BOARD OF PHARMACY
COMPOUNDING COMMITTEE
DRAFT MINUTES
October 14, 2019
Embassy Suites by Hilton
1100 SE 17th Street
Ft. Lauderdale, FL 33316
(954) 527-2700
1:00 p.m. ET

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

I. CALL TO ORDER/ROLL CALL

Ms. Rivera called the meeting to order at 1:00 p.m. ET.

MEMBERS PRESENT
Blanca Rivera, MPharm, MBA, Chair
Mark Mikhael, PharmD
Rich Montgomery, BPhram, MBA
David Wright, BPharm
Jonathan Hickman, PharmD
Jeenu Philip, BPharm

STAFF PRESENT
Jennifer Wenhold, Executive Director
Traci Zeh, Program Administrator

BOARD COUNSEL
David Flynn, Esq.
Senior Assistant Attorney General
Timothy Frizzell, Esq.
Assistant Attorney General

COURT REPORTER
Phipps Reporting
Barbara L. Kent
blkrmr@gmail.com
www.phippsreporting.com
Office: (888) 811-3408
Cell: (269) 808-5061

II. DISCUSSION ITEMS

a. USP 797 and USP 800

i. USP 797 General Chapter, Pharmaceutical Compounding – Sterile Preparations
ii. USP 800 General Chapter, Hazardous Drugs – Handling in Healthcare Settings
iii. USP 797 Version Contrast
iv. USP Compounding Standards and Beyond-Use Dates Reference Guide

Ms. Rivera addressed the Committee and the public regarding USP 795, 797, and 800 and the update regarding the USP Compounding Standards and the published revisions to USP 797. As the revisions are currently under appeal, the earliest the revisions to 797 would go into effect would be June of 2020.

Mr. Flynn addressed the committee regarding regulating compounding and what the Board's role is when considering rule making.

After discussion, the Committee recommended placing USP 800 on the next Committee agenda for discussion.

v. Proposed Letter to USPC

Mr. David Joseph, R. Ph., FIACP, was present and sworn in by the court reporter and addressed the Committee.

vi. Memorandum of Understanding

Ms. Wenhold addressed the Committee regarding the Memorandum of Understanding.

b. Correspondence from FLAVORx

Ned Limenkovich, PharmD, JD, representative of FLAVORx, a company that supplies custom-flavoring systems to pharmacies across the United States, submitted an inquiry to the Board, requesting the Board implement a regulation expecting the safe administration of flavoring from the definition of compounding.

Chad Baker, Senior Vice President of FLAVORx, was sworn in by the court reporter and addressed the Committee.

Mr. Flynn addressed the Committee and reiterated the USP 795 has not been adopted in our rule chapter and the definition of sterile compounding and non-sterile compounding are clear within our statutes.

c. 64B16-26.302, F.A.C., Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education

This rule controls the specific subject areas of the continuing education required of a licensed Consultant Pharmacist to be able to renew their license. A review of the rule revealed that compounding is not one of the areas listed. Therefore, the rule was presented for the discussion of adding compounding as a specific subject area of continuing education that may be taken by a Consultant Pharmacist for purposes of receiving C.E. credit for licensure renewal.

Proposed Amendment Language to Rule 64B16-302 was presented for consideration and discussion of the Committee.

64B16-26.302 Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education

A Consultant Pharmacist License Renewal Continuing Education Program must contain at least three (3) hours of training in any of the subjects specified below. Duplicate courses are not acceptable

(1) Through (3) No Change

Compounding of sterile and nonsterile human drugs or both. Any compounding continuing education course for a consultant pharmacist shall not be entitled to board approval unless the primary focus of the Continuing Education course is compounding.

The State laws and rules specific to compounding; the Federal laws, rules, and U.S. Food and Drug Administration's guidance documents related to compounding.

Authoritative Literature and compendiums on compounding to include relevant Chapters of the United States Pharmacopeia.

The standards applicable to compounding sterile and nonsterile human drugs.

Motion: by Dr. Hickman to approve the proposed rule language to be presented to the Full Board.
Second: by Dr. Mikhael
Vote: Unanimous

Motion: by Dr. Hickman to find that the proposed revisions do not have an adverse impact on small businesses.
Second: by Dr. Mikhael
Vote: Unanimous

Motion: by Dr. Hickman that no part of this rule or a violation of this rule should be designated as a minor violation.
Second: by Dr. Mikhael
Vote: Unanimous

Motion: by Dr. Hickman to find the proposed revisions would not likely directly or indirectly increase regulatory costs to any entity including government in excess of $200,000 in the aggregate in Florida within one year after the implementation of the rule.
Second: Dr. Mikhael
Vote: Unanimous

Michael Jackson, President of the FPA, addressed the Board.

After discussion the Committee moved to modify the language.

64B16-26.302 Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education

A Consultant Pharmacist License Renewal Continuing Education Program must contain at least three (3) hours of training in any of the subjects specified below. Duplicate courses are not acceptable.

(1) through (3) No Change

(4) Compounding sterile or nonsterile human drugs, or both.

Motion: by Mr. Wright to approve the modified language.
Second: by Dr. Hickman
Vote: Unanimous

d. 64B16-27.797, F.A.C., The Standards of Practice for Compounding Sterile Products

Mr. Flynn addressed the Committee.

III. FOR YOUR INFORMATION

a. Update on USP Compounding Standards

The Board received an update regarding the USP Compounding Standards and the published revisions to USP 797. As the revisions are currently under appeal, the earliest the revisions to 797 would go into effect would be June of 2020.

IV. PUBLIC COMMENT

Peter Day addressed the Committee regarding USP 800 Air Filtration single pass versus Redundant Filtration. Mr. Wright confirmed that this is not within the scope of the Board of Pharmacy.

Dean Pedalino addressed the Committee regarding regulatory costs of external ventilation requirements to become compliant with proposed changes to USP 800. Mr. Mikhael confirmed that USP 800 is not within the Department's inspectors' guidelines and that these topics will be addressed when the Committee discusses USP 800 at our next Committee meeting.

Martin Dicks, Esq., on behalf of Taylor pharmacy addressed the Committee.

Mr. Flynn addressed the Committee regarding possible veterinary issues of animal compounding in the near future.

V. ADJOURNMENT

There being no further business, the meeting adjourned at 2:45 p.m.