

**BOARD OF PHARMACY
JOINT COMMITTEE MEETING
RULES COMMITTEE MEETING
DRAFT MINUTES
October 13, 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 Joint Rules Committee 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

Christopher Dierlam, Esq.
Assistant Attorney General

COURT REPORTER

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

JOINT COMMITTEE MEMBERS PRESENT

Hector Vila, MD, Board of Medicine
Sarvam TerKonda, MD, Board of Medicine
Joel R. Rose, DO, Board of Osteopathic Medicine

II. JOINT RULES COMMITTEE DISCUSSION

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

On August 24, 2020 the Board of Pharmacy held a Rules Workshop with 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. Subsequent to the Rules Workshop, the Full Board voted on the draft language for Chapter 31, F.A.C., Collaborative Practice and Test and Treat Certifications. The rules were adopted on October 8, 2020 and should take effect October 28, 2020.

64B16-31.001 Collaborative Practice Certification (CPC).

Applicants for CPC shall submit an application using Form DH5059-MQA (eff. 08/20), "Application for Pharmacist Collaborative Practice Certification" that is hereby incorporated by reference and available at

October 13, 2020 Joint Rules Committee and Board of Pharmacy Rules Committee DRAFT Minutes
Page 1 of 15

<http://www.flrules.org/Gateway/reference.asp?No=Ref-> or <http://floridaspharmacy.gov> Applicants for certification shall meet and comply with all requirements in section 465.1865, F.S. Rulemaking Authority 465.1865 F.S. Law Implemented 465.1865 F.S. History-New

64B16-31.003 Collaborative Practice Certification: Initial Certification Course.

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH5061-MQA (eff. 08/20) "Application for Initial Collaborative Practice Certification Course" that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref-> or <http://floridaspharmacy.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 I 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 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 hours of the course shall be offered through a live seminar or a live video conference.

(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 F.S. Law Implemented 465.1865 F.S. History-New _____.

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://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 F.S. Law Implemented 465.1865 F.S. History-New _____.

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

Rulemaking Authority 465.1865 F.S. Law Implemented 465.1865 F.S. History-New _____.

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 F.S. Law Implemented 465.1865 F.S. History-New, _____.

64B16-31.033 Test and Treat Certification (TTC).

Applicants for TTC shall submit an application using Form DH5060-MQA (eff. 08/20), "Application for Pharmacist Test and Treat Certification" that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref> or <http://floridaspharmacy.gov>. Applicants for certification shall meet and comply with all requirements in section 465.1895, F.S.

Rulemaking Authority 465.1895 F.S. Law Implemented 465.1895 F.S. History-New, _____.

64B16-31.035 Test and Treat Certification: Initial Certification Course.

(1) Applicants for Initial Certification Course approval shall submit an application using Form DH5062-MQA (eff. 08/20) "Application for Initial Test and Treat Certification Course" that is hereby incorporated by reference and available at <http://www.flrules.org/Gateway/reference.asp?No=Ref> or <http://floridaspharmacy.gov>.

(2) Initial test and treat certification courses shall be a minimum of 20 hours in duration, and shall meet all the following mandatory requirements:

(a) The course may only be offered by a program provider who is accredited by the Accreditation Council for Pharmacy Education (ACPE), a program provider who is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit, or a program provider approved by the American Osteopathic Association to offer continuing medical education credits.

(b) The course content and objectives offered by an approved provider shall be developed in conjunction with an individual licensed to practice pharmacy and an individual who is a licensed allopathic or osteopathic physician.

(c) The course content shall include all those areas enumerated in section 465.1895(2)(b), F.S., and shall also cover the following areas:

1. Laws and rules applicable to test and treat certifications; and

2. Writing and entering into a written protocol.

(d) No less than 8 hours of the course shall be offered through a live seminar or a live video teleconference.

(3) A pharmacist who successfully completes a Board approved test and treat certification course shall be awarded 20 hours of general continuing education credits. Rulemaking Authority 465.1895 F.S. Law Implemented 465.1895 F.S. History-New

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 F.S. Law Implemented 465.1895 F.S. History-New

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 and 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 Law Implemented 465.1895 History-New, _____.

64B16-31.041 Test and Treat Certifications: 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 F.S. Law Implemented 465.1895 F.S. History-New,

64B16-31.043 Test and Treat Certification: Follow-up Care.

A pharmacist must provide written information to a patient advising the patient when to seek follow-up care from his or her primary care physician. A pharmacist shall provide follow-up 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 judgement that the patient should follow-up with his or her primary care provider.

