BOARD OF PHARMACY
RULES COMMITTEE MEETING
DRAFT MINUTES
June 15, 2022
1:00 p.m. ET
Rosen Plaza Hotel
9700 International Drive
Orlando, FL 32819
(407) 996-9700

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 1:00 p.m. ET.

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

STAFF PRESENT
Traci Zeh, Program Administrator
Genessis Mills, Senior Management Analyst

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

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II. RULES DISCUSSION

a. 64B16-26.1031. F.A.C., Vaccine Certification Program

HB 1209 authorizes a certified registered pharmacy technician to administer vaccines and immunizations to adults under the supervision of a certified pharmacist. To become certified by the Board of Pharmacy, a registered pharmacy technician must complete six hours of approved immunization-related training. As a renewal condition, an additional two hours of approved continuing education must be completed.

Due to the legislative change the following proposed rule language was provided for the Committees review.

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 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 11, 2021, Adult Immunization Schedule by the United States Centers for Disease Control and Prevention, entitled "Recommended Adult Immunization Schedule – United States – 2021," which is hereby incorporated by reference. The Schedule may be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-13874, 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 April 30, 2021, which may be found in the CDC Health Information for International Travel (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.

(3) The Board shall approve for initial certification of registered pharmacy technician administration of vaccines, programs of study, accredited by the Accreditation Council for Pharmacy Education (ACPE), not less than 6 hours that include coursework covering all of the following:

(a) Technique for drawing up and administering immunizations in a safe and effective manner

(b) Administration routes

(c) Recognizing and responding to allergic vaccine reactions and other emergency situations

(d) Needle selection based on vaccines and patient age and size

(e) Documentation procedures

(f) Procedures and requirements for vaccine recalls

(g) Live demonstration of a successful technique when administrating an intramuscular and

subcutaneous injection which shall include distraction techniques during administration and universal precautions as they pertain to blood borne pathogens.

Dr. Ghazvini addressed the Committee regarding what would be considered live courses.

Dr. Hickman addressed the Committee and Dr. Ghazvini stating the Committee should not redefine live courses within our rule as continuing education can be completed virtually and be considered for live credit.

Mr. Philip addressed the Committee in agreeance in Dr. Hickman.

Dr. Ghazvini stated the administration technique should be taught and completed live meaning “in person”.

Dr. Segovia addressed the Committee and suggested changing the language to the following: (g) A real time competency validation through the observation and return demonstration of a complete successful administration of an intramuscular and subcutaneous injection to a human being which shall include distraction techniques during the administration and universal precautions as they pertain to blood borne pathogens. She also suggested that CPR should be listed as a requirement of the certification.

Michael Jackson, Florida Pharmacy Association (FPA) President, addressed the Committee regarding the process of approval of courses which includes being reviewed by the Tripartite Committee. He stated the Committee is very knowledgeable and will assure compliance with the rule before approval.

Dr. Hickman addressed the Committee regarding the CPR requirement and reiterated the responsibility of CPR lies with the pharmacists as the pharmacist will be supervising the technicians’ providing immunizations. He stated the addition of CPR would not be needed in the rule language.

Mr. Philip addressed the Committee in agreeance with Dr. Hickman.

Suzanne Peerney, Representative from CEimpact, addressed the Committee regarding the success of their training when offered virtually and stated that virtual learning is becoming a “best in class” process.

Lauren Paul, CVS Health, addressed the Committee regarding the CPR requirement of CVS employees.

After the discussion the Committee did not move forward with adding CPR as a requirement of the initial course content.

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

Motion: by Dr. Hickman to find no economic impact, to find that a Statement of Estimated Regulatory Cost was not necessary, that the rule will not need legislative ratification, that this rule or a violation of this rule should not be designated as a minor violation and to find that this rule shall not include a sunset provision
Second: by Mr. Wright
Vote: Unanimous

g. 64B16-26.103 Continuing Education Credits; Renewal

Due to the legislative change in HB 1209 the following proposed rule language was provided for the Committees review.

64B16-26.103 Continuing Education Credits; Renewal

(1)Prior to biennal renewal of pharmacist licensure, a licensee shall complete no less than 30 hours of approved courses of continued professional pharmaceutical education within the 24 month period prior to the expiration date of the license. The following conditions shall apply.

