

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

**Pharmacy Advisory Committee
Meeting held via remote WebEx
Boston, Massachusetts, 02114
November 10, 2020**

Advisory Committee Members Present

Antoinette Lavino, RPh, BCOP (Expert in USP<797>)
Caryn D. Belisle, RPh, MBA (Expert in USP<71>)
John Walczyk, RPh, PharmD (Expert in USP<795>)
Francis McAteer (Expert in Microbiology)
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)
LCDR John Mistler, PharmD, CPH, USPHS (Expert in cGMP)

Board of Pharmacy Member Present

Andrew Stein, PharmD Board of Pharmacy Member

Advisory Committee Members Not Present

James Lavery, JD BHPL Director (chair)

Board Staff Present

David Sencabaugh, RPh, Executive Director
Monica Botto, Assistant Executive Director
Heather Engman, JD, Board Counsel
William Frisch, RPh Director of Pharmacy Compliance
Michelle Chan, RPh Quality Assurance Pharmacist
Joanne Trifone, RPh, Director of Investigator
Sam Penta, RPh Senior Investigator
Nathan Van Allen, PharmD, RPh Pharmacy Investigator
Ed Taglieri, MSM, NHA, RPh, PSUD Supervisor

TOPIC I. Attendance by roll call:

Time: 10:03 AM

Call to Order, by: Ed Taglieri and announces meeting is being recorded.

Roll call attendance: Antoinette Lavino; Caryn D. Belisle; Judith Barr; Sylvia B. Bartel; Karen B. Byers; Keith B. Thomasset; LCDR John Mistler

Not Present: James Lavery; John Walczyk; Francis McAteer; Michael J. Gonyeau; David H. Farb;

Join meeting once started: John Walczyk; Francis McAteer; Michael J. Gonyeau; David H. Farb

TOPIC II. Approval of Agenda

TIME: 10:06 AM

Agenda: 11/10/20

Changes: None

Motion by C. Belisle, seconded by S. Bartel and voted unanimously by those present to approve the agenda no noted changes by roll call vote.

Topic III Approval of Board Minutes

1. Minutes

Draft 6/24/20

Time: 10:07 AM

Changes: None

Motion by M. Gonyeau, seconded by C. Belisle and voted unanimously by those present to approve the 6/24/20 minutes no noted changes by roll call vote.

TOPIC IV Discuss: Draft "Advisory on Non-Sterile Compounding"

Time: 10:08 AM

E. TAGLIERI: Introduces Andy Stein

A. STEIN: Discussed previous meeting regarding USP 795 and would like to receive feedback

E. TAGLIERI: Hand off to Bill and Michelle for intro

B. FRISCH: Presented background current draft, looking for expert input advisory on non-sterile compounding. To go through line by line and receive feedback.

E. TAGLIERI: Note for the record that David Farb joined in roughly 10:08 AM.

M. CHAN: Intended as one stop shop overview guidance document.

M. CHAN: Reviewed Section I

M. CHAN: Reviewed policies and procedures bullet point. Requests comments or questions.

E. TAGLIERI: Note for record that John Walczyk is here over the phone

M. CHAN: Reviewed personal point. Requests comments or questions.

B, FRISCH: Would like to point out that these were drawn from USP into this guidance document.

K. THOMASSET: Suggests to spell out SOPs

J. WALCZYK: If we already have chapter 18, why do we need a secondary advisory

M. CHAN: Answer that this is more a guidance document, more applied to nonresident compounders. General information.

M. CHAN: Reviews simple constitution bullet point. Requests comments or questions.

J. WALCZYK: Mentions it would be cautious about language of may/must/shall/should.

M. CHAN: Reviews constitution log bullet point. Request comments or questions.

C. Belisle: Suggests the term constitution log is fine but may want to use broader language, documentation instead of log.

