COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN PHARMACY

Pharmacy Advisory Committee
Meeting held via remote WebEx.
Boston, Massachusetts, 02114
January 25, 2023

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>)
Sylvia B. Bartel, RPh (Expert in USP<797>)
Karen B. Byers, MS, RBP, CBSP (Expert in Microbiology)
John P. Mistler, Pharm. D, RPh, MBA, BCSCP, CPH (Expert in cGMP)
Patrick Gannon, RPh, MS, FABC additional expert member
Timothy D Fensky,RPh,DPh,FACA (Expert in USP<71>)
Keith B. Thomasset, BS, PharmD, MBA, BCPS (Pharmacoeconomics)

Board of Pharmacy Member Present

Caryn Belisle, RPh, MBA
Sami Ahmed, PharmD, RPh, BCPS, BCSCP

Advisory Committee Members Not Present

Michael J. Gonyeau, RPh, PharmD, Med, BCPS, FNAP, FCCP (Expert in Clinical Pharmacology)
David H. Farb, PhD (Expert in Clinical Pharmacology
Francis McAteer (Expert in Microbiology)
Judith Barr, MEd, ScD, FASHAP (Expert in Pharmacoeconomics)

Board Staff Present

David Sencabaugh, RPh, Executive Director
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
Sam Penta, RPh Senior Investigator
Nathan Van Allen, PharmD, RPh Pharmacy Investigator
Joanne Trifone, RPh, Director of Investigations

TOPIC I. Attendance by roll call:

Call to Order, by Ed Taglieri at 10:03am and announces that the meeting is being recorded.

Roll call attendance: E. Taglieri, A. Lavino, S. Bartel, K. Byers, J. Mistler, P. Gannon, K. Thomasset
T. Fensky, J. Walcyzk joined meeting at 10:06am.

Not Present: D. Farb, F. McAteer, M. Gonyeau, J. Lavery (Ed Taglieri appointed chair by J. Lavery for this meeting); J. Barr

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TOPIC II. **Approval of Agenda** **TIME: 10:06am**
Agenda: 1/15/23
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 **Time: 10:07am**
Draft 9/28/22

Changes: None

Motion by P. Gannon, seconded by A. Lavino, and voted unanimously by those present to approve the minutes from the 9/28/2022 meeting with no noted change by roll call vote.

TOPIC IV: Presentation of Recommendation Document 23-01, "Review of Draft Regulations, 247 CMR 18.00 NON-STERILE COMPOUNDING"

Time: 10:08am

S. Ahmed – Requests Pharmacy Advisory Committee to review and provide input on changes made to 247 CMR 18.00 Non-sterile Compounding.

TOPIC V: Review and provide expert input to the Draft Regulations, 247 CMR 18.00 NON-STERILE COMPOUNDING

Time: 10:10am
Recused:
Presented: Bill/Michelle
Discussion:

W. Frisch – Undergone changes since last approval on 4/2021 and due to revision of USP 795 released. The document has been streamlined and duplicative standards eliminated. Hazardous drug standards have been reincorporated into each individual compounding regulation. Legislature required regulations to be developed for complex non-sterile compounding. Additional edits made upon advisory committee meeting comments submitted prior to meeting.

M. Chan – Describes changes within each section below.

1: Authority and Purpose.
-No comments

2. Licensure Requirements
- Added hazardous drug (HD) compounding to requirements.
- Members commented about complex non-sterile compounding definitions for licensees, application to out of state pharmacies, and a timeline for implementation of the licensing aspect.

3. General
- Members commented on definition of "d0emonstrably difficult" and inclusion of "the Board" in determination of such compounding procedures. Some members commented that the FDA should be the driver of such determinations.
- Member commented that a compounder that conducts complex compounding procedures should be allowed to do so with proper training unless the FDA says otherwise.
- Inclusion of verbiage allows for flexibility by the Board to include additional quality assurance standards that may be stricter than FDA. Waiver process would be available.
- Member noted that if situation were to occur, having "by the board" within the regulation may help in expediting action.

4. General Facility and Equipment
- Member commented that clarification may be needed between "all surfaces" and "work surfaces", specifically, cabinetry material versus countertop. Notes differences between USP 795 labs and USP 800 labs.
- Member commented on the addition of "adjacent to" regarding sink placement.

5. Hazardous drugs
- Members recommended adding clarification for USP 800 as standard reference document.
- Members commented on operational limitations regarding use of equipment and/or chemicals, labeling procedures, and made comparisons to other dosage forms such as sterile compounding).

6. Components
- Members commented on definition and timeframe for "readily retrievable."
- Documents are to be maintained for 2 years.

7. Beyond use date
- Members commented on language of regulation 247 CMR 18.07 and USP 795 standard BUDs. Concerned it may cause confusion for licensee.
- Inclusion in regulation allows for flexibility if there is public safety concern and a change needed to be made.
- Member commented that it could be waived if necessary. All Board Policies are published, and licensee would know of change.

8. Master Formulation Records
- Member commented to change "produced" to "prepared."

9. Compounding Record
   - No comments

10. Packaging and Labeling
   - No comments

11. Counseling
   - No comments

VI: Next meeting: March 14, 2023, at 10am **Time: 10:55 AM**

E. Taglieri/W. Frisch – Discussed next steps and next meeting; Meeting will be in March, but not 3/14/23. Notice will be sent to attendees.

VII: Closing remarks and Adjournment of Meeting **Time: 11:00am**

Comments:
Next meeting to be conducted in March 2023. Official date TBD.

Adjournment:

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