and ARCOS were run and showed no activity.
- On May, 2017 the Board voted to send a letter requesting Heritage Biologics either operate as a pharmacy within 60 days or close.

As a result, on June 15, 2017, Heritage Biologics appeared before the board and was approved for several waivers.

<u>ACTION</u>: Motion by A. STEIN, seconded by W. COX and voted unanimously by those present, to close SA-INV-10485, discipline not warranted.

RECUSAL: none. DISCUSSION:

TOPIC VIII

EXECUTIVE SESSION

DISCUSSION: None

<u>ACTION</u>: At 8:55 am President T. FENSKY read the statement on reasons for Executive Session.

At 10:15, T. FENSKY called for a motion to enter Executive Session: Motion by P. GANNON, seconded by W. COX and voted unanimously by roll call to enter into Executive Session. E. TAGLIERI; yes, T. FENSKY; yes, P. BOUVIER; yes, C. BASILE; yes, S. CORNACCHIO yes, A. STEIN: yes G. CAVANAUGH: yes; R.TINSLEY; yes, P. GANNON; yes, A. RAJA; yes, W.COX; yes

Minutes of the General Session 6/29/2017, approved August 3, 2017

TOPIC IX

Adjudicatory Session

DISCUSSION: None

<u>ACTION</u>: At 8:55 am motion by P. GANNON, seconded by G. CAVANAUGH and voted unanimously to enter into Adjudicatory session.

<u>ACTION</u>: At 9:17 am motion by P. GANNON, seconded by G. CAVANAUGH and voted unanimously to enter into Adjudicatory session for a second time.

TOPIC X

M.G.L. c. 65C Session

DISCUSSION: None

<u>ACTION</u>: At 9:00 am motion by E. TAGLIERI, seconded by P. GANNON and voted unanimously to enter into M.G.L. c. 65C Session.

<u>ACTION</u>: At 9:32 am motion by A. STEIN, seconded by P. BOUVIER and voted unanimously to enter into M.G.L. c. 65C Session for a second time.

TOPIC XI.

ADJOURMENT OF MEETING

DISCUSSION: NONE

<u>ACTION</u>: At 10:30 am motion by E. TAGLIERI, seconded by C. BASILE, and voted unanimously to adjourn the meeting.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. Draft Agenda of the 6/29/2017 General Session
- 2. Draft Minutes of the 6/15/2017 Meeting
- 3. Application of Partners Health Care Pharmacy, for New Community Pharmacy
- 4. Application of Teamsters Care for Renovation
- 5. Application of Birds Hill Pharmacy Transfer of Ownership to A & J Rx, Inc.
- 6. Report on applications approved pursuant to Licensure Policy 13-01
- 7. Report of Board Delegated Review Session from 6/15/2017
- 8. Report of Above Action Level pursuant to Policy16-04
- 9. Investigation report in the matter of SA-INV-10485, Heritage Biologics, DS89956
- 10. Board of Pharmacy Advisory of Staff Ratios, including Update FAQs

Respectfully submitted by:

S. CORNACCHIO, JD, RN, Secretary