Draft Minutes

August 26, 2020
TELEPHONE CONFERENCE CALL
8:00 a.m. ET
Call In Number: (888) 585-9008
Conference Code: 599-196-982(#)

Richard Montgomery, BPharm, MBA
Chair

Jonathan Hickman, PharmD
Vice-Chair

Jessica Sapp, Executive Director

BOARD OF PHARMACY
GENERAL BUSINESS MEETING AGENDA
TELEPHONE CONFERENCE CALL
DRAFT MINUTES
August 26, 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, Mr. Montgomery, at 8:00 a.m. ET.

Those present during the meeting included the following:

MEMBERS PRESENT:
Richard Montgomery, BPharm, MBA, Chair
Jonathan Hickman, PharmD, Vice – Chair
David Wright, BPharm
Jeenu Philip, BPharm
Blanca R. Rivera, PharmD, MBA
Mark Mikhael, PharmD
Jeffrey J. Mesaros, PharmD, JD
Gavin Meshad, Consumer Member

STAFF PRESENT:
Jessica Sapp, Executive Director
Traci Zeh, Program Administrator

BOARD COUNSEL:
David Flynn, Senior Assistant Attorney General
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. DISCIPLINARY CASES - Rich Montgomery, BPharm, MBA, Chair

A. SETTLEMENT AGREEMENT

i. Harmony B. Schneider, R. Ph., Case No. 2017-11519 (PCP – Glass & Mikhael)

The Respondent was present and represented by Lauren Leikam, Esq.

Mr. Pietrylo presented the case to the Board. The Respondent was charged with the following violation(s): Section 456.072(1)(hh), F.S. (2017) by being terminated or failing to comply with a treatment program for impaired practitioners.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- Reprimand
- $5,000 Fine to be paid within one hundred and eighty (180) days of the filing of the Final Order.
- Costs of $2,000 to be paid within one hundred and eighty (180) days of the filing of the Final Order.
- Successful completion of a twelve (12) hour laws and rules course to in be in addition to the hours required for renewal and to be completed within one (1) year of the filing of the Final Order.

Motion: by Mr. Meshad to reject the proposed settlement agreement.
Second: by Dr. Rivera
Vote: Unanimous

Motion: by Mr. Meshad to counteroffer with the following penalties:

- Appearance
- Suspension until determined safe to practice by way of a Professional Resource Network (PRN) evaluation.
- $5,000 Fine to be paid within one hundred and eighty (180) days of the filing of the Final Order.
- Costs of $2,000 to be paid within one hundred and eighty (180) days of the filing of the Final Order.
- Successful completion of a twelve (12) hour laws and rules course to in be in addition to the hours required for renewal and to be completed within one (1) year of the filing of the Final Order.

Second: by Dr. Hickman
Vote: Unanimous

ii. Fuller-Selle LLC d/b/a Pharmacare Services, Case No. 2019-51416 (PCP – Weizer & Meshad)

Mr. Camacho presented the case to the Board. The Respondent was charged with the following violation(s): Section 465.023(1)(c), F.S. (2019) through violations of Rule 64B16-797(1)(a), F.A.C., by failing to perform sterile compounding in accordance the minimum standards of Chapter 797 of the United States Pharmacopeia.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- $1,000 Fine to be paid within ninety (90) days of the filing of the Final Order
- Costs of $1,511.14 to be paid within ninety (90) days of the filing of the Final Order
- Successful completion of a twelve (12) hour sterile compounding course to be completed by the Consultant Pharmacist within one (1) year of the filing of the Final Order.

- Probation for one (1) year with semi-annual passing inspections at the Respondent's cost

Motion: by Dr. Hickman to accept the proposed settlement agreement.
Second: by Dr. Rivera
Vote: Unanimous

Motion: by Dr. Hickman to accept the costs imposed.
Second: by Mr. Wright
Vote: Unanimous

iii. John R. Barron, R. Ph., Case No. 2019-30770
(PCP – Weizer & Mikhael)

This case was tabled and will be heard at the October meeting.

iv. Rasesh B. Patel, R. Ph, Case No. 2017-05242
(PCP – Weizer & Philip)

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

Mr. Pietrylo presented the case to the Board. The Respondent was charged with the following violation(s): Section 456.072(1)(k), F.S. (2016), through Section 465.022(11)(a), F.S. (2016), through Rule 64B16-28.140(4)(g)(h), F.A.C. and/or Rule 64B16-27.797(1)(a), F.A.C., by failing to perform statutory obligations of a license and for failing to comply with the rules adopted as the prescription department manager.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- $1,000 Fine to be paid within ninety (90) days of the filing of the Final Order
- Costs of $1,791.08 to be paid within ninety (90) days of the filing of the Final Order
- Successful completion of a twelve (12) hour sterile compounding to in be in addition to the hours required for renewal and to be completed within one (1) year of the filing of the Final Order.

Motion: by Dr. Hickman to accept the proposed settlement agreement and the continuing education course that Mr. Patel has completed.
Second: by Dr. Rivera
Vote: Unanimous

Motion: by Dr. Hickman to accept the costs imposed.
Second: by Dr. Rivera
Vote: Unanimous

v. Promise Pharmacy, LLC, Case No. 2018-06234
(PCP – Hickman & Mesaros)

Mr. Pietrylo presented the case to the Board. The Respondent was charged with the following

violation(s): Count I: Section 465.023(1)(c), F.S. (2018), through Rule 64B16-797(1)(a), F.A.C., Count II: Section 465.023(1)(c), F.S. (2018), through Rule 64B16-797(1)(a), F.A.C., by failing to perform sterile compounding in accordance the minimum standards of Chapter 797 of the United States Pharmacopeia.

A Settlement Agreement was presented to the Board with the following terms:

- Appearance
- Letter of Concern
- $500 Fine to be paid within ninety (90) days of the filing of the Final Order
- Costs of $2,221.51 to be paid within ninety (90) days of the filing of the Final Order
- Successful completion of a twelve (12) hour laws and rules course to be completed by the Prescription Department Manager within one (1) year of the filing of the Final Order.