(a) Upon a licensee's first renewal of licensure, the licensee must document the completion of one (1) hour of board approved continuing education which includes the topics of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome; the modes of transmission, including transmission from a healthcare worker to a patient and the patient to the healthcare worker; infection control procedures, including universal precautions; epidemiology of the disease; related infections including tuberculosis (TB); clinical management; prevention; and current Florida law on AIDS and its impact on testing, confidentiality of test results, and treatment of patients. In order to meet this requirement, licensees must demonstrate that the course includes information on the State of Florida law on HIV/AIDS and its impact on testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to Sections 381.004 and 384.25, F.S. Any HIV/AIDS continuing education course taken during the second or subsequent renewal of licensure may be applied to satisfy the general continuing education hours requirement.

(b) The initial renewal of a pharmacist license will not require completion of courses of continued professional pharmaceutical education hours if the license was issued less than 12 months prior to the expiration date of the license. If the initial renewal occurs 12 months or more after the initial licensure, then 15 hours of continued professional pharmaceutical education hours shall be completed prior to the renewal of the license but no earlier than the date of initial licensure.

(c) Prior to renewal a licensee must complete, within the 24 month period prior to the expiration date of the license, a two-hour continuing education course approved in advance by the Board on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. Hours obtained pursuant to this section may be applied by the licensee to the requirements of subsection (1).

(d) Five hours of continuing education in the subject area of risk management may be obtained by attending one full day or eight (8) hours of a board meeting at which disciplinary hearings are conducted by the Board of Pharmacy in compliance with the following:

1. The licensee must sign in with the Executive Director or designee of the Board before the meeting day begins,

2. The licensee must remain in continuous attendance,

3. The licensee cannot receive continuing education credit for attendance at a board meeting if required to appear before the board; and,

4. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(e) A member of the Board of Pharmacy may obtain five (5) hours of continuing education in the subject area of risk management for attendance at one Board meeting at which disciplinary

hearings are conducted. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(f) Up to five hours per biennium of continuing education credit may be fulfilled by the performance of volunteer services to the indigent as provided in Section 456.013(9), F.S., or to underserved populations, or in areas of critical need within the state where the licensee practices. In order to receive credit, the licensee must make application to and receive approval in advance from the Board. Application shall be made on form DH-MQA 1170 (Rev. 02/09), Individual Request for Continuing Education for Volunteers, which is hereby incorporated by reference. The form can be obtained from the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254. One hour credit shall be given for each two hours volunteered in the 24 months prior to the expiration date of the license. In the application for approval, the licensee shall disclose the type, nature and extent of services to be rendered, the facility where the services will be rendered, the number of patients expected to be serviced, and a statement indicating that the patients to be served are indigent. If the licensee intends to provide services in underserved or critical need areas, the application shall provide a brief explanation as to those facts. A licensee who is completing community service as a condition of discipline imposed by the board cannot use such service to complete continuing education requirements.

(g) Continuing education credit shall be granted for completion of post professional degree programs provided by accredited colleges or schools of pharmacy. Credit shall be awarded at the rate of 5 hours of continuing education credit per semester hour completed within the 24 months prior to the expiration date of the license.

(h) Continuing education may consist of post-graduate studies, institutes, seminars, lectures, conferences, workshops, correspondence courses, or other educational opportunities which advance the practice of the profession of pharmacy if approved by the Board. A course shall be approved prior to completion and will be evaluated by the Tripartite Committee using the standards found in Rule 64B16-26.601, F.A.C. Individuals must submit requests for course approval at least 45 days in advance of the program or course by completing the approved application form DOH/MQA/PH 112, (Rev. 6/12), entitled Individual Requests for Continuing Education Credit, which is incorporated by reference, and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-01636, and the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or from the website located at http://www.doh.state.fl.us/mqa/pharmacy. Individuals seeking course approval must attach to the application a detailed program outline, overview or syllabus which describes the educational content, objectives and faculty qualifications.

(i) Any volunteer expert witness who is providing expert witness opinions for cases being reviewed by the Department of Health pursuant to Chapter 465, F.S., shall receive five (5) hours of credit in the area of risk management for each case reviewed in the 24 months prior to the expiration date of the license, up to a maximum of ten (10) hours per biennium.

(j) The presenter of a live seminar, a live video teleconference or through an interactive computer-based application shall receive 1 credit for each course credit hour presented, however presenter will not receive additional credit for multiple same course presentations.

