



Formulary Committee Draft Meeting Minutes

**Florida Boards of Medicine, Osteopathic
Medicine, And Pharmacy**

April 1, 2019 at 1:00

**Mission Inn
10400 County Road
Howey-in-the-Hills, Florida 34737
352-324-3101**

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.

The meeting was called to order by Executive Director, Claudia Kemp, at 1:15 p.m.

Roll Call: All members were present except for Dr. Jorge Lopez and Non-Board member, Josh Lenchus.

Committee Members:

Jorge Lopez, MD, Board of Medicine
Seela Ramesh, MD, Board of Medicine
Joel Rose, DO, Board of Osteopathic Medicine
Jeffrey J. Mesaros, PharmD, JD, Board of Pharmacy
Jeenu Phillip, BPharm, Board of Pharmacy
David Wright, BPharm, Board of Pharmacy
Josh Lenchus, Non-Board Member

Attorneys:

Ed Tellechea, Chief Assistant Attorney General
Donna McNulty, Senior Assistant Attorney General
Lawrence Harris, Senior Assistant Attorney General

Board Staff:

Claudia Kemp, JD, Executive Director
Jennifer Wenhold, MSW, Interim Executive Director
Amber Greene, Program Operations Administrator

Claudia Kemp, Executive Director for the Board of Medicine provided opening remarks to the committee. The first item of business was to elect the officers for this committee.

Motion: by Jeenu Phillip, to nominate Jeffrey Mesaros as Chair. Motion passed unanimously.

Motion: by Jefferey Mesaros, to nominate Joel Rose as Vice-Chair. Motion passed unanimously.

Lawrence Harris, Senior Assistant Attorney General, provided an overview of the formulary of medicinal drugs which may be ordered and dispensed by pharmacists.

Mr. Harris stated in 465.186(1) there are categories of medications in which the committee can evaluate and determine whether appropriate to add by rule to the formulary. For each of those medicinal drugs there is a dispensing procedure and dispensing rule. The purpose for today is to consider whether Naloxone is subject to be added to the formulary. There is a standing order that allowed certain pharmacies to dispense Naloxone pursuant to the standing order with a physician or prescriber. However, it's not added to the formulary where a pharmacist can stock and dispense. The statute list 7 classes of drugs that can be added to formulary, Naloxone currently does not fit any of those statutory categories, because it is pending over the counter

(OTC) statute by the federal government, so the committee can't take affirmative action today, but did advise the committee that they could discuss preemptively adding Naloxone and establish the procedures.

Mr. Tellechea asked Mr. Harris if the boards and committee to formally approve Narcan as OTC drug it must either be an over the counter (OTC) or pending OTC approval by FDA. Mr. Harris stated it is currently not in either status but it's getting there, the FDA is moving quickly to place item into that pending status. It would be appropriate for the committee take contingent action therefore the committee's recommendation could be to be presented to all three boards, and all three boards must approve.

Motion: by Joel Rose, to add both the Naloxone nasal spray and Naloxone injectable to the formulary. Motion passed unanimously.

The committee discussed dispensing procedures to include instructions for use of both the injectable and nasal spray.

Mr. Harris indicated that Rule 64B16- 27.220, F.A.C., is the rule which list the medicinal drugs that can be ordered by pharmacist. There is also a companion rule which is 64B1627.210, F.A.C., General Terms and Conditions, to be followed when ordering or dispensing approved medicinal drug products. Mr. Harris indicated both rules would require minor modifications to include mandatory counseling for the administration of the medication. The committee suggested rule language to include risk factors for opioid overdoses; strategies to prevent overdoses; signs of overdose; steps in responding to an overdose; info on Naloxone; procedure for administering Naloxone and proper storage and expiration.

Mr. Harris suggested to Dr. Mesaros that the next step is to prepare draft language, he then will work with Mr. Tellechea and Mrs. McNulty for revisions, prepare draft language that represents the committee's actions, submit draft language through Board of Pharmacy. Mr. Tellechea suggested a conference call for the formulary committee to approve and present to the respective boards.

Mr. Phillip suggested that the formulary committee reconvene at a future date to review the rule as a whole as some information is outdated. Ms. Wenhold to schedule a future meeting of this formulary committee.

Motion: by Ed Tellechea, to adjourn at 2:23 p.m. Motion passed unanimously.