Motion: by Mr. Wright to accept the proposed settlement agreement.
Second: by Dr. Mikhael
Vote: Unanimous

vi. Tequesta Drugs, Inc., Case No. 2020-03770
(PCP – Hickman & Mesaros)

Mr. Pietrylo presented the case to the Board. The Respondent was charged with the following violation(s): Section 456.072(1)(k), F.S. through a violation of Rule 64B16-27.700(3)(g), F.A.C., by failing to perform sterile compounding in accordance the minimum standards of Chapter 797 of the United States Pharmacopeia.

A Settlement Agreement was presented to the Board with the following terms:

- $500 Fine to be paid within ninety (90) days of the filing of the Final Order
- Costs of $1,072.41 to be paid within ninety (90) days of the filing of the Final Order
- Successful completion of a twelve (12) hour laws and rules course to be completed by the Prescription Department Manager within one (1) year of the filing of the Final Order.

Motion: by Mr. Wright to accept the proposed settlement agreement.
Second: by Mr. Philip
Vote: Unanimous

A. Prosecution Services Report – Andrew Pietrylo

Mr. Pietrylo presented the prosecution services case report to the Board and explained the current caseload is at 276 cases, from 300.

Motion: by Dr. Mikhael to allow prosecution to continue prosecuting cases older than one year.
Second: by Dr. Hickman
Vote: Unanimous

III. APPLICATIONS FOR REVIEW – David Wright, BPharm

A. Pharmacists

i. Heather Kelley

The applicant was present.

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

After further discussion the Board took the following action:

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

ii. Timothy Hayes

The applicant was present.

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

After further discussion the Board took the following action:

Motion: by Dr. Mikhael to accept the application.
Second: by Mr. Montgomery
Vote: Unanimous

iii. Linda McCaffrey

The applicant was present.

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

Ms. McCaffrey withdrew her application.

iv. Andrew Murdock

The applicant was present.

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

After further discussion the Board took the following action:

Motion: by Mr. Meshad to accept the application.
Second: by Dr. Rivera
Vote: 7/1. Dr. Mikhael opposed.

v. Alan Theriault

The applicant was present.

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

After further discussion the Board took the following action:

Motion: by Dr. Rivera to accept the application.
Second: by Dr. Mikhael
Vote: Unanimous

vi. James Kobs

The applicant was present.

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

Mr. Kobs withdrew his application.

vii. Tyler Rogers

The applicant was present.

The applicant applied for a pharmacist license and answered yes to the 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. Mikhael
Vote: Unanimous

B. Registered Pharmacy Technician

i. Kelsie Snyder

The applicant was present.

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

After further discussion the Board took the following action:

Motion: by Mr. Montgomery to accept the application.
Second: by Dr. Mikhael
Vote: Unanimous

ii. Selena Isom

The applicant was present.

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

After further discussion the Board took the following action:

Motion: by Mr. Meshad to accept the application.
Second: by Mr. Montgomery
Vote: Unanimous

iii. Reginald Delva

The applicant was present.

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

After further discussion the Board took the following action:

Motion: by Mr. Meshad to accept the application.
Second: by Mr. Philip
Vote: Unanimous

iv. Deena Russell

The applicant was present.

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

Ms. Russell requested a continuance of her application.

After further discussion the Board took the following action:

Motion: by Dr. Hickman accept the continuance of the application.
Second: by Mr. Philip
Vote: Unanimous

v. Margarita Avellaneda

The applicant was present.

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

Ms. Avellaneda withdrew her application.

vi. Myriam Jimenez

The applicant was not present nor represented by Counsel.

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

After further discussion the Board took the following action:

Motion: by Dr. Hickman to require Ms. Jimenez to appear at the October meeting.
Second: by Dr. Rivera
Vote: Unanimous

vii. Meghan Wagner

The applicant was present.

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

After further discussion the Board took the following action:

Motion: by Dr. Mikhael to accept the application contingent upon being deemed safe to practice by way of an evaluation from PRN. The Board Chair has delegated authority to review the evaluation for determination of licensure. Should Ms. Wagner fail to complete the evaluation within 6 months her application shall be denied.
Second: by Dr. Rivera
Vote: Unanimous

viii. Candice Meredith

The applicant was present.

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

After further discussion the Board took the following action:

Motion: by Mr. Wright to accept the application.
Second: by Mr. Meshad
Vote: Unanimous

ix. Andrew Andreasen

The applicant was present.

The applicant applied for a registered pharmacy technician license and answered yes to the criminal history questions on his application.
After further discussion the Board took the following action:

Motion: by Dr. Mikhael to accept the application contingent upon being deemed safe to practice by way of an evaluation from PRN. The Board Chair has delegated authority to review the evaluation for determination of licensure. Should Mr. Andreasen fail to complete the evaluation within 6 months his application shall be denied.

Second: by Dr. Hickman
Vote: Unanimous

x. Carol Marsh

The applicant was present.

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

Mr. Marsh requested a continuance of her application.

After further discussion the Board took the following action:

Motion: by Mr. Montgomery to continue the application to be heard at the December Meeting.
Second: by Mr. Philip
Vote: Unanimous

xi. Angelica Bradley

The applicant was not present nor represented by Counsel.

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

After further discussion the Board took the following action:

Motion: by Dr. Mikhael to require Ms. Bradley to appear at the October Meeting.
Second: by Dr. Hickman
Vote: Unanimous

C. Pharmacy Permits

i. Doctor's Parenteral & Enteral Pharmacy

The applicant was present.

The applicant applied for a Special-Parenteral and Enteral Pharmacy Permit. Due to two failed inspections, this application was placed on the agenda for Full Board review.

The applicant requested a continuance of their application.

After further discussion the Board took the following action:

Motion: by Mr. Montgomery to continue the application and allow the applicant to receive a new inspection.
Second: by Mr. Philip
Vote: Unanimous

ii. Accredo Health Group, Inc.

The applicant was present.

Mr. Montgomery recused himself due to personal and professional association.

The applicant applied for a Non-Resident Pharmacy Permit and answered yes to the discipline history question on the application.

