BOARD OF PHARMACY
RULES COMMITTEE MEETING
DRAFT MINUTES
December 14, 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
David Wright, BPharm
Patty Ghazvini, PharmD, BCGP
Jonathan Hickman, PharmD

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

BOARD COUNSEL
David Flynn, Esq.
Senior Assistant Attorney General
Kara Aikens, Esq.
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II. RULES DISCUSSION

a. 64B16-26.2031, F.A.C., Licensure by Examination (Non-U.S. Graduates); Application

64B16-26.2031 Licensure by Examination (Non-U.S. Graduates); Application.
In order for a foreign pharmacy graduate to be admitted to the professional licensure examination, the applicant must be a graduate of a four year undergraduate pharmacy program at a school or college outside the United States and have completed an internship program approved by the Board.

(1) All applications for licensure by examination must be made on form DH-MQA 103 (Rev. 08/2021), Pharmacist Examination Application For Non-U.S. Graduates, which is hereby incorporated by reference, and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-13938, the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or the Board's website at http://floridaspharmacy.gov/. The application must be accompanied with an examination fee and an initial license fee as set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(2) In addition to the requirements of subsection (1), the applicant must submit proof of having met the following requirements:

(a) Successfully pass the foreign pharmacy graduate equivalency examination, given by the Foreign Pharmacy Graduate Equivalency Commission, with a minimum score of 75%;

(b)1. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language (TOEFL), which is administered by the Educational Testing Service, Inc., with a score of at least 550 for the pencil and paper test or 213 for the computer version and by passing the Test of Spoken English (TSE) with a score of 50 on the recalibrated TSE; or

2. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language Internet-based test (TOEFL ibt) with scores of: Listening – 18; Reading – 21; Speaking – 26; and Writing – 24; and,

(c) Complete 2080 hours of supervised work activity, of which a minimum of 500 hours must be completed within the State of Florida. Such experience must be equivalent to that required in the internship program as set forth in Rule 64B16-26.2033, F.A.C. The work experience program, including both the preceptor and the permittee, must be approved by the Board of Pharmacy. Work experience shall be documented on form DH-MQA 1153 (Rev. 07/16), Foreign Graduate Registered Intern Work Activity Manual, which is hereby incorporated by reference, and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-07405; the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254; or the Board's website at http://floridaspharmacy.gov/Applications/info-foriegn-grad-reg-intern-manual.pdf. No program of supervised work activity shall be approved for any applicant until said applicant has obtained the specified passing scores on the Foreign Pharmacy Graduate Equivalency Examination.

The Committee discussed the TOEFL scoring criteria during the October Rules Committee meeting. The discission was continued to December to allow the NABP to address the Committee.

Neal Watson, Representative of the National Association of Boards of Pharmacy (NABP), addressed the Committee regarding the TOEFL exam. Passing the TOEFL is a requirement to pass in order to sit for the FPGEE. Mr. Watson confirmed that NABP assembled a task force to determine the passing TOEFL requirements and he expressed that passing rates of the NAPLEX are 18% higher for candidates after passing the TOEFL.

After the discussion the Committee instructed Board Counsel to research the scores and draft rule language to be presented to the Board.

b. 64B16-26.600, F.A.C., Tripartite Continuing Education Committee

64B16-26.600 Tripartite Continuing Education Committee.

(1) The Tripartite Continuing Education Committee will be composed of equal representation from the Board of Pharmacy, Colleges or Schools of Pharmacy in the State, and practicing pharmacists within the State. The members of the Committee shall be selected by the Board of Pharmacy and shall serve for a period of two years. The Chair of the committee shall be selected by the Chair of the Board.

(2) The Tripartite Continuing Education Committee shall perform the following duties pursuant to Rule 64B16-26.601, F.A.C.:

(a) Review continuing education providers and make recommendations to the Board;

(b) Approve the following continuing education courses or programs to be offered by approved providers or individuals that are non-approved providers:

1. General;

2. Initial Consultant Pharmacist Certification;
3. Consultant Recertification;
4. Nuclear Recertification;
5. Medication Errors;
6. HIV/AIDS;
7. Laboratory Tests;
8. Laws and Rules;
9. Quality Related Events;
10. Validation of Prescriptions for Controlled Substances.
11. Technician Immunization Initial Immunization Program
12. Technician Immunization Recertification Program

(3) The Tripartite Continuing Education Committee shall perform auditing and monitoring activities pursuant to Rule 64B16-26.601, F.A.C. The Tripartite Committee shall perform an audit on each approved continuing education provider 90 days prior to the end of the biennium. The approved provider shall submit the following information for one program of the provider's choosing and one program selected by the Board:

(a) Title, date and location of the program;
(b) Program Number;
(c) Any co-sponsors;
(d) Total number of pharmacists attending;
(e) Rosters of attendees with appropriate license numbers;
(f) Brochures of program announcement;
(g) CV's of each speaker;
(h) Handouts, copy of CE Credit statement, educational materials distributed as part of the program; and,
(i) Summary report of program evaluations.

(4) The Committee shall hold meetings as may be convened at the call of the Chair of the Committee.

Rulemaking Authority 465.005, 465.009(5) FS. Law Implemented 465.009 FS. History–New 10-18-79, Amended 7-29-81, Formerly 21S-13.01, 21S-13.001, 21S-26.600, 61F10-26.600, 59X-26.600, Amended 10-15-01, 3-10-05, 6-11-09, 6-7-16, _____.

The Committee discussed the rule language and determined amending the language was not appropriate at this time.

c. 64B16-27.831, F.A.C., Standards of Practice for the Dispensing of Controlled Electronic Prescribing; Mandatory Continuing Education

64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.

