

AGENDA

DEPARTMENT OF HEALTH BOARD OF PHARMACY RULES COMMITTEE MEETING

August 9, 2016

Immediately Following the Board Meeting
St. Petersburg Marriott Clearwater
12600 Roosevelt Boulevard, North
St. Petersburg, Florida 33716

Committee Members

Jeffrey J. Mesaros, PharmD, Chair
Jeenu Philip, BPharm
Lee Fallon, PhD., BPharm
Goar Alvarez, PharmD

Board Staff

Allison Dudley, Executive Director
Alexandra Meredith, Regulatory Supervisor

Board Counsel

Lawrence Harris, Assistant Attorney General
David Flynn, Assistant Attorney General

PLEASE TURN OFF ALL CELL PHONES, PAGERS AND BEEPERS DURING THE MEETING. PARTICIPANTS IN THIS PUBLIC MEETING SHOULD BE AWARE THAT THESE PROCEEDINGS ARE BEING RECORDED.

1. Roll Call

2. Rule 64B16-27.104, Conduct Governing Pharmacists and Pharmacy Permittees; Prescription Department Managers.
 - Suggested revisions

3. Rule 64B16-27.450, Prescription Department Managers
 - New rule draft

4. Public Hearing

- Rule 64B16-26.2032
- Rule 64B16-26.2033
- Rule 64B16-26.400

5. Rule 64B16-26.351, Standards for Approval of Registered Pharmacy Technician Training Programs

- Suggested Language

6. Rule 64B16-26.103, Continuing Education Credits; Renewal

- Additional discussion

7. Rule 64B16-26.204

- Possible discussion if JAPC concerns

8. Rule 64B16-26.400

- Possible discussion if JAPC concerns

9. New Business

10. Public Comment

Board Counsel's REVISED suggested language to address JAPC concerns June, 2016.

64B16-27.104 Conduct Governing Pharmacists and Pharmacy Permittees; Prescription Department Managers.

(1) A pharmacist or pharmacy shall be permitted to advertise medicinal drugs other than those controlled substances specified in Chapter 893, F.S., and patent and proprietary preparations so long as such advertising is not false, misleading or deceptive.

(2) No pharmacist, employer or employee of a pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Florida Board of Pharmacy, from which to solicit, accept or dispense prescriptions.

(3) No pharmacist or pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with any physician or other practitioner or nursing home or extended care facility for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement of any kind, whereby in any way a patient's free choice of a pharmacist or pharmacy is or may be limited.

(4) No pharmacist, employer or employee of a pharmacy may knowingly place in stock of any pharmacy any part of any prescription compounded for, or dispensed to, any customer of any pharmacy and returned by said customer, unless otherwise permitted by Rule 64B16-28.118, F.A.C.

(5) Prescription Department Managers. Pursuant to Sections 465.018 and 465.022, F.S., a permit for a community pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager.

(a) Registration as prescription department manager. The Board shall not register a prescription department manager as the manager of more than one pharmacy. The Board shall grant an exception to this requirement upon application by the permittee and the prescription department manager showing circumstances such as proximity of permits and limited pharmacist workload that would allow the manager to carry out all duties and responsibilities required of a prescription department manager.

(b) Responsibilities of the prescription department manager. Prescription department managers are responsible for ensuring the pharmacy permittee's compliance with all statutes and rules governing the practice of the profession of pharmacy, including maintenance of all drug records and ensuring the security of the prescription department, and shall competently and diligently exercise their responsibilities as a prescription department manager. Prescription Department Managers shall spend such time in the prescription department as is necessary to exercise these responsibilities by, at a minimum:

1. Within seven (7) days of being designated as the prescription department manager of a pharmacy, the pharmacist so designated shall conduct an on-site visit of the pharmacy. During this on-site visit, the prescription department manager shall verify that the pharmacy is in compliance with all statutes and rules, and shall also perform the tasks ~~identified~~ identified in subparagraph (b)2., below.

