

**BOARD OF PHARMACY
JOINT RULES COMMITTEE
DRAFT MINUTES
June 25, 2020
9:00 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

Dr. Mesaros called the meeting to order at 9:00 a.m. ET.

MEMBERS PRESENT

Jeffrey Mesaros, PharmD, JD, Chair
Jeenu Philip, BPharm,
Jonathan Hickman, PharmD
Mark Mikhael, PharmD
David Wright, BPharm

STAFF PRESENT

Jessica Sapp, Executive Director
Traci Zeh, Program Administrator

BOARD COUNSEL

David Flynn, Esq.
Senior Assistant Attorney General
Christopher Dierlam, Esq.
Assistant Attorney General

BOARD OF MEDICINE MEMBERS:

Hector Vila, MD
Sarvam TerKonda, MD

BOARD OF OSTEOPATHIC MEDICINE MEMBERS:

Joel B. Rose, DO
Michelle R. Mendez, DO

COURT REPORTER

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II. RULES DISCUSSION

- a. HB 389 Practice of Pharmacy
 - i. Chapter 64B16-31, F.A.C., Collaborative Practice and Test and Treat Certifications

This bill was enrolled and signed into law with an effective date of July 1, 2020. This adds to the definition of the practice of pharmacy the ability to initiate, modify, discontinue drug therapy under a collaborative practice agreement with a physician, for patients with chronic illnesses. It also allows a pharmacist to test for and treat certain nonchronic health conditions. The bill requires additional education and training requirements that will create two certification types: Collaborative Practice Certification (CPC) and the Test and Treat Certification (TTC). The bill outlines the requirements to

obtain the certifications as well as terms and conditions are to be included in a collaborative practice pharmacy agreement and in the written protocol between a pharmacist and a physician. The bill requires continuing education to maintain the certifications and it requires the Board to adopt by rule a formulary of medicinal drugs that a pharmacist may prescribe for the treatment of non-chronic health conditions.

The Board of Pharmacy Rules Committee held a meeting on June 2, 2020 to review and discuss draft rule language for Chapter 64B16-31, F.A.C. Subsequent to the Rules Committee Meeting, Ms. Sapp sent out invitations to the Board of Medicine (BOM) and the Board of Osteopathic Medicine (BOOM) to request representatives from each Board in order to form a Joint Rules Committee to review the draft rule language.

The BOM reviewed and discussed the draft rule language during their June 3, 2020 Board Meeting and determined that Dr. Vila and Dr. TerKonda would represent the BOM. The BOOM held a meeting on June 9, 2020 to discuss and review the language and determined that Dr. Rose and Dr. Mendez would represent BOOM.

The Joint Committee reviewed the below proposed draft rule language.

The Committee along with BOM and BOOM determined to only discuss the rules that require collaboration between the three Boards.

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 Certification¹" 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 must 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.

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 Course²" 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) or a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit.

(b) 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;

2. Writing and entering into a collaborative practice agreement;

3. Place holder for discussion with Board to determine appropriate content list in consultation with BOM and BOOM.

(c) No less than 12 hours of the course shall be offered through a live seminar or a live video teleconference.

Place holder for discussion with Board to determine appropriate format of specific hour requirements with BOM and BOOM.

(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.

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.

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) Osteoporosis and osteo-arthritis;

6) Opioid use disorder;

7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.; and

8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services.

Place holder for discussion with Board to determine appropriate list of chronic health conditions in consultation with BOM and BOOM.

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

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.

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 Certification³” 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 must 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.

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 Course⁴” 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) or a program provider who is accredited to provide educational activities designated for the American Medical Association Physician’s Recognition Award Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit.

(b) 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;

2. Writing and entering into a written protocol;

3. Place holder for discussion with Board to determine appropriate content list in consultation with BOM and BOOM.

(c) No less than 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 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.

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.