After further discussion the Board took the following action:

Motion: by Dr. Mikhael to accept the application.
Second: by Mr. Philip
Vote: Unanimous

iii. Valor Compounding Pharmacy, Inc.

The applicant was present.

The applicant applied for a Non-Resident Pharmacy Permit and answered yes to the discipline history question on the application.

After further discussion the Board took the following action:

Motion: by Dr. Rivera to accept the application.
Second: by Dr. Mikhael
Vote: Unanimous

iv. Maple Rose Enterprises, Inc.

The applicant was present.

The applicant applied for a Non-Resident Pharmacy Permit and answered yes to the discipline history question on the application.

The applicant requested a continuance of the application.

After further discussion the Board took the following action:

Motion: by Dr. Mikhael to continue the application to the December agenda.

Second: by Dr. Rivera
Vote: Unanimous

IV. REQUEST TO APPROVE PDM AT TWO LOCATIONS

A. Millad Ayyad

Mr. Ayyad submitted a request to the Board to allow him to assume the role as the Prescription Department Manager at two locations while in the process of opening a new pharmacy.

Motion: by Mr. Wright to grant the request and approve Mr. Ayyad to act as the PDM for two locations for a period of one (1) year.
Second: by Dr. Mikhael
Vote: Unanimous

V. PETITION FOR VARIANCE OR WAIVER

A. Leslie Olsher, 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. Olsher requested a variance so that she may meet the on-site requirement remotely as currently many facilities are not open to the public and preceptors are working remotely.

After further discussion the Board took the following action:

Motion: by Dr. Rivera to grant the petition.
Second: by Dr. Mikhael
Vote: Unanimous

B. Tanya Thomas, 64B16-26.351, F.A.C., Standards of Approval for Registered Pharmacy Technician Training Programs

The petitioner was present.

Ms. Thomas submitted a petition of variance or waiver for Rule 64B16-26.351, F.A.C. Ms. Thomas was unable to provide proof of completion of a Board-approved training program. Ms. Thomas requested that her Target pharmacy technician training and work experience be considered equivalent to the requirements set forth in Rule 64B16-26.351, F.A.C., for a pharmacy technician training program.

The Board determined Ms. Thomas' training meets the requirements per Board Rule.

Ms. Thomas withdrew her petition.

Motion: by Dr. Mesaros to grant the application.
Second: by Mr. Philip
Vote: Unanimous

VI. PETITION TO INITIATE RULEMAKING

A. Dynavax Technologies Corporation, 64B16-27.630, F.A.C., Additional Immunizations or Vaccines Which May Be Administered

Holly Katsaros was present and addressed the Board. Dynavax Technologies Corporation petitioned the Board to initiate rulemaking in order to add Hepatitis B to the list of vaccinations to Rule 64B16-27.630, F.A.C.

Mr. Philip addressed the Board indicating Hepatitis is already listed within the Immunization Schedules by the Centers for Disease Control and Prevention as a vaccine to be administered. He indicated the dosing series is the only listed difference; therefore, this vaccine is not new, and rulemaking would not be needed.

Motion: by Mr. Philip to deny the petition on the basis that it is clear within Section 465.189, F.S.
Second: by Mr. Montgomery
Vote: Unanimous

VII. RULE DISCUSSION

A. 64B16-27.4001, F.A.C., Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist

i. Letter from the Joint Administrative Procedures Committee

Board Counsel, Christopher Dierlam addressed the Board.

64B16-27.4001 Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist.

(1) No change.

(2) Supervision: Delegated tasks must be performed under the direct supervision of a pharmacist <u>who shall make certain all applicable state and federal laws, including, but not limited to confidentiality, are fully observed.</u> ~~and pursuant to the following definitions and requirements:~~ <u>The supervising pharmacist, in consultation with the Prescription Department Manager or Consultant Pharmacist of Record, will determine the appropriate methods of supervision based on the following definitions and requirements. No other person, permittee, or licensee shall interfere with the exercise of the supervising pharmacist's independent professional judgment in determining the supervision of delegated tasks.</u>

(a) through (b) No change.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.014 FS. History–New 12-31-14, Amended 12-17-18, _____.

Motion: by Dr. Rivera to approve the amended language
Second: by Dr. Hickman
The Board allowed for public comment.
No public comments received.
Vote: Unanimous

Motion: by Mr. Montgomery to find no economic impact.
Second: by Dr. Rivera
Vote: Unanimous

Motion: by Dr. Rivera to find that a Statement of Estimated Regulatory Cost was not necessary, and the rule will not need legislative ratification.
Second: by Mr. Wright
Vote: Unanimous

Motion: by Dr. Rivera to find 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. Mikhael to find that this rule shall not include a sunset provision.
Second: by Dr. Rivera
Vote: Unanimous

B. Consultant Pharmacist of Record, On-Site Inspections

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.

Motion: by Mr. Wright to direct Board Counsel to explore methods of renewing the emergency Order.
Second: by Dr. Mikhael

The Board allowed for public comment.

James Rosenswag, president of Performance Consultant Inc. addressed the Board regarding Modified II B Facilities and the process in which Consultant Pharmacists conduct inspections. He indicated that pharmacists are often completing their inspections without patient contact. He expressed they have not experienced these difficulties within these specified facilities.

Douglas Nee, Consultant Pharmacist, addressed the Board regarding the health of clinicians while entering the facilities to complete on-site inspections and the value pharmacists bring to completing these on-site inspections.

Tom Quomo, Consultant Pharmacist, addressed the Board regarding the need for consultant pharmacists to continue their responsibilities as pharmacists are critical health care providers during this time.

Rick Folly, Consultant Pharmacist and former president of the Florida Long Term Care Society addressed the Board regarding the regulatory requirements of entering facilities considering the

expiration of the emergency rule.

Vote: Unanimous

Dr. Hickman momentarily excused himself from the meeting.

C. Application Redesign

i. 64B16-26.2032, F.A.C., Application for Pharmacy Intern Registration.

Ms. Sapp addressed the Board regarding the amendments to the applications and provided an overview of the Departments application redesign project.

The Board tabled this discussion to the October agenda.