(k) All programs approved by the ACPE for continuing education for pharmacists are deemed approved by the Board for general continuing education hours for pharmacists. Any course necessary to meet the continuing education requirement for HIV/AIDS, medication errors, or consultant pharmacist license renewal shall be Board approved.

(l) General continuing education earned by a non-resident pharmacist in another state that is not ACPE approved, but is approved by the board of pharmacy in the state of residence can be applied to meet the requirements of license renewal in subsection (1), above.

(m) At least ten (10) of the required 30 hours must be obtained either at a live seminar, a live

video teleconference, or through an interactive computer-based application.

(2) Prior to renewal a consultant pharmacist shall complete no less than 24 hours of Board approved continuing education in the course work specified in Rule 64B16-26.302, F.A.C., within the 24 month period prior to the expiration date of the consultant license. The hours earned to satisfy this requirement cannot be used to apply toward the 30 hours required in subsection (1), above. However, if consultant recertification hours are earned and not used to meet the requirements of this paragraph, they may be applied by the licensee to the 30 hours required in subsection (1).

(a) If the initial renewal of a consultant pharmacist license occurs less than 12 months after the initial licensure, then completion of consultant courses of continuing education hours will not be required.

(b) If the initial renewal of a consultant pharmacist license occurs 12 months or more after the initial licensure, then 12 hours of consultant continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(3) Prior to renewal a nuclear pharmacist shall complete no less than 24 hours of Board approved continuing education in the course work specified in Rule 64B16-26.304, F.A.C., within the 24 month period prior to the expiration date of the nuclear pharmacist license. The hours earned to satisfy this requirement cannot be used to apply toward the 30 hours required in subsection (1), above. However, if nuclear pharmacist license renewal hours are earned and not used to meet the requirements of this paragraph, they may be applied by the licensee to the 30 hours required in subsection (1).

(a) If the initial renewal of a nuclear pharmacist license occurs less than 12 months after the initial licensure, then completion of courses of nuclear pharmacy continuing education hours will not be required.

(b) If the initial renewal of a nuclear pharmacist license occurs 12 months or more after the initial licensure, then 12 hours of nuclear pharmacy continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(c) All programs approved by the ACPE for continuing education for nuclear pharmacists are deemed approved by the Board for general continuing education hours for nuclear pharmacists.

(4) Prior to renewal a registered phamacy technician shall complete no less than twenty (20) hours of Board approved continuing education in the course work specified in Rule 64B16-26.355, F.A.C., within the 24 month period prior to the expiration date of the phamacy technician registration. For a registered pharmacy technician that maintains an immunization certification, an additional two (2) hours of continuing education is required in the area of vaccine administration.

(a) Upon a pharmacy technician's first renewal, registrtant must document the completion of one (1) hour of board approved continuing education which includes the topics of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome; the modes of transmission, including transmission from a healthcare worker to a patient and the patient to the healthcare worker; infection control procedures, including universal precautions; epidemiology of the disease; related infections including tuberculosis (TB); clinical management; prevention; and current Florida law on AIDS and its impact on testing, confidentiality of test results, and treatment of patients. In order to meet this requirement, licensees must demonstrate that the course includes information on the State of Florida law on HIV/AIDS and its impact on testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to Sections 381.004 and 384.25, F.S. Any HIV/AIDS continuing education course taken during the second or subsequent renewal of registration may be applied to satisfy the general continuing education hours requirement.

(b) If the initial renewal of a pharmacy technician registration occurs less than 12 months after the initial licensure, then completion of courses of a pharmacy technician registration education

hours will not be required.

(c) If the initial renewal of a pharmacy techician registration occurs 12 months or more after the initial licensure, then 12 hours of registered phamacy technician continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(d) All programs approved by the ACPE for continuing education for pharmacy technicians are deemed approved by the Board for general continuing education hours for registered pharmacy technicians. Any course necessary to meet the continuing education requirement for HIV/AIDS license renewal shall be Board approved.

(e) Prior to renewal a licensee must complete, within the 24 month period prior to the expiration date of the license, a two-hour continuing education course approved in advance by the Board on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. Hours obtained pursuant to this section may be applied by the licensee to the requirements of subsection (1).

(f) Five hours of continuing education in the subject area of risk management may be obtained by attending one full day or eight (8) hours of a board meeting at which disciplinary hearings are conducted by the Board of Pharmacy in compliance with the following:

1. The registratrant must sign in with the Executive Director or designee of the Board before the meeting day begins,

2. The registrant must remain in continuous attendance,

3. The registrant cannot receive continuing education credit for attendance at a board meeting if required to appear before the board; and,

4. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(g) At least four (4) of the required 20 hours must be obtained either at a live seminar, a live video teleconference, or through an interactive computer-based application.