2. Following the initial on-site visit, the prescription department manager shall, no less than semi-annually, perform the following tasks:

- a. Review the prescription department's records and documentation, including
 - i. drug records, inventory logs and minutes of meetings of the Continuous Quality Improvement ("CQI") Committee ~~minutes~~ established by Rule 64B16-27.300(3)(a)1.;
 - ii. employee training (including training materials, policies and procedures manuals, and documentation of compliance with training requirements);
 - iii. compliance with Board rules regarding pharmacist to technician ratios;
 - iv. other documentation required by state and federal laws and rules.
- b. Review the pharmacy's drug stocks and inventory for compliance with Rule 64B16-28.110, F.A.C.;

3. Prescription Department Managers shall document compliance with paragraph (5)(b), above, and shall provide such documentation to the Board or Department upon request. Documentation shall, at a minimum, be sufficient to identify the date and time on-site visits and records/documentation reviews occurred; shall be signed and dated by the prescription department manager; and shall contain a general summary of the the findings of the on-site visits and records/documentation reviews.

Specific Authority 465.005, 465.0155, 465.018, 465.022 FS. Law Implemented 465.018, 465.022, 465.024 FS. History—New 10-20-81, Formerly 21S-1.20, 21S-1.020, Amended 7-30-91, Formerly 21S-27.104, 61F10-27.104, 59X-27.104, Amended 11-18-07,_____.

NEW RULE 27.450 - PRESCRIPTION DEPARTMENT MANAGERS

(1) Designation as Prescription Department Manager.

(a) Initial Designation. Pursuant to Sections 465.018, 465.0197, and 465.022, F.S., a permit for a community or internet pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager. Designation is accomplished as part of the Application for a Community Pharmacy Permit, utilizing Form DH-MQA 1214, incorporated in Rule 64B16-26.100, F.A.C., or application for an Internet Pharmacy Permit, utilizing Form DH-MQA 1216, incorporated in Rule 64B16-28.100, F.A.C.

(b) Change of prescription department manager. No later than ten (10) days after a change of designated prescription department manager for a community pharmacy, or thirty (30) days for an internet pharmacy, both the pharmacy Permittee and the newly designated prescription department manager shall notify the Board of the change and the identity of the newly designated prescription department manager. Notification shall be accomplished by completing Form DOH/MQA/PH10, 08/16, Change of Prescription Department Manager, which is hereby incorporated by reference and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref->, the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or the Board's website at <http://floridaspharmacy.gov/Applications/app-change-perscription-dept-manager.pdf>.

(c) Submission of Fingerprints. In addition to submission of Form DOH/MQA/PH10, the newly designated prescription department manager shall submit to the Department of Health a set of fingerprints for submission to the Florida Department of Law Enforcement to conduct state and national criminal history checks.

(2) Responsibilities of Prescription Department Managers.

(a) Prescription department managers are responsible for ensuring the pharmacy permittee's compliance with all statutes and rules governing the practice of the profession of pharmacy, including maintenance of all drug records and ensuring the security of the prescription department, and shall competently and diligently exercise their responsibilities as a prescription department manager.

(b) Prescription department managers shall spend such time in the prescription department as is necessary to exercise their responsibilities by, at a minimum:

1. Within seven (7) days of being designated as the prescription department manager of a pharmacy, the pharmacist so designated shall conduct an on-site visit of the pharmacy. During this on-site visit, the prescription department manager shall verify that the pharmacy is in compliance with all statutes and rules and shall also perform the tasks identified identified in subparagraph (b)2., below. If the on-site visit reveals the pharmacy is not in compliance with all applicable statutes and rules, the prescription department manager shall prepare a corrective action plan which includes identification of deficiencies and timelines for correction.

2. Following the initial on-site visit, the prescription department manager shall, no less than semi-annually, perform the following tasks:

a. Review the prescription department's records and documentation, including

i. drug records, inventory logs and minutes of meetings of the Continuous Quality Improvement ("CQI") Committee minutes established by Rule 64B16-27.300(3)(a)1.;

ii. employee training (including training materials, policies and procedures manuals, and documentation of compliance with training requirements);

iii. compliance with Board rules regarding pharmacist to technician ratios;

iv. other documentation required by state and federal laws and rules.

b. Review the pharmacy's drug stocks and inventory for compliance with Rule 64B16-28.110, F.A.C.

(c) Prescription department managers shall document compliance with this subsection or creation of a corrective action plan, and shall provide such documentation to the Board or Department upon request. Documentation shall, at a minimum, be sufficient to identify the date and time on-site visits and records/documentation reviews occurred; shall be signed and dated by the prescription department manager; and shall contain a general summary of the the findings of the on-site visits and records/documentation reviews. If a corrective action plan was prepared, the documentation shall contain a complete copy of the corrective action plan.

