BOARD OF PHARMACY
RULES COMMITTEE MEETING
DRAFT MINUTES
June 9, 2021
9:00 a.m. ET
Holiday Inn Orlando Disney Springs
1805 Hotel Plaza Boulevard
Lake Buena Vista, FL 32830
(407) 828-8888

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 Rules Committee meeting to order at 9:00 a.m. ET.

MEMBERS PRESENT
Jeffrey Mesaros, PharmD, JD, Chair
Jeenu Philip, BPharm,
Jonathan Hickman, PharmD
Patty Ghazvini, PharmD, BCGP

STAFF PRESENT
Jessica Sapp, Executive Director
Traci Zeh, Program Administrator

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

COURT REPORTER
Jane Heneghan
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II. RULES DISCUSSION

a. 64B16-28.108, F.A.C., All Permits – Labels and Labeling of Medicinal Drugs

Mr. Richard Montgomery, Board Member, requested the Rules Committee consider the proposed amendments to rule 64B16-28.108, F.A.C.

Mr. Montgomery provided an overview of the language as presented. He explained that there are labeling requirements that differ in an Institutional setting than a Community pharmacy setting.

64B16-28.108 All Permits – Labels and Labeling of Medicinal Drugs.
Each container of medicinal drugs dispensed shall have a label or shall be accompanied by labeling.

(1) Definitions.

(a) "Controlled substance" means any substance named or described in Schedules II-V of Section 893.03, F.S.

(b) "Customized medication package" means a package that:

1. Is prepared by a pharmacist for a specific patient.
2. Is a series of containers.
3. Contains two (2) or more solid oral dosage forms.

(c) “Labeling” means a label or other written, printed, or graphic material upon an agent or product or any of its containers, wrappers, drug carts, or compartments thereof, as well as a medication administration record (MAR) if a medication administration record is an integral part of the unit dose system.

(d) “Radiopharmaceutical” means any substance defined as a drug in Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any of those drugs intended to be made radioactive. This includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance, but does not include drugs which are carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(e) “Serial number” means a prescription number or other unique number by which a particular prescription or drug package can be identified.

(2) The label affixed to each container dispensed to a patient shall include:

(a) Name and address of the pharmacy.

(b) Date of dispensing.

(c) Serial number.

(d) Name of the patient or, if the patient is an animal, the name of the owner and the species of animal.

(e) Name of the prescriber.

(f) Name of the drug dispensed (except where the prescribing practitioner specifically requests that the name is to be withheld).

(g) Directions for use.

(h) An Expiration Date or Beyond-Use Date: The expiration date must be the date provided by the manufacturer, repackager, or other distributor. The beyond-use date must not exceed the expiration date and it shall not be a date greater than one year from the date the medicinal drug is filled. The board finds that the use of a “discard-after-date” or “do not use after date” to be equivalent of a beyond-use date.

(i) If the medicinal drug is a controlled substance, a warning that it is a crime to transfer the drug to another person.

(3) The label on the immediate container of a repackaged product or a multiple unit prepackaged drug product shall include:

(a) Brand or generic name.

(b) Strength.

(c) Dosage form.

(d) Name of the manufacturer.

(e) Expiration date.

(f) Lot number:

1. Manufacturer’s lot number; or

2. Number assigned by the dispenser or repackager which references the manufacturer’s lot number.

(4) A medicinal drug dispensed in a unit dose system by a pharmacist shall be accompanied by labeling. The requirement will be satisfied if, to the extent not included on the label, the unit dose system indicates clearly the name of the resident or patient, the prescription number or other means utilized for readily retrieving the medication order, the directions for use, and the prescriber’s name.

(5) A unit dose system shall provide a method for the separation and identification of drugs for the individual resident or patient.

(6) A customized patient medication package may be utilized if:

(a) The consent of the patient or the patient’s agent has been secured; and,

(b) The label includes:

1. Name, address and telephone number of the pharmacy.

2. Serial number for the customized medication package and a separate serial number for each medicinal drug dispensed.

3. Date of preparation of the customized patient medication package.

4. Patient's name.

5. Name of each prescriber.

6. Directions for use and any cautionary statements required for each medicinal drug.

7. Storage instructions.

8. Name, strength, quantity and physical description of each drug product.

9. A beyond use date that is not more than 60 days from the date of preparation of the customized patient medication package but shall not be later than any appropriate beyond use date for any medicinal drug included in the customized patient medication package.

