COMMONWEALTH OF MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

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

March 24, 2015

Board Members Present

Board Members Not Present

Patrick Gannon, RPh, MS, President
Edmund Taglieri Jr., RPh, MSM, NHA
President-elect
Richard Tinsley, MBA, MEd., Secretary
Catherine Basile, Pharm D, RPh
Garrett Cavanaugh, RPh
Karen Conley, RN, DNP
Susan Cornacchio, JD
William Cox CPht
Timothy Fensky, RPh, FACA
Michael Godek, RPh

Board Staff Present

James Lavery, JD, Director, Division of Health Professions Licensure 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

TOPIC: I

CALL TO ORDER

<u>DISCUSSION</u>: A quorum of the Board was present. President 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.

<u>ACTION</u>: AT 5:31PM P.GANNON, called the March 24, 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, C.BASILE; yes, G.CAVANAUGH; yes, K. CONLEY; yes, S. CORNACCHIO; yes, W. COX; yes, T.FENSKY; yes, M. GODEK; yes.

TOPIC: II

APPROVAL OF AGENDA

<u>DISCUSSION:</u> D. SENCABAUGH asked to defer the Guideline for pharmacist continuing education: Sterile and Non-Sterile Compounding to a future meeting. <u>ACTION</u>: Motion by T. FENSKY, seconded by R. TINSLEY, and voted unanimously to approve the agenda with the noted changes.

TOPIC: III POLICIES

TOPICS for the Advisory Committee Consideration.

<u>DISCUSSION</u>:D.SECABAUGH lead the discussion on the formation of the Pharmacy Advisory Committee as established by chapter 159 of the Acts of 2014.D.SENCABAUGH proposed that first two topics that the Pharmacy Advisory Committee consider be:

- 1. Responding to and remediating above action limit environmental monitoring results
- 2. Oversight of 503B outsourcing facilities

K. BARNES updated Board members on the needs for definitions of "state of control" and the need for guardrails with respect to actionable limits for environmental monitoring.

D.SENCABAUGH outlined a proposed communication process and vehicle between the Board and the Advisory Committee. D. SENCABAUGH recommended that:

- 1. T.FENSKY, serve as the Board's liaison to the Pharmacy Advisory Committee.
- 2. K. BARNES to present to the Pharmacy Advisory Board to provide historical background
- 3. Vote on Recommendation Document 15-01, "Abnormal Results"
- 4. Vote on Recommendation Document 15-02, "Outsourcing Facilities"

<u>ACTION:</u> Motion by E.TAGLIERI, seconded by C.BASILE, and voted unanimously to approve, T.FENSKY as Board of Pharmacy liaison to the Pharmacy Advisory Committee, K.BARNES to provide historical background to the Pharmacy Advisory Committee, Recommendation Document 15-01, "Abnormal Results", and Recommendation Document 15-02, "Outsourcing Facilities"

TOPIC: IV Time Start: 5:44PM Time End: 8:01PM

REGULATIONS:

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

DISCUSSION: The Board continued its discussion on 247 CMR 9.00 beginning at proposed 9.07 "Automation". The draft proposed regulation was displayed on the 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 the screen for Board members and the audience to view. The Board discussion concluded at 247 CMR 9.14 (15). During the discussion the Board debated the possible inclusion of Pharmacy Intern in proposed Draft 247 CMR 9.12 "Prospective Drug Utilization Review". The Board engaged in a spirited discussion regarding Drug Utilization Review to include drug age related situation and the amount of time a pharmacy computer system or pharmacist should "look back" for drug utilization review. The Board reviewed proposed new language requiring pharmacist counseling on all new prescriptions. The Board recommended the incorporation of requirements for the separations external use products from internal use products along with the addition of requirements to account for "look alike- sound alike" products when arranging products on shelves to make the dispensing process safer.

BREAK 7:01PM- 7:10PM

TOPIC V:

ADJOURNMENT DISCUSSION: None

<u>ACTION</u>: At 8:02PM, motion by K. CONLEY, seconded by G. CAVANAUGH, and voted unanimously to adjourn

Respectfully submitted,

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

LIST OF EXHIBITS USED DURING THE MEETING

Preliminary Agenda for the March 24, 2015 Scheduled Meeting Proposed Memo to Advisory Committee re: Board Regulations Pertaining to Above Action Level Environmental Monitoring Results Memo re: Board Members' Request to Advisory Committee Regarding Regulations Pertaining to Above Action Level Environmental Monitoring Results

Specific Questions for Advisory Committee

Recommendation Document 15-01

Recommendation Document 15-02

Minutes of the Regularly Scheduled Meeting held March 24, 2014 Approved April 7, 2015.

Draft Proposed Regulation: 247 CMR 9:00, Code of Professional Conduct; Professional Standards for Registered Pharmacist, Pharmacies, and Pharmacy Departments