BOARD OF PHARMACY
RULES COMMITTEE
DRAFT MINUTES
June 2, 2020
1:00 P.M. ET
Call In Number: (888) 585-9008
Conference Code: 599-196-982(#)

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the board's website.

I. CALL TO ORDER/ROLL CALL

Dr. Mesaros called the meeting to order at 1:00 p.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

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II. RULES DISCUSSION

a. Legislative Review
    i. HB 389 Practice of Pharmacy

Ms. Sapp provided an overview of the bill.

This 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 is required to work in consultation with the Board of Medicine and the Board of Osteopathic

Medication to adopt rules to implement this bill. The rule drafts below have been provided to those Boards for discussion at there upcoming Board Meetings.

During the April 30, 2020 is was established that Dr. Mesaros would begin working with Board Counsel on rule language and the drafting of the new certification applications. The below language was provided for the Committees review.

CHAPTER 64B16-31 COLLABORATIVE PRACTICE AND TEST AND TREAT CERTIFICATIONS

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[1]" that is hereby incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-07519 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.

Motion: by Mr. Philip to open the rule for development and approve the proposed language and present to the Board.
Second: by Mr. Wright
Vote: Unanimous

The Committee reviewed and discussed the below proposed language.

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[2]" that is hereby incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-07519 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 the following providers:
1. A state or national program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE) and any state or national program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit; or
2.Place holder for discussion with Board to determine appropriate list of additional providers in consultation with BOM and BOOM.
(b) The course content shall include all those areas enumerated in section 465.1865 (2)(c), F.S., and shall also meet the following requirements:
1. One hour shall be dedicated to covering the laws and rules applicable to the collaborative practice for the treatment of chronic health care conditions;
2. Place holder for discussion with Board to determine appropriate content list in consultation with BOM and BOOM.

(c) The course shall be offered through a live seminar, a live video teleconference, or through an interactive computer-based application.
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 continuing education credits towards the continuing education mandates of Rule 64B16-16.301, F.A.C.
Rulemaking Authority 465.1865, FS. *Law Implemented* 465.1865, FS. *History – New* XX-XX-20.

The Committee allowed for public comment.

Michael Jackson, Executive Vice-President of the Florida Pharmacy Association (FPA), addressed the Committee regarding the providers authorized to provide the course and asked if the intention of the language is for the course to be offered in conjunction by providers.

The Committee and Board Counsel clarified that is not the intention and will revise the draft language in (2)(a)1 to say "…accredited by the Accreditation Council for Pharmacy Education (ACPE) ***or*** any provider who is accredited…"

Dr. Angela Garcia addressed the Committee.

Mary Thomas, Representative of Florida Medical Association (FMA) and Florida Osteopathic Medical Association (FOMA), addressed the Committee and provided proposed amendments to subsection 2(a)1 to include the correct name of the American Medical Association Physician's Recognition ***Award*** Category 1.

Mr. Philip addressed the Committee and suggested the removal of state or national program.

Mr. Wright suggested adding a content area to the training program to include writing and entering into a collaborative practice agreement.

Michael Jackson, FPA, asked the Committee if the draft language limits the ability to have the course provided through a home study option.

Susie Weiss, Licensed Pharmacist, addressed the Committee.

Mr. Flynn, Board Counsel, addressed the Committee and confirmed the language could be amended to incorporate home study hours. The committee would like to see a hybrid of live and home study hours. Dr. Hickman suggested having 8 hours home study and 12 hours live.

Mr. Dierlam, Board Counsel, addressed the Committee regarding the method of how the course is provided and relayed that the rule language was pulled from Rule 64B16-26.103, F.A.C.

Dr. Angela Garcia addressed the Committee.

Mr. Philip addressed the Committee regarding the overlap of the two certification courses and if a combined 30-hour course can be approved.

Mr. Flynn, Board Counsel, suggested that should the Committee move to combine the two certifications, that would be outlined at a later time in a separate rule.

Mr. Dierlam, Board Counsel, confirmed that the statute does not require the Committee to outline the specific hours that must be applied to each subject area.

The Committee does not want to specify a length requirement for the laws and rules content area as that should be left up to the provider.

Motion: by Dr. Mikhael to open the rule for development
Second: by Mr. Wright
Vote: Unanimous

The Committee reviewed and discussed the below proposed language.

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, 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 a modification to, or renewal of, an existing collaborative pharmacy practice agreement, the pharmacist shall submit the updated version of the agreement to the Board Office within 5 business days.
Rulemaking Authority 465.1865, FS. *Law Implemented* 465.1865, FS. *History – New* XX-XX-20.

