

**BOARD OF PHARMACY  
RULES COMMITTEE  
DRAFT MINUTES  
June 2, 2020  
8:00 A.M. ET  
Call In Number: (888) 585-9008  
Conference Code: 599-196-982(#)**

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

**I. CALL TO ORDER/ROLL CALL**

Dr. Mesaros called the meeting to order at 8:00 a.m. ET.

**MEMBERS PRESENT**

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

**STAFF PRESENT**

Jessica Sapp, Executive Director  
Traci Zeh, Program Administrator

**BOARD COUNSEL**

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

**COURT REPORTER**

For the Record  
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**II. RULES DISCUSSION**

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

During the April 30, 2020 Rules Committee meeting, the Committee reviewed proposed rule language provided by Board Counsel. Board Counsel provided the proposed language with the Committee's amendments.

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

(1) Delegation: A pharmacist shall not delegate more tasks than he or she can personally supervise and ensure compliance with this rule. A pharmacist may delegate those non-discretionary delegable tasks enumerated in rule 64B16-27.420, F.A.C., to the following types of pharmacy technicians:

(a) Registered Pharmacy Technicians (RPT): are those technicians who are duly registered with the board pursuant to section 465.014(2), F.S.;

(b) Pharmacy Technicians in Training (PTT): are those technicians who are receiving practical (non-didactic) training in delegable tasks as part of employer-sponsored or non-

employer sponsored board-approved pharmacy technician training programs who are not required to be duly registered with the board as pharmacy technicians.

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

(a) Direct Supervision: means supervision by a pharmacist who is readily and immediately available at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who provides personal assistance, direction and approval throughout the time the delegated tasks are being performed. "Readily and immediately available" means the pharmacist and technician(s) are on the same physical premises, or if not, technology is used to enable real time, two-way communications between the pharmacist and technician(s).

(b) Use of Technology: A pharmacist, as an adjunct to assist in the direct supervision of the pharmacy technician, may employ technological means to communicate with or observe the pharmacy technician. A pharmacist shall make certain all applicable state and federal laws, including, but not limited to confidentiality, are fully observed when employing technological means of communication and observation. If technology is being used to provide direct supervision of pharmacy technician(s), such technology shall be sufficient to provide the personal assistance, direction and approval required to meet the standard of practice for the delegated tasks.

Motion: by Mr. Wright to approve the proposed language and present to the Board.

Second: by Dr. Hickman

The Committee allowed for public comment.

Mr. Montgomery addressed the Committee and confirmed he was in favor of the proposed rule language.

Michael Jackson, President of the Florida Pharmacy Association, addressed the Committee.

Vote: Unanimous

Motion: by Dr. Hickman to find that no economic impact and that a Statement of Estimated Regulatory Cost was not necessary, and the rule will not need legislative ratification.

Second: by Dr. Mikhael

Vote: Unanimous

Motion: by Dr. Mikhael to find that no part of this rule or a violation of this rule should be designated as a minor violation.

Second: by Dr. Hickman

Vote: Unanimous

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

- b. Legislative Review
  - i. HB 59 Automated Pharmacy Systems

Ms. Sapp provided an overview of the bill.

This bill amends section 465.0235, F.S., to allow community pharmacies to use automated pharmacy systems for outpatient dispensing under certain circumstances. The bill has been enrolled and but not yet signed into law. The proposed effective date is July 1, 2020.

During the April 30, 2020 Committee Meeting, it was established that Mr. Wright would work with Board Counsel to review current rule language and determine if revisions were necessary.

Mr. Montgomery addressed the Committee.

Mr. Wright addressed the Committee regarding defining essential businesses should this bill pass.

Board Counsel, Mr. Flynn, addressed the Committee regarding the rule making process should this bill be signed into law.

The Committee allowed for public commit.

Mr. Jackson, President of the Florida Pharmacy Association, addressed the Committee and inquired if the bill authorizes the Board for rule making authority.

Mr. Flynn addressed the Committee and confirmed rule making authority as outlined in the statute.

Cynthia Henderson, Representative for Epic Pharmacy, addressed the Committee.

- ii. HB 599 Consultant Pharmacists

Ms. Sapp provided an overview of the bill.

This bill and was enrolled and signed into law with an effective date of July 1, 2020. This bill revises requirements and responsibilities of a consultant pharmacist and authorizes the use of collaborative practice agreements. It includes the ordering and evaluating of any laboratory or clinical testing, conducting patient assessments, and implementing, modifying, discontinuing, or administering medicinal drugs pursuant to s. 465.0125.

During the April 30, 2020 Committee Meeting, it was established that Mr. Montgomery would work with Board Counsel on drafting proposed rule language.

Board Counsel, Mr. Dierlam, addressed the Committee and provided a brief overview of the language and recognized Mr. Montgomery and Mr. Wright for their assistance with amending the rule language.

The Committee reviewed and discussed the provided language.