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

Motion: by Dr. Hickman to find no economic impact, to find that a Statement of Estimated Regulatory Cost was not necessary, that the rule will not need legislative ratification, that this rule or a violation of this rule should not be designated as a minor violation and to find that this rule shall not include a sunset provision
Second: by Mr. Wright
Vote: Unanimous

b. Annual Regulatory Plan

Mr. Flynn addressed the Committee regarding the Annual Regulatory Plan (ARP).

Motion: by Dr. Hickman to delegated Dr. Mesaros to coordinate with Board Counsel and sign off on the ARP.
Second: Dr. Ghazvini
Vote: Unanimous

c. Joint Administration Procedures Committee Correspondence

Mr. Flynn addressed the Committee and provided a brief description of JAPC and the provided correspondence.

i. 64B16-27.211, F.A.C., Prescription Refills
ii. 64B16-27.410, F.A.C., Registered Pharmacy Technician to Pharmacist Ratio
iii. 64B16-27.520., F.A.C., Positive Drug Formulary

Mr. Flynn indicated the comments and changes to these rules would be corrected with a technical change.

iv. 64B16-27.615, F.A.C., Possession and Disposition of Sample Medicinal Drugs

Mr. Flynn indicated this rule would be placed on the ARP for review and possible amendments.

v. 64B16-27.831, F.A.C., Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronics Prescribing; Mandatory Continuing Education

Mr. Flynn indicated this rule would be placed on the ARP for review and possible amendments.

vi. 64B16-27.850, F.A.C., Standards of Practice for Orthotics and Pedorthics
vii. 64B16-27.851, F.A.C., Record-Keeping for Orthotics and Pedorthics

Mr. Flynn indicated the comments and changes to these rules would be corrected with a technical change.

b. 64B16-28.140, F.A.C., Record Maintenance Systems for All Pharmacy Permits

Dr. Mesaros provided an overview of the proposed rule.

64B16-28.140 Record Maintenance Systems for All Pharmacy Permits.

(1) Requirements for records maintained in a data processing system.

(a) The pharmacy must comply with the provisions of 21 C.F.R. Section 1304.04 (a regulation of the Federal Drug Enforcement Administration), which is hereby incorporated by reference as of March 1, 1998, when such is applicable to operate such a data processing system if any controlled substances (as that term is used in Chapter 893, F.S.) are dispensed from the pharmacy.

(b) Any pharmacy using a data processing system must meet the requirements of 21 C.F.R. Section 1306.22, which is hereby incorporated by reference as of March 1, 1998.

(c) If a pharmacy's data processing system is not in compliance with this subsection, the pharmacy must maintain a manual recordkeeping system as specified in Rule 64B16-27.800, F.A.C., and Section 893.07, F.S.

(d) Original prescriptions, not received in written form including prescriptions received as provided for in ~~Rule 64B16-28.1003, F.A.C., Transmission of Prescription Orders~~, shall be reduced to writing or recorded electronically if permitted by federal law ~~a hard copy if not received in written form~~. All original prescriptions shall be retained for a period of not less than four (4) years from date of last filling. To the extent authorized by 21 C.F.R. §1304.04, a pharmacy may, in lieu of retaining

the actual original prescriptions, use an electronic imaging recordkeeping system, provided such system is capable of capturing, storing, and reproducing the exact image of the prescription, including the reverse side of the prescription if necessary, and that such image be retained for a period of no less than four (4) years from the date of last filling.

(e) Original prescriptions shall be maintained in a two or three file system as specified in 21 C.F.R. §1304.04(h).

(f) Requirements for back-up systems.

1. The pharmacy shall maintain a back-up copy of information stored in the data processing system using disk, tape or other electronic back-up system and update this back-up copy on a regular basis, at least weekly, to assure that data is not lost due to system failure.

2. Data processing systems shall have a workable (electronic) data retention system which can produce an audit trail of drug usage for the preceding four (4) years as specified in Rule 64B16-27.800, F.A.C.

(g) Change or discontinuance of a data processing system.

1. Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records of dispensing to the new data processing system, or

b. Purge the records of dispensing to a printout which contains the same information required on the daily printout as specified in paragraph (3)(b), of this section. The information on this hard-copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription chronologically.

