COMMONWEALTH OF MASSACHUSETTS Board of Registration in Pharmacy

NOTICE OF THE SPECIAL MEETING OF THE BOARD OF REGISTRATION IN PHARMACY

January 22, 2018 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 Beth Rabasco, Phone: 617-624-5291 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
3:30	Ι	CALL TO ORDER		M. Godek
3:30	II	 APPROVAL OF AGENDA Introduction of Interns 		
3:30	III	 APPROVAL OF BOARD MINUTES Draft of December 7, 2017 Regular Session Minutes 		
3:35	IV	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 evaluate Probation Compliance, and evaluate the Good Moral Character as required for registration for pending applicants.		CLOSED SESSION
4:05	V	M.G.L. c. 112, § 65C SESSION		CLOSED SESSION

Agenda

4:30	VI	 REPORTS Applications approved pursuant to Licensure Policy 13-01 Monthly report from probation Board Delegated Complaint Review pursuant to licensure policy 14-02 Above Action Levels approved by Staff Action 16-04 PSUD Monthly Reports 	R. Harris D. Sencabaugh E. Taglieri
4:35	VII	APPLICATIONSNew England Life Care- New Community Pharmacy	
4:50	VIII	 FLEX Election of Officer-Secretary NABP 	
5:10	IX	 REGULATIONS 247 CMR 6.00: Registration, Management and Operation of a Pharmacy 247 CMR 15:00 Continuous Quality Improvement Program 247 CMR 20.00: Reporting 247 CMR 9:00: Professional Practice Standards 	
	X	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

January 22, 2018

Board Members Not Present

Phillippe Bouvier, RPh

Ali Raja, MD, MBA, MPH

Board Members Present

Michael Godek, RPh. President Andrew Stein, Pharm D, RPh. President Elect Kim Tanzer, PharmD, RPh, Secretary Susan Cornacchio, JD, RN Stephanie Hernandez, Pharm D, BCGP, RPh Patrick Gannon, RPh (via phone) Timothy Fensky, RPh Julie Lanza, CPhT Carly Jean-Francois, RN, NP Dawn Perry, JD Leah Giambarresi, Pharm D, RPh

Board Staff Present

David Sencabaugh, RPh, Executive Director Monica Botto, CPhT, Associate Executive Director Heather Engman, JD, MPH, Pharmacy Board Counsel Michelle Chan, RPh. Quality Assurance Pharmacist William Frisch, RPh. Director of Pharmacy Complinace Joanne Trifone, RPh., Director of Pharmacy Investigations Kimberly Morton, CPhT, Compliance Officer Joe Santoro, RPh. Contract Investigator Greg Melton, JD, PharmD, BCPS, RPh, Investigator Julienne Tran, Pharm D, RPh Investigator Ed Taglieri, MSM, NHA, RPh PSUD Supervisor Richard Harris, Program Analyst

TOPIC I. Attendance by roll call:

CALL TO ORDER 3:35 PM

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

Roll call attendance: M. Godek, yes; A.Stein, yes; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; D. Perry, yes; D. Jean-Francois, yes; J. Lanza, yes.

TOPIC II.Approval of AgendaAgenda January 22, 2018DISCUSSION:No changes to the agenda.Approval of Agenda

ACTION:

Motion by K. Tanzer, seconded by T. Fensky, and voted unanimously by roll call vote to approve the agenda. M. Godek, yes; A.Stein, yes; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; D. Perry, yes; D. Jean-Francois, yes; J. Lanza, yes.

Topic IIIApproval of Board MinutesMinutesDraft, December 7, 2017 Regular Session Minutes

Changes:

Correct spelling of Hernandez last name Topic VI: Flex election of officers for 2018. Action:

Motion by S. Hernandez, seconded by K. Tanzer, and voted unanimously by roll call vote to approve the regular session minutes. M. Godek, yes; A.Stein, yes; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; D. Perry, yes; D. Jean-Francois, yes; J. Lanza, yes.

Topic IV

EXECUTIVE SESSION

<u>DISCUSSION</u>: None <u>ACTION</u>: At 3:43 PM President M. GODEK read the statement on reasons for Executive Session.

At 3:45 PM, M. GODEK called for a motion to enter Executive Session: Motion by T. Fensky, seconded by A. Stein and voted unanimously by roll call to enter into Executive Session.