Rulemaking Authority 465.1895 F.S. Law Implemented 465.1895 F.S. History-New,

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 be reviewed in accordance with subsection (1), shall begin the rule repeal process in accordance with the Administrative Procedures Act.

Rulemaking Authority 465.1895 F.S. Law Implemented 465.1895 History-New

Dr. Mesaros addressed the Joint Committee and expressed the gratitude for all involved that have played a pivotal role in the implementation of HB 389.

Board Counsel, Christopher Dierlam addressed the Committee regarding the rule promulgation process and thanked the Committee, Joint Committee Members, and Board Staff for the participation in drafting rule language. He confirmed that the rules were adopted on October 8, 2020 and will be effective on October 28, 2020. He provided a brief description of the comments received from the Joint Administrative Procedures Committee (JAPC) and the response from Board Counsel addressing the concerns from JAPC. He asked the Board to review the comments relating to 64B16-31.003(2)(b), F.A.C. and 64B16-31.007(4), F.A.C.

Mr. Philip addressed the Committee regarding the JAPC comments for 64B16-31.003(2)(b), F.A.C. (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 and confirmed the Committee decided that the instructors of the course do not need to be Florida licensees as some of these courses could be nationally certified.

Dr. TerKonda suggested that the language be specified to assure that the instructor has a Clear/Active unencumbered license.

Mr. Wright addressed the Committee in agreeance with Mr. Philip and inquired if we monitor instructors for current continuing education providers as it relates to their licensure status.

Mr. Philip confirmed that the Committee needs to focus on the JAPC comments and the rules that have already been voted on and reiterated that any changes to the rules would need to take place after the effective date.

Mr. Dierlam confirmed that any changes to the rule language would have to be made after the October 28, 2020 effective date.

Dr. Hickman addressed the Committee regarding the importance of having expertise outside of Florida. He conveyed his appreciation for the national conferences he has attended and the educational benefits they provide.

Mr. Dierlam addressed the Committee regarding the comments received from JAPC on 64B16-31.007(4), F.A.C., (4) Smoking cessation. Smoking cessation may not be the proper term as it relates to a health condition and requested clarification from the Committee.

Mr. Philip suggested to amend the language to “Nicotine Dependence”.

Dr. Mikhael addressed the Committee in support of “Nicotine Dependence”.

Mr. Wright concurs with “Nicotine Dependence”.

Dr. Vila addressed the Committee in agreeance of “Nicotine Dependence”.

Motion: by Dr. Hickman to amend the language from Smoking Cessation to Nicotine Dependence

Second: by Mr. Wright

Dr. Mesaros opened the floor for public comment.

No public comments received.

Vote: Unanimous

Mr. Dierlam confirmed with the Committee that the change to the rule language will be presented to the full board for approval and will be made after the current effective date of October 28, 2020.

Mr. Philip addressed the Committee regarding 64B16-31.043, F.A.C., and suggested striking (3) When the pharmacist determines in his or her judgement that the patient should follow-up with his or her primary care provider to eliminate any confusion.

Ms. Sapp addressed the Committee to clarify that the language was taken directly from the statute.

Mr. Dierlam confirmed that the statute was explicit in the requirements of what would need to be outlined in the rule.

Ms. Sapp indicated that Board Staff will monitor the questions received from the public and should there be confusion we can visit the rule language in the future.

Dr. Mesaros opened the floor for public comment.

Michael Jackson, Florida Pharmacy Association Vice President, addressed the Committee and commended all involved for fast tracking these rules. He confirmed that the association is working on a course to be submitted for review.

Mallory Harrell representing the Florida Chapter American College of Cardiology addressed the Committee and inquired if the only discussion taking place was the current language the Committee has already voted on.

Dr. Mesaros addressed Ms. Harrell and confirmed that was correct.

Mr. Wright inquired with Mr. Jackson regarding a timeline for having a course submitted for the Test and Treat Certification.

Mr. Jackson confirmed that the process takes about three months for development, but they have a library of courses they are currently reviewing and hope to have a course submitted to the Board for review within thirty to forty-five days.

Dr. Mesaros addressed the Committee and expressed his gratitude for the Joint Committee Members being in attendance and for the collaboration during the implementation of HB389.

The Joint Rules Committee adjourned at 9:50 a.m. ET.

Dr. Mesaros called the Rules Committee meeting to order at 10:00 a.m. ET.