Place holder for discussion with Board to determine if it wants to provide additional requirements for the written protocol in consultation with BOOM and BOM pursuant to Section 465.1895(5)(a)6.

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

64B16-31.039 Test and Treat Certification: Formulary of Medical Drugs

(1) Pursuant to section 465.1895, F.S., the Board hereby incorporates the following as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a written test and treat protocol:

(a) All medicinal drugs approved by the United States Food and Drug Administration (“FDA”);

(b) 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.

Placeholder for discussion with Boards regarding additional drugs that should be excluded.

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

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.

Place holder for discussion with Board regarding reasonable time frame for production of records.

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

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;

(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.

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.

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.

The Joint Committee reviewed and began discussion on 64B16-31.003, F.A.C., Collaborative Practice Certification.

Dr. Rose addressed the Committee regarding (2)(a) and suggested to strike “category” in subsection (1)(a): American Medical Association Physician’s Recognition Award Category 1 as they are subject to change.

Dr. Hickman addressed the Committee and inquired if taking the course by one of these associations listed in the rule, meet the requirements for the certification, or would the pharmacist need to complete a course that is specifically ACPE accredited.

Mr. Flynn confirmed that yes, this would apply in the state of Florida for general education credit hours if taken by one of the listed providers.

Dr. Vila addressed the Committee regarding the content of the course and suggested requiring specific hours in evaluation and management of chronic diseases and suggested those hours be completed on a human simulator.

Dr. Hickman confirmed that when the BOP reviews courses for approval, the course content will be reviewed to assure all requirements are being captured.

Mr. Philip addressed the Committee and agreed with Dr. Vila that the requirements of the evaluation and management is outlined in the statute and will be included in the approved course.

Dr. Mendez addressed the Committee regarding the intent of the certification and what setting it would be utilized in.

Mr. Philip stated the bill does not specify what setting the certification is to be utilized in and the intent is to be available to any practitioners whom qualify for the certifications.

Dr. Mendez stated that laboratory testing can be very different depending on what setting the pharmacist and collaborating physician are practicing.

Dr. Mikhael addressed the Committee and Dr. Mendez and confirmed that the intent is to increase patient access.

Dr. TerKonda addressed the Committee regarding the provider of the course and suggested the highlighted change in subsection (2)(a): The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE) ~~or~~ and a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit as he would like to see the course be offered in conjunction with ACPE, AMA and AOMA.

Mr. Wright addressed the Committee regarding the benefits of the course being offered in conjunction with multiple accrediting bodies but was not sure if historically had ever been done.

Dr. Vila suggested splitting up the required course hours between the accrediting bodies and requiring specific hours per entity.

Mr. Flynn addressed the Committee and suggested requiring the instructor of the course be a licensed physician.

Dr. Mesaros summarized the discussion.

Dr. Villa inquired with the Committee regarding how the rule will capture the requirement of the patient's medical records and the communication between the pharmacist and the collaborating physician.

Mr. Philip addressed Dr. Villa's inquiry and stated the rule should not be prescriptive, as that would be outlined in the collaborative practice agreement and the certification should capture if a pharmacist has the knowledge, skills, and ability to enter into an agreement.

Dr. Mesaros opened the floor to additional Board Members.

No additional Board Member comments were provided.

Dr. Mesaros opened the floor for public comment.

Nicole Garrett, Clinical Ambulatory Pharmacist in Florida, addressed the Committee regarding the term CPA and that the statute requires the delegation be appropriate to the pharmacist's education and training and to the physician's scope of practice. She indicated pharmacists and physicians will only enter into an agreement in which both parties feel comfortable.

Mary Thomas, representing the Florida Medical Association (FMA) and the Florida Osteopathic Medical Association (FOMA), addressed the Committee regarding the continuing education requirements for physicians in order to diagnose patients and inquired what the process will be for approving the continuing education courses.