**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), 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;

(b) Successfully complete a consultant pharmacist course of no fewer than twelve (12) 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 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. Demonstrate ability to conduct patient assessments		
d. Demonstrate ability to order and evaluate laboratory or clinical tests.		
e. Demonstrate ability to perform the administration of medicinal drugs.		
f. 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.		
Place holder to discuss additional requirement regarding interaction with physicians et al pursuant to written collaborative practice agreement		

(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,\_\_\_\_\_.*

Dr. Angela Garcia, Consultant Pharmacist, addressed the Committee.

Board Counsel, Mr. Flynn, provided an overview of the history of the Rule.

Dr. Dan Buffington, Clinical Pharmacology Services, addressed the Committee.

Dr. Bill Kernan, President of the Florida Society of Health System Pharmacists, addressed the Committee.

John Armitstead, Pharmacist from Lee Memorial Health, addressed the Committee.

Dr. Kathy Baldwin, a Representative from FSHP, addressed the Committee.

Dr. Mesaros, addressed the Committee and stated that based on discussion the Committee is considering amending the rule to remove the consultant pharmacist course as it is taught within the course curriculum within a pharmacy program.

After Discussion, the Committee proposed the followed amendments to the Rule.

**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), 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.

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

(b) Successfully complete a consultant pharmacist course of no fewer than twelve (12) 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 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:~~

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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.		

<del>c. Demonstrate ability to conduct patient assessments</del>		
<del>d. Demonstrate ability to order and evaluate laboratory or clinical tests.</del>		
<del>e. Demonstrate ability to perform the administration of medicinal drugs.</del>		
<del>e. f. 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.</del>		
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.

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29-10, 6-23-16,\_\_\_\_\_.

Motion: by Dr. Mikhael to accept the proposed amended language  
Second by Dr. Hickman  
Vote: Unanimous

Board Counsel, Dr. Flynn addressed the Committee and advised that the proposed changes would require amendments to the current application and proposed reviewing the final language at the next Rules Committee Meeting.

The committee reviewed and discussed Rule 64B16-26.301 and considered what language would need to be incorporated in Rule 64B16-26.300.

Board Counsel, Mr. Dierlam addressed the Committee and confirmed that based on the discussion he would amend the proposed rule language to combine the training requirements from 64B16-26.301 into 64B16-26.300.

**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.

(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.

6. Conducting patient assessments.

7. Administration of medication.

8. Ordering and evaluation of laboratory or clinical tests.

(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

(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.
  - (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.
- (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, \_\_\_\_\_.*

Dr. Kathy Baldwin addressed the Committee.

Board Counsel, Mr. Dierlam addressed the Committee and advised that he will review the additional rules that regulate Consultant Pharmacists to address the concerns of the Committee.

Mary Thomas, Representative from the Florida Medical Association (FMA), addressed the Committee and relayed that on behalf of the FMA and the Florida Osteopathic Medical Association (FOMA), they were in objection of removing the preceptor requirements from Rule 64B16-26.300.

Michael Jackson, President of the FPA, addressed the Committee regarding the preceptorship training.

Joseph Skurl addressed the Committee regarding the two distinct paths of Consultant Pharmacists.

Motion: by Dr. Mikhael to amend Rule 64B16-26.300(3)(b) and remove “sponsored by an accredited college of pharmacy”, and the course should be no fewer than 16 hours and directed Counsel to provide amended rule language at the next Rules Committee meeting.

Second: by Mr. Philip

The Committee allowed for public comment.

Steve Grabowski addressed the Committee.

Vote: Unanimous

**64B16-27.120 Ordering and Evaluation of Laboratory Tests.**

~~Those consultant pharmacists and pharmacists holding the Doctor of Pharmacy degree that meet the continuing education requirements of Rule 64B16-26.320, F.A.C., may order and evaluate laboratory tests to the extent allowed by the provisions of Section 465.0125, F.S. Evidence of such training and authorization to perform these tasks shall be furnished to the board, the patient, or the patient’s physician upon request.~~

~~Rulemaking Authority 465.0125(3) FS. Law Implemented 465.0125(2) FS. History–New 2-23-98, Repealed \_\_\_\_\_.~~

Motion: by Dr. Mikhael to approve the repeal of Rule 64B16-27.120 as it is already outlined in the statute and present to the full Board.

Second: by Mr. Philip  
Vote: Unanimous

The Committee reviewed the correspondence from the Florida Society of Health System Pharmacists (FSHP).

To allow for public comment this discussion along with the applicable rules will be tabled to the next Committee meeting.

Motion: by Mr. Philip to move the FSHP correspondence to the next Committee Meeting.  
Second: by Mr. Wright  
Vote: Unanimous

At this time the Committee allowed for public comment.

Kathy Baldwin, FSHP, addressed the Committee regarding HB 59.

### **III. ADJOURNMENT**

There being no further business the meeting adjourned at 11:20 a.m.