Specific Authority 465.005, 465.0155, 465.022(1), (10) FS. Law Implemented 465.018(2), 465.0197(1), (3)(b), 465.022(2), (3), (10), (11), 465.023(1), FS. History—New _____.

EDITS TO 26.2032 as approved by Board June 8, 2016

64B16-26.2032 Application for Pharmacy Intern Registration.

(1)(a) Students/Graduates of ACPE Accredited Programs. Students currently enrolled in, or graduates of, colleges or schools of pharmacy which are accredited by the Accreditation Council of Pharmaceutical Education (ACPE) shall apply for pharmacy intern registration on form DH-MQA 104, Pharmacy Intern Application for ACPE Accredited Students/Graduates and Instructions, 07/16, which is hereby incorporated by reference and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-> , the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or the Board's website at <http://floridaspharmacy.gov/Applications/app-pharmacy-intern-us.pdf>.

(b) Graduates of non-ACPE Accredited Programs. Graduates of colleges or schools of pharmacy which are not ACPE accredited shall apply for pharmacy intern registration on form DH-MQA 102, Pharmacy Intern Application for Foreign Graduates and Instructions, 07/16, which is incorporated by reference and which can be obtained from <http://www.flrules.org/Gateway/reference.asp?No=Ref-> , the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or the Board's website at <http://floridaspharmacy.gov/Applications/app-pharmacy-intern-foreign.pdf>.

(2) In addition to the application required by subsection (1), an applicant for pharmacy intern registration must submit proof satisfactory to the Board of:

(a) Enrollment in an intern program at an accredited college or school of pharmacy; or

(b) Graduation from an accredited college or school of pharmacy and who is not yet licensed in the state. For purposes of this rule only, any individual who has been accepted by the Foreign Pharmacy Graduate Examination Commission to sit for the Foreign Pharmacy Graduate Equivalency Examination, or who has obtained a passing score on the Examination, shall be considered a graduate of an accredited college or school of pharmacy.

(3) Upon the receipt of proof satisfactory to the Board that the applicant meets the requirements of this rule, and unless there exists good cause for the Board's refusal to certify an applicant as set forth in Section 465.013, F.S., the Board shall certify the applicant to the Department for registration as an intern.

Rulemaking Authority 465.005, FS. Law Implemented 456.013(1), (2), (3), (13), 465.003(12), (13), 465.007(1)(c), 465.0075(1)(c)2., F.S. History New 4-1-07, Amended 7-7-10, 10-7-12, _____.

EDITS TO Rule 26.2033 as approved by Board June 8, 2016

64B16-26.2033 Approved Pharmacy Internship Programs.

(1) For the purpose of qualifying for licensure by examination pursuant to Section 465.007(1)(c), F.S., or for licensure by endorsement pursuant to Section 465.0075(1)(c)2., the following are determined to be "internship programs approved by the Board:"

(a) Internship programs offered by schools or colleges of pharmacy which are accredited by the Accreditation Council on Pharmacological Education (ACPE);

(b) Internships that are required to obtain the doctor of pharmacy degree from institutions which are accredited as provided by Section 465.007(1)(b)1., F.S. Documentation of graduation from such institutions after January 1, 2001 with the doctor of pharmacy degree shall constitute satisfactory proof the applicant has satisfied the requirements of this paragraph; or

(c) For current students or graduates of institutions which are not ACPE accredited, or were not accredited at the time of graduation, internship programs which meet all requirements of subsection (2), below.

(2) The Board will approve internship programs other than those accredited programs enumerated in paragraphs (1)(a) - (b), above, upon presentation of proof satisfactory to the Board of the following.

(a) The internship experience shall be obtained in a community pharmacy, institutional pharmacy or any Florida Board of Pharmacy approved pharmacy practice, which includes significant aspects of the practice of pharmacy as defined in Section 465.003(13), F.S., provided such pharmacy:

1. Holds a current license or permit issued by the state in which they are operating and shall have available all necessary equipment for professional services and necessary reference works, in addition to the official standards and current professional journals;

2. Is operated at all times under the supervision of a pharmacist and shall be willing to train persons desiring to obtain professional experience;

3. Demonstrates that the pharmacy fills, compounds and dispenses a sufficient number, kind and variety of prescriptions during the course of a year so as to afford to an intern a broad experience in the filling, compounding and dispensing of prescription drugs; and

4. Has a clear record as to observance of federal, state and municipal laws and ordinances covering any phase of activity in which it is engaged.

