

COMMONWEALTH OF MASSACHUSETTS

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

July 16, 2015
Department of Public Health,
250 Washington St., Boston, MA
Henry I. Bowditch Public Health Council Room, 2nd Floor

*** **PLEASE NOTE LOCATION** ***

Agenda

| Time | # | Item | Exhibits | Contact |
|-------|-----|--|----------|--|
| 9:00 | I | CALL TO ORDER | | |
| 9:05 | II | APPROVAL OF AGENDA | | |
| 9:10 | III | APPROVAL OF BOARD MINUTES <ul style="list-style-type: none">Draft of June 30, 2015 Regular Session Minutes | | |
| 9:15 | IV | REGULATIONS: Proposed new regulation, 247 CMR 17.00: Sterile Compounding. | | H. Engman; D. Sencabaugh; K. Barnes; W. Frisch |
| 12:00 | V | 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 <u>Good Moral Character</u> as required for a hearing pertaining to alleged probation violation | | CLOSED SESSION |
| 12:30 | VI | M.G.L. c. 112, 65C SESSION | | CLOSED SESSION |
| 1:00 | VII | ADJOURNMENT | | |

**COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY**

**MINUTES OF SCHEDULED MEETING
250 Washington Street, Second Floor
Henry I. Bowditch Public Health Council Room
Boston Massachusetts, 02114**

July 16, 2015

Board Members Present

Patrick Gannon, R.Ph., MS, President
Edmund Taglieri, Jr. R.Ph
Timothy Fensky, R.Ph, FACA
Garrett Cavanaugh, R.Ph.
Catherine Basile, Pharm D, R.Ph.
Susan Cornacchio, JD, RN.
William Cox CPht
Michael Godek, R.Ph.
Phillippe Bouvier, R.Ph.
Karen Conley

Board Members Not Present

Richard Tinsley, MBA, M.Ed.,
Secretary
Andrew Stein, Pharm D, R.Ph.

Board Staff Present

David Sencabaugh, R.Ph, Executive Director
David Dunn, R.Ph, Associate Executive Director
Heather Engman, JD, MPH Board Counsel
Kelly Ann Barnes, JD, R.Ph, Director of Pharmacy
Quality Assurance
William Frisch, R.Ph, Director of Pharmacy Compliance
Richard Harris, Program Analyst

TOPIC: I

CALL TO ORDER

DISCUSSION: 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. D. SENCABAUGH thanks both the board members and audience for giving of their time for critical important topic. D Sencabaugh informed the Board and the audience that Board staff would be posting the current Draft version of the regulations being considered at the meeting to the Board's website following the meeting.

ACTION: At 9:00AM P. GANNON, called the July 16, 2015, meeting of the Board of Registration in Pharmacy to order. Quorum was established by roll call, P. GANNON; yes, E.TAGLIERI; yes, G. CAVANAUGH; yes, S.CORNACCHIO; yes, W. COX; yes; M. GODEK; yes, C. BASILE; yes, P. BOUVIER; yes, K. CONLEY; yes, T. FENSKY; yes.

TOPIC II.

APPROVAL OF AGENDA

Time: 8:34AM

DISCUSSION: D.DUNN informed the Board at the general session minutes from the June 30th meeting would be deferred to a future meeting. D.DUNN informed the Board members at the request of the participant all matters scheduled for M.G.L c 112 65C session would be deferred to a future meeting.

ACTION: Motion by W. COX, seconded by E. TAGLIERI, and voted unanimously to approve the Agenda with the noted changes.

TOPIC III.

DISCUSSION: H. ENGMAN displayed draft proposed new regulation on the screen for the board members and the audience board members suggestions and comments were captured and reflected in track changes. The review began at page six Environmental Monitoring Program K. BARNES and W. FRISCH informed the Board members highlighted for the Board which requirements, mirrored USP <797>, sought to clarify the chapter, and requirements that would exceed the chapter. Board members sought clarification of terms “trained and qualified” K. BARNES indicated that these terms would be addressed in the definition section of proposed regulation to be considered at a future meeting. The Board debated the wording and process for hand washing and hand hygiene, seeking to modify the language to reflect current CDC standards. Board members directed board staff to review alternative sources to develop a workable regulation. Additional discussions were had relating to Beyond Use dating pertaining to storage conditions of implantable pumps. The Board also deliberated on the BUD of CSP compounded from stock solutions developing guidelines for BUD spaced on storage conditions and days of therapy for the patient. It was noted that the best practices are not in USP <797> and stakeholder feedback would be welcome. The Board sought clarification and guidance regarding “Sterility & Bacterial Endotoxin testing” and “Sterilization and Depyrogenation of High Risk Level CSPs.” K. BARNES clarified the information and indicated that the information would be reorganized. The discussion concluded after consideration of the “Policies and Procedures” section as all material prepared by Board staff had been reviewed in the customary line by line presentation format.

TOPIC

VII. ADJOURNMENT

DISCUSSION: P. GANNON thanked the Board Staff for their work on the new Sterile Compounding regulations. P. GANNON provided an open invitation to the pharmacy community to provide feedback to Board staff while the regulations are being drafted. P. GANNON cautioned that the Sterile Compounding regulation would need to strike the appropriate balance of raising the bar on practice and meeting the USP standards in order to be the best possible regulation and standards to insure the safety of the public.

ACTION: At 12:07PM Motion by M. GODEK, seconded by C. BASILE, and voted unanimously to adjourn the meeting.

LIST OF EXHIBITS USED DURING THE MEETING

1. Draft proposed Agenda for the July 16, 2015, Scheduled Meeting.

2. Draft proposed new regulations, 247 CMR 17.00: Sterile Compounding.
3. Draft proposed new regulations, 247 CMR 17.00: Sterile Compounding with track changes.

Respectfully submitted by:

Richard Tinsley, MBA, M.Ed., Secretary