(7) Compounded intravenous compounds (this does not include plain IV solutions or floor stock) The label shall to include:

1. Names of active ingredients
2. Amounts or concentrations of active ingredients
3. BUD and time
4. Storage requirements (if applicable)
5. Identification of responsible compounding personnel
6. Labels for batch-prepared CSPs must also include: • Control or lot number • ~~Appropriate~~ auxiliary labeling (including precautions) • Device-specific instructions ~~(when appropriate)~~

For patient individualized intravenous preparations the label must also include

1. Patient's name
2. The locaation the medication is to be delivered to
3. Directions for use and applicable accessory and cautionary instructions

Mr. Wright addressed the Committee and suggested the Committee begin the discussion of adding hazardous drugs to the labeling requirements.

Mr. DiFiore, Pharmaceutical Program Manager, addressed the Committee and suggested the rule be specific to define the requirements for a Community Pharmacy and an Institutional Pharmacy separately as the requirements can differ.

Mr. Flynn addressed the Committee and requested they allow Board Counsel to further research the implications of further outlining the rule and continue the discussion at the next Committee Meeting with proposed language.

Gillian Staikos, Senior Pharmacists, addressed the Committee regarding the importance of inspectors knowing where the drugs were compounded and what Class III Institution they were received from.

Motion: by Mr. Philip to approve the proposed language as amended and present to the Full Board.
Second: by Dr. Hickman
Vote: Unanimous

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

Vote: Unanimous
Motion: by Dr. Hickman to find that no part of this rule or a violation of this rule should be designated as a minor violation.
Second: by Mr. Philip
Vote: Unanimous

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

b. 64B16-28.830, F.A.C., Special – Closed System Pharmacy

During the June 4, 2020 Board Meeting the Board reviewed a Petition for Variance of Waiver of rule 64B16-28.830, F.A.C., to allow Guardian Pharmacy's seven special closed system pharmacy locations to dispense prescription drugs to their employees and immediate relatives.

The Board requested for this rule to be placed on the agenda for further discussion and possible amendments. Board Counsel provided proposed language for the Committee's review.

64B16-28.830 Special – Closed System Pharmacy.

(1) A Special – Closed System Pharmacy permit is a type of special pharmacy as provided for by section 465.0196, F.S., which dispenses medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, ALF's (Adult Congregate Living Facilities), ICF-IIDs (Intermediate Care Facilities – Developmentally Delayed, also known as ICF – Individuals with Intellectual Disabilities), or other custodial care facilities when defined by AHCA rules and which the Board may approve.

(2) A special – closed system pharmacy permittee shall maintain a policy and procedure manual including drug procurement, storage, handling, compounding, dispensing, record keeping and disposition, as well as procedures for preventing the dispensing of controlled substances based upon fraudulent prescriptions.

(3) A special – closed system pharmacy permittee shall provide twenty-four-hour emergency and on-call service.

(4) A special – closed system pharmacy permittee may dispense parenteral and enteral medications as provided by rule.

(5) A special – closed system pharmacy permittee shall be under the supervision of a prescription department manager who is responsible for maintaining all drug records, providing security of the prescription department and following other rules as relate to the practice of pharmacy. The prescription department manager of a closed system pharmacy shall not be the prescription department manager of any other pharmacy permit except when the permit is within the premises of a community pharmacy permit.

(6) The utilization of registered pharmacy interns and registered pharmacy technicians is as provided by rules 64B16-26.400, 64B16-27.4001, 64B16-27.410, and 64B16-27.420, F.A.C.

(7) A special – closed system pharmacy may dispense medicinal drugs for outpatient use to their employees, their employees' spouses, and their employees' dependents.

Mr. Wright has also provided proposed language for the Committee's review.

64B16-28.830 Special – Closed System Pharmacy.

(1) A Special – Closed System Pharmacy permit is a type of special pharmacy as provided for

by section 465.0196, F.S., which dispenses medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, ALF's (Adult Congregate Living Facilities), ICF-IIDs (Intermediate Care Facilities – Developmentally Delayed, also known as ICF – Individuals with Intellectual Disabilities), Patient Centered Medical Home, or other custodial care facilities when defined by AHCA rules and which the Board may approve.

(7) A special – closed system pharmacy may dispense medicinal drugs for outpatient use to their employees, their employees' spouses, and their employees' dependents.