2. Other records. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system, or

b. Purge the records to a printout which contains all of the information required on the original document.

3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for four (4) years from the date of initial entry into the data processing system.

(h) Loss of Data. The prescription department manager shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(2) All transfers of prescriptions must be strictly in accordance with the provisions of Section 465.026, F.S., and Rule 64B16-27.105, F.A.C.

(3) Records of dispensing.

(a) Each time a prescription drug order is filled or refilled, a record of such dispensing shall be entered into the data processing system.

(b) The data processing system shall have the capacity to produce a daily hard-copy printout of all original prescriptions dispensed and refilled. This hard copy printout shall contain the following information:

1. Unique identification number of the prescription,

2. Date of dispensing,

3. Patient name,

4. Prescribing practitioner’s name,

5. Name and strength of the drug product actually dispensed, if generic name, the brand name or manufacturer of drug dispensed,

6. Quantity dispensed,

7. Initials or an identification code of the dispensing pharmacist; and,

8. If not immediately retrievable via CRT display, the following shall also be included on the

hard-copy printout:

a. Patient's address,

b. Prescribing practitioner's address,

c. Practitioner's DEA registration number, if the prescription drug order is for a controlled substance,

d. Quantity prescribed, if different from the quantity dispensed,

e. Date of issuance of the prescription drug order, if different from the date of dispensing; and,

f. Total number of refills dispensed to date for that prescription drug order.

(c) The daily hard-copy printout shall be produced within 72 hours of the date on which the prescription drug orders were dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of non-controlled substances.

(d) Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document (e.g., J.H. Smith, or John H. Smith) within seven days from the date of dispensing.

(e) In lieu of producing the printout described in paragraphs (b) and (c), of this section, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of four (4) years after the date of dispensing provided, however, that the data processing system can produce the hard-copy printout on demand by an authorized agent of the Department of Health. If no printer is available on site, the hard-copy printout shall be available within 48 hours with a certification by the individual providing the printout, which states that the printout is true and correct as of the date of entry and such information has not been altered, amended or modified.

(f) The prescription department manager and the permit holder are responsible for the proper maintenance of such records and responsible that such data processing system can produce the records outlined in this section and that such system is in compliance with this subsection.

(g) Failure to provide the records set out in this section, either on site or within 48 hours for whatever reason, constitutes failure to keep and maintain records.

(h) In the event that a pharmacy which uses a data processing system experiences system downtime, the following is applicable;

1. An auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded or that authorization from the prescribing practitioner has been obtained prior to dispensing a refill; and,

2. All of the appropriate data shall be retained for online data entry as soon as the system is available for use again.

(4) Compounding records. A written record shall be maintained for each batch/sub-batch of a compounded product under the provisions of Rule 64B16-27.700, F.A.C. This record shall include:

(a) Date of compounding.

(b) Control number for each batch/sub-batch of a compounded product. This may be the manufacture's lot number or new numbers assigned by the pharmacist. If the number is assigned by the pharmacist, the pharmacist shall also record the original manufacture's lot number and expiration dates. If the original numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the component.

(c) A complete formula for the compounded product maintained in a readily retrievable form including methodology and necessary equipment.

(d) A signature or initials of the pharmacist or pharmacy technician performing the

compounding.

(e) A signature or initials of the pharmacist responsible for supervising pharmacy technicians involved in the compounding process.

(f) The name(s) of the manufacturer(s) of the raw materials used.

(g) The quantity in units of finished products or grams of raw materials.

(h) The package size and number of units prepared.

(i) The name of the patient who received the particular compounded product.

(5) Authorization of additional refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:

(a) On the daily hard-copy printout, or

(b) Via the CRT display.

(6) Any other records, policy and procedure manuals, or reference materials which are not specifically required by statute or rule to be kept in a hard copy may be kept in a readily retrievable data processing system which complies with the provisions of subparagraph (1)(f)1.

Dr. Mesaros indicated that the proposed language captures the clarification directly from Chair 893, Florida Statutes.

Motion: by Dr. Hickman to open rule 64B16-28.140 for development and approve the proposed language to be presented to the Full Board.
Second: by Mr. Wright
Vote: Unanimous

Motion: by Dr. Hickman to find no economic impact, to find that a Statement of Estimated Regulatory Cost was not necessary, that the rule will not need legislative ratification, that this rule or a violation of this rule should not be designated as a minor violation and to find that this rule shall not include a sunset provision
Second: by Mr. Wright
Vote: Unanimous

c. 64B16-28.1191, F.A.C., Unclaimed Prescriptions

Dr. Mesaros provided an overview of the current rule and opened the discussion for possible amendments.