J. WALCZYK: Also, currently “should” if board intends to have it, maybe “shall”

M. CHAN: Since this is an advisory, can’t make policy it is only best practice.

E. TAGLIERI: We look at advisories as best practice.

M. CHAN: Reviews flavoring agents bullet point. Requests comments or questions.

M. CHAN: Reviews breaking or splitting drugs bullet point. Requests comments or questions.

M. CHAN: Reviews compounding kits bullet point. Requests comments or questions.

M. CHAN: Reviews designated persons bullet point. Requests comments or questions.

M. CHAN: Reviews preparations based on master formulation bullet point. Requests comments or questions.

M. CHAN: Refers to Board’s USP <800> advisory. Requests comments or questions.

M. CHAN: Reviews must not compound commercially available drugs bullet point. Requests comments or questions.

J. WALCYZK: Mentions that you can copy commercial products however you must log them.

H. ENGMAN: Federal Food, Drug, Cosmetic Act does say you are not allowed to compound commercially available drugs.

M. CHAN: Reviews pharmacy emergency kit bullet point. Requests comments or questions.

E. TAGLIERI: Fran McAteer has joined the meeting.

M. CHAN: Reviews surfaces bullet point. Requests comments or questions.

C. BELISLE: Question about what surfaces do you mean, all surfaces like walls, ceiling, floors?

M. CHAN: Depending on what they are doing, retail – work surface, compounding – expect everything room walls.

M. CHAN: Reviews sink, utensils, and equipment bullet point. Requests comments or questions.

J. MISTLER: Mention how FDA recently released guidance for unsanitary conditions. Suggest that it is good to mention that it is there and explain FDA's definition of unsanitary conditions.

M. CHAN: Reviews USP <795> orderly placement of equipment bullet point. Requests comments or questions.

M. CHAN: Reviews recommendation for retail pharmacies to have a designated compounding area bullet point. Requests comments or questions.

C. BELISLE: Is it just retail pharmacies that need to apply for complex nonsterile license or any pharmacy?

M. CHAN: Only retail pharmacies.

K. THOMASSET: Adding on if licensed retail pharmacy with no intent for complex nonsterile compounding will they need a dedicated area?

M. CHAN: They will need a designated area not a dedicated area.

M. CHAN: Reviews carpeting is not allowed bullet point. Requests comments or questions.

M. CHAN: Reviews scales and balances bullet point. Requests comments or questions.

M. CHAN: Reviews defective drug log bullet point. Requests comments or questions.

M. CHAN: Reviews BUDs accordance bullet point. No comments.

M. CHAN: Reviews statement of nonsterile compounded drug preparation bullet point. No comments.

M. CHAN: Reviews pharmacy participation in research studies bullet point. No comments.

M. CHAN: Reviews renovations policy. No comments.

M. CHAN: Requests comments or questions on section.

M. CHAN: Transition to Section II Complex non-sterile compounding

M. CHAN: Reviews examples of complex non-sterile compounding

B. FRISCH: Anything missing from this list?

J. WALCYZK: Add after API, bulk substances.

C. BELISLE: Is the NIOSH list specifically called out in the statute?

M. CHAN: No.

M. CHAN: Reviews pharmacy specialty bullet point. No comments.

M. CHAN: Reviews recommended dedicated room bullet point. No comments.

M. CHAN: Reviews HD and non-HD compounding bullet point. B. FRISCH and M. CHAN reached out to USP for clarification.

M. CHAN: Reviews extreme caution bullet point.

M. CHAN: Reviews compound using bulk substances bullet point.

B. FRISCH: This is from the FDA document?

M. CHAN: Yes.

B. FRISCH: Move this bullet to the general section.

M. CHAN: Reviews valid certificate bullet point. No comments.

M. CHAN: Reviews yearly reporting bullet point. No comments.

M. CHAN: Reviews draft regulations at 247 CMR 18 and USP 795 and 800

M. CHAN: Reviews repairs/service advisory. No comments.

M. CHAN: Reviews pharmacists engaged in non-sterile compounding must obtain 3 CE each year. No comments.

J. WALCYZK: Is reporting per chapter 18 or if it does not go through?

M. CHAN: It is in statute not in 18, it will be required.

J. WALCYZK: For the CE, may spell out needing CE in non-sterile compounding.

A. STEIN: How is this document enforced?

M. CHAN: This is a review of the requirements not used as an enforcing document.

B. FRISCH: We're working with NABP for inspections using a universal tool to survey what people are doing.

B. FRISCH: Any more comments? We want this to be a toolkit having all the information in one place.

E. TAGLIERI: Next step, A. STEIN will bring input to the board in the next meeting or meeting after.

E. TAGLIERI: Any open questions before adjournment?

V: Closing Comments and Adjournment of Meeting**Time: 10:54 AM****Comments:**

J. WALCYZK motions to discuss MOU at the next meeting, C. BELISLE seconded. Voted unanimously (F. MCATEER abstained audio problems.)

Adjournment:

ACTION: Motion by M. Gonyeau seconded by K. Thomasset, and voted unanimously by those present, to adjourn from meeting by roll call vote.