Motion: by Dr. Hickman to approve the proposed language submitted by Board Counsel and present to the Full Board.
Second: by Dr. Ghazvini
Vote: Unanimous

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

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

The rule will be placed on a future Committee agenda to consider Mr. Wrights proposed language.

c. 64B16-30.001, F.A.C., Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances
    i. HB 241: Parents' Bill of Rights
    ii. SB 1934: Health Care Practitioner Discipline

Ms. Sapp provided an overview of HB 241 and SB 1934.

Board Counsel provided proposed language for the Committee's review to comply with the law changes to Section 456.072, Florida Statutes.

28. Failure to comply with the parental consent requirements of s. 1014.06 (Section 456.072(1)(rr), F.S.)	MIN: Reprimand and a fine of $250; MAX: $500 fine and one (1) year of probation.	MIN: $500 fine and one (1) year of probation; MAX: Revocation.	MIN: Reprimand; MAX: Suspension and corrective action plan.	MIN: Suspension and corrective action plan; MAX: Revocation.

29. Being convicted or found guilty of, entering a plea of guilty or nolo contender to, regardless of adjudication or committing or attempting, soliciting, or conspiring to commit an act that would constitute a violation of any of the offenses listed in s. 456.074(5) or similar offense in another jurisdiction. (Section 456.072(1)(ss), F.S.)	MIN: $10,000 fine and Revocation MAX: $10,000 fine and Revocation	.	MIN: $10,000 fine and Revocation MAX: $10,000 fine and Revocation	

The board shall be entitled to deviate from the above-mentioned guidelines upon a showing of aggravating or mitigating circumstances ~~by clear and convincing evidence~~ presented to the board prior to the imposition of a final penalty.

(a) Aggravating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the enhancement of a penalty beyond the maximum level of discipline in the guidelines shall include but not be limited to the following:

1. History of previous violations of the practice act and the rules promulgated thereto.

2. ~~In the case of negligent acts~~, The magnitude and scope of the damage or potential damage inflicted upon the patient or the general public by the licensee's misfeasance.

3. Evidence of violation of professional practice acts in other jurisdictions wherein the licensee has been disciplined by the appropriate regulatory authority.

4. Harm occurred ~~or potential harm~~.

(b) Mitigating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the lessening of a penalty beyond the minimum level of discipline in the guidelines shall include but not be limited to the following:

1. ~~In cases of negligent acts,~~ the minor nature of the damage or potential damage to the patient's or the public's health, safety, and welfare resulting from the licensee's misfeasance.

2. Lack of previous disciplinary history in this or any other jurisdiction wherein the licensee practices his profession.

3. Restitution of any monetary damage suffered by the patient.

4. The licensee's professional standing among his peers.

5. Steps already taken by the licensee to insure the non-occurrence of similar violations in the future, including continuing education.

6. The degree of financial hardship incurred by a licensee as a result of the imposition of fines or the suspension of his practice.

(4) All fines imposed by the Board shall be paid within a period of ninety (90) days from the date of the final order entered by the Board. This time limitation may be modified by the Board for good cause shown in order to prevent undue hardship.

Motion: by Mr. Philip to approve the proposed language and present to the Full Board.
Second: by Dr. Ghazvini
Vote: Unanimous

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

Board Counsel indicated that no part of this rule or a violation of this rule should be designated as a minor violation as the rule being amended is the disciplinary guidelines.

d. SB 768: Administration of Vaccines
    i. 64B16-26.1031, F.A.C., Vaccine Certification Program

Ms. Sapp provided an overview of SB 768.

Board Counsel provided proposed language for the Committee's review to comply with the law changes to Section 465.189, Florida Statutes.

64B16-26.1031 Vaccine Certification Program.

(1) All applications for vaccine certification programs shall be made on board approved form DH-MQA 1234, "Board of Pharmacy Immunization Certification Program Provider Application," dated 08/15, which is hereby incorporated by reference. To obtain an application go to http://www.flrules.org/Gateway/reference.asp?No=Ref-06807, or contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850)488-0595, or download the application from the web at ~~http://www.doh.state.fl.us/mqa/pharmacy~~ https://floridaspharmacy.gov.