64B16-28.1191 Unclaimed Prescriptions.

Prescriptions that are unclaimed may be retained by a pharmacy and reused for a period up to one year from the date of filling; however, any product reaching the product's expiration date prior to one year or any product subject to a recall shall not be reused.

Dr. Mesaros inquired with the Committee regarding a manufactured stock bottle exceeding one year expiration and indicated that would maintain the manufacturer expiration date.

Dr. Segovia addressed the Committee and reiterated there was a difference "discard after" and "expiration date" verbiage.

Mr. Flynn addressed the Committee regarding the statutory requirements of a products expiration date.

Motion: by Dr. Hickman to open rule 64B16-28.1191 for development and approve the following proposed language to be presented to the Full Board

64B16-28.1191 Unclaimed Prescriptions.

Prescriptions that are unclaimed may be retained by a pharmacy and reused for a period up to one year from the date of filling; however, any product reaching the product's expiration date prior to one year or any product subject to a recall shall not be reused. If the unclaimed product is in its original manufacturer's packing, then the expiration date shall revert back to the date as listed on the original manufacturer's packaging.

Second: by Mr. Wright
Vote: Unanimous

Motion: by Dr. Hickman to find no economic impact, to find that a Statement of Estimated Regulatory Cost was not necessary, that the rule will not need legislative ratification, that this rule or a violation of this rule should not be designated as a minor violation and to find that this rule shall not include a sunset provision
Second: by Dr. Ghazvini
Vote: Unanimous

d. 64B16-27.420, F.A.C., Pharmacy Technician – Delegable and Non-Delegable Tasks

During the August 25, 2021 and October 14, 2021 Rules Committee meeting, the Committee reviewed a request from Sr. Director of Pharmacy Affairs for CVS Health, Lauren Paul, PharmD, MS., and proposed the Board discuss 64B16-27.420, F.A.C., to allow technicians to transfer prescriptions verbally. During the discussion Mr. Flynn addressed the Committee regarding 465.026, Florida Statutes, Filling of Certain Prescriptions, and stated the authority lies with the pharmacist. He recommended the Committee place this discussion on a future agenda to allow time to research the statutory authority for rule change.

This will be placed on the agenda for further discussion.

64B16-27.420 Pharmacy Technician – Delegable and Non-Delegable Tasks.

A pharmacy technician may only assist a pharmacist in executing or carrying out the practice of the profession of pharmacy, but shall never themselves engage in the practice of the profession of pharmacy as defined in Chapter 465, F.S. Therefore, pharmacy technicians may only perform delegable tasks as identified and defined pursuant to this rule.

(1) Delegable Tasks – Delegable tasks are those tasks that are performed pursuant to a pharmacist's direction, without the exercise of the pharmacy technician's own judgment and discretion, and which do not require the pharmacy technician to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy.

(2) Non-Delegable Tasks – The following tasks may not be delegated and the pharmacy technician shall not:

(a) Receive new non written prescriptions or receive any change in the medication, strength, or directions of an existing prescription;

(b) Interpret a prescription or medication order for therapeutic acceptability and appropriateness;

(c) Conduct final verification of dosage and directions;

(d) Engage in prospective drug review;
(e) Monitor prescription usage;
(f) Override clinical alerts without first notifying the pharmacist;
(g) Transfer a prescription;
(h) Prepare a copy of a prescription or read a prescription to any person for purposes of providing reference concerning treatment of the person or animal for whom the prescription was written;
(i) Engage in patient counseling;
(j) Receive therapy or blood product procedures in a permitted nuclear pharmacy, or
(k) Engage in any other act that requires the exercise of a pharmacist's professional judgment.

Mr. Flynn addressed the Committee conveying the Board has no statutory authority to implement this request through rulemaking. He indicated the statute is clear and prescription transfers are the responsibility of the pharmacist.

Edwin Bayo, Esq. addressed the Committee and indicated the intent of correspondence was to open the discussion with the understanding that statutory changes may be required.

After discussion the Committee did not move forward with proposed rule language.

III. ADJOURNMENT

There being no further business the meeting adjourned at 4:00 p.m. EST.