

Draft Minutes

December 3, 2020

TELEPHONE CONFERENCE CALL

1:00 p.m. ET

Call In Number: (888) 585-9008

Conference Code: 599-196-982(#)



Jonathan Hickman, PharmD
Chair

Jessica Sapp, Executive Director

**BOARD OF PHARMACY
GENERAL BUSINESS MEETING AGENDA
TELEPHONE CONFERENCE CALL
DRAFT MINUTES
October 14, 2020
8:00 a.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

Call to Order - The meeting was called to order by Board Chair, Dr. Hickman, at 1:00 p.m. ET.

Those present during the meeting included the following:

MEMBERS PRESENT:

Jonathan Hickman, PharmD, Chair
David Wright, BPharm
Jeenu Philip, BPharm
Jeffrey J. Mesaros, PharmD, JD
Gavin Meshad, Consumer Member
Patty Ghazvini, PharmD, BCGP
Dorinda Segovia, PharmD
Maja Gift, BPharm, MHA, CPH

STAFF PRESENT:

Jessica Sapp, Executive Director
Traci Zeh, Program Administrator

BOARD COUNSEL:

Christopher Dierlam, Assistant Attorney
General

PROSECUTION ATTORNEY:

Andrew Pietrylo, DOH Prosecution Services
Alejandro Camacho, DOH Prosecution Services

COURT REPORTER:

For the Record
150 Mahan Drive, Suite 140
Tallahassee, FL 32308
(850) 222-5491
(850) 224-5316 (Fax)

II. APPLICATIONS FOR REVIEW – David Wright, BPharm

A. Pharmacists

- i. Sanjeev Seenath

The applicant was present and represented by Edwin Bayo, Esq.

The applicant applied for a pharmacist license and answered yes to criminal history questions on his application.

After further discussion the Board took the following action:

Motion: by Mr. Philip to accept the application.
Second: by Mr. Meshad
Vote: 4/1. Dr. Hickman opposed.

ii. Theresa Ballington

The applicant was present.

The applicant applied for a pharmacist license and answered yes to criminal history questions on her application.

After further discussion the Board took the following action:

Ms. Ballington requested to waive the 90-day requirement of her application to allow her time to supply the Board with a copy of her evaluation completed in the state of Illinois.

Motion: by Dr. Hickman to approve the request to continue her the application and to delegate Mr. Wright to review the evaluation to determine if Ms. Ballington is sufficiently safe to practice.
Second: by Dr. Mesaros
Vote: Unanimous

B. Registered Pharmacy Technician

i. James Morrell

The applicant was present.

The applicant applied for a registered pharmacy technician license and answered yes to criminal history questions on his application.

After further discussion the Board took the following action:

Motion: by Dr. Hickman to accept the application.
Second: by Dr. Mesaros
Vote: Unanimous

ii. Jessica Leavesley

Mr. Wright stated for the record he is professionally associated with the applicant. Due to his recusal, the application was tabled to the December 16, 2020 meeting due to lack of quorum.

iii. Malinda Barconey

The applicant was present.

The applicant applied for a registered pharmacy technician license and answered yes to health history questions on her application.

Mr. Philip stated that even though Ms. Barconey completed her training through Walgreens, he

has no professional association with Ms. Barconey and would not need to recuse himself.

After further discussion the Board took the following action:

Ms. Barconey requested to waive the 90-day requirement of her application to allow her time to receive an evaluation from Professional Resources Network (PRN).

Motion: by Dr. Hickman to approve the request to continue her the application for six months and to delegate Mr. Wright to review the evaluation to determine if Ms. Barconey is sufficiently safe to practice.

Second: by Dr. Mesaros

Vote: Unanimous

iv. Zabella Thompson

The applicant was present.

The applicant applied for a registered pharmacy technician license and answered yes to criminal history questions on her application.

After further discussion the Board took the following action:

Motion: by Mr. Philip to accept the application.