(b) Pharmacists serving as preceptors of pharmacy interns shall:

1. Willingly accept the responsibility for professional guidance and training of the intern and be able to devote time to preceptor training sessions and to instruction of the intern;

2. Only supervise one (1) intern at any one time;

3. Hold current licensure in the state in which pharmacy is practiced;

4. Be ineligible to serve as a preceptor during any period in which the pharmacist's license to practice pharmacy is revoked, suspended, on probation, or subject to payment of an unpaid fine levied by lawful Board order, or during any period in which the pharmacist's license is the subject of ongoing disciplinary proceedings;

5. Agree to assist the school or college of pharmacy in the achievement of the educational objectives set forth and to provide a professional environment for the training of the intern; and

6. Provide documentation or evidence of the pharmacist's continued professional education and of an active involvement in a patient-oriented practice.

(c) In the event an internship program meets all the requirements set forth in subsections (a) and (b), any applicant submitting it for the purpose of qualifying for licensure must show in addition to successful completion of the internship:

1. Approval of the program by a state board of pharmacy; and

2.a. Sufficient hours to total two thousand eighty (2080) hours; or

b. Licensure in another state and work performed as a pharmacist for a sufficient number of hours to total two thousand eighty (2080) hours when combined with the internship hours.

(3) All internship hours may be obtained prior to the applicant's graduation. Hours worked in excess of fifty (50) hours per week prior to the applicant's graduation or in excess of sixty (60) hours per week after an applicant's graduation will not be credited toward meeting the required internship hours.

(4) Proof of current licensure in another state and work as a pharmacist for up to two thousand eighty (2080) hours may substitute for all or part of the internship requirement. However, pursuant to section 465.007(1)(b)2., F.S., all foreign pharmacy graduates must complete five hundred (500) hours of supervised work activity within the state of Florida. The supervised work activity program experience shall be documented on form DH-MQA 1153, "Foreign Graduate Registered Intern Work Activity Manual," incorporated by reference in Rule 64B16-26.2031, F.A.C. Further, supervised work activity hours may not be credited to any applicant until said applicant has obtained the passing score on the Foreign Pharmacy Graduate Equivalency Exam as provided in Section 465.007(1)(b)2., F.S. and as defined in Rule 64B16-26.203, F.A.C.

(5) Governmental and private radiopharmacy internship programs are not approved by the Board.

(6) Proof of completion of an internship program shall consist of the program's certification that the applicant has completed the program. If additional hours are required to total two thousand eighty (2080) hours, satisfactory proof of the additional hours shall consist of the program's certification of completion of the additional hours.

(7) Effective {rule effective date}, all board approved internship programs shall ensure interns complete the required number of internship hours within twenty-four (24) months of beginning the program.

Rulemaking Authority 465.005, 465.007(1)(c) FS. Law Implemented 465.003(12, (13), 465.007(1)(c), 465.0075(1)(c)2., 465.013, 465.015(1)(b), (2)(b) FS. History--New 4-1-07, Amended 7-7-10, 10-7-12,_____ .

Changes to 26.400 as approved by Board on June 8 2016

64B16-26.400 Pharmacy Interns; Employment; Supervision.

(1) A pharmacy intern is required to be registered with the Department of Health as an intern before being employed as an intern in a pharmacy in Florida.

(2) Effective {effective date of rule}, a pharmacy intern may only practice as an intern, and registration as a pharmacy intern shall only be effective, for a period of twenty-four (24) months. Pharmacy Interns registered prior to {effective date of rule} shall be allowed to continue to practice as registered pharmacy interns, and their registrations shall continue to be effective, for twenty-four (24) months from {effective date of rule}.

(3) No intern shall perform any acts relating to the filling, compounding, or dispensing of medicinal drugs unless it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy in this state.