Board Counsel and Mr. Montgomery will attend the Board of Medicine meeting on September 10, 2020 observe the discussion regarding the updated health history questions.

Motion: by Mr. Montgomery to open rule 64B16-26.2032, F.A.C. for development
Second: by Dr. Mikhael
Vote: Unanimous

ii. 64B16-26.303, F.A.C., Nuclear Pharmacist Licensure

iii. 64B16-26.350, F.A.C., Requirements for Pharmacy Technician Registration

VIII. REPORTS – Rich Montgomery, BPharm, MBA, Chair

A. Board Chair

Mr. Montgomery addressed the Board and thanked staff for their hard work as well as provided a brief overview of the ASHP meeting he attended virtually.

Dr. Mesaros provided an overview of the NABP District III meeting he attended virtually.

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

i. Financial Reports

These reports were provided for information purposes only.

Ms. Sapp provided an overview of the current application processing numbers within the Board Office.

Ms. Sapp also provided an overview of the Interactive Executive Office Forum that she will be attending virtually with the NABP. Mr. Philip offered to attend the meeting on behalf of the Board.

C. Board Counsel Report - David Flynn, Senior Assistant Attorney General

i. Rules Status Report

ii. 2020 Comprehensive Rules Review

Mr. Flynn provided the Board with an updated Rules report and an overview of the extension of the 2020 Comprehensive Rules Review.

Mr. Flynn addressed the Board regarding the Annual Regulatory Plan.

D. Committee Report

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

a. Rules Committee Update

Committee Chair, Dr. Jeffery Mesaros, provided the Board with an overview of the discussion from the July 29, 2020 Joint Rules Committee and the August 24, 2020 Rules Committee meeting.

Dr. Mesaros presented the proposed rules to the Board in the following order.

The Committee approved the proposed language to be provided for Full Board review and approval.

64B16-31.033 Test and Treat Certification (TTC)
Applicants for TTC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), "Application *for* Pharmacist Test and Treat Certification[1]" that is hereby incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX or http://floridapharmacy.gov. Applicants for certification shall meet and comply with all requirements in Section 465.1895, F.S.

Rulemaking Authority 465.1895, FS. *Law Implemented* 465.1895, FS. *History – New* XX-XX-20.

Motion: by Dr. Mikhael to approve the proposed rule language.
Second: by Mr. Philip

The Board allowed for public comment.

No public comments received.

Vote: Unanimous

Motion: by Mr. Philip to find no economic impact on small businesses as this certification is voluntary and the implementation of this rule would advance small businesses.
Second: by Mr. Wright
Vote: Unanimous

Motion: by Mr. Philip 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. Mikhael to find that no part of this rule or a violation of this rule should be designated as a minor violation.
Second: by Mr. Meshad
Vote: Unanimous

64B16-31.035 Test and Treat Certification: Initial Certification Course
(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) "Application *for* Initial Test and Treat Certification Course[2]" that is hereby incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX or http://floridapharmacy.gov.
(2) Initial test and treat certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:
(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE), a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, or a program provider approved by the American Osteopathic Association to offer continuing medical education credits.
(b) The course content and objectives offered by an approved provider shall be developed in conjunction with an individual licensed to practice pharmacy and an individual who is a licensed allopathic or osteopathic physician.
(c) The course content shall include all those areas enumerated in section 465.1895 (2)(b), F.S., and shall also cover the following areas:
1. Laws and rules applicable to test and treat certifications; and
2. Writing and entering into a written protocol.
(d) No less than 8 hours of the course shall be offered through a live seminar or a live video teleconference.
(3) A pharmacist who successfully completes a board approved test and treat certification course shall be awarded 20 hours of general continuing education credits.

Rulemaking Authority 465.1895, FS. *Law Implemented* 465.1895, FS. *History – New* XX-XX-20.

Motion: by Mr. Wright to approve the proposed rule language, to find that there would be no economic impact on small businesses and 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 as this rule is related to the certification and is mandated by statute and this certification is voluntary. The Board engaged in the opportunity to expand and considered the least regulatory costs as it is not limited to Pharmacy and expands to the Board of Medicine and Osteopathic Medicine.
Second: by Dr. Mikhael

The Board allowed for public comment.

Dr. Hector Vila, Representing the Board of Medicine, addressed the Board in favor of the language and in support of the motion.

Vote: Unanimous

64B16-31.037 Test and Treat Certification: Written Protocol and Written Protocol

Submission
(1) Within 5 business days of entering into a written protocol with a supervising physician pursuant to section 465.1895, F.S., the pharmacist shall submit a copy of the written agreement to the Board Office through the pharmacist's online licensure account at http://www.flhealthsource.gov or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.
(2) In the event of an addendum to the material terms of an existing written protocol, the pharmacist shall maintain a copy of the addendum and the initial agreement. Material terms shall be defined as those terms enumerated in Section 465.1895(5)(a), F.S.

Rulemaking Authority 465.1895, FS. *Law Implemented* 465.1895, FS. *History – New* XX-XX-20.

Motion: by Mr. Montgomery to approve the proposed rule language.
Second: by Mr. Philip

The Board opened the floor for public comment.

No public comments received.

Vote: Unanimous

Motion: by Mr. Philip to find that there would be no economic impact on small businesses and 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 as this requirement is mandated by the statute and the rule provides guidance on the timing of submission of the written protocol.
Second: by Mr. Wright
Vote: Unanimous

64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs
(1) Pursuant to section 465.1895, F.S., the Board hereby incorporates all medicinal drugs approved by the United States Food and Drug Administration ("FDA") as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a written test and treat protocol.
(~~b~~a) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.
(2) A pharmacist may not prescribe controlled substances as described in s. 893.03 or 21 U.S.C. s. 812.

Rulemaking Authority 465.1895, FS. *Law Implemented* 465.1895, FS. *History – New* XX-XX-20.

The Board discussed subsection (2) regarding the exemption within Section 893 that allows pharmacists to dispense certain scheduled five substances without a prescription.

Mr. Flynn will continue to research and provide further clarification.

At this time Dr. Hickman rejoined the meeting.