Ms. Sapp addressed the Committee regarding the process of approving continuing education courses and indicated that through this rulemaking the process, the rule shall outline who the course will be given by and what requirements will be included in the course. Courses will be reviewed by our staff pharmacist to ensure they meet the requirements in the statute and rule.

Mr. Flynn confirmed that the course will be approved by the Board of Pharmacy.

Dr. Vila suggested having multiple courses depending on the subject area.

Mr. Dierlam addressed the Committee indicating the bill requires a 20-hour course and outlines the requirements of the course and suggested the course be widely applicable.

Dr. Schwimmer, Vice-Chair of the BOOM, addressed the Committee and asked Mr. Flynn if anything in the statute prohibits the physician from requiring additional training for the pharmacists.

Mr. Flynn addressed Dr. Schwimmer and the Committee and confirmed, the CPA is a contractual agreement that is driven by the physician. A physician has the authority to select, create, and enter into an agreement with their pharmacist of choice. A pharmacist may not enter into an agreement unless they are appropriately qualified. Mr. Flynn indicated that requiring additional training would strictly be up to the physician when entering into an agreement.

Dr. Hickman indicated this agreement is between one practitioner and one pharmacist for the specific patient and the agreement could not be applied to multiple patients.

Louis Adams addressed the Committee regarding if a consultant license would qualify a pharmacist for this certification.

Mr. Flynn stated this statute stands independently and would be a separate certification.

Mr. Dierlam addressed the Committee regarding the requirements of a Consultant Pharmacist.

Dr. Villa addressed the Committee regarding how the course would be presented, either live, online, or otherwise and suggested no less than three hours of the course be live with interactive patient scenarios.

Dr. Mikhael addressed Dr. Vila regarding the human simulator.

Dr. Hickman and Dr. Mikhael addressed the Committee and agree with Dr. Vila for a live interaction requirement within the course.

Dr. Rose and Dr. Schwimmer suggested to be cognizant of COVID-19 and the difficulties with live hours during these times.

Dr. Mesaros thanked everyone for the discussion and stated that the Committee would take the comments into consideration when amending the draft rule language.

The Joint Committee began discussion on Rule 64B16-31.007, F.A.C., Collaborative Practice Certification: Chronic Health Conditions.

Dr. Mesaros summarized the proposed rule language and opened the floor for discussion.

Mr. Philip addressed the Committee regarding the chronic health conditions outlined in the rule. He indicated the agreement entered will be between a single physician and single pharmacist to manage a specific patient. The goal is to work together to ensure that the patient's quality of care is improved. Terms and conditions must be appropriate to a pharmacist's education and training to assure the pharmacist participating in the agreement be educated and prepared for that specific condition of the patient.

Mr. Wright addressed the Committee and agrees with, (7) Those chronic health conditions enumerated in section 465.1865(1)(b), F.S.; and stated this lets the physician determine states of the disease that can be covered.

Dr. Hickman addressed the Committee and agreed with Mr. Philip regarding evidence based in improving patient care and advised that, (8) Any disease state that is expected to last greater than one (1) year or more and will require ongoing medical treatment and drug therapy services., is necessary as there are a lot of additional chronic medical conditions that are not listed within the proposed rule.

Dr. Rose addressed the Committee regarding subsection 8 and expressed the intent of the legislature was not to put a catch all. He stated this option would bypass the ability for the Boards to collaborate on what chronic diseases could listed and would prefer to only list what is outlined in the bill.

Dr. Mendez addressed the Committee and would prefer to start slow and be deliberate when considering additional chronic conditions.

Dr. TerKonda addressed the Committee and agreed with Dr. Rose regarding his concerns with subsection 8.

Dr. Vila addressed the Committee and stated he has no opposition with the six additional diseases listed; however, would like to remove subsection 8.

Chris Nuland, representing the Florida Chapter, American College of Physicians, addressed the Committee and recommended the deletion of subsection 8.

