FLORIDA | Board of Pharmacy
Compounding Committee Meeting

DRAFT
July 25, 2018 – 1:00 p.m.

Telephonic Conference Call
Conference Call Number: (888) 670-3525
Conference Code Number: 5134896685

Mark Mikhael, PharmD,
Chair, Compounding Committee

C. Erica White, MBA, JD
Executive Director

Wednesday, July 25, 2018

Those present for all or part of the Compounding Committee Teleconference Meeting included the following:

COMMITTEE MEMBERS PRESENT:

- Mark Mikhael PharmD – Chair
- Richard Montgomery, BPharm, MBA
- Blanca Rivera, BPharm, MBA
- David Wright, BPharm

BOARD MEMBERS PRESENT:

- Jeenu Philip BPharm

BOARD COUNSEL:

- David Flynn, Assistant Attorney General
- Lawrence Harris, Assistant Attorney General

STAFF PRESENT:

- C. Erica White, MBA, JD, Executive Director

AUDIO from this meeting may be found online at: http://floridaspharmacy.gov/

The Committee Discussion convened at approximately 1:00 p.m.

Call to Order:
(*Facilitator – Dr. Mikhael)*

Dr. Mikhael called the meeting to order and thanked everyone for attending the call. Dr. Mikhael stated that we had a lengthy call and wanted to jump straight to the letter to be sent to USP regarding the rewrite to Chapter 795. Dr. Mikhael reviewed the letter and submitted some edits to the Board Office.

Dr. Mikhael asked if Ms. Rivera had any comments to add to the letter, and she did not. Mr. Wright stated that the draft letter repeats the statement that the proposed comments were "overreaching" several times and suggested that these additional references to "overreaching" be removed. Dr. Mikhael and Mr. Montgomery agreed with Mr. Wright's suggestion, and since the second paragraph already states this position, the additional references to "overreaching" should be removed. Mrs. Rivera expressed that she thinks taking the words "overreaching" out diminishes the impact of how strongly the Board feels about. the issues expressed in the letter.

Mr. Philip agreed with Ms. Rivera suggested that we use other synonyms that would provide convey our thoughts about the language being "overreaching". Mr. Philip suggested that the word "onerous" be used instead of "overreaching" in certain sections. Mr. Montgomery stated that the simpler we keep it, then the better it is. Mr. Philip suggested to include the language in the beginning of the letter: We suggest the following revisions because we believe that the following suggested revisions are onerous and

overreaching to the practice of pharmacy." A motion was made by Mr. Wright and seconded by Mr. Montgomery to include the language suggested by Mr. Philip in the beginning of the letter.

Draft Revisions to USP Chapter 795 / Public Comment

Mr. Flynn stated that he wanted to make sure regarding proposed revision #14 involving "Complaints". The current language in the draft letter states:

Comment: The Board's position is that complaints should not be going to USP, but rather should go to the relevant Board of Pharmacy Office. If there are complaints against a pharmacy, it should go to the Board Office responsible for governing (or licensing) the individual pharmacy for action or follow-up. This language has no bearing on the compounding of sterile or non-sterile products.

Mr. Flynn stated as he reads the revision to USP 795, the complaint process and complaint handling (Complaint Handling and Adverse Reporting Section) was related to the compounding facility making sure that they had standard operating procedures for the receipt, acknowledging, and handling of complaints (starting at line 665). Dr. Mikhael read Section 13.1, from the proposed revision to the Committee:

> *<u>13.1 Complaint Handling</u>*
> *671 The designated person must review all complaints to determine whether*
> *672 the complaint indicates a potential quality problem with the CNSP. If it does,*
> *673 a thorough investigation into the cause of the problem must be initiated and*
> *674 completed. The investigation must consider whether the quality problem*
> *675 extends to other CNSPs. Corrective action, if necessary, must be*
> *676 implemented for all potentially affected CNSPs. Consider whether to initiate*
> *677 a recall of potentially affected CNSPs and whether to cease nonsterile*
> *678 compounding processes until all underlying problems have been identified*
> *679 and corrected.*
> *680 A readily retrievable written or electronic record of each complaint must be*
> *681 kept by the facility, regardless of the source of the complaint (e.g., e-mail,*
> *682 telephone, mail). The record must contain the name of the complainant, the*
> *683 date the complaint was received, the nature of the complaint, and the*
> *684 response to the complaint. In addition, to the extent that the information is*
> *685 known, the following should be recorded: the name and strength of the*
> *686 CNSP, the prescription or medication order number, and the lot number, if*
> *687 one is assigned.*
> *688 The record must also include the findings of any investigation and any*
> *689 follow-up. Records of complaints must be easily retrievable for review and*
> *690 evaluation for possible trends and must be retained in accordance with the*
> *691 record-keeping requirements in 14. Documentation. A CNSP that is returned*
> *692 in connection with a complaint must be quarantined until it is destroyed after*
> *693 completion of the investigation and in accordance with applicable laws and*
> *694 regulations of the regulatory jurisdiction.*

Dr. Mikhael stated that after reading this section a second time, that he doesn't see the need to notify USP. Mr. Montgomery stated that in Lines 703 – 705 contains the requirement to report to Med Watch:

703 state and local laws and regulations. In addition, adverse events associated
704 with a CNSP should be reported to the FDA through the MedWatch program
705 for human drugs and through Form FDA 1932a for animal drugs.

Based on discussion of this information, the Committee moved to strike Proposed Comment #14 from the draft letter. The motion was made by Mr. Montgomery and seconded by Mr. Wright. Motion passed unanimously.

After receiving no further public comment, the Committee voted to send the revised draft letter to USP, also allowing for the Board Office and Board Counsel to make any non-substantive grammatical changes to the letter as necessary. The motion was made by Mr. Wright and seconded by Mr. Montgomery. Motion passed unanimously.

Dr. Mikhael thanked Board Staff, Board Counsel, Board Members and Committee members, and to Dr. Lauren Paul from CVS Health for writing the initial letter. Motion to adjourn made by Mr. Montgomery and seconded by Mr. Wright.

The Committee Discussion concluded at approximately 1:23 p.m.