Motion: by Mr. Meshad to approve the proposed rule language.
Second: by Mr. Philip

The Board opened the floor for public comment.

No public comments received.

Vote: Unanimous

Motion: by Dr. Mikhael to find that there would be no economic impact on small businesses and 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 and that this requirement is mandated by the statute.
Second: by Mr. Wright
Vote: Unanimous

64B16-31.041 Test and Treat Certification: Patient Records
Upon receipt of a patient request, a pharmacist shall furnish patient records to a health care practitioner designated by the patient within a reasonable time frame, not to exceed 5 business days.

Rulemaking Authority 465.1895, FS. *Law Implemented* 465.1895, FS. *History – New* XX-XX-20.

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

The Board opened the floor for public comment.

No public comments received.

Vote: Unanimous

Motion: by Dr. Mesaros to find that there would be no economic impact on small businesses and 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 and that this requirement is mandated by the statute.
Second: by Dr. Mikhael
Vote: Unanimous

64B16-31.043 Test and Treat Certification: Follow-up Care
A pharmacist must provide written information to the patient advising the patient when to seek follow-up care from his or her primary care physician. A pharmacist shall provide follow-up care written information:
(1) Immediately prior to performing testing, screening, or treatment services on a patient for the first time; or
(2) As outlined in the written protocol; and
(3) When the pharmacist determines in his or her judgment that the patient should follow-up with his or her primary care provider.

Rulemaking Authority 465.1895, FS. *Law Implemented* 465.1895, FS. *History – New* XX-XX-20.

Motion: by Mr. Montgomery to approve the proposed rule language.
Second: by Dr. Mikhael

The Board opened the floor for public comment.

No public comments received.

Vote: Unanimous

Motion: by Dr. Mikhael to find that there would be no economic impact on small businesses and 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 and indicated that this requirement is mandated by the statute and is voluntary.
Second: by Mr. Montgomery
Vote: Unanimous

64B16-31.045 Test and Treat Certification: Mandatory Continuing Education.
A licensee shall not be required to complete the 3-hour continuing education related to minor, nonchronic health conditions if the initial certificate was issued less than 12 months prior to the expiration date of the license.

Rulemaking Authority 465.1895, FS. *Law Implemented* 465.1895, FS. *History – New* XX-XX-20.

Motion: by Mr. Meshad to approve the proposed rule language.
Second: by Mr. Montgomery

The Board opened the floor for public comment.

No public comments received.

Vote: Unanimous

Motion: by Mr. Montgomery to find that there would be no economic impact on small businesses and 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. Meshad
Vote: Unanimous

64B16-31.001 Collaborative Practice Certification (CPC).
Applicants for CPC shall submit an application using Form DH-MQA XXXX (eff. 0X/20), "Application *for* Pharmacist Collaborative Practice Certification[3]" that is hereby incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX or http://floridapharmacy.gov. Applicants for certification shall meet and comply with all requirements in Section 465.1865, F.S.

Rulemaking Authority 465.1865, FS. *Law Implemented* 465.1865, FS. *History – New* XX-XX-20.

Motion: by Montgomery to approve the proposed rule language.
Second: by Dr. Mikhael

The Board opened the floor for public comment.

No public comments received.

Vote: Unanimous

Motion: by Dr. Mikhael to find that there would be no economic impact on small businesses and 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 as this certification is voluntary and the implementation of this rule would advance small businesses.
Second: by Mr. Montgomery
Vote: Unanimous

64B16-31.003 Collaborative Practice Certification: Initial Certification Course.
(1) Applicants for Initial Certification Course approval shall submit an application using Form DH-MQA XXX (eff. XX/20) "Application *for* Initial Collaborative Practice Certification Course[4]" that is hereby incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-XXXX or http://floridapharmacy.gov.
(2) Initial collaborative practice certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:
(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE), a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, or a program provider approved by the American Osteopathic Association to offer continuing medical education credits.
(b) The course content and objectives offered by an approved provider shall be developed in conjunction with an individual licensed to practice pharmacy and an individual who is a licensed allopathic or osteopathic physician.
(c) The course content shall include all those areas enumerated in section 465.1865 (2)(c), F.S., and shall also cover the following areas:
1. Laws and rules applicable to the collaborative practice for the treatment of chronic health care conditions; and
2. Writing and entering into a collaborative practice agreement.
(d) No less than 8 ~~12~~ hours of the course shall be offered through a live seminar or a live video teleconference.
(3) A pharmacist who successfully completes a board approved collaborative practice certification course shall be awarded 20 hours of general continuing education credits.

Rulemaking Authority 465.1865, FS. *Law Implemented* 465.1865, FS. *History – New* XX-XX-20.

Motion: by Mr. Meshad to approve the proposed rule language.
Second: by Dr. Mikhael

The Board opened the floor for public comment.

Dr. Vila addressed the Board in favor of this rule.

Vote: Unanimous
Motion: by Dr. Mikhael to approve the proposed rule language, to find that there would be no economic impact on small businesses and 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 as this rule is related to the certification and is mandated by statute and this certification is voluntary. The Board engaged in the opportunity to expand and considered the least regulatory costs as it is not limited to Pharmacy and expands to the Board of Medicine and Osteopathic Medicine.
Second: by Dr. Rivera
Vote: Unanimous

64B16-31.009 Collaborative Practice Certification: Mandatory Continuing Education.
A licensee shall not be required to complete the 8-hour continuing education related to collaborative pharmacy practice if the initial certificate was issued less than 12 months prior to the expiration date of the license.

Rulemaking Authority 465.1865, FS. *Law Implemented* 465.1865, FS. *History – New* XX-XX-20.

Motion: by Mr. Meshad to approve the proposed rule language.
Second: by Dr. Hickman

The Board opened the floor for public comment.

No public comments received.