(2) The Board shall approve for initial certification of pharmacist and pharmacy intern administration of vaccines, programs of study not less than 20 hours that include coursework covering all of the following:

(a) Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

(b) Immunization Schedules;

(c) Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry;

(d) Vaccine storage and handling;

(e) Bio-Hazardous waste disposal and sterile techniques;

(f) Entering, negotiating and performing pursuant to physician oversight protocols;

(g) Community immunization resources and programs;

(h) Identifying, managing and responding to adverse incidents including but not limited to potential allergic reactions associated with vaccine administration;

(i) Procedures and policies for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS);

(j) Reimbursement procedures and vaccine coverage by federal, state and local governmental jurisdictions and private third party payors;

(k) Administration techniques;

(l) Administration of epinephrine using an autoinjector delivery system;

(m) The immunization and vaccine guidelines in the ~~February 1, 2015~~ February 11, 2021, Adult Immunization Schedule by the United States Centers for Disease Control and Prevention, entitled "Recommended Adult Immunization Schedule – United States – ~~2015~~ 2021," which is hereby incorporated by reference. The Schedule may be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-06808, and the Board office at the address in

subsection (1);

(n) The immunizations or vaccines recommended by the United States Centers for Disease Control and Prevention for international travel as of ~~July 1, 2015~~ April 30, 2021, which may be found in the CDC Health Information for International Travel (~~2014~~ 2020 Edition), which is incorporated herein by reference. The material incorporated is copyrighted material that is available for public inspection and examination, but may not be copied, at the Department of State, Administrative Code and Register Section, Room 701, The Capitol, Tallahassee, Florida 32399-0250, and at the Board office at the address in subsection (1);

(o) State of emergency administration of immunizations or vaccines;

(p) Review of Section 465.189, F.S.; and,

(q) Cardiopulmonary Resuscitation (CPR) training.

Successful completion of the certification program must include a successful demonstration of competency in the administration technique and a cognitive examination.

Motion: by Dr. Hickman to approve the proposed language and present to the Full Board.
Second: by Dr. Ghazvini
Vote: Unanimous

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

Motion: by Dr. Hickman to find that no part of this rule or a violation of this rule should be designated as a minor violation.
Second: by Dr. Ghazvini
Vote: Unanimous

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

ii. 64B16-27.630, F.A.C., Additional Immunizations or Vaccines Which May Be Administered

~~**64B16-27.630 Additional Immunizations or Vaccines Which May Be Administered.**~~

~~In addition to the immunizations or vaccines listed in the United States Centers for Disease Control and Prevention Adult Immunization Schedule as of February 1, 2015, the Board hereby authorizes administration of the following additional immunizations or vaccines by persons certified pursuant to Section 465.189, F.S.~~

~~(1) Meningococcal B (MenB).~~

~~(2) Zoster Vaccine Recombinant, Adjuvanted.~~

Motion: by Dr. Hickman to approve the repeal of rule 64B16-27.630, F.A.C., and present to the Full Board.
Second: by Dr. Mesaros
Vote: Unanimous

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

e. SB 262: Dispensing Medicinal Drugs
    i. 64B16-28.6021, F.A.C., Institutional Class II and Class III Pharmacy - Emergency Department Dispensing

Ms. Sapp provided an overview of SB 262.

Board Counsel provided proposed language for the Committee's review to comply with the law changes to Section 465.019, Florida Statutes.

64B16-28.6021 Institutional Class II and Class III Pharmacy – Emergency Department Dispensing.

(1) Individuals licensed to prescribe medicinal drugs in this state may dispense from the emergency department of a hospital holding a Class II or Class III, Institutional pharmacy permit. Such dispensing must meet the requirements provided in subsection 465.019(4), F.S., and this section.

(2) The following records of prescribing and dispensing must be created by the prescriber/dispenser and maintained by the consultant pharmacist of record within the facility:

(a) Patient name and address.
(b) Drug and strength prescribed/dispensed.
(c) Quantity prescribed/dispensed.
(d) Directions for use.
(e) Prescriber/dispenser.
(f) Prescriber DEA registration, if applicable.
(g) Reason community pharmacy services were not readily accessible.

(3) Labeling of the prescription container must meet the requirements of section 465.0276, F.S.

~~(4) Quantity dispensed must not exceed a 24-hour supply or the minimal dispensable quantity, whichever is greater.~~

Motion: by Dr. Hickman to approve the proposed language and present to the Full Board.
Second: by Dr. Ghazvini
Vote: Unanimous

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

Motion: by Dr. Hickman to find that no part of this rule or a violation of this rule should be designated as a minor violation.
Second: by Dr. Ghazvini
Vote: Unanimous

Motion: by Dr. Hickman to find that this rule shall not include a sunset provision.
Second: by Dr. Ghazvini

Vote: Unanimous

f. 64B16-26.1004, F.A.C. Inactive License Election; Renewal; Fees

Board Staff recently discovered a discrepancy with the inactive renewal fee. Section 465.012(2), Florida Statutes, requires that an inactive renewal fee may not exceed the active renewal fee. Currently a licensed pharmacist is charged $245.00 to either one, place their license on inactive status during renewal or two, renew their inactive license. The current active licensure renewal fee is $200.00. This was placed on the agenda for amendments to adhere to statutory requirements.