III. BOARD OF PHARMACY RULES COMMITTEE DISCUSSION

- a. 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

During the August 26, 2020 General Business Meeting, the Board voted on the proposed rule language for 64B16-26.300, F.A.C., and 64B16-26.301, F.A.C., The Board Office received public comments from Carlsen Evans regarding removing the preceptorship hours from the rule. This was placed on the agenda for the Committee's review.

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 ~~twelvetwenty~~ (1220) 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) 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) 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 appropriate 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 assessments.

(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.

Mr. Dierlam addressed the Committee and confirmed it would be appropriate at this time to allow for public comment regarding the proposed rules.

Mr. Evans addressed the Committee and confirmed that the comments received were from him personally and not representing Nova. He inquired with the Committee regarding the deletion of the forty-hour preceptorship.

Dr. Hickman addressed Mr. Evans regarding the hardships for individuals attempting to find a preceptor to complete the preceptorship. He also reiterated that the course content is being included within the education of the pharmacy program.

Bob Parrado addressed the Committee regarding the importance of the preceptorship.

Gore Alvarez representing himself as a Consultant Pharmacist expressed the importance of the hands-on component of the preceptorship.

Bob Lipman addressed the Committee in opposition of deleting the forty-hours preceptorship.

Dan Buffington addressed the Committee and expressed the Committee discussed this in great lengths and the requirements would be encompassed within their pharmacy training programs and the training would be achieved within the practice settings. He confirmed the settings could differ depending on where the pharmacist is employed.

Kathy Baldwin addressed the Committee on behalf of herself as a Consultant Pharmacists regarding the hardships pharmacists face when trying to find a preceptor.

Rolanda Qualls addressed the Committee and confirmed she has completed the 12-hour required course but indicated she is having a difficult time finding a preceptor to complete the requirements of the preceptorship.

Dr. Mikhael addressed the Committee and confirmed that the training of the preceptorship will be obtained with the employer and the education is obtained within the pharmacy program.

Dr. Hickman addressed the Committee in agreeance with Dr. Mikhael.

Gary Daylan addressed the Committee in favor of the elimination of the preceptorship and suggested the required hours be included in the pharmacy program.

Emely McKitrick representing the University of Florida addressed the Committee regarding the hardship of new graduates finding a preceptor.

After discussion the Committee concluded there were no changes that need to be made to the proposed language.

b. HB 59 Automated Pharmacy Systems

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

Mr. Dierlam 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.

Dr. Mesaros opened the discussion to the Committee.

Mr. Wright addressed the Committee regarding the bill language and where these automated pharmacy systems can be located and who will be managing them.

Bob Parrado addressed the Committee regarding remote systems and the locations of automated pharmacy systems and expressed his concerns regarding the safety of the systems.

Dr. Hickman thanked Mr. Parrado for his points on the security and safety of the automated pharmacy systems and provided a counterpoint that there is a national healthcare crisis with a delay of care that we may see in the coming years and the need of additional access to medications is crucial.

Dr. Mikhael conveyed there are three key points to address; patient access, safety, and accuracy of the automated pharmacy system, and expressed if you change one of them you can change the outcome of the other two. He reiterated there is a balance that must be maintained.

Michael Jackson, Florida Pharmacy Association Vice President, addressed the Committee and encouraged the Board to look at the supervision requirements of the systems.

Richard Penski representing MediVal addressed the Committee and reiterated the location and the supervision of the automated pharmacy systems is outlined in the statute. The location purposes of these systems are to improve patient access.

Mr. Wright expressed his concerns regarding the locations of the automated pharmacy systems and reiterated that the Board must think of the safety of the systems.

Mr. Philip addressed the Committee regarding possible amendments to 64B16-28.141, F.A.C., Requirements for use of an Automated Pharmacy System by a Community Pharmacy, to define the location and supervision requirement.

Mr. Dierlam confirmed with the Committee that a statute will take president over a current rule.

Mr. Philip expressed that the Bill is very prescriptive regarding where these systems can be located. He conveyed the Board needs to look at the training of the inspectors to ensure proper inspections.

Mr. Sapp confirmed with the Committee that Board Staff has been working with the Bureau of Enforcement regarding inspections and confirmed she will provide the Committee's comments with that office.

Dr. Hickman confirmed that these systems would be held to the same standards as a pharmacy.

Mr. Dierlam addressed the Committee and confirmed that he and Board Counsel David Flynn will review the current language in 64B16-28.141, F.A.C., with the Committee's two main issues of the location and supervision of the automated pharmacy system and present any needed changes at a future meeting.

IV. ADJOURNMENT

There being no further business the meeting adjourned at 11:30 a.m. ET.