Vote: Unanimous

Motion: by Dr. Mesaros to approve the proposed rule language, to find that there would be no economic impact on small businesses and 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 and indicated that this requirement is mandated by the statute and is voluntary.
Second: by Dr. Hickman
Vote: Unanimous

64B16-31.005 Collaborative Practice Certification: Collaborative Pharmacy Practice Agreement Submission.
(1) Prior to providing or implementing patient care services under a Collaborative Pharmacy Practice Agreement or immediately after the renewal of such an Agreement, the Pharmacist shall submit the executed Agreement to the Board Office through the pharmacist's online licensure account at http://www.flhealthsource.gov or via U.S. Mail to 4052 Bald Cypress Way, Bin C-04, Tallahassee, FL 32399.
(2) In the event of an addendum to the material terms of an existing collaborative pharmacy practice agreement, the pharmacist shall maintain a copy of the addendum and the initial agreement pursuant to Section 465.1865(3)(c), F.S. Material terms shall be defined as those terms enumerated in Section 465.1865(3)(a), F.S.

Rulemaking Authority 465.1865, FS. *Law Implemented* 465.1865, FS. *History – New* XX-XX-20.

Motion: by Dr. Mikhael to approve the proposed rule language and to find that there would be no economic impact on small businesses and 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 as this is strictly administrative and legislatively

mandated and that this certification is voluntary therefore not required.
Second: by Mr. Meshad

The Board opened the floor for public comment.

No public comments received.

Vote: Unanimous

64B16-31.007 Collaborative Practice Certification: Chronic Health Conditions.
Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:
1) Hyperlipidemia;
2) Hypertension;
3) Anti-coagulation management;
4) Smoking cessation;
5) Opioid use disorder;
6) Heart / Cardiovascular Disease (*Cont. Discussion*);
7) Behavioral Health (*Begin Discussion*); and
8) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.

Rulemaking Authority 465.1865, FS. *Law Implemented* 465.1865, FS. *History – New* XX-XX-20.

Dr. Mesaros opened the floor for discussion.

Mr. Meshad suggested striking subsection 6) Heart / Cardiovascular Disease and 7) Behavioral Health and move forward with the current language.

Mr. Wright addressed the Board regarding the discussion from August 24, 2020 Committee Meeting. He indicated Heart Failure should be included in the language based on the data that was reviewed and considered during the meeting.

Dr. Hickman addressed the Board regarding the patient population in Florida and stated it would be a disservice to the public not to add Heart Failure to the list. He indicated there are numerous studies corroborating that having a pharmacist added to the care team improves the quality of care to the patient.

Mr. Meshad inquired if moving forward with the proposed language would delay the process of implementing the rule.

Dr. Mesaros addressed Mr. Meshad and clarified that the bill required the Board to adopt rules in consultation with the Board of Medicine and the Board of Osteopathic Medicine and that the Committee has held multiple meetings to review and discuss proposed language.

Dr. Vila Representing the Board of Medicine addressed the Board regarding the collaboration that has taken place between the three Boards. He indicated Heart Failure is an acute condition with a high mortality rate and should not be included right off the start. He recommended continuing the discussion later. He indicated if the Full Board votes to proceed with the proposed languages as

is, it is likely to be challenged.

Dr. Mesaros addressed Dr. Vila to clarity that the purpose of this legislation was to treat chronic heart failure not acute conditions.

Mr. Flynn addressed the Board regarding the rule promulgation process.

Dr. Rivera and Mr. Meshad suggested striking Heart Failure and move the language forward.

Dr. Hickman reiterated his statements regarding the numerous studies of having a pharmacist added to the care team improves the care of the patient and he indicated that this is merely voluntary.

Dr. Mesaros addressed the Board regarding how close the Boards are coming to an agreement and inquired on the best way to move forward.

Dr. Vila addressed the Board regarding the understanding of the rule as it indicates a physician not cardiologist to enter into a collaborative practice agreement. He expressed concern that we do not know what this will look like moving forward and he asked the Board to put this off and visit the addition of Heart Failure in the future.

Mr. Philip addressed the Board regarding additional education that he feels needs to happen on both sides and expressed that there is a misunderstanding of the bill. He indicated that the Board's are closure to an agreement and the collaborative practice certification comes with a technicality that should be fully explored. He suggested moving forward with sections 1-5 and table 6) Heart / Cardiovascular Disease and 7) Behavioral Health to a future meeting.

Motion: by Mr. Philip to approve the language as amended and indicated any additions with be made at a later time in consultation with the Board of Medicine and the Board of Osteopathic Medicine:

Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to section 465.1865, F.S., can provide specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:
1) Hyperlipidemia;
2) Hypertension;
3) Anti-coagulation management;
4) Smoking cessation;
5) Opioid use disorder;
~~6) Heart / Cardiovascular Disease (*Cont. Discussion*);~~
~~7) Behavioral Health (*Begin Discussion*);~~ and
~~8~~6) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.

Second: by Dr. Rivera

The Board opened the floor for public comment.

Mr. Wright addressed the Board and the public regarding the importance of supplying data to corroborate Heart Failure not being included in the list of chronic health conditions.

Dr. Mesaros suggested scheduling a call to continue the discussion.

Dr. Rivera inquired with the Board regarding Section 5) Opioid Use Disorder.

Mr. Flynn clarified that this should not be confused with Test and Treat and that the pharmacist is not diagnosing the Opioid Disorder.

Raquel Rodriguez, representing the Florida Chapter of the American College of Cardiologists (ACC), addressed the Board in favor of tabling the discussion on heart failure.

Dr. David Perloff, president of the Florida Chapter of the ACC, addressed the Board in favor of tabling the discussion on heart failure.

Dan Buffington, a Florida pharmacist from the University of South Florida addressed the Board regarding the confusion of the bill and that this is not the introduction of a collaborative practice agreement and confirmed this is already being utilized in certain settings.

Vote: 6/2. Mr. Wright and Dr. Mikhael opposed.

Motion: by Dr. Hickman to find that there would be no economic impact on small businesses and 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 and indicated this is expands the service of practitioners and is statutorily mandated.
Second: by Mr. Meshad
Vote: Unanimous

64B16-31.050 Mandatory Review of Rule Chapter 64B16-31, F.A.C.
(1) No later than 90 days prior to December 31, 2025, the Board shall review each rule in this Chapter and amend, modify or repeal any rule that creates barriers to entry for private business competition, is duplicative, outdated, obsolete, overly burdensome, or imposes excessive costs.
(2) In the event the Board fails to complete this review, the board, for any rule that has not been reviewed in accordance with subsection (1), shall begin the rule repeal process in accordance with the Administrative Procedures Act.