Specific Authority 465.005, FS. Law Implemented 465.013, 465.015(1)(b), (2)(b), FS. History—Amended 8-20-63, 5-19-72, 8-18-73, Repromulgated 12-18-74, Amended 11-10-80, 4-30-85, Formerly 21S-1.21, Amended 10-20-88, Formerly 21S-1.021, Amended 7-31-91, 1-10-93, Formerly 21S-26.400, 61F10-26.400, 59X-26.400, Amended 3-10-05,_____.

64B16-26.351 Standards for Approval of Registered Pharmacy Technician Training Programs.

(1) The following programs are approved Registered Pharmacy Technician Training programs:

(a) Pharmacy technician training programs accredited as of August 1, 2016, by the Pharmacy Technician Accreditation Commission (PTAC);

(b) Pharmacy technician training programs accredited as of August 1, 2016, by the Accreditation Council on Pharmacist Education (ACPE);

~~(c)(a)~~ Pharmacy technician training programs accredited, as of August 1, 2016, on or before January 1, 2011 by the American Society of Health-System Pharmacists;

~~(d)(b)~~ Pharmacy technician training programs at institutions accredited, as of August 1, 2016, on or before January 1, 2011 by the Southern Association of Colleges and Schools;

~~(e)(c)~~ Pharmacy technician training programs approved as of August 1, 2016, on or before January 1, 2011 by the Florida Commission for Independent Education;

~~(f)(d)~~ Pharmacy technician training programs provided by a branch of the federal armed services as of August 1, 2016, on or before January 1, 2011;

~~(g)(e)~~ Pharmacy technician training programs at institutions accredited as of August 1, 2016, on or before January 1, 2011 by the Council on Occupational Education.

(2) All other programs offered or accredited by an entity not listed in paragraphs (1)(a) through ~~(f)(e)~~, and which are not employer based programs, must:

(a) Meet the requirements of and be licensed by the Commission for Independent Education pursuant to Chapter 1005, F.S., or the equivalent licensing authority of another state or jurisdiction or be within the public school system of the State of Florida; ~~and:~~

(b) Offer a course of study that includes classroom study and clinical instruction that includes the following:

1. Introduction to pharmacy and health care systems:

a. Confidentiality,

b. Patient rights and Health Insurance Portability and Accountability Act (HIPAA),

2. Pharmacy law:

a. Federal law,

b. Florida State law,

c. Florida State rules,

d. Pharmacy technician Florida rules and law,

3. Pharmaceutical – medical terminology, abbreviations, and symbols:

a. Medication safety and error prevention,

b. Prescriptions and medication orders,

4. Records management and inventory control:

a. Pharmaceutical supplies,

b. Medication labeling,

c. Medication packaging and storage,

d. Controlled substances,

e. Adjudication and billing,

5. Interpersonal relations, communications, and ethics:

a. Diversity of communications,

b. Empathetic communications,

c. Ethics governing pharmacy practice,

d. Patient and caregiver communication,

6. Pharmaceutical calculations.

(c) Apply directly to the Board of Pharmacy on approved form DH-MQA 1239 “~~Board of Pharmacy~~ Application for Registered Pharmacy Technician Training Programs,” 08/16, effective December 2010, <https://www.flrules.org/gateway/reference.asp?NO=Ref-00717>, which is hereby incorporated by reference. ~~To obtain an a~~ Applications may be obtained from <https://www.flrules.org/gateway/reference.asp?NO=Ref-00717> 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 board’s website at

<http://floridaspharmacy.gov/Applications/app-reg-pharm-tech-prog.pdf> <http://www.doh.state.fl.us/mqa/pharmacy> and All applications must include provide the following information:

1. Sample transcript and diploma;
2. Copy of curriculum, catalog or other course descriptions; and
3. Faculty credentials.

(d) Use materials and methods that demonstrate that:

1. Learning experiences and teaching methods convey the content stated above.
2. Time allocated for each participant shall be sufficient to meet the objectives of each activity.
3. Principles of adult education are utilized in determining teaching strategies and learning activities.

(e) Demonstrate that the faculty is qualified to teach the subject-matter by complying with the following:

1. The program shall provide evidence of academic preparation or experience in the subject matter by submitting a job description, resume or curriculum vitae which describes the faculty member's work experience and level of academic preparation.

2. When the subject matter of an offering includes pharmacy technician practice, a licensed pharmacist or registered pharmacy technician with expertise in the content area must be involved in the planning and instruction.

3. Pharmacy technician faculty supervising learning experiences in a clinical area in this State shall be licensed or registered.

