

**BOARD OF PHARMACY
TEMPERATURE REVIEW COMMITTEE
DRAFT MINUTES**

August 5, 2019

**Four Points by Sheraton Suites Tampa Airport Westshore
4400 W. Cypress Street
Tampa, FL 33607
(813) 873-8675
9:00 a.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.

MONDAY, AUGUST 5, 2019 at 9:00 a.m. ET

I. CALL TO ORDER/ROLL CALL

MEMBERS PRESENT

Mark Mikhael, PharmD, Chair
David Bisailon, Consumer Member
David Wright, BPharm
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

ABSENT MEMBERS

Blanca Rivera, MPharm, MBA

COURT REPORTER

American Court Reporting
Cindy Green
3213 Hargill Drive
Orlando, FL 32806
(407) 896-1813

II. DISCUSSION ITEMS

A. Mail Order/Temperature Control

- i. 64B16-28.10801, F.A.C.

The Board tasked Board Counsel, Mr. Frizzell with researching whether the Board of Pharmacy had the statutory authority to regulate the delivery of medications from the pharmacy to the consumer, specifically for the purposes of temperature control. Mr. Frizzell provided that Chapter 465, F.S. gives the Board of Pharmacy broad discretion to establish rules over pharmacies and drug safety measures.

The following proposed rule language was provided to the committee for review.

64B16-28.10801 All Permits – Delivery of Medicinal Drugs

All pharmacies regulated under chapter 465, F.S., must have policies and procedures to ensure medicinal drugs are not adulterated as defined in s. 499.006, F.S, at the time of receipt by the patient or their agent.

Rulemaking Authority 465.005, 465.022(1) FS. Law Implemented 465.022(1)(a) FS. History–New

At this time the Board allowed for public comment.

Loretta Boesing, Nationwide Patient Advocate and Founder of Unite for Sale Medications, addressed the Committee. She requested that the Committee refer to the USP for outlining language in the rule.

Hannah Davis, addressed the Committee and expressed her personal experience with delivered medications.

Dr. Angela Garcia, Chairman of Directors, Florida Pharmacy Association, addressed the Committee. Dr. Garcia stated she was not speaking on behalf of the FPA. She expressed the importance of health literacy and patient safety related to temperature control policies and procedures.

Dr. Dan Buffington, University of South Florida, addressed the Committee.

Dr. Mikhael requested Board Staff in collaboration with the Department to distribute public education regarding temperature control and the procedures of filing a formal complaint.

After discussion, Board Counsel proposed the following rule language with the outlined edits.

64B16-28.10801 All Permits – Delivery of Medicinal Drugs

Neither a pharmacy nor a pharmacist shall dispense or deliver an adulterated medical drug. All pharmacies regulated under Chapter 465, F.S., must have and follow policies and procedures to ensure medicinal drugs are not adulterated as defined in s. 499.006, F.S. at the time of receipt by the patient or their agent. The policies and procedures shall cover providing instructions to patient on how to report concerns with delivery and storage of medicinal drugs.

Rulemaking Authority 465.005, 465.022(1) FS. Law Implemented 465.022(1)(a) FS. History–New

Motion: by Mr. Wright to approve the proposed rule language to be presented to the Full Board.

Second: by Mr. Bisailon

Vote: Unanimous

Motion: by Mr. Wright that no part of this rule or a violation of this rule should be designated as a minor violation.

Second: by Mr. Bisailon

Vote: Unanimous

Motion: by Mr. Wright to find that the proposed revisions do not have an adverse impact on small businesses.

Second: by Mr. Bisailon

Vote: Unanimous

III. PUBLIC COMMENT

No general comments.

IV. ADJOURNMENT

There being no further business, the meeting adjourned at 10:47 a.m.