Rulemaking Authority 465.1895, FS. *Law Implemented* 465.1895, FS. *History – New* XX-XX-20.

Motion: by Mr. Wright to approve the proposed rule language.
Second: by Dr. Rivera

The Board opened the floor for public comment.

No public comments received.

Vote: Unanimous

Motion: by Dr. Mesaros to find that there would be no economic impact on small businesses and 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 and indicated this is statutorily mandated.
Second: by Dr. Rivera

Vote: Unanimous

Motion: by Mr. Wright to find that no part of Chapter 31 or a violation of Chapter 31 should be designated as a minor violation.
Second: by Mr. Meshad
Vote: Unanimous

64B16-26.300 Consultant Pharmacist Licensure.

(1) No person shall serve as consultant pharmacist as defined in Section 465.003(3), F.S., unless that person holds a license as a consultant pharmacist.

(2) Application for consultant pharmacist licensure shall be made on form DOH-MQA 1109, (Rev. ~~12/15~~ xx/2020), Consultant Pharmacist Application ~~and Information~~, which is hereby incorporated by reference, and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-06933 and the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or from the website located at http://floridaspharmacy.gov/Applications/app-consultant-pharmacist.pdf. The application shall be accompanied by an application fee.

(3) In order to be licensed as a consultant pharmacist, a person must meet the following requirements:

(a) Hold a license as a pharmacist which is active and in good standing; and

(b) Successfully complete a consultant pharmacist course of no fewer than ~~twelve~~twenty (~~12~~20) hours~~, sponsored by an accredited college of pharmacy, and~~ approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and covers the subject matter set forth in rule 64B16-26.301, F.A.C. The course shall be instructionally designed to include a cognitive test on which the applicant must score a passing grade for certification of successful completion of the course.

~~(c) 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. The training shall include:~~

~~Minimum Skills Required~~	~~Percent of Time~~	~~Hours~~
~~Minimum of 40 Hours in Maximum of Three Months~~		
~~1. Regimen review, documentation and communication.~~	~~60%~~	~~24~~
~~a. Demonstrate ability to carry out process and understand documentation functions.~~		
~~b. Understand and perform drug regimen review. Communicate findings to appropriate individuals or groups.~~		
~~c. The applicant is responsible for learning other skills needed to perform in his/her type of facility where he/she is or will be the consultant Pharmacist of Record.~~		
~~2. Facility review.~~	~~20%~~	~~8~~
~~Demonstrate areas that should be evaluated, documentation, and reporting procedures.~~		
~~3. Committee and Reports.~~	~~5%~~	~~2~~

~~Review quarterly Quality of Care Committee minutes and preparation and delivery of pharmacist quarterly report.~~		
~~4. Policy and Procedures.~~	~~5%~~	~~2~~
~~Preparation, review, updating Policy and Methods.~~		
~~5. Principles of formulary management.~~	~~5%~~	~~2~~
~~Demonstrate ability to manage formulary.~~		
~~6. Professional Relationships.~~	~~5%~~	~~2~~
~~Knowledge and interaction of facility administration and professional staff.~~		

~~(4) In order to act as a preceptor, a person shall:~~

~~(a) Be a consultant pharmacist of record at an institutional pharmacy which is required to have a consultant pharmacist under the provisions of chapter 465, F.S., and these rules.~~

~~(b) Have a minimum of one (1) year of experience as a consultant pharmacist of record.~~

~~(c) Maintain all pharmacist licenses in good standing with the Board.~~

~~(d) Not act as a preceptor to more than two (2) applicants at the same time.~~

~~(5) Upon completion of the requirements set forth above, the applicant's preceptor shall confirm that the applicant's assessment and evaluation have met the requirements and that the applicant has successfully completed all required assignments under the preceptor's guidance and supervision.~~

(~~6~~4) After licensure a consultant pharmacist's license shall be renewed biennially upon payment of the fee set forth in rule 64B16-26.1003, F.A.C., and upon completing twenty-four (24) hours of board approved continuing education based upon the provisions of rule 64B16-26.302, F.A.C.

(~~7~~5) The number of hours earned in recertification programs by a consultant pharmacist, if applied to the twenty-four (24) hours required for consultant pharmacist license renewal, may not be used toward the thirty (30) hours of continued professional pharmaceutical education credits as set forth in rule 64B16-26.103, F.A.C.

~~(8) An applicant who applies for a consultant pharmacist license after the effective date of this rule shall be required to complete the assessment and evaluation required in paragraph (3)(c), prior to being licensed as a consultant pharmacist.~~

Rulemaking Authority 456.013, 465.005, 465.0125 FS. Law Implemented 456.013, 465.0125 FS. History–New 5-19-72, Revised 4-19-74, Repromulgated 12-18-74, Amended 10-17-79, 4-8-80, 7-29-81, 7-1-83, 4-10-84, 4-30-85, Formerly 21S-1.26, 21S-1.026, Amended 7-31-91, 10-14-91, Formerly 21S-26.300, 61F10-26.300, Amended 9-19-94, 3-28-95, 3-10-96, Formerly 59X-26.300, Amended 5-22-01, 5-5-05, 11-29-06, 3-29-10, 6-23-16.

64B16-26.301 Subject Matter for Consultant Pharmacist Course~~Training Program~~.

(1) Jurisprudence.

(a) Laws and regulations, state and federal, pertaining to institutional pharmacy and health care facilities.

(b) Laws and regulations, state and federal, pertaining to the safe and controlled storage of alcohol and other related substances, and relating to fire and health-hazard control.

(c) Laws and regulations, state and federal, pertaining to collaborative practice agreements.

(2) Policy and Procedures.

(a) Written procedures for outlining the medication system in effect.