(3) All other training programs must be employer based. Any pharmacy technician training program sponsored by a Florida permitted pharmacy, or affiliated group of pharmacies under common ownership, must contain a minimum of one hundred sixty (160) hours of training, that extends over a period not to exceed six (6) months; is provided solely to employees of said pharmacy or affiliated group; and has been approved by the Board. An application for approval of a Registered Pharmacy Technician Training Program shall be made on Board of Pharmacy approved form DH-MQA 1239 "~~Board of Pharmacy~~ Application for Registered Pharmacy Technician Training Programs," ~~effective December 2010~~. The applicant must attach to the application a copy of the curriculum, ~~catalog~~ or other course description. All employer based programs must:

(a) ~~Meet the requirements of paragraphs (2)(a), (2)(d), and (2)(e), above; Offer a course of study that includes a classroom study and clinical instruction that includes the following:~~

~~1. Introduction to pharmacy and health care systems:~~

~~a. Confidentiality,~~

~~b. Patient rights and Health Insurance Portability and Accountability Act (HIPAA).~~

~~2. Pharmacy law:~~

~~a. Federal law,~~

~~b. Florida State law,~~

~~e. Florida State rules,~~

~~d. Pharmacy technician Florida rules and law.~~

~~3. Pharmaceutical medical terminology, abbreviations, and symbols:~~

~~a. Medication safety and error prevention,~~

~~b. Prescriptions and medication orders.~~

~~4. Records management and inventory control:~~

~~a. Pharmaceutical supplies,~~

~~b. Medication labeling,~~

~~e. Medication packaging and storage,~~

~~d. Controlled substances,~~

~~e. Adjudication and billing.~~

~~5. Interpersonal relations, communications, and ethics:~~

~~a. Diversity of communications,~~

~~b. Empathetic communications,~~

~~e. Ethics governing pharmacy practice,~~

~~d. Patient and caregiver communication.~~

~~6. Pharmaceutical calculations.~~

(b) Use materials and methods that demonstrate that:

~~1. Learning experiences and teaching methods convey the content stated above.~~

~~2. Time allocated for each participant shall be sufficient to meet the objectives of each activity.~~

~~3. Principles of adult education are utilized in determining teaching strategies and learning activities.~~

~~(c) Demonstrate that the faculty is qualified to teach the subject matter by complying with the following:~~

~~1. The program shall provide evidence of academic preparation or experience in the subject matter by submitting a job description, resume or curriculum vitae which describes the faculty member's work experience and level of academic preparation.~~

~~2. When the subject matter of an offering includes pharmacy technician practice, a licensed pharmacist or registered pharmacy technician with expertise in the content area must be involved in the planning and instruction.——~~

~~3. Pharmacy technician faculty supervising learning experiences in a clinical area in this State shall be licensed or registered.~~

~~4. When an offering includes clinical practice training in Florida, a Florida licensed pharmacist competent in the practice area shall provide supervision.~~

~~(b)(d)~~ Give participants an opportunity to evaluate learning experiences, instructional methods, facilities and resources used for the offering. To ensure participants will be given an opportunity to evaluate the program, the applicant must submit a sample evaluation to be reviewed by the Board.

~~(c)(e)~~ Ensure that self-directed learning experiences, including but not limited to home study, computer programs, internet or web-based courses evaluate participant knowledge at the completion of the learning experience. The evaluation must include a minimum of one hundred (100) questions. The participant must achieve a minimum score of seventy percent (70%) on the evaluation to receive the certificate of completion. The evaluation must be graded by the provider.

~~(d)(f)~~ Designate a person to assume responsibility for registered pharmacy technician training program. If the contact person is not a licensed pharmacist or registered pharmacy technician, provision shall ~~should~~ be made for insuring licensed pharmacist or registered pharmacy technician input in overall program planning and evaluation.

~~(e)(g)~~ Establish written policies and procedures for implementation of the registered pharmacy technician training program.

~~(f)(h)~~ Maintain a system of record-keeping which provides for storage of program information.

~~(g)(i)~~ Maintain program records for a period not less than three (3) years during which time the records must be available for inspection by the board or department.

~~(h)(j)~~ Furnish each participant with an authenticated individual Certificate of Completion.

