

**BOARD OF PHARMACY
RULES COMMITTEE MEETING
DRAFT MINUTES
April 14, 2021
1:00 p.m. ET
Call In Number: (888) 585-9008
Conference Code: 599-196-982(#)**

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

Dr. Mesaros called the Rules Committee meeting to order at 1:00 p.m. ET.

MEMBERS PRESENT

Jeffrey Mesaros, PharmD, JD, Chair
Jeenu Philip, BPharm,
Jonathan Hickman, PharmD
Patty Ghazvini, PharmD, BCGP

STAFF PRESENT

Jessica Sapp, Executive Director
Traci Zeh, Program Administrator

BOARD COUNSEL

David Flynn, Esq.
Senior Assistant Attorney General

COURT REPORTER

For the Record
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II. RULES DISCUSSION

a. White and Brown Bagging Emerging Practices

The Board of Pharmacy received correspondence from the Florida Society of Health System Pharmacists, Inc (FSHP). regarding White and Brown Bagging Practices. This was placed on the agenda for discussion.

Bill Kernan, Immediate Past President, FSHP, addressed the Committee and provided an overview of white and brown bagging. He explained white bagging as the dispensing of patient-specific medication from an outside pharmacy to a physician's office, hospital, or clinic for purposes of administration and brown bagging as the dispensing of a medication from a pharmacy directly to the patient, who then transports the medication(s) to a physician's office for purposes of administration. He expressed the concerns with the regulation of these medications and asked the Committee to create an Ad-Hoc Committee to review and address their concerns.

Jorge Garcia, representative from Baptist Health, Oncology Services, addressed the Committee and provided patient case samples.

Dr. Hickman addressed the Committee in favor of developing a work group consisting of Board Committee Members, FSHP Members, and Specialty Pharmacy Members to review the concerns and uphold patient safety.

Mr. Flynn addressed the Committee regarding the concerns as discussed. He explained the focus appears to be on managed health care companies and confirmed the Board has no jurisdiction to regulate these companies.

Mr. Kernan reiterated the request that was before the Committee and asked the Board of Pharmacy to assemble a committee to elevate this issue and provide recommendations for quality patient safety.

Mr. Philip addressed the Committee. He explained the examples that were provided are pharmacy services issues with payer practice, which the Board does not have oversight of those policies. He would like to review what areas the Board does have authority over as outlined in the laws and rules and recommended moving forward with a special committee.

Mr. Wright addressed the Committee and suggested the Board review the delivery of medications rule and how would these issues relate to a community pharmacy.

Kyle Rob, State Policy and Advocacy Associate, American Society of Health Systems Pharmacists (ASHP), addressed the Committee in support of FSHP's request to form an Ad-Hoc Committee. He expressed recommendations for the Committee to consider such as establishing a formal definition on clinician administered drugs, establishing limitations to payer policies of brown bagging, establishing regulations of a specialty pharmacy to ensure safe delivery of medications including same day delivery, on call clinicals, and temperature of medications, and confirming the medications can be delivered from a specialty pharmacy ready to be administered.

Dr. Michael Diaz, representative from Florida Cancer Specialist and Research Institute and practicing oncologist addressed the Committee in opposition of white and brown bagging due to patient safety and quality of care issues.

Motion: by Dr. Hickman to present the discussion to the Full Board and suggest the formation an Ad-Hoc Committee.

Second: by Mr. Philip

Vote: Unanimous

- b. Petition to Initiate Rulemaking
 - i. 465.0235, F.S., Automated pharmacy systems used by long-term care facilities, hospices, or state correctional institutions, or for outpatient dispensing

The Florida Pharmacy Association (FPA) submitted a petition to initiate rulemaking to adopt rules implementing section 465.0235, Florida Statutes.

Michael Jackson, Executive Vice President and CEO, FPA, addressed the Committee and provided an overview of the submitted petition.

TJ Morton, Esq., General Counsel to the FPA addressed the Committee regarding HB59 and the location of the automated pharmacy systems (APS). He expressed that he believes the Board has rule making authority as outlined in 465.0325(1), Florida Statutes. He outlined where the Board may adopt rules, which included specified locations, indoor environment rules, definitions of which medical facilities and the locations the APS's can be located, labeling and record keeping requirements. He

suggested the Board hold a rules workshop to hear from interested parties and allow them to express their concerns.

Mr. Jackson addressed the Committee regarding the two previous letters sent on behalf of FPA that were reviewed during previous Committee meetings which expressed their concerns with the inspection regulations and the defining of qualified individuals who are authorized to stock the APS.

Mr. Philip addressed the Committee confirming the statute is prescriptive of what is mandated regarding the safety and security of the APS. He expressed if the legislative intent was to limit the locations, it would have specified such. He conveyed his apprehensions with limiting the locations as the intent was to create more access to healthcare.

Dr. Hickman addressed the Committee in agreeance with Mr. Philip. He explained that access to a pharmacy is becoming an issue as there are less and less 24-hour pharmacies. These locations can increase access to patient care. He inquired with the Committee if the Board should look at strengthening the regulation of who can stock the APS.

Dr. Ghazvini addressed the Committee in agreeance with Dr. Hickman regarding the stocking requirements of the systems.

Mr. Flynn addressed the Committee and explained section 465.0235(11), Florida Statutes and confirmed that all federal and state laws still apply. He suggested that any tasks that wish to be additionally outlined could possibly be placed in the delegable task rule.

Mr. Jackson inquired with the Committee regarding the inspection process and asked the Department or the Board provide a better understanding.

Ms. Sapp addressed Mr. Jackson and explained the Department's inspection process.

Motion: by Dr. Ghazvini to deny the petition to initiate rule making and for the Committee to look at potential rule making in other rules within the pharmacy practice act.

Second: by Dr. Hickman

Vote: Unanimous

This discussion will be placed on the next Rules Committee meeting agenda.

III. ADJOURNMENT

There being no further business the meeting adjourned at 3:40 p.m. ET.