Dr. Schwimmer, addressed the Committee and agreed with the deletion of subsection 8 and suggested adding behavioral health conditions.

Dr. Mikhael addressed the Committee regarding becoming too restrictive and expressed he believes the intent of subsection 8 was to fall back on the physician's responsibility with the pharmacist to determine what conditions are appropriate. Deleting this addition could be doing a disservice to accessing patient care.

Toni Large, representing the Florida Society of Rheumatology, addressed the Committee in opposition to (5) Osteoporosis and osteo-arthritis and expressed that most patients who go to a rheumatologist have potentially been treated by several physicians prior to being under the care a specialist to manage their conditions.

Mary Thomas, FMA, addressed the Committee in opposition of subsection 8 and suggested the bill does not authorize a catchall provision.

Kathy Baldwin, representing the Florida Society of Health-System Pharmacists (FSHP), addressed the Committee regarding the benefits of physicians collaborating with pharmacists as pharmacists can effectively manage medications and create an efficient path for patient access.

Jason Wynn, representing the Florida Osteopathic Medical Association, addressed the Committee in opposition of subsection 8.

Dr. Vila addressed the Committee regarding what items should be listed in the CPA.

Mr. Philip addressed Dr. Villa and the Committee and confirmed that the requirements of the CPA are outlined in the statute and those are also identified in the proposed application.

Mr. Flynn addressed the Committee regarding the statutory requirements of rulemaking and confirmed a statute should not be duplicated in rule.

Dr. TerKonda dismissed himself from the call.

Dr. Mendez dismissed herself from the call.

The Joint Committee began discussion on Rule 64B16-31.035, F.A.C., Test and Treat Certification: Initial Certification Course

Dr. Mesaros addressed the Committee and indicated that comments and suggestions from the discussion regarding the Collaborative Practice Certification will be incorporated in the Test and Treat Certification proposed rule language.

Mr. Philip addressed the Committee and stated he had no additional content areas to be added to the list as they are outlined in the statute and suggested lowering the requirement for live hours from twelve to eight.

Dr. Vila addressed the Committee regarding adopting the philosophy of not being too broad as that will delay the implementation of the proposed rules.

Dr. Rose addressed the Committee regarding the follow up care requirement.

Mr. Flynn indicated that the follow up requirement will be outlined within Rule 64B16-31.043, F.A.C., Test and Treat Certification: Follow-up Care.

Dr. Rose commented on the authority for compounded drugs within the drug formulary outlined in (b) All compounded medicinal drugs that utilize only active pharmaceutical ingredients approved by the FDA.

Dr. Hickman addressed the Committee and confirmed (b) was outlined due to the Tamiflu shortage.

Mr. Flynn confirmed the rule will be dictated by what is in the written protocol and indicated he indicated the current language will be clarified to specifically exclude controlled substances. The formulary shall include a list of US FDA approved active ingredients as the proposed language could be open for potential abuse of compounded drugs.

Dr. Rose dismissed himself from the meeting.

Dr. Schwimmer addressed the Committee regarding the formulary to Medicaid patients and should the rule address a Medicare formulary.

Mr. Wright addressed the Committee regarding the formulary and how it may potentially alleviate the concern with compounding.

Dr. Hickman agreed with Mr. Wright and volunteered to work with Mr. Flynn on amending the proposed language to address the concerns.

Dr. Vila addressed the Committee and inquired about the electronic medical records.

Mr. Philip addressed Dr. Vila's concerns and confirmed this would depend on how communication is set up between each physician.

Dr. Mikhael addressed the Committee and extended his gratitude for the open discussion today.

Dr. Mesaros opened for public comment.

No public comments were received.

Ms. Sapp addressed the Committee and confirmed the comments from the discussion will be taken into consideration and amendments to the proposed rules will be presented at the next Committee Meeting.

III. ADJOURNMENT

There being no further discussion, the meeting adjourned at 12:45 p.m.