1. Traditional systems.

2. Unit-dose systems.

a. Centralized.

b. Decentralized.

c. Automated medication systems.
3. Routine and emergency use of drugs.
4. After hours procedure for medication dispensing.
5. Managing drug shortages.
(b) Record keeping and reports.
1. Controlled substance control and record-of-usage.
2. Alcohol inventory and record-of-usage.
3. Patient drug use control and records.
a. Recalls.
b. Medication use evaluation.
c. Medication errors.
4. Drug charges, methods, accountability, and reports.
5. Statistical reports of usage, volume, etc.
6. Written collaborative practice agreement records.
(c) Regimen review, documentation and communication
1. Performing drug regimen review.
2. Documentation of drug regiment review.
3. Communication of findings to appropriate individuals or groups.
(3) Administrative Responsibilities.
(a) Fiscal Control.
1. Perpetual and traditional inventory systems.
2. Application of EDP techniques.
(b) Personnel Management, orientation and training.
(c) Intra-professional relations pertaining to medication use.
(d) Inter-professional relations with other members of the institutional health care team.
1. Pharmacy & Therapeutic Committee.
a. Rational drug therapy; review of medication use and prescribing.
b. Formulary development – evaluation, appraisal, selection, procurement, storage, distribution, medication safety, criteria for use development and safety.
c. Automatic stop orders on potent and dangerous drugs.
d. Controls on storage and use of investigational drugs.
2. In-service education of nurses and other health-related personnel.
3. Infectious Disease Committee.
(e) Facility Review
1. Areas appropraite for evaluation
2. Documentation of evaluations
3. Reporting of evaluations
(4) Professional Responsibilities.
(a) Drug information retrieval and methods of dispersal.
(b) Development of pharmacy practice.
(c) Development of an IV Admixture service.
(d) Procedures to enhance medication safety.
1. Availability of equipment, technique, etc., to prepare special dosage forms for pediatric and geriatric patients.
2. Preparation of sterile dosage forms.
3. Proper writing, transcribing and initiating and/or transferring patient medication orders; development of physician's chart order copy system.
4. Safety of patient self-medication and control of drugs at bedside.

5. Reporting and trending adverse drug reactions.
6. Screening for potential drug interactions.
7. Development and maintenance of up-to-date emergency kits.
(e) Maintain drug quality and safe storage.
1. Procedures for eliminating out-dated drugs.
2. Requirements for safe and appropriate storage conditions.
(f) Maintain drug identity.
1. Procedures for labeling, transferring of bulk medications, etc.
2. Manufacturing and packaging procedures.
3. Pre-packaging control and supervision.
(g) Conducting patient assesments.
(h) Ordering and evaluating laboratory or clinical tests.
(i) Administration of medicinal drugs.
(5) The Institutional Environment.
(a) The institution's pharmacy function and purpose.
(b) Interdepartmental relationships important to the institutional pharmacy.
(c) Understanding of scope of service and in-patient care mission of the institution.
(d) Special training with respect to the operation of nursing homes and Extended Care Facilities (ECF)/pharmacy relationship and special procurement procedures.
(6) Nuclear pharmacy.
(a) Procurement.
(b) Compounding.
(c) Quality control procedures.
(d) Dispensing.
(e) Distribution.
(f) Basic radiation protection and practices.
(g) Consultation and education to the nuclear medicine community; including patients, pharmacists, other health professionals, and the general public.
(h) Research and development of new formulations.
(i) Record keeping.
(j) Reporting adverse drug reactions and medication errors.
(k) Screening for potential drug interaction.

Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0125 FS. History–New 5-19-72, Amended 12-18-74, 10-17-79, Formerly 21S-1.27, 21S-1.027, Amended 7-31-91, Formerly 21S-26.301, 61F10-26.301, 59X-26.301, Amended 5-5-05.

Motion: by Mr. Wright to approve the proposed rule language.
Second: by Dr. Rivera
Vote: Unanimous

Motion: by Mr. Montgomery to find that there would be no economic impact on small businesses and 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 as this amendment reduces the barriers for licensure and to find that no part of this rule or a violation of this rule should be designated as a minor violation.
Second: by Dr. Rivera
Vote: Unanimous

Motion: by Mr. Montgomery to find that this rule shall not include a sunset provision.
Second: by Dr. Rivera
Vote: Unanimous

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

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

As of August 2020 - Non-Sterile Pharmacy inspections currently at 4,653 inspections completed; Sterile Compounding Pharmacy inspections completed 443 of inspections.

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

A. Ratification of Issued Licenses/Certificates

i. Pharmacist (Licensure) – 327
ii. Pharmacist (Exam Eligibility) – 617
iii. Pharmacist Interns – 106
iv. Consultant Pharmacist – 47
v. Pharmacy/Facilities – 83
vi. Registered Pharmacy Technicians – 978
vii. Registered Pharmacy Technician Training Program – 16
viii. Nonresident Sterile Compounding – 2
ix. Approved CE Providers – 2
x. Approved CE Courses – 46
xi. Individual Pharmacist Request for Approval of CE - 6

Motion: by Mr. Philip to accept the ratification lists.
Second: by Dr. Rivera
Vote: Unanimous

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

B. Review and Approval of Meeting Minutes

i. June 2, 2020 Rules Committee Meeting

Motion: by Dr. Rivera to accept the meeting minutes.
Second: by Dr. Mikhael
Vote: Unanimous

ii. June 3, 2020 General Board Meeting

Motion: by Dr. Rivera to accept the meeting minutes.
Second: by Dr. Mikhael
Vote: Unanimous

iii. June 4, 2020 General Board Meeting

Motion: by Dr. Rivera to accept the meeting minutes.
Second: by Dr. Mesaros
Vote: Unanimous

iv. June 25, 2020 Joint Rules Committee Meeting

Motion: by Dr. Mikhael to accept the meeting minutes.
Second: by Dr. Mesaros
Vote: Unanimous

v. July 29, 2020 Joint Rules Committee/Rules Workshop Meeting

Motion: by Dr. Mikhael to accept the meeting minutes.
Second: by Dr. Rivera
Vote: Unanimous

XI. FOR YOUR INFORMATION

A. CE Broker Quarterly Report

This was provided for informational purposes only.

XII. ADJOURNMENT

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