64B16-26.1004 Inactive License Election; Renewal; Fees.

(1) A pharmacist licensee may elect:

(a) At the time of license renewal to place the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of ~~$245~~ $200 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of ~~$245~~ $200 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status, submits the reactivation fee of $70, and the current active renewal fee set forth in Rule 64B16-26.1001, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status and submits the reactivation fee of $70, a change of status fee of $25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(2) A consultant pharmacist licensee may elect:

(a) At the time of license renewal to place the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the consultant pharmacist license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status consultant pharmacist license to active status, provided the consultant pharmacist licensee meets the continuing education requirements of subsection 64B16-26.103(2), F.A.C., for each biennium the license was on inactive status and by submitting a reactivation fee of $25, and the active consultant pharmacist renewal fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status, and submits the reactivation fee of $25, a change of status fee of $25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(3) A nuclear pharmacist licensee may elect:

(a) At the time of license renewal to place the nuclear pharmacist license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the nuclear pharmacist license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status license to active status, provided the nuclear pharmacist meets the continuing education requirements of Rule 64B16-26.304, F.A.C., for each biennium the license was on inactive status, and by submitting a reactivation fee of $50, and the active nuclear license renewal fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the nuclear pharmacist licensee meets the continuing education requirements of Rule 64B16-26.304, F.A.C., for each biennium the license was on inactive status and by submitting a reactivation fee of $50, a change of status fee of $25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(4) A registered pharmacy technician may elect:

(a) At the time of renewal to place the registered pharmacy technician registration on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of renewal, if the registered pharmacy technician registration is inactive, to continue the registration on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of renewal to change the inactive status registration to active status, provided the registered pharmacy technician meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the registration was on inactive status, and by submitting a reactivation fee of $50, and the active registration fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than renewal to change the inactive status registration to active status, provided the registered pharmacy technician meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the registration was on inactive status and by submitting a reactivation fee of $50, a change of status fee of $25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

Motion: by Dr. Hickman to approve the proposed language and present to the Full Board.
Second: by Dr. Ghazvini
Vote: Unanimous

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

Motion: by Dr. Hickman to find that no part of this rule or a violation of this rule should be designated as a minor violation.
Second: by Mr. Philip
Vote: Unanimous

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

g. 465.0235, F.S., Automated pharmacy systems used by long-termcare facilities, hospices, or state correctional institutions, or for outpatient dispensing

The Florida Pharmacy Association (FPA) submitted a petition to initiate rulemaking to adopt rules implementing section 465.0235, Florida Statutes. This petition was denied during the April 14, 2021 Rules Committee meeting. The Committee requested this be placed on the June meeting to continue the discussion for possible amendments to Rule 64B16-27.4001, F.A.C., Delegation to and Supervision of Pharmacy Technician; Responsibility of Supervising Pharmacist. The was placed on the agenda for further discussion.

After discussion the Committee identified that the requirements of an automated pharmacy system are outlined in the statute and there would be no need to additional rule making.

III. NEW/OLD BUSINESS

a. White and Brown Bagging Emerging Practices

The Board of Pharmacy received correspondence from the Florida Society of Health System Pharmacists, Inc (FSHP) regarding White and Brown Bagging Practices. This was placed on the April 14, 2021 Rules Committee agenda for discussion. The Committee continued the discussion at the June meeting.

After discussion the Committee advised Board Staff to request volunteers from the Full Board to create an Ad Hoc Committee to continue the discussion and review the concerns presented to the Committee.

Mr. Philip confirmed the NABP would be forming a Committee and meeting this fall to discuss this topic as a number of other state Boards are having a similar discussion.

Jeff Bush, President of the Florida Society of Health-System Pharmacists (FSHP), addressed the Committee and confirmed FSHP would like to be apart of the discussion.

At this time the Board recognized Mr. Richard Montgomery for his time and service on the Board.

IV. ADJOURNMENT

There being no further business the meeting adjourned at 12:15 p.m. ET.