Second: by Dr. Mesaros

Vote: Unanimous

v. Joshua Camesa

The applicant was present.

The applicant applied for a registered pharmacy technician license and answered yes to health history questions on his application.

After further discussion the Board took the following action:

Mr. Camesa requested to waive the 90-day requirement of his application to allow him time to receive an evaluation from Professional Resources Network (PRN).

Motion: by Mr. Meshad to approve the request to continue the application for six months and to delegate Mr. Wright to review the evaluation to determine if Mr. Camesa is sufficiently safe to practice.

Second: by Dr. Hickman

Vote: Unanimous

vi. Jarvis Manns

The applicant was present.

The applicant applied for a registered pharmacy technician license and answered yes to criminal history questions on his application.

After further discussion the Board took the following action:

Mr. Manns requested to waive the 90-day requirement of his application.

Motion: by Mr. Meshad to approve the request to continue the application for six months to allow time to retrieve additional criminal documentation.

Second: by Dr. Hickman

Vote: Unanimous

vii. Mark Stevenson

The applicant was present.

Mr. Philip stated that even though Mr. Stevenson completed his training through Walgreens, he has no professional association with Mr. Stevenson and would not need to recuse himself.

The applicant applied for a registered pharmacy technician license and answered yes to criminal and health history questions on his application.

After further discussion the Board took the following action:

Mr. Stevenson requested to waive the 90-day requirement of his application to allow him time to receive an evaluation from Professional Resources Network (PRN).

Motion: by Dr. Hickman to approve the request to continue the application for six months and to delegate Mr. Wright to review the evaluation to determine if Mr. Stevenson is sufficiently safe to practice.

Second: by Mr. Meshad

Vote: Unanimous

C. Pharmacy Permits

i. Total Veins Pharmacy, LLC.

The applicant was present.

The applicant applied for a Nonresident Sterile Compounding Permit. The applicant answered yes to disciplinary questions on the application.

After further discussion the Board took the following action:

Motion: by Dr. Hickman to accept the application.

Second: by Mr. Philip

Vote: Unanimous

ii. Maple Rose Enterprises, Inc.

The applicant was present.

The applicant applied for a Nonresident Pharmacy Permit. The applicant answered yes to disciplinary questions on the application.

During the August Board Meeting, it was requested that Maple Rose Enterprises, Inc. reappear before the Board in December with a new inspection report.

After further discussion the Board took the following action:

Motion: by Mr. Philip to accept the application.

Second: by Dr. Hickman

Vote: Unanimous

iii. At Home Infusion Services, Inc.

The applicant was present.

The applicant applied for a Community Pharmacy Permit. The applicant answered yes to disciplinary questions on the application.

After further discussion the Board took the following action:

Motion: by Dr. Hickman to accept the application.

Second: by Mr. Meshad

Vote: Unanimous

III. PETITION FOR VARIANCE OR WAIVER

A. Mirlande Pierre, 64B16-26.300, F.A.C., Consultant Pharmacist Licensure

The petitioner was present.

Pursuant to Rule 64B16-26.300(3)(c), F.A.C., a pharmacist wishing to become licensed as a consultant pharmacist must “successfully complete a period of assessment and evaluation under the supervision of a preceptor within one (1) year of completion of the course set forth in paragraph (b), above. This period of assessment and evaluation shall be completed over no more than three (3) consecutive months and shall include at least 40 hours of training in the following practice areas, 60% of which shall occur on-site at an institution that holds a pharmacy permit.

Ms. Pierre requested the rule be temporarily waived as she is unable to complete the on-site requirement at an institution due to restrictions of entering facilities during COVID-19.

After further discussion the Board took the following action:

Motion: by Dr. Hickman to grant the petition contingent upon the completion of an additional eight (8) hours of Consultant Pharmacist continuing education within six (6) months.

Second: by Dr. Mesaros

Vote: Unanimous

B. Mounica Jammu, 64B16-26.300, F.A.C., Consultant Pharmacist Licensure

The petitioner was present.