The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment. Pharmacists should not fear disciplinary action from the Board or other regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. Every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind. Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.

(1) Definitions: For purposes of this rule the following definitions shall apply:

(a) Valid Prescription. A prescription is valid when it is based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose.

(b) Invalid Prescription. A prescription is invalid if the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose.

(c) Validating a Prescription. Validating a prescription means the process implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose.

(2) General Standards for Validating a Prescription: Each prescription may require a different validation process and no singular process can fit each situation that may be presented to the pharmacist. There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.

(a) When validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment.

(b) When validating a prescription, the pharmacist shall ensure that all communication with the patient is not overheard by others.

(c) When validating a prescription, if at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

(3) Minimum Standards Before Refusing to Fill a Prescription.

(a) Before a pharmacist can refuse to fill a prescription based solely upon a concern with the validity of the prescription, the pharmacist shall attempt to resolve those concerns and shall attempt to validate the prescription by performing the following:

1. Initiate communication with the patient or the patient's representative to acquire information relevant to the concern with the validity of the prescription,

2. Initiate communication with the prescriber or the prescriber's agent to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(b) In lieu of either subparagraph 1. or 2., but not both, the pharmacist may elect to access the Prescription Drug Monitoring Program's Database to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(c) In the event that a pharmacist is unable to comply with paragraph (a), due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required.

(4) Duty to Report: If a pharmacist has reason to believe that a prescriber is involved in the diversion of controlled substances, the pharmacist shall report such prescriber to the Department of Health.

(5) Electronic Prescriptions: All controlled substances listed in Schedule II through V may be electronically prescribed pursuant to the provisions of section 456.42(2), F.S. ~~(2015)~~, and pursuant to applicable federal law. ~~For more information related to the federal requirements, access http://www.deadiversion.usdoj.gov/ecomm/index.html.~~

(6) Mandatory Continuing Education: All pharmacists shall complete a Board-approved 2-hour continuing education course on the Validation and Counseling of Prescriptions for Controlled Substances and Opioids. The course content shall include the following:

(a) Ensuring access to controlled substances for all patients with a valid prescription;

(b) Use of the Prescription Drug Monitoring Program's Database;

(c) Assessment of prescriptions for appropriate therapeutic value;

(d) Detection of prescriptions not based on a legitimate medical purpose;

(e) The laws and rules related to the prescribing and dispensing of controlled substances.

(f) Proper patient storage and disposal of controlled substances;

(g) Protocols for addressing and resolving problems recognized during the drug utilization review to include but not limited to the following:

1. Drug/drug interactions;

2. Side effects;

3. High dose/low dose guidelines; and

(h) Education on the provision of section 381.887, F.S., Emergency treatment for suspected opioid overdoses and on the State Surgeon General's Statewide Standing Order for Naloxone (eff. May 19, 2017) for as long as the Order is valid and effective.

(i) Pharmacist initiated counseling of patients with opioid prescriptions; and

(j) Available treatment resources for opioid physical dependence, addiction, misuse, or abuse.

(7) All licensed pharmacists shall complete the required ~~course during the biennium ending on September 30, 2019. A~~ 2-hour course ~~shall be taken~~ every biennium ~~thereafter~~. The course shall count towards the mandatory 30 hours of CE required for licensure renewal. All newly licensed pharmacists must complete the required course before the end of their first biennial renewal period. ~~A licensee who completed the mandated Validation of Prescription for Controlled Substances course between October 1, 2017 and July 1, 2018 shall be deemed to have complied with this subsection for the biennium ending on September 30, 2019.~~

(8) Summary Record: Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of section 893.07(4), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substances being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substances being dispensed to a specific patient.

Board Counsel provided comments from the Joint Administrative Procedures Committee (JAPC).

Motion: by Dr. Hickman to strike the date and last sentence of (5) and present to the Full Board.
Second: by Mr. Wright
Vote: Unanimous

Motion: by Dr. Hickman to accept the amendments in (7) 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 as the change reduces regulatory burdens, to find 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

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

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, including prescriptions received as provided for in Rule 64B16-28.1003, F.A.C., Transmission of Prescription Orders, shall be reduced to 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.

Board Counsel provided comments from the Joint Administrative Procedures Committee (JAPC).

Motion: by Mr Philip to approve the proposed language present to the Full Board.
Second: by 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 as the change reduces regulatory burdens, to find 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

e. 64B16-31.007, F.A.C., Collaborative Practice Certification; Chronic Health Conditions

64B16-31.007 Collaborative Practice Certification; Chronic Health Conditions.
Pursuant to Section 465.1865, F.S., the Board hereby adopts the following list of chronic health conditions for which a pharmacist certified pursuant to Section 465.1865, F.S., can provide

specified patient care services to patients of a collaborating physician pursuant to a pending Collaborative Pharmacy Practice Agreement:

(1) Hyperlipidemia:
(2) Hypertension;
(3) Anti-coagulation management;
(4) Nicotine Dependence;
(5) Opioid use disorder;
(6) Those chronic health conditions enumerated in Section 465.1865(1)(b), F.S.

The Committee reviewed the correspondence from Lee Health and their request to add Hepatitis C Infection to the list of chronic health conditions.

The Committee will call a joint rules committee meeting with the Boards of Medicine and Osteopathic Medicine to consider the changes to the rule.

III. OLD BUSINESS

a. Drug Enforcement Administration (DEA) Guidance Document

This was provided for information purposes only.

IV. ADJOURNMENT

There being no further business the meeting adjourned at 3:10 p.m. ET.