Rulemaking Authority 465.005, 465.014(7), FS. Law Implemented 465.014(2), (4) FS. History—New 6-23-10, Amended 11-17-11, _____.

Board Counsel Suggested Revisions to update rule.

64B16-26.103 Continuing Education Credits; Renewal.

(1) Pharmacists. Prior to biennial renewal of pharmacist licensure, a licensee shall complete no less than thirty (30) hours of approved courses of continued professional pharmaceutical education within the twenty-four (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 twelve (12) months prior to the expiration date of the license. If the initial renewal occurs twelve (12) months or more after the initial licensure, then fifteen (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 (5) hours of continuing education in the subject area of risk management may be obtained by attending one (1) 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 (5) 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. 08/16 02/09)~~, Individual Request for Continuing Education for Volunteers, which is hereby incorporated by reference. The form can be obtained from <https://www.flrules.org/gateway/reference.asp?No=Ref->, from the Board's website at

<http://floridaspharmacy.gov/Forms/info-request-ce-credit-volunteer.pdf>, or from the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254. One (1) hour credit shall be given for each two (2) hours volunteered in the twenty-four (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 served, 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 five (5) hours of continuing education credit per semester hour completed within the twenty-four (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 forty-five (45) days in advance of the program or course by completing the approved application form DOH/MQA/PH 112, (~~Rev 08/16-6/12~~), 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 Board's website located at <http://floridaspharmacy.gov/Forms/ind-ce-approval-form.pdf> ~~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 twenty-four (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 one (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 American Council for Pharmaceutical Education (ACPE) for continuing education for pharmacists as of January 1, 2013, 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 thirty (30) hours must be obtained either at a live seminar, a live video teleconference, or through an interactive computer-based application.

(2) Consultant Pharmacists. Prior to renewal, a consultant pharmacist shall complete no less than twenty-four (24) hours of Board approved continuing education in the course work specified in Rule 64B16-26.302, F.A.C., within the twenty-four (24) month period prior to the expiration date of the consultant license. The hours earned to satisfy this requirement cannot be applied used to apply toward the thirty (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 thirty (30) hours required in subsection (1).

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

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

(3) Nuclear Pharmacists. Prior to renewal, a nuclear pharmacist shall complete no less than twenty-four (24) hours of Board approved continuing education in the course work specified in Rule 64B16-26.304, F.A.C., within the twenty-four (24) month period prior to the expiration date of the nuclear pharmacist license. The hours earned to satisfy this requirement cannot be applied 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 thirty (30) hours required in subsection (1).

(a) If the initial renewal of a nuclear pharmacist license occurs less than twelve (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 twelve (12) months or more after the initial licensure, ~~then~~ twelve (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 as of January 1, 2013, are deemed approved by the Board for general continuing education hours for nuclear pharmacists.

(4) Registered Pharmacy Technicians. Prior to renewal, a registered pharmacy 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 twenty-four (24) month period prior to the expiration date of the pharmacy technician registration.

(a) Upon a pharmacy technician's first renewal, the registrant 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 twelve (12) months after the initial licensure, ~~then~~ completion of ~~courses of a~~ registered pharmacy technician continuing registration education hours will not be required.

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

(d) All programs approved by the ACPE for continuing education for pharmacy technicians as of January 1, 2013, are deemed approved by the Board for general continuing education hours for registered pharmacy

technicians. Any course necessary to meet the HIV/AIDS continuing education requirement for registration ~~HIV/AIDS license~~ renewal shall be Board approved.

(e) Prior to renewal a licensee must complete, within the twenty-four (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 (5) hours of continuing education in the subject area of risk management may be obtained by attending one (1) 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 registrant 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 twenty (20) hours must be obtained either at a live seminar, a live video teleconference, or through an interactive computer-based application.

Rulemaking Authority 456.013(9), 456.033, 465.009 FS. Law Implemented 456.013(~~67~~), (9), 456.033, 465.009 FS. History—New 3-19-79, Formerly 21S-6.07, Amended 1-7-87, Formerly 21S-6.007, Amended 7-31-91, 10-14-91, Formerly 21S-26.103, 61F10-26.103, Amended 7-1-97, Formerly 59X-26.103, Amended 7-11-00, 10-15-01, 1-2-02, 1-12-03, 4-12-05, 5-26-09, 5-27-10, 9-20-12,_____.