The Committee discussed the length of time a pharmacist should have to submit the agreement to the Board Office and agreed upon the proposed language.

Motion: by Mr. Wright to open the rule for development
Second: by Dr. Hickman

The Committee allowed for public comment.

Jason Wynn, a representative from FOMA, addressed the Committee regarding the submission of the agreement.

Mr. Flynn, Board Counsel, addressed Mr. Wynn's concerns regarding when the Collaborative Practice Agreement (CPA) is submitted to the Board Office.

Mr. Philip addressed the Committee regarding if a pharmacist would have to modify the CPA every time a patient is added or removed from the CPA.

Mr. Philip volunteered to work with Board Counsel to review subsection 2 of the rule for amendments to clarify that any modifications relating to substantive changes are to be sent to the board.

Vote: Unanimous

The Committee reviewed and discussed the below proposed language.

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

2) 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.

Mr. Philip addressed the Committee regarding the list of chronic health conditions outlined in the statute and any other chronic conditions should be established between the pharmacist and the physician within the collaborative practice agreement. He also indicated that the Centers for Disease Control (CDC) provides a definition for chronic illnesses.

Mr. Flynn, Board Counsel, will incorporate the CDC's definition into the rule.

Mary Thomas, FMA, addressed the Committee and objects to leaving chronic health conditions open ended.

Mr. Flynn, Board Counsel, addressed Ms. Thomas's concerns and directed the committee to 465.1865(1)(b)7, F.S., which allows the Board to adopt other chronic health conditions Mr. Flynn also directed the committee to 465.1865(3), F.S., which indicates that the terms and conditions of the practice agreement must be appropriate to the pharmacist's training.

Mr. Philip suggested incorporating subsection 3 into this rule.

Based on the Committee's comments and concerns Board Counsel will be providing amended language at the next Committee Meeting.

Motion: by Mr. Wright to open the rule for development
Second: by Dr. Hickman
Vote: Unanimous

The Committee reviewed and discussed the below proposed language.

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.

The Committee allowed for public comment.

No public comments were received.

Motion: by Mr. Wright to open the rule for development
Second: by Dr. Mikhael
Vote: Unanimous

The Committee moved to table the application to the next Committee Meeting in order to make the porposed amendments to the language reviewed today.

The Committee took a 10-minute break.

The Committee reviewed and discussed the below proposed language.

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[3]" that is hereby incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-07519 or http://floridapharmacy.gov. Applicants for certification must meet and comply with all requirements in Section 465.1895, F.S.

The Committee allowed for public comment.

Joseph Scuro, a representative from FPA, addressed the Committee regarding the definition of a supervising physician

Mr. Flynn, Board Counsel, addressed Mr. Scuro's concerns and indicated the statute refers to a pharmacist entering into a written protocol with a supervising physician if testing and treating for nonchronic health conditions.

Motion: by Dr. Mikhael to open the rule for development.
Second: by Philip
Vote: Unanimous

The Committee reviewed and discussed the below proposed language.

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[4]" that is hereby incorporated by reference and available at http://www.flrules.org/Gateway/reference.asp?No=Ref-07519 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 the following providers:
1. A state or national program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE) and any state or national program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Category 1 credit or the American Osteopathic Association Category 1-A continuing medical education credit; or
2.Place holder for discussion with Board to determine appropriate list of additional providers in consultation with BOM and BOOM.
(b) The course content shall include all those areas enumerated in section 465.1895 (2)(b), F.S., and shall also meet the following requirements:
1. One hour shall be dedicated to covering the laws and rules applicable to the testing or screening for and the treating of minor, nonchronic health conditions;
2. Place holder for discussion with Board to determine appropriate content list in consultation with BOM and BOOM.
(c) The course shall be offered through a live seminar, a live video teleconference, or through an interactive computer-based application.
(3) A pharmacist who successfully completes a board approved test and treat certification course shall be awarded 20 hours of continuing education credits towards the continuing education mandates of Rule 64B16-16.301, F.A.C.

Mr. Flynn, Board Counsel, addressed the Committee and confirmed that previous comments provided from the Committee regarding the Collaborative Practice Certification (CPC) rules, would be applied to this rule as well.

Mr. Wright addressed the Committee and agreed with Board Counsel.

Motion: by Mr. Wright to open the rule for development.
Second: by Mr. Philip

The Committee allowed for public comment.

No public comments were received.

Vote: Unanimous

The Committee reviewed and discussed the below proposed language.

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 a modification to, or renewal of, an existing written protocol, the pharmacist shall submit the updated version of the agreement to the Board Office within 5 business days.
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.

Dr. Hickman and Mr. Philip addressed the Committee regarding the expiration of the written protocol and when the written protocol would need to be renewed.

The Committee decided it would not be necessary to identify an expiration date in rule.

Motion: by Dr. Hickman to open the rule for development.
Second: by Mr. Wright

The Committee allowed for public comment.

No public comments were received.

Vote: Unanimous

The Committee reviewed and discussed the below proposed language.

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 for the treatment of the minor, nonchronic health conditions outlined section 465.1895(1), F.S., as the formulary of medicinal drugs that a pharmacist may prescribe pursuant to a test and treat written protocol.
(2) A pharmacist may not prescribe the following prescription drugs for the treatment of minor, nonchronic health conditions pursuant to a test and treat written protocol:
(a) controlled substances as described in s. 893.03 or 21 U.S.C. s. 812;
(b) Place holder for discussion with Board regarding additional drugs that should be excluded.

Mr. Wright addressed the Committee regarding compounding medications.

Mr. Flynn, Board Counsel, addressed the Committee regarding Mr. Wright's comments and believes that this language would be restricted to US Food and Drug Administration (FDA) approved prescription medication only and would not include compounded drugs or controlled substances.

The Committee allowed for public comment.

Michael Jackson, FPA, addressed the Committee inquiring if the drug restrictions would apply to a Schedule V drug as outlined in Section 893 F.S.

David Flynn, Board Counsel, will research Mr. Jackson's inquiry and provide additional comments at the next Committee Meeting.

Dan Buffington, Clinical Pharmacology Services, addressed the Committee regarding on whether the bill language is limited to FDA approved medications or if it only specifies that the formulary must include FDA approved drugs

The committee believes this can be addressed within the written protocol established with the physician but wants to include language that would allow for the use of FDA approved active ingredients.

Mr. Flynn will work on revising the language for the next committee meeting.

Motion: by Mr. Philip to open the rule for development.
Second: by Mr. Wright
Vote: Unanimous

The Committee reviewed and discussed the below proposed language.

64B16-31.041 Test and Treat Certification: Patient Records
(1) 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.

Dr. Hickman addressed the Committee regarding patients whom do not have an established primary care physician.

Mr. Flynn, Board Counsel, addressed Dr. Hickman's concerns and stated this only applies if the patient requests their records to be provided to a health care provider.

The Committee allowed for public comment.

No public comments were received.

Motion: by Dr. Mikhael to open the rule for development.
Second: by Mr. Wright
Vote: Unanimous

The Committee reviewed and discussed the below proposed language.

64B16-31.043 Test and Treat Certification: Follow-up Care
Immediately prior to performing testing, screening, or treatment services on a patient for the first time, 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.

Mr. Philip addressed the Committee regarding the requirement of providing written information to patients.

Dr. Mesaros addressed the Committee regarding the language that was provided by the Florida Pharmacy Association (FPA).

Mr. Wright addressed the Committee in favor of the language provided by the FPA.

Mr. Dierlam, Board Counsel, addressed the Committee and proposed combining the provided draft language with the language provided by the FPA.

The Committee agreed to combine the language which indicates written information shall be provided prior to performing testing and treatment, when to seek follow-up care and if the pharmacist determines in their professional judgement that the patient should seek follow-up care.

The Committee allowed for public comment.

Motion: by Mr. Philip to open the rule for development.
Second: by Mr. Wright

The Committee allowed for additional public comment.

No public comments received.

Vote: Unanimous

Mr. Flynn, Board Counsel proposed to open a new rule, which is not yet titled, to incorporate the consolidation of the two initial certification courses.

Motion: by Mr. Wright to open the rule for development.
Second: by Mr. Philip

The Committee allowed for public comment.

No public comments were received.

Vote: Unanimous

The Committee reviewed and discussed the below proposed language.

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

Mr. Flynn, Board Counsel, addressed the Committee regarding the requirements of the mandatory review.

Motion: by Dr. Mikhael to open the rule for development.
Second: by Mr. Wright

The Committee allowed for public comment.

No public comments were received.

Vote: Unanimous

The Committee discussed scheduling the next Rules Committee meeting the week of June 22, 2020.

Joseph Scuro addressed the Committee regarding a liability waiver.

Mr. Flynn, Board Counsel, addressed Ms. Scuro's comments and indicated that would require a statutory mandate.

Jason Wynn, FOMA, addressed the Committee regarding their letter they sent in April requesting a joint committee between the three boards and whether that letter is available to the public.

Mr. Flynn indicated that letter was received and is already included in the rulemaking file.

III. ADJOURNMENT

There being no further business, the meeting adjourned at 5:00 p.m.