BOARD OF PHARMACY
RULE DEVELOPMENT WORKSHOP
RULES COMMITTEE
DRAFT MINUTES
August 24, 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 DEVELOPMENT WORKSHOP

a. 64B16-31.007, F.A.C., Collaborative Practice Certification: Chronic Health Conditions

On August 3, 2020 the Board of Pharmacy received a request for a Rules Workshop from the Florida Psychiatric Society (FPS) and the Florida Chapter, American College of Cardiology on Rule 64B16-31.007, F.A.C., Collaborative Practice Certification: Chronic Health Conditions.

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.

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

Dr. Mesaros presented the draft language that was amended based on the discussion from the July 29, 2020 Rules Workshop and Joint Rules Committee.

Mr. Philip addressed the Committee and stated that many states do not identify specific disease states in their respective laws and rules. The chosen disease states are predicated upon a joint decision made by the pharmacist and physician. Mr. Philip believes that our rule does not need to be very descriptive and referenced literature to support his point. Mr. Philip stated that heart failure should be added to Rule 64B16-31.007, F.A.C.

Dr. Mikhael concurred with Mr. Philip regarding pharmacist and physician discretion when managing patients. Pharmacists are the drug experts and should be the authority on drug management. Dr. Mikhael also agreed that heart failure should be added to the proposed rule.

Mr. Wright stated that the purpose of the pharmacist-physician collaboration is to manage a condition, including medication management. The pharmacist is not diagnosing the patient and should act as an extension of the physician in regard to managing medications. Mr. Wright is looking forward to seeing collaborative practice take shape in Florida.

Dr. Hickman addressed the Committee in support of the addition of heart failure to the list.

Dr. Vila, representing the Board of Medicine, and Dr. Hayden and Dr. Rose, representing the Board of Osteopathic Medicine, addressed the Committee and expressed their support for the collaborative practice certification.

Dr. Hayden, representing the Board of Osteopathic Medicine, addressed the Committee in favor of the collaboration. She conveyed that these types of collaborative practice agreements (CPA) are currently being used within her health care clinics. She expressed concerns regarding the alteration of a patient's medication.

Dr. Hickman reminded everyone that another pharmacist cannot alter a patient's medication as this is very specific between the doctor, the patient, and the pharmacist. The agreements will be as specific as the physician wishes them to be.

Dr. Hayden expressed her gratitude for the explanation and reiterated she was in favor of the CPA.

Dr. Rose thanked the Committee for collaborating with physicians. He wants to see this be quickly implemented. He stated at any time, the rule can be amended to add additional disease states.

Mr. Flynn provided an overview of the steps to implement rule language and the timeframe.

Dr. Mesaros opened the floor for public comment.

Mallorie Harrell, representing the Florida Chapter of the American College of Cardiologists (ACC), expressed concern over the addition of cardiovascular disease to the rule. Ms. Harrell introduced Dr. David Perloff, president of the Florida Chapter of the ACC.

Dr. Perloff addressed the Committee in opposition of the addition cardiovascular diseases. He stated that he has concern over the practical application and implementation of the law. Dr. Perloff expressed that this law may create a scenario where multiple pharmacists are managing medications without adequate supervision. He also indicated that heart disease is a very broad category and questioned whether a CPA would be comprehensive enough to address every condition under the heart disease umbrella. Dr. Perloff also expressed concern over the 20-hour initial certification course and a pharmacist's ability to evaluate laboratory tests, i.e. EKG. Dr. Perloff wants to ensure that a pharmacist has adequate training and experience prior to participation in a collaborative practice agreement.

Dr. Hickman stated that the law focused on collaborative practice, not on a pharmacist being an independent practitioner. He stated that many of Dr. Perloff's concerns are addressed in the statute.

Mr. Flynn echoed Dr. Hickman and confirmed that many of Dr. Perloff's concerns were addressed in the statute.

Dr. Mesaros thanked Dr. Perloff for his input and for taking the time to attend the meeting.

Dr. Vila addressed the Committee and stated that this process may be more comprehensible for physicians if a template collaborative practice agreement was provided.

Mr. Flynn indicated that each collaborative practice agreement is very specific to the patient's uniqueness and it may be difficult to create a template; however, this is something that could be researched.

Dr. Perloff addressed the Committee and stated that he would like for the statute to be implemented with adequate safeguards in place. He expressed his opposition of the addition of cardiovascular disease to the rule.

Dr. Mikhael recognized Dr. Perloff's concern. He expressed that there is much literature and research that supports a pharmacist's involvement in patient care. The patient's outcome is improved with the collaboration of a pharmacist. Dr. Mikhael introduced Dr. Austin Satterthwaite and Dr. Kyle Thorner, Florida pharmacists, to the Committee.

