

COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

MINUTES OF THE REGULARLY SCHEDULED MEETING
239 Causeway Street, Fourth Floor Room 417A
Boston Massachusetts, 02114

January 6, 2015

Board Members Present

Patrick Gannon, RPh, MS Acting Chair
Edmund Taglieri Jr., RPh, MSM, NHA
Acting Secretary
Richard Tinsley, MBA, MEd.
Garrett Cavanaugh, RPh
William Cox CPht
Timothy Fensky, RPh, FACA
Michael Godek, RPh

Board Members Not Present

Catherine Basile, Pharm D, RPh
Karen Conley, RN, DNP

Board Staff Present

David Sencabaugh, RPh, Executive Director
David Dunn, RPh, Associate Executive Director
Heather Engman, JD, MPH Board Counsel
Kelly Ann Barnes, JD, RPh, Director of Pharmacy
Quality Assurance
William Frisch, RPh, Director of Pharmacy Compliance
Christina Mogni, Pharmacy Investigator
Monica Vasquez, Compliance Officer
Colleen Collins, RPH, Contract Investigator

I

TOPIC:

1. CALL TO ORDER

DISCUSSION: A quorum of the Board was present. Acting-Chair P.GANNON chaired the meeting and asked if anyone in the audience was recording the meeting; no one indicated that they were recording the meeting. P. GANNON also announced that the Board was recording the meeting.

ACTION: AT 8:31AM P.GANNON, called the January 6, 2015, meeting of the Board of Registration in Pharmacy to order. Quorum was established by roll call, P. GANNON; yes, E.TAGLIERI; yes, R. TINSLEY; yes, G.CAVANAUGH; yes, W. COX; yes, T.FENSKY; yes, M. GODEK; yes

TOPIC:

2. APPROVAL OF AGENDA

DISCUSSION: Approval of the minutes will be deferred to a future meeting.

ACTION: Motion by P.GANNON, seconded by E.TAGLIERI, and voted unanimously to approve the agenda with the noted changes.

TOPIC:

3. APPLICATIONS

A. Application for a New Community Pharmacy

1. Heritage Biologics, 1460 Fall River Ave, Suite 5 , Seekonk

DISCUSSION: Marybeth Donaldson, MOR, Christopher Quesenberry, and Anthony Carici presented this application. Heritage Biologics will be a closed door specialty pharmacy specializing in anti-hemophilia products Factor 8 & 9 and Stimate® nasal spray. Board questioned applicants regarding limited hours of operation, the employ of a single pharmacist (MOR Donaldson), and the delivery model and requirements for delivering the hemophilia products.

ACTION: Motion by R.TINSLEY, seconded by T.FENSKY, and voted unanimously to approve Heritage Biologics' application to Manage and Operate a New Community Pharmacy pending a successful inspection, receipt of Attestation for <795> and <797> compounding activities, Amended controlled Substance Application removing Schedules CII, CIII, CIV, and CV, and appropriate waivers to support Heritage Biologics limited compounding activity.

TOPIC:

4. REPORTS

A. BOARD DELEGATED COMPLAINT REVIEW PURSUANT to POLICY 14-02

DISCUSSION: D.SENCABAUGH indicated that a Board Delegated Complaint review was held on December 11, 2014 with Board Member E.TAGLIERI present.

New Board member W.COX was present and observed the session. D.

SENCABAUGH provided the following summary of the session:

Total Cases Reviewed	38
Returned to Full Board for consideration	11
Closed Staff Assignments	21
Dismissed Complaints	3
Return to OPP for additional investigation	1
Staff Assignments elevated to Complaint	2
Other	1

ACTION: So Noted

B. Applications Approved Pursuant to Licensure Policy 13-01

DISCUSSION: R.HARRIS noted that during the past month there had been nine (9) changes of managers, and one (1) new community pharmacy.

ACTION: So Noted

TOPIC:

5. FLEX SESSION

A. Joint Policy 2015-01 and FAQ on Pharmacist Administration of Vaccines

D.SENCABAUGH presented the proposed changes to the Joint Policy 2015-01 on Pharmacist Administered Vaccines. D.SENCABAUGH indicated that the language has changed in the new Joint Policy 2015-01 to allow for Pharmacist to administer all CDC approved vaccinations to patients 18 years of age and older. The change would eliminate the specific listing of individual vaccines that would limit the joint policy as new vaccinations become available and approved by the CDC.

ACTION: Motion by W.COX, seconded by M. GODEK, and voted unanimously to approve Joint Policy 2015-01

B. Ratification of Staff Action Policies

D.SENCABAUGH, reviewed with the Board the process of staff authority to carry out routine day to day functions and report back to the Board. D SENCABAUGH wanted the Board to be knowledgeable of the policies that provided Board Staff the administrative authority.

1. Staff Action on Licensure Applications and Notices Policy 13-01, Policy adopted January 8, 2013, Revised April 2, 2013,
2. Implementation of Plans of Correction, Policy 13-02, W. FRISCH indicated that the policy will be deferred to a future meeting.
3. Delegation of Signature Authority Policy 13-03, Policy adopted February 5, 2013.
4. Delegation of Board President Authority Policy 13-04; Adopted April 2, 2013.
5. Staff Action to Identify Registration Application requiring Good Moral Character evaluation, Policy 14-01; Adopted January 7, 2014.
6. Board Delegated Compliant Review; Adopted May 6, 2014; revised September 9, 2014.

ACTION: Motion by E. TAGLIERI, seconded by R.TINSLEY and voted unanimously to approve Staff Action Policies 13-01, 13-03, 13-04, 14-01 and 14-02.

C. ELECTION OF OFFICERS

1. President: Nominee P. GANNON; unopposed

ACTION: Motion by E. TAGLIERI, seconded by R.TINSLEY and voted unanimously to elect P. Gannon as president by a roll call vote. P.GANNON; yes,

E.TAGLIERI; yes, R.TINSLEY; yes, G.CAVANAUGH; yes, W.COX; yes, T.FENSKY; yes, M.GODEK; yes

2. President –elect: Nominee E.TAGLIERI; unopposed

ACTION: Motion by P. GANNON, seconded by T.FENSKY, and voted unanimously to elect E. Taglieri as president-elect by a roll call vote.

P.GANNON; yes, E.TAGLIERI; yes, R.TINSLEY; yes, G.CAVANAUGH; yes, W.COX; yes, T.FENSKY; yes, M.GODEK; yes

3. Secretary: Nominee R.TINSLEY; unopposed

ACTION: Motion by T.FENSKY, seconded by G.CAVANAUGH, and voted unanimously to elect R. Tinsley as secretary by a roll call vote. P.GANNON; yes, E.TAGLIERI; yes, R.TINSLEY; yes, G.CAVANAUGH; yes, W.COX; yes, T.FENSKY; yes, M.GODEK; yes

Break 9:20 AM- 9:29AM

TOPIC:

7. REGULATIONS

9:29AM- 10:55AM

1. Proposed amendments to 247 CMR 6.00 Licensure of Pharmacies

DISCUSSION: The final draft of the proposed amendments to 247 CMR 6.00 Licensure of Pharmacies and the Summary Memo were presented to the Board. The Board review to verify that recommendation had been captured in the final draft.

ACTION: Motion by P.GANNON, seconded by M.GODEK, and voted unanimously to approve the proposed amendments to 247 CMR 6.00 and proceed with the EO485 process and if substantive changes are not required by the EO485 process, send the proposed amendments to 247 CMR 6.00 out for public comment and hearing.

2. Proposed amendments to 247 CMR 9.00, Code of Professional Conduct; Professional Standards for Registered Pharmacist, Pharmacies, and Pharmacy Departments.

DISCUSSION: The Board reviewed 247 CMR 9.01, Practice Standards for Pharmacists and Pharmacies. The draft proposed regulation was displayed on screen for Board members and the audience to view. Board Counsel H.

ENGMAN captured Board members concerns and changes to the Draft document via track changes on screen for Board members and the audience to view.

BREAK 10:55AM-11:07AM

TOPIC:

8. TERMINATION OF PROBATION

1. Adam Deletetsky, PH27726, PHA-2012-0175

Presented by: V.BERG

DISCUSSION: Prior Board vote to offer a consent agreement for stayed probation for a minimum of a three month period. The Licensee has satisfied the terms of consent agreement. The Board has now established a general rule of allowing a licensee up to three (3) months to complete a stayed probation requirement allowing for earlier termination of the stayed probation once requirements are met.

ACTION: Motion by R.TINSLEY, seconded by T FENSKY, and voted unanimously to approve the termination of Adam Deletesky's probation and restore his registration to good standing.

TOPIC:

9. OPEN MEETING LAW PRESENTATION

Presented by H.ENGMAN

DISCUSSION: Board members and the audience viewed the Attorney General's Open Meeting Law presentation titled "Open Meeting Law: Balancing Government Transparency with Government Efficiency" dated February 28, 2013.

LUNCH BREAK 12:09PM-1:21PM

TOPIC

10. ADJUDICATORY SESSION (M.G.L. c. 30A, §18)

DISCUSSION: P.GANNON noted that the Board would not return to open session following closed session.

ACTION: At 1:21PM by W. Cox, seconded by E.TAGLIERI, and voted unanimously to enter into Adjudicatory Session.

TOPIC:

11. M.G.L. c 112§65C. Session

DISCUSSION: None

ACTION: At 1:26PM, motion by T.FENSKY, seconded by R.TINSLEY and voted unanimously by roll call vote to enter into M.G.L. c. 112 65C.

12. Executive Session (M.G.L. c 30A, §21(a) 1

DISCUSSION: None.

ACTION: At 2:26PM, motion by T.FENSKY, seconded by M.GODEK and voted unanimously by roll call vote to enter into Executive Session. P.GANNON; yes, E.TAGLIERI; yes, R.TINSLEY; yes, G.CAVANAUGH; yes, W.COX; yes, T.FENSKY; yes, M.GODEK; yes

TOPIC

13. M.G.L c. 112 §65C Session

DISCUSSION: None

ACTION: At 3:32PM, motion by E.TAGLIERI, seconded by G.CAVANAUGH, and voted unanimously to re-renter M.G.L. c. 112 65C Session.

TOPIC

14. ADJOURNMENT

DISCUSSION: None

ACTION: At 4:55PM, motion by E.TAGLIERI, seconded by T.FENSKY, and voted unanimously to adjourn

Respectfully submitted,

Richard J. Tinsley, MBA, M.Ed.
Secretary

LIST OF EXHIBITS USED DURING THE MEETING

1. Preliminary Agenda for the January 6, 2015 Regularly Scheduled Meeting
2. Application to Manage and Operate a New Community Pharmacy, Heritage Biologics
3. Applications approved pursuant to Licensure Policy 13-01 January 6, 2015
4. Board Delegated Compliant Review pursuant to Policy 14-02
5. Joint Policy 2015-01 and FAQs on Pharmacist Administration of Vaccines
6. Licensure Policy 13-01 Staff Action on Licensure Applications and Notices
7. Enforcement Policy 13-02 Implementation of Plans of Correction
8. Administrative Policy 13-03, Delegation of Signature Authority
9. Administrative Policy 13-04, Delegation of Board President Authority
10. Licensure Policy 14-01, Staff Action to identify Individual Registration Applications requiring Good Moral Character evaluation
11. Policy 14-02, Board Delegated Complaint Review
12. Memorandum re: Adam Deletetsky
13. Open Meeting Law: "Balancing Governmental Transparency with Government Efficiency
14. Memorandum: Summary of Proposed Amendments to 247 CMR 6.00
15. Proposed Amendments to 247 CMR 6.00
16. Proposed Amendments to 247 CMR 6.00 with track changes made during Board meetings
17. Proposed Amendment to 247 CMR 9.01