Pursuant to Rule 64B16-26.300(3)(c), F.A.C., a pharmacist wishing to become licensed as a consultant pharmacist must “successfully complete a period of assessment and evaluation under the supervision of a preceptor within one (1) year of completion of the course set forth in paragraph (b), above. This period of assessment and evaluation shall be completed over no more than three (3) consecutive months and shall include at least 40 hours of training in the following practice areas, 60% of which shall occur on-site at an institution that holds a pharmacy permit.

Ms. Jammu was seeking a waiver of Rule 64B16-26.300(3)(c), F.A.C, as she is unable to locate a preceptor during the current COVID-19 climate.

After further discussion the Board took the following action:

Motion: by Mr. Wright to grant the petition contingent upon the completion of an additional eight (8) hours of Consultant Pharmacist continuing education within six (6) months.

Second: by Dr. Mesaros

Vote: Unanimous

C. Jelisabel Irizarry-Gonzalez, 64B16-26.300, F.A.C., Consultant Pharmacist Licensure

The petitioner was present.

Pursuant to Rule 64B16-26.300(3)(c), F.A.C., a pharmacist wishing to become licensed as a consultant pharmacist must “successfully complete a period of assessment and evaluation under the supervision of a preceptor within one (1) year of completion of the course set forth in paragraph (b), above. This period of assessment and evaluation shall be completed over no more than three (3) consecutive months and shall include at least 40 hours of training in the following practice areas, 60% of which shall occur on-site at an institution that holds a pharmacy permit.

Ms. Irizarry Gonzalez was seeking a waiver of Rule 64B16-26.300(3)(c), F.A.C, as she is unable to locate a preceptor during the current COVID-19 climate.

After further discussion the Board took the following action:

Motion: by Mr. Wright to grant the petition contingent upon the completion of an additional eight (8) hours of Consultant Pharmacist continuing education within six (6) months.

Second: by Dr. Mesaros

Vote: Unanimous

D. Stellar Pharmacy Services, Inc.

The petitioner was present.

The Petitioner was seeking a variance from 465.0235, Florida Statutes, Automated pharmacy

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systems used by long-term care facilities, hospices, or state correctional institutions, or for outpatient dispensing. The petitioner was seeking guidance regarding allowing a Florida licensed Non-Resident Pharmacy be substituted for a Community Pharmacy, a medical provider deliver patient counseling, and for the allowance of an out of state licensed pharmacist supervise an automated pharmacy system.

The Petitioner withdrew the petition.

IV. PETITION TO INITIATE RULEMAKING

A. RxSafe, LLC., Panama Pharmacy, and Pine Brook Pharmacy, 64B16-28.108, F.A.C., All Permits – Labels and Labeling of Medicinal Drugs

The Petitioner was present and represented by Edwin Bayo, Esp.

RxSafe, LLC., Panama Pharmacy, and Pine Brook Pharmacy petitioned the Board to initiate rulemaking for the purpose of amending Rule 64B16-28.108, F.A.C., to reflect a “beyond use date” that would be consistent to allow a pharmacy that provides customized patient medication packaging to dispense a ninety day supply.

64B16-28.108 All Permits – Labels and Labeling of Medicinal Drugs.

(6) A customized patient medication package may be utilized if:

- (a) The consent of the patient or the patient’s agent has been secured; and,
- (b) The label includes:

1. Name, address and telephone number of the pharmacy.
2. Serial number for the customized medication package and a separate serial number for each medicinal drug dispensed.
3. Date of preparation of the customized patient medication package.
4. Patient’s name.
5. Name of each prescriber.
6. Directions for use and any cautionary statements required for each medicinal drug.
7. Storage instructions.
8. Name, strength, quantity and physical description of each drug product.
9. A beyond use date that is not more than **60 120** days from the date of preparation of the customized patient medication package but shall not be later than any appropriate beyond use date for any medicinal drug included in the customized patient medication package.

