

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

**Pharmacy Advisory Committee
Meeting held via remote WebEx.
Boston, Massachusetts, 02114
September 28, 2022**

Advisory Committee Members Present

Ed Taglieri, MSM, NHA, RPh (chair designee by James Lavery)
Antoinette Lavino, RPh, BCOP (Expert in USP<797>)
John Walczyk, RPh, PharmD (Expert in USP<795>)
Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)
Judith Barr, MEd, ScD, FASHAP (Expert in Pharmacoeconomics)
Sylvia B. Bartel, RPh (Expert in USP<797>)
David H. Farb, PhD (Expert in Clinical Pharmacology)
Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)
Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics) (leaves meeting at 11:00 AM)
John P. Mistler, Pharm. D, RPh, MBA, BCSCP, CPH (Expert in cGMP) (leaves meeting at 11:00 AM)
Patrick Gannon, RPh, MS, FABC additional expert member

Board of Pharmacy Member Present

Caryn Belisle, RPh, MBA

Advisory Committee Members Not Present

Timothy D Fensky RPh, DPh, FACA (Expert in USP<71>)
Francis McAteer (Expert in Microbiology)

Board Staff Present

Monica Botto, Assistant Executive Director
Jacqueline Petrillo, PharmD, RPh, JD General Counsel
Michael Egan, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Nathan Van Allen, PharmD, RPh Pharmacy Investigator

TOPIC I. Attendance by roll call:

Call to Order, by Ed Taglieri at 10:05am and announces that the meeting is being recorded.

Roll call attendance: E. Taglieri, P. Gannon, J. Mistler, M. Gonyeau, K. Thomasset, K. Byers, A. Lavino, J. Barr, J. Walczyk

S. Bartel, D. Farb joined meeting at 10:12.

Not Present: T. Fensky, F. McAteer, J. Lavery (Ed Taglieri appointed as chair by J. Lavery for this meeting)

TOPIC II.

Approval of Agenda

TIME: 10:08am

Agenda: 9/28/22

Changes: None

Motion by P. Gannon, seconded by K. Thomasset, and voted unanimously by those present to approve the agenda with no noted change by roll call vote.

Topic III

Approval of Board Minutes

1. Minutes

Draft 3/30/22

Time: 10:09am

Changes: Minor edit to credential and attendance.

Motion by P. Gannon, seconded by K. Byers, and voted unanimously by those present to approve the minutes from the 3/30/2022 meeting with the noted changes by roll call vote.

K. Thomasset - Abstain

TOPIC IV: Presentation of Recommendation Document 22-02, “Review of Draft Regulations, 247 CMR 17.00 STERILE COMPOUNDING”

Time: 10:10am

Recused: None

Presented: Caryn Belisle, RPh, MBA

Discussion: Recommended that PAC review proposed edits to 247 CMR 17.00 STERILE COMPOUNDING

TOPIC V: Review and provide expert input to the Draft Regulations, 247 CMR 17.00 STERILE COMPOUNDING

Time: 10:10am

Recused: None

Presented: W. Frisch/M. Chan

Discussion:

W. Frisch: Initiated discussion on edits to 247 CMR 17.00 DRAFT. Included in discussion was statutory language used as the basis for increased quality requirements for patient safety.

M.Chan: Presented document to members. Covered section by section requesting comments for each.

17.01: No comments.

17.02:

- Members and staff discussed these additional points for clarification.
- Exclusion of Nuclear Pharmacies from requirements of 247 CMR 17.00 as new USP <825> standard is requirement. Pharmacies conducting sterile compounding require and additional permit specific for sterile compounding. No pharmacy licensed by the Board can also conduct business as an outsourcing facility.

17.03:

- Members and staff discussed multiple points of clarification in the proposed changes to this section.
- Board staff explained that edits in this section resulted in removal of duplicative regulations that are included in the USP standard. Other regulations belonged elsewhere within the regulations and were relocated to those sections.
- Members expressed concern with language discussing compounding ingredients for final CSPs that may be available commercially, compounding of non-sterile preparations within a PEC utilized for sterile compounding, and containment segregated compounding areas (C-SCA) utilized for hazardous compounding.
- Board staff explained that regulations were designed to minimize risk to the patient. Also explained that facility utilizing this type of design can apply for waiver.

17.04 Members and Board staff discussed concerns with dedicated changing areas and also storage of drugs within a classified space.

17.05 No comments.

- 17.06** Members expressed concern regarding exclusion of C-SCAs for HD compounding. Note conflict with USP <800>. Institutions may utilize C-SCA with more than 1 PEC. Note that built-in redundancy has been goal.
- 17.07** Members expressed need for clarity on recommended location for placement of autoclave. Additional inquiry made regarding waiver process availability for this requirement.
- 17.08** Members noted that acknowledgement with signature includes initiation and completion of remediation efforts and investigation for deficiencies identified.
- 17.09** Members provided notes for clarification.
- 17.10** Members recommend using USP designated temperature ranges for classified spaces.
-
- 17.11** No comments.
- 17.12** Members noted that the signature is with purpose and not solely to complete the task. Member noted that rigorous follow up should be instituted if actionable growth is identified.
- 17.13** Members expressed concern with difference from USP standard for environmental monitoring.
- 17.14** No comments.
- 17.15** Members briefly discussed inability to monitor laundering of scrubs.
- 17.16 – 17.17** No comments.
- 17.18** Member expressed concern with language requiring second sterilization procedure to be conducted prior to dispensing.
- 17.19 – 17.22** No comments.
- 17.23** Members and Board staff discussed labeling additions for clarity.
-Members expressed concern with language requiring phone number for outpatient facility administered medications.
- 17.24** Members provided comments regarding exemptions for counseling of patient in specified facilities.

VI: Closing remarks and Adjournment of Meeting

Time: 11:15am

Comments:

Next meeting to be conduct in early spring 2023 prior to 3/31/23. Remote meetings currently can continue until 3/31/23. We will keep you posted as we hear if there are any changes to this.

Adjournment:

Motion by P. Gannon, seconded by K. Byers, and voted unanimously by those present to close the meeting by roll call vote.

J. Mistler, K. Thomasset – Not present for vote
