

# COMMONWEALTH OF MASSACHUSETTS

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

November 24, 2015  
239 Causeway Street ~ Room 417 A&B  
Boston, Massachusetts 02114

### Agenda

Time	#	Item	Exhibits	Contact
5:30 PM	I.	CALL TO ORDER		
5:35 PM	II.	APPROVAL OF AGENDA		
5:40 PM	III.	APPROVAL OF BOARD MINUTES 1. Draft October 6, 2015 Regular Session Minutes 2. Draft November 3, 2015 Regular Session Minutes		
5:45 PM	IV.	REGULATIONS:  1. Proposed new regulation, 247 CMR 17.00: Sterile Compounding.		
8:00 PM	V.	ADJOURNMENT		

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

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

**November 24, 2015**

**Board Members Present**

Patrick Gannon, R.Ph., MS, President  
Edmund Taglieri, Jr. R.Ph. President-Elect  
Timothy Fensky, R.Ph, FACA  
Garrett Cavanaugh, R.Ph.  
Susan Cornacchio, JD, RN.  
William Cox CPhT arrives @ 5:35PM  
Michael Godek, R.Ph.  
Karen Conley, DNP, RN arrives @ 5:58PM  
Andrew Stein, Pharm D, R.Ph. arrives @ 5:32PM  
Phillippe Bouvier, R.Ph.

**Board Members Not Present**

Richard Tinsley, MBA, M.Ed. Secretary  
Catherine Basile, Pharm D, R.Ph.

**Board Staff Present**

David Sencabaugh, R.Ph, Executive Director  
Heather Engman, JD, MPH Board Counsel  
David Dunn, R.Ph, Associate Executive Director  
Kelly Ann Barnes, JD, R.Ph, Director of Pharmacy QA  
William Frisch, R.Ph, Director of Pharmacy Compliance

**TOPIC: I**

**CALL TO ORDER**

**DISCUSSION:** A quorum of the Board was present. President P. GANNON opened the meeting at 5:30PM, 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. Quorum was established by a roll call vote: P. GANNON; yes, E. TAGLIERI; yes, T. FENSKY; yes, M. GODEK; yes, G. CAVANAUGH; yes, S. CORNACCHIO; yes, P. BOUVIER; yes. W. COX, K. CONLEY, and A. STEIN were not present for the discussion on vote on this mater

TOPIC II.

**APPROVAL OF AGENDA**

**Time: 5:31PM**

DISCUSSION: None.

ACTION: Motion by M.GODEK, seconded by P BOUVIER, and voted unanimously to approve the Agenda. W. COX and K Conley were not present for the discussion or vote of this matter

TOPIC III.

**APPROVAL OF BOARD MINUTES**

**TIME: 5:32PM**

1. Draft October 6, 2015, Regular Session Minutes

DISCUSSION: none

ACTION: Motion by P BOUVIER, seconded by M, GODEK and voted unanimously to approve the draft regular session minutes from October 6, 2015. W. COX and K Conley were not present for the discussion or vote of this matter

2. Draft November 3, 2015, Regular Session Minutes

DISCUSSION: none

ACTION: Motion by P. BOUVIER, seconded by M. GODEK and voted unanimously to approve the draft regular session minutes from November 3, 2015. W. COX and K Conley were not present for the discussion or vote of this matter

TOPIC IV

**REGULATIONS**

1. Proposed new section 247 CMR 17:00: Sterile Compounding

DISCUSSION: D SENCABAUGH opened the discussion by thanking the members for their attendance at the special night meeting noting member's dedication to the profession and public safety. D. SENCABAUGH remarked that this meeting was a key moment in the promulgation of regulations resulting from chapter 159 of the "Acts of 2014". D. SENCABAUGH stated that "Massachusetts General Law chapter 112 section 39G was enacted as part of the Pharmacy Regulatory Act. It is arguably the center of the reform law, around which all of the rest revolves. Although you have worked have worked so hard, or so long, on many new sections of 247 CMR, as well as some extensive revisions to others, this section is by far, the section on which the most time has been spent."

Board members were informed that since the last review of section 17, the section had been reorganized, duplicative language eliminated, board member, and stakeholder feedback incorporated. Board members were informed that areas that still required input would be noted with a comment boxes with new or updated language highlighted in red and sections with no substantive changes displayed in blank font. H. ENGMAN captured all board member input in track changes displayed on the screen for board members and the audience to view. It was the consensus of the members that a section by section review of the document would be the most prudent way to review the final draft of the proposed new section.

K. BARNES informed the members that this final draft of proposed new section 17 did not address radiopharmaceuticals or hazardous drugs as these items had not been addressed at previous meetings noting that these items would be addressed at future

meetings. K BARNES informed the board that section 17 seeks clarifies areas of ambiguity in the current USP standard. K BARNES noted that the proposed section did seek to raise the bar on the USP <797> in the areas of environmental, personnel, and product monitoring. K BARNES indicated that it is not enough to trend monitoring as proposed in the current draft of <797>, but that it was essential to tie increase monitoring to products that pose an increase risk to the public.

**ACTION:** Motion by T. FENSKY, seconded by M. GODEK, and voted unanimous to approve the proposed new section 247 CMR 17.00: Sterile Compounding and proceed with the EO562 process and if substantive changes are not required by the EO562 process, send the proposed amendments to 247 CMR 17.00: Sterile Compounding out for public comment and hearing.

**TOPIC V.  
ADJOURNMENT**

DISCUSSION: None

ACTION: At 8:21 PM motion by M. GODEK, seconded by T. FENSKY, and voted unanimously to adjourn the meeting.

**Exhibits used during the meeting**

1. Draft Agenda for the General Session of the Scheduled Meeting November 24, 2015.
2. Draft General Session Minutes October 6, 2015.
3. Draft General Session Minutes November 3, 2015.
4. Draft proposed new regulation 247 CMR 17.00: Sterile Compounding
5. Draft proposed new regulation 247 CMR 17.00: Sterile Compounding with track changes.

Respectfully submitted by,

Richard Tinsley, MBA, M.Ed.  
Secretary