Dr. Satterthwaite and Dr. Thorner currently work in a collaborative practice environment with physicians as it pertains to the management of heart failure and amiodarone. Dr. Satterthwaite and Dr. Thorner provided an overview of their daily practice and presented

research findings to the Committee. The pharmacists expressed support for the addition of cardiovascular disease to the list.

Mr. Wright addressed Dr. Perloff and inquired if any research or anecdotal evidence is available to support concerns of the addition of cardiovascular disease.

Dr. Perloff reiterated his main concern is with moving forward with the language as written and inquired about collaborative practice in a retail setting.

Kathy Baldwin, representing the Florida Society of Health-Systems Pharmacists, addressed the Committee. Ms. Baldwin expressed that Ohio has implemented collaborative practice in a community/retail setting. Many of these programs relate to the management of tobacco cessation and diabetes.

Mr. Philip indicated that the initial 20-hour certification course is not intended to make a pharmacist an expert on specific disease states. The purpose is to provide an overview of collaborative practice; a pharmacist's education and experience provide the requisite training for specific disease states.

Dr. Vila addressed the Committee and expressed concern with the implementation of collaborative practice in a community/retail pharmacy setting.

Dan Buffington, a Florida pharmacist from the University of South Florida, addressed the Committee and indicated that collaborative practice has been in practice for years. Participation in collaborative practice is completely voluntary.

Monica Sanford, an acute care APRN from Pensacola, expressed concern for the potential for abuse and requested that Board research the implications of adding heart conditions further prior to adding them to the rule.

Kevin Duane, an independent pharmacy owner, addressed the Committee and shared his concern over making the rule too prescriptive.

Dr. Mikhael expressed support over the addition of heart disease to the rule; however, was concerned that the addition may delay the implementation of the rule.

Mr. Flynn addressed the Committee and suggested behavioral health be stricken from the rule at this time and discussed at a later date due to time constraints.

Motion: by Dr. Mikhael to table the discussion of behavior health until the October meeting.
Second: by Mr. Wright.
Vote: Unanimous

Motion: by Mr. Wright to add Heart / Cardiovascular Disease to Rule 64B16-31.007, F.A.C.

Dr. Mikhael inquired if the addition of heart disease to the proposed language should be delayed, would this impact the test-and-treat certification.

Mr. Flynn indicated that the addition of heart disease to the list may prompt a rules hearing. Mr. Flynn assured the Committee that their decision will still need to go through the administrative process.

Dr. Mesaros indicated that there may be a need to schedule another Joint Rules Committee meeting.

Mr. Wright stated that a rule challenge may be inevitable; however, this should not slow down the implementation process.

Mr. Philip requested clarification on the word choice of Heart / Cardiovascular Disease. Mr. Philip expressed support if the term heart failure was incorporated in the rule in lieu of Heart / Cardiovascular Disease.

Motion: by Mr. Wright to amend the Heart / Cardiovascular Disease language to heart failure.
Second: by Dr. Mikhael.
Vote: Unanimous.

III. RULES DISCUSSION

a. HB 389 Practice of Pharmacy
   i. Chapter 64B16-31, F.A.C., 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-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.

Dr. Mesaros opened for public comment.

No public comments were received.

Motion: by Dr. Hickman to approve the proposed rule language to be presented to the Full Board.
Second: by Mr. Wright.
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[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 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.

Place holder for consultation with BOM and BOOM.

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

Dr. Mesaros opened for public comment.

No public comments were received.

Motion: by Dr. Mikhael to approve the proposed rule language to be presented to the Full Board.
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.
Dr. Mesaros opened for public comment.

No public comments were received.

Motion: by Dr. Hickman to approve the proposed rule language to be presented to the Full Board.
Second: by Mr. Wright.
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.

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.

Dr. Mesaros opened for public comment.

No public comments were received.

Motion: by Mr. Wright to amend the Heart / Cardiovascular Disease language to state Heart Failure.
Second: by Dr. Mikhael.
Vote: Unanimous.

Motion: by Dr. Mikhael to table the discussion of behavior health until the October meeting.
Second: by Mr. Wright.
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.

Dr. Mesaros opened for public comment.

No public comments were received.

Motion: by Dr. Mikhael to approve the proposed rule language to be presented to the Full Board.
Second: by Mr. Philip.
Vote: Unanimous

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-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.

Dr. Mesaros opened for public comment.

No public comments were received.

Motion: by Dr. Mikhael to approve the proposed rule language to be presented to the Full Board.
Second: by Mr. Wright.
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[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 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.