Motion: by Dr. Mesaros to table this discussion to be considered at a Rules Committee Meeting and requested the Petitioner to provide data from other states on how many times they have to rework the packaging of the medications.

Second: by Dr. Hickman

Vote: Unanimous

V. RULE DISCUSSION

A. Consultant Pharmacist of Record, Emergency Rule

Due to the concerns surrounding the spread of COVID-19, the Board held an Emergency Rule Hearing to address the obligations of Consultant Pharmacists under 64B16-28, F.A.C. Emergency Rule 64B16ER20-21 was effective March 19, 2020 through June 19, 2020 which suspended the

requirement of a Consultant Pharmacist completing their required inspections “on-site”.

This was placed on the agenda for further Board discussion.

During the October meeting the Board directed Board Counsel to provide language for another emergency rule. The Following language was provided for the Board’s review.

64B16ER20-42 (64B16-28.501) Consultant Pharmacist of Record; Initial Designation; Change. (1) through (4) No change.

(5) Off-site consultant pharmacists of record shall not be required to perform inspections and on-site consultations at permitted institutional pharmacies as referenced in Rules 64B16-28.501(3), F.A.C.; Rules 64B16-28.702(2)(b), (c), and (d) F.A.C.; Rule 64B16-28.850(16), F.A.C., and Rules 64B16-28.870(3)(c) and (d), F.A.C., when the consultant pharmacist of record is not regularly present at the location and the permit holder refuses to grant access due to COVID-19 concerns. This rule shall in no way modify any obligations stemming from State or Federal laws requiring drug regimen reviews.

Motion: by Mr. Wright to approve the proposed emergency rule language.

Second: by Dr. Hickman

Vote: Unanimous

The Board opened the floor for public comment.

Kathy Baldwin addressed the Board.

Motion: by Mr. Wright to find that there would be no economic impact on small businesses.

Second: by Mr. Philip

Vote: Unanimous

Motion: by Mr. Wright to find that the proposed rule would not likely directly or indirectly increase regulatory costs to any entity (including government) in excess of \$200,000 within 1 year after the implementation of the rule.

Second: by Dr. Hickman

Vote: Unanimous

Motion: by Mr. Wright to find that no part of the rule should be designated as a minor violation.

Second: by Dr. Hickman

Vote: Unanimous

B. Application Redesign

- i. 64B16-26.2032, F.A.C., Application for Pharmacy Intern Registration
- ii. 64B16-26.303, F.A.C., Nuclear Pharmacist Licensure
- iii. 64B16-26.350, F.A.C., Requirements for Pharmacy Technician Registration
- iv. 64B16-300, F.A.C., Consultant Pharmacist for Licensure

Ms. Sapp provided the Board with a summary of the application revisions.

Motion: by Mr. Wright to approve the application revisions and open the applicable rules open for development.

Second: by Mr. Philip

Vote: Unanimous

Motion: by Mr. Wright to find that there would be no economic impact on small businesses.

Second: by Dr. Hickman

Vote: Unanimous

Motion: by Dr. Hickman to find that the proposed rule would not likely directly or indirectly increase regulatory costs to any entity (including government) in excess of \$200,000 within 1 year after the implementation of the rule.

Second: by Mr. Wright

Vote: Unanimous

Motion: by Dr. Hickman to find that no part of the rule should be designated as a minor violation.

Second: by Mr. Wright

Vote: Unanimous

Motion: by Mr. Wright to find that this rule shall not include a sunset provision.

Second: by Dr. Hickman

Vote: Unanimous

VI. REPORTS – Jonathan Hickman, PharmD, Chair

A. Board Chair

Dr. Hickman addressed the Board and recognized the outgoing Members. Mr. Richard Montgomery, Dr. Mark Mikhael, and Dr. Blanca Rivera for their years of service on the Board. He also welcomed the new Members, Dr. Patty Ghazvini, Dr. Dorinda Segovia, and Ms. Maja Gift to the Board.

B. Executive Director's Report – Jessica Sapp, Executive Director

Ms. Sapp provided an overview of 2021 legislation.

HB29, Dispensing Medicinal Drugs, was recently filed. This bill authorizes a prescribing health care practitioner to dispense up to a 48-hour supply of a medicinal drug to an inpatient upon discharge or to a patient discharged from an emergency department of a hospital that operates a Class II or Class III Institutional pharmacy. It also allows up to a 72-hour supply when a state of emergency has been declared for an area in the state pursuant to section 252.36, Florida Statutes (F.S.). Ms. Sapp will provide updates at each meeting with the status of the bill and any other bills filed throughout the 2021 legislative season.

i. Financial Reports

These reports were provided for informational purposes only.

ii. 2021 Probable Cause Panel Dates

The 2021 PCP dates were provided for the Board's review.

Board staff will make updates to the PCP schedule and bring back to a future meeting for review.

iii. Human Trafficking CE Requirement

Ms. Sapp reminded Board Members and others present at the meeting that all currently licensed pharmacists and registered pharmacy technicians are required to complete the one-time, one-hour course on Human Trafficking by January 1, 2021 and provided information on where licensees can find approved courses.

iv. Virtual Chat Agent: ELI

Ms. Sapp provided an overview of virtual chat agenda, ELI that launched on the Board of Pharmacy's website on October 28, 2020.

ELI (Enforcement – Licensure – Information) is MQA's new artificial intelligence system that is transforming the customer service MQA provides by enabling the workforce to deliver exceptional service to our customers through online chat.

ELI is designed to answer common questions in a variety of different areas. Some areas include: licensure requirements, renewal requirements, fees, contact information, background screening, public records, and more.

v. Staff Recognition

This was provided for informational purposes only.

C. Board Counsel Report – Christopher Dierlam, Assistant Attorney General

i. Rules Status Report

Mr. Dierlam provided an overview of the rules report.

D. Committee Report

i. **Rules Committee – Jeffery J. Mesaros, PharmD, JD**

a. Rules Committee Update

No report was provided at this time.

E. Investigative Services Report – Robert Difiore, Pharmaceutical Program Manager

Mr. Dilworth provided a brief update on the inspection results as of October 2020.

As of December 2020 - Non-Sterile Pharmacy inspections, currently 883 inspections have been completed; Sterile Compounding Pharmacy inspections are currently at 33 inspections completed.

VII. NEW BUSINESS – Rich Montgomery, BPharm, MBA, Chair

A. 2021 Election of Officers

This item was tabled to the December 16, 2020 meeting.

B. Ratification of Issued Licenses/Certificates

- i. Pharmacist (Licensure) – 250
- ii. Pharmacist (Exam Eligibility) – 330
- iii. Pharmacist Interns – 384
- iv. Consultant Pharmacist – 46
- v. Pharmacy/Facilities – 108
- vi. Registered Pharmacy Technicians – 1085
- vii. Registered Pharmacy Technician Training Program – 16
- viii. Nonresident Sterile Compounding – 3
- ix. Approved CE Courses – 45
- x. Individual Pharmacist Request for Approval of CE – 6

Motion: by Mr. Philip to accept the ratification lists.

Second: by Mr. Meshad

Vote: Unanimous

VIII. OLD BUSINESS – Rich Montgomery, BPharm, MBA, Chair

A. Review and Approval of Meeting Minutes

- i. October 13, 2020 Rules Committee Minutes
- ii. October 13, 2020 General Board Meeting Minutes
- iii. October 14, 2020 General Board Meeting Minutes

Motion: by Mr. Wright to accept the meeting minutes.

Second: by Mr. Meshad

Vote: Unanimous

IX. FOR YOUR INFORMATION

A. Sophic Medical Presentation

Mr. Bob Parrado addressed the Board.

X. ADJOURNMENT

There being no further business the meeting adjourned at 5:30 p.m. ET.