M. Godek, yes; A.Stein, yes; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; D. Perry, yes; D. Jean-Francois, yes; J. Lanza, yes.

Topic V.

65 C Session M.G.L. c. 112 § 65C

DISCUSSION: None

<u>ACTION</u>: At 3:56 PM motion by T. Fensky, seconded by K. Tanzer and voted unanimously by roll call to enter into Executive Session.

M. Godek, yes; A.Stein, yes; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; D. Perry, yes; D. Jean-Francois, yes; J. Lanza, yes.

TOPIC VII:APPLICATIONS1. New England Life CareNew Community Pharmacy

Time 5:30 PM

<u>RECUSAL</u>: Carly Jean-Francois

<u>DISCUSSION</u>: New England Life Care was represented by Bret Snow, Regional Director of Pharmacy, Al Loriaux, proposed Manager of Record, and Mark Smith of Alliance Builders.

NELC, planning to provide home infusion therapy to patients, answered all the questions from the Board Member to their satisfaction, and Board staff has reviewed the blueprints. NELC requested waivers in 247 CMR 6.-01 section 5 (a) regarding a balance, glassware, and other compounding equipment they will not need. NELC will not be compounding any high risk meds, chemotherapy, or hormones.

<u>ACTION:</u> Motion by T. FENSKY, seconded by K. TANZER, and voted unanimously in the affirmative to approve the application for New England Life Care's new community pharmacy, with waivers, pending a successful inspection by roll call.

M. Godek, yes; A.Stein, yes; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; D. Perry, yes; D. Jean-Francois, yes; J. Lanza, yes.

Executive Director D. SENCABAUGH 5:39 PM introduces new Board of Registration in Pharmacy new Board members: Julie Lanza, CPhT; Carly Jean-Francois, RN, NP; Dawn Perry, JD; Lean Giambarresi, PharmD RPh. Next introductions are the 3 Pharmacy Students on rotation; Hannah Boudreau, Western New England College; Mitchell Price, Mass College of Pharmacy and Eniola Tuby-Lukan from Northeastern. Lastly students present in the audience are welcomed and asked to stand to introduce themselves.

TOPIC VI

REPORTS

5:39 PM

Applications approved pursuant to Licensure Policy 13-01 Presented by: Monica Botto

Discussion: Since the last Board Meeting, Board Staff has processed 23 Change of Manager applications and one transfer of ownership.

So noted

TOPIC VI

Monthly Report from Probation Presented by: Dave Sencabaugh

Discussion:

No report at this time to present

So noted

TOPIC IV

Monthly Report from BDCR pursuant to Policy 14-02 Presented by: Monica Botto

Discussion:

No report at this time to present

So noted

TOPIC VI

Above Action Levels Approved by Staff Action 16-04 Presented by: Michelle Chan **Discussion:** Noted that there were two (3) above action level reports. All 3 were closed and resolved.

REPORTS

So noted

TOPIC IV

PSUD Monthly Report Presented by: Ed Taglieri

Discussion:

Noted: There was one new referral and 8 active participants. Two requested changes to their plan, which had been approved by the REC. There are currently 3 active members pending admission. So noted

Flex Session

TOPIC VIII:

Election of Secretary 2018:

Two members were nominated at the 12/7/17 Board meeting for the open Secretary Post. They were S. Hernandez and K. Tanzer. A roll call vote was taken at this time:

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5:41 PM

5:41 PM

5:45 PM

5:42 PM

TIME: 5:45 PM

REPORTS

REPORTS ant to Policy 14

REPORTS

Votes for S. Hernandez: M. Godek, A. Stein, L. Giambarresi, S. Hernandez, T. Fensky (5 votes received)

Votes for K. Tanzer: S. Cornacchio, K. Tanzer, D. Perry, C. Jean-Francois, J. Lanza, P. Gannon (6 votes received)

K. Tanzer is elected secretary.

NABP Update by David Sencabaugh, Executive Director

TIME: 5:48 PM

1. Annual Meeting:

Dave discusses the importance of NABP and the need for a delegate to attend and vote. The date of the meeting is 5/5 to 5/8/18. People interested will contact Dave. A decision will be made at the 2/1/18 Board meeting to whom will represent Massachusetts Board of Pharmacy and attend.

2. MPJE writing opportunities:

Dave discussed the importance of attending the MPJE exam writing session at NABP in Chicago on 3/6 to 3/8/18. Two members from Massachusetts will attend. It could be Board members or staff. People interested will contact Dave. A decision will be made at the 2/1/18 Board meeting to whom will represent Massachusetts and attend.

3. APHA Institute:

Dave discussed the importance of attending the APHA Institute, especially with our new PSUD Program to be held this year 5/30 to 6/3/18. E. Taglieri, PSUD Supervisor and T. Fensky attended last year and discussed and explained the APHA Institute. People interested will contact Dave. A decision will be made at the 2/1/18 Board meeting to whom will represent Massachusetts and attend.

IX. REGULATIONS

1. 247 CMR 20.00 Reporting **Presented By: H. Engman**

Discussion:

- Public comment was reviewed by H. Engman via the tracking change tool distributed
- P. Gannon wanted to clarify the reporting requirement for Wholesalers regarding drug loss and the number of days required (calendar vs. business days)
- H. Engman will clarify the Wholesaler drug loss reporting and report to the Board at their 2/1/18 meeting
- No action taken at this time.

So noted:

TIME: 6:05 PM

Time: 6:10 PM

2. 247 CMR 15.00 Continuous Quality Improvement Program Time: 6:10 PM Presented By: H. Engman Discussion:

• Public comment was reviewed by H. Engman via the tracking change tool distributed

• No comments or further input.

<u>ACTION:</u> Motion by P. Gannon, seconded by T. Fensky, and voted unanimously by roll call vote in the affirmative to approve 247 CMR 15.00 to proceed to administrative review and promulgation.

M. Godek, yes; A.Stein, yes; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; D. Perry, yes; D. Jean-Francois, yes; J. Lanza, yes.

3. 247 CMR 6.00 Registrations, Management and Operation of a Pharmacy Time: 6:36 PM Presented by: H. Engman

Discussion:

- Public comment was reviewed by H. Engman via the tracking change tool distributed at the previous Board meeting
- Updated language will be reviewed and distributed at the 2/1/18 Board meeting.
- No action taken at this time

So noted:

4. 247 CMR 9.00 Professional Practice Standards Presented by: H. Engman Discussion:

Time: 6:38 PM

- Public comment was reviewed by H. Engman via the tracking change tool distributed
- Input from the Board was noted.
- This process was begun, but not completed and will continue at future board meetings.
- No action taken at this time.

So noted

Topic X: ADJOURMENT OF MEETING

DISCUSSION: NONE

<u>ACTION</u>: At 8:00 pm motion by P. Gannon, seconded by S. Hernandez, and voted unanimously by roll call to adjourn the meeting.

M. Godek, yes; A.Stein, yes; S. Cornacchio, yes; L. Giambarresi, yes; K. Tanzer, yes; S. Hernandez, yes; P. Gannon, yes; T. Fensky, yes; D. Perry, yes; D. Jean-Francois, yes; J. Lanza, yes.

EXHIBITS USED DURING THE OPEN SESSION OF THE MEETING

- 1. Draft Agenda of the 1/22/18 General Session
- 2. Draft Minutes of the 12/7/17 Meeting
- 3. Report on Applications approved pursuant to Licensure Policy 13-01
- 4. Report on probation-none this month
- 5. Report on Delegated Complaint Review pursuant to licensee policy 14-01-none this month
- 6. Report on Above Action Levels approved by Staff Action 16-04
- 7. Report on Pharmacy Substance Use Disorder Program 12/17
- 8. Application To Manage & Operate a New Community Pharmacy. New England Life Care
- 9. Regulations 247 CMR 15.00 Continuous Quality Improvement Program
- 10. Summary of Public Comments 247 CMR 15.00
- 11. Regulations 247 CMR 20.00 Reporting
- 12. Summary of Public Comments 247 CMR 20.00
- 13. Regulations 247 CMR 6.00 Registration, Management and Operation of a Pharmacy
- 14. Summary of Public Comments 247 CMR 6.00
- 15. Regulations 247 CMR 9.00 Professional Practice Standards
- 16. Summary of Public Comments 247 CMR 9.00

Respectfully submitted by:

K. Tanzer, PharmD, RPh, Secretary