Place holder for consultation with BOM and BOOM.

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

Dr. Mesaros opened for public comment.

No public comments were received.

Motion: by Dr. Hickman to approve the proposed rule language to be presented to the Full Board.
Second: by Dr. Mikhael.
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.

Dr. Mesaros opened for public comment.

Michael Jackson, representing the Florida Pharmacists Association, addressed the Committee. Mr. Jackson inquired about the protocol submission and as to whether that item had to be submitted prior to the certification being granted.

Ms. Sapp and Mr. Flynn provided clarification and confirmed the certification could be granted prior to the submission of the protocol.

Motion: by Mr. Wright to approve the proposed rule language to be presented to the Full Board.
Second: by Dr. Hickman.
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) 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.

Mr. Wright addressed the Committee regarding (2) and what controlled substances a pharmacist can prescribe and dispense as it relates to certain exemptions.

Mr. Flynn will perform further research to address Mr. Wright's question.

Dr. Mesaros opened for public comment.

No public comments were received.

Motion: by Mr. Wright to approve the proposed rule language to be presented to the Full Board.
Second: by Dr. Mikhael.
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.

Dr. Mesaros opened for public comment.

No public comments were received.

Motion: by Mr. Philip to approve the proposed rule language to be presented to the Full Board.
Second: by Mr. Wright.
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.

Dr. Mesaros opened for public comment.

No public comments were received.

Motion: by Mr. Philip to approve the proposed rule language to be presented to the Full Board.
Second: by Dr. Hickman.
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. Wright to approve the proposed rule language to be presented to the Full Board.
Second: by Dr. Hickman.
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.

Dr. Mesaros opened for public comment.

No public comments were received.

Motion: by Mr. Wright to approve the proposed rule language to be presented to the Full Board.
Second: by Dr. Hickman.
Vote: Unanimous

b. HB 599 Consultant Pharmacists
    i. 64B16-26.300, F.A.C., Consultant Pharmacist Licensure
    ii. 64B16-26.301, F.A.C., Subject Matter for Consultant Pharmacist Training Program

Ms. Sapp provided an overview of HB 599 Consultant Pharmacists.

Mr. Dierlam addressed the Committee and summarized the proposed revisions.

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 regimen 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.

Nicole Garett, Clinical Ambulatory Pharmacist in Florida, addressed the Committee and inquired about the recertification hours for Consultant Pharmacists not being applied to the general continuing education credits for Pharmacists.

Mr. Dierlam indicated that the focus of the rule was to modify the current requirements for initial licensure rather than renewal requirements.

Mr. Wright addressed the Committee regarding the addition of USP 797 and USP 800 to the subject matters in Rule 64B16-26.301, F.A.C.

Mr. Dierlam confirmed that this has been discussed. Mr. Dierlam's goal was to incorporate aspects of the preceptorship to the initial course content requirements.

Gore Alvarez from Nova Southeastern University addressed the Committee and inquired about the number of hours required for recertification.

Mr. Dierlam confirmed the proposed changes only affect the initial licensure requirements.

Debra Glass, Florida pharmacist, stated there may be a benefit to making the course content requirements more specific. She also inquired about the proposed requirements being retroactively applied to currently licensed consultant pharmacists.

Mr. Dierlam indicated this would only impact individuals whom apply for a consultant pharmacist after the rule becomes effective.

Gary Daleman, Florida licensed consultant pharmacist, indicated that there are two different aspects of consultant pharmacist practice: administrative and clinical. The subject matter is so diverse and not every course should address all topics.

Motion: by Dr. Mikhael to approve the proposed rule language to be presented to the Full Board.
Second: by Mr. Philip.
Vote: Unanimous

c. HB 59 Automated Pharmacy Systems
    i. 64B16-28.141, F.A.C., Requirements for use if an Automated Pharmacy System by a Community Pharmacy

Ms. Sapp provided an overview of HB 59.

64B16-28.141 Requirements for use of an Automated Pharmacy System by a Community Pharmacy.

(1) Definitions:

(a) “Automated pharmacy system (APS)”means a mechanical system that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.

(b) “Establishment” means one general physical location that may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings.

(c) “Pharmacist” means a pharmacist as defined by section 465.003, FS.

(2) General Requirements. A pharmacy may use an automated pharmacy system provided that:

(a) The automated pharmacy system is located within the prescription department, adjacent to the prescription department, or is located on the establishment of the licensed pharmacy, and the operation of the automated pharmacy system is under the supervision of a pharmacist. An automated pharmacy system that is not located within the prescription department shall be operated as an extension of the licensed pharmacy and the automated pharmacy system shall not require an independent and separate community pharmacy permit. An automated pharmacy system that is not located within the prescription department shall have conspicuously displayed on the automated pharmacy system the name, address, contact information and the permit number of the community pharmacy that is responsible for the operation of the automated pharmacy system.

(b) The pharmacy develops and maintains a policy and procedure manual that includes:

1. The type or name of the system including a serial number or other identifying nomenclature.

2. A method to ensure security of the system to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.

3. A process of filling and stocking the system with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.

4. A method of identifying all the registered pharmacy interns or registered pharmacy technicians involved in the dispensing process.

5. Compliance with a Continuous Quality Improvement Program.

6. A method to ensure that patient confidentiality is maintained.

7. A process to enable the prescription department manager or designee to revoke, add, or change access at any time.

(c) The system ensures that each prescription is dispensed in compliance with the definition of dispense as defined by section 465.003, F.S., and the practice of the profession of pharmacy. The system shall include a mechanism to ensure that the patient or an authorized agent of the patient has a means to communicate with a pharmacist responsible for dispensing the medical drug product. The means of communication may include in person, electronic, digital, or telephonic.

(d) The system shall maintain a readily retrievable electronic record to identify all pharmacists, pharmacy interns, registered pharmacy technicians, or other personnel involved in the dispensing of a prescription.

(e) The system shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(3) Additional Requirements for Patient Accessed Automated Pharmacy Systems. A pharmacy may use a patient accessed automated pharmacy system, provided that:

(a) The requirements in subsection (2), above, are met.

(b) Except as provided in paragraph (d), below, the stocking or restocking of a medicinal drug shall only be completed by the following:

1. A pharmacist;

2. A pharmacy intern under the direct and immediate personal supervision of a pharmacist; or

3. A registered pharmacy technician under the direct supervision of a pharmacist.

(c) Access to the Automated Pharmacy System in the absence of a pharmacist for purposes of servicing and maintenance by non-pharmacy licensed personnel shall be permitted provided that the system is capable of tracking individual access and preventing unauthorized access, and the system employs user based access or other technology that will prevent access to areas of the dispensing cabinet where drugs are stored. If the system does not employ such technology, access to the system for servicing and maintenance is permitted only under the direct supervision of a pharmacist.

(d) If the automated pharmacy system uses removable cartridges or containers to store the drug or uses unit of use packages, the stocking or restocking of the cartridges, containers or unit of use packages may occur at a licensed repackaging facility and may be sent to the provider pharmacy to be loaded by personnel designated by the pharmacist if:

1. A pharmacist verifies the cartridge, container or unit of use packages have been properly filled and labeled.

2. The individual cartridge, container or unit of use package is transported to the provider pharmacy in a secure, tamper-evident container.

3. The automated pharmacy system uses a bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to

ensure that the cartridge, container or unit of use package is accurately loaded into the automated pharmacy system.

4. The pharmacist verifying the filling and labeling retains responsibility if the cartridge, container or unit of use package is stocked or restocked incorrectly by the personnel designated to load the cartridges or containers.

(e) The automated pharmacy system must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID), visual verification or similar process to ensure that the proper medication is being dispensed from the automated system.

(f) The medication shall bear a patient specific label that complies with rule 64B16-28.108, F.A.C.

(g) The record of transactions with the patient accessed automated pharmacy system shall be available to authorized agents of the Department of Health. The record of transactions shall include:

1. Name of the patient.
2. Name, strength, and dosage form of the drug product dispensed.
3. Quantity of drug dispensed.
4. Date and time of dispensing.
5. Name of provider pharmacy.
6. Prescription number.
7. Name of prescribing practitioner.
8. Identity of the pharmacist who approved the prescription or order.
9. Identity of the person to whom the drug was released.

(4) The pharmacist responsible for filling, verifying, loading or supervising the automated pharmacy system shall be responsible for her or his individual action.

(5) A prescription dispensed pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.022 FS. History–New 11-29-04, Amended 12-30-07, 1-1-10, 7-5-18.

Mr. Flynn addressed the Committee and summarized the bill language.

Mr. Wright inquired about the meaning of the term “essential goods” and requested that there be further clarification.

Mr. Flynn stated he will analyze the language in lines 34-39 of the bill and determine if clarification is needed. Mr. Flynn recommended opening the rule for development.

Motion: by Dr. Mikhael to open Rule 64B16-28.141, F.A.C., for development.
Second: by Mr. Wright.
Vote: Unanimous.

IV. ADJOURNMENT

There being no further business the